Global Academic Nursing Journal

REVIEW ARTICLE

The traceability of implantable medical devices and the unique device identification system: a bibliometric study

La trazabilidad de los dispositivos médicos implantables y el sistema único de identificación de dispositivos: un estudio bibliométrico

A rastreabilidade de dispositivos médicos implantáveis e o sistema único de identificação de dispositivos: um estudo bibliométrico

Joice Alves Cabral[1]
ORCID: 0000-0002-0411-2355
Daniel Aragão Machado[1]
ORCID: 0000-0003-0680-5291
Adriana Carla Bridi[2]
ORCID: 0000-0003-2018-4604
Cristiano Bertolossi Marta[2]
ORCID: 0000-00022-0635-7970
Paulo Afonso Lopes da Silva[3]
ORCID: 0000-0003-1337-2201
Jorge Luiz Alves Junior[2]
ORCID: 0000-0001-59822-6761
Natalia Barroso[4]
ORCID: 0000-0001-5781-3924
Caroline de Araújo Mendes[5]
ORCID: 0000-0002-8021-0520
Valeria Mesquita Joazeiro[6]
ORCID: 0000-0001-8976-141X
Luana Borges Dutra[1]
ORCID: 0000-0002-6132-3255
Raphael Barreiros Neves[1]
ORCID: 0000-0002-0272-3187

[1]Universidade Federal do Estado do Rio de Janeiro. Rio de Janeiro, Brazil.
[2]Universidade do Estado do Rio de Janeiro. Rio de Janeiro, Brazil.
[3]Instituto Militar de Engenharia. Rio de Janeiro, Brazil.
[4]Instituto Nacional de Estudos e Pesquisas Educacionais Anísio Teixeira. Rio de Janeiro, Brazil.
[5]Prefeitura da Cidade do Rio Janeiro. Rio de Janeiro, Brazil.
[6]Takeda Pharmaceutical – Biolife Plasma Center. Florida, United States.

How to cite this article:
Cabral JA, Machado DA, Bridi AC, Marta CB, Silva PAL, Junior JLA, Barroso N, Mendes CA, Joazeiro VM, Dutra LB, Neves RB. The traceability of implantable medical devices and the unique device identification system: a bibliometric study. Glob Acad Nurs. 2021;2(4):e200. https://dx.doi.org/10.5935/2675-5602.20200200

Corresponding author:
Joice Alves Cabral
E-mail: joicecabral@gmail.com

Submission: 07-08-2021
Approval: 08-19-2021

Abstract

The aim was to systematize and analyze the national and international scientific production on the traceability of implantable medical devices and the use of the Unique Device Identification System in 126 academic articles. Data were retrieved from the Scopus database and analyzed using inferential statistics to reach conclusions about a larger group. Thus, the coefficient of determination and the chi-square test of adherence were adopted, using the Microsoft Excel® software and the R statistical program to assess the scientific production activity related to the terms' traceability and unique identification of the device. A map was generated in the VOS software, which provided the analysis of the behavior parameters and some presentations of the results in the form of tables and graphs, examined according to descriptive statistics. It was found that there was theoretical and empirical growth in the field of traceability of implantable medical devices and in the use of the Unique Device Identification System.

Descriptors: Bibliometric; Mass Screening; Equipment and Supplies, Process Assessment, Health Care; Monitoring.

Resumén

El objetivo fue sistematizar y analizar la producción científica nacional e internacional sobre la trazabilidad de dispositivos médicos implantables y el uso del Sistema Único de Identificación de Dispositivos en 126 artículos académicos. Los datos se recuperaron de la base de datos Scopus y se analizaron utilizando estadísticas inferenciales para llegar a conclusiones sobre un grupo más grande. Así, se adoptó el coeficiente de determinación y la prueba chi-cuadrado de adherencia, utilizando el software Microsoft Excel® y el programa estadístico R para evaluar la actividad de producción científica relacionada con los términos trazabilidad e identificación única del dispositivo. Se generó un mapa en el software VOS, que brindó el análisis de los parámetros de comportamiento y algunas presentaciones de los resultados en forma de tablas y gráficos, examinados según estadística descriptiva. Se encontró un crecimiento teórico y empírico en el campo de la trazabilidad de dispositivos médicos implantables y en el uso del Sistema Único de Identificación de Dispositivos.

Descriptores: Bibliometría; Tamizaje Masivo; Equipos y Suministros; Evaluación de Procesos, Atención de Salud; Monitoreo.

Resumo

Objetivou-se sistematizar e analisar a produção científica nacional e internacional sobre a rastreabilidade de dispositivos médicos implantáveis e a utilização do Sistema Único de Identificação de Dispositivos em 126 artigos acadêmicos. Os dados foram recuperados da base de dados Scopus e analisados à luz da estatística inferencial, a fim de se chegar a conclusões sobre um grupo maior. Assim, foram adotados o coeficiente de determinação e o teste de aderência do qui-quadrado, utilizando o *software Microsoft Excel®* e o programa estatístico R para avaliar a atividade de produção científica relacionada com os termos rastreabilidade e identificação única do dispositivo. Foi gerado um mapa no software VOS, que proporcionou a análise dos parâmetros de comportamento e algumas apresentações dos resultados em forma de tabelas e gráficos, examinados de acordo com a estatística descritiva. Verificou-se que houve crescimento teórico e empírico no campo da rastreabilidade de dispositivos médicos implantáveis e na utilização do Sistema Único de Identificação de Dispositivos.

Descritores: Bibliometria; Programas de Rastreamento; Equipamentos e Provisões; Avaliação de Processos em Cuidados de Saúde; Monitoramento.

Introduction

Implantable Medical Devices (IMD) are products that involve high technology and high value[1], used in medical, dental, and physical therapy procedures, as well as in the diagnosis, treatment, rehabilitation and/or patients monitoring. They can be permanent like stents or hip implants, or temporary like accesses for chemotherapy or pins to repair fractured bones, removed after treatment.

It is estimated that there are at least eight thousand types of IMD[1,2], each group having its own characteristics and risks associated with their uses. For the purposes of this research, will be considered IMDs linked to an invasive medical or dental procedure, in addition to the materials used as specific instruments for its implantation.

As for the risks associated with the IMD, surgical risks during its insertion or removal, the possibility of infection on its site of implantation and failures of implantation/implanted materials are included[1]. Therefore, patient safety requires the rapid detection of any defect - a practice known as surveillance of materials, organized at European and international levels, in order to harmonize laws on medical devices; this implies the need to track the lifespan of a device based on the IMD batch number, by traceability, which is intended to quickly identify medical device holders in the event of product recalls, and medical devices in case of incident[3], with each center responsible for organizing the traceability of its devices using strict labeling rules to ensure a safe use. Such practice is one of the fundamental rights of patients once everyone has the right to be informed about their health status.

To carry out traceability, a European and worldwide database was created to make the Unique Device Identification (UDI) mandatory in the European Union[3], considering that the French law lists five types of traceability: financial, logistical, legal, scientific and health related.

In the present study, considering the view of the recent scientific approach to the traceability of IMD, it was difficult to find publications on the subject in journals. The publications found dealt with the evolution and relevance of the topic, regarding to patient safety, UDI, and post-marketing surveillance. The articles were separated by English and French languages in chronological order, with the aid of the Mendeley Desktop® tool, for a better organization. It is noteworthy that there were no articles published in Brazil on the subject, although the National Health Surveillance Agency (Anvisa) already has rules regarding the traceability of IMDs.

Using the advanced search mode of the Journal Portal of the Coordination for the Improvement of Higher Education Personnel (Capes) with the keywords: "traceability" and "implantable medical device", applying the search operators "any" and "contains", 36 articles were found, 15 related to the theme. In the same portal, still on the advanced search mode, the keywords "traceability" and "UDI" were applied, with "any" and "contains", resulting in 127 articles. With filters on “government policy”, “medical equipment-law”, “legislation medical policy”, “regulations”, “product safety”, “medical device”, “bar codes”, “traceability”, “patient safety”, where 46 articles related to regulation, prostheses and implants, health care industry, medicine, software, medical devices, and medical technology were found.

The 2011 “Medical Devices-Balancing Regulation and Innovation” article by Gregory D. Curfman and Rita F. Redberg[4] addressed the case of DePuy® metal-metal hip prostheses, which were banned due to serious problems caused to patients who had this device implanted. The purpose of their study was to discuss the serious risks brought by the entry of untested and potentially dangerous medical devices on the market. It also points out that, in the same year, the Institute of Medicine released a report commissioned by the Food and Drug Administration (FDA) on the process of IMD release in the North American market and, among other recommendations, suggested monitoring of medical devices throughout its life cycle, especially in the post-marketing period, through a formal surveillance system for IMD.

In view of the recall events that occurred that same year, the North American article 'Product safety and security in the global supply chain: issues, challenges and research opportunities' addressed the security problems that results on the delivery of an unsafe or ineffective product, for example, the counterfeiting that can occur from the selection of the raw material to the final product, reaching the market through a distributor, wholesaler, or retailer. Due to the difficulties in tracing the path of supply, particularly when passing through international trade zones, counterfeiting is considered a crime that is difficult to detect. In this perspective, it is suggested that image and tracking technologies be adopted in inventory management, such as bar codes, holograms, optical character recognition (OCR) and radio frequency identification (RFID).

Also in 2011, the American Congress authorized the FDA to establish a unique identification system for medical devices, which would exclusively identify the product through distribution and use.

Marucheck, Greis, Mena and Cai[5] concluded that many problems in the areas of product safety and protection could be solved by operation management. The authors pointed out that there was an increasing literature on risk, quality, and supply chain management subjects, although they noted few papers discussing the challenges of product safety and protection. They also highlighted the fact that the medical device industry is working to guarantee security, given the accelerated pace of technological changes, and listed four key areas for research in operations management, relating to safety and security issues: regulations and standards, product lifecycle management, traceability and supplier and recalls management.

In the review article “Materials vigilance and traceability”, from 2016, Tracol[3] defined traceability, among other terms related to the theme, and brought cases of IMD incidents that occurred in Europe that fostered the reformulation of the approval and safety regulation of devices doctors, as well as providing a historical overview of the evolution of legislation in the European Union in conjunction with the law of the United States.

European regulations enact the free movement of medical devices throughout the European Union, with each Member State responsible for security in its own territory. This means that health authorities are responsible for monitoring the market and any incidents.

The European Union, in response to the PIP® breast implant case, in 2012, drafted new regulations, amended by the European Parliament the following year, to ensure the long-term safety of patients and, at the same time, protecting innovation. The objective was to reinforce the assessment of the safety and performance of IMD prior to labeling and release, as well as to reinforce post-marketing surveillance, increasing transparency and the collection of risk-benefit data. For the first time, a control system was created for regulated bodies to monitor their activities. The clinical investigation and incident data are collected in the European Databank on Medical Devices (EUDAMED), an open access database.

The change in the organization of traceability is currently underway and will take place in the form of UDI. These changes will be reflected in harmonized label data, bar codes and standardized terminology. According to Tracol[3], a worldwide database was planned to be created by 2017, to make the UDI mandatory in the European Union; however, so far it has not been established.

The article also reports that the FDA and the European Union have decided to introduce the principle of unique identification for each medical device and that the regulations for these devices were revised by two European directives in 2012. The aim of the UDI is to improve market surveillance and the traceability of medical devices between countries to facilitate access to the European databases of EUDAMED and the Global Data Synchronization Network (GDSN).

More than facilitating traceability, UDI will improve product identification, post-marketing incident reporting and product recall, in addition to standardizing documentation and limiting counterfeiting and medical error. In the long term, UDI will provide an ideal implant identification card, allowing the type of CMS to be retrieved along with the patient's identification in the database. This will involve international standardization of labeling and identification of the medical device.

The UDI principle is based on three pillars: database, unified nomenclature protocol and barcode. The EUDAMED database, which came into force in May 2011, was created with the purpose of strengthening market surveillance and transparency in relation to medical devices placed on the European market. In the United States, it is the Global Unique Device Identification Database (GUDID) that sends information to the FDA about medical devices that have UDI. In collaboration with the United States National Library of Medicine, the FDA created a portal, called AccessGUDID, to make device identification data available to everyone - including patients, caregivers, healthcare professionals, hospitals, and industry. On a long run, an international database will be created. Regarding the second pillar, the protocol for data exchange will be the Global Medical Device Nomenclature (GMDN). This identifier should allow notification of serious incidents related to medical devices and corrective measures necessary to be determined as part of surveillance.

The bar code comprises two types of data: the device identifier and the production identifier. The first one is a unique numeric or alphanumeric code that specifies the model or version of the medical device, also used as an access code for information in the UDI database. The second is a numeric or alphanumeric code identifying the unit of production of the device, which comprises the serial number, the batch and production number and/or the expiration date. This data must be written and displayed as standard numeric codes.

In the area covered by the European Union, according to Tracol[3], manufacturers must assign an UDI to the device, following international standards, that is, labeling each level of packaging with it, and transmit the information present in the UDI to the bank EUDAMED database. Importers and distributors must check the manufacturer's UDI and insert them into medical devices along with the buyer's data, manipulating their own information systems.

Importers must also ensure that the device has been registered on EUDAMED. Health institutions, in turn, need to register the UDI of their medical devices and, for certain devices, link it to the patient in question. Both must ensure the means of the labels reading and the communication with the international database. In the United States, the goal was to establish the UDI system by 2015; and, in Europe, the UDI would become mandatory for all medical devices by 2017[3]; currently, these goals remain in the structuring phase.

Currently, the surveillance of materials is perfectly structured in a national level on the Member States of the European Union, counting on the active involvement of health professionals. Thus, it can be said that the new European Union regulations have improved the safety, innovation and European conformity marking (CE) of medical devices. With the implementation of the UDI and the European and international databases, planned for 2016, according to the author, the safety of the circulation of medical devices worldwide will be maximized, also optimizing the management of the patient in case problems[3].

In Brazil, the health control of medical devices is the same adopted in most countries where there is infrastructure and legal force to operate in this segment, as in Canada and the United States, as well as it follows the model recommended by the Pan American Health Organization and the World Health Organization (PAHO/WHO)[1,2]. Such control covers two main risk factors: the product and the use. In the first case, control is related to product registration and knowledge of manufacturing conditions; therefore, to the pre-market phase; as for use, the control focuses on the problems associated with the use of the product in the post-market phase and is also known as technovigilance[1].

Allied to the sanitary regularity of implantable devices, it is necessary to observe the issues related to the

traceability of medical products, as foreseen in RDC/Anvisa No. 2, of January 25, 2010[6], from which data are extracted that assist in the investigation process, since, in numerous situations, investigations of infectious outbreaks involving implantable ones come up against the lack of traceability records, sometimes rendering the cases inconclusive[1].

In the scope of patient safety, it is proposed that the team involved in the procedure record all the attributes of the IMD to be implanted in the patient during the surgical act in the surgical description, in the consumption record of the room and in the patient's record. That is: name of the material, manufacturer or importer, brand and model, size, lot, registration with Anvisa, validity, date of use, name of the professional responsible for the procedure, patient, supplier, invoice number and description of the implant performed. In addition, occurrences must also be recorded in detail, such as adverse events, non-conformities presented by the CMS or any other quality deviation[7].

Thereby, the creation and standardization of the UDI within the scope of international regulatory agencies, including Anvisa, aims to establish a unique and globally harmonized system, capable of identifying medical devices. With this system, healthcare professionals and patients will no longer need to access multiple, inconsistent, and incomplete sources to identify a medical device and its main attributes. It is important to note that the benefits of UDI are directly linked to the ability to track all health products, especially IMD, throughout the production chain[8].

This work is a bibliometric study that aims to identify the main authors in the light of Lotka[9]; identify the journals most devoted to the topic in the light of Bradford[10]; identify the most used words that best describe the topic in the light of Zipf[11,12] and determine the elite group of authors.

Methodology

This is a bibliometric study carried out exclusively with secondary data in the public domain; for this reason, the approval of the Research Ethics Committee was not necessary, according to the recommendations of Resolution No. 466, of the National Health Council[13].

To assess the relevance indicators, the main bibliometric laws used are Lotka's[9], Bradford's[10], Zipf's[14] and Goffman's Theory[12], which focus on, respectively, the productivity of journals and authors, the frequency of occurrence of words, the estimate of the growth and decay coefficient of a subject area, as well as the relevance of lines of research in specific areas of knowledge[9,10,12,15].

To obtain the bibliometric data, the Scopus® database was used, which has advanced tools as its search filters, providing more quality to the search. The selected terms in English were “Unique Device Identification”, with the string ALL (“Unique Device Identification”) AND (EXCLUDE (SUBJAREA, “BIOC”) OR EXCLUDE (SUBJAREA, “PHAR”) OR EXCLUDE (SUBJAREA, “CENG”) AND (EXCLUDE (SUBJAREA, “MATH”) OR EXCLUDE (SUBJAREA, “PHYS”) AND (EXCLUDE (SUBJAREA, “CHEM”) AND EXCLUDE (SUBJAREA, “NEUR”), aiming at a greater range of works related to IMD traceability. It is worth mentioning that the data that are not opened are interpreted by Scopus® as undefined, while others are classified as different, such as the total number of articles.

Figure 1. Flowchart for obtaining survey data. Rio de Janeiro, RJ, Brazil, 2019

After this first process, search refinement filters were added with the following parameters: all periods, countries, languages, area of knowledge (health sciences, medicine, engineering, nursing, computer science, materials science, social sciences, decision science, business, and management) and document types.

Finally, to evaluate the scientific production about the term “Unique Device Identification”, the laws of Lotka[9], Bradford[10], Zipf[11,12] and Price[16,17] were applied, as well as the co-citation. Through the VOS® software, maps were generated and based on them, the behavior parameters were analyzed. The results presented in the form of tables and graphs were examined in the light of descriptive statistics, as shown in Chart 1. To exemplify the bibliometric theories so far cited, Chart 1 was prepared.

Chart 1. Laws and principles of bibliometrics. Rio de Janeiro, RJ, Brazil, 2019

Bibliometrics		
Laws and principles	**Title of journals**	**Main Applications**
Bradford’s	Study focus	Estimation of relevance degrees of journal titles in areas of knowledge.

Lotka's	Authors	Estimate of the relative degrees of relevance of the authors in the areas.
Zipf's	Words	Conceptual analysis of scientific writing and automatic or semi-automatic indexing of scientific articles.
Co-citations	Citations	Estimate of the relative degrees of connection of two or more articles (prospective analysis).
Goffman's Theory of Epidemics	Citations	Estimate of the degree of growth and decline of a subject area and the importance of lines of research in specific areas of knowledge.
Law of elitism (Prince's Law)	Citations	Identification and description of the elite, formed by authors who participated intensively in scientific production in specific areas of knowledge.

Results

Due to the extensive amount of data, the discussion was divided into subtopics.

Distribution of articles by countries

Through the research data, information was obtained from countries that published about the theme of this article. As shown in Table 1, the United States has the highest productivity related to UDI, with 74 articles published (49%), while in Brazil no publication was found.

Distribution of articles by language

With the research data, the languages they published on the topic under study emerged, that the largest number of articles published was in English, totaling 119 (92%).

Distribution of articles per year

Figure 2 shows that the number of publications on the topic has increased, with a peak in the number of publications in 2014, with 28 articles (22%).

Distribution of articles per author: Price's Law

According to the Table 2, in a total of 126 articles and 96 authors, 62 articles (49%) were produced by 13 authors (14%), which gives an average of 4.77 articles per author, which corroborates Price's Law, since there was an elite of more productive authors, since the square root of the total number of authors comprises, at least, half of the production of the articles produced.

Table 1. Distribution of articles by countries. Rio de Janeiro, RJ, Brazil, 2019

Countries	Number of articles	%
United States	74	49%
United Kingdom	10	7%
France	9	6%
Germany	7	5%
Australia	5	3%
Canada	4	3%
Finland	3	2%
India	3	2%
Italy	3	2%
Sweden	3	2%
Switzerland	2	1%
Turkey	2	1%
Austria	1	1%
Belgium	1	1%
China	1	1%
Cuba	1	1%
Czech Republic	1	1%
Japan	1	1%
Mexico	1	1%
Poland	1	1%
South Korea	1	1%
Undefined	18	12%
Total*	152	100%

Note: * Of this total, only 126 have open data.

Figure 2. Distribution of articles per year 2006-2018. Rio de Janeiro, RJ, Brazil, 2019

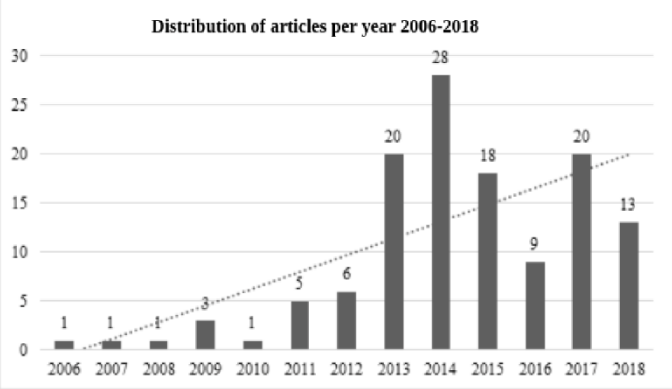
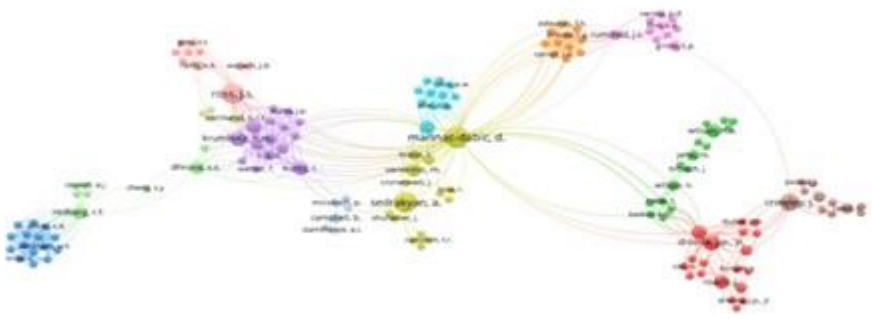


Table 2. Cumulative percentage of production by the number of authors. Rio de Janeiro, RJ, Brazil, 2019

Number of authors	Number of articles	%	Accumulated %
1	34	27,0%	27,0%
2	17	13,5%	40,5%
3	18	14,3%	54,8%
4	17	13,5%	68,3%
5	13	10,3%	78,6%
6	8	6,3%	84,9%
7	3	2,4%	87,3%
8	1	0,8%	88,1%
9	6	4,8%	92,9%
10	3	2,4%	95,2%
12	3	2,4%	97,6%
13	1	0,8%	98,4%
16	2	1,6%	100,0%
Total	**126**	**100,0%**	

The map made in VOSviewer® corroborates the graphics produced based on the data obtained in Scopus®. Regarding co-citation and the authorship of publications, Marinac-Dabić, JS Ross and A Sedrakyan stood out among the 10 most productive authors (Figure 3).

Figure 3. Co-authorship map. Rio de Janeiro, RJ, Brazil, 2019



Bradford's Law application

According to Bradford's Law, if journals are arranged in order of decreasing productivity on a given topic, they may be distributed in a group of journals more particularly devoted to that subject and in different groups or zones containing the same number of articles as the group, whenever the number of journals and successive zones is equal to 1: n: n2, considering n = 3 and the frequency of 1: 3: 9. As in this study there are 88 journals and the nucleus contains a part of them, zone I will have three parts; and zone II, nine parts.

Thus, 88 was divided by the total number of parts; in this case, 13 (1 + 3 + 9). Therefore, 88/13 = 6.77, that is, approximately 7 were obtained (Tables 3 and 4). So, the expected frequency for the core is 7, for zone I it is 20 and for zone II it is 61.

Table 3. Expected number of journals versus number obtained in the sample. Rio de Janeiro, RJ, Brazil, 2019.

Zones	Number of expected journals	Number of obtained journals
Core	7	11
Zone I	20	35
Zone II	61	42

Table 4. Number obtained in the sample. Rio de Janeiro, RJ, Brazil, 2019

Zones	Number of journals	Bradford's Multiplier	Accumulated articles	*Rank*
Core	11		42	11
Zone I	35	3,181818182	84	46
Zone II	42	1,2	126	88

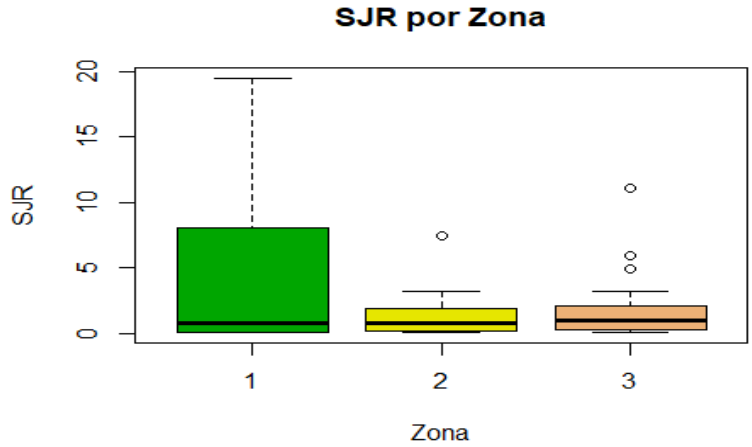
The Chi-square test of adherence at 5% significance level was performed to see if these data followed Bradford's Law. With the p-value <0.05, there is significant evidence that the number of journals on UDI does not follow this law.

SCImago Journal Rank boxplot

In this study, three boxes were placed side by side to compare the variability of the SCImago Journal Rank (SJR) between the three zones according to Bradford's Law. With this type of graph, the median, the first quartile, the third quartile, the lowest value and the highest value in the data set were obtained, as well as the outliers.

As for the quartiles, it was noticed that there is a symmetrical distribution between zones II and III regarding the variation in the SJR values since the median is in the center of each rectangle. However, in zone III a higher SJR value was achieved than in zone II. In zone I, on the other hand, are the highest values of the SJR, which configures comparatively greater prestige among the journals in zone I, in contrast to zones II and III, as shown in Figure 4.

Figure 4. Bradford's zones boxplot versus SCImago Journal Rank. Rio de Janeiro, RJ, Brazil 2019



Zipf's first law

One of the data generated by the Scopus® database was the list of words used by the authors in the articles of this research. From it, we applied the First Zipf Law as a way of inferring about the main subjects treated in the selected articles with the words associated with them. The terms used are of English origin, considering that the dataset retrieved from the database used only that language.

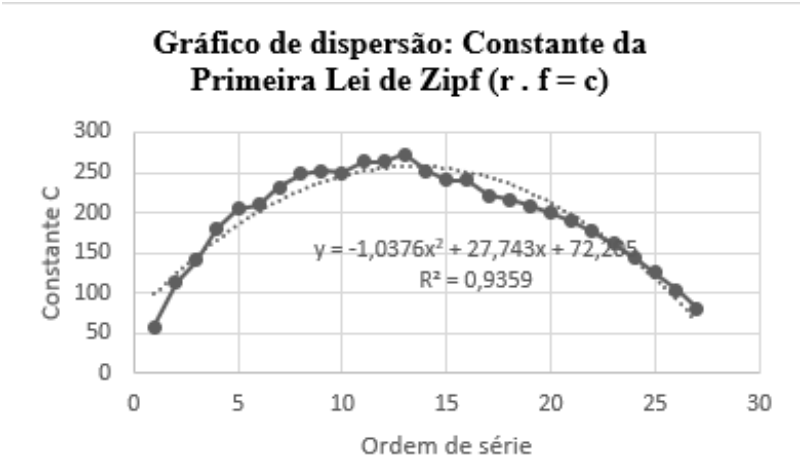
In this way, words that had the same meaning or were repeated in the plural and singular were unified, so that there were no repeated terms that would compromise further analysis. After this filtering procedure, 830 unique and exclusive words were mapped, and then the corresponding tabulation was promoted. It is noteworthy that the articles presented 830 words, with different levels of frequency. For the calculation of the equation in the First Zipf Law, Table 5 was prepared, in which the series of words was ordered according to their frequency in the data set retrieved from the Scopus® base.

Table 5. Frequency of words for the application of Zipf's first Law. Rio de Janeiro, RJ, Brazil, 2019

Number of words classified in the "R" series order	"R" series order	Frequency of occurrence "F"	Constant of Zipf's first Law (R. F = C)
1	1	125	125
1	2	92	184
1	3	73	219
1	4	69	276

1	5	59	295
1	6	58	348
1	7	56	392
1	8	47	376
1	9	45	405
1	10	41	410
1	11	38	418
1	12	34	408
3	13	31	403
1	14	28	392
1	15	25	375
1	16	24	384
1	17	23	391
2	18	22	396
2	19	21	399
1	20	19	380
2	21	18	378
1	22	14	308
5	23	13	299
3	24	12	288
7	25	11	275
6	26	10	260
6	27	9	243
16	28	8	224
12	29	7	203
6	30	6	180
19	31	5	155
37	32	4	128
53	33	3	99
104	34	2	68
529	35	1	35

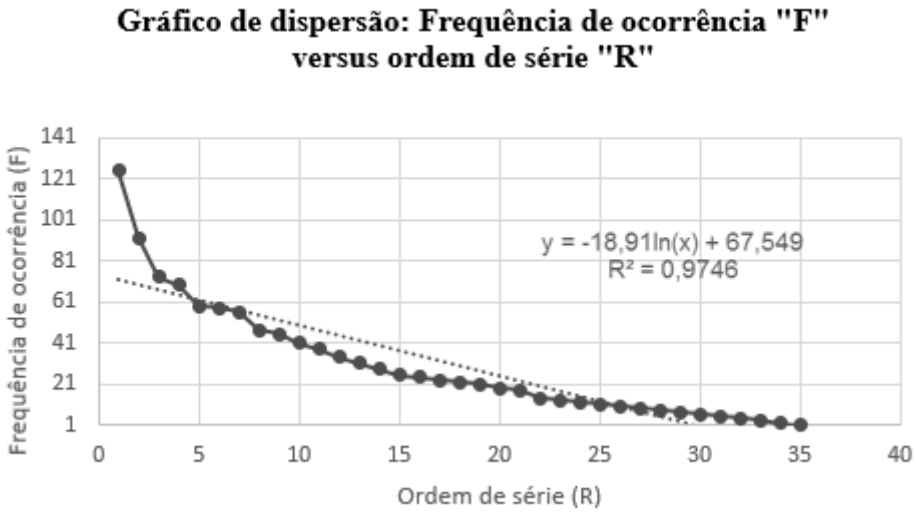
Figure 5. Dispersion – Constant of the First Law of Zipf (R. F = C). Rio de Janeiro, RJ, Brazil, 2019



The results for the tests of the First Zipf's Law can be better visualized in Figures 5 and 6, elaborated with the objective of illustrating the behavior of Zipf's C constant along the serial orders of the words. As for the Figure 5, a parable with a constant trend line was expected, so that Zipf's First Law could be applied to scientific production on UDIs, that is, the dashed line does not demonstrate the trend of constancy, signaled by Zipf, when the serial order is multiplied by the frequency of occurrence. We can see that the coefficient of determination (R^2) is equal to 93.35%,

which fits well with the model applied. However, the C constant of Zipf's Law does not follow what was expected. Bearing in mind that there is a heterogeneous dispersion and that this law applies to high frequency words, we can assume that this is the reason for not applying the first law, where C = R x F (Figure 5). In Figure 6, the coefficient of determination (R^2) is equal to 97.46%, which fits well with the model applied. We observe the behavior of words, regarding the order of series and the frequency of occurrence: the higher the order of series, the lower the frequency in which the words occur, corroborating with what Zipf recommended. In Figure 5, it is possible to notice that the trend line approaches the function line of the graph.

Figure 6. Dispersion – Frequency of occurrence "F" versus "R" series order. Rio de Janeiro, RJ, Brazil, 2019



Zipf's Second Law or Zipf-Booth's Law: Goffman's Transition Point (T)

In this work, Goffman's point T is located around the words with frequency 65, corresponding to the set: postmarket surveillance /postmarketing product surveillance / postmarketing surveillance / product surveillance / product surveillance, postmarketing / post-market /postmarketing e medical device / medical devices.

$$529 \times 8 = 4.232$$
$$4.232 - 1 = 4.231$$
$$\sqrt{4231} = 65{,}04$$

Zipf spheres

In addition to applying the formula for the First Zipf Law, in this study the data were treated in the spheres or zones of Zipf's Law, having as the first sphere the most common words within the text and in the second sphere words that occurred in a smaller number than those mentioned in the first sphere. As they are not in common use, they are considered more important within publications related to the UDI. In the third sphere are the words considered noises in the text.

With the mathematical basis, it is possible to trace a series of phenomena just by analyzing the frequency at which certain words appear in a text. The mathematical basis of the law is:

$$\sqrt{TW} = FS$$
$$\sqrt{FS} = SS$$

Where: "TW" is the total of words (occurrences); "FS" is the first sphere; "SS" is the second sphere.

This study has: √ 830 = 28,80 (first sphere) and √ 28,80 = 5,36 (second sphere).

Thus, the first sphere represents the words that have at least 29 occurrences, and the second sphere is composed of those that had at least five occurrences (S1 Table and S2 Table).

Productivity by area of knowledge: Lotka's Law

Regarding to the area of knowledge related to the theme of this research, of the 126 articles, the area of medicine published 60% of the articles found; engineering, 17%; and nursing, 3%.

Document Type

The data obtained in this research revealed the types of publication. To resolve any translation errors regarding the types of documents, it was decided to keep the types of documents in English. Thus, it was found that, of the total number of publications retrieved from the database, the highest percentage were Articles, with 57%.

Productivity by Affiliation

From the survey data, 160 entities emerged whose publications are linked to them. We chose to highlight, in Table 7, the 10 entities that published the most, which reaches together a total 79 publications. The FDA obtained 18 (6%) articles affiliated with it, and as shown in Table 6, the institutions featured are from the United States, which confirms the highest percentage of publications shown in

this study. The other institutions percentage presented less than 1% of representativeness in the total of publications.

Table 6. Productivity by affiliation: the 10 most published entities. Rio de Janeiro, RJ, Brazil, 2019

Affiliation	Number of articles	%
Food and Drug Administration	18	6%
Harvard Medical School	13	4%
Food and Drug Administration, Center for Devices and Radiological Health	9	3%
Weill Cornell Medical College	7	2%
Yale University School of Medicine	6	2%
Beth Israel Deaconess Medical Center	6	2%
Yale University	5	2%
Yale-New Haven Hospital	5	2%
UCL	5	2%
Duke Clinical Research Institute	5	2%

Discussion

A bibliometric study comprises techniques for reading, selecting, filing, and archiving topics of interest for research, with the aim of knowing the scientific contributions that have been made on a given subject. Aiming to portray the behavior and development of scientific production in each area of knowledge, within a quantitative approach[16].

The IMD subject is complex, as it involves multiple actors and interrelated interests: patients, doctors, other health professionals, manufacturers, input suppliers and health service providers, each assuming their share of responsibility in the use chain.

In Brazil, the Ministry of Health prepared the Manual of good management practices for Orthoses, Prostheses and Special Materials, and Anvisa has guidelines to regulate the internal market and the use of health products, as well as to monitor the use of IMD[7].

Given the relevance of the topic (UDI), linked to IMD and traceability, the number of publications found was small - 126 articles -, compared to other topics related to patient safety, for example.

Lotka's Law is related to the calculation of the productivity of scientific articles authors. According to this law, there is a coexistence, within the scope of the scientific specialty of a small number of authors who have a high degree of productivity, confronted with many less productive scientists. Therefore, it appears that some researchers, theoretically with greater authority in an area of knowledge, produce a lot, while other researchers, theoretically of lesser influence, produce little[14,15].

Considering the methodology used in this study, through the data retrieved from the database, it was found that the United States has the highest productivity on the topic, with 49% of the articles published. As for the language of publications, most articles were published in English (92%). It is noteworthy that, despite the worldwide relevance of the English language, other countries, such as France, have published articles in good detail on the theme of traceability of IMD.

About the distribution of articles per year, it was found that, in the period from 2006 to 2018, there was an increase in the number of publications, contrary to the declination tendency of the publications. It was also observed that in 2014 there was a peak in publications, representing 22% of published articles. Therefore, Price's Law says that the number of members of the elite corresponds to the square root of the total number of authors, and half of the total production is taken as criteria for knowing whether the elite is productive or not[14,16,17]. As for Price's Law, 49% of the publications were produced by 13 authors, these being the most productive in the theme of this study[16,17].

Following Bradford's Law[10], tests showed that the behavior should follow the 7:20:61 ratio (expected frequency), and the observed ratio was 11:35:42. Considering the 5% significance for the Chi-square test [2], a p-value <0.05 was obtained, proving that the findings of this study do not follow the Bradford Bibliometric Law.

As for the words, all in the English language, Zipf's First Law was applied, showing great dispersion and heterogeneity among them, not finding a constant according to the law. This finding surprised the researchers in the present study.

Referring to Zipf's Second Law and Goffman's point T, words were found that relate to the theme of this study: “postmarket surveillance” and “medical devices”. Post-market surveillance associated with medical devices is at the heart of the use of UDI, since integrating the identification of IMD facilitates its traceability, achieving better surveillance and regulation.

Analyzing the theory of Zipf's Second Law, words with low frequency had the same occurrence of those with high frequency. For this reason, the Second Law of Zipf, modified by Booth, presents the behavior of the words of low frequency of occurrence. In this region, it is noted that there are many words with the same frequency[14,19].

Due to the importance of the UDI theme and the traceability of the IMD, the need to insert, in the discussion of the data, another parallel that could be traced in this

article was identified: the relevance of the studies carried out in other countries, confirming the need to encourage the publication on the theme, as well as the worldwide unification in the DMI traceability process, in view of the cases of process failures, from manufacturing to post-marketing, in addition to the lack of knowledge on the subject by the authors involved: manufacturers, vendors, hospitals, healthcare teams and patients.

The proper functioning of the medical device and the well-being of its recipients should have a higher priority for the FDA and the manufacturers of IMD, but the need was pointed out to the United States Congress to adopt new actions to protect patients with implantable material. In his article, Maisel [20] reports that patients with revoked AMD were not entitled to a visit with their health care provider, at no cost to themselves, to discuss the health or recall implications.

One of the studies reinforced that the risk regulation of medical devices is a neglected area in social science and health policy research, especially regarding the usefulness of traceability, which is so necessary for information about a recall to reach the patient or doctor. in a standardized way, through a single registry. He also reported that the idea of patient records and databases was, at that time, being considered by the United States and the European Union, and that both were in the process of introducing UDI[21].

Another study sought to identify "best practices" among these countries, which could support the public health goals of all IMD regulatory systems. Although only limited quantitative measures of post-market surveillance guide health policy decisions, the study assessed the variety of post-market surveillance strategies in four major medical device markets: The United States, the European Union, Japan, and China[22].

For the authors of one of the analyzed articles, considering that an increasing number of devices have been applied and used in medical care in recent years - each year, more than 300,000 artificial hip and knee joints are implanted in Germany alone - and taking into account that more information and communication technologies will be used in healthcare, resulting in an increasing number of clinical records, cohort studies, etc., it is expected that data related to medical devices will increasingly come from the field of research in health services, and this, in turn, will become an increasingly important source of knowledge for post-market surveillance of medical devices[23].

Some authors reinforced the importance of the UDI for increasing the effectiveness and efficiency of post-market surveillance within the database and for the traceability of IMD, in the event of the need for recalls:

> *"Given the unavailability of a Device Identifier (UDI), which should ensure traceability of the implant in the event of a product recall, cooperation with manufacturers to implement the RIAP MD Library integrated with the registry data collection is crucial. As a future perspective, the development of an IDU as a harmonized system at European level will be the best way to guarantee the effective traceability of MDs in the European Union and support the interoperability of different systems to monitor the use of MDs at national and international level.[24]"*

The article points out that, in the literature, there are no comparative studies between the laws related to the UDI. The authors also pointed out that establishing the UDI system in the digital environment is challenging and that there are difficulties in implementing the UDI-based tracking system for two reasons: the relevant legislation does not provide detailed information on how the UDI system will be implemented, and each type of medical device has its own UDI labeling difficulties. In Turkey, the authors noted that stakeholders in the medical device industry, especially manufacturers, are not yet ready for UDI-based tracking, and that the current registration system is not effective for tracking medical devices and sharing Data[25].

Conclusion

The study dealt with the analysis of the 126 articles retrieved from the Scopus® database, published in 88 journals from 2006 to 2018, all foreign, with no record of publications from Brazil or in Portuguese, which indicates the low productivity of Brazilian researchers on UDI and IMD traceability subjects.

The increasement of publications number over 12 years was demonstrated, as well as the origin of the articles, the most published journals on the theme and their geographical locations. As for the authors, it was noticed that, in the universe of 96 individuals, 62 articles (49%) were produced by 13 of them (14%); being that, in the average of three authors, the accumulated percentage of publication corresponded to 54.8% of the production, corroborating with Price's Law.

Regarding the words, all in English, Zipf's First Law could be partially applied since there was no constant relationship between rank and frequency. From the words cited in the retrieved articles, it was found that 64% of them were used only once, while others, which represented 36%, were used in a variability of two to 125 times, which reveals a great dispersion of the indexed terms used and suggests a strong heterogeneity of themes covered in articles about UDI.

On the other hand, the term "medical device" was used in 58 articles - almost half of the universe analyzed. And despite been a word that is not enough to designate a theme or subject around UDI, it is included in some situations, probably to make easier the indexing of the searches carried out. The term "Unique Device Identification" was used 23 times, while the word "traceability" was mentioned only 12 times, which perhaps corroborates in the recent scientific production on the topic.

Still about the words, was made its distribution by spheres. Thus, those that are relevant to index the theme of this research emerged - those in the second sphere. It is noted that the words were those mentioned in topics related to regulatory agencies and the International Forum of Regulators for Health Products (IFRHP), to the methodology applied to ID through the UDI, both linked to patient safety, also addressed in this study.

Applying Zipf's second law and Goffman's T point, were found words related to the theme, such as "postmarket surveillance" and "medical devices", corroborating Zipf's

Law regarding thematic indexing, derived from the analysis of a representative sample of documents on a given subject. In the transition region, therefore, are the words with the highest semantic content in each text, indicating that it is possible to determine the semantic content of publications with the application of Zipf's laws and their derivations.

In addition, the journals that carried out the research, the institutions to which they are linked, and their geographic location stood out. In this regard, it is evident that the issue remains isolated among researchers from the United States and european countries, confirming the formation of intercountry and interinstitutional collaboration networks, as well as the involvement of countries in the production and insertion of new health technologies in the market.

Despite having data and empirical facts as a theoretical basis, Lotka's Law and Price's Law confirmed the hypothesis that the journals most devoted to the topic are the most productive, in addition to showing that the more specific the theme, the more delimited will be the possibility of identifying elite groups of authors.

Regardless of the notorious importance of the UDI theme and traceability to the area of knowledge on health and patient safety, the scientific engagement on the journals with the greatest impact has not been directly proportional. However, the fact that it is a science and technology theme in the health area would justify the higher percentage of publications in a specific engineering journal.

Another important aspect within the areas of knowledge of the domain of recovered articles and journals, which needs to be considered, refers to the hegemony of the field of medicine in the publication of articles, since the development of health technologies is strongly linked to their use in this field. area (tests, development and use in the market), corroborating the appearance of journals related to information management, management in administration, economics, and information technology.

As a contribution, the results of this study, as well as its methodological framework, may serve as a basis for other research, thus filling a gap in the scope of bibliometric research in nursing. It is also reinforced that research on the triad UDI versus traceability versus IMD should be further explored by nursing, in view of the performance of this professional in the areas of health management, health audit, accreditation programs, quality of care in patient health and safety[26].

As a limitation, the small number of publications on the subject and the fact that all the words used were in English are cited. moreover, synonyms were not used for the descriptor used, as UDI does not have entertainment. It can be inferred that, due to the reduced number, the Bradford Bibliometric Law could not be proven, which encourages and instigates new studies on UDI.

References

1. Agência Nacional de Saúde Suplementar (ANSS). Relatório final: grupo de trabalho externo de Órteses, Próteses e Materiais Especiais (GTEOPME) [Internet]. Brasília (DF): ANS; 2016 [acesso em 14 fev 2020]. Disponível em: http://www.ans.gov.br/images/stories/Particitacao_da_sociedade/2016_gt_opme/gt-opme-relatoriointegral.pdf
2. Organização Mundial da Saúde (OMS). Segundo desafio global para a segurança do paciente: cirurgias seguras salvam vidas (orientações para cirurgia segura da OMS) [Internet]. Rio de Janeiro (RJ): OMS; (2009) [acesso em 14 fev 2020]. Disponível em: https://bvsms.saude.gov.br/bvs/publicacoes/seguranca_paciente_cirurgias_seguras_salvam_vidas.pdf
3. Tracol P. Materials vigilance and traceability. Orthop Traumatol Surg Res. 2016;102(1):95–103. DOI: 10.1016/j.otsr.2015.05.013
4. Curfman GD, Redberg RF. Medical devices: balancing regulation and innovation. N Engl J Med. 2011;365(11):975–977. DOI: 10.1056/NEJMp1109094
5. Marucheck A, Greis N, Mena C, Cai L. Product safety and security in the global supply chain: issues, challenges and research opportunities. J. Oper. Man. 2011;29(7):707–720. DOI: 10.1016/j.jom.2011.06.007
6. Agência Nacional de Vigilância Sanitária (Anvisa) Resolução n.º 2, de 25 de janeiro de 2010. Dispoõe sobre o gerenciamento de tecnologias em saúde em estabelecimentos de saúde [internet]. Brasília (DF): Anvisa; 2010 [acesso em 23 fev 2020]. Disponível em: https://bvsms.saude.gov.br/bvs/saudelegis/anvisa/2010/res0002_25_01_2010.html
7. Ministério da Saúde (BR). Manual de boas práticas de gestão das Órteses, Próteses e Materiais Especiais (OPME) [Internet]. Brasília (DF): MS; 2016 [acesso em 3 mar 2020]. Disponível em: https://bvsms.saude.gov.br/bvs/publicacoes/manual_praticas_gestao_proteses_materiais_especiais.pdf
8. International Medical Device Regulators Forum (IMDRF). Medical devices: post-market surveillance: national competent authority report exchange criteria and report form [Internet]. Brasília (DF): IMDRF; 2017 [acesso em 3 mar 2020]. Disponível em: https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-170921-pms-ncar-n14-r2.pdf
9. Lotka AJ. The frequency of distribution of scientific productivity. J. Wash. Acad. Sci [internet]. 1926 [acesso em 3 mar 2020];16(12). Disponível em: https://www.scirp.org/(S(czeh2tfqyw2orz553k1w0r45))/reference/ReferencesPapers.aspx?ReferenceID=2137230
10. Bradford SC. Sources of information on specific subjects. Engineering. 1934;137. DOI: 10.1177/016555158501000407
11. Goffman W. Mathematical approach to the spread of scientific ideas: the history of mast cell research. Nature. 1966;212(5061):449–452. DOI: 10.1038/212449a0
12. Goffman W, Newill VA. Generalization of epidemic theory: an application to the transmission of ideas. Nature. 1964;204(4955):225–228. DOI: 10.1038/204225a0
13. Conselho Nacional de Saúde (CNS). Resolução n.º 466, de 12 de dezembro de 2012. Considerando o respeito e a dignidade humana e pela especial proteção devido aos participantes das pesquisas científicas envolvendo seres humanos [Internet]. Brasília (DF): CNS; 2012 [acesso em 3 mar 2020]. Disponível em: https://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf

14. Guedes VL, Borschiver S. Bibliometria: uma ferramenta estatística para a gestão da informação e do conhecimento, em sistemas de informação, de comunicação e de avaliação científica e tecnológica. Encontro Nacional de Ciência da Informação [Internet]. 2005 [acesso em 3 mar 2020];6(1). Disponível em: http://www.cinform-anteriores.ufba.br/vi_anais/docs/VaniaLSGuedes.pdf
15. Santos RN, Kobashi NY. Bibliometria, cientometria, infometria: conceitos e aplicações. PBCIB [Internet]. 2009 [acesso em 4 mar 2020];2(1). Disponível em: https://brapci.inf.br/index.php/res/v/119278
16. Price, DJ. Little science, big science. New York: Columbia University Press; 1963.
17. Price DJ. Networks of scientific papers. Science [Internet]. 1965[acecsso em 4 mar 2020];149(3683):510–515. Disponível em: https://jast-journal.springeropen.com/
18. Andrade SR, Schimitt MD, Storck BC, Piccoli T, Ruoff AB. Análise documental nas teses de enfermagem: técnica de coleta de dados e método de pesquisa. Cogitare Enferm. 2018;23(1). DOI: 10.5380/ce.v23i1.53598
19. Booth AD. A "law" of occurrences for words of low frequency. Inf. Control. 1967;10(4):386–393. DOI: 10.1016/S0019-9958(67)90201-X
20. Maisel WH. Semper fidelis: consumer protection for patients with implanted medical devices. N Engl J Med. 2008;358(10):985–987. DOI: 10.1056/NEJMp0800495
21. Altenstetter C. Medical device regulation in the European Union, Japan and the United States: commonalities, differences and challenges. Innovat Eur J Soc Sci Res. 2012;25(4)362–388. DOI: 10.1080/13511610.2012.723328
22. Kramer DB, Tan YT, Sato C, Kesselheim AS. Postmarket surveillance of medical devices: a comparison of strategies in the US, EU, Japan, and China. PLoS Med. 2013;10(9). DOI: 10.1371/journal.pmed.1001519
23. Zippel C, Joschko SB. Post market surveillance in the german medical device sector – current state and future perspectives. Health Policy. 2017;121(8):880–886. DOI: 10.1016/j.healthpol.2017.06.005
24. Torre M, Romaníni E, Zanoli G, Carrani E, Luzi I, Leone L, et al. Monitoring outcome of joint arthroplasty in Italy: implementation of the national registry. Joints. 2017;5(2):70–78. DOI: 10.1055/s-0037-1603899
25. Bayrak T, Çopur FÖ. Evaluation of the unique device identification system and an approach for medical device tracking. HPT. 2017;6(2):234–241. DOI: 10.1016/j.hlpt.2017.04.003
26. Queiroz Freitas dos Santos MA, Moraes dos Santos C, Nogueira Vieira da Silva AL, da Silva Orlandi T, Duarte de Oliveira L. Auditoria de enfermagem: aspectos da qualidade da assistência e do seu registro no prontuário. Glob Acad Nurs. 2020;1(2):e33. DOI: 10.5935/2675-5602.20200033