

**ARTICLE**

The dissemination of scientific information as a guarantee of the legitimacy of the results of clinical trials

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ABSTRACT

This study aims to identify in the literature publications that portray the need to disseminate the results of clinical trials as a criterion for their transparency and validation. For that, it was used the documentary survey technique in the biomedical literature of documents that deal with transparency in clinical trial results. For the search, the descriptor "Clinical Trial" and the keyword "transparency" - ("transparency" [All Fields] AND "Clinical Trial" [All Fields]) were used. The Medical Literature Analysis and Retrieval System Online (MEDLINE) database of the National Library of Medicine (NLM) in the United States was selected. 394 documents were recovered, possible duplicates were removed and 226 documents of interest for the research were selected. In an integrated manner, the relationship of Information Science was established as the area that is dedicated to sharing information through the organization, communication and dissemination of science.

KEYWORDS

Publications. Information dissemination. Medical research. Test reliability. Disclosure.

A disseminação da informação científica como garantia da legitimidade dos resultados de ensaios clínicos

RESUMO

Este estudo tem o objetivo de identificar na literatura as publicações que retratam a necessidade de disseminação dos resultados de ensaios clínicos como critério de transparência e validação destes. Para isso, utilizou-se da técnica levantamento documental na literatura biomédica de documentos que versam sobre a transparência em resultados de ensaios clínicos. Para a busca, foram utilizados o descritor "Clinical Trial" e a palavra-chave "transparency" - ("transparency"[All Fields] AND "Clinical Trial"[All Fields]). Foi selecionada a base de dados Medical Literature Analysis and Retrieval System Online (MEDLINE) da National Library of Medicine (NLM) dos Estados Unidos. Foram recuperados 394 documentos, retiradas possíveis duplicatas e selecionados 226 documentos de interesse para a pesquisa. De forma integrada foi estabelecida a relação da Ciência da Informação como a área que se dedica ao compartilhamento da informação através da organização, comunicação e divulgação científica.

PALAVRAS-CHAVE

Publicação. Disseminação da informação. Pesquisa médica. Confiabilidade do teste. Divulgação.



JITA: BG. Information dissemination and diffusion.

1 INTRODUCTION

The need to organize, store and make available the information after the 'information explosion' after WWII made emerge a new area of knowledge Information Science (CI). This science, since its inception, had as concerns access to information, presenting their problems interlaced with the process of communication as described in 1949 by Shannon and Weaver (sender, message / channel and receiver).

In the mid-70s, it was amply recognized that the basis of CI said about the human communication processes (ie, a deepening of the finitism proposed by Bush), or as Belkin and Robertson (1976) summarized: 'the purpose of CI is to facilitate the communication of information between human beings'. (SARACEVIC, 1996, p. 47).

In order to define Information Science, Saracevic (1995, p. 2) still affirms that this field is concerned with the issue of the communication of knowledge in society in the context of individual or collective information needs. In the same vein, Yeps (2010, p. 105) states that CI "has as a study object a peculiar process of information composed of emitting subjects, messages, medium and receiving subject".

It is observed that since the 18th century, and especially the 19th century, the effects of product industrialization and increasing technological development in Europe have already been presented as an exponent factor of intellectual growth. As a result, there were successive and numerous inventions and, as a consequence, the inevitable agglomeration of records on scientific advances and discoveries.

In this same sense, Oliveira (2006, p. 25) points out that, after the changes of the Renaissance, "the 19th century had the privilege of observing the emergence of a new era in medicine based on experiment and therapy. The era of scientific criticism and systematic verification of the safety and efficacy of medicines was passed".

Thus, therapeutic research has developed too much and, as it has a variety of objectives, the results of these researches have come to be presented in various formats, including clinical studies with human beings (clinical trials).

The scientific communication achieved in the publication of clinical trials provides those who need the information - be they patients, professionals, researchers, financiers and other interested parties - public and updated records on the studies, adverse events and the results found.

However, although these trials have produced advances, been regulated and improved over time, there are still major challenges to be faced that limit the complete transparency of clinical trial data: such as volunteer selection bias, hypothesis bias and publication bias.

This article aims to conduct a systematized review of the biomedical literature to understand how the practice of disseminating information can help the transparency of clinical trials.

2 INFORMATION SCIENCE AND DISSEMINATION OF INFORMATION

Bearing in mind that in all periods of human history there were discoveries, to a greater and lesser extent, and that in some way these were recorded, Fontoura (2012, p. 89) states that "finding a way to coordinate all information about something was the main focus of Paul Otlet,

and he set out to do this aware of the advantages of the existence of a system or method that would allow this to be achieved in a practical and coordinated way”.

Paul Marie Ghislain Otlet, Belgian lawyer, born in Brussels in 1868, today, is considered the father of Documentation. Since his internship at a law firm, Paul Otlet has been involved with scientific publications in the legal field. Its main focus was to build a universal repertoire in which all publications could be organized and retrieved for everyone with an interest. With his positivist ideals, Otlet also believed that he could apply rules and procedures in the Social Sciences that had already been applied successfully in the Natural Sciences.

In the office Otlet was able to meet Henri La Fontaine, a lawyer and politician, with whom, in 1893, he created the International Institute of Sociological Bibliography (IISB). This institute represents the conception of Otlet's thought, shared with La Fontaine, on the logical and rational organization of scientific work. (LÓPEZ-YEPS, 1995, p. 62).

In addition to this aspect, the two lawyers identified themselves with pacifist actions and defended the thesis that treating information was a political act and for reducing social inequalities. In this perspective, Otlet and La Fontaine take on the task of organizing and publishing specialized bibliographies in the areas of Law, Psychology and Sociology. For Otlet, “they [bibliographies] are the source of information related to existing books and the basis of all documentation. They are the intermediaries between books and readers” (OTLET, 1934, p. 286).

The vision of Paul Otlet and Henri La Fontaine is summarized in the maximum organization and dissemination of recorded information. This perspective reveals the need already recognized by them that access to information is indispensable for the progress of society. Fontoura, a scholar of Otlet's work, states that he:

in 1892 he wrote an article for the Palais newspaper of the “Cercle du Jeune Barreau de Bruxelles” entitled “Un Peau de Bibliographie” in which he considers the immense possibilities of scientific advancement, if it were possible to obtain a greater organization of registered human knowledge (FONTOURA, 2012, p. 132).

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The lack of information organization, understood here as the lack of systems that facilitate the control, ordering and grouping of information, and even the difficult access to information, bring to the researcher complexity in the research and knowledge production process. And they can cause problems and delays at work and even make their results unfeasible.

In times of exponential and sudden advances in information technologies and the advent of the web, this need for sharing, interactivity and information creation has been enhanced, allowing the individual to be, in addition to being a receiver, the information generator.

In the face of so much information available, it becomes increasingly difficult to accurately and consistently retrieve desirable information. At the same time, there is the impression that, in all areas of knowledge, much information is not accessed.

Taking into account that the communication processes were, from the beginning, a concern of Information Science and, as José López-Yepes (2010) affirms that it is a general discipline for the service of all knowledge, that is, a type of science for science, it is possible to affirm the relation of CI in the communicative methods of all sciences.

In this sense, in the area of Health Sciences, more specifically in clinical studies, more and more, there is a need to disseminate and share information on procedures and results of clinical trials. This is due to the understanding that the advertising of these records makes the investigation more transparent and, consequently, more ethical.

In the literature, the process of sharing information between peers is called scientific communication. According to Caribé (2015, p. 90), it is attributed to John Desmond Bernal the responsibility of the term scientific communication, described in the chapter Scientific communication of the book *The Social Function of Science* (1939).

It is observed that, historically, since the 15th century, the exchange of letters and documents with less formality criteria was the communication mechanism between researchers. With the invention of the press in Europe, around the beginning of the 16th century, the distribution of scientific books facilitated the sharing of scientific studies. But it was only in the 17th and 18th centuries that the communication of science took on greater proportions.

Valeiro and Pinheiro (2008, p. 161) point out, in the book *Communication: the essence of Science* (1979), that Garvey and Griffith define scientific communication “as the set of activities associated with the production, dissemination and use of information” . In other words, these authors understand that scientific communication begins before the act of spreading information to a community, but begins in the first moments of scientific research and extends to the use of this by its recipients.

Scientific knowledge, then, is the result of research, production and communication. And it is through this last aspect that one can undergo the critical examination and tests carried out by other scientists in order to validate that knowledge as true and useful.

Mueller and Passos (2000, p. 14) emphasize that "if a scientist accepts a theory it is because he admits that it can explain a phenomenon or allows predictions about the behavior of that phenomenon". Thus, the approval of other scientists gives the content of the document the endorsement of 'scientific knowledge'.

Such communication makes possible the expansion of the study, new opportunities, possible exchanges of knowledge and practical advances, as well as ensuring the non-duplication of research and, with this, expenditure of human and financial resources in research already carried out.

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2.1. *Scientific Divulcation*

In this context of democratization of knowledge there is also scientific dissemination - a term that seeks to reflect the translation of scientific knowledge into terms and concepts that are easy for non-scientists to understand. This process envisions the summary and teaching practices of sharing a certain content, once written in a language recognized by few, for a given social group with a more accessible language.

Scientific knowledge is an integral part of full citizenship and of the process of social inclusion, since it enables the individual to have access to the minimum information essential to active and transformative citizenship. On the other hand, democracy is not limited to the distribution of knowledge, although it is essential for its constitution (CALDAS, 2010, p. 39).

In this orientation, scientific dissemination has both educational, cultural, political and ideological functions (ALBAGLI, 1996, p. 397). This is due to the intended results when there is an effort to share and contextualize scientific information.

Thinking about the educational function, scientific dissemination plays the role of providing society with a critical view of the benefits, or even the harm, of scientific production. As for the cultural one, the transmission of scientific information generates in individuals a curious proximity that makes them establish a pattern of constant search for knowledge for their daily problems.

This growing socio-economic insertion of science supposes, in turn, the acceptance, by society, of the beneficial character of scientific activity and its applications. Likewise, it implies a rapid assimilation, in the daily lives of individuals, of technical-scientific artifacts transformed into objects of consumption, given the speed with which innovations in this field have been taking place. Society itself broadens its interest and concern in better knowing - and also controlling - what is done in science and what results from it (ALBAGLI, 1996, p. 396)

The political and ideological results achieved with scientific dissemination directly reflect the citizen's civic position, particularly in matters dear to science. When well informed, individuals are better able to express their opinions in the choice of priority public policies and in government decision-making.

There are countless advantages to the popularization of science, even more if the technological factor that cooperates for agility and massification of scientific dissemination is added. Valeiro and Pinheiro defend the hypothesis that communication and scientific dissemination are increasingly approaching through Information and Communication Technologies (ICTs). For them, the target audience “[...] is perceived with new dimensions, conforming or forming in new contours, provided by the ICTs that allow to cover, in a fraction of seconds, distances never imagined until very recently” (VALEIRO; PINHEIRO, 2008, p. 167).

2.2 Clinical Tests and Scientific Communication

The clinical trial is an instrument that reports in detail biomedical research that seeks to know “from the potential human application of new laboratory findings to the generation of robust evidence on preventive treatments or interventions in care” (HUDSON; LAUER; COLLINS, 2016, p. 1353).

Clinical research involving human beings has undeniable benefits for scientific progress. However, over the centuries, the practice has shown openness to experimentation without criteria, with illegitimate and even abusive and unethical objectives.

In 1947, as a result of the judgment of doctors involved in abusive experiments carried out during the Second World War, the first international document (Nuremberg Code) was prepared, which guided the ethical aspects of research with human beings. Recognizing some flaws in this code, in 1964, the World Medical Association drafted the Declaration of Helsinki, during the 18th World Medical Assembly.

Taking into account the Nuremberg Code, the Declaration of Helsinki and other international documents that issued statements and guidelines for research involving human beings, in Brazil, the National Health Council, of the Ministry of Health, approved Resolution 196 on 10 DE OCTOBER 1996, which “became the first national landmark for the regulation of research involving human beings” (LORDELLO; SILVA, 2017, p. 8)

This resolution was updated by Resolution No. 466, of December 12, 2012, inspired by the bioethical principles of beneficence, non-maleficence, autonomy and others. Through it, guidelines and regulatory standards for research involving human beings were addressed, as well as the recommendation of submitting any research project involving human beings to an ethical review by the CEP / CONEP System.

However, some criticisms were made by the researchers of Human and Social Sciences, calling “bioethical imperialism the movement of the biomedical sciences to demand that the investigations of the human and social sciences be conducted according to their criteria”

(LORDELLO; SILVA, 2017, p. 8), demonstrated even in the academic training of participants in the CEP / CONEP System.

In view of the situation, on April 7, 2016, the National Health Council approved Resolution 510, which takes into account the ethical aspect as “a human, therefore historical, social and cultural construction” (BRASIL, 2016), which assumes the pluralistic and specific character of the Human and Social Sciences.

During two decades of updates, it is worth mentioning that the resolutions of 2012 and 2016 take into account the availability of research results in a final report format for the patients involved and for the CEP / CONEP System. But only resolution 466/12 makes the researcher responsible for “forwarding the results of the research for publication, with due credit to the associated researchers and to the technical staff members of the project” (BRASIL, 2012).

It should be noted that the Helsinki Declaration, which had seven revisions between 1975 and 2013, highlights the need to register research and disseminate the results that contribute to governing ethical aspects in clinical investigations in human beings. The Declaration highlights some articles that reveal the importance of the registration, availability and scientific communication of research protocols.

Article 17 of the Declaration requires registration and monitoring of possible risks in medical research. Article 22 determines the description and justification of the design and performance in a research protocol that contains the main information from clinical research. And articles 35 and 36 portray the need for publication.

35. The entire clinical trial must be registered in a publicly accessible database before recruiting the first participant.

36. Researchers, authors, promoters, reviewers and editors all have ethical obligations regarding the publication and dissemination of research results. Researchers have a duty to make the results of their research on human beings publicly accessible and are responsible for the accuracy and completeness of their reports. Everyone should abide by guidelines in force on ethical reporting. Not only positive results but also negative or inconclusive results should be published, or at least made publicly available. Funding sources, institutional links and conflicts of interest must be declared at the time of publication. Investigation reports that do not comply with the principles of this Declaration should not be accepted for publication. (WMA, 2013)

However, in view of these and other efforts, it is still verified that the dissemination of clinical research results is not completely reliable. It is often influenced by commercial interests. In experiments with human beings, communication and scientific dissemination are essential to generate trust and credibility, in addition to avoiding the exposure of patients to interventions that have already been studied and that have had the results known to be ineffective.

Based on a systematized review, this article seeks to understand the state of the art of clinical trial transparency assessments, the value of disseminating information, and to list, in a systematic way, categories to group the recovered documents.

3 METHODOLOGICAL PROCEDURES

The methodological procedures of this study were undertaken based on bibliographic research for the theoretical foundation of the study, followed by a documentary survey in the biomedical literature of documents that portrayed the evaluation of publication and transparency in clinical trial results.

We opted to select papers, reports and scientific editorials that are evaluated by peers, a situation not present in other types of scientific dissemination. The “full text” filter was used to guarantee full access to the recovered documents. The delimited period for this research is 6 (six) years (2014-2019). This choice was based on the year of the last revision of the Declaration of Helsinki (2013) in which it highlighted the “ethical obligations regarding the publication and dissemination of research results [of clinical trials]” (WMA, 2013), as already discussed in this work.

For the search, the Medical Literature Analysis and Retrieval System Online (MEDLINE) database of the National Library of Medicine (NLM) of the United States was selected. This database was chosen for the study due to its international literary representation in the field of biomedicine, in which approximately 5,400 journals from the United States and over 80 countries are indexed.

On July 5, 2019, the search strategy was applied: ("Clinical Trial" AND "transparency") - and 394 records were retrieved, in English, Portuguese and Spanish. The title and summary were read to select publications that identified the relevance of transparency in the efficiency, quality and ethics of clinical trial publications.

After completing the steps for selecting and reading the titles and abstracts, a sample of 226 articles was found, which were read to complete the analysis form and thus grouped into categories. Grant and Booth (2009, p.103) identify this process of “including one or more elements of the systematic review process” with flexibility in the aspects of search and evaluation as one for Systematized Literature Review.

As with the Systematic Review, the Systematized Review requires a pre-defined construction of criteria for the selection, evaluation and codification of the results obtained, which are modeled on a small sample of eligible documents.

4 ANALYSIS AND DISCUSSION OF RESULTS

Three hundred and ninety four documents were recovered and, when possible duplicates were discarded, an initial sample of 386 documents was obtained (table 1). Of these, 58.55% are related to the discussion between the need for transparency and the dissemination of results of clinical trials (table 2). The other documents discarded from the analysis were related because they deal with tests with transparent products, because they require a transparent budget, because they apply transparency in direct practices with patients, or because they have the word transparency in the document with other meanings than that sought in this research.

Table 1. Search results in the PubMed database

Recovered	Duplicate	Total
394	8	386

Source: the authors

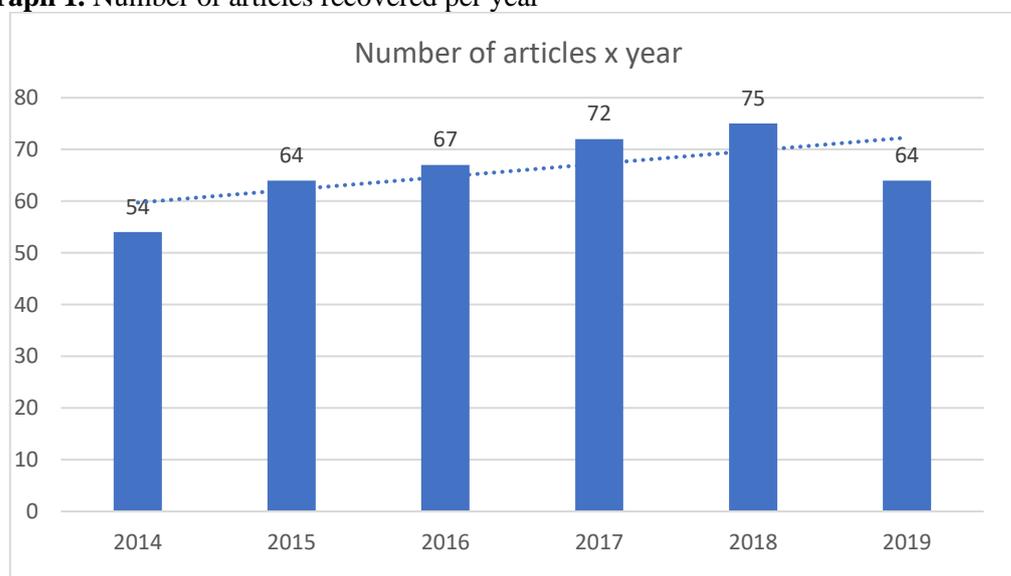
Table 2. Result of the search analysis

Total recovered	Selected	Percentile
386	226	58,54%

Source: the authors

There was a tendency to increase the publication of articles with the selected theme through the search strategy. It should be noted that the survey was carried out in the middle of the year 2019 and, therefore, the amount recovered this year is less than the previous year. Adding that, depending on the journals' processing deadlines, a published article can take months to be retrieved from a database (graph 1).

Graph 1. Number of articles recovered per year



Source: the authors

After filling out the analysis form, the retrieved articles can be organized into five categories: a) suggested changes to the protocols, that is, review of current practices for initial and final registration; b) more active participation of the patients involved, including reports of success with scientific dissemination; c) data control, which includes the observation of missing data in test records, the obstacles to data reuse and ethics in reports; d) biases, such as publication, selection, interests and reporting; and e) the need for transparency in clinical trial processes, which covers the importance of open access, the adoption of technologies and the transparency of contracts.

Among the selected documents, there is a greater ethical and protocol discussion in clinical trials practiced in countries such as the United States, Mexico, France, China and Estonia. In Brazil and India there were also publications that analyzed the clinical trial process, mainly, as Petryna reports, the low cost of research and the fragility of the health system attract the clinical trial industry “giving legitimacy to experimentation that, in other circumstances, it would be denied” (PETRYNA, 2011, p. 131).

It is noteworthy that, among all the articles categorized in changes in protocols, discussions were found on how the recording and publication of results have been practiced. In

some way, all the selected documents criticize the methodological instrument of the essays. This is due, according to the authors, due to possible loopholes for publication bias or 'beautification' of the results found.

One of the papers selected in the category of active patient participation, by the authors Yusuf Yazic and Hasan Yazic, highlights the role of the Informed Consent Form that "must also be the main source of information for the public about the reasons for the planned study, which is known in the field about the proposed study and what to expect in relation to effectiveness and damage" (YAZICI, Y; YAZICI, H, 2010, p. 121).

These authors point out that the document that registers the patients' consent must remain public and be submitted to the Institutional Review Board. They argue that in addition to the initial registration, the trials should be published so that any "interested person can have full access to the way of conducting the tests before, during or after being conducted, [...] making higher ethical standards" (YAZICI, Y; YAZICI, H, 2010, p. 121).

It is pointed out in the various articles that the transparency of clinical trials is a desired standard for the development of the area and leads to several advantages. Given the categories found, it is clear that there are still criteria to be followed and improved, including the correct, safe and complete dissemination of information.

Among the articles listed in the 'need for transparency in clinical trial processes' category, we highlight a study published in the Journal of Clinical Epidemiology that analyzes 2,132 clinical trial results reports produced at University Medical Centers in Germany between 2009 and 2013. The the authors state that "The results of clinical trials build the backbone of evidence-based medicine [...]. Non-disclosure or delayed dissemination of test results negatively affects all of these decision-making processes "(2019). And they conclude: "there is still a strong delay or even lack of disclosure of results in many trials". (WIESCHOWSKI; RIEDEL; WOLLMANN, et al., 2019)

Finally, we point out the report published in the Expert Review of Clinical Pharmacology, which was also grouped under the category of 'need for transparency in clinical trial processes', which identifies which clinical trials in the past three years have been translated into an appropriate language to the public. The report warns that "timely and effective dissemination of clinical trial results is not only essential for the development, diagnosis and treatment of medical conditions, but also fulfills an ethical obligation to inform patients and the public" (GETZ, K; FARIDES -MITCHELL, J, 2019).

The results found in the recovered documents reinforce the statement already mentioned by Valeiro and Pinheiro that communication and scientific dissemination are increasingly approaching. In several articles, the importance of sharing trial information is mentioned both for peers and for society, especially for those involved in clinical research.

5 FINAL CONSIDERATIONS

Information Science, known as the science of science since its birth, has been concerned with the problem of the organization and dissemination of information. For scientific progress in all areas, the dissemination of information without borders is required.

In relation to advances in health sciences investigations, the development of reliable clinical trials is the gold standard required for the construction of scientific knowledge. For this purpose, scientific communication and dissemination are responsible for the characterization of scientific quality. However, in recent years, it has been observed that this paradigm has been

diluted in low levels of transparency, selective reports and influence of funders to the published results.

In view of a bibliographic survey in the biomedical literature, 226 (two hundred and twenty six) scientific articles were selected that reported the flawed scientific behavior regarding the quality of transparency, lack of data, bias and conflicts of interest.

Taking into account that the Declaration of Helsinki fostered the ethical duty of those involved in the public dissemination of the results of research with human beings, an increasing appreciation of scientific communication was observed over the last 6 (six) years.

Despite this, the analysis of these documents points out that the quality of clinical trials is closely related to the quality of the available data, which makes a feedback cycle, that is, a quality clinical study depends on other quality results already produced. The contrary can provide a partial or inaccurate picture of the results.

With the exponential growth of available information, sharing data is not a simple task, as it requires organization and methods. However, it is a practice that can be aided by Information Science and that allows to legitimize scientific production through a critical examination carried out by other scientists in order to validate such data as true and useful.

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