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Research Article

Increasing Efficiency and Safety of Clinical Trials by Implementing Information Technologies and Social Media

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Abstract

In the paper, authors discuss issues related to implementation of IT technologies and social media in clinical research, as well as practical problems of human subjects' protection. Technological development and development of health technologies, in particular, draw significant global attention to bioethics. Information security and confidentiality in clinical trials has much greater importance for clinical trials involving information technologies and social media. Authors concluded that protection of human subjects' rights and interests require development of recommendations on implementation of information technologies and social media in clinical research.

Keywords: Information technologies, social media, ethics in clinical trial, human subjects' protection

Introduction

The spread of the Internet and increasing popularity of social networks provide many opportunities for their use in the organization and conduct of clinical trials.

80% of the internet users are specifically looking for information about health topics

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such as diagnosis or treatment [1]. Information technology helps to increase the level of information openness, allowing potential participants of clinical trials to have better understanding of goals and objectives, possible risks and benefits, which ultimately should encourage them to make more informed decisions about participating or refusing to participate in the trial.

Social media includes online platforms for dissemination and discussion of ideas, thoughts and contents on a public resource. Existing social networks can be represented in the following categories: professional communities (LinkedIn, Doximity, Facebook), content generators (Twitter, blogs), distribution of images ("Pinterest", Instagram) and video (YouTube, Snapchat, Periscope) [2].

To avoid problematic situations, it is necessary to carefully study and understand not only benefits, but also possible risks and negative aspects associated with the use of information technology in medical research. Thus, the use of social media provides an opportunity to reach a wide range of potential participants and discuss information within the social network groups in which information will be posted. On the other hand, it is important to ensure confidentiality of information obtained through the interaction with group members. Despite the fact that often participants of the research were warned about the need for confidentiality and non-disclosure of information, they can discuss their participation in Facebook, VKontakte, Twitter or other social networks. Research subjects can share secret knowledge in the social media such as telltale side effects, track their own outcomes independently of researchers, and even conduct their own statistical analyses [3]. When blind method is used in the study, research subjects can compare medical evidence in social media and make assumptions about the medications they are obtained, especially if clinical trial is conducted on several groups, including placebo. Such actions of research subjects may negatively affect the quality and results of a clinical trial and cause biases.

Despite the above-mentioned problems, the use of social media helps to attract a wide range of potential participants. With over 2.0 billion monthly active Facebook (FB) users worldwide, FB's ad platform serves as an invaluable recruitment tool [4]. When an announcement about an ongoing study and invitation to participate in clinical trial is placed in specialized social network groups, potential participants have an opportunity to discuss prospects for participation both inside and outside the group, which can help them to make more informed decision. However, there is a risk that the dominant group members can influence potential research subjects about their participation in the study.

Often participants of clinical trials place information about their experience in social media. In that vein, if participants of the previous phase of clinical trial share their experience in social media, it can help to attract more participants to the next phase. Researchers often discuss ongoing research, results and emerging problems at specialized forums, professional networks and on their pages in social media that also contribute to increasing availability of information about ongoing researches. Thus, social media allows receiving information about ongoing researches in "real-time mode".

Advanced targeting capabilities of social media and an enormous user base, are as effective and time efficient mechanism for recruiting subjects that will complete the course of a clinical trial [4]. Moreover, by analyzing forums, blogs and other networks on a particular topic, researchers can identify groups of potential participants who might be invited to participate in the clinical trial. The use of advanced analysis and search technics allow determining not only the location of a person, but also his gender and presumably age that can also be used for targeting audience by using contextual advertising. For example, data on the location of groups of potential participants obtained from the

social media can significantly help in choosing the location of the study, which will be most convenient for those groups.

Among the main advantages of using e-technologies in clinical trials can be named the following: improving efficiency, lowering cost, fostering research and development, involving stakeholders and facilitation of information dissemination. Despite the many advantages, there are some limitations and challenges that require additional careful consideration: privacy and confidentiality issues, keeping up with technology, adequate infrastructure, data accuracy and provider attitudes, etc. [5]

Technologies-issues in bioethics

Back in the IV-III centuries, BC Hippocrates indicated ethical norms and rules that must be followed by medical practitioners. However, when trying to find new forms and methods of treating certain diseases, doctors often found themselves in a situation when it was necessary to choose between several options that could have different consequences for patients. To ensure future technological development, it was necessary to understand the potential and limitations of human body under the impact of new technologies. For example, for the development of aviation, it was important to understand the limitations of human body associated with changes in external factors such as temperature, pressure, amount of oxygen, etc. To solve the emerging issues that could limit the use of certain technologies, it was required not only to reach theoretical understanding, but also to prove the theory by experiment.

As history shows, rights and interests of participants in medical experiments were not always in the foreground. Everyone knows about terrible Nazi medical experiments conducted by German physicians on thousands of concentration camp prisoners during the Second World War. Among such experiments were high-altitude experiments, creation of special pressure chambers for pressure experiments that followed by surgery to determine an effect of experiment on human brain; the study of malaria treatment methods in which prisoners were infected with malaria, and then tested various treatment options; experiments with sulfanilamide to determine its effectiveness for the treatment of streptococcus, tetanus and anaerobic gangrene. By conducting these experiments, the physicians believed that they were acting exclusively in the interests of the development of medicine and science in general. In 1947, the Doctors' Trial was conducted under the Nuremberg Military Tribunals and the Nuremberg Code was adopted as a set of research ethics principles for human experimentation. However, the line of violation of human rights in medical research is so thin that despite of taken measures, the concept of morality in medicine remains subjective. In subsequent periods, fundamental ethical principles continued to be violated in one way or another [6].

Thus, in the period 1946 - 1948 years in Guatemala, a number of prisoners, patients of the local psychiatric hospital, and Guatemalan soldiers were infected with syphilis and other sexually transmitted diseases in order to study the efficacy of penicillin. The team of scientists was headed by John Charles Cutler, who later also participated in the Tuskegee experiment with syphilis. This experiment was conducted in Guatemala because it was not allowed in the United States. In 2010, when information about this study was published, the US officially apologized to Guatemala.

In the period of 1932-1972 years, the Tuskegee experiment was conducted in Alabama, to study natural progression of untreated syphilis on a group of rural African-American men. Participants of that experiment were not informed that they were research subjects. When information about this research was officially published, the experiment was condemned by the society as violating ethical norms and human rights. In 1972, the experiment

was stopped as ethically unjustified and the government paid $ 9 million and provided free medical assistance to survivors and family members.

The consequence of such a violation of human rights was adoption by the US Congress in 1974 year; the National Law on Scientific Research, which imposed prohibition against non-therapeutic studies on human subjects. Also such important documents as the Helsinki Declaration (1964) and the Belmont Report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" (1979) were adopted. These documents proclaimed basic ethical principles for protection of research subject rights and necessity to consent participants of clinical trials.

Development of innovative technologies leads to the emergence of new aspects of bioethics related to the development of biomedical knowledge, expansion of research in the field of neurobiology, genetic engineering, transplantology, and at the same time to increase using Internet technologies in the process of conducting clinical trials. Ashish Galia claims that many countries still do not have sufficient methodological base and guidelines on the use of media in clinical research and medical practice [7]. Most of the existing recommendations provide clarifications on the delineation of content for posting in social networks for personal and professional purposes. At the same time, it should be noted that the expansion of the use of social media in research is associated with the emergence of a large number of problematic issues that need to be considered and discussed in order to develop necessary recommendations and guidelines.

Experience of the United States of America in developing recommendations for the use of social media in clinical trials

The widespread of social media in clinical trials has skyrocketed. Researchers increasingly use social media to promote awareness and encourage research subjects to participate, but by doing so, they have to comply with regulations. The National Institute of Health of the United States has developed Guidelines for the Involvement of Participants in Clinical Trials Using Social Networks [8]. Despite the fact that this document is oriented to the reality of the American system, key provisions of this document can also be used to guide scientists of other countries.

It is important to consider all possible consequences of a breach of confidentiality in a new environment of social networks. In this direction, researchers have to ensure protection of confidentiality of information received in social media from potential participants (completed questionnaires, correspondence, and the like). Researchers should consider the fact that information posted in social media can be copied and storied in the future, this information may become the subject of use by the third parties. At the same time, it is necessary to take into account that the settings of confidentiality in social media may differ depending on the device from which a user is accessing the network. For instance, if a user has set the privacy settings on a computer, these settings might not work, when he access the account from a mobile phone. In addition, after automatic software updates on mobile phone, the privacy settings can be reset, and if the user has not checked and set them again, the privacy may be lost. In this regard, researchers should carefully study privacy policy and security system of the network in which information will be posted.

When attracting specific groups (groups of people united by certain diseases, support or advocacy groups), researchers should be very careful and sensitive in communication so as not to undermine people's trust in clinical research and informed consent.

An invitation to participate in clinical trial, placed in social media should be in a copy-protected and amended format, in order to ensure correctness and accuracy of

transmitting information. Furthermore, it is necessary to obtain approval of the ethics committee for the content of the advertisement message. It is especially important when information contains data that goes beyond a name, purpose of the study (in simple language), summary of the protocol, main criteria for inclusion in the study, location and contact details for more information. If the information posted in an unprotected format, researcher should point out to the ethics committee of how it will be posted. Strategies for placing information about clinical trial in social media, as well as strategies for interaction with potential participants and information protection should be included in the materials submitted for consideration and approval of an ethics committee.

Researchers are encouraged to review and educate themselves about the potential risks to privacy and confidentiality and consider utilizing all available privacy settings to reduce these risks. They are also mindful of the possibility that any electronic communication can have a high risk of public discovery.

Information security in clinical trials will always have a valid concern, especially in relation to computer systems and IT security practices. Researchers also might consider encrypting their email server connection and using encryption protocols to send information by emails.

Applying information technology on the stage of informed consent

It should be noted that clinical trials on human subjects should be conducted only if risks do not exceed benefits, while the health of research participants should not be harmed as well as confidentiality and privacy of participants' information should be protected. Potential participants in medical research should receive sufficient amount of information about the goals, methods, research process, risks and benefits, methods of confidentiality protection, etc., to be able to make a decision about participation in research or decision to refuse participation. This information should be provided in the informed consent form. Informed consent should be signed before subject joins research and it should be written in such a way that an "ordinary person" who does not have special knowledge relevant to the field of research could understand the content. Unfortunately, some researchers and research subjects are still approaching the process of signing informed consent formally. Often researchers are loaded with work and do not have enough time for detailed discussion of issues related to clinical trial with potential participants and do not take actions to control accuracy of understanding of the information contained in informed consent. In addition, for part of clinical trials, especially in fields such as oncology, informed consent materials can contain 50 pages or more that complicate the process. Besides, if potential participants do not have experience in participating in clinical trials and do not have knowledge in the field, it is likely that information represented in informed consent may not be interpreted correctly. To improve informed consenting process, video-based consent method was proposed. Video-based consent makes it possible to present information in a better format for understanding and helps to improve participants' comprehension of key issues related to the research. Potential candidates can use tablets or computers to view video, which can be divided into several parts with small tests at the end of each part to control the correct understanding of material. In case the wrong answer is given on the test, the correct answer will be shown, and if there are additional questions, it is possible to write these questions in the system for subsequent discussion with the researcher. After this, potential candidate should read the full text of informed consent. It is also possible to watch video and study informed consent outside the researcher's office, which allows potential research subjects to discuss questions related to participation in the clinical trial with friends and family. Moreover, researchers can get statistics on the time of viewing each part of the video and answers to the

tests, as well as the time that was spent on reading each section of the informed consent. This technology will allow researcher to pay attention to the points that will be useful for further discussion with the potential participant before signing the informed consent.

Using information technologies and social media at the stage of engaging potential participants in a clinical trial will allow greater accessibility and transparency of information, as well as better understanding and comprehension of the informed consent materials. Better understanding of the informed consent will decrease the likelihood of ethical problems and improve protection of rights and interests of clinical trial subjects. However, despite all advantages provided by the use of social media and information technologies, researchers should take greater responsibility to ensure confidentiality of information.

To ensure information security research, organizations should establish data privacy policies, restrict access to information system, etc. The use of information technologies and social media to engage potential participants in clinical trials will allow greater accessibility and transparency of information about the study, at the same time, it will make it easier for potential research participants to understand the content and will shorten time that researches spent at the stage of the informed consent. As a result of a better understanding the content of informed consent, the likelihood of ethical problems will decrease and the protection of the rights and interests of research participants will definitly be improved.

The development and dissemination of the Internet and media technologies assure that in the future, their role and application in clinical trials will grow. Social media helps to increase the level of information openness, allowing potential participants better understand the risks and benefits related to clinical trial and make more informed decisions regarding their participation in the trial. At the same time, Bertalan Meskó claims that despite the fact that social media provides faster, more interactive and achievable way of communication, it creates a hidden challenge which is that medical professionals have never been trained to address such issues [9]. To overcome this challenge it is important to provide research integrity and research ethics trainings for clinical researchers. In this regard, it is necessary to ensure additional training on the use of information technology and social media in clinical trials and include such courses as well as the courses on ethical aspects of using information and media technologies in clinical trials into the curriculum of medical universities. Physicians and researchers can also use online platforms that offer free courses on the use of media technology for clinical research and practice [10]. These resources include Coursera, TEDx, The Social MEDia and other platforms that offer relevant online training programs.

An important issue remains which is the development of recommendations and guidelines for the use of social media in clinical practice and in life science research that would cover emerging ethical issues. The development of these documents and materials will preclude possible harms and violations of human subject rights in clinical trials involving information and media technologies.

Summery

1. Clinical trials on human subjects should be conducted only if risks do not exceed benefits, while the health of research participants should not be harmed as well as confidentiality and privacy of participants' information should be protected. Potential participants in medical research should receive sufficient amount of information about the goals, methods, research process, risks and benefits, methods of confidentiality protection, etc., to be able to make a decision about participating in research or decision to refuse participation.
2. Informed consent should be written in a way that a person who does not have

special knowledge relevant to the field of research could understand the content. Video-based format helps to simplify consenting process and improve participants' comprehension of key issues related to the research.

3. Widespread use of social media in clinical trials emphasizes the importance of considering all possible consequences of a breach of confidentiality in a new environment of social networks. In this direction, researchers have to ensure protection of confidentiality of information received in social media from potential participants. Researchers should consider the fact that the information posted in social media can be copied and storied in the future, this information may become the subject of use by the third parties. At the same time, it is necessary to take into account that the settings of confidentiality in social media may differ depending on the device from which a user is accessing the network.

4. An invitation to participate in clinical trial, placed in social media should be in a copy-protected and amended format, in order to ensure correctness and accuracy of transmitting information.

5. It is necessary to obtain an approval of the ethics committee for the content of the advertisement message, especially when information contains data that goes beyond name, purpose of research (in simple language), summary of protocol, main criteria for inclusion in the study, location and contact details for more information. If the information is posted in an unprotected format, researcher should point out to the ethics committee of how it will be posted. Strategies for placing information about clinical trial in social media, as well as strategies for interaction with potential participants and information protection should be included in the materials submitted for consideration and approval to an ethics committee.

6. Development and dissemination of the Internet and media technologies assure that in the future, their role and application in clinical trials will grow. Using the information technologies and social media in clinical trials obliges researchers to ensure protection of privacy and confidentiality of information related to research subjects. To ensure information security research, organizations should establish data privacy policies, restrict access to information system, etc.

7. It is also important to provide research integrity and research ethics trainings for life science researchers. In this regard, it is necessary to ensure additional training on the use of information technology and social media in clinical trials and include such courses as well as the courses on ethical aspects of using information and media technologies in clinical trials into the curriculum of medical universities. An important issue remains which is the development of recommendations and guidelines on using social media in clinical practice and in life science research that would cover emerging ethical issues.

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