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Review Article

Application and Exploration of Broad Informed Consent in Hospital of China

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Abstract

Broad informed consent is a special form of informed consent designed to allow hospitals to use medical data and patient residual biological samples for a wide range of applications in medical research. It is suitable for clinical research with low risk and uncertain research purpose. Applications of broad informed consent in hospitals include biobank management, in vitro diagnostic kit clinical trials, hospital teaching and research, and data use of hospital big data platforms. Despite the challenges of implementing it, broad informed consent contributes to scientific progress and public health. In this paper, we define the elements of broad informed consent, outline the challenges of its application in hospitals, and explore broad informed consent implementation. We believe that broad informed consent plays an important role in the development of medical research. This paper aims to improve the implementation efficiency of broad informed consent through implementation plans and measures to motivate medical personnel.

Keywords: Broad Informed Consent; Hospitals; Medical data; Patients' remaining biological samples

Introduction

With the deepening of medical research and the advancement of technology, the medical data and patients' remaining biological samples generated by hospitals have become valuable research resources. However, how to use these resources legally and ethically, while protecting patients' right to informed consent and privacy, has become an urgent issue. As an innovative informed consent model, broad informed consent provides a new way to solve this problem [1]. This paper will discuss the concept, characteristics, application scenarios, implementation challenges and related benefits of broad informed consent, and put forward implementation suggestions to promote its effective application in hospitals.

Broad Informed Consent

Broad informed consent (hereinafter referred to as "broad informed consent") is a special form of informed consent, which is used to make use of medical data generated by hospitals and the remaining biological samples of patients for a wide range of applications in medical research [2].

Clinical studies using general consent are characterized by the following: the medical data and residual biological samples involved pose a relatively low risk to the subject, and the investigator bears the responsibility to fully inform the subject that these data and samples may be used for future research; On this basis, researchers are committed to maximizing the application value of these resources in future research, ensuring that their research activities not only meet ethical standards, but also make substantial contributions to scientific progress and public health [3]. Not all research is suitable for broad informed consent. For research projects where specific uses have been identified, particularly those involving the collection of identifiable biological materials or medical data, more specific informed consent modalities should be adopted to ensure the legality and ethics of the research. This means that in the implementation of clinical research, the scope of application of broad informed consent must be carefully defined in order to maintain the right to informed consent and privacy of patients [4].

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The broad informed consent falls between specific informed consent and waiver of informed consent which is used when the specific purpose of the research cannot be determined. Exemption from Informed Consent that under certain circumstances, researchers can conduct research without the informed consent of subjects. Exemption from Informed Consent generally applies when the study does not involve direct contact with the subject, or the subject is unable to provide informed consent, and the risk of the study is very low. The exemption of informed consent is also subject to review and approval by the Ethics Committee to ensure the legitimacy of the study and the protection of subjects' rights and interests.

In summary, broad informed consent provides the flexibility to allow the use of medical data or residual biological samples in future research, informed consent focuses on the clear purpose of the research project and the immediate consent of the participants, and waived informed consent waives the conventional informed consent requirement in certain circumstances. All three aim to balance the need for research with the protection of subjects' rights.

Application of Broad Informed Consent in Hospitals

The specific circumstances of the application of broad informed consent in hospitals are as follows:

Use of biobank: Biobanks hold great promise for future advances in medical science [5-8]. In the management of biobanks, it is necessary to use broad informed consent to collect the remaining samples of patients for future research. During the treatment in the hospital, after obtaining the patient's broad informed consent, the patient's surgical excision, biopsy tissue and cells, stool, blood, urine, pleural fluid, secretory fluid, hair, nail and other solid samples were collected for biological sample storage [9].

Use of in vitro diagnostic kits in clinical trials: For hospitals that are able to conduct clinical trials of in vitro diagnostic kits, broad informed consent is required. For patients entering medical and health institutions, in the course of clinical diagnosis and treatment, it is necessary to conduct broad informed consent for patients who may be used for research in the future before collecting samples, and use the remaining samples for clinical trials of in vitro diagnostic kits.

The application and implementation of broad informed consent is the focus and difficulty of clinical trials of in vitro diagnostic reagent project. Sponsors of in vitro diagnostic reagent project are more inclined to hospitals with good broad informed consent implementation, so how to improve the broad informed consent signature rate of hospitals will be the key work to be solved by hospitals.

Hospital teaching and scientific research: For teaching hospitals and hospitals engaged in scientific research, the remaining samples of patients should be used. It should be noted that the remaining samples in the first study are used for secondary purposes in other studies, and the informed consent for future studies must be included in the informed consent signed for the first study [10].

Data use of hospital big data platform: All kinds of medical data generated in clinical diagnosis and treatment or research, including electronic medical records, imaging data, clinical examination and monitoring data, etc. (including extracts of examination data from other hospitals) may be used for research in this medical and health institution in the future, and the authorized use of data for clinical diagnosis and treatment of patients requires the patient's broad informed consent.

The Broad Informed Consent Implementation Challenges in Hospitals

At present, the implementation of broad informed consent in hospitals also faces many difficulties and challenges. How to carry out the extensive implementation of broad informed consent in hospitals, including the application of electronic signature and other technical problems are the difficulties and challenges of broad informed consent implementation in hospitals; From the implementation difficulties of medical staff, complaints caused by the busy daily work of medical staff, lack of understanding of broad informed consent content, and patients' insufficient understanding of broad informed consent content have affected the enthusiasm of doctors to seek broad informed consent from patients. At the patient level, the signing rate of broad informed consent is usually low due to patients' concerns about the donation of remaining samples, which limits the application of medical data and patient remaining samples in hospital clinical research to a certain extent.

Correlation Gain

The broad informed consent should inform the possible benefits of future research. Including the benefit of donors and the benefit of society. The benefit to society is the purpose for which the biological sample or information is collected. Medical institutions should establish appropriate mechanisms for feedback of research findings to donors. The hospital can adopt hierarchical broad informed consent to provide donors with the choice of whether they want to obtain the research results[11]. The hospital information system can be set up to link the relevant examination of biological samples provided by donors with personal health data in the public account, and the relevant examination results or research results can be fed back to donors. When the relevant research of donor samples or information has validity analysis, clinical significance and applicable research results, involving major health problems and have direct clinical utility, life-saving information and data should be fed back to donors. It is important to note that feedback on specific genetic results should take into account the need for individual counselling for donors, and that donors should be reminded that providing individual diagnoses is not the purpose of future research projects, in order to prevent false reassurance of donors without active feedback on the findings of studies.

The benefit of the donor is the guarantee and purpose of the smooth collection of biological samples or information. In the implementation of broad informed consent, hierarchical broad informed consent can be implemented, that is, hierarchical questions are set in the broad informed consent of the electronic system and the paper system: if the sample or information donation is successfully entered into the relevant research, and the sample or information has scientific validity or clinical importance, the relevant fees are determined according to the cost budget provided by the research project.

The Broad Informed Consent Recommendations Implemented in Hospitals

For the broad informed consent implementation plan, there are two proposed implementation plans for electronic system authorization and non-electronic system authorization:

Electronic system authorization implementation plan: Pop-up window in the interface of outpatient medical system and medical record system prompts doctors to ask patients whether they agree to use biological samples or information for medical research, and whether they voluntarily sign broad informed consent in the electronic system.

The electronic information system for outpatient and inpatient medical treatment will pop up the broad informed consent interface when the patient is seeking medical treatment, and remind the patient whether he/she agrees to donate biological samples or information for teaching and medical research in the content of the informed consent statement.

For non-medical biological sample donors, set the broad informed consent interface on the personal center interface of the hospital public number, set whether to agree to donate biological samples or information for teaching and medical research, and set the type of donated biological samples in the content of the informed consent statement. Voluntary donors contact the relevant biological sample management staff to collect.

Introduce the knowledge related to sample or information donation in the relevant public accounts of hospitals and popular science publicity videos.

Implementation plan for authorization of non-electronic systems: The publicity manual column shall be set up in the outpatient hall and the public area of the inpatient department of the hospital, and the relevant clinical research manuals and broad informed consent forms of the hospital shall be placed in the publicity manual column, so that the medical patients or donors can fully understand the benefits of clinical research, the rights and interests of the subjects, the importance of sample or information donation and other relevant knowledge.

Posters related to the significance of clinical research, samples or information donation are placed in the hospital consultation room and examination area, so that medical patients or donors can fully understand the significance of sample or information donation.

In the consultation room, doctor's office, examination room, etc., place the relevant paper manual of sample or information donation, consult the doctor or donor's opinion, so that the donor can sign in time.

Paper manuals related to sample or information donation can be provided in community free clinic and community publicity activities, so that medical patients or donors can fully understand the significance of sample or information donation.

In addition to the above two implementation schemes, how to motivate medical staff to encourage donors to sign broad informed consent opinions will greatly promote the implementation of broad informed consent hospitals.

Specific Implementation Suggestions Are as Follows

Performance bonus. It is proposed that a percentage of the funding for clinical trials using broad informed consent be used to reward medical staff who successfully get patients to sign broad informed consent.

Honorary title recognition. The medical staff with outstanding performance in the work of broad informed consent will be awarded the honorary title of "Excellent Worker of Clinical trial" and awarded a certificate.

Offer opportunities for advancement. The honorary title of "Excellent Clinical Trial Worker" is used as a bonus in promotion assessment, providing promotion channels for medical staff with excellent performance in broad informed consent work.

Intensified publicity and training. In order to ensure that medical personnel involved in the use of patients' broad informed consent can fully understand and effectively convey project information and obtain patients' broad informed consent, the paper version of broad informed consent and project-related publicity brochures are placed in the doctor's office. This information is not only the embodiment of legal and ethical requirements, but also a key link to safeguard the rights and trust of patients, to ensure that patients fully understand the content of the study, and can make their own decisions about whether to participate in the study.

Training and advocacy may include: Educate and train health care workers on broad informed consent to ensure that they understand its importance and the correct way to implement it, including understanding how to communicate information effectively, respect the wishes of patients, and address patients' questions and concerns.

Emphasize donor rights: Emphasize the autonomy and choice of donors throughout the process, ensuring that they know they have the right to withdraw consent at any time. At the same time, clearly inform them how their personal information will be protected and whether they will gain any benefit from it.

Through the above strategies, medical personnel can effectively strengthen the soliciting of donors' broad informed consent opinions, improve the signing rate of broad informed consent, promote the effective use of medical data and biological samples, and ensure that the rights and interests of donors are fully respected and protected.

Conclusions

As a flexible form of informed consent, broad informed consent provides convenience for hospitals to use medical data and patients' remaining biological samples for medical research, while protecting patients' rights and interests [2]. Although there are many challenges in the implementation process, the signature rate and implementation effect of broad informed consent can be effectively improved through the authorization of implementation plans in electronic and non-electronic systems, as well as incentives for medical personnel.

The application of broad informed consent not only helps to promote medical research and scientific progress to bring substantial benefits to patients and society, but also is an important embodiment of medical ethics and the protection of patients' rights and interests. In the future, with the continuous development of technology and the improvement of ethical standards, broad informed consent is expected to be more widely promoted and applied in hospitals.

Author Statements

Data Availibility Statement

The original contributions presented in the study are included in the article, further inquiries can be directed to the corresponding author.

Ethics Statement

Written informed consent was obtained from the individual for the publication of any potentially identifiable images or data included in this article. Ethical review and approval were performed by the Medical Ethics Committee of The Central Hospital of Wuhan, Tongji Medical College, Huazhong University of Science and Technology, China.

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Author Contributions

Designed the manuscript: YX, JL. Analyzed the manuscript: YX, XYR, JL. Wrote and reviewed the manuscript: YX, JL.

Disclosure of Potential Conflicts of Interest

The authors indicate no potential conflicts of interest.

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