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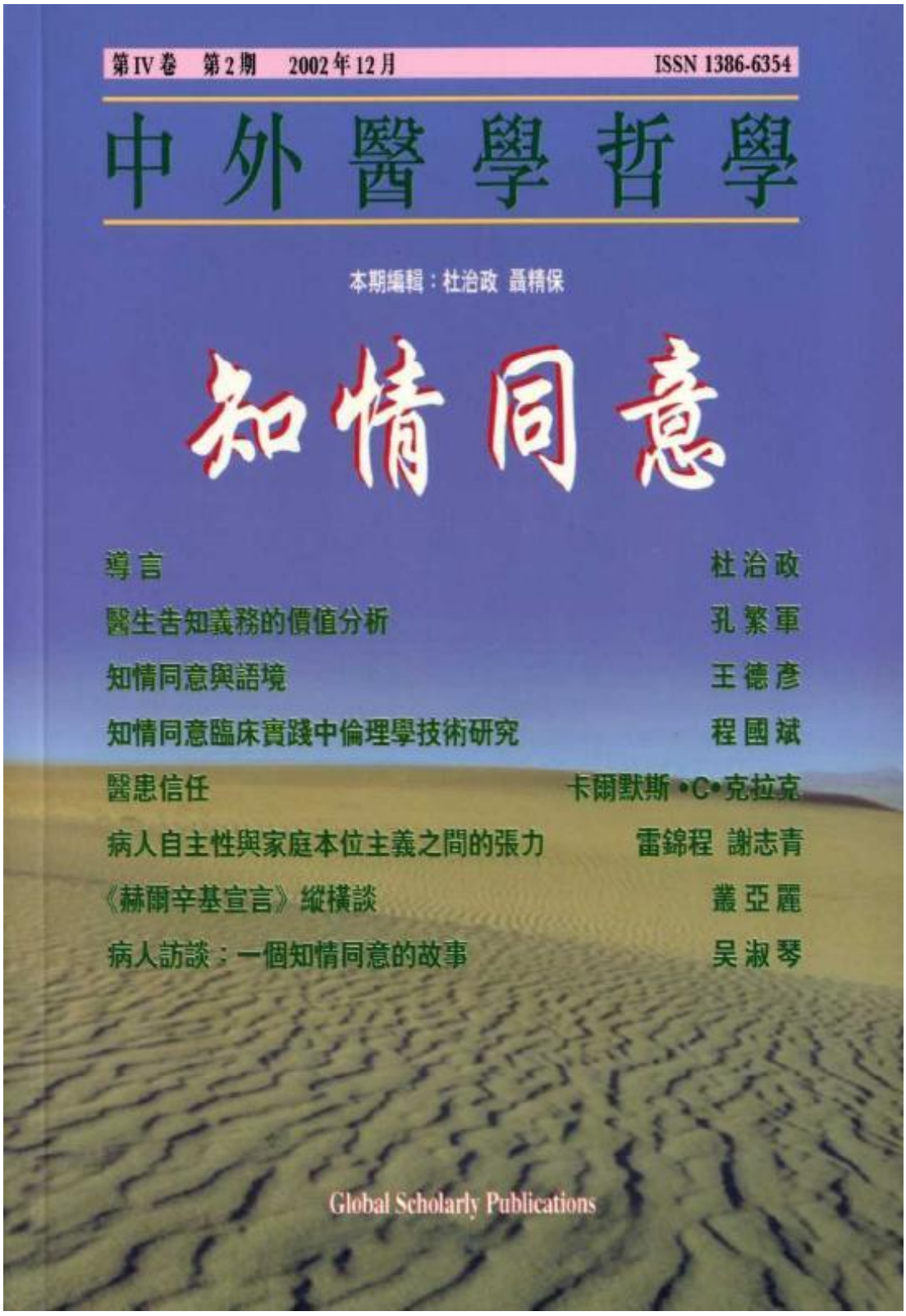


Order

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# 知情同意
# Informed Consent

本期編輯：杜治政、聶精保
Issue Editor: Du Zhizheng, Nie Jingbao

## 醫生告知義務的價值分析

孔繁軍

摘要

醫生的告知義務，是指在醫療工作中，醫方應當就患者的診療資訊向患者做出適當的說明和解釋。醫生告知義務突顯了患者的人格獨立，在法律上體現為醫生的普遍行為準則，並具有對醫療行為的歸責意義。適當的履行告知義務有利於增強和提高治療效果，有利於建立良好的醫患關係，從而促進醫療事業的發展。應當注意的是，在利益多元化的社會中，患者的知情同意與社會利益及生命價值的衝突，告知義務與保護性醫療的衝突必須予以關注，明確衝突中的價值排序。

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## 知情同意與語境

王德彥

摘要

理解是實現知情同意的基礎，而理解與知情同意的語境學問題有密切關係。醫生常常抱怨病人聽不懂，病人也認為醫生的解釋過於術語化。問題就在於醫患雙方語境的差異。２０世紀 ８０年代對知情同意的研究已經開始從告訴病人什麼資訊轉向了怎樣告訴病人的研究。因此醫生除了關心病人敘述的意義之外，還需要關注以各種日常語言為中介與事實之間所建立的聯繫，注意語句的規範性以及正確把握雙方的語言意圖和目的。本文試圖對知情同意進行語義學、語形學和語用學的分析，以便從這三者統一上來透視和闡述知情同意的各種語境的規定性，以提高知情同意的可理解性。

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# 知情同意臨床實踐中倫理學技術研究

程國斌

摘要

具體實踐中的知情同意是一種倫理學技術，注重利用現有的文化傳統、理論資源和法律工具，合理有效地分析問題、解決問題，強調它作為體現對病人基本權利的尊重和調節醫患關係手段的作用。在民主社會，知情同意乃是建立醫患權責關係的必要條件。知情同意來自於醫療活動的自發秩序：醫患雙方通過知情同意活動，明確醫療活動中雙方的權利和青責任界限，進行有成效的醫療實踐。知情同意既是對基本人權的尊重，又是確保雙方責任的工具。具體實踐中的知情同意，提供一種促進多種價值觀和平共存、通過學習和對話實現平衡的運行機制，在社會整體利益優先與個人最基本權利不可侵犯的框架下滿足雙方不同的價值需求。臨床"知情同意"活動的目的在於：促進患者自主權的行使；明晰醫療活動中的權責關係，在合法限度內為醫療活動的正常進行提供保護。實踐中追求資訊的"充分"，取決於志方要求的"主觀的充分"。臨床醫療活動中，醫方要不斷提高患方知情的充分程度。隨著知情程度的增加，患方自主程度隨之自動上升。目前開於"知情同意"的理論研究中，缺少對知情同意的狀況、分佈及相關因素的實地調查和量化分析，研究多集中在道德、文化理論上，實踐策略的指導意義不強。應當把知情同意視作貫穿於整個臨床醫療活動的一個連續的整體。要關注本社區成員的文化和心理結構的特殊性，從本社區歷史特點出發，建立本社區知情同意情況的常規模式和量化標準。還應當設計臨床知情同意調查制度，作為醫方制定知情同意策略的依據，同時又可作為說明醫療活動發生的真實過程的法律檔。

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# 病人自主性與家庭本位主義之間的張力

雷錦程、謝志青

摘要

在中國幾千年，J、農經濟和傳統文化背景下，個人利益、個人權利一直被置於家庭之下，個人自主性被包含在家庭自主性之內，表現為一種家庭本位主義。源自西方歷吏、丈化的知情同意移植到中國後，受傳統文化觀念的影響，中國人對知情同意的認知、理解以及實踐方式均不同於西方人。這種不同集中表現在人們對家屬同意權的認可。

以個人本位主義為背景的病人自主性與中國文化中的家庭本位主義之間存在張力。對知情同意在不同文化環境中不同踐行方式，應以文化寬容主義的態度對待之。不同文化背景下的倫理觀念，不僅存在差異。牲，而且也存在可通約性和相容性。由於種種原因，家庭同意並不能等同於病人本人的意願。隨著全球化進程的加速和人們相互交往的密切，類似知情同意這樣一些原本屬於個人的自然權利，將會愈來愈多地為各國人民接受。我們應當在某些條件具備時，盡可能地將家屬同意限制在合理的範圍，讓病人更好地表達自己的意願。

目錄

## 《赫爾辛基宣言》縱橫談

叢亞麗

摘要

自從 20 世紀 80 年代末，隨著中國和其他國家在生物醫學科研上合作的增多，與之有關的倫理問題隨之增加。尤其是 20 世紀以來，如果說科研倫理學是生命倫理學領域的一顆新星不過分的話，那麼，赫爾辛基宣言就是科研倫理學的核心的說法是很洽當的。為了提高科研倫理學的意識，保護受試者的權益，預防潛在的倫理問題的發生，順著赫爾辛基宣言發展的歷史並找尋其中變遷的線索是非常必要的。

具體來說，從紐倫堡法典產生的背景和內容開始，追溯 1964、1975、1983、1989、1996、2000 和 2002 年赫爾辛基宣言變化的原因，並把主要變化的內容單獨標注出來，以利於讀者進行比較分析。探詢歷史發展的軌跡，是為了從中吸取經驗教訓，完善對受試者保護權益保護的機制。本文所有的材料都是為了這個目的服務的。

關於國際前沿性的對最新的赫爾辛基宣言的爭論，讀者頭腦中要有各國對科研倫理學原則的多元化的理解這樣一個觀念，同時要知道聲音最大的背後的原因，而且更重要的是要有結合中國情況的意識，以及是否適合中國的情況的分析，否則仍要停留在被動停留的地位，不能真正實現科研倫理學的實踐性價值。

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## 病人訪談：一個知情同意的故事

吳淑琴

摘要

本故事提出了如下一些知情同意方面的問題：面對沒有文化‘且毫無醫學知識的病人，如何履行知情同意 2 在病情緊急情況下應否免除知情同意或待病情穩定後再向病人或家屬補充說明？如果是後者，這種事後的同意有何意義？在醫院追逐利潤並與病人利益發生衝突的情況下，費用成為病人關注的重要問題，病人女。何有效的表示自己的意見？在病人本人沒有經濟能力、又無醫療保險的條件下，一切依賴家屬，病人士。何維護自己的權益？病人本人的意願有何意義？如何面對既不能否定家屬的同意又有可能出現家屬違背病人本人意願行事可能的困境？

目錄

# Values and the Doctors' Obligation to Inform

**Kong Fanjun**

Abstract

The doctors' obligation to inform means that the doctor shall inform the patient of related information on diagnosis and treatment. Specifically, it includes the following three aspects: l) Explanation of diagnosis, that is, the explanation mad+ part in fulfilling the responsibility of the doctor. Whether the doctor has performed obligation to inform should be taken as important evidence in judging whether a medical error has occurred. If harms to the patient or delay of treatment happen due to the doctor's insufficient or inappropriate explanations about the risks of invasive diagnosis measures and treatment schedule, the doctor should take the responsibility of tort or harm compensation for his or her failure in informing. Reflecting the change of modern medicine from a bio-medical model to a bio-psycho-socio model, to inform the patient fully will help the patient gain an all-around and correct knowledge about his or her illness and take an active role in treating the disease. The process of informing is also a process of medical and health care education. To inform the patient fully will help to establish and maintain a good, reasonable and harmonious doctor-patient relationship.

What should be noted is we should give close attention to the conflicts of various values in informed consent, including social and individual interests and duties to inform the patient and to protect the others. Acknowledging and ranking these conflicting values is thus important. Generally speaking, when patient's autonomy conflicts with public interests, the patient's autonomy should be limited by public interests. When the patient's autonomy endangers his own health and life, the protection of the patient's health and life will be the prime value. Protective treatment is an important rule of medical ethics and legal obligation. But the practice of protective treatment will deprive the patient's autonomy and individuality as it relieves the patient's suffering. Nevertheless, protective treatment is a reality and the solution to the problem will only depend on the careful discretion of the doctor.

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# Informed Consent and the Context

**Wang Deyan**

Abstract

Understanding, being closely associated with the context, is the basis of realization of informed consent. Physician often complains that patients cannot well comprehend medical information, while patients are often unsatisfied with the explanatory statements and technical terms given by physicians. Since 1980s the emphasis in the studies of informed consent has shifted from what should be presented to patient to how to present the related information to patients. Besides being concerned with the meaning of the narratives of patients, physician should pay close attention to the connection of the medical facts or information and the everyday language, to maintain the norms of the syntax, and to understand the real goal and intention of the patients. This paper aims to approach the context of informed consent by semantic analysis, syntax and pragmatics.

Informed consent involves much more than merely reading and signing a paper. It normally has two essential parts: a document and a process. The document of informed consent should be understandable to any ordinary patient in the local population. It should be written in such a way that anyone with an education level of the ninth grade or lower can read it. To make the document of informed consent easy-to-read, the following requirements should be met. First, the language is everyday language and familiar to the readers. Any scientific, medical, or legal terms should be defined clearly. Second, terms and key concepts should be consistent throughout the document. Third, sentences should be short, direct, and easy to comprehend. Fourth, the paragraph should be short too. Each paragraph coveys one major idea only. Fifth, every idea should be clear and logically sequenced. Last but not least important, readability analysis should be to determine the reading level of the document.

The process of informed consent process requires physicians to provide the patient with ongoing explanations so that patients can make his or her informed decisions. This is to say, before the patient makes his or her decisions, the physician should fully discuss related issues with the patient. Of course, the physician's communication skills are usually difficult to change. However, physicians can improve their communication skills through learning and practicing.

Of course, in China, not only researchers and physicians, but patients and research participants, including the public who can be regarded as the potential subjects, lack the full understanding of the principle of informed consent. It is thus

important to improve the nationwide level of education, for it is only by doing that the principle of informed consent can be carried out in reality. The current level of education of the nation is not high yet, and many people even cannot fully understand some basic terms in medical and life sciences. There is still a still considerable amount of illiterates in China. In medical education, especially in the educating of medical ethics, we have not paid enough attention to on the principle of informed consent so that some medical students even never heard the term "informed consent." As a result, there is still a long way for us to go.

Informed consent, serving as an effective measure to protect the subjects and patients, has enjoyed the wide recognition in the fields of medical and related laws. It has become the paradigm of consent in medical research and clinical practice internationally. Many international relative organizations have regarded informed consent a basic ethical requirement. Legally speaking, physicians and patients are equal. But in reality they are not equal. There is an imbalance of medical knowledge between doctors and patients. Although the patient has the right to make his or her own decision, he or she is often not capable of deciding and choosing. It is necessary to establish the law in order to guarantee the realization of the patient's rights such as informed consent.

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# Informed Consent as an Ethical Technique in Clinical Practice

**Cheng Guobin**

Abstract

Informed consent is an ethical technique which emphasizes using the existing cultural traditions, theoretical resources and legal instruments to analyze and solve the problems reasonably and effectively. Informed consent can thus play a significant role in adjusting the relationship between patients and physicians. As an ethical technique, it focuses on the method of applying various ethical resources and not simply on the combination of the logical consequence and criteria. In a democratic society, informed consent is a necessary requirement for the right-duty relationship between patients and physicians. Informed consent is seen as a prerequisite obligation to physicians and implies certain rights for patients. Patients and physicians are bound by informed consent so that they are able to "trade" equally. Informed consent is not only a means to confirming the property rights but also a tool of reducing the costs of "trade". In practice, informed consent helps to promote and achieve the peaceful co-existence of pluralistic values. It can do so by learning and having conversations with the other sides so that different parties can satisfy under the framework which gives priority to the total interests of society and guarantees the fundamental rights of individuals.

The aims of informed consent in clinical practice are to promote the self-determination of patients and to clarify rights and duties in medical activities. In practice, the sufficiency of information depends on the subjective sufficiency of patients. Physicians should ensure that the patient comprehend the information and follow the appropriate procedure to manage and supervise. The most active method for physician to take is to increase the degree of informational sufficiency. The degree of the patient's self-determination increases accordingly with the increase of informational sufficiency. Their relationship can be described by a curve like "S".

The current studies on informed consent in China lack the empirical data from field research. Most studies focus on the theoretical issues of morality and culture. As a result, research results are hardly applicable in clinical practice. Informed consent should a holistic entity in clinical practice. We should pay more attention to the specificity of the cultural and psychological structure of members of every community. We should establish the ordinary model and criteria of informed consent in the particular community. We should also design an applicable and legally-bond system of informed consent to regulate clinical practice.

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# The Tension between the Patient's Autonomy and Familism

**Lei Jin-cheng, Xie Zhi-qing**

Abstract

Family has a long history. With China's small-scale peasant economy and traditional cultural background for centuries, family has been the most basic unit of polity, economy, and socio-cultural life. Interests and rights of the individual are always placed below those of family; individual autonomy is often included in family autonomy. All this can be called familism. There are deeper and determining economic reasons for familism. The economy of the family is controlled by the head of the family or clan so that the individual usually has no independent economic measures to support his or her autonomous rights.

Informed consent originated in the Western culture. The theoretical premise of informed consent is respect for the patient's autonomy. The patient's autonomy is closely related with individualism in the West. After informed consent is spread from the West to China, due to the influence of traditional Chinese culture, the Chinese perception, understanding, and practice of are different from those of the West. The difference mainly lies in Chinese familism. To focus on the autonomy of the family reflects the influence of traditional familism upon informed consent. As a result, there exits a tension between the patient's autonomy based on individualism and familism in Chinese culture.

Informed consent is not a culture issue, but it is closely related with cultural tradition. It is impossible to get away with cultural norms in the practice of informed consent. To different practicing methods of informed consent in different cultural contexts, the spirit of cultural tolerance is needed. In China, with the principle of cultural tolerance as a practical guidance, we should establish a set of procedure and ways of practicing informed consent with Chinese characteristics. Fundamentally, informed consent is to balance the unbalanced power between doctors and patients. According to the principle of cultural tolerance, the difference in the practice of informed consent at different cultural contexts should be tolerated so long as the basic purpose of informed consent is not violated. There exists a variety of cultural ideas among contemporary Chinese. The individual patient and his or her family are essential part of informed consent, with both having their rationality. Thus, we shouldn't reject absolutely some methods. From the angle of historical development, it is worthwhile noticing the transformation from family determination to individual autonomy. National and cultural differences are integrating in the age of globalization. Since laws, ethics,

and customs in different countries and cultures are mutually exchanging, we should promote to make the practice of informed consent to become similar.

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# On the Declaration of Helsinki and Its Implications for China

**Cong Yali**

Abstract

Along with the development of biomedical research cooperation between China and other countries since late 1980s, many ethical issues have occurred. It is not exaggerating to claim that research ethics is a bright star in the field of bioethics, especially since the end of the 20th-century. It is also appropriate to say that the Declaration of Helsinki consists of the core of contemporary research ethics. This paper will trace the history of Declaration of Helsinki and seek for the clue for positive changes. To do so should be able to help to raise the consciousness of research ethics in people, to protect the rights and welfare of human subjects, and to prevent some potential ethical problems from happening.

This article will describe in detail on the background from the Nuremberg Code to the Declaration of Helsinki and on changes happened in different versions of the Declaration of Helsinki in 1964, 1975, 1983, 1989, 1996, 2000 and 2002.

The obvious and significant changes of different versions will be highlighted for the convenience of the reader. The aim of this historical review is to learn the experiences and related lessons in the West and thus to develop the system of human subject protection in China. All the materials of the article are directed to this aim. Regarding the current ethical debates on the latest version of the Declaration of Helsinki, we should be aware of the moral pluralism and plurality among different countries. It is important to analyze and understand the strongest voice in the debate and the background of this voice.

Yet, the most challenging task is to find out what is suitable for our country-China--and what is not. In other words, while we need to learn from the West about human subject protection such as the historic and influential document like the Declaration of the Helsinki, it is crucial to root Chinese research ethics in our particular conditions in China. Otherwise, we will always in the status of simply following the West blindly and cannot fulfill the practical significance of research ethics in Chinese reality.

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# A Story on the Difficulties in Informing the Patient

**Wu Shuqing**

Abstract

The story reported in this article raises some questions on informed consent. To patients with no education and no medical knowledge, how do medical professionals perform informed consent? In the situation of emergence, should medical professionals be excused from the obligation of informed consent? Or should the patient and his or her family be informed after the illness is cured? If this is so, what is the meaning of informed consent? With the conflict between the interests and the patient and the hospital, the cost is a very importance issue. How does the patient express his or her opinions effectively? Patients who have no economic capacity and no medical insurance depend on their families for medical care. How can their rights and interests are protected? What medical professionals should do if the decision of the family is against the will and interests of the individual patient?

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