知情同意的伦理阐释与法制建构

陈化 著

INFORMED CONSENT IN CHINA

ETHICAL AND LEGAL ANALYSIS

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序　一

在过去的一个世纪，知情同意已经成为全球（包括西方医疗体制与中国医学）高质量医疗照护的重要组成部分。《知情同意的伦理阐释与法制建构》这本非同一般且内容翔实的著作里，陈化教授讨论了知情同意的理论基础（第一章至第三章），在临床与研究境遇中的具体实践（第四章至第七章），存在的问题以及在法律与道德两个层面的出路（第八章至第十章）。该书的最终目的在于，通过检审中西医实践中的理论与实践挑战，在中国建构关于知情同意的跨文化的生命伦理学概念。为此，陈化博士使用了三种方法：(1) 规范分析研究；(2) 对于当下中西实践作批判性阐释；(3) 包括问卷调查与案例研究的实证研究。

尽管我从未在中国行医，但我已在美国做临床医生逾 50 年。关于知情同意何以成为美国卫生保健的核心要素，我愿意分享一些观点。

西医的医患关系史可划分为家长主义时代与自主时代两个阶段。家长主义时代持续数千年，描绘了医学中基本的权威类型。“医生知道何为最好”模式以对医生技术与道德地位的信任为前提，其典型特征是患者的依从性与医生的控制。父权主义模式强调的是患者的照护而不是患者的意愿，是患者的需求而不是患者的权利，是医生的道德权威而不是患者自主或自我决定。

肇始于二战后的现代医学时代被称为自主时代。对自主的彰显得益于广泛的政治与社会运动，它们以追求权利与卫生服务资源分配的公平为目标，以减少医患之间的等级壁垒。在 20 世纪 50 年代，美国掀起了一场始

于民权与种族平等的人权运动，并延伸至女权、学生权利与病人权利。人权运动进一步强化了自主与知情同意。正如陈化教授在著作中阐述的，自主只是尊重人这一伦理原则的一部分。尊重人与自主要求我们承认完全行为能力个体的道德权利，它允许人们选择与遵循自我生命的计划与行为。

过去的 70 年，尽管医患之间仍维持着二重关系，但是权力的天平在理论上从医生向患者发生微妙的位移。作为法律原则的知情同意与医疗事故（用于诉讼没有获取知情同意的医生侵权或疏忽）的潜在威胁共同成为现代医学新的重要组成部分。

尊重人及其自主作为伦理原则，要求医生尊重患者的意愿、价值观与决定，而这些常常通过知情同意机制得以表达。在此，我简要地讨论医生获得患者知情同意的临床、法学与心理学意义。

其一，知情同意的临床意义。与患者协商知情同意对于好的临床照护至关重要。尊重患者自主表明，在推荐医疗方案后，医生应当尊重患者的偏好，尤其是临床中的合理选择。作出同意治疗的患者应当给予他们的医患关系足够信任，更好地配合实施临床决策，并对医疗保健表示满意。实证研究也表明，慢性病患者如高血压、糖尿病、关节炎患者，甚至心理抑郁症患者，当他们提问、表达他们的选择并对治疗作出知情同意时，他们会有更佳的健康效果。在 2007 年，由卢与同事对美国 3500 名患者的随机调查表明，91.0% 的患者更倾向于自主或共享自主（患者与医生的共同决策）的医疗模式，仅 9.0% 的患者赞同医生按照自己的偏好对待患者的家长主义模式。

其二，知情同意的法律意义。美国法律认识到所有人均具有控制其身体以及免遭不必要侵犯的权利。两个早期的司法判例清楚地陈述了该原则：(1) 每一位心智正常的成年人有决定应当如何处置身体的权利。没有患者的知情同意而实施手术，医生将对其侵犯行为的损害承担责任。(1914 年，斯契伦道夫诉纽约州立医院案) (2) 英裔美国法则以绝对的自我决定为始基。它认为，每一个体都被看作是其身体的主人，在心智正常的情况下，他可能会拒绝救治生命或其他医疗措施的实施。法律并不允许医生用

其本人的判断替代患者的同意。（1960 年，纳坦森诉堪萨斯克莱因案）

美国 50 个州的法律均要求医疗必须实施知情同意，紧急情况下除外。知情同意保护患者对其身体的控制权，在知情同意缺失的情况下实施手术，医生将会面临医疗侵权或疏忽的诉讼。最后，尊重患者通过知情同意表达的价值观与偏好也被证明是对医生最好的保护，以免遭遇玩忽职守的法律诉讼与医疗暴力。

其三，知情同意的心理学意义。尊重患者的知情同意具有重要的心理学意义，因为它确保了患者作为人的价值。由于受到疾病的威胁，患者常有一种获得控制感的心理需求。当患者的治疗没有经过其同意时，他们很可能不相信甚至漠视医生的推荐方案，常常体现为不配合、生气或敌对的态度。

在美国，知情同意奠基于西方哲学的自主概念、自我决定与尊重人，它建构了患者表达自我偏好与作出医疗选择的权利理念。患者偏好构成了医患关系在临床、法律、伦理与心理的核心维度。在最基本的层面，知情同意的价值更是显而易见：任何时候患者都可以选择是否寻求医疗照护，建立或终止医患关系，同意或拒绝医生的临床方案。在美国，是患者而不是医生拥有通过表达个体偏好建立、维持与终止医患关系的道德与法律权威。完全行为能力患者表达个体偏好的常规方式就是临床知情同意。譬如，在标准的临床照护中，手术或治疗方案代表了医患之间的讨论与协商。最理想的情况是，协商会促进良好的医患沟通，医患治疗同盟的达成，以及患者的自主选择。当患者真切地期待其治疗结果，提前预料到可能的并发症，并同意与医生作为真心诚意的合作者接受医疗计划时，这将会极大地推动医生的工作。从这个意义上说，适度协商的知情同意将有利于医患双方。

在临床诊疗中，知情同意被界定为医生充分告知推荐的管理计划及其风险和受益，以及替代医疗方案及其受益和风险之后，由病人自愿接受医疗干预。知情同意是医患双方沟通与协商，以帮助患者作出自我决定的过程。重要的是，知情同意远比签署同意书的内涵更丰富，同意书只是表明知情同意过程已经发生的一纸文书。尽管知情同意在法律上是必要的，但

并不具有伦理与法律上的充分性。

在美国，目前有三种不同的标准判断医生的告知是否充分：理性医生标准；理性病人标准；个体病人标准，该标准具有极强的主观性且摇摆不定。美国目前的司法审判倾向于理性病人标准，即对理性病人充分告知后由病人作出自愿理性的决定。尽管理性病人在法律上具有合法性，但是那些与患者建立良好医患关系的医生经常尝试满足个体病人标准。理性病人标准在伦理上是充分的，但是个体病人标准更为理想。信息告知在伦理与法律上的要求常常伴随临床情景而改变。随着临床情景从紧急情况向选择性照护、研究性程序变化，告知的标准更高、更严格。信息告知的最高标准与人体研究或实验息息相关。

陈化教授的杰出之作从中西跨文化的视角讨论了中国的知情同意。著作的核心部分（第四章至第七章）准确地聚焦了中国知情同意在临床与研究中的实践。它们重点讨论我在序中讨论的几点内容，包括知情同意标准的紧密联系以及医患关系从家长主义向自主模式的变迁。著作中第六章清楚地阐明，在中国和美国，紧急情况下不实施知情同意而抢救病人可以获得充分的辩护。易言之，紧急情况下医疗家长主义能得到伦理辩护，基于医学有利概念：当患者缺失同意能力时照护病人的义务。除此之外，陈化教授为中国语境下知情同意实践重要性进行辩护，指出它反映了现代医学的道德与伦理标准及医学职业精神。

我真诚地希望陈化教授的著作能得到中国学界的认可，并翻译成英译本出版。该著作将是在已有知情同意著作基础上的重要补充，并为西方读者展示知情同意在中国的状况！

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2018 年 1 月 20 日

Foreword to "Informed Consent in China"

During the past 100 years, informed consent (IC) has become one of the principal components of high quality medical care throughout the world, both in Western medical systems as well as in Chinese medicine. In this extraordinary, informative book on IC in China, Professor Hua Chen discusses the theoretical basis for IC (chapters 1, 2, and 3), the practical application of IC in clinical and research situations (chapters 4, 5, 6, and 7) and certain special problems related to legal standards and professional codes that apply to IC (chapters 8, 9, and 10). The ultimate goal of the book is to formulate a trans-cultural bioethical conception of IC in China by examining theoretical and practical challenges to IC in Chinese and Western medicine. Dr. Hua Chen uses three methods to achieve this goal: 1) normative analytic studies; 2) critical interpretations of current IC practices in China and the West; and 3) empirical techniques that include questionnaire surveys and case studies.

Although I have never practiced medicine in China, I have practiced medicine for 50 years in the United States. I would like to offer some thoughts on why IC has emerged as a core factor in U.S. health care.

The history of the physician-patient relationship in Western medicine can be divided into two periods: the Age of Paternalism and the Age of Autonomy.

The Age of Paternalism lasted thousands of years and represented the basic

authoritarian strain in medicine. This model of medicine–the "doctor knows best" model – was premised on trust in the physician's technical skills and moral stature, and was characterized by patient dependency and physician control. The paternalistic model emphasized patient care rather than patient wishes, patient needs rather than patient rights, and physician moral authority rather than patient autonomy or self-determination.

The modern medical era, which began after World War II, is called The Age of Autonomy. This emphasis on autonomy was sparked by widespread political and social movements to gain entitlements and rights, achieve equity and equality in the distribution of health services, and reduce the hierarchical barriers between the patient and the physician.

In the U.S., a new focus on human rights emerged in the 1950s that began with civil rights and racial equality and later extended to women's rights, students' rights and eventually to patients' rights. This human rights movement further encouraged an emphasis on autonomy and informed consent. As Professor Chen makes clear in this book, autonomy is part of a larger ethical principal: respect for persons. Respect for persons and autonomy both demand that we acknowledge the moral right of competent individuals to choose and follow their own life plans and actions.

During the past 70 years, the dyadic relationship between physician and patient has been maintained, but the theoretical balance of power shifted subtly from physician to patient. Informed consent legal doctrine, as well the potential threat of malpractice suits for battery or negligence against physicians who failed to obtain IC, have become a new and important part of modern medicine.

Respect for persons and their autonomy is the ethical principal that requires doctors to honor the wishes, values and decisions of their patients. These values are often expressed through the mechanism of IC. Let me briefly discuss the

clinical, legal and psychological significance of physicians obtaining IC from patients.

Clinical Significance of Informed Consent. Negotiating IC with patients is essential for good clinical care. Respect for the autonomy of the patient implies that a physician should, after offering recommendations, honor the patient's preferences, especially among medically reasonable options. Patients who consent to treatment have great trust in their relationship with physicians, cooperate more fully to implement clinical decisions, and express greater satisfaction with their health care. Empirical research has also shown that patients with chronic diseases such as hypertension, diabetes, arthritis, and even psychological depression, have better health outcomes when they ask questions, express their opinions and give informed consent for treatment. A 2007 survey by Lo and colleagues of 3500 randomly selected patients in the United States showed that 91% preferred a medical model of either autonomy or shared autonomy (that is, shared decision making between patients and their doctors), while only 9% favored a paternalistic model, where the physician treats the patient according to the physician's preferences.

Legal Significance of Informed Consent. American law recognizes that all persons have a fundamental right to control their own bodies and a right to be protected from unwanted intrusions. Two early judicial opinions state this principle clearly:

1."Every human being of adult years and sound mind has a right to determine what shall be done with his own body. A surgeon who performs an operation without his patient's informed consent commits an assault for which he is liable for damages." (Schloendorff v. Society of New York Hospital, New York, 1914)

2."Anglo-American law starts with the premise of thorough self-

determination. It follows that each man is considered to be master of his own body, and he may, if he be of sound mind, prohibit the performance of life-saving surgery or other medical treatment. The law does not permit a doctor to substitute his own judgment in place of the consent of the patient." (Natanson v. Kline, Kansas, 1960)

All fifty U. S. states now have laws requiring informed consent for medical treatments except in cases of emergency. Informed consent protects the legal rights of patients to control what is done to their bodies. Without IC, performing surgery or administering medical treatment may open the physician to charges of battery or negligence. Finally, a respect for patient values and preferences as expressed through informed consent has been shown to be the best protection physicians have against malpractice law suits and physical violence against the physician.

Psychological Significance of Informed Consent. Respect for patient values as expressed through informed consent is psychologically important because this assures the patient of a sense of personal worth. The patient, already threatened by disease, often has a need for a sense of control. When patients are treated without their consent, they are likely to distrust and disregard physicians' recommendations and often become uncooperative, angry, or hostile.

In the United States, IC is based on Western philosophical concepts of autonomy, self-determination, and respect for persons. IC establishes the rights of patients to exercise their own preferences and to make their own medical choices. Patient preferences form the clinical, legal, ethical and psychological core of the physician-patient relationship. This is obvious at the most basic level– patients can at any time choose whether or not to seek medical care; whether to establish or terminate a relationship with a physician; and whether to agree or disagree with a physician's clinical recommendations. To repeat: In the United

States, patients, not physicians, have the primary ethical and legal authority to establish, maintain and end doctor-patient relationships by expressing personal preferences. The usual vehicle for the expression of a competent patient's preferences is the clinical process of informed consent. Informed consent for standard clinical care, for example, for surgery or treatment with medications, represents a discussion or negotiation between patient and physician. At its best, such a negotiation leads to good communication, the development of a therapeutic alliance between patient and physician, and to voluntary choices by the patient. A properly negotiated informed consent benefits the physician as well as the patient because the physician's work is facilitated when the patient has realistic expectations about outcomes of treatment, is prepared in advance for possible complications, and consents to be a willing collaborator with the physician in the treatment plan.

Informed consent for clinical care is defined as the willing acceptance of a medical intervention by a patient after adequate disclosure by the physician of the proposed management plan, its risks and benefits, as well as alternative treatments with their risks and benefits. Informed consent is a process of communication and negotiation between the patient and the physician that helps the patient make a decision that is right for the patient. Importantly, informed consent is more than signing a consent form, an act that merely documents that the process of informed consent has occurred. While signing a consent form may be legally necessary, it is not ethically or legally sufficient.

Currently, in the United States, there are three different standards for determining whether the physician's disclosure is adequate: 1) the reasonable physician standard; 2) the reasonable patient standard; or 3) the individual-patient standard, which is highly subjective and variable. Laws in most U.S. jurisdictions currently favor the reasonable patient standard, that is, a standard

based upon the level of disclosure that a reasonable or prudent person would need to make a voluntary, rational decision. Although the reasonable person standard may be legally acceptable, physicians who establish strong doctor-patient relationships with a patient often attempt to meet the requirements of the individual-patient standard. Thus, the reasonable patient standard may be ethically sufficient, but the individual-patient standard is ethically ideal. The ethical and legal requirements for disclosure vary according to the clinical situations. Thus, disclosure standards become higher and more stringent as the situation moves from emergency care, to elective care, to research procedures. The highest level of disclosure is associated with research or experimental procedures involving human subjects.

This superb book by Professor Hua Chen examines informed consent in China while also presenting a Chinese-Western cross-cultural perspective. The heart of the book, chapters 4, 5, 6 and 7, focuses appropriately on informed consent in China for both clinical and research patients. These chapters highlight several of the points that I discussed earlier in this foreword, including the close relationship between informed consent standards and the evolution of the doctor-patient relationship from a paternalistic to an autonomy model. The book makes clear in chapter 6 that in emergency situations, both in China and the U.S., there are reasons to provide care for patients even without informed consent. That is, there is justification for medical paternalism in emergencies that is based on the concept of "medical beneficence," a duty to care for patients even when they lack the capacity to consent. Aside from the situation of medical emergency, Professor Hua Chen strongly defends the central importance of informed consent in China as reflecting the moral and ethical standards of modern medicine and of medical professionalism.

My great hope is that Professor Chen's book will be so well-received in

China that it will be translated into English. This book will be a great addition to the existing literature of informed consent and will illuminate for Western readers the status of informed consent in China.

Mark Siegler
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2018-01-20

序　二

陈化教授邀我给他这部专著写个序，我欣然应命。

这倒不是因为我们对于知情同意这个重大的生命伦理学问题观点一致。事实上，我对于儒学家庭主义情有独钟，而陈化却十分担心其弊端。在他看来，在现实中，家属参与侵犯患者权益的现象屡见不鲜，如何平衡患者权益与家属意见，成为知情同意实践中必须回应的问题。但我们都对当代的医疗权威主义深恶痛绝。如果说，传统的医疗权威主义还携带着善良利人的文化基因，是为了病人的利益而独断专行的话，那么今天的医疗权威主义则渗透着自私自利的不公平色彩，为了自己的方便、效率、面子、名誉甚至创收，懒得提供全面的信息，故意进行不充分的告知，鲜有说明替代治疗方案，绝不承认自己的无知或能力的有限性。记得几年前我在陈化的学院进行学术访问时，陈化曾经义愤填膺地向我提起一些他所了解的恶劣医疗事件。他的率真、纯正，我依然记忆犹新。

当然，我们两人都知道，并不是每位医生都不做认真的知情同意实践，也不是每个病人及其家属都是通情达理之辈。而且，许多问题的产生及持续，绝不能仅仅归结为医生的操守不够或德性不强。这些都表明，知情同意问题横跨政策、法律、制度、机构等各个方面，涉及医生、病人、家属等不同的行为主体，饱含着文化、经济乃至政治的普遍性元素，需要细致的理论梳理及实践研究。

这正是陈化的这部专著所提供的。

国内的医学伦理学及生命伦理学领域充斥着编写教科书式的研究：对一个问题要么没有一个明确的观点、要么只有一个跟随流行的观点，不去做细致的分析，更没有充分的论证，而是东抄一点、西找一段，把别人的看法罗列起来，就成了一篇论文，而且贯穿其中的有不少不求甚解乃至断章取义的东西。洋洋洒洒一大堆，但却难以找出对于已经存在的文献作出一点真实贡献的内容。

陈化的探索是认真的、实在的。他在多年前选定了这一课题之后，一直潜心研究。读者可以看出，本书是在他这些年发表的许多论文的基础上调整、修改、加工和完善而得以成形的，显示了他的研究的扎实作风和不断进展。

本书分为理论篇、实践篇、问题与出路三个部分，共十章加结语。对比近年来西方出版的有关知情同意的著作（它们一般仅仅探讨知情同意的一个具体侧面或很小范围的问题），陈化的这部著作还是显得十分“完整”、不够“专门”：也许整个著作仅仅聚焦于三个部分中的一个部分，提供更多的细节、更详尽的论证，可能会更加出彩。“魔鬼总在细节中”，涉猎全面、范围很广，就不容易集中力量，突出自己的思想重点。只有取其一点、“小题大做”，才能深入钻研，并从四面八方来进行全方位的分析和论证。这一点，应该是陈化及我自己都应在以后的研究中更加留心的事情。

但本书的确是从中国语境出发来考察知情同意的第一部系统性著作。本书三部分的结构理路是清晰的：知情同意的理论肇始于西方，所以陈化按照自己的理解作出了概括说明。这里，他虽然不得不利用一些一般概念，但并没有加入太多华而不实的内容，而是尽可能联系实际情况和历史脉络来作出阐述，为他后面的两个有关中国的部分埋下伏笔。我觉得，他的务实风格也受到芝加哥大学的生命伦理学家、同时也是临床医生的辛格勒的影响。辛格勒在美国生命伦理学界很有名望，他的一种看法广为人知：那些不接触临床医学的抽象哲学家们做不出有实际用途的生命伦理学研究。陈化在辛格勒那里做了一年的访问学者，同辛格勒有实际的交往。

我很欣赏陈化在探索中国特色知情同意模式的研究中所遵循的一种中庸的态度：在食洋不化的文化普遍主义与固步自封的文化本质主义之间寻求一种中和的、实用的中国知情同意进路。这种态度是儒家文化的一种核心态度，引导他认真了解当代中国人的实际想法。他花了一年多的时间，在北京、广东以及其他一些地区进行了有关知情同意的定量调查，收回了有效的病人答卷 901 份、医务人员答卷 2975 份，获得了扎实的第一手资料。

他的调查结果透露出明显的儒家家庭主义文化特征。例如，在病人方面，对于“知情同意权的所属主体”，9.4% 认为是“家属”，29.1% 认为是“患者或家属”，41.8% 认为是“患者与家属”；对于“您的病情希望谁先知道”，16.4% 认为是“家属”，31.1% 认为是“患者或家属”，20.8% 认为是“患者与家属”；对于“治疗方案”的决定，3.9% 认为应该“完全由家属决定”，31.6% 认为应该“主要由家属决定”，35.2% 认为应该“有时候由家属决定”，只有 29.3% 认为应该“完全由自己决定”。在医务人员方面，对于上述相关的问题也得到了类似的结果，只是在“内容告知”方面，还存在着明显的医疗家长主义倾向。

陈化的结论是，应该走向“共同决策模式”。他强调，这一模式是单纯的知情同意的升级版，它取消一维的权威模式，强调病人与医生之间的权威分享与责任共担，既有助于克服传统的医疗家长主义的缺陷，也有助于克服自由主义的自主模式的缺陷。

我很欣赏他的这一结论，只是觉得，我们需要明确这个模式中的病人、家属和医生的三维结构的和谐，而不只是重视病人与医生的二维统一。有人认为，只要加入家属，就会面对他们发生意见分歧时应该由谁说了算的问题，不如明确病人的权威了事。当然，如果病人和家属达不成一致意见时应该怎么办，的确是需要研究的问题。然而，即使强调由病人说了算，接受病人自主模式，问题并不会消失：如果病人做了一个明显不利于自己的决定，医生应当听从吗？如果病人无法作出决定，那么医生应该