5 Informed consent

A critical response from a Buddhist perspective

Ellen Y. Zhang

Introduction

According to UNESCO Declaration of Bioethics and Human Rights (UDBHR), informed consent process requires four characteristics to be valid: voluntariness, disclosure, understanding and capacity. Whenever one of these elements is missing, informed consent can be compromised. In their *Principle of Biomedical Ethics*, Tom L. Beauchamp and James F. Childress claim that informed consent is an individual's autonomous authorization. They postulate seven structural elements, including threshold elements (competence to understand and decide; voluntariness in deciding), information elements (disclosure of material information; recommendation of a plan; understanding of the information and recommended plan) and consent elements (decision in favour of the plan; authorization of the chosen plan). In this chapter, I will first look at these four characteristics and then discuss their ethical implications (e.g. individual autonomy and human rights), followed by a critical response of these implications from a perspective of Buddhism.

Voluntariness

Beauchamp and Childress argue that virtually all codes of medical ethics and institutional regulations should require physicians to obtain informed consent from patients before substantial interventions, with the protection of patient autonomy as the primary justification for this requirement. Voluntariness is usually seen as a choice being made from a person's free will instead of coercion or duress. Voluntariness is, as such, closely associated with the protection of a person's autonomy. Such an idea in history can be traced back to *the Nuremberg Code* and *the Declaration of Helsinki* regarding permissible medical experiments.¹ Nowadays, informed consent focuses on both medical treatments and [medical] research projects.²

The word "autonomy" is etymologically derived from old Greek and is a compound of the word *autos*, which means "self," and the word *nomos*,

which means “rule” or “governance.” Today the word is used in quite diverse meanings. It, thus, does not refer to a univocal concept, as Beauchamp and Childress have put it, “like many philosophical concepts, ‘autonomy’ acquires a more specific meaning in the context of a theory.”³ Nevertheless, two conditions are essential in terms of the concept of autonomy: (1) liberty (i.e. independence from controlling influences) and (2) agency (i.e. capacity for intentional action). It follows that the idea of “voluntariness” implies that the patient, as an autonomous individual, should be absent from any substantial control by others and that the patient acts intentionally. In addition, Beauchamp and Childress add the third condition, that is, an autonomous agent should have a complete understanding of his/her action. Therefore, voluntariness needs to meet three conditions: liberty, agency and understanding. The basic idea is to respect self-determination concerning the patient’s health.

Disclosure

What must a physician disclose to the patient? What does it mean by “permission to disclose”? Disclosure means that the medical professional is obligated to disclose a core set of information to the patient or subject regarding the treatment or research. According to the UDBHR document, “Disclosure means giving subjects all the relevant and right information about the research, including the risks, potential benefits, nature and other therapeutic alternatives. . . . The principle of autonomy and obligation truth-telling, places disclosure on always providing the complete information to every patient.” However, at the same time, the document indicates that based on the principle of beneficence and the principle of non-maleficence, the information disclosed to the patient can be partial. However, the question of “standards of disclosure” or the need for “intentional or deliberate nondisclosure” has by no means been answered without further qualifications. Regarding nondisclosure, for example, Beauchamp and Childress assert four conditions that are essential to justify the use of intentional nondisclosure in medical research: (1) it is essential to obtain vital information; (2) no substantial risk is involved; (3) the subjects are informed that deception is a part of the study and (4) the subjects give their consent to participate under these conditions.⁴

Understanding

Since informed consent emphasizes the autonomous choice as mentioned in the idea of voluntariness, informed consent in this sense “occurs if and only if a patient or subject, with substantial understanding and in substantial

absence of control by others, intentionally authorizes a professional to do something.”⁵ Nevertheless, without understanding the patient’s part, or the autonomous subject, information disclosure has no real meaning. However, the idea of “substantial understanding” is a tricky one even if he or she is *adequately* informed since it has a lot to do with the capacity for intentional action and the capacity for grasping the [highly professional] information being disclosed. Therefore, the UDBHR document states that “appropriate, precise and relevant information should be provided in a language and format that patients fully understand (UNESCO 2005).”

Capacity

Capacity is essential in terms of voluntariness and understanding. A patient needs to have the capacity of self-determination to reflect, decide and consider when deciding to participate in a clinical trial or receiving medical treatment. It is also true that “(a)s the importance of the decision increases, and the information given is more specific and accurate, the threshold for considering a patient capable, is also higher.” The patient’s health literacy level will influence his/her capacity for understanding.

The four characteristics described earlier indicate several key components that link with ethical implications: individual autonomy, the virtue of rationality, human rights and equality, and the latter two are especially implied in the idea of “improving the readability, design and obtaining process of consent forms taking into account the conscious and unconscious bias by the investigator.”

Critical responses

A critical response from multiculturalism and interreligious perspectives

Whenever we deal with a dynamic interaction between universal principles and multiculturalism or and interreligious perspectives, we need to acknowledge the complexity of cultural, societal and religious differences. At the same time, we should also recognize the importance of generalization as a tool to understand the existing common ground or overlapping consensus among different cultures, societies and religions.

As a universal principle, informed consent is generally acknowledged as an ethical ideal. Universal recognition of the merits of the principle has in no way been accompanied by a universally accepted definition of it. Take the four characteristics of informed consent, for example. Different cultures may interpret voluntariness, disclosure, understanding and capacity

differently. Another example, in Japan, informed consent is understood as “explanation and agreement” (*setsumei to doi*), which may not be the same as giving individuals clear information about alternative treatments and potential risks and benefits, or the patient can make an informed choice. The Chinese translation is “knowing the information and consent” (知情同意), but in its application, both “informed disclosed” and “consent” entail more complex meanings other than what is indicated in the general principle. In China, informed consent sometimes becomes legal protection of the medical professionals rather than one for patients, thus creating arbitrariness of physicians’ relation to patients.

Moreover, there are two questions to be considered: 1) the “thin principle” (harm principle or restraining human experiments in medical research, all patients are equal in terms of informed consent) is more likely to be accepted than the “thick principle” (like self-determination, individual’s specific rights). 2) The implied cultural clashes (like individualism vs. familism or collectivism). As a result, informed consent is sometimes employed in non-Western cultural contexts without justifying or even spelling out the definition and without selecting empirical measures that match the stipulated (or intended) definition. The thin principle of informed consent comprises the formal or instrumental aspects of the principle. These instruments can be applied in any functioning medical system, regardless of its political or religious ideology, level of democracy or level of liberalism. The thick principle of informed consent, in contrast, incorporates economic systems, forms of traditional values, circumstances of religious faith and interpretations of human rights or duties.

Informed consent has been accepted today as both an ethical and legal binding between medical professionals and patients, yet the clash between the principle of informed consent and traditional (or premodern) values remains—for example, the question of trust. Trust is traditionally favoured in China, which is subjective and often based on human relations. While local culture may shape people’s perception over time, people are more likely to trust experts that share a similar tradition with them. However, such trust is challenged by the modern style of hospitals where patients and their family members are often “at the mercy of a stranger.” It is a kind of situation many people do not feel comfortable if they are sceptical about the professionalism of their doctors (like the situation in China today). Alternatively, an ethical dilemma arises when (Western trained) medical professionals seeking informed consent have very different values and belief systems from those (very often uneducated) whose consent is being sought.

Ethical unity in the face of cultural diversity has been an issue that needs to be addressed. Globalization in past decades attempted to promote a universal approach to humanity that enables the formation of a “cosmopolitan”

community. The idea of “a shared morality” has been accepted to a certain degree. The voice of cultural and religious particularism should be heard as well. Now, I will turn to Buddhism to address bioethical unity in the context of multiculturalism and religious pluralism.

A critical response from Buddhism

Respect for the dignity and autonomy of patients is a fundamental idea of ethical decision-making, which is well reflected in the principle of informed consent. However, such concepts as individual dignity and autonomy and human rights are not derived directly from Buddhist doctrines. Then, how do we understand informed consent from Buddhism?

As my earlier essay on human dignity and human rights has submitted. However, the Buddhist tradition has no language equivalent to “human dignity” or “human rights.” It would have no problem accepting the thin concept of human rights, especially when the fundamental right to life is violated or threatened. In other words, human rights are necessary because they reflect certain moral standards of how humans should be treated and how a violation of such standards should be condemned. From this perspective, we can see that UDBHR uses the general concept of human rights “to underline the importance of biodiversity and its conservation as a common concern of humankind.”⁶ The rights talk implied in informed consent serves the same purpose in that the key idea of informed consent is to protect the patient’s interest (endorsed by the principle of beneficence and the principle of non-maleficence). That means Buddhism would accept a qualified notion of human rights as a protective mechanism.

Buddhism would be very cautious about using the rights language since human rights suggested in informed consent is used as a means not only to protect individuals but also to affirm “moral individualism.” Although people talk about collective rights, that is, the rights of a particular group or community (such as children’s, women’s and gay rights), the idea of human rights, whether positive or negative, is based on free-standing individuals and individual autonomy. From the perspective of Buddhism, “invoking rights has the inevitable effect of emphasizing individuals and their status, thereby strengthening the illusion of self. While Buddhism has a holistic view of life, the rights perspective is essentially atomistic.”⁷

As voluntariness is based on autonomy, it requires two conditions: liberty or freedom to choose an agent’s capacity for intentional action. Nevertheless, if we scrutinize these two conditions from Buddhism, we will find them somehow ambivalent. Autonomy means self-determination, self-governance or choosing without the controlling influence of others. However, the question is how “the controlling influence of others” be defined.

According to the Buddhist doctrine of (inter)dependent-origination, absolute self-determination is impossible since “self” is causally produced by “others,” particularly in cultures like China and Japan, where the self cannot be fully defined without an adequate understanding of the family dynamics. In the case of informed consent, it is very often difficult for physicians (and patients) to determine if a patient’s deferral of decision-making is his/her own choice or the result of formative influences of the family. It follows that the patient’s capacity for intentional action is also questionable. Voluntariness involves the idea of “free will,” which would be problematic for Buddhists, and medical decision-making based entirely on patient-centred orientation would be problematic for Buddhists.

Autonomy is at the core of human agency in Western philosophy. Reconceptualization of autonomy as “personal” autonomy” enables persons to be self-governing in their personal lives.⁸ Let us talk about autonomy as self-determination and self-governance first. The self in Buddhism can be understood in two ways: self in the ultimate reality (*paramartha*) and self in the conventional reality (*samvrti*). From the perspective of ultimate reality, the self is an illusion and an impossibility due to the nature of impermanence. From the perspective of the conventional reality, the “self” has no substance or “self-nature” due to the nature of dependent origination of all things. The Buddhist concept of *anatman* (usually translated as “no-self”) denies the notion of a unitary, unchanging self or the idea of self-identification and self-sufficiency. In other words, Buddhism questions the ontological/epistemological reality of the self.

According to the Buddhist tradition, what is conceived as an individual consists of five types of aggregates (*skandhas*) that serve as the bases of designating persons or personhood: (1) material form or body (*rūpa*); (2) sensations (*vedanā*); (3) apperception or perception (*saṃjñā*); (4) volitions or mental formations (*saṃskāra*) and (5) consciousness (*viññāna*). Although various Buddhist schools interpret the five aggregates in somewhat different ways, they all agree that the self has something to do with the phenomenon of self-consciousness and self-identification. The early Buddhist teaching on no-self is recorded in a well-known dialogue between Greco-Bactrian King Milinda and a Buddhist sage named Nagasena. The latter uses the metaphor of chariot to explicate the idea of self or personhood. Nagasena asked whether the collection of all these objects could be called the chariot (picture them piled up together). The king replied, “No.” Nagasena then asked whether the chariot could be found *outside* that collection of objects, and the answer was no. The dialogue then continued as follows:

NAGASENA: “Then, ask as I may, I can discover no chariot at all. Just a mere sound is this ‘chariot.’ But what is the real chariot? Your Majesty has

told a lie, has spoken a falsehood! There really is no chariot . . .” Milinda: “I have not, Nagasena, spoken a falsehood. For it is independence on the pole, the axle, the wheels, the framework, the flag-staff, etc., that there takes place this denomination ‘chariot,’ this designation, this conceptual term, a current appellation, and a mere name.”

NAGASENA: “Your Majesty has spoken well about the chariot. It is just so with me. In dependence on the thirty-two parts of the body and the five aggregates (*skandhas*) there takes place this denomination ‘Nagasena,’ this designation, this conceptual term, a current appellation, and a mere name. In ultimate reality, however, this person cannot be apprehended.”⁹

The point here is not that there is no chariot, but there no chariot-hood, or totality of chariot outside that collection of objects, that is, the pole, the axle, the wheels, the framework, the flag-staff, yoke, reins and so on. Likewise, there is no “absolute,” “enduring” and “permanent” self that is perceived as “personhood” that goes beyond the five principles components of a human being, that is, the interdependent aggregates which are not fixed and in constant change themselves. Therefore, we read:

Nothing is permanent. The illusion of permanence causes suffering.

The everlasting self is impermanent.

Clinging to the false notion that an enduring self exists increases suffering.¹⁰

The question of “who or what am I” is, then, answered by the notion of a causally dependent self rather than an enduring self. It follows that “self” in self-identification and self-determination cannot be absolutely atomic and autonomous. From a psychological perspective, an individual’s self-consciousness is dependent on the “psychophysical continua” that form the momentary usage of the term “self.”¹¹ What one has experienced that arrives at a sense of continuous self-awareness is nothing but “a bundle of successive impressions or perceptions” if we borrow an expression from David Hume. Nevertheless, the bundle of experiences one has is not, according to Buddhism, a *random* collection of experiences in any case; instead, one is in a particular kind of collection brought about by a particular set of causes and effects. As Nagasena’s metaphor demonstrates, there is a certain kind of reality to the “self,” just as there is a reality to a chariot. Along this line of thinking, voluntariness is determined by looking at the totality of the circumstances rather than an individual-centred reality or merely the idea of self-determination. What one considers the “I” is in actuality “certain clusters of physical and mental events” linked causally dependent arising.¹²

As for the patient's capacity for intentional action, Buddhism promotes meditative practice that will enable the agent to understand his/herself fully. Buddhism pays special attention to intention as a mental designation, as any action is influenced by intentionality, which is determined by how the mind perceives things. For Buddhists, intentional action is a rational decision yet cannot be reduced to physical mechanisms. The Buddhist concept "karma" also means "intentional action." As it said, "I am the owner of my actions (karma), heir to my actions, born of my actions, related through my actions, and have my actions as my arbitrator" (*Aṅguttara Nikāya*, 5, 57). The Buddhist idea here is that one should take responsibility for one's actions.

Nevertheless, the question is whether the patient identified in informed consent has the capacity for intentional action. Let us not talk about external influences by others, but how about internal influences when the agent is confronting a life-and-death situation. Can we expect a patient to be always rational enough so that he/she can fully understand his/her intention? That is why the Buddhists recommend meditation, and the practice of meditation itself can be understood as a way of "cultivating the mind" (*citta-bhāvana*) for developing the capacity for "autonomy." According to the Buddhist doctrine of (inter)dependent-origination, however, autonomy is always relational autonomy. In informed consent, the patient autonomy cannot be separated from physicians, family members or communities. Buddhists are also concerned with the patient's psychological maturity to handle the language used when disclosing information about risks of medical treatment.

In his article "Taking Ownership: Authority and Voice in Autonomous Agency," Paul Benson points out that very often, autonomous preferences or values are subject to "direct normative constraints."¹³ Some preferences are non-autonomous because of the content, so it is called a "strong substantive account" of autonomy. For example, a patient's position in his/her family would have a strong influence on his/her decision-making, even if consent is an exercise of autonomy. Meanwhile, Benson also discusses what he called a "weak substantive account" of autonomy, subject to some "normative content." Yet, it does not directly constrain the content of preferences or values. Compared with the strong account, the weak account recognizes the role of autonomy while acknowledging the nature of relationality and the nature of self-limitation. It is crucial to acknowledge the formation of individual reflections, the development of competencies and the capacity to bring one's reflections into action.

Similar to this view, Buddhism maintains that "I" exist is true only as a "convention." Buddhist scholar Jay L. Garfield speaks of synchronic unity rather than diachronic unity, contending that as long as autonomy is considered central to human agency, it requires a notion of "constructed self" that serves as the substratum.¹⁴ At the moral level, to believe in the "self"

as an enduring entity is, for Buddhists, predicated on “greed, desire, and attachment,” ultimately leading to suffering. Also, the desire to construct “self-determination” inevitably leads to “selfish” concerns. Therefore, the “aim of Buddhism is . . . to realize selflessness, both metaphysically and ethically.”¹⁵

While Buddhism challenges an individual-oriented approach to autonomy, it also challenges an individual-oriented approach to rights. Buddhism would accept “negative rights” as a protective means for the patient’s interests and yet have problems with using the language of rights without qualification to grapple with every moral issue. In addition, Buddhism would also speak of the importance of duty along with the right talk. For example, in the case of vaccination, Buddhism will use duty rather than right to argue for it. In other words, it is not someone’s right (i.e. individual’s autonomy) to have or not have vaccination; instead, it is someone’s duty to protect oneself and others in society through proper prevention of the infection and its respective immunization. Since vaccination concerns public health, Buddhists today will generally use vaccines to ensure their health is protected. However, according to some Buddhists, if the vaccine is derived from any life form (e.g. animal by-products, tested on animals), its use is debatable.¹⁶ Those who reject using vaccines argue that treatments like antibiotics and vaccines that depend on animal experiments would generate bad karma that causes diseases.¹⁷ However, I do not think that any Buddhist texts either support such kind of position. Given that Buddhism is not a religion confined to dogmas and one that emphasizes consequentialist considerations. Buddhism would be more acceptable to vaccination that concerns public health. One example to support this argument is vegetarianism. Despite that Buddhists practice vegetarianism in general, they can eat meat when there is no choice.

Some problems of implementing informed consent in China

There seem several potential barriers to informed consent in contemporary Chinese medical/clinical practice. In the Chinese medical or clinical setting, informed consent has not been well adopted although the idea is no longer novel. There are several problems in implementing informed consent: (1) Many people perceive informed consent due to a lack of trust due to the misunderstanding of the concept by physicians and patients.¹⁸ (2) The ethical principle of patient autonomy and self-determination is viewed as “un-Chinese.” (3) Paternalistic physicians and protective family members would counteract informed consent and very often try to make medical decisions to promote their patients’ well-being independent of their wishes and values. As a result, we see the problems of misusing informed consent

and persistence in obtaining consent. Treatment decisions for incompetent patients, the HIV and AIDS endemics, or minors (the vulnerable group) are another issue that required further consideration. As indicated in the document, vulnerable groups are especially susceptible to being unduly influenced into providing consent. They have a “compromised ability to protect their interests and provide informed consent” and, therefore, have a rightful claim to special consideration or protection.

In some situations, informed consent is simply a formality obtained without the patient’s understanding of the physician’s recommendations or adequate time to think and reflect on the recommendations. In terms of information disclosure, the physician sometimes prefers to release the information to the patient’s family members rather than the patient. Some scholars in China argue that informed consent has failed to describe the role of family members in decision-making and may not work with a culture like Chinese where a physician–patient relationship becomes a physician–family–patient relationship. In some situations, excessive protection of a patient by the patient’s family may also counteract informed consent. The family–patient relationship sometimes takes on a more decisive and influential role in making medical decisions than the physician–patient relationship.¹⁹

Many patients and family members in China (especially those from small towns and countryside) are more comfortable with the paternalistic model of the physician–patient relationship. It is still not uncommon for physicians to make unilateral decisions in the clinical setting. From a Buddhist perspective, the paternalistic model of the physician–patient relationship is sometimes necessary and, thus, should not be perceived as something consistently disruptive to informed consent. The Buddhist idea of “skillful means” (*upāya*) suggests that one should not be confined to a particular doctrine or principle; instead, one should look at a specific case in a specific context and decide accordingly.

In sum, informed consent is a complicated concept and may have desirable and undesirable effects on medical/clinical practice. Nevertheless, it is better to have it.

Notes

- 1 *The Nuremberg Code* says: “The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.” Likewise, *the Declaration of Helsinki* says, “In any research on human beings,

each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participate at any time. The physician should then obtain the subject's freely-given *informed consent*, preferably in writing.

- 2 Informed consent is originally a legal doctrine and was introduced into clinical medicine in the United States in the mid-1950s. Social movements regarding the rights of vulnerable groups such as minorities, women, consumers, and prisoners stimulated patients' awareness of their right to information and self-determination in clinical settings.
- 3 Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* (Oxford: Oxford University Press, 1994), 121.
- 4 *Ibid.*, 157.
- 5 *Ibid.*, 143.
- 6 See UDBHR, Article 2(h).
- 7 Craig Ihara, "Why There Are No Rights in Buddhism: A Reply to Damien Keown," in *Buddhism and Human Rights*, ed. Damien Keown, et al. (Richmond: Curzon Press, 1998), 51.
- 8 People who argue for personal autonomy focus on the idea of autonomous agents whose preferences and desires are genuinely their own—as those who critically reflect in the "appropriate" way to evaluate their preferences, motives, and desires. For detailed argument, see *Autonomy and the Challenges of Liberalism*, ed. Joel Anderson and John Christman (Cambridge: Cambridge University Press, 2005).
- 9 Christmas Humphreys, *The Wisdom of Buddhism* (London and New York: Routledge, 1995), 79–80.
- 10 The idea of "impermanence" (*anitya*, Chin. *wuchang*) which refers to the conditioned phenomena arising and passing away is part of "three basic facts of existence" in early Buddhist teaching.
- 11 Matthew MacKenzie, "Self-Awareness without a Self: Buddhism and the Reflexivity of Awareness," *Asian Philosophy* 18, no. 3 (2008): 256.
- 12 Rupert Gethin, *The Foundations of Buddhism* (Oxford: Oxford University Press, 1998), 138.
- 13 Paul Benson, "Taking Ownership: Authority and Voice in Autonomous Agency," in *Autonomy and the Challenges of Liberalism*, ed. Joel Anderson and John Christman (Cambridge: Cambridge University Press, 2005), 133. Also see Benson, "Free Agency and Self-Worth," *Journal of Philosophy* 91, no. 12 (1994): 650–668.
- 14 Jay L. Garfield, *Engaging Buddhism* (Oxford: Oxford University Press, 2015), 99–100.
- 15 Rupert Gethin, *The Foundations of Buddhism* (Oxford: Oxford University Press, 1998), 147.
- 16 In fact, in some poor Buddhist countries like Cambodia and Laos, getting the vaccine is a luxury. In an area with a high degree of getting diseases, people (religious or not) do not say no to anything that might improve their odds of survival.
- 17 Francis Story, *Dimensions of Buddhist Thought: Collected Essays* (Sri Lanka: Buddhist Publication Society, 2012), 93.

- 18 Many Chinese physicians and patients do not know why and how informed consent was developed in the US (due to a series of court judgments).
- 19 For this argument, see Guobin Cheng, "Ethical Implication of Informed Consent:—A Case Study of 'Family Decisions' in Contemporary China," *International Journal of Chinese and Comparative Philosophy of Medicine* 15, no. 2 (2017): 21–41.