Informed consent – A Critical Response from a Buddhist Perspective

According to the UDBHR document, “informed consent process requires of four characteristics to be valid: voluntariness, disclosure, understanding and capacity. Whenever one of these elements is missing, informed consent can be compromised.” Tom L. Beauchamp and James F. Childress in their Principle of Biomedical Ethics claim that informed consent is an individual’s autonomous authorization, whereby 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 favor of the plan; authorization of the chosen plan). 1 In this paper I will first look at these four characteristics, and then discuss their ethical implications (for example, individual’s autonomy and human rights), followed by a critical response of these implications from a perspective of Buddhism.

1. Voluntariness

Beauchamp and Childress argue that virtually all codes of medical ethics and institutional regulations should require physicians to obtain informed consent from patients prior to substantial interventions, with the protection of patient autonomy as the primary justification for this requirement. Voluntariness is usually seen as a choice being made of a person’s free will, as opposed to being made as the result 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 with regards to permissible medical experiments. Nowadays, informed consent focuses on both medical treatments and [medical] research projects. The word “autonomy” is from 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, and 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”. Nevertheless, there are two conditions that 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 full understanding of his/her action. Therefore, voluntariness needs to meet three conditions: liberty, agency, and understanding. The basic idea is to respect self-determination with regards to the patient’s health.
2. 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.” But 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 in order 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.

3. 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”[16]. Yet without understanding on the part of the patient, or the autonomous subject, information disclosure has no real meaning. The idea of “substantial understanding” is, however, a tricky one even if he or she is adequately informed since it has a lot to do with not only the capacity for intentional action, but also the capacity for grasping the [highly professional] information being disclosed. Therefore, the document states that “appropriate, precise and relevant information should be provided in a language and format that patients fully understand (1, 3, 5).”

4. Capacity

Capacity is important in terms of voluntariness and understanding. A patient needs to have the capacity of self-determination to reflect, decide and consider, when making a decision of participating in a clinical trial (1, 6) 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 above 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.” As for the informed consent in terms of vaccination, the UDBHR policy aims at universal principles for informed consent, including requirements for vulnerable populations, centered barriers, etc. The ethical concerns behind vaccination are basically the same as that embedded in the principle of informed consent in general. Nevertheless, as indicated in the document, consent to vaccines may not entirely an individualistic decision in specific situations. In other words, the notion of voluntariness in the case of vaccination may not apply like other medical interventions, because unvaccinated individuals can present an element of risk to other members of
society. Obviously, informed consent in vaccination emphasizes two ethical principles: respect of an individual’s autonomy and the protection of the vulnerable.

**Critical Responses:**

1. A critical response in terms of multiculturalism and interreligious perspectives
   Whenever we deal with a dynamic interaction between universal principles and multiculturalism or interreligious perspectives, we need to acknowledge the complexity of cultural, societal, and religious differences. Yet 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. Yet the 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 in informed consent for example, different cultures may interpret voluntariness, disclosure, understanding and capacity differently. For example, in Japan, informed consent is understood as “explanation and agreement” (setsumei to doi), which may not the same as giving individuals clear information about alternative treatments and potential risks and benefits.

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   In China, inform consent sometimes becomes a legal protection of the medical professionals rather than one for patients, and thus has created arbitrariness of physicians’ relation to patients.
   Moreover, there are two questions to be considered: 1) the “thin principle” (e.g., harm principle or restraining human experiments in medical research, in which all patients are equal in terms of informed consent) that are likely to be accepted than “thick principle” (such as self-determination and individual’s specific rights); 2) the implied cultural clashes (like individualism vs. familism or collectivism).

   As result, inform consent is sometimes employed in non-Western cultural context 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 and that 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 particular 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 favored in China, which is subjective and often based on human relations. Such kind of trust is challenged by the modern style hospitals where patients and their family members are very
often “at the mercy of a stranger,” a kind of situation many people do not feel comfortable if they are skeptical about professionalism of their doctors (like the situation in China today). Or, an ethical dilemma arises when those [Western trained] medical professionals seeking informed consent have very different values and belief systems from those (very often uneducated) whose consent is being sought. Obviously, ethical unity in the face of cultural diversity has been an issue that need 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 the question regarding 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, although 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 in a situation when 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

The Universal Declaration on Bioethics and Human Rights uses the general concept of human rights “to underline the importance of biodiversity and its conservation as a common concern of humankind.”. The rights talk implied in informed consent serves the same purpose in that the key idea of informed consent is to protect the interest of the patient (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.

That being said, Buddhism would be very cautious to use 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.” Despite that people talk about collective rights, that is, the rights of a particular group or community (such as children’s rights, women’s rights 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”. In addition, the traditional Buddhist monastic codes also offer ethical principles relevant to issues of individual choice and consent.

As voluntariness is based on the concept of autonomy that requires two conditions, that is, liberty or freedom to choose and agent’s capacity for intentional action. Yet if we examine these two conditions carefully from Buddhism, we will find them somehow ambivalent. Autonomy means self-determination, self-governance, or making a choice without the controlling influence of others. Yet the question is how “the controlling influence of others” be defined. According to the Buddhist doctrine of (inter)dependent-origination, the absolute self-determination is impossible since “self” is causally produced by “others,” particularly in cultures like China and Japan where self cannot be
fully defined without adequate understanding of the family dynamics. In the case of informed consent, it means very often difficult for physicians (as well add for 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-centered orientation would be problematic for Buddhists as well.

Autonomy is considered to be 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. Let’s 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 (paramarthasa), and self in the conventional reality (samvrtisat). From the perspective of the ultimate reality, self is an illusion and an impossibility due to the nature of impermanence; From the perspective of the conventional reality, “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 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 (samjñā); (4) volitions or mental formations (samskāra); and (5) consciousness (vijñāna). Although various Buddhist school interpret the five aggregates in somewhat different ways, they all agree that 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 in which the latter uses the metaphor of chariot to explicate the idea of self or personhood. Nagasena asked whether the collection of all of 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 in dependence 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” (Humphreys 1995, 79-80).

The point here is not that there is no chariot, but there no chariot-hood, or a 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 not “absolute”, “enduring”, and “permanent” self that is perceived as “personhood” that goes beyond the five principles components of a human being, i.e., 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 (Sias 2015, 3). The question of “who or what am I” is, then, answered by the notion of a causally dependent 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”12. 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 experience 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. To follow this line of thinking, voluntariness is determined by looking at the totality of the circumstances rather than an individual-centered 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 arising13. As for the patient’s capacity for intentional action, Buddhism promotes meditative practice that will enable the agent to fully understand his/herself. Buddhism pays special attention to the notion of intention as mental designation, as any action is influenced by intentionality, which is determined by how things are perceived by mind. For Buddhists, intentional action is a rational decision, yet cannot be reduced to physical mechanisms. The Buddhist concept “karma” also mean “intentional action”, as it is 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” (Anguttara Nikāya, 5, 57). The Buddhist idea here is that one should take responsibility for one’s action. Yet the question is whether the patient identified in informed consent has the capacity for intentional action. Let us not talk about possibility external influences by others, but how about internal influences when the agent is confronting with life-and-death situation. Can we expect a patient to be always rational enough, so that he/she can fully understand his/her own intention? This 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 the situation of informed consent, the patient autonomy cannot be separated from physicians, family members, or communities. Buddhists are also concerned with the psychological maturity of the patient to handle with 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”14. 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 of his or her decision-making even if the consent is viewed as an exercise of autonomy. Meanwhile, Benson also discusses what he called a “weak substantive account” of autonomy which is 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 one has to bring one’s own 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. 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”.

Nevertheless, the Buddhist idea of “right speech” would offer the proper line between truth-telling and confidentiality in the case of informed consent. Withholding the truth in certain cases may be acceptable, for instance, when a family needs to balance the individual’s self-determination and the right to the truth about his or her condition with the general well-being of the patient and the family.

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 interests of the patient, yet having 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 a proper prevention of the infection and its respective immunization. Since vaccination concerns public health, Buddhists today will generally use vaccines to make sure their health is protected. But 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.

Those who reject using vaccines argue that treatments like antibiotics and vaccines that depend on animal experiments would generate bad karma that causes diseases. However, I don’t think that there are any Buddhist texts that support such kind of position. Given that Buddhism is not a religion confined to dogmas and that it is a religion emphasizing consequentialist considerations, Buddhism would be more acceptable to vaccination that clearly concerns public health.

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 as a result of lack of trust due to the misunderstanding of the concept by both physicians and patients; (2) The ethical principle of patient autonomy and self-determination is viewed “un-Chinese”; and (3) Paternalistic physicians and protective family members would counteract informed consent and very often they 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 of informed consent and persistence in obtaining consent. Treatment decisions for in-
competent patients, the HIV and AIDS epidemics, or minors (the vulnerable group) are another issue required further consideration. As it indicates in the document, vulnerable groups are especially susceptible to being unduly influenced into providing consent, and they have a “compromised ability to protect their interests and provide informed consent,” and thus have a rightful claim to special consideration or protection.

In some situations, informed consent is simply a formality when it is obtained without the patient’s understanding of 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 patient’s family members rather than the patient. Some scholars in China tend to 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. Yet 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 stronger and more influential role in making medical decisions than does the physician-patient relationship.

Many patients and family members in China (especially those from small towns and countryside) are more comfortable with the paternalistic model of physician-patient relationship. It is still not uncommon for physicians to make unilateral decisions in the clinical setting. From a Buddhist point of view, the paternalistic model of physician-patient relationship is sometimes necessary, and thus should not be perceived as something always disruptive to informed consent. The Buddhist idea of “skillful means” (upāya) suggests that one should not be confined to particular doctrine or principle; rather one should look at a specific case in a specific context, and make a decision 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
2 In the Nuremberg Code, it 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, in the Declaration of Helsinki it 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”.
3 Informed consent is originally a legal doctrine and was introduced into clinical medicine in the United States in the mid of 1950s. Social movements regarding the rights of vulnerable groups such as minorities, women, consumers and prisoners at that time stimulated patient’s awareness to their right for information and self-determination in clinical setting.
5 Ibid. 157.
6 Ibid. 143.
Cambridge University Press. 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. See Friedman, M. 2003. Autonomy, Gender, Politics. Oxford: Oxford University Press.


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) don’t say no to anything that might improve their odds of survival.


Many Chinese physicians, as well as patients, do not know why and how informed consent developed in the US., such as a series of court judgments that promoted the idea in the US.