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Informed Consent and the Patients of Bangladesh

ABSTRACT

In medical practice, informed consent plays a vital role in making ethical decisions. In recent years, informed consent also appears to be a key issue in biomedical discussion. Several definitions of informed consent have already been proposed. However, the socio-economic conditions of different countries are not the same. Many countries differ culturally as well as in literacy rate. Therefore, a unified concept of informed consent might not be justified in every context. This paper discusses the importance of informed consent, different views regarding informed consent and the limitations of applying one single idea of informed consent in every context. It argues that the most plausible concept of informed consent which is achievable for developing countries, like Bangladesh, is based on care ethics. The paper concludes that informed consent could be a 'natural outcome' and is really not a barrier in the patient-physician relationship if the idea is seen from the perspective of care ethics.

Keywords: autonomy, care ethics, informed consent, patient-physician relation, respect, risk.

1. Introduction

Informed consent is a core component of treatment decisions. It also expresses quite explicit the patient-physician relationship. Different ethicists propose different conceptions of informed consent. Some of them, e.g. Faden, Beauchamp and Childress's conceptions, are used widely in the biomedical issues, though their conceptions have been criticized by O'Neill, and care ethicists such as Dodds, Mackenzie and Stoljar. In this paper, we will discuss the importance of informed consent, different views regarding informed consent and its limitations. Then we will examine which conception is possible to gain in Bangladesh context. It seems strange

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that there is a tendency to use one dominant concept of informed consent in many and different contexts. We will carefully examine this trend. At the end of the paper, the idea of relational autonomy will be justified in Bangladesh perspective.

2. Why is informed consent important in the patient-physician relationship?

Informed consent is a world-wide well-known medical or ethical notion. Informed consent is important because it has a legal urge, and many health laws have included this conception as a vital clause. Secondly, almost all medical codes and guidelines have incorporated this requirement in order to protect the patient or the human subject from harm. In the patient-physician relationship informed consent procedure is valuable for the treatment. By informed consent procedure the competent patient's voluntariness is protected. The practice and requirements of informed consent ensure the patient's autonomy to decide for treatment and limit medical paternalism. Capron has indicated two basic justifications of informed consent: the first one, "protection from harm" and the second, "protection of autonomy" (Beauchamp and Childress 1983, 67).

Any medical intervention or clinical research has to fulfil the crucial requirement of informed consent to be considered as ethical. Medical treatment may involve risk, and benefit as well. Before starting a treatment the physician has an obligation to inform the patient about underlying risks and probable benefit. Informed consent might serve as a way of providing information about the treatment. Sometimes informed consent procedures may help the patient to decide in favour of between alternative diagnostic or medical intervention.

According to Childress, informed consent gives the physician a special right and the patient transfers this right to the physician. He writes, "Consent is one possible ground for special rights that are created, or transferred, by transactions between parties. These rights are special because they depend on relationships..." (Childress 1982, 79).

Therefore, informed consent is not only an "approval" but also a contract exercising some special "rights". Another importance of informed consent is that it is a legal document and can be used for judicial purpose. As Schermer writes, "The doctrine of informed consent, however, is not only...a product of medical ethics. It developed within the framework of law and medical practice... and is directed by legal and practical considerations" (Schermer 2001, 40).

Schermer has pointed out the importance of four points about informed consent. First, informed consent is a “means” of gaining patient’s autonomy. Second, it could be an “expression” of respecting patient’s autonomy. Third, informed consent is a “promoter” of the well-being of the patient. Finally, it supports “rationality” and “self-determination” (Schermer 2001, 40-41).

Therefore, we may conclude that informed consent is important for protecting a patient’s autonomy, promoting patient’s rationality and self-choice, providing treatment information and guarding legally as well as ethically from coercion.

3. Different concept of informed consent

There is an ongoing debate about the meaning and procedure of informed consent. Some ethicists (e.g. Beauchamp and Childress) argue that informed consent protects the patient’s autonomy and respect for persons. Others (e.g. O’Neill) hold that informed consent prevents us from coercion whereas genuine informed consent is impossible to gain. Recently, care ethicists argue that the traditional conception of informed consent and autonomy are too individualistic. In this section, we will first explain different concepts of informed consent and their limitation. In the next section, we will then examine these conceptions in current Bangladesh context.

I. Faden, Beauchamp and Childress: Faden and Beauchamp, in their book *A History and Theory of Informed Consent* (1986) develop the notion of informed consent as an ethical and legal principle. In addition, they have presented the “conceptual” foundation of informed consent as an “ethical requirement”. Faden and Beauchamp separate two senses of informed consent. In the first sense, informed consent is an “action” by which a patient or subject declares his or her “autonomous authorisation” while in the second sense, informed consent is an institutional or legal “effective procedure” rather than autonomous authorisation. The goal of informed consent in the former sense is to fulfill moral requirement whereas in the later sense to satisfy legal or institutional requisite (Schermer 2001, 41).

Faden and Beauchamp hold that an autonomous action has to satisfy three basic criteria: “1.intentionality, 2.with understanding, and 3.without controlling influences” (Schermer 2001, p.42). Intentionally means willing as a conscious agent. An autonomous patient will perform an action willingly as well as consciously. Actions that happen accidentally or suddenly may not be considered as an intentional action. Some authors (e.g. Schremer) hesitate to accept intentionality as necessary for informed consent. Since when we give our consent it implies that we do so intentionally (Schermer 2001, 43).

Second, understanding refers that “...a patient must understand both the fact *that* he is giving an authorisation as well as all the material information pertaining to the treatment or procedure he is authorising”(Schermer 2001, 43). The importance of understanding is that the patient has to realize he or she is allowing authoritatively the intervention. The third criterion is about the voluntariness. Voluntariness ensures that the action has been performed without any influence or coercion (Schermer, 2001, 46).

According to Beauchamp and Childress, the three basic components of competence are: “capacity to understand”, “deliberate” and “decide” (Beauchamp and Childress 2001, p.72). They write, “...a person is usually considered competent if able to understand a therapeutic or research procedure, to deliberate regarding its major risks and benefits, and to make a decision in light of this deliberation” (Beauchamp and Childress 2001, 72).

The authors hold that competence and autonomy are closely related. An autonomous person is competent and able to give his or her consent. An autonomous person should have the capacity of making decision, understanding the (material) facts about the treatment procedure and use the information to make his or her own judgment.

The disclosure refers to an obligation of the physician while understanding refers to an obligation of the patient. Disclosure is a legalistic procedure which involves necessary information. Beauchamp and Childress write, “Disclosure, like treatment, is a task that belongs to physicians because of their professional expertise and commitment to the patient’s welfare” (Beauchamp and Childress 2001, 82).

Understanding is reasoning, communicating for authorising a treatment. It is associated with the patient’s knowledge, reasoning ability and projection. Understanding includes the ability to analyze, use and evaluate information regarding treatment. The minimum requirement for understanding is, “Patients...should understand at least what a health care professional...believes a patient...needs to understand in order to authorize an intervention. Diagnoses, prognoses, the nature and purpose of the intervention, alternatives, risks and benefits, and recommendations are typically essential” (Beauchamp and Childress, 2001, 88-89).

Finally, the voluntariness implies absence of others’ influence. Voluntariness could have two senses as Beauchamp and Childress mention, one is narrow and the other is broad. In a broad sense voluntariness has a similar meaning to autonomy while in a narrow sense voluntariness is controlling any influence. Beauchamp and Childress state, “...a person acts voluntarily to the degree that he or she wills the action without being under the control of another’s influence” (Beauchamp and Childress 2001, 93).

Although Faden, Beauchamp and Childress present a systematic and standard analysis of informed consent their views have been criticized strongly by some authors. O'Neill, Dodds, Mackenzie, Stoljar are prominent of them. We will analyze their views.

II. O'Neill: O'Neill argues that present framework and procedure of gaining informed consent is misleading. The authors who claim that informed consent requirement is sufficient to protect patient's autonomy are over demanding. In many cases informed consent is not possible to obtain. She holds that informed consent conception has significant limitations. We should incorporate as well as relax some constraint of informed consent. Although she is doubtful about the necessity of formal practice of informed consent in the medical practice, she does not reject its strength. Yet, she argues that the consent conception needs to redesign. She writes, "Given that informed consent is problematic for so many patients, it can hardly be necessary for medical treatment" (O'Neill 2002, 40).

According to O'Neill, informed consent is meaningful only when both parties participate "willingly" and they are "aware" about the main theme of the consent. They should have a clear idea about how the contract will work. O'Neill says that informed consent creates greater "difficulty" in medicine than in its usual use in daily life. She identifies four limitations in the informed consent requirement. (O'Neill 2003, 4-5). Firstly, incompetent people cannot give their consent. She writes, "We cannot give informed consent when we are very young or very ill, mentally impaired, demented or unconscious, or merely frail or confused" (O'Neill 2003, 4).

Secondly, informed consent is incompatible with constructing a unified public health policy. Since public policy is a unified conception and it is not possible to set a policy by taking consent from each and every person.

Thirdly, the patient has to disclose related family and genealogical information without obtaining consent from family members. Fourth, people such as "vulnerable", "prisoners" are unable to "refuse" when they are being asked to give consent.

According to O'Neill, consent should be simple as much as possible. Consent form should obviously not be "overwhelmed" by the information. Some patients want only basic information while others want more. So, the patient will choose how much information he or she needs to give consent (O'Neill 2003, 6). She states, "This balance can perhaps be achieved by giving them a limited amount of accurate and relevant information and providing user friendly ways for them..." (O'Neill 2003, 6)

III. Care ethics: Further, care ethicists have also criticized the traditional approach. Dodds identifies some limitations of autonomy-based informed consent practice. Firstly, giving the physician a responsibility to gain informed consent by providing

information is an “overturn” of paternalism. Since the physician is the only person who holds the power to give adequate information and the possible treatment. It is no more than paternalism except disclosing some information. Secondly, by the informed consent requirement bioethics isolated the conception of autonomy from its greater circumstances. As the notion of free speech which is isolated and protected by law from the social customs and practices. Only protecting the free speech without protecting freedom, or social customs is like protecting head without protecting the body. Thirdly, isolating informed consent implies that the physician’s ethical concern is only to obtain the patient’s consent and not to participate into the decision-making process. That is, there are some vital issue between providing information and gaining consent such as how does the physician present the information to the patient, in what language, these issues are ignored (Dodds 2000, 213-214).

According to care ethicists (like Dodds), the traditional concept of informed consent is too individualistic. Since this conception ignores the patient’s social bonding and inner power of relationship. The patient who is supposed to give consent is not out of the context. She is a small part of the whole society. Traditional informed consent does not truly reflect the patient’s values, thought or perception about the treatment. At best informed consent could be merely a choice (Dodds 2000, 216-217).

Feminist bioethics proposes three constituents or procedures, namely “choice”, “control” and “care”, to develop an alternative theory of autonomy and informed consent as well. A choice will not be made separately rather the physician will listen the patient’s desire, wishes, and provide the information that they would like to have. The physician will help to decide. Control means that, for example, especially the women have the choice to control her reproductive capability. Care implies a caring relationship in an interconnected socio-cultural context. Hence, the feminist conception about autonomy and informed consent is that these are not isolated individual choices but rather a caring interrelationship among the patient, physician, society and culture (Dodds 2000, 218-222).

So, in a care ethics approach informed consent is not just a formal document or protector of autonomy. Informed consent is more than that, where the physician will help the patient to understand sympathetically, empathetically and feel what information will be necessary for the patient’s consent. In this approach informed consent could be an outcome of empathetic relationship contrary to a contract. As Rosenberg and Towars write, “The relationship should be reshaped...patient care that combines the biomedical analysis of disease with an empathic understanding of the patient’s illness experience. Truly informed consent is viewed as a natural outcome of the application of this more comprehensive framework” (Rosenberg and Towar 1986, 181).

As we have seen the traditional conception of autonomy-based informed consent is too individualistic and problematic. Therefore, the care ethicists propose a richer conception of autonomy where the self is embedded as well as differentiated. This new conception of autonomy is shaped as “relational autonomy” which gives more value to the interconnectedness, dependent relationships, and some human qualities like love, care, empathy, sympathy and so forth. Mackenzie and Stoljar define “relational autonomy” as,

“The term “relational autonomy”... is rather an umbrella term, designating a range related perspectives...a shared conviction, the conviction that persons are socially embedded and that agents’ identities are formed within the context of social relationships and shaped by a complex of intersecting social determinants, such as race, class, gender, and ethnicity” (Mackenzie and Stoljar 2000, 4).

Some basic characteristics of relational autonomy are: firstly, relational autonomy is a complete idea, i.e. it requires a holistic approach. Individuals are not isolated from the circumstances. Individuals and the society are internally related. It is shared conception between individuals, society and culture. So, we should treat the person as a “socially embedded” individual. The individual will not be identified as a rootless separate member, rather a deep rooted “social relationship” will identify the individual. So, the main claim of relational autonomy is that the agent can protect his or her autonomy within the social context, social relationship with others. It is difficult for the agent to be isolated from every social identity.

Secondly, relational autonomy is against all sorts of oppression and could be defined as an identifier of “agent’s social location”. As McLeod and Sherwin say relational autonomy could be “...defined and pursued in a social context and that social context significantly influences the opportunities an agent has to develop or express autonomy skills” (McLeod and Sherwin 2000, 259-260).

Thirdly, relational autonomy is a “capability” of functioning as a “well-being of person”. As Brison says that relational autonomy, “...is one kind of relational account of autonomy that holds that an agent’s autonomy is dependent on her having an adequate capability to function...” (Brison 2000, 282-283).

4. Which conception of informed consent is possible to gain in Bangladesh?

In Bangladesh, the current scenario of getting and respecting informed consent is painful. One of the major areas where informed consent plays a crucial role is patient-

physician relationship. Unfortunately, in most cases exists an unhealthy relationship between patient and physician in Bangladesh. Elsewhere I have discussed the patient-physician relationship in Bangladesh context in detail and argued that “As a result, the patient-physician relationship turns out to be very paternalistic. However, in a situation where people are vulnerable (economically, physically, and emotionally), that would instead require care with sympathy, communication, active and proper treatment, sufficient health information, and so on; this can rarely be found in healthcare practices in Bangladesh” (Talukder 2011, 68). I conclude that an alternative model, instead of the traditional one, which is committed to care and respects patient autonomy is more appropriate for Bangladesh. Recently, a context-sensitive patient-physician relationship model in Bangladesh context has been outlined (Talukder 2016). Patients do not enjoy the privilege of informed consent in Bangladesh. Many of these patients are poor and thus they do not get a chance to go to or visit doctors at District hospitals. Because of the several incapability (such as poor income, illiteracy, distance) they often go to either village doctors or to different notorious or unhealthy and unhygienic hospitals. However, it is often seen that in these hospitals the patients are poorly treated, medical staff is performing operations or suggesting medicines, physicians are inhospitable and uncooperative as they are burdened with many tasks and interests. They believe informed consent to be no more than a signature which will provide legal protection if the patient dies or harmed.

In district hospitals, when the patients, after long hours of waiting, finally get an appointment with the doctor and visit him or her, they find that the doctors are very busy. Sometimes it is seen that many doctors are reluctant to get informed consent, even if they are not busy. It seems that physicians wish to keep the patients in darkness and to keep these innocents in a frantic, agonizing and unethical state of worry and mental harassment by not explaining their health condition and available treatment. Sometimes patients are just told by the assistants that they have to take this specific treatment or operation. This mentally harasses the patient in the sense that he or she shall want to know why the doctor recommends this solution, what are the other possible solutions, what are the benefits of this treatment or operation over others, what are its risks and many other things. When the patient does not get the answer of these questions, he or she shall increasingly become suspicious and hypertensed, thus being harassed mentally. The main aim of this kind of physician is to earn black money through repeated visits in the private clinic or diagnostic centre where they are affiliated with and thus to get more payments. So, unfair business in spite of respecting patients autonomy takes place. Informed consent appears for these patients as a piece of paper where they are obliged to sign.

However, business attitude among physicians may not be the only drawback in the informed consent practice. Insufficient knowledge and level of consciousness among

physicians about it is also vital. A study conducted on Bangladeshi physicians about their knowledge level of informed consent shows that “...although the majority of the physicians were conscious about informed consent, a large number of them did not possess sufficient knowledge about basic elements and fundamental characteristics of informed consent” (Hossain et al. 2005, 25). So, the study suggested “...to include more details of research ethics in the syllabus of undergraduate and postgraduate medical courses, particularly in developing countries” in priority basis (Ibid, 25). It implies that lack of a good number of ethics courses in the medical curriculum is another point to consider.

A good knowledge of ethics and updated medical Declarations will create confidence, higher responsibility and inspiration among physicians to successful communication with vulnerable patients. After conducting a research on pregnant women in rural Bangladesh and Sweden Lynöe et al. commented “The vulnerability of potential research subjects demands that researchers take seriously their responsibility to ensure the rights of the participants” (Lynöe et al. 2001, 461). The research shows that although illiteracy, poor income, miserable patient-physician ratio and so on prevail in the developing countries, the subjects can be vulnerable both in developed and developing countries. Only a caring and responsible physician or researcher can help to ensure an effective informed consent procedure.

Now, we could realize that some of the vital requirements of genuine informed consent are not possible to fulfill for an uneducated, poor patient. Although they have the capacity of making choice, some understanding about the treatment, these are not enough to give the consent. Moreover, in order to understand written disclosure they have to seek someone’s help primarily the physician’s. This sort of dependency might violate the criterion of voluntariness. Therefore, it might be impossible to gain genuine informed consent from the illiterate, poor patient of Bangladesh. O’Neill’s conception of informed consent seems more pragmatic in Bangladesh context than Faden, Beauchamp and Childress. Yet the question is: who will provide the information to the illiterate patient and how? The conception of informed consent as presented by care ethics seems more compatible in Bangladesh context. Since the poor and illiterate patient’s autonomy may not be viewed as individualistic. The health workers and the physician should gain informed consent in a more relational way.

5. Justification of ‘relational autonomy’ (from care ethics perspective) in Bangladesh

Respecting patient’s autonomy and obtaining informed consent is a great challenge in developing countries like Bangladesh. The risk of exploitation is much higher here for several reasons. One way of protecting patient’s autonomy and their rights could be to consider community and family bonding, cultural embeddedness, social values, linguistic heritage, collaborative partnership, etc. Emanuel et al. argued that in developing countries the process of informed consent is complex and hence special concentration should be given to language, social traditions, and cultural and family practices. They suggested five benchmarks for obtaining informed consent. The second of these benchmarks says, “disclosure of information should be sensitive to the local context. It should be done using the local language, culturally appropriate idioms, and analogies that the prospective participants can understand. This obviously entails a need for collaborative partnership” (Emanuel et al. 2004, 934). The “partnership” among different parties including physician, patient, medical staffs, patient’s family members, researchers must be based, in my view, on a common value which is *caring*.

Campbell points out the same issue and argues that even though there are complexities and barriers to obtain informed consent in developing countries it cannot be a “myth”, rather it is a “reality”. However, making informed consent real in developing countries he suggested “Rather than assuming the inability of some people to grasp western biomedical concepts, researchers need to realize that understanding suffers in *both* developed and developing settings and that the real focus should be on adapting the universal paradigms of research to local cultural norms, ideas, and literacy levels” (Campbell 2013, 3). Therefore, it follows that we should consider western biomedical norms such as autonomy and informed consent in relation to local cultural and social values, socio-economic condition, literacy level and the level of understanding of common patients.

Bhutta observes that in developing countries we should not just focus on a formal informed consent practice but rather look beyond it. One of the main roles of researchers or physicians in the wide conception of informed consent is being caring and compassionate. He writes, “This may only be possible in an environment where human rights are respected and the fundamental principles of justice govern the design and conduct of research. While the role of a caring and compassionate researcher is fundamental to conducting appropriate research in developing countries, the following permutations of the process and regulations may make it both easier and more ethical” (Bhutta 2004, 775). Bhutta’s permutations include the change of focus in informed consent, implementing innovative materials, alternative

way of documentation and involving senior community members. He suggested a partnership model for obtaining a true informed consent in developing countries, as he mentions here, “While ethics review committees can help in oversight, only an active and transparent partnership between research sponsors, investigators and the community can make this happen” (Ibid, 776). In a partnership model where caring as a means of transparency is the common value, obtaining informed consent will be seen more than a procedure. Only then we can see the informed consent an *outcome* of mutual respect, not just a procedure.

The eminent physicians of Bangladesh also indicated a need for a partnership model that could be based on care ethics, as they themselves considered *care giver* and patients *care seeker* while recommending, “The civil society, the political parties, patients (care seekers), the doctor (care givers) community all have to play important role in this matter” (Islam and Jhora 2012, 55).

Therefore, we can assume that genuine informed consent may not be possible to gain in developing countries, including Bangladesh. We support care ethicists’ criticism against traditional autonomy and informed consent, and argue for a richer conception of autonomy specifically ‘relational autonomy’ from care ethics perspective.

The crucial question then appears: what is the advantage of the ‘relational autonomy’ conception? The main advantage is that relational autonomy considers patient’s rights as well as the physician’s obligation to care choice. It seems that to patients, autonomy and informed consent are secondary choice of patients and care is the first concern. Unlike paternalism, caring does not undermine the patient’s rights which are nourished through sympathy, care and relationship.

Could relational autonomy conception be justified in Bangladesh context? In order to answer this question we may consider some important factors: firstly, although all patients are not poor and illiterate in Bangladesh the reality is that most of them are plagued by poverty and illiteracy. The patients are helpless, not being able to bear their medical expenses. When they become ill they have to face many problems such as inadequate medicine, overdependence on the physician for lacking the ability to read or write, scarcity of beds in the hospital, as a whole they become ill not only physically but also psychologically. All these things can be seen as a great obstacle to making autonomous decisions in a true sense. How can we imagine that such a patient being isolated will understand the meaning of disclosure, treatment procedure, will show a standard degree of competence, deliberation and decision making ability, and that their decision will be voluntary? Secondly, the patients are embedded within culture and family. It is a brute fact that many poor patients laying on the floor of the hospital, not getting enough care, recover disease partially for receiving very sympathetic, responsible, loving-care from the family members.

They serve the patient by providing invaluable labour, care, and support in making decision. Therefore, the patients might not be interested to isolate themselves from the family and to make decisions alone. Thirdly, the patients really expect sympathy and care even though they receive insufficient treatment. Fourth, the patients want to see the physician as the most trustful, sympathetic person; the only one who can treat, inform and advise. In considering these factors with socio-cultural status relational autonomy conception can be justified for Bangladesh.

6. Conclusion

To summarize, after discussing the importance and different conceptions of informed consent in the patient-physician relationship we hold that care ethics approach provides the most plausible conception which is achievable in Bangladesh context. We have argued that the relational conception of autonomy from care ethics perspective is more appropriate for the illiterate, poor patient of Bangladesh. If we incorporate relational autonomy concept rather than traditional individualistic autonomy this will be more pragmatic and applicable. Informed consent in this sense is a “natural outcome” of the patient-physician relationship which supports that patients’ illiteracy might not be a barrier for giving their consent.

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Informirani pristanak i pacijenti u Bangladešu

SAŽETAK

Informirani pristanak ima ključnu ulogu u etičkom donošenju odluka u medicinskoj praksi. Izgleda kako je posljednjih godina informirani pristanak ključno pitanje u biomedicinskim raspravama. Dosada je predloženo nekoliko definicija informiranog pristanka. No, socioekonomski uvjeti različiti su u raznim zemljama. Mnoge su zemlje kulturološki različite, ali postoje i razlike u postotku pismenosti stanovništva, stoga objedinjeni koncept informiranog pristanka možda ne bi bio opravdan u svakom pojedinom kontekstu. U ovom se radu raspravlja o važnosti informiranog pristanka, različitim pogledima na informirani pristanak i ograničenjima koje donosi primjena samo jednog koncepta informiranog pristanka u svakom kontekstu. Argumentira se da je za zemlje u razvoju, poput Bangladeša, najprikladniji koncept informiranog pristanka onaj koji se temelji na etici skrbi. Zaključuje se da, iz perspektive etike skrbi, informirani pristanak može biti 'prirodni ishod' i da ne bi trebao biti prepreka u odnosu liječnika i bolesnika.

Ključne riječi: autonomija, etika skrbi, informirani pristanak, odnos liječnika i bolesnika, poštovanje, rizik.