IMPLICATIONS OF INFORMED CONSENT IN HEALTHCARE: LUXURY OF WEST OR BASIC HUMAN RIGHT .

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ABSTRACT: Traditionally, healthcare in developing countries, esp. those working in rural areas, was provided by people with an 'all good' approach, but with the development of robust programmes, the practice in developing world has demanded the same scrutiny as developed world with evidence based practice. There is an active debate about the informed consent. The article discusses the implications of consent in treatment and clinical research in developing countries.

KEYWORDS: Informed Consent, Developing world, Competence, Treatment, Clinical Research.

IMPLICATIONS OF CONSENT:

There is an active debate about the informed consent and the value of consent is increasingly coming under discussion in many authorities including the courts of law **(1).** In healthcare with developing world healthcare in particular, the issue of consent arise in the following contexts.

Treatment
Clinical Research
Financial decisions (e.g., mental capacity while making a will)

Here in this paper, the consent issues with regards to treatment and clinical research are discussed.

CONSENT WITH REGARD TO TREATMENT:

World Health Organization has clear guidelines which are adapted largely in developed world stating that a doctor needs consent for examination, treatment or care [(2)]**.** However, it is also acknowledged that although doctors need to seek the patient's consent, consent does not need to have a cumbersome exercise. It can be written, oral or non-verbal. A signature on a form does not imply that consent is valid. However, for consent to be valid, there are three basic conditions:

- The patient must be ***competent*** to give consent
- The consent must be based on ***adequate information***
- The consent must be ***voluntarily*** given [(3)]

Competency is the first condition, which means many patients cannot give consent. The list will include:

- Children under 16 years of age, unless they are Gillick competent [(4)]
- Any person on anybody else's behalf (e.g., family or friends)
- Incompetent adult

Lack of competency is once described in a court case as having the following parameters. The case dealt with a child's case, but the principles are applied the same way while making sure of anybody's competency. The judge, in the said case, adopted the three-stage test, which had been developed in earlier cases involving adults [(5)]. This implies that whether the person is capable of:

- Comprehending and retaining treatment information
- Believing it
- Weighing it in the balance to arrive at choice

A significant development in the law in United Kingdom has established that while a competent child may consent to medical treatment, the child's refusal will not necessarily be valid. A parent (or other with parental responsibility) may give a valid consent to medical treatment notwithstanding the child' refusal [(6).]

Sometimes, in healthcare, we come across patients who are not competent due to a particular reason, which could be their disease or drugs etc. The law, all over the world, and ethics allow the doctors to treat a patient if the treatment is in their best interests. 'Best interests' go beyond the best 'medical interests', as healthcare professionals need to consider factors such as patient's wishes and beliefs when they were competent, their current wishes, their general well being and their spiritual and religious welfare. People close to patient can help the doctors with some of this information rendering, but they do not have the power to give consent for adults [(2).] Staff working in developing countries work with the carers to provide them support especially, as it is well immersed in cultural values as well. Staff also may need to provide support if they find it difficult to accept the patient's medical interests. Sometimes, patients have indicated in the past an 'advanced refusal' to treatment, which medical staff should comply with. Once again, families can find it hard to accept the request for 'advanced refusal' and may need support and empathetic approach.

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It needs emphasizing that consent to treatment goes beyond surgical procedures. Its remit involves simple interventions like drug prescription, administration of drugs and rectal examination. Drug prescription needs careful discussion as the patient needs to know about the side-effects as it is regarded as an important factor for the patients to lose confidence in the drug and therefore to stop medication [7]. It is also important, as patient need to know about their responsibilities about drug intake e.g., driving regulations. One way to give adequate information is to hand out a patient information leaflet such as patient information leaflet on for opioids [8]. Adequate information is important to achieve a valid consent. A doctor has a legal obligation to convey this information to the patient. In Islamic heritage, consent after full knowledge is well respected. Hazrat Ali (AS) uttered: *'That knowledge which remains only on your tongue is very superficial. The intrinsic value of knowledge is that you act upon it.'* [9]

The definition of adequate information is hard to standardise. However, most literature suggests one of the three approaches.

1. ***Reasonable Physician Standard:*** What would a typical physician say about this intervention?
2. ***Reasonable patient standard:*** What would the average patient need to know in order to be an informed participant in the decision?
3. ***Subjective Standard:*** What would this patient need to know and understand in order to make an informed decision? [10]

It is generally accepted that adequately informed consent includes a discussion of:

- The nature of the decision/procedure
- Reasonable alternatives to the proposed intervention
- The relevant risks, benefits and uncertainties related to each alternative
- Assessment of patient understanding
- The acceptance of the intervention by the patient

Sometimes, patients refuse a particular type of treatment, even after it was explained fully. Refusal, however, should be considered as a flag to pursue further the patient's beliefs, concerns, fears and understanding. On the other hand, there is always a risk of coercive situations to arise as it will be contradictory to ethos of medical care. One way to deal with that is for inviting an independent observer to be present while discussing these decisions.

CONSENT WITH REGARD TO CLINICAL RESEARCH:

Broadly speaking, same conditions will apply in research as for treatment. However, in terms of research, patients in developing world can be deemed vulnerable [11]. It is argued that vulnerable patients should only be excluded from research, as the idea of researching these patients could be cruel and cumbersome. This attitude has led to lack of research in some fields including the field of palliative care, making palliative care patients 'therapeutic orphans'. [12]

It is observed that although there is general discontent with 'presumed consent' in ethical committees, other methodology has been innovative. Cluster randomisation or cluster consent may be appropriate for some particular types of researches [13]. Prospective consent is also used in some researches for end-of-life interventions [14].

There are practical difficulties including high level of gratitude leading to coerciveness, which again can be dealt with by involving a staff member not primarily involved in patient's direct care. There is indication that now Research Ethics Committees around the world recognise that they should not be over-zealous in the protection of apparently vulnerable research participants [12].

RELEVANCE TO PAKISTAN AND MUSLIM COUNTRIES:

Medical ethics is a universal topic. Much before western world benefited by Emanuel Kant or Peter Singer's moral philosophical theories, Islamic traditions had seen the discourses of Ibne Sina, Al-Kindi and Ghazali. In fact the root of not taking consent and not allowing freewill is found in the days of *Jahiliya* (days of ignorant). Even the western scholars recognise that one of the primary jobs Holy Prophet (SAWW) had to perform was to discourage the trait of *muruwwa* (manliness), instead emphasizing on the traits of humility and piety [15]. In effect, that means discouragement of paternalism. In our medical circles, where there has been a culture of 'doctor knows best', this is a stark reminder that this attitude is directly in confrontation with Islamic principles.

CONCLUSION:

It was always felt 'right' to provide healthcare in developing countries as it was always received with gratitude from patients as it was always with best intention. However, subconscious conflicts of motivation, even of helping to the best of one's ability, sometimes may override patient autonomy or sometimes non-consent. Patient-centred care is the fundamental ethos of healthcare and a simple checklist for a clinical team working in developing world will help avoid any difficult circumstances later, which may result from failure to gain consent.

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