



Review Article

Clinico-legal aspects of informed consent and NABH accreditation: A review

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Article Received on: 29/07/2021; Accepted on: 12/08/2021.

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ABSTRACT:

National Accreditation Board for Hospitals and Healthcare Providers (NABH) has partnered with Insurance Regulatory and Development Authority (IRDA). Entry level certification of hospitals has been made mandatory to hospitals providing cashless insurance facility in their premises. High quality of care and patient safety is ensured by NABH. Standard 4 of chapter 4 of NABH standards is, "Informed consent is obtained from the patient or family about their care". To fulfill this standard 5 objective elements are prescribed, out of which 3 belongs to "Core Category". Assessment of core category objectives is mandatory at all levels of assessment. Informed consent should be obtained from the patient or family all specified procedures/care. Risks, benefits and alternatives are the key components of information which should be included in this document. Patients and families have a right to get information and education about their healthcare needs. NABH standards have given emphasis on the development of effective patient-centered communication by the organization. Communication is a key in prevention of many negligence suits.

KEY WORDS: Informed consent, NABH accreditation, Proxy consent

INTRODUCTION:

National Accreditation Board for Hospitals and Healthcare Providers (NABH) has partnered with Insurance Regulatory and Development Authority (IRDA). Entry level certification of hospitals has been made mandatory to hospitals providing cashless insurance facility in their premises. High quality of care and patient safety is ensured by NABH. Building a quality culture across all levels of healthcare sector is the objective of this process.¹

There are total 651 Objective Elements in latest edition of "NABH ACCREDITATION STANDARDS FOR HOSPITALS APRIL 2020" out of which 102 are listed under core category. Their assessment is mandatory during each part of assessment.²

Chapter 4 of "NABH ACCREDITATION STANDARDS" is "Patient Rights and

Education (PRE)". Intention of this chapter is protection and promotion of the patient and family's rights and responsibilities. According to these standards, healthcare institute should make the staff aware of patient's rights. It should also ensure their training to protect these rights.³

Standard 4 of chapter 4 is, "Informed consent is obtained from the patient or family about their care". To fulfill this standard 5 objective elements are prescribed, out of which 3 belongs to "CORE CATEGORY".⁴

Information is the basic right of patient as "Autonomy" is one of the main four medical ethics.⁵ Patient should get full knowledge regarding his disease, diagnosis and treatment which he may need from doctor who is treating him/ her; whether medical or surgical.⁶

Consent has been defined as “voluntary agreement, compliance or permission for a specified act”.⁷ The Indian contract act, section 13 states “two or more persons are said to consent when they agree upon the same thing in the same sense”.⁸

In clinical setup consent is a very important legal document which can save doctor from unnecessary complications.

MATERIALS AND METHODS:

Textbooks of forensic medicine and medical jurisprudence, law and various research article published on consent were reviewed. Only clinical aspects of informed consent were reviewed for this article as ethical aspects of clinical research in a separate vast area for study. Guidelines of “NABH ACCREDITATION STANDARDS FOR HOSPITALS APRIL 2020” were also studied in detail. Based on this review concept of informed consent with special reference to clinical practice was done.

Aim of the study:

1. To review the concept of consent legally
2. To study situations in which it is necessary
3. To study guidelines for informed consent as per NABH manual
4. To understand benefits of consent

DISCUSSION:

Prior consent from patient is necessary for Healthcare providers. Consent can be different for legal purposes. It can be expressed in different ways. Protection from liability for assault can be obtained from a consent. Inadequately informed consent may lead to accusations of negligence.

Types of consent:

- According to information provided to patient.
 1. Uninformed consent- information partially or completely hide.
 2. Informed consent
- According to way patient communicates it to doctor.
 1. Implied

2. Express
3. Blanket

In all the above types, **Informed Written Consent** is considered as legally valid. Because in this consent following points should be explained to the patient;⁹

1. Nature of the illness
2. Nature of the proposed treatment or procedure
3. Alternative procedure
4. Risks and benefits involved in both the proposed and alternative procedure
5. Potential risks of not receiving the treatment
6. Relative chances of success or failure of both procedures

From whom consent can be obtained:

1. Conscious, mentally sound adults
2. Children above 12 years of age
3. Spouse of patient undergoing sterilization
4. Guardian of children less than 12 years of age
5. Permission of loco parentis

Consent by substitute:

In following conditions, consent can be obtained from relatives or friends, this type of consent is known as “Proxy Consent”.¹⁰

1. In case of mentally ill patient when he is unable to understand due to the mental illness.¹¹
2. Unconsciousness patient where lifesaving procedures need to be done.¹²
3. Intoxication¹³
4. In case of Child less than 12 years, consent can be obtained from parents or guardian for examination. But assent of the paediatric patient is obtained sometimes.¹⁴

When informed consent is necessary¹⁵

1. In small OPD, informed consent may not be required, here patient approach can be considered as implied consent for general checkup. But for procedures performed over OPD basis informed consent is required.
2. In institutes, when patient registers a general consent is necessary according to NABH guidelines.

3. In following conditions consent is required,
 - a. Minor procedures like I & D , etc.
 - b. Major procedures; all surgeries.
 - c. Diagnostic invasive procedures
 - d. Vulnerable patient
 - e. Blood transfusion
 - f. HIV testing
 - g. Medico legal cases
 - h. Panchakarma
 - i. Ksharsutra
 - j. Kriyakalpa

Guidelines for informed consent¹⁶

1. It should be in language understandable to patient. Here regional or patients own language is must. Also medical technical terms should be avoided.
2. Doctor should explain proposed procedure, its benefits, involved risk and if any other alternative is there.
3. Document should contain name and address of the hospital
4. Basic information of patient like age name sex address should be there.
5. It should be signed by relative of the patient.
6. A third person should also sign the document as a witness.
7. Doctor should put sign, date and time at the time of taking consent to avoid any legal complications later.
8. If any complications occur during procedure, then additional consent should be taken from the relatives.
9. In case of emergency, when patient is unaccompanied by anyone only lifesaving procedures can be done without any consent.

CONCLUSION:

NABH standards give emphasis on quality care to patients. Patients' rights and responsibilities are very important in improvement of quality care. Informed consent should be obtained from the patient or family all specified procedures/ care. Risks, benefits and alternatives are the key components of information which should be included in this document. Patients and families have a right to get information and education about their healthcare needs. Language and manner should be such that is understood by patients easily. NABH standards have given emphasis on the development of effective patient-centred communication by the

organization. Communication is a key in prevention of many negligence suits.

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Cite this article as:

Jayant Phadke, Anuja A. Wadadekar, Clinico-legal aspects of informed consent and NABH accreditation: A review, PDEAS Int. J. R. Ayu. & A. Sc., 3(2); Aug 2021, p. 37-39.