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Role of Informed Consent in Psycho-Social Research and Clinical Practice

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ABSTRACT

Informed consent' (IC) is a mandatory document prioritized before execution of any invasive procedures, life threatening test, risky methods and protocols, intimate examinations and minimal to major surgeries. Application of IC is called 'Informed Consent Process'. IC plays vital role in both, research and clinical practice of healthcare domains for protection of patient's legal rights to guide ethical approach and the procedures to be carried out. IC enables patient to choose the choice of treatment/procedure in clinical practice and subjects/participants in research (if conscious). In case of unconscious patient's, family members/relatives/guardians rule the mode of action for procedures. Looking back in history, emergence of IC dates back to over a century ago started with the aim to protect subject/patient from unwarranted intrusions into their body thus providing discretion in selecting treatment as a personal choice. As research amplified with passage of time, IC became a major part in all research activities and also clinical trials or practice simultaneously to avoid misuse of an individual. Before implementation of an IC, certain pre-requisite are to be present without failure following which if not available, the concerned act shall either be not be allowed to be carried or postponed till the necessary consent is achieved. These are strictly followed across the globe and stated as individual being an adult (more than 18 years of age), conscious, alert, mentally sound, responsive to verbal and visual commands. In procedures or treatments involving children as subjects or patients, parents/guardians/relatives should pose the same qualities. While in case of capacitated individuals (children or adult) family members/guardians/relatives are expected to be present on the spot before instigating the components of the IC. In the present article, author would concentrate on all components to be considered while de-signing an IC. Modifications according to perception either for research or clinical practice should be implemented accordingly.

KEY WORDS: INFORMED, CONSENT, PROCESS, RESEARCH, CLINICIAN, COMPONENT, TREATMENT.

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INTRODUCTION

'Informed consent' (IC) is a mandatory document prioritized before execution of any invasive procedures (Rao, 2008), life threatening test, risky methods and protocols, intimate examinations (Habiba et al., 2004;Sepucha et al., 2007) and minimal to major surgeries (Sharp., 2004; Braddock et al., 2008; Black et al., 2009) in case of emergencies (Akkad et al., 2004; Akkad et al., 2006) or routine procedure. Application of IC is called 'Informed Consent Process'. IC plays vital role in both, research and clinical practice of healthcare domains for protection of patient's legal rights to guide ethical approach and the procedures to be carried out (Hall et al., 2012). IC enables patient to choose the choice of treatment/procedure in clinical practice and subjects/participants in research (if conscious) (Bhatt, 2015). In case of unconscious patient's family members/relatives/guardians rule the mode of action for procedures. Looking back in history, emergence of IC dates back to over a century ago started with the aim to protect subject/patient from unwarranted intrusions into their body (Sutrop, 2011) thus providing discretion in selecting treatment as a personal choice (Dankar et al., 2019).

As research amplified with passage of time, IC became a major part in all research activities (Dankar et al., 2019) and also clinical trials (Kass et al., 2015) or practice simultaneously (Dankar et al., 2019) to avoid misuse of an individual. Before implementation of an IC, certain pre-requisite are to be present without failure following which if not available, the concerned act shall either be not be allowed to be carried or postponed till the necessary consent is achieved. These are strictly followed across the globe and stated as individual being an adult (more than 18 years of age), conscious, alert, mentally sound, responsive to verbal and visual commands. In procedures or treatments involving children as subjects or patients (Miller, 2009), parents/guardians/relatives should pose the same qualities. While in case of capacitated individuals (children or adult) family members/guardians/relatives are expected to be present on the spot before instigating the components of the IC. In the present article, author would concentrate on components to be considered while designing an IC. Modifications according to perception either for research or clinical practice should be implemented accordingly.

While designing and preparing an IC, various parameters dominating the fields of research and or clinical practice have to been taken care of and explained to the subject/patient (Kadam, 2017). The components to be expressed without failure shall be discussed in points for the ease of future readers, researchers and clinicians.

1. Clear terminology expressing the pathology/dysfunction/disorder/disease/condition/deformity, the patient is sufering from should be the foremost component of a professionally sound IC (Rao, 2008; Sreenivasan, 2003; Pandiya, 2010)

2. Necessity for the procedure in consideration along with the emergence required to perform the same should be attentively addressed (Rao, 2008).

3. The normal route of containment and spread of condition (if any) should be explained (Michie and Lester, 2005).

4. All temporary and permanent complications, risk, discomforts etc. associated with the procedure/treatment in context to the prevalent condition should be narrated in simple and patient's understandable language. In addition, any effects which can be presumed to originate in future should also be discussed enabling the concern to concentrate his temperament in tolerance with the complications (Madhava, 2000; Kharawala and Dalal, 2011; Gupta and Kharawala, 2012).

5. Side effects following non participation in the recommended procedure and their impact on the individual's psychological, social, mental and financial wellbeing should be prioritized (Rao, 2008).

6. Detailed information regarding all treatment strategies available within reach of the patient should be explained (De Costa et al., 2004) In addition, procedure far from patient's reach should at least be put to discussion, as sometime patients seeking long term effects of the procedure enhancing their quality of life take financial support from sources and go ahead with the higher benefited procedures.

7. Benefits and risk associated with the procedure/intervention maintaining the hierarchy with the treatment/procedures with minimum risk should be explained first following moderate to the ones ofering the least. This procedure can be used vice-versa according to the researcher/clinician choice depending on their convincing ability to make the participant/patient ready for the considered activity (Hudak et al., 2008).

8. Duration of treatment (Madhava, 2000) covering both, in-patient at the hospital/nursing home/clinic etc and out-patient department for the procedure should be explained.

9. Confirmative cost of treatment should be openly and clearly discussed with the patient (if conscious), while if the patient is unconscious, family members/relatives/friends should be explained the same, ensuring their decision to be the final for betterment of concerned individual.

10. Expected outcomes from the procedures/treatments should be explained via verbal communication. If required use of pictures, graphics and flow chart representation for a clear image of the expression should be instituted by the health staff intends to convey the information written in the IC.

11. Cost and days required for follow up wherein post treatment, the number of days to be required as in-patient

and later continuing as out-patient department should be narrated effciently.

12. Statement stating benefits that could be incurred by the individual during and on completion of procedure/ treatment should be wisely addressed.

13. Information regarding storing of records/data (Francis, 2004; Surendra and Mohan., 2017; Ohmann et al., 2017) by either the individual or health staff should be addressed with the final approval mentioned in the IC to prevent future conflicts between the individual and health care professional concerning disruption in privacy.

14. A provision of 'anonymity' (Beauchamp et al., 2001) should be created in an IC to increase the rate of participation for conducting research procedures and clinical trials. This aspect relates to acts involving patient's emotional, physical and personal attributes being a major concern for affecting the rate of participation in studies. People in developed countries being open minded in attitude respond more and faster to procedures with minimal or no anonymity, but population from developing countries (Fitzgerald et al., 2002) are usually seen to be hesitant and recommend maintenance of anonymity if asked to be a part of the procedure/treatment.

15. Disclosure of small to large remuneration during the entire course should be addressed as focusing this concern in later stages of IC, as initially the major concern should be to convince individuals buy showing the benefits of the procedures/treatment on their health which is major part of ethics in healthcare. Still if individuals are not willing to be part of the act, if approved by the ethical committee of the university/college/hospital/agency, remuneration can be ofered, but this is not mandatory to be part in all IC forms. Remuneration providing financial support lures individuals to participate without putting any burden on self-finances.

16. Details of contact personal in case of emergency should be documented making sure that the personals are adult in nature (more than 18 years). The concerned should provide their telephone numbers and address. A minimum of 2 references should be maintained in the IC.

17. A statement stating consent for clicking photographs, if need to be clicked during and after the procedure should be clearly mentioned. In addition, the use of the photographs to be for either educational/symposium/ conferences by the researcher or clinician should be mentioned. Provision of blindfolding of face should be explained. If not addressed in the IC, later it can put the re-searcher/clinician in legal trouble if the individual proves the expression of photographs in public without his/her consent.

18. Explanation of all technical, specific and complex words should be discussed and explained in the individuals easy and layman understandable language (Pandiya, (2010); Bhansali et al., 2009). If required, the same details can be explained to the attendants who can try to convince for the procedures to be implemented for betterment. If still the individual finds being in dilemma, videography (Wirshing et al., 2005); Deyo et al., 2000; Jimison et al., 1998) to explain the aspects can be used for a thorough and clear representation.

19. Apart from the above components necessary to be documented in an IC, any consideration in alteration to psychological (Kharawala and Dalal., 2011); (Gupta and Kharawala., 2012), physical, emotional (Kharawala and Dalal., 2011); (Gupta and Kharawala., 2012) and financial distress should be discussed without failure to prevent keeping the individual in darkness for self benefit by the researcher/clinician (Nijhawan et al., 2013).

20. Finally, a statement regarding final acceptance keeping in view of all explained factors and parameters associated with the present and future, procedures/test in case of research and treatment in case of pathology/ condition/dysfunction/ailment should be stated in the last under which the participant is asked to provide a signature or a thumb impression if illiterate.

CONCLUSION

An IC for research/clinical practice should address and document concerns in clarity stating the benefits to the individual involved during and after completion of the procedure or treatment. It should be matured enough to contain and preserve the ethical spirit by preventing misleading of the individual thus, averting any possible legal conflicts in future. This goal can only be achieved when a well contented IC form with all necessary information and in depth inoculation is designed and eventually brought in use. This well designed IC protects both, the individual and health care professional from legal; aspects giving full description of the patient to choose the type, time of treatment, refusal and withdraw from the procedure at any instinct of time during both, invasive and non-invasive surgeries. Finally, a clear presentation of a procedure is important for an individual who lets an external person to intervening in their body. This procedure should be executed using tremendous care and safety measures for betterment of the individual.

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