REVIEW PAPER

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Informed consent process: challenges in clinical practice

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Abstract

The concept of informed consent dates back to nearly a century ago. It was instituted with the aim to safeguard a patient from unreasonable intrusion and abuse to their body integrity and to enrich patients with the ability of own choice for selecting the type of treatment as per their will. In other words, any action by a clinician, either for trial or practice purposes, involving an intrusion inside the patient's body has to be conducted only after the approval of the patient (if conscious) or acceptance from family members, relatives, or friends of the patient (if unconscious). Application of informed consent prior to any procedure follows its implementation called 'informed consent process'. In the present review article, the author focused on the challenge encountered by clinicians while implementing an informed consent process. Various databases were searched from inception to August 2020. Only English language articles were searched, with the following keywords: "Informed consent", "Informed consent process", and "Consent form", linked with Boolean words "AND", "OR", and "NOT". Informed consent process implementation should overcome various setbacks which have been experienced by clinicians working in government and private hospitals, nursing homes, clinics, old age homes, etc. These challenges were discussed in this review under various headings for proper identification, justifying the cause and measures to minimize their impacts.
Key words: informed consent, clinical, children, patient, procedure, treatment

Introduction

The concept of informed consent (IC) dates back to nearly a century ago [1]. It was instituted with the aim to safeguard a patient from unreasonable intrusion and abuse [2] to their body integrity [3] and to enrich patients with the ability of own choice for selecting the type of treatment as per their will. Over the years, there have been modifications in the meaning of IC, with the latest one widely referring to a document duly signed before any invasive or non-invasive procedure, test, risk experiment, minimal to major surgical procedure, intimate examination [4, 5] by giving the supreme choice of being a part as a patient by choosing the type and time of execution of a treatment. In other words, any action by clinician, either for trial or practice purposes, involving an intrusion inside the patient's body has to be conducted only after the approval of the patient (if conscious) or acceptance from family members, relatives, or friends of the patient (if unconscious). Application of IC prior to any procedure follows its implementation called 'informed consent process' (ICP). This process is carried out as a systematic, regularized procedure mentioning and encompassing all essential components to be mandate in an IC and followed where and whenever required [6]. For the best results, implementation of ICP should overcome various setbacks which have been experienced by clinicians working in government and private hospitals, nursing homes, clinics, old age homes, etc. In the present article, the author focused on the challenge encountered by clinicians while implementing ICP. These challenges were discussed under various headings for proper identification, justifying the cause and measures to minimize their impacts.

Complexity in the written content

The application of scientific and medical terminologies, technical jargon, and abbreviations, as well as an excessive use of paragraphs make it difficult for individuals to understand aspects expressed in IC [7]. This prevents them from realizing the concern and thus from making a smooth connection with other associated parameters mentioned in the IC [6]. While developing IC, clinicians should keep the comprehensive level of language to be similar to that of 8th grade, as people with a higher education level feel competent in reading and understanding the content [8], but issue rises while dealing with patients from low educational background, who present with inability to understand the basic and in-depth configuration being explained by the clinician via the IC. While preparing IC, one should keep in mind the educational level of the place [9] where the practice is being planned to be executed for an easeful transfer of information, which would engrain a higher involvement of the patient's interest [8]. So, documentation of the content in a point-by-point manner rather than in a paragraph will deliver an easy visibility for reading and comprehending.

Language as barrier

Each country has a native spoken and written language. Around the world, the most widespread language used is English. Clinicians, if using English as a mode of their written communication, will always apply the same while devising an IC. This can be configured to a population who can read and write the same, but in practice, a hardly English-speaking common man would find it difficult to understand the mes-

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sage to be conveyed by the clinician. To prevent oneself from this effect, while preparing an IC, consideration of the laymen's written language should be prioritized for an easy reading and understanding of the contents, which would impart a clear representation of the message [10]. In return, this will increase the patient's confidence owing to a definitive understanding of the concept, treatment, protocol, etc. Additionally, the patient will be convinced after reading, and the availability of the document as a proof will provide them with mental satisfaction [11]. This has been proved by researchers where even after giving a consent to undergo a procedure or treatment, the patient surprisingly did not know the contents of the IC as they found written and spoken language to be a barrier between them and the clinician. Researchers concluded this issue to rise, firstly, because the IC was not written in the laymen's language, and secondly, the clinicians could not explain the notion to the patient owing to the sophisticated language and medical terminology used while preparing the IC and using a language which was difficult to understand by the individuals in the said geographical area.

Poor understanding on the part of the patient

While preparing an IC form, a clinician should elaborate components in succession depending on their priority, with simple and understandable words of the patient's native language, enabling the laymen population to understand the message to be conveyed and generate interest and active and higher participation rate [12]. At times, clinicians present only superficial aspects, missing the temporary and permanent risk, complications, and discomforts which could be involved at the moment or in near future [8, 13, 14]. These concerns should be noted and explained without failure. Poor IC understanding can make patients withdraw from the procedure participation.

Patient incompetency

Factors such as geriatric population, cognitive disabilities, psychological depression, severe mental issues, patient in the last stage of disease, mood imbalance, or influence of alcohol affect the decisional ability of the patient [15, 16]. This ability keeps reducing as the severity of the above mentioned health conditions increases, either gradually or rapidly [17]. As a result, even the best mode, procedure, or treatment adopted by the clinician and explained in the patient's layman language will not be able to convince the patient, thus leading to their withdrawal or minimal interest.

Patient's perception of the procedure or treatment

Patients suffering from diseases that have gravely impacted on their lives are generally depressed, in low mood, and agitated owing to their social, personal, and financial irregularities, as well as their resources becoming limited with the passage of time [18]. Convincing such patients becomes a challenge for a clinician as the patients themselves or their family members configure their participation as an extra burden on the financial recourses, which are already in poor shape [19, 20]. Because of own incompetency and lack of interest even from family members, these patients make all sorts of excuse so as not to be part of the procedure [21]. In such cases, if possible, looking for all measures and sources, benefits in any form can be planned and presented to increase the rate of participation.

Influence of religion and belief

This is another challenge of concern seen by clinicians in certain studies. If the procedure or treatment is not perceived beneficial by the patient, influence on the psychological basis will not solve the issue. This sometimes refers to particular geographical locations where people practise a religion that makes them not willing to undergo treatment [21]. This leads to biasing. Factors which affect the rate of participation involve gender, beliefs, daily life habits.

Treating a vulnerable patient

By vulnerable patients, the author means people who are absolutely or relatively not able to protect their rights, as well as to understand, interpret, or question the given information [22]. With such patients, their closest family members, relatives, or friends (in descending order available) have to be taken into consideration by a clinician while describing and discussing the components of the IC form, from the smallest to the major ones [23].

Children as patients

The treatment of children requires consent from their parents, guardians, or close relatives (in descending order). Most parents are reluctant to make their children undergo surgery, fearing later development of sickness, physical damage, or mental imbalance [24]. It is the task of the clinician to find ways to explain the treatment required for the child and convince the legal guardians in the interest of the child's health [25]. Treatments and interventions involving individuals aged below 18 years mandate an approval from the legal guardians of the child.

Patients' fear of newly developed treatments

As the wind blows in different directions, news and gossips are spread regarding new treatments as false, risky, fake, or compromised [26]. The wrong information prevents patients from taking part in therapeutic interventions or specified surgeries. Pressure from a family member, relatives, or friends can make the condition even worse by demoralizing the patient, thus making them avoid surgery and, finally, quality of life improvement. This is a commonly observed situation, when an unconcerned individual dominates the future of a patient.

Conclusions

Though engulfed with a list of challenges, IC still remains an important and mandatory tool for clinicians across the globe. Any invasive procedure involving humans as patients requires going through an ICP. The procedure should be viewed as a vital step in enabling a healthy and long-term communication with the patient. It prevents or at least lowers the occurrence of withdrawals, which greatly affects compliance, thus securing the patient till completion of the aim being focused on. Safety concerns and rights of the patient should be prioritized during the commencement, administration, and termination of treatment so that the involved patient presents a positive attitude towards healthcare team members who were concentrated on making the patient maximally independent and thus improving the overall quality of life. Effective implementation of ICP requires clear, direct, brief, point-by-point documentation for an easy understanding of the procedure concerned in research or clinical set-

tings. Professionals' efficiency in convincing, respect, code of conduct, working within ethical limits, making use of latest technologies, extended discussions, and audio-visual digitalization help augment the participance of individuals in research trials and therapeutic interventions.

Ethical approval

The conducted research is not related to either human or animal use.

Disclosure statement

The author does not have any financial interest and did not receive any financial benefit from this research.

Conflict of interest

The author states no conflict of interest.

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