Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Review

Consent in covid: A researcher's dilemma

Heena Garg*, Puneet Khanna

All India Institute of Medical Sciences (AIIMS), New Delhi, India

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ABSTRACT

An informed consent is a vital component of health care and forms an important component of any research study. Informed consent is the process where a health care provider educates a patient about the risks, benefits, and alternatives of a given procedure or intervention. A proper consent is imperative to ensure safety of the patients. However, obtaining a consent in the hospital settings has become a matter of concern in the times of this coronavirus-19 (COVID-19) pandemic. This brief review describes the additional complexities added to the consent for research and the various modifications needed in view of this pandemic. The current consent proformas need to be modified and individualised to the patient ensuring patient safety during research in the ongoing pandemic. We need to become more familiar with the technology and electronic tools as the acceptable alternative tools of communication in the current scenario. There is a need to incorporate a separate covid consent with due consideration to deferred consent, pre-emptive consent or waiver of a consent.

Contents

1. Introduction

An informed consent is imperative in health care for medical procedures, surgical interventions as well as clinical research. Obtaining consent encompasses updating the patient about their rights, any intervention that needs to be done. If a research is planned, the participant should be informed about the purpose of the study and the potential risks and benefits with the assurance of confidentiality the maximum possible [1]. A consent should be explained in detail and preferably in person. However, in the wake of this pandemic, the conversations have switched from being close to the patient to now becoming unrecognizable under personal protective equipment. For many health care providers, the interaction has completely shifted from in-person conversation to telephonic or video chat conversations. Hence, the consent makes a

* Corresponding author.
E-mail addresses: gargheena11@gmail.com (H. Garg), k.punit@yahoo.com (P. Khanna).

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stronger point with a more detailed documentation. We find here the modifications of consent for research in the current COVID-19 pandemic.

1.1. Obstacles in obtaining consent

1.1.1. Reallocation of health care workers

There has been an enormous shortage of staff due to redirection of health care workers for management of covid-19 pandemic. This makes obtaining consent a task, especially when one is being obtained for research. Any individual needs a detailed discussion before being enrolled in the research and shortage of staff can hamper or put a crunch on the already overworked staff.

1.1.2. Difficult communication

In-person consent poses another challenge in the wake of this pandemic. To reduce the exposure, alternate ways need to be looked for obtaining consent which may not be able to suffice for a written consent. Close in-person contact with the research participant might be needed for which adequate personal protective equipment (PPE) will be needed [2]. The availability and shortage of the PPE kits is another issue being faced by the health care workers in these times.

1.1.3. Difficulty in getting research participants

Very little is known about this virus and maximum studies are being done all over the world to isolate it and extract the maximum information so as to prevent the spread and develop a cure. Many therapies have been developed to decrease the virulence and symptoms of the infection. Active research is ongoing for development of an effective vaccine. In these times, when people are wary about the covid-19 pandemic, it becomes difficult to get participants for covid as well as non-covid studies.

1.2. Deferred consent

In the current COVID-19 pandemic, many researchers are applying to research ethics committees for deferred-consent procedures for protocols that aim either to test treatments or to obtain tissue or samples from research participants. Consent for continuation of trial enrolment and data collection is obtained only when the patient is capable of providing informed consent or the representative is available [3].

The Randomised Evaluation of COVID19 Therapy (RECOVERY) trial in which patients were randomly assigned to various treatment protocols, has asserted upon the use of deferred consent and consent from the treating physician as valid consent for the ongoing drug trial. They have stated that “Due to the poor outcomes in COVID-19 patients who require ventilation, patients who lack capacity to consent due to severe disease and for whom a relative to act as the legally designated representative is not immediately available, randomisation and consequent treatment will proceed with consent provided by a treating clinician, who will act as the legally designated representative. Consent will then be obtained from the patient’s personal legally designated representative or directly from the patient if they recover promptly at the earliest opportunity” [4].

Graaf et al. have asserted deferred consent should be allowed in conditions like the current pandemic where no vaccine or effective treatment is available, for which it may be of the utmost importance to collect real-time data and samples to guide treatment decisions and to understand this emerging disease [3].

1.3. Pre-emptive consent

If a COVID-19 patient is stable, a pre-emptive consent can be made use of in these patients for inclusion at a later time when their condition deteriorates and authorization is no longer possible, or they may be pointed to potential COVID-19 studies [3]. Pinder et al. asserted upon the use of pre-emptive consent and global consent, where a consent is taken for enrolment into more than one study [5]. The policy of pre-emptive informed consent enabled them to overcome some of the problems with regards to patient enrolment in critical care research. This is necessary in times of this pandemic too, where the search for vaccine and effective drugs takes utmost priority.

1.4. Waiver of consent

The Indian Council of Medical Research (ICMR) in their guidelines for research in covid times state that the ethics committee (EC) can approve a waiver of a consent where it is difficult to carry out the research without the waiver. The waiver stands scientifically justified in studies like retrospective studies where the participants are de-identified or cannot be contacted. Waiver of consent can also be obtained for research on investigation based studies where data can be used in an anonymous form or where the data is available in the public domain [6].

2. Research on dead patients

Research of the deceased in pandemic situations is crucial to know the future clinical care and protect other patients. Establishing the histopathological cause of death could be valuable in understanding the pathogenesis of COVID-19in critically ill patients who are at a higher risk of mortality.

Post-mortem examination including autopsies could carry an inherent risk of infection and obtaining tissue biopsies and samples immediately after death seems to be prudent. Since the current guidelines do not provide for any advance written directive for consent for post-mortem research, proxy consent may be considered. However, obtaining consent from emotionally distressed family members at such a time presents a challenge. While it is morally upsetting to deliver the bad news telephonically, it is callous to request consent for urgent research in the same conversation. ICMR has directed for a waiver of consent in these situations [7]. A waiver of consent seems prudent in such a situation where it will be difficult to obtain one.

3. Validity of telephonic consent

Telephonic conversations carry much more weightage in the current times, especially where electronic informed consent is not feasible. The consent should be explained to the prospective participants or their legal representatives in detail over the telephone call by the investigator. A recording of the conversation should be made to keep a valid record. A streamlined steps of conversation should be followed in all calls. This should begin with identification, review of the informed consent document and response to any questions. This should be acknowledged by the participants with a verbal confirmation, they should clearly state that their queries have been addressed and that they would like to participate in the trial.

The Food and Drug Administration (FDA) have recommended that the participants should put their signature and date on a blank paper with a written statement that they voluntarily agree to participate in the protocol. They should also mention the Protocol number and brief protocol title on the same paper. The consenter

should send a photograph of the statement by text message or mail to the investigator. The record of each trial participant should document that informed consent was obtained before enrolment in the trial [8]. Also, a test of the comprehension of the informed consent should be done in the end to make sure that every point has been understood.

3.1. Consent on WhatsApp/digital platforms

In these testing times, alternative methods of communication need to be explored to avoid direct interaction with the patient in isolation. We need to become more familiar with the technology and electronic tools like podcasts, audio-visual aids, social media groups, text, and interactive websites to communicate with the patient more effectively. The consent process can be documented via audio or video recording [6,8]. The ICMR draft guidelines have stated that patients selected for clinical trials can give their consent electronically through a text message, WhatsApp or other mobile-based applications because of mobility restrictions due to coronavirus [6].

However, the digital platforms are not without the associated problems. Electronically assisted forms will need to be drafted in an understandable fashion and confidentiality needs to be ensured. Drew et al. developed a mobile application to collect large scale population data and make it accessible to scientists globally [9]. They asserted that mobile phone applications and web-based tools facilitate self-guided collection of population-level data at a larger scale. Such digital tools can be used for controlled research settings leading to higher recruitment [9].

4. Recommendation

Informed consent is a continuous process encompassing three main components – providing relevant information, confirming proficiency, ensuring understanding and voluntariness. Obtaining consent has become intricate in these times. The consent forms need to be tailored specific to each institute, detailing the various aspects of patient safety during research in or for the ongoing pandemic. We need to become more familiar with the technology and electronic tools as the acceptable alternative tools of communication in the current scenario. The current consent proformas need to be modified and individualised to the patient and need to incorporate a separate covid consent with due consideration to deferred consent, pre-emptive consent or waiver of a consent.

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