



Informed Consent for Emergency Obstetric Care During COVID-19 Pandemic

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Received: 14 May 2020 / Accepted: 15 June 2020 / Published online: 3 July 2020
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Abstract

Informed consent process has become a challenging issue before surgery for any emergency obstetric care during this COVID pandemic. There is an increased risk of morbidity if there is a need of intensive care unit postoperatively and a risk of high mortality if patient has symptoms of COVID-19. Admission to intensive care unit adds on to the financial burden to the patient. Also, there is an increased risk of perinatal anxiety and depression during the COVID pandemic. When an asymptomatic carrier develops symptoms of COVID after delivery or caesarean section, the morbidity increases. So we have designed an informed consent form for patients undergoing emergency obstetric surgeries incorporating some points specific for COVID-19.

Keywords COVID-19 · Pandemic · Informed consent

Introduction

Pregnancy and delivery pose unique challenges during the coronavirus disease (COVID-19) pandemic due to altered maternal immune system [1]. In India, the institutional deliveries have been increased in last decade and there is a huge burden in hospital settings during this pandemic. Obtaining a valid informed consent in humanitarian emergencies such as COVID-19 is a challenge. There are practical difficulties in identifying a COVID-19 positive patient. According to the recent ICMR (Indian Council of Medical Research) guidelines, if a woman meets the criteria for COVID-19 testing like travel history from an affected area or close contact

with a confirmed case of COVID-19, she should be tested. Until RT-PCR (real-time reverse transcription polymerase chain reaction) test results are available, she should be treated as though she has confirmed COVID-19 [2]. So during that time it is a challenge to obtain the consent from the patient covering all aspects of the informed consent process. Informed consent is a continuous process involving three main components—providing relevant information, ensuring competence, ensuring comprehension and voluntariness [3]. In addition, the decisional capacity of the hospitalized patient would be very low during this pandemic. Also, there is an increased risk of the need of intensive care unit (ICU) for ventilator facilities as well as an associated risk of high morbidity and mortality if the patient exhibits symptoms of COVID-19 in the postoperative period.

Therefore, we have devised a new informed consent format for all patients undergoing emergency obstetric surgeries incorporating a few points specific for the COVID-19 disease.

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Discussion

Informed consent for emergency obstetric care, which is a critical component of surgical practice, has become a challenging issue in the time of COVID-19 infection. There are few specific requirements which need to be discussed pre-op

during this pandemic with the patient and the relatives, in order to avoid any unnecessary medico legal issues. Reports have shown that over a recent 5-year period, 65% of medico legal cases involving informed consent were surgical and only 21% of these cases were decided in favor of the surgeon [4]. It is mandatory that prior to obtaining consent for the proposed surgery, the obstetrician must provide the patient with detailed information about the nature of the surgery, the expected risk and benefits, alternate treatments and the consequence of not having the surgery [5].

In India, the need for ICU and ventilator support in the post-op period, if required, must be discussed with the patient's relative as it involves an increased financial burden. There are also concerns about the lack of pre-op COVID testing due to paucity of commercial testing kits. But pre-op COVID testing should be done for elective surgeries if

the facilities are available. A normal patient may develop or contract coronavirus infection in the peri- or postoperative period which should be again documented in the consent form. All the potential risks, short term or long term should be informed to the patient.

Hence, a detailed modified consent form was designed exclusively for the patients who require emergency obstetric surgeries during this pandemic.

Compliance with Ethical Standards

Conflict of interest The author declares that there is no conflict of interest.

Ethical Statement This article does not contain any studies with animals performed by any of the authors.

Appendix

INFORMED CONSENT DURING COVID-19 (Should be translated in local language)

Facility: *Covid / Non Covid ward* **COVID Status:** *Positive/ Negative/ Unknown*
Place of Consent: *Triage area/ at admission/ before surgery*
Contact history with confirmed case of COVID: *Positive/ Negative*
Travel history to affected area: *suggestive/non-suggestive*
History of Fever/ Cough/ Respiratory symptoms: *Yes/ No*
Resident of containment zone: *Yes/ No*

I _____ (patient name) Age _____ Address _____ having Hospital No/ Aadhar no _____ understand that I am admitted for an emergency/elective surgery during the COVID-19 pandemic.

I understand that COVID-19 is extremely contagious and is believed to spread by person-to-person contact. However, given the nature of the virus, I understand that there is an inherent risk of becoming infected with COVID-19 by virtue of proceeding with this emergency/elective surgery.

I hereby acknowledge and assume the risk of becoming infected with COVID-19 through this surgery, and I give my express permission for the treating doctor Dr _____ and concerned staffs to proceed with the same.

I understand that, even if I have been tested for COVID and received a negative test result, the tests in some cases may fail to detect the virus or I may have contracted COVID after the test. I understand that, if I have a COVID-19 infection, and even if I do not have any symptoms for the same, proceeding with this surgery can lead to a higher chance of complication and death.

I understand that possible exposure to COVID-19 before/during/after my surgery may result in the following: a positive COVID-19 diagnosis, extended quarantine/self-isolation, additional tests, hospitalization that may require medical therapy, Intensive care treatment, and possible need for intubation/ventilator support, short-term or long-term intubation, other potential complications, and the risk of death.

I understand that COVID-19 may cause additional risks, some or many of which may not currently be known at this time, in addition to the risks described herein, as well as those risks for the treatment/procedure/surgery itself.

I have been counselled adequately by Dr _____ and staffs in the language that I/my patient can understand.

I have been given the option to refuse /defer my surgery. However, I understand all the potential risks, including but not limited to the potential short-term and long-term complications related to COVID-19, and I would like to proceed with my desired surgery. I will not hold the doctor, the hospital or its staffs morally or legally accountable for any reason.

This is to state that I _____ have comprehensively explained the information above along with the explanation provided by the doctor to the patient and/or her attendant have informed me that they have understood the information completely.

Signature of Patient Signature of Legally acceptable authorizer (LAR)/Witness

Name of the patient: Name of the LAR/Witness

Address:

Contact No:

Date and Time:

Signature of Surgeon:

Name & Designation:

Address:

Contact no:

Date and Time

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Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

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