

Being Legally Sound in the COVID-19 Era

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Abstract

All the three Indian gastroenterology societies (Society of Gastrointestinal Endoscopy of India, Indian Society of Gastroenterology, and Indian National Association for the Study of the Liver) jointly recommend to consider only emergency and urgent endoscopy procedures for the next 1 month or till the current threat due to coronavirus disease 2019 (COVID-19) is over.

Two laws that are penal in nature are now applicable in the current pandemic, namely the Epidemics Diseases Act 1897 and the Indian Penal Code 1860. No act of an endoscopist should be seen to be in contravention of any of the aforementioned laws, and the sections thereunder as provisions of the Indian Penal Code can be attracted in the current scenario for spreading an infectious disease either knowingly (Section 270) or unknowingly or negligently (Section 269).

Section 4 of the Epidemics Disease Act 1897 gives legal protection to every person who has acted under this Act or the directions issued under this Act subject to only one condition, that is, the act must have been done in good faith.

Though the hospitals are obliged to ensure personal safety of its staff legally, morally and ethically, because of the huge gap in demand and supply of personal protective equipment (PPE), it is advisable to arrange PPE on one's own to first protect oneself and then, by extension, to prevent the spread to others. The dictum is "take care of yourself." Self-preservation is a supreme law.

In the current COVID-19 pandemic conditions, certain additional information, to be agreed upon by the patient, needs to be incorporated in the consent. It should be incorporated in the consent that:

- While all the necessary precautions are being taken, there is a finite though small risk that the patient may contract the infection from the hospital.
- He/she indemnifies the hospital and the endoscopist against any such liability arising out of any action taken while doing the procedure.
- Furthermore, to protect the patient him/herself, he/she agrees to get the preprocedural test for COVID-19 as well as bear the additional cost of the PPE used by the endoscopist and support staff.

Several of those who have undergone an endoscopy would require a follow-up consultation. As it is difficult to have physical interaction, teleconsultation may be done as per the telemedicine practice guidelines issued by the Medical Council of India (MCI).

Keywords

- consent
- COVID-19
- telemedicine
- the Epidemics Disease Act

We are amidst a pandemic (coronavirus disease 2019 [COVID-19]), unprecedented in scale of devastation, with 210 countries affected with more than 2.6 million cases and deaths nearing 1,90,000 mark (as on April 23, 2020). Out of these, India accounts for 21,700 cases and 686 deaths. A large number of health care workers (HCWs) including doctors, nurses, and technicians have been infected, which is not really surprising because they are the frontline workers exposed to the infection through the patient.

Being gastroenterologists, we would be called upon to perform various endoscopic procedures, including on COVID patients. Under the changed circumstances, for the safety of both the patient and the endoscopist alike, several riders have been put on how and when to perform the endoscopic procedures. All the three Indian gastroenterology (GE) societies (Society of Gastrointestinal Endoscopy of India, Indian Society of Gastroenterology, and Indian National Association for the Study of the Liver) jointly recommend to consider only emergency and urgent endoscopy procedures for the next 1 month or till the current threat due to COVID-19 is over. Routine endoscopic procedures can be postponed for the next 4 weeks unless a change in a patient's clinical status mandates an emergency or urgent endoscopy in the intervening period.¹

Because of the constraints, the endoscopists are called upon to work under, all due precautions must be observed to be on a sound wicket, legally lest one is accused of medical malpractice.

Two laws are now applicable in the current pandemic, namely the Epidemics Diseases Act 1897 and the Indian Penal Code 1860. On March 11, 2020, all the States and Union Territories were directed to invoke Section 2 of the Epidemic Diseases Act 1897. These two laws, which are penal in nature, are now therefore applicable to everyone—doctors, hospitals, patients, and general public. Both these laws give rise to criminal liability and hence imprisonment is one of the consequences of not following them. Section 2 of the Epidemic Act empowers the State Government to take suitable temporary measures to prevent an outbreak or threatened outbreak or spread of an epidemic. Once this Act is invoked, the State government can give directions and take the required steps to contain the spread or outbreak of an epidemic disease. *Section 4 gives legal protection to every person who has acted under this Act or the directions issued under this Act subject to only one condition that the act must have been done in good faith.*

Section 188 of the Indian Penal Code prescribes punishment of upto 6 months and fine of upto 1,000 Indian Rupees for not following government orders. There are two more provisions of the Indian Penal Code that can be attracted in the current scenario for spreading an infectious disease either knowingly (Section 270) or unknowingly or negligently (Section 269). The former attracts imprisonment or 2 years, which is far more than the 6 months under Section 188 of the Indian Penal Code. Hence, it is of paramount importance that no act of the endoscopist should be seen to be in contravention of any of the above laws and the sections thereunder.

The endoscopist is bound to take all the precautions to safeguard him/herself and the patient from spreading this infection. Donning personal protective equipment (PPE) is of utmost importance. Under such circumstances, the State and its various agencies are bound to make available PPE to all HCWs. However, the Supreme Court order of April 8, 2020, to ensure the supply of PPE to the HCWs. Notwithstanding, the ground reality is that the demand has far exceeded the supply at present. On one hand, the endoscopist is bound to perform a life-saving procedure, but, on the other hand, he may find him/herself getting infected if the PPE is not made available to him. Furthermore, unwittingly he may pass on this infection to other patients and may be sued by them, though he is legally “protected” under section 4 of the Epidemic Diseases Act 1897. As (s)he is facing this ethical dilemma on a daily basis, it is advisable to arrange PPE on his own to first protect himself and then, by extension, prevent the spread to others. The dictum is “take care of yourself.” Self-preservation is a supreme law. Hospitals are obliged to ensure the personal safety of its staff. This is not only a legal obligation but also an ethical and moral one.

An important thing to keep in mind is to ensure that patients who have been referred from another facility for a procedure only, report back to their facility. One should report to the authorities about any patient who refuses to follow medical advice or acts dangerously.

Consent

Consent is a process and not merely an act of signing the consent form. It involves giving relevant information about the proposed treatment/intervention and discussing with the patient, arriving at a mutual agreement, and then filling and signing the consent. Hence, it must not be reduced to a routine, mechanical act.

It has been laid down by the Hon'ble Supreme Court of India in the 2008 Dr. Prabha Manchanda versus Samira Kohli case that consent must be taken only after complete disclosures and proper explanation, neither by unduly scaring nor falsely alluring the patient into acceptance.²

Consent is probably the most important aspect of documentation, more so in the current scenario. General information about consent can be found elsewhere.^{3,4} Certain additional information, to be agreed upon by the patient, needs to be incorporated in the consent in the present special circumstances. It should be incorporated in the consent that:

- While all the necessary precautions are being taken, there is a finite, though small risk that the patient may contract the infection from the hospital.
- He/she indemnifies the hospital and the endoscopist against any such liability arising out of any action taken while doing the procedure.
- Furthermore, to protect the patient him/herself, he/she agrees to get the preprocedural test for COVID-19 as well as bear the additional cost of the PPE used by the endoscopist and support staff.

One must give the patient reasonably enough time, depending on the situation, to make a decision for giving consent after counselling, except in emergency situations such as severe bleeding.

There have been instances, where in the court of law the patient has taken a plea that he signed the consent under duress. Therefore, in cases where the procedure is high risk and the patient or the family appears to be a difficult one, the preconsent counseling session should be video-recorded, especially in high-risk cases (only if the requisite facilities are easily available). Ensure that the CCTV signage is present in the counseling room and the patient is specifically informed of this fact.

High-Risk Consent

If the endoscopic procedure is being performed on a COVID-positive patient, inform the patient specifically of the high risk involved in the procedure; duly record the same in the medical records and take an elaborate "high-risk" consent if the patient is in a critical or unstable state or is even otherwise at high risk due to comorbid conditions. Also, in situations where the rate of failure of the procedure is significant or there are significant chances of recurrence, for example, gastrointestinal bleed after endotherapy, a high-risk consent should be taken.

Another important reason to take a high-risk consent is when the patient has a potential for creating trouble.

Ideally, the patient's consent should be taken in the presence of at least one independent witness especially in case of high-risk consent.

Except under pressing circumstances, the witness should not be connected to or employed by the GE specialist or the hospital. A patient's relative having a good understanding of the language, in which the consent has been taken, can be an independent witness.

As an abundant caution, ensure that the patient does not write anything on the consent form that cannot be understood by the doctor or hospital staff.

Consent in Emergencies

Law requires a doctor to attend to the emergency without any undue delay. Therefore, one must not wait for consent in emergencies if waiting could be detrimental to the patient. One should proceed with lifesaving treatment by taking oral consent of the patient or the attendant, especially if the patient is incompetent to consent and in appropriate cases even without consent. A proxy consent from another doctor or medical superintendent or head of the hospital can also be taken if possible and without wasting time and effort. Record specifically in the patient's medical records and the consent form the life-threatening emergency as well as the reason(s) for not obtaining consent or for obtaining proxy consent. This exercise can even be done once the emergency is over.

It is a good policy to confirm before starting every procedure whether the operating room nurse has personally checked the consent form(s) in the patient's medical records and it is signed by the patient and complete in all respect.

No separate consent is required for sending any part, tissue, fluid, or organ removed from the patient's body for usual cytological or histopathological examination. But as the COVID-19 is a relatively new disease entity, where further research is needed, sending such tissue or fluid for research purpose requires separate specific consent as per the Indian Council of Medical Research guidelines.

A patient may allege negligence on the part of the endoscopist if his procedure, considered as routine, is deferred. In such cases, the defense is the guidelines or standard operating procedure issued by the societies.¹

Follow-Up of Patients

Several of those who have undergone an endoscopy would require a follow-up consultation. As it is difficult to have physical interaction, teleconsultation may be done as per the telemedicine practice guidelines issued by the Ministry of Communications and Information.⁵

Telemedicine includes all channels of communication with the patient that leverage information technology platforms including voice, audio, text, and digital data exchange. It should be remembered that it entails the same professional accountability as in the traditional in-person consult. Hence, telemedicine consultation should be limited to first aid, life-saving measures when there is no other alternative available, counseling, and advice on referral. It should be avoided for emergency care when alternative in-person care is available.

There are certain specific restrictions in prescribing medicines, which are as follows:

- List O, which comprises those medicines that are safe to be prescribed through any mode of teleconsultation.
 - Medicines that are used for common conditions and are often available "over the counter" (paracetamol, ORS solutions, cough lozenges, etc.).
 - Medicines that may be deemed necessary during public health emergencies.
- List A:
 - Those that can be prescribed during the first consult, which is a video consultation, and are being re-prescribed for refill in case of follow-up.
 - This would be an inclusion list, containing relatively safe medicines with low potential for abuse.
 - Medication that the GE specialist can prescribe to a patient who is undergoing follow-up consultation in addition to those that have been prescribed during in-person consultation for the same medical condition.
- Prohibited list:
 - Medicines listed in Schedule X of the Drug and Cosmetic Act 1940 and Drug and Cosmetic Rules 1945 or any narcotic and psychotropic substance listed in the Narcotic Drugs and Psychotropic Substances, Act 1985.

A gastroenterologist performing endoscopic procedures is standing at cross-roads today. On the one hand, he/she is

ethically, morally, and legally bound to perform emergency procedures. On the other hand, if he/she is compelled to do such a high-risk procedure without the requisite PPE, he/she is exposing himself to the lethal virus and is unwittingly contravening the law by becoming an instrument of spread of disease.

Conflict of Interest

None.

References

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