

Online Consent mechanism

There have been several issues regarding consent :

1. It should not be on pre-printed stationery
2. It should not be generic and should be customised for the procedure
3. It should not be given to the patient just before procedure (and sign on dotted lines)

In addition to above following points are required in good consent :

- a. **Hospital Specific** : facilities available in the hospital (and not available)
- b. **Doctor Specific** : qualification of the doctor/s should be clearly mentioned
- c. **Disease/diagnosis Specific** : Diagnosis of the patient should be clearly mentioned in the consent along with different treatment modalities available to the patient.
- d. **Disease severity specific** : Severity of the disease should be clearly mentioned on the consent so that it helps the doctor in case there is litigation at a later date
- e. **Anaesthesia Specific** : Whether the procedure is being done with local / regional / spinal / general anaesthesia should be mentioned on the consent along with statement that anaesthesia may have to be changed during the course of surgery
- f. **Procedure Type specific** : It is better to mention whether the procedure is minor / medium or major surgery.
- g. **Procedure specific** : Risks involved in a particular procedure should be clearly informed to the patient
- h. **Comorbidity specific** : Whether the patient has any comorbidity and associated risk factors should be mentioned.
- i. **Co-morbidity control specific** : Whether the comorbidity is controlled with medicines or whether the patient has uncontrolled comorbidity should be mentioned
- j. **Patient specific** : Whether the patient has any other illnesses, addictions, habits etc may have bearing on the outcome of the treatment
- k. **General risks** : Whether there are any other risks including financial issues etc should be mentioned

Obviously nobody has time and energy to write down tailormade consent taking into consideration all above points. Therefore there is a general tendency to use pre-printed stationery, but in that case there is a limitation to customise the consent for individual patients. Above problems can be sorted out by using online consent, mechanism of which will be as under

- A. Hospital registers in this mechanism by entering its name, address etc which will be used as the letterhead of the consent.

- B. Below the letterhead it will be mentioned that the consent is as per procedure specific draft developed by the Association of (expert group) of doctors.
- C. Below this it will be mentioned that the consent has been approved by experts in the medicos legal aid association and is as per the necessary professional standards.
- D. Hospital will add / edit / delete or modify as and when required regarding availability of facilities and infrastructure in the hospital and WHAT IS NOT AVAILABLE e.g. Blood bank or pathology laboratory etc. so as to protect the hospital subsequently
- E. Name of the doctor who will conduct the procedure will be entered along with qualifications OR selected from pre filled list of doctors working in the hospital
- F. Diagnosis of the patient and its severity will be SELECTED from list of illness usually treated in the hospital e.g. (LSCS for) Primigravida or (Hysterectomy for) DUB in OBGY setup
- G. LSCS for previous LSCS, LSCS for Preeclampsia, LSCS for heart disease all have additional risks and hence **when these diagnoses are selected** PREFILLED risk information will be added to the consent.
- H. Anaesthesia type can be selected from dropdown and risk related to that type of anaesthesia will be entered in the consent form with the line that type of anaesthesia may be changed at the time of procedure for which risks in the anaesthesia information sheet may be involved. (anaesthesia risk document will be separate)
- I. Procedure type will be selected to get a list of procedures under that type. Whereas there is a chance of bleeding in major surgery, it may not be so in minor surgery. Accordingly, statements can be added to the consent.
- J. Procedure specific risk will be added to the consent. Procedure will be selected from list of procedures and text for the procedure approved by the association for that speciality will be added to the consent. E.g.
 - a. LSCS for primigravida there may be statement about risk of fetal distress
 - b. LSCS for previous LSCS may have additional statement for bladder injury
- K. Comorbidities will be selected from a list and a statement of risk for each comorbidity will be added to consent form e.g. risk of cardiac event in case of IHD and risk of sudden hypoglycemia OR infection in case of diabetic patient.
- L. Comorbidity control will be recorded so that in uncontrolled cases risk will be higher than in controlled cases
- M. **Patient's habits** such as Tobacco, Smoking, Alcohol, Narcotic Drugs, Irregular eating, Irregular bowel, Self medication, Lack of exercise, Excessive exercise, Dietary experiments etc will be selected from drop down and statements regarding each of present risk factors will be added to the consent.

- N. There will be a text box to enter general risks in which the provider can enter any additional information which may have bearing on the outcome e.g. financial issues etc.

Above will be mostly by selection from available options. This will be a user -friendly manner to generate customised consent for individual patients. Operation of consent

1. Hospital visits the website of the organisation and enters login details. Hospital's name is shown as a letterhead along with the name of the organisation and statement that the consent has been approved by medico legal experts etc.
2. Hospital enters patient details i.e. name, age, sex etc with email address / mobile no of the patient and designated relatives
3. Hospital makes appropriate selections on the webpage.
4. On selection of a doctor the association of which he is a member will be shown on the consent document.
5. On selection of procedure, the text related to that procedure will be entered in the consent.
6. Hospital saves the consent. Simultaneously message will be sent to the Patient and Designated relatives (3 nos) by email / SMS / whatsapp (where ever possible / applicable)
7. Patient reads the message which contains a link to the consent. On clicking the link the system opens consent document on website of organisation where patient can read the consent in english (and regional language as and when available)
8. Patients can click on the I agree checkbox and click on the SAVE button. Consent will be saved on the patient's computer in PDF format which the patient can print. The PRINT button will send the consent directly to the printer connected to the patient's computer.
9. Patients can sign the printed document and bring it to the hospital at the time of admission. If a patient can not print / does not get a paper document, it will be printed in the hospital using patient ID and procedure related information saved in the system.
10. (If required, the organisation will file an affidavit that the ABC patient had signed consent for PQR procedure at XYZ hospital on dd/mm/yyyy at hh/mm/ss using an online mechanism provided by the organisation. Cost of signing such an affidavit to be borne by the hospital.)
11. 25% of service charges will be paid to the speciality association and 25% will be paid to the medicolegal association while 50% will be paid to software companies to develop the program and run the system 24x7x365 online.
12. Charges for the service can be Rs. 10/= per consent for non members and Rs. 5/= per consent for members of both associations, or as may be discussed in the meeting of the organisation. Purpose is to get continuous flow of money for the association and ongoing protection to members.