The current issue of the journal contains an extremely useful study by Farhan Amin and colleagues entitled “An audit of information provided during pre-operative informed consent” which highlights the practice of obtaining informed consent in our public healthcare facilities. The authors have concluded that the practice is below international standard and ethical acceptability. The quality of informed consent can be improved by increasing awareness regarding ethical issues and educating the healthcare professionals regarding patient’s rights.

Patients have a right to fully participate in the decision regarding their treatment but what goes on in most of our hospitals is just a formality wherein the patients or their relatives are asked to put in their thumb impression or signature. They are seldom provided the detailed information simply because the treating physicians are too busy and have no time. Not only that it is usually the technicians, nursing staff or paramedics who carry these papers to the patients for thumb impression/signature. In few cases it could be the resident medical staff but seldom the attending physician.

In one such case, a patient admitted in a surgical ward for excision of recurrent hemangiopericytoma was found in a state of shock and depressed. Enquiries revealed that patient was depressed on seeing a very big resected area without any skin covering on his back. It was a mistake on the part of the surgical team that while taking informed consent, the patient was not fully informed about the expected size of resection. After counseling and reassurance with the facts about skin grafting, the patient started taking interest in his treatment.1

Bhutta has alluded to the difficulties faced while obtaining informed consent from patients in developing countries particularly for clinical research. Even procedures recommended in different guidelines are difficult to follow for various reasons. He has emphasized the importance of “understood consent” rather than going for informed consent.2

The Consent Form which the patient or his/her relatives must have signed is not a proof that the patient was fully informed regarding material risks inherent in treatment, invasive, surgical procedures and whether the patient did understand the information fully. It is also important that the patient is competent to give informed consent.

The information provided to the patients must include the nature of patient’s condition, the need for suggested mode of treatment or invasive, surgical procedure, what it entails, the anticipated prognosis, duration of treatment, procedure, risks involved and the expected benefits, alternate treatment options available, cost, whether the procedure is irreversible, time required for the procedure, recovery period, need for monitoring and long term follow up if needed and the consequences if treatment is not provided at all. If the
patient is educated, it is always helpful to pro-
vide him/her some written information about
the treatment modality, procedure before any
discussion takes place between the treating
physician and the patient. This discussion
should be continued on each visit and the in-
formed consent should be taken when it is de-
cided to initiate treatment.1-3 However, what
happens in our healthcare facilities is that the
healthcare professionals do not give due im-
portance to patient’s rights and informed con-
sent. Moreover, since the treating physicians
are too busy, signature or thumb impression
on Consent Form is obtained at night before
the procedure or a day earlier which is not
correct. It is also important that salient points
of the discussion which takes place and par-
ticularly if the patient asks some questions to
have more information should be documented.
The documentation should include procedure
specific information and name of the physician
taking informed consent. If the patient is un-
educated, it is still no excuse to bypass the pro-
cess of the consent. It is just that it is harder for
the person who is taking consent to come down
to the level of communication that such a per-
son can understand.

Who should take informed consent: Ideally it is
the senior member of the treating team since
he or she has the overall responsibility. The
physician involved in discussions with the pa-
tient should be fully competent having suffi-
cient knowledge so that he or she can commu-
nicate the risk, benefits or alternate treatment
options. The professional specialty organiza-
tion can play a vital role in developing proce-
dure specific scientific information outlining
material risks. The patient can also be suggested
to have second opinion before signing the Con-
sent Form. This will minimize the chances of
any litigations in case of any serious side ef-
fect.

In case of medical emergency when the pa-
tient is unconscious, hence not able to give con-
sent, the patient is considered to have given
consent to treatment. However it is essential
that the circumstances of emergency and the
patient’s incompetence to give consent, should
be properly documented. For example in the
aftermath of the recent earthquake in Azad
Kashmir, Northern Areas and some parts of
NWFP in Pakistan, many emergency surger-
ies were performed; some of which even in-
volved amputations. The patients can chal-
lenge the decision to opt for amputation in the
absence of their informed consent. While tak-
ing patients informed consent, patient’s com-
petency, comprehension, needs and desire for
details must be considered.

Patient’s relatives or members of the
healthcare teams cannot give consent on be-
half of patients who are incompetent or un-
conscious. In all such cases it is desirable that
the healthcare teams should involve those who
are close to the patients to find out patient’s
values and preferences before their loss of ca-
pacity to give informed consent, unless there
are previous instructions by the patient not to
involve some particular individuals.4

As regards informed consent by paediatric
patients, it must be understood that a child
achieves his capacity to give consent on his
behalf not when he reaches a particular age
but “when the child achieves sufficient under-
standing and intelligence to enable him to un-
derstand fully what is proposed.” And in case
of conflict between the parents as to which
parent might provide consent, or between par-
ents and child whether the child is competent
to give consent on his/her behalf, some coun-
tries have relevant laws making it necessary to
refer the matter to courts to give a decision.3
However, the person who is asked to consent
on behalf of an incompetent person should re-
ceive the same detailed information regarding
risks, as the person who would be treated, if
that person was competent to give consent.

The Federal Health Ministry, Government of
Pakistan has now constituted a National Bio-
ethics Committee. Pakistan Medical Research
Council (PMRC) in collaboration with WHO
EMRO recently organized a training workshop.
One of its recommendations is that Institutional
Ethics Review Committees (IERCs) will be con-
stituted in all the healthcare facilities/medical
institutions to ensure ethical clearance of all
scientific research studies in which informed consent is an important component. These committees can also ensure improvement in the practice of taking informed consent from patients being treated in these hospitals. At present different medical institutions, healthcare facilities have different set of Forms for obtaining informed consent. In some cases while consent is taken for any invasive, surgical procedure, the patient is seldom asked to give consent for anesthesia nor are they informed about any of their adverse effects. A vast majority of the patients in developing and Third World countries including Pakistan which have low literacy rate, are either not aware of their rights or cannot appreciate the importance of informed consent. Apart from educating the public, the healthcare professionals also need to be educated about the importance of patient’s rights and the value of their informed consent so that the patients can fully participate in their disease management. It will be ideal if we can develop a comprehensive Informed Consent Form which can then be translated into Urdu and different regional languages so that the purpose of obtaining informed consent is fully met and the patients get full information about their disease management which they also understand. Hopefully in the days to come sufficient progress will be made to improve the practice of obtaining informed consent which is ethically and internationally acceptable.

REFERENCES