

the other features of the setting (19).

We believe that in our case, the doctor on duty could have gone ahead with the intervention without seeking a second informed consent, as long as an informed consent form was handed in, approved and signed when the first operation took place. The acute and life-threatening nature of the complication was justification enough not to seek a futile document which only became the source of a legal controversy.

Conclusions

The insertion of a shunt for the treatment of an acute hydrocephalus is a life-saving procedure. Seeking informed consent for an urgent life-saving procedure is senseless. Doing so will further increase the confusion of the proxies, who have little time to understand in emergency conditions, and thus to decide, and will increase the chances of the case ending in litigation. Needless to say, the lack of time given to a proxy to take a decision in an emergency situation creates a feeling of mistrust.

Albanian criminal law and legislation, in general, has no provisions yet regarding the main ethical issues related to important medical decisions, such as those on euthanasia, end-of-life decisions and informed consent (20).

The view that informed consent might do more harm than good in emergency conditions is not the only objection to the overall applicability of such consent in medical settings. For half a century, informed consent has been considered a trap for the unwary, and has recently been branded legal fiction (1, 21). With ethicists already criticising the informed consent process as being culturally biased, legalistic, ritualistic and unbalanced, seeking a second informed consent, especially in emergency conditions, is inadvisable as it will probably double all the challenges mentioned above (22).

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Commentary

Informed consent for a life-saving operation in Albania and in India

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Some general remarks

As in Albania, so in India, the use of written consent in medical practice is of relatively recent origin. Before the advent of

European medical education in India, I am not aware of any written consent obtained by medical doctors before performing invasive procedures on their patients. In this

respect, Albanian doctors were far in advance, registering informed consent in court five centuries earlier (1).

The recent moves in India for placing truly informed consent from patients on record was motivated more by a sense of ethical propriety than by the fear of litigation. The latter remains relatively infrequent when compared to the incidence in other more “advanced” countries.

As in Albania, so in India, cultural difficulties are formidable. Rampant illiteracy, total dependency of the poor on those in power in our villages and the dominance of *panchayats*, leads the powerless villager to delegate rights, including decisions on such matters as clinical trials and epidemiological studies, to local leaders, nullifying the concept of informed consent by the individual. Even within families, women tend to leave decisions on interventions and operations on themselves to their husbands or male elders in the family, meekly placing their thumbprints or signatures as directed.

The case study

Informed consent was obtained from the patient’s eldest son for the major operation on the brain tumour.

As has been rightly pointed out by the authors, the deterioration in the patient’s clinical condition on the 7th postoperative day was unusual in two respects.

1. Surgery on a cerebral tumour is usually followed by swelling at the site of surgery and around it. This swelling, if severe, causes confusion in the mind of the patient and produces abnormal drowsiness – a slow and progressive event.
2. In this case, the deterioration in the reported patient’s condition was sudden and was due to hydrocephalus.

We are not told of the sequence of events from the development of somnolence on the seventh day to deep coma at midnight. The decision was made at 2 am to insert a shunt into the brain to drain the abnormal collection of cerebrospinal fluid.

The controversy revolves around whether it was right to have obtained the consent of the only relative present when this decision was made. The eldest son was not available then.

Some relevant facts need to be considered.

1. In the surgeon’s opinion, this was a life-saving operation on a patient in deep coma.
2. Consent of the patient was not available in view of the coma.
3. The relative available in the hospital was presumably an adult (this is not specifically stated in the report).
4. After initial hesitation, the relative signed the consent form on behalf of the comatose patient.
5. It is standard practice that for life-saving operations, consent is obtained from the relative available by the patient’s bedside. Attempts at obtaining consent from other relatives would

entail a delay that could prove fatal to the patient. *When no relative is available, the practice in Indian hospitals is for the surgeon to certify the life-saving nature of the surgery, inform the administrative head of the institution and proceed to perform the surgery in the best interest of the patient. In effect, the surgeon provides the legal consent for the surgery.*

6. The next morning after the operation, this relative “withdrew his approval”.

I am not aware of the legal status of such withdrawal of consent *after the event*. Certainly it is illogical since the surgery has already been performed.

Differences of opinion between relatives must be sorted out between themselves, the treating doctors and the institution playing no role in this event.

Ethical pitfalls

The authors list two ethical pitfalls.

Emergency of the situation

This decision can only be made by the treating physician or surgeon and is offered as his considered opinion to the patient, relative(s). This opinion is accompanied by a recommendation for corrective action and the likely consequences of such step(s). Questioning this decision later is fraught with danger as it amounts to offering an opinion without being present at the time and without being in full possession of the facts.

Availability of a competent decision-making relative

It is assumed that the relative looking after the patient’s welfare in the hospital in the middle of the night is a competent authority to grant consent. In 2014, with the universal availability of telephone facilities, it should not take more than a few minutes for this relative to consult others – in this instance, the eldest son – if such a need is felt.

A third pitfall

Not listed as such but posed under the heading “Ethical pitfalls” is the question of the medical specialist bypassing the decision made by the relative by the patient’s bedside on the ground that the relative cannot understand midnight explanations.

It is foolhardy for a medical attendant to take this step. Just as this relative’s consent is valid reason to proceed with surgery, the relative’s refusal to permit surgery is also valid. Under such a circumstance, the medical specialist has two options: a) to inform the person who had earlier given consent (in this case, the eldest son) and obtain a directive on the telephone, to be later confirmed in writing b) to inform the head of the institution and follow his/her instructions.

The authors suggest two other solutions.

1. Obtaining an informed consent approved and signed initially when the first operation is proposed in anticipation of a complication. This is debatable on two major grounds. First, complications are often unexpected. In this case, hydrocephalus was a remote possibility.

Second, it would be necessary to discuss in detail each of several possible complications and obtain written consents for the treatment of each of them.

2. Doing away with the obtaining of informed consent for life-saving procedures. "Seeking informed consent for a life-saving procedure is senseless. Doing so will further increase the confusion of the proxies, who have little time to understand in emergency conditions and thus to decide, and will increase the chances of the case ending in litigation."⁽¹⁾. This is unethical and illegal in India.

A definitive solution would be to obtain (i) the names, telephone numbers and addresses of those authorised to permit invasive tests and treatments when the patient is admitted to hospital, and (ii) a statement permitting the relative present at the patient's bedside to grant permission for treatment (including surgery) in an emergency.

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