Abstract
Informed consent has become a part of medical practice in Albania only recently, during a time when there has been a substantial increase in claims of malpractice. Its original aim was to provide patients with information to help them make decisions on particular health interventions. We describe the case of a patient who developed an unexpected surgical complication and desperately needed a second intervention, and the futility of obtaining informed consent in the setting of a medical emergency. The circumstances of the emergency might turn out to be too complicated and confusing for the proxies. The role of proxies is not defined in the Albanian laws and bylaws. Seeking and eventually obtaining the necessary signatures and permissions in an emergency cannot be justified because the lack of time in such circumstances might be a major obstacle to sound and comprehensive communication, and lack of communication could give rise to mistrust, with all its potential consequences.

Introduction
Written consent is a relatively recent concept in the history of medicine. Although historically considered unnecessary and bypassed due to the notion that the doctor's verbal explanations suffice, there have been differing opinions underlining the controversies that would have accompanied the application of written consent, with some authors considering it a kind of trap for unwary relatives or patients (1). Written consent came to be widely used around the 1950s, when it was a form of the so-called "informed consent" and was in the nature of a shared decision between the physician and the patient (2).

We will get a broader perspective on the issue if we examine the historical sources. An impressive format of informed consent, written in the Ottoman language and registered in a competent court five centuries ago, has been discovered and published by Selel (3). The existence of other such contractual documents in the Ottoman Empire has been suggested (a fact which speaks of the necessity for making a thorough scrutiny of court archives) (3,4).

The major controversial issue in the entire history of informed consent has been the main purpose of such consent. In fact, two aspects, not necessarily compatible with each other, should have pushed doctors to propose and apply informed (written) consent. One aspect has to do with safeguarding physicians from liability. In the present-day world, in which malpractice lawsuits abound, this aspect has acquired great importance (5). The other aspect, which should have provided the initial impetus for the formulation of written consent as a tool, has to do with the patient's autonomy and his/her rights within the healthcare system (6).

The inadequacies in applying informed consent may be explained by different factors. The setting plays an important part, while cultural issues and the age of the patient are two of the major concerns. Informed consent becomes problematic when the physician is treating a foreign patient or a patient whose native language differs from his/her own (7,8). The dire shortage of time associated with several unforeseeable and unexpected medical events might be another of the factors that pose a challenge.

Case study
The patient, a Caucasian woman, aged 54 years, was hospitalised in a private facility in Tirana, the capital of Albania. She was suffering from rapidly advancing and severe neurological deficit, with seizures and right hemiparesis. Following a computed tomography (CT) scan of the head and magnetic resonance imaging (MRI), the patient was diagnosed with left frontal-parietal lobe glioblastoma. She underwent neurosurgery for the removal of the tumour. The biopsy showed that the tumour was malignant.

The woman's condition worsened on the seventh day after the operation. She became somnolent and confused. A CT scan of the head was carried out urgently at midnight, and it showed an acute hydrocephalus. The neurosurgeon on night shift considered this complication a major emergency because of the rapidity of the evolution of the hydrocephalus. Hydrocephalus, an enlargement of the brain ventricles due to an obstacle in the flow of cerebrospinal fluid, is considered an uncommon complication following surgery for glioblastoma. As a rule, it develops in a surreptitious, delayed and chronic form (9).

With the patient in a deep coma, the neurosurgeon decided to intervene after 2 am that very night. In this second operation,
a shunt would be inserted into the brain ventricles to treat the hydrocephalus. Before this intervention, an informed consent form was handed to the only relative present in the hospital at that late hour. The relative, who would be unexpectedly playing the role of a proxy, was a first-degree relative (cousin) and initially hesitated to sign the form. Following the general agitation after the patient fell into a deep coma, he signed. This was to be the second surgical intervention on the glioblastoma patient. It must be noted that the natural chances of survival of glioblastoma patients remain poor and, at best, they may survive for one or two years (10).

Legal consequences

The controversies and debates started immediately the next morning, when the other relatives, even closer in degree to the patient than the one who had signed the consent form for the emergency intervention, arrived in the hospital. The relative who had unexpectedly found himself in the unauthorised role of giving proxy consent the night before withdrew the consent he had granted, claiming that he had been given very little time to think over the matter. He also claimed that he had signed only because of the pressure put on him by the staff; because of the late hour at which the unexpected complication occurred; and because there had not been enough time to understand the details of the risks and benefits of the second operation.

Although the patient eventually survived the second operation, the closer relatives sued the hospital for intervening surgically a second time without discussing the situation and without obtaining the approval of the relevant proxy. Until the occurrence of the sudden complication that put the woman’s life at immediate risk, her oldest son had been taking all the decisions, playing the role of a healthcare surrogate. He had been unavailable during the night of the second operation.

The lawsuit was filed in a competent civil district court, but withdrawn before the first hearing was to take place. The hospital negotiated an out-of-court settlement with the patient’s family, and the case was closed with a payoff, as agreed between the parties.

Ethical pitfalls

Although the insertion of an intraventricular shunt is a shorter and simpler intervention than the removal of a brain tumour, it remains a surgical and an invasive procedure which requires general anesthesia. Ethical questions were logically raised when dealing with our case, since the events affecting the life prognosis of a critically ill patient were complex, and unexpected. The two main ethical pitfalls related to the case, but probably not the only ones, pertain to (i) the emergency nature of the situation, and (ii) the availability of a competent proxy or of the surrogate.

When analysing these drawbacks post factum, it is important to remember that informed consent should not be looked upon as a means of urging someone to make a decision or as a signature on a form. It should, instead, be seen as a process (11). If, for some reason, the process requires time, one might wonder how it can be carried out expeditiously enough in an emergency.

Second, even if we ignore the question of whether a proxy appointed unexpectedly (instead of the surrogate) is in a position to make the appropriate decision, we will encounter another dilemma. Should a medical specialist bypass a surrogate or proxy decision if there is reason to believe that the proxy is mistaken (12)? If a doctor is professionally convinced of what he is doing, giving the proxy midnight explanations and expecting her/him to understand under dire time constraints verges on the absurd. Such an absurd state of affairs is not quite in keeping with the duty to take ethical decisions, and with the immediacy of dealing with a human in peril (13).

Discussion

There is an increasing need for the wide application of informed consent in all its forms, mainly the written one. There are many reasons for this need, but “rampant malpractice claims” seem to be the most important one (14).

Informed consent may be viewed merely from an oversimplified, strictly judicial perspective, but we should not forget that a patient who has granted consent is an indispensable element of the therapeutic alliance. Before becoming a legal issue, informed consent has been a major theme in the area of ethics, in general, and medical ethics, in particular. In addition, it is a reflection of the patient’s right to participate in decision-making (15).

In our opinion, obtaining informed consent in emergency cases might be not only a futile, but also a dangerous proposition. In fact, no medical or paramedical staff member attending to a traumatised patient who is unconscious will ever think of seeking informed consent for performing cardioconversion or an external chest massage, or even for artificially assisted respiration. It is quite logical that informed consent should not be sought in emergency cases, in which death is imminent if no intervention is made immediately. It must also be mentioned that since the patients encountered in emergency settings are almost always unconscious, the notion of “treatment refusal” also seems quite inapplicable. However, the inapplicability of informed consent in emergency cases is not always self-evident: some countries have provided for treatment refusal even in the case of unconscious, comatose patients (16).

Informed consent has often been criticised on the ground that it is aimed more at minimising the physician’s liability than educating patients and enabling them to take their own medical decisions (17). On the other hand, if surgeons or practitioners need to perform or perform a medical procedure that is different from the one for which consent was granted; they might be sued (18). In this context, it is important to carefully consider the cultural background of the family and
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).

References

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