

## Legal aspects of training

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### Abstract

Training is essential to achieve medical education and acquire skill allowing good medical practice. Training involves legal aspects such as liability of the trainer or supervisor, need to obtain a clear consent from the patients involved in teaching activities and measures which have to be taken in order to ensure that confidentiality and medical secret are not submit to any breach. Also there are differences between training of already qualified doctors and training of students; legal aspects are different if the training is given in private practice or in university hospital. Legislation is evolving and it is probably time to establish clear guidelines useful for every professional involved in teaching /training activities.

**Key words:** legal, consent form, legal, liability of trainer, medical education, medical secret, training.

Training is essential and cannot be made entirely through simulation. Therefore patients are involved in the training process thus leading to potential medico-legal litigations.

First of all it is necessary to distinguish several forms of training:

- training involving medical students often in the context of medical school and where professor act as preceptor/trainer to teach surgical techniques for example,
- training involving already fully qualified doctors who want to acquire a new technique in reference centre,
- on site training where the trainer is the proctor/supervisor ensuring that the doctor starts a new technique under proper guidance, for example to introduce robotic surgery in a new theatre.

These different situations have clearly not the same legal implications.

However, even if the liability of a preceptor or a proctor/supervisor is not the same, in all cases, information, consent from the patients and sharing of confidentiality are the common factors in every situation.

### Information and consent

Obtaining consent before engaging patients in teaching activities is essential.

Different situations are possible:

#### *in case of consultation attendance*

Presence of medical students is evidently subject to consent from the patients, even if in the past this consent was not required in teaching hospitals.

#### *in case of OR attendance*

The presence of medical students as observers in the operating theatre is sometimes overlooked as a form of teaching activity, in which patients could have become unwitting or unwilling participants. In a cross sectional voluntary survey Leung and Patil (2011) have proposed a guided questionnaire on 225 patients in a teaching hospital. More than two thirds of patients would accept student observers and regard a prior consent process as essential.

Interestingly, 10% of patients who were happy to participate in bedside teaching would not accept theatre observers. In the contrary, 25% of patients having not accepted bedside teaching, would accept theatre observers.

Authors conclude that consent process is essential to teaching even when students are simply acting as observers, and that patients who are willing to participate in ward based teaching should not be presumed to accept theatre observers.

In France this consent is rarely asked since general assumption is that patients, who are admitted in teaching (university) hospital, are aware of the presence of students more or less at all the stages of treatment.

However, the recent Kouchner law in France has reinforced the patients' rights and therefore it is very likely that this kind of consent will be required in the very next future.

– in case of practise of examination under anaesthesia by medical student and trainee

Medical students need to undertake supervised pelvic examination to achieve competence for example. This experience is often obtained by conducting pelvic examinations on anaesthetized patients who are going to have gynaecological surgical procedure.

A Canadian survey (Wainberg et al., 2010) studied what procedures might undertake according to the patients and whether patients would give consent for pelvic examination.

72% expected to be asked for consent before medical students undertook examination during anaesthesia. 62% would consent, 5% would consent for female students only, 18% were not sure and 17% would refuse.

So clearly majority of patients wishes to help medical students to learn but expect consent to be sought if medical students are to perform pelvic examination during anaesthesia.

Martyn and O'Connor (2009) also studied the lack of written consent in Ireland and underline that such consent form did not exist at the time of their article and should be quickly promoted as a national guideline.

For Ubel et al. (2003) in USA, consent should also be very explicit.

In France no consents are generally required for examinations during anaesthesia, but once again the general tendency as well as the expectations of patients are that consent is essential.

In our best knowledge, no medical legal actions have been initialized so far on the assumption

of unauthorized examination during anaesthesia; nevertheless transparency towards the patients should prevail at least orally if not by a written consent.

*in case of realisation of procedures by the trainee*

What have been said concerning pelvic examination is also true concerning procedure which might be done by trainee.

Even if it is generally assumed that patients do not agree for students participating to surgery, another Canadian study suggests that a vast majority of patients agree to the participation of students during surgery (Gan et al., 2009). This prospective study has been made on patients waiting for cataract surgery; 95,3% of patients agreed to the participation of students to their surgery.

It seems evident that information is the key. This information has to be delivered in a comprehensive and reassuring manner, and patient's choice should be respected.

Another important parameter is the quality of the trainee: whereas it is quite easy in a teaching hospital to propose surgical operation performed by junior but qualified doctor since patients expect more or less not to be operated by the head of department, it is much more difficult to imagine the same process in private institutions where patients expect to be operated by the surgeons they have chosen.

If the trainee is a fully qualified doctor who wishes to acquire a new technique it seems a little easier to ask for a patient consent, providing that in all cases supervision is assumed by a senior doctor.

## Medical secret

*sharing of the medical secret with the trainee and access to the patient file*

By definition when trainees are involved in the treatment scheme they have to share part of the confidential information with the doctor in charge. It is critical to ensure that there is no breach in this confidentiality. We should recommend a special written agreement signed by the trainee prior to any involvement in teaching activity in which the trainee acknowledges the fact that he must respect strict confidentiality of all medical information he may share during the training of after.

In the same manner patients should be asked to consent that their file may be seen by the trainee under strict conditions.

In France misconduct by any doctor about the medical secrecy is severely sanctioned by the medical council (Conseil de l'Ordre) which frequently forbids the doctor to work for a period varying from 1 month to 6 months and sometimes for ever if the misconduct is repeated and very serious.

## Liability

### *when training in public/ university hospital*

Since one of the key missions in these cases is teaching, liability of professor or preceptor is usually very limited, in case of a problem. It is generally the institution which is responsible and it is the insurance of the hospital which will cover damages if medical malpractices have been identified (Zorn et al., 2009).

In a same manner the trainee is very generally exempt of any liability except in case of very serious misconduct considered as totally foreign to the medical care delivered. In France it is the concept of: "faute detachable du service" (mistake without relation to normal care).

These serious misconducts are generally considered as criminal offence and treated by the courts as such.

### *when training in private practice*

More and more in France medical students or trainees are sent to be taught in selected private centres with the evident advantages to allow trainees to see various techniques and approaches in public as well as private practices.

However it recently occurred that the liability of the preceptor could be engaged if the university from which the student/ trainee comes from has no special insurance covering the activities of the trainee in such circumstances.

### *difference in proctoring/supervising and preceptorship/training*

In case of proctorship, the liability of the proctor/supervisor should not be engaged since it is the liability (and the professional insurance) of the proctored which would intervene in case of litigation.

Nevertheless, some in USA for example, recommend to establish a consent form which

delineates the proctor's responsibilities during the operation (Livingston and Harwell, 2002).

## Conclusion

Medico legal actions are more and more frequent in the world, in case of complications or supposed malpractice. Indeed, when such problems occur during an activity involving training, it is evident that the risks to be sued are even greater.

Prevention is based on information and consent of the patients, and by a clear definition of each responsibility.

The patients now more and more expect information and consent and doctors have to change their behaviour. For instance, attendance of students in the OR should be stated and consent obtained: 10 years ago it was generally admitted that the consent was implicit by the patients and, therefore, never formally required.

Delineation of each responsibility is also critical; three parts may be involved in liability: the institution, the preceptor/proctor and the trainee.

We have seen that most of the time, liability is supported by the institution, but that does not prevent individual involved in teaching activities to ensure that their liability is, or is not engaged according to their implication in the operations. This last point is far from completely clarified: for example if the liability of a proctor acting as a spectator should not be engaged, we still miss bylaws delimitating clearly the responsibilities of preceptors.

In this instance liability carrier such as insurance company should be asked to clarify their coverage of each actor involved in teaching activities.

To conclude, the medico-legal aspects of training are strong advocate to develop virtuality and simulation in training whenever it is possible.

## References

- Gan KD, Rudnisky CJ, Weis E. Discussing resident participation in cataract surgery. *Can J Ophthalmol.* 2009;44:651-4.
- Leung GK, Patil NG. Medical students as observers in the theatre: is an explicit consent necessary? *Clin Teach.* 2011;2:122-5.
- Livingston EH, Harwell JD. The medicolegal aspects of proctoring. *Am J Surg.* 2002;184:26-30.
- Martyn F, O'Connor R. Written consent for intimate examinations undertaken by medical students in the operating theatre. Time for national guidelines? *Ir Med J.* 2009;102:336-7.
- Ubel PA, Jepson C, Silver-Isenstadt A. Don't ask, don't tell: a change in medical student attitudes after obstetric/gynecology clerkships toward seeking consent for pelvic examinations on anesthetized patients. *Am J Obstet Gynecol.* 2003;188:575-9.
- Wainberg S, Wrigley H, Fair J et al. Teaching pelvic examinations under anaesthesia: what do women think? *J Obstet Gynaecol Can.* 2010;32:49-53.
- Zorn KC, Gautam G, Shalhav AL et al. Training, credentialing, proctoring and medicolegal risks or robotic urological surgery: recommendations of the society of urologic robotic surgeons. *J Urol.* 2009;182:1126-32.