

POINT OF VIEW

## Sedation for gastrointestinal endoscopy and intrusionism: Legal aspects

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### INTRODUCTION

This is still an unresolved matter despite its having been debated for the last few years.

One of the last, valuable attempts to bring nearer a solution was the session included in the annual meeting of *Sociedad Española de Patología Digestiva*, held in Madrid in 2005, under the heading "Sedation in digestive endoscopy: By whom? For whom? Where and how?".

The controversy that brought about a specific session in this meeting was started by a paper published in the January 2005 issue of *Revista Española de Enfermedades Digestivas* by two prestigious doctors –F. López-Timonedá (anesthesiologist) and J. A. Ramírez-Armengol (endoscopist)– with the title "Who should be responsible for sedation techniques in gastrointestinal endoscopy?" The results from a survey by *Sociedad Gallega de Patología Digestiva* were also published in that issue, where the fact that endoscopists themselves performed sedation in 85% of endoscopy units was reported.

These reports ignited once again the fuse of a latent, unresolved issue that includes in a "totum revolutum" the problem of medical specialties and their interaction, the adequacy of a graduate's degree in medicine to entitle the holder to medical practice, all the liabilities generated by medical malpractice, professional intrusionism, and –to top it all– a few drops of deontology according to the declaration by *Comisión Central de Deontología* on February 3, 1998.

Responses in favor of either thesis soon appeared: need for a specialist in anesthesia or adequacy of the endoscopist and his or her team. There followed letters to the editor of the publishing journal, an editor's note, a paper with the title "I the intruder", etc.

In view of the newly reopened controversy, and given the fact that the annual meeting of *Sociedad Española de Patología Digestiva* was upcoming, Professor José Ramón Armengol-Miró shoehorned a "Special Consensus Session" into the Congress within a month of its initiation. Dr. Armengol-Miró, with a praiseworthy desire for conciliation and clarification, invited all confronted parties with special dedication, as well as legal specialists (*Magistrado de la Sala de lo Contencioso Administrativo del Tribunal Superior de Justicia de Cataluña*, Mr. Joaquín J. Ortiz-Blasco; *Magistrado de lo Social*, Mr. Jacobo Quintans-García, and the lawyer Mr. Ricardo de Lorenzo y Montero as Chairman of *Asociación Española de Derecho Sanitario*).

It is here, responding to the offering of my good friend José Ramón Armengol, where I will discuss a few notes on what I best know, namely the legal interpretation of state regulations on medical specialties, and the liabilities physicians may incur in their practice whether within or without professional intrusionism. I may help to somewhat wind things down and clear ill-founded concerns and alarms (the goal Dr. Armengol-Miró pursued and –in my view– reached when he called the Consensus Session).

### PRIMARY APPLICABLE LEGISLATION FOR THE ARRANGEMENT OF HEALTHCARE PROFESSIONS AND RESPONSIBLE MEDICAL PRACTICE IN GENERAL

Given the short length this article demands I will do without historic legislation –still in force nowadays– and focus on two laws of compulsory knowledge: Law 41/02

of November 14 on patient autonomy and entitlement to clinical information and documentation, which I will eventually discuss when dealing with informed consent, and Law 44/03 of November 22 for the arrangement of healthcare professions.

This Law regulates the conditions of professional practice as entitling to the practice of medicine and surgery, and includes highly interesting topics regarding the debated issue: entitling qualifications, university qualifications (official degree) for a specific practice, areas of shared competence, and areas reserved for selected specialties.

To summarize the portion of its contents that is relevant here we may conclude that:

The Law does not distribute competences amongst professionals, but invites them to design, according to legal regulations and through conflict-avoiding alliances, their exclusive ones, with the right understanding that neither the common tree of the medical profession-degree, nor the enriching and adorning branches of specialties should not be curtailed or pruned abusively or in a selfish manner (group or corporative interests).

This wider entitlement to professional practice, based on Articles 35 and 36 of the Spanish Constitution, cannot be trimmed by lower regulatory hierarchy laws such as the aforementioned 44/03. Hence Art. 6.2.a in this Law empowers graduates of medicine to indicate and perform activities regarding health maintenance and promotion, illness prevention, and patient diagnosis, management, therapy and rehabilitation, as well as judgement and prognosis regarding procedures of interest. One can hardly find a greater extent of faculties to be developed by graduates of medicine and surgery. The above-mentioned Article only opposes the function of physicians to that of pharmacists, dentists, and veterinarians, as well as health science specialists (psychologists, chemists, biologists, biochemists, etc.).

Generic limitations to professional practice are dangerous indeed, and not a legislator's goal. Regulating a profession is one thing, curtailing it for fear of potential deviations is another. Thus, the aforementioned Law establishes in its Art. 4.5 that professionals will base their activities in service to society, the interests and health of citizens cared for, rigorous compliance with deontologic obligations as determined by professions themselves according to legal regulations in force, and their profession's normal practice or –when appropriate– customary uses.

This Law is comprehensive and clear, specifies the various specialties available, and provides newer degrees. It establishes obligations and controls, but does not provide watertight compartments for each specialty. Should "Lex Artis" be infringed with third-party (patients or practitioners) damages, legal means and court procedures are available to make up for said damages using all sorts of sanctions, whether civil, administrative, or criminal, and compensatory liability. Let us not forbid or

limit professional practice for fear of irresponsible individuals who may abuse it.

Within the generic group of graduates of medicine current specialties (MIR program) are defined. A specialist degree is needed to specifically use a designation of specialist to practice medicine as such, and to take up work positions under such designation in both private and public centers and institutions. The above is pointed out as a preferential but not exclusive right. It is only this that explains the coexistence of specialists with degrees dating back to pre-MIR-program times, and the fact that public work post announcements for specialists may be taken up, when vacant, by non-specialist physicians, or physicians with a different specialty, whenever a professional with the required specialist degree is not available.

Law 44/03 not only establishes specialties in the various fields of medicine, but gains an even deeper insight into specialization (a fact unavoidable today not only in medicine), and defines at least two additional degrees: certificate's degree in the specific area, and certificate of advanced accreditation.

Now all this graduated specialization system, while useful and necessary, is not to originate excluding tight compartments in medical practice. Cannot pre-MIR specialists, or non-specialists in vacant specialist work posts perform the same functions? Better still, will MIR specialist be forbidden to perform the functions of specific-area certificate holders, and the latter those of advanced certificate holders?

As specified by the herein discussed Law, specialties are a guarantee of specific knowledge for patients, and are essential to take up posts requiring a specialist's degree in the public healthcare system; in private practice they are proof for patients that their carer has adequate knowledge and experience in a particular field, and his or her fees are fair (many formal complaints for alleged intrusionism deal about the charging of specialist honoraria by non-specialists).

In summary: there is a need to solve –through interprofessional pacts prior to any regulatory legislation– the issue of competence areas for healthcare professions, with the will to simultaneously recognize both shared competence areas and the highly relevant profession-specific areas. That is why the Law we are discussing has not attempted to establish competences for the various professions in an excluding, tight way, but provides the grounds for interprofessional alliances so that professional daily life in multidisciplinary organizations may evolve in a non-conflicting but collaborative, transparent environment.

Where does this Law lead to? To the use of common sense and cooperation (team working, Art. 9), and to gradual specialization as a need, and certificate's degrees as an "inter pares" merit. The ball has been put in the court of the medical profession and its institutions. Laws will not bring a solution, as their role is to let professionals alone, and only regulate ultimate areas of conflict

when the legally protected issue –health as a fundamental right– is in jeopardy.

### **INTRUSIONISM –AN UNCLEAR, EVER-DEVELOPING CONCEPT**

The paper by Dr. López-Timoneda and Dr. Ramírez –quoted above– in obvious good faith and with true concern introduced the issue that the performance of sedation procedures by non-anesthesiologists might represent professional intrusionism, an alarming idiom not only included in common language, but that constitutes a specific crime. That reference to intrusionism increased alarm in readers, a concern that was still apparent in some speeches made in the already-mentioned annual meeting.

Indeed, the feared intrusionism –characterized as an offense of falsification by Art. 403 in the current Criminal Law– is defined as the performance of activities typical of a profession with no corresponding educational degree as issued or recognized in Spain. If the person additionally claims the professional status corresponding to said degree, penalty increases (publicizing a degree that was not obtained).

Years ago the jurisprudence of the Supreme Court and the Constitutional Court followed the thesis formulated by Magistrate Ruiz Vadillo (successively a member of both Courts), according to which a non-specialist physician acting knowingly and willingly as such, certain that he or she is not entitled to that sort of practice (fraudulent act) incurs an offense of intrusionism. However, if the physician was not aware that his graduate's degree in medicine granted no authorization for the practice of such specialty he or she would then incur an offense of negligence, an "error of prohibition", and his or her conduct would not be punishable (we are speaking of professional practice, not of its outcomes, which may be damaging and the result of criminal negligence, a topic absolutely different from intrusionism) (sentence passed by the Supreme Court, Criminal Courtroom, on 6-13, 1990).

Six years later this same magistrate, now a member of the Constitutional Court, passed sentence 13-2-96, in which the petitioner was denied legal protection, and then convicted for the following fact: he was a graduate of medicine who practised as an advertised odontologist with no specialist degree. This sentence recalled the traditional doctrine by which "neither before, nor after the Law of Specialties, promulgated in 1955, could or can a graduate of medicine and surgery perform the activities of odontology or stomatology unless a degree in one of these specialties has been obtained".

This doctrine has now been superseded by a new one, which includes the relevant sentence 1-4-03 by the Supreme Court (which should be compulsory reading), acting as reporter Magistrate Cándido Conde-Pumpido (presently Attorney General), by which the defendant, a graduate of medicine and surgery who practised in the

field of oncology without a specialist degree, was acquitted. This sentence explains that, while there is an official (academic) regulation of the medical profession, such regulation has no legal status, and that there is no constitution for a specific profession in which specialists are ascribed selected medical activities exclusively. The sentence clarifies that to commit offense of intrusionism the absence of an official or academic degree (a specialty) does not suffice, but there should be proof of activities pertaining to a profession (the profession is only that of physician) other than that to which one is entitled. As we repeatedly noted (sp. Art. 6.2 of the Law 44/03 for the Arrangement of Healthcare Professions presently in force), a non-specialist physician may perform what is clearly summarized by a ruling from the legal department, Colegio Oficial de Médicos de Baleares, wherein it is pointed out: "a physician may perform any medical activity, whether pertaining or not to any specialty, provided such activity is not advertised as a specialty, which means that a physician may perform all sorts of medical, surgical or related activities, but only a specialist may advertise his or her special dedication.

Again we consider intrusionism an offense of deceit, of fraud, of advertising and getting paid for what one is not regardless of "Lex Artis"; if it results in damage because of negligence (absence of essential knowledge, lack of means, etc.) the practitioner will be liable according to civil, administrative (if practising in the public health system), or even criminal law in case of lesions or death from negligence; but all this is the case regardless of the presence or absence of a specialist degree.

Where does liability for damages to patients derive from? Purely objective liability is absent from our legal arrangement (as would be the case with simply paying for a damage); guilt (subjective), negligence, malpractice are required to a greater or lesser extent. What should be borne in mind is that in medicine negligence is not (only) a matter of outcomes, but of means employed.

Civil liability will include all damages occasioned to a patient not from an absence of specialty but from imprudence or negligence during practice. Such damages include: emerging damage or damage assessed as already present (sequels, etc.), loss of profit or financial harm resulting from what will not be received in the future because of the damage, and moral damage.

Civil liability is not covered by the benefits provided by the Social Security System alone (for negligence in public health care), but the harmed person may initiate a civil lawsuit against the liable physician for all damages induced until fully compensated.

The problem of civil liability is easily solved by taking out an insurance policy to cover potential risk. In this case it must be clearly noted that the covered risk should not only include damages deriving from the endoscopy procedure as such, but also from all supplementary and related activities regarding said procedure –sedation and its risks in our present case.

Regarding criminal liability, which is of greatest concern for professionals, criminal negligence requires the following:

- A behavior entailing inobservance of the duty of care.
- A damage to the legal asset to be protected: a person's health.
- A cause-effect relationship between professional activity and outcome.

Negligence consists of acting or failing to act in a manner that is contrary to a duty whose observance is required by the legislator regarding an activity, with this activity resulting in danger when performed without diligence.

Notwithstanding the above, not all activities resulting in damage generate professional liability. Thus, from the sentence by the Supreme Court on May 20, 1988 we may specify that:

Diagnosis errors and treatment errors are not punishable unless resulting from a consistent, repeated conduct of negligence and reckless disregard, or from reiterated non-fulfilment of basic duties.

Criminal liability is also not incurred by a lack of either outstanding expertise or a qualified specialization in a certain field of medicine.

Anyway, no fixed criteria can be established, but the circumstances of each individual case are to be taken into account.

With very few exceptions, the diligence demanded from a professional of medicine is what may be required from a standard physician, according to his or her education and training, to prevent an outcome of harm.

## INFORMED CONSENT

The informed consent topic is not directly related to the subject discussed in this paper, namely the definition of the risk for intrusionism within its limits and in association with its current jurisprudential approach, thus blowing away the storm clouds hovering over the attendants to the above-mentioned Congress session, over medical practice, and over sedation techniques when performed by physicians lacking a specific specialty.

Notwithstanding the foregoing, this topic is brought to attention in order to complete the study of liability as related to physicians—healthcare professionals in general—leaving it out or obtaining it without the requirements stipulated by the Law and legal courts of justice to avoid liability, all this regardless of damage, or professional negligence.

This is furthermore a topic that was addressed in that session, and on which an attendant lawyer sitting at the board of speakers, Mr. Ricardo de Lorenzo y Montero, wrote an exhaustive text (“Patient Rights and Duties”) in order to discuss Law 41/02.

Every therapy or surgical procedure performed by a physician must be preceded by providing the patient with

information, and inobservance thereof may result in liability.

What underlies this not only moral or ethical but also legal duty? It is generally grounded in the Spanish Constitution, Articles 15 (physical integrity), 18.1 and 4 (personal privacy regarding health information), and in other hierarchically essential resolutions. Thus Art. 4 in Annex II of Council of Europe's “Convention on the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine”, in force in Spain following its ratification by a Cabinet Meeting on 11-19, 1996, establishes that a healthcare procedure may only be carried out once the affected person has freely and unequivocally given his or her consent after being adequately informed on said procedure's objective, nature, risks, and consequences. Consent is not irrevocable and may be withdrawn by the patient or legal proxy at any time.

Regarding ordinary legality, Articles 4 and 8 onwards in Law 41/02 of November 14 establish the right of every patient—in the setting of any activity regarding his or her health—to know all the information available regarding his or her health, and the procedures to be performed thereupon, and to freely and voluntarily give his or her consent to them.

Autonomous Communities—except for the autonomous cities of Ceuta and Melilla—have all been transferred their health competencies, and issued regulations on informed consent. In Catalonia, for example, Llei 21/00 of December 29 established in Art. 2 that patients have the right to know all information collected on their health, and that their will not to be informed must also be respected. Information must be veritable and understandable (in so-called plain language or popular parlance) so that the patient may make his or her decisions freely and with full knowledge of the facts.

How should information be given to patients?

Verbal information would in principle suffice, but the Law requires that it be in writing in the following cases:

- Surgical procedures.
- Invasive diagnostic and therapeutic procedures.
- All activities entailing risks or disadvantages that may be expected. To, or notoriously have a negative impact on health.

A piece of advice: given the imprecision of the Law, and to be completely sure, always obtain a signed copy in writing from the patient (only effective evidence in a lawsuit).

The patient must be informed using terms that he or she can understand. The patient is not to receive a scientific treatise on the various aspects and details of the procedure, but sufficient data in a language understandable according to his or her age, education, etc.

Information cannot be a “totum revolutum”, but should deal with each specific activity and its associated risks. For sedation during endoscopy, information should include the risks associated to endoscopy itself and its related sedation techniques.

—Who must be informed?

—The patient whenever possible.

Persons related to the patient by family or de facto, provided the patient expressly or tacitly grants his or her authorization. If a patient does not want his or her loved ones to receive any information, he or she must expressly state it (always in writing is recommended). In this respect, see the sentence by the Supreme Court's Chamber 1 on 5-24, 1995 (a case of tubal ligation with the husband's consent).

If a patient is permanently or transiently incapacitated, legally or otherwise, or a doctor judges he or she is unable to understand the information provided, persons related to the patient by family or de facto will also be informed.

Has the duty to inform any limitations?

Yes. When the patient makes it clear that he or she does not want to be informed. Other limitations exist, including emergency situations with a patient that is unconscious or unable to comprehend information (it is recommended that witness evidence or other efficient proof is obtained that the patient's status did not allow or encourage his or her being informed. Sentence by the Supreme Court on 12-28, 1999).

When the patient and relatives cannot be informed, it is the physician who decides; jurisprudence wonders here whether the resulting procedure would have been authorized had the patient been informed (a case of cervical myelopathy that would have resulted in tetraplegia or

death had the doctor not intervened; sentence by SC on 12-28, 1999), or banned (surgery for scoliosis in an underage patient, which resulted in paraparesis, with the mother having not been informed on the risk or less aggressive alternatives; sentence by SC on 4-23, 1992).

For procedures that are not curative but ameliorative or intended to relieve symptoms or pain, as would be the case with some sedation techniques, informed consent should be an even tighter requirement, as the activity is not healing or strictly necessary. However, the demand for medical cosmetic procedures or sedation for pain relief has considerably increased in recent times. In such cases jurisprudence considers that the need for information not only remains valid, but should be even more strongly emphasized.

In summary: a physician will incur liability if he or she fails to inform the patient or to obtain the patient's informed consent, even if no damage results. If damage or a foreseeable harm results, whether the activity was appropriate or negligent, an absence of consent may increase the indemnity to be paid. In contrast, when risk is assumed and accepted by a properly informed patient, negligence liability will only include the activity, never the outcome (malpractice, inadequate means or lack of expertise in their use, lack of foresight, etc.).

The main problem from a procedural perspective is lack of evidence as faced by an improvident physician, as to him or her corresponds the burden of proof when sued. The best help comes from a patient's signed informed consent.