Medical error – whose business is it?

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According to an old saying "medical errors are hidden in the light and holy land of graveyards". This has been true for thousands of years. But in the modern world this is no longer the case; in fact the increase of knowledge and the awareness of fundamental rights are pushing societies towards litigation against medical doctors and health institutions.

Errare humanum est – is it? Is it human, to err? Everybody would answer yes, it is. However, one might say that *not to err* is even more

human… for doing things right was basically the way humans had to follow in order to distinguish themselves from other creatures on earth.

That's why we are here today, in this afternoon's session about medical errors.

1. I'm a lawyer… and my *first question* is: **why me? Is medical error the business of law?**

Well… medical error is, of course, everybody's business.

Medical error is a matter for the **media**, as we can easily see everyday in newspapers and television programs. Journalists keep saying quite frankly that medicine and court-related news is among the best selling news they can provide to customers, nowadays. Besides being valuable to sell, this kind of news doesn't even need to be correct and reliable; in fact, true and detailed stories about medical errors are, indeed quite rare to find, and nobody really cares about accuracy in this field, as long as the story leads to emotion and increased circulations and ratings.

Medical error is undoubtedly the business of the **medical profession**. Doctors show a deep concern about this issue for various reasons. These range from understandable fear of being sued to strong feelings of being guilty for some wrongdoing which is totally against the goals and aims of medical training and practice. Physicians feel themselves to be under great pressure due to the so called “malpractice crisis” and they can choose either to be depressed or to practice “defensive medicine” which, besides being responsible for the tremendous increase of health costs, may turn out to be a heavy burden upon patient’s comfort and safety.

Medical error is the business of **patients**, of course. Patients suffer more than anybody from the outcomes of slips, lapses and mistakes which are quite common in admissions in health institutions, probably all over the world, and they are facing a less than acceptable mortality rate due to iatrogenic causes, The well known Harvard Medical Study and the Australian Quality in Healthcare Study have made it clear that “preventable adverse events resulting from medical therapy are much more common than

had previously been supposed"[1]; and the recently published report from the Institute of Medicine (IOM) – *To err is human* - made some astonishing statements like "more people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516), and "although more than 6,000 Americans die from workplace injuries every year, in 1993 medication errors are estimated to have accounted for about 7,000 deaths[2].

Adverse accidents are the business of **engineers and information technology experts**, as well. In fact, some of the most effective improvements in mortality rates – mainly in anaesthesia - came from industry by redesigning medical devices[3] or by freeing health care workers from repetitive and boring tasks, which led them often to distraction and failure[4].

[1] MERRY, A.; MCCALL SMITH, A. – *Errors, medicine and law*, Cambridge University Press, 2001, p. 43.

[2] KOHN LT, Corrigan JM, DONALDSON MS, Eds. *To err is human: building a safer health system*. Washington, D.C: National Academy Press, 2000, p. 26-7 .

[3] Such was the case with anesthetic machines – MERRY, A.; MCCALL SMITH, A. – *Errors, medicine and law*, Cambridge University Press, 2001, p. 120.

[4] MERRY, A.; MCCALL SMITH, A. – *Errors, medicine and law*, Cambridge University Press, 2001, p. 53-4.

The issue, which has brought us together, is, obviously, a matter for **lawyers**. The legal system is expected to organise litigation in accordance with three main goals: disciplinary reaction within professional bodies or organizations, compensation for damages and criminal prosecution. And there is no doubt the law is more and more involved in medical errors, as we can notice just by the increased number of physicians now getting insurance policies…

2. My second question is: **who is happy with the way things are?**

I'm sure **television and newspapers** feel happy. Adverse outcomes from medical treatment turn out to be show business, there are no signs that the public will get more demanding as to the way stories are presented, medical news will continue to be splendid value for money.

It's quite likely that the **medical equipment industry** is pleased with the great explosion in health demand from the public and with the great

concern about safety in health care. In the future there will be clear opportunities for big business, in spite of cost cuttings, rationalising or even the menace of bankruptcy in national health systems.

Probably nobody else can share this optimism.

Patients cannot be happy. There is evidence that only a small number of harmed people gets due compensation after litigation. In the first place, the number of claims brought to the courts is but a small percentage of cases where harm has been produced by medical error, whether negligent or not[5]; secondly, legal processes are slow and expensive, bringing little or no compensation for the plaintiff, in the end[6]; thirdly, the percentage of successful actions within the area of medical error is half the rate of successful actions for civil liability in other areas[7], which probably shows not only that claimants in malpractice cases face a heavier burden of proof, but also that claims may be grounded in misunderstandings or in the sole

[5] BRENNAN, Troyen, et. Al. – *Relation between negligent adverse events and the outcomes of medical-malpractice litigation*, The New England Journal of Medicine, number 26, 1996, p. 1963; VINCENT, Charles; YOUNG, Magi; PHILIPS, Angela – *Why do people sue doctors? A study of patients and relatives taking legal action*, The Lancet, , vol. 343, 1994, p. 1613;

[6] BRENNAN, Troyen, et. al. – *Relation between negligent adverse events and the outcomes of medical-malpractice litigation*, The New England Journal of Medicine, Vol. 335, No. 26, 1996, p. 1963; MERRY, A.; MCCALL SMITH, A. – *Errors, medicine and law*, Cambridge University Press, 2001, p. 212.

[7] MASON; MCCALL SMITH – *Law and Medical Ethics*, fifth ed., Butterworths, London, Edinburgh, Dublin, 1999, p. 222.

intention of revenge on the doctor for total lack of attention during admission in hospital.

Doctors might be happy with the present situation, bearing in mind the small number of legal claims compared to rates of error; but I'm sure they aren't. Doctors feel upset by the present litigation rate, low though it may be. And they are more and more aware of the unbearable rate of preventable errors, which is against their professional commitment as lifesavers.

Finally, **lawyers** cannot feel comfortable, as they know how the present system fails to compensate everyone that should be compensated, fails to sanction wrongdoers, fails to act as a deterrent factor, and fails to make available to the harmed patients a clear understanding of what went wrong.

Besides being ineffective for the purposes of compensation – which is likely to be unsatisfactory to patients, as I've said – it seems that litigation is

no more successful as a deterrent factor[8]. It cannot be taken for granted that the threat of civil claims or criminal prosecution may reduce incidence of adverse events, at least when it comes to simple slips or lapses like drug administration error; for instance, drug errors continue to occur, in spite of some well publicised criminal decisions in New Zeeland[9]; and there are no noticeable differences in medical practice and care between doctors in the United States and in Canada, although American doctors are five times more likely to be sued for malpractice than their Canadian counterparts[10].

3. My third question is: **what can any of these professional bodies do** in order to improve the efficiency of the system?

Law may improve some of the tools we've got to deal with medical error, particularly in trying to reach the main goal of compensating damages.

[8] However, successful actions for to obtain adequately informed consent cause doctors to send some more time with each patient, in Canada – MERRY, A.; MCCALL SMITH, A. – *Errors, medicine and law*, Cambridge University Press, 2001, p. 213.

[9] MERRY, A.; MCCALL SMITH, A. – *Errors, medicine and law*, Cambridge University Press, 2001, p. 50.

[10] MERRY, A.; MCCALL SMITH, A. – *Errors, medicine and law*, Cambridge University Press, 2001, p. 213.

It is likely that the *burden of proof* resting upon patients' shoulders is heavier than in other areas of civil liability[11]. In fact, full proof of causality and full proof of negligence seems to be too much for the patient to ascertain, taking into account the highly complex nature of medical intervention, the often recognised therapeutic equivalence of medical treatment, and the solidarity of the medical body which tends to turn a blind eye to their colleagues' errors. This peculiar nature of medical litigation should perhaps be taken into account in order to support some change in proving negligence; perhaps it would be fairer if the law system gave some help to the weaker part of the relationship, burdening the doctor with the proof of diligence instead of requiring from the patient the proof of the doctor's negligence. This "presumption of negligence" and some changes in order to shortening the duration of processes and in reducing their costs would probably make things easier for the patients and therefore allow them to get due compensation in more cases than they manage to today. In arriving at this overall result, the legal system would be pursuing, at the same time, the goal of getting an explanation for what happened, the aim of

[11] MASON; MCCALL SMITH – *Law and Medical Ethics*, fifth ed., Butterworths, London, Edinburgh, Dublin, 1999, p. 222.

increasing accountability and the purpose of making physicians more aware of patients' rights[12].

A more effective way of reaching the payment of damages could be to shift to a *non-fault system* of compensation – like in New Zeeland and in Scandinavia and, in some way, in France and Austria. According to this regulatory model, harmed patients always get compensation without having to show the negligence of a doctor or of an institution. Some drawbacks[13] however are acknowledged in this system: doctors will feel themselves less subject to public accountability, which is discouraging in terms of professional performance[14], and avoids the opportunity for harmed patients to get an explanation about what went wrong. And yet as far as accountability is concerned, non-fault compensation is perfectly compatible with strict disciplinary practice, pursued both by employers and professional bodies, granting full accountability of doctors; on the other hand decisions taken at the end of these disciplinary proceedings would be enough to clarify errors and to satisfy the understandable curiosity of harmed patients.

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[12] VINCENT, Charles; YOUNG, Magi; PHILIPS, Angela – *Why do people sue doctors? A study of patients and relatives taking legal action*, The Lancet, , vol. 343, 1994, p. 1612.

[13] VINCENT, Charles; YOUNG, Magi; PHILIPS, Angela – *Why do people sue doctors? A study of patients and relatives taking legal action*, The Lancet, , vol. 343, 1994, p. 1612-3.

[14] MASON; McCall Smith – *Law and Medical Ethics*, fifth ed., Butterworths, London, Edinburgh, Dublin, 1999, p. 217.

However, it is much less plausible to suggest that *more and better litigation* amounts to improving health care by contributing to a reduction in preventable accidents. In fact this improvement in health care requires total and systematic reporting and a full understanding of wrongs in the fullest possible sense[15]; and it's very likely that litigation makes the disclosure of error highly improbable, as physicians become very cautious about providing information that may be used against them[16]. On the other hand, any legal response to medical error – either criminal or civil – is focused upon the person who holds "the smoking gun"[17]. The legal system deals only with "the active error", performed by the person "in the frontline", forgetting "latent errors" – those several unrecognized factors that come together, in a highly complex system like health services, and may result in multiple types of active errors[18]. The system's latent weaknesses remain,

[15] KOHN L.T., CORRIGAN JM, DONALDSON MS, eds. *To err is human: building a safer health system*. Washington, D.C: National Academy Press, 2000, p. 98-100.

[16] KOHN LT, CORRIGAN JM, DONALDSON MS, eds. *To err is human: building a safer health system*. Washington, D.C: National Academy Press, 2000, p. 109-10.

[17] MERRY, A.; MCCALL SMITH, A. – *Errors, medicine and law*, Cambridge University Press, 2001, p. 14 , 32.

[18] Nonetheless, whenever is not possible to sue and charge an individual doctor as having been the one responsible for a bad outcome , clearly not happened to occur, legal systems try to burden the organization itself, according to an old French legal doctrine (*faute de service*).

making it prone to failure. Therefore litigation is not an effective way to deter the recurrence of error [19].

Let me say a word about the **Portuguese legal regime** with regard to this trend of punishing the man holding "the smoking gun". Portuguese law ruling civil claims within the National Health Service happens to be an up-to-date system… by chance, I must say! According to this legal regime compensation is obtained from health care institutions themselves, not from doctors; and health care institutions cannot get their money back from the doctor who has failed unless the doctor had grossly departed from the standard of diligence. This amounts to saying that the Portuguese legal regime spares doctors both blame and financial costs in some of the cases where modern research suggests doctors should be spared, like in some common drug error cases, some common drug administering mistakes, slow response to machine failure in anaesthesia and slips or lapses due to fatigue, on the grounds that most of the "errors should be viewed as due primarily to

[19] KOHN LT, CORRIGAN JM, DONALDSON MS, eds. *To err is human: building a safer health system*. Washington, D.C: National Academy Press, 2000, p. 54-60.

failures of institutional systems rather than failures of individuals"[20]. This legal regime dates back to 1967, therefore it could not have taken into consideration modern studies on accidents, organizations and human psychology, like today's classic *Normal Accidents*, by Charles Perrow; that regime intended probably just to protect doctors at a time when the power of the "white coat" was considerably higher than today, in a society lacking democratic principles of organization. But the legal regime seems now to be up-to-date in its statutory impositions, and we should just applaud it on the basis of our modern understanding of failures within complex systems.

Let's go back to analysing the improvement in law dealing with medical errors.

Besides trying to be more effective in compensating damages, could law help in some way to *reduce medical error*? Well… it's hardly possible, considering the way law functions.

[20] BLENDON, Robert J. et al. – *Views of practicing physicians and the public on medical errors*. The New England Journal of Medicine, Vol. 347, No. 24, 2002, p. 1938. MERRY, A.; MCCALL SMITH, A. – *Errors, medicine and law*, Cambridge University Press, 2001, p. 241-8.

Unless it can help in an oblique way, by imposing *informed consent* more firmly. In fact, there is evidence showing that successful actions for failure to obtain informed consent lead doctors to spend more time with patients, thereby increasing communication[21]. It may be that better communication, besides contributing to a more trusting medical-patient relationship, tends to create the framework for more accurate technical observation; according to a recent study, 78% of the answers of the lay public said that spending more time with patients is the best way to eliminate medical error[22]; finally, the IOM's report holds that informing patients in great detail and encouraging them to share responsibility for their own treatment can be the final "fail-safe" step[23].

Law and the enforcement of the doctrine of informed consent could thus turn out to be an indirect way of increasing the prevention of errors.

However effective legal improvements could be, it seems that reducing medical error is definitely the business of the **medical profession**.

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[21] G. ROBERTSON, *apud* MERRY, A.; MCCALL SMITH, A. – *Errors, medicine and law*, Cambridge University Press, 2001, p. 213.

[22] BLENDON, Robert J. et al. – *Views of practicing physicians and the public on medical errors*. The New England Journal of Medicine, Vol. 347, No. 24, 2002, p. 1936.

[23] KOHN LT, CORRIGAN JM, DONALDSON MS, eds. *To err is human: building a safer health system*. Washington, D.C: National Academy Press, 2000, p. 196.

It's broadly accepted that reducing medical errors requires a broad use of *incident reporting*. Reporting systems are a tool for gathering information and allow understanding about how systems work and fail. They are extremely useful mainly to find and bring together rare accidents, otherwise perceived as unpreventable risk. It is obvious that large scale reporting has nothing to do with litigation and analysis focused solely upon cases brought to courts. On the other hand reporting systems do not have a primary interest in negligence and blame, although in a deeper level negligence may be important to understand why a particular failure has occurred. It could be argued that the close proximity of law systems and law proceedings is damaging for the perfect functioning of full reporting, because doctors will hide information if they fear being sued on the grounds of their own reports[24]. In this sense, law not only can't help but it actually can ruin the effect of reporting systems.

In other words, I along with many others find hetero-regulation a less suitable way of improving medical safety. **I definitely trust self-regulation**,

[24] KOHN LT, CORRIGAN JM, DONALDSON MS, eds. *To err is human: building a safer health system*. Washington, D.C: National Academy Press, 2000, p. 43, 109-110.

as a much more effective way to get extensive knowledge of what is going on in order to redesign medical procedures, medical training and the organization of health institutions at large, engaging many professionals besides doctors, like engineers, information technology experts and system managers. This shift of course will suppose the abandonment of a culture of blame and exhortation and will suppose the growth of a culture of safety based on evidence and redesign[25].

Some people don't trust increasing self-regulation, as self-regulation tends to keep external agencies and lay people apart from control over medical bodies and practice, and somehow weakens the protection of the public against bad doctors; these opponents of self-regulation say that it seems like trying to watch the fox by putting it in charge of the chickens… Some regrettable cases are indeed well known, but in the first place it is to be shown that a different system of governing medical profession gives better results; on the other hand, concerns about bad doctors and with their continued practice is quite an important issue but, as it has already been said, "The real problem isn't how to stop bad doctors from harming (…) their

[25] *Not again*! BMJ, vol. 322, 2001, p.247.

patients. It's how to prevent good doctors from doing so" [26]. This means that reducing medical error and increasing safety is a much broader issue than controlling performances which are clearly below average. It is arguable that controlling poor performances can actually be done by external legal agencies and the law; on the contrary, in terms of dealing with good doctors making errors and producing harm at least once in their life time, this has to be done far from external legal agencies and lay people, this has to be done in internal agencies devoted to large scale reporting and assessment instead of blaming and punishing.

I conclude, going back to my first question: **is medical error the business of law?** To me, the right answer is: basically, it isn't. In accordance with this answer the title of my paper could have been: ***Law on medical error – less is better.***

Feb 03
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[26] The journalist A. Gawande, apud MERRY, A.; MCCALL SMITH, A. – *Errors, medicine and law*, Cambridge University Press, 2001, p. 113.