

Monographs of
the Víctor Grífols 07
i Lucas Foundation

The management of medical errors

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INTRODUCTION

Medical errors are something which we will always have to deal with, and this is precisely why it is so important that we analyse their causes, improve how we manage them, and strive to prevent them. While these might seem like logical proposals, the fact that there is still some resistance to recognizing these issues makes the need for discussion more vital than ever. This is why the decision of the Víctor Grífols i Lucas Foundation, at the urging of its President, to organize the seminar presented here is particularly welcome.

To start with, we lack a precise definition of what the concept of ‘medical error’ includes. At its broadest, it ranges from individual negligence to incidents which are the result of the risks inherent in taking a particular drug or those associated with standard clinical practice, to give just a couple of examples. Our first task, then, is to define the concept itself in more detail, because there can clearly be no single solution to such a widespread problem. One thing which appears to be clear is that, above and beyond instances of individual negligence, which occur in specific cases and are relatively easy to delimit, medical errors occur within the context of health systems which are not infallible, and where the clinical activity which carries the greatest risks is practised within the most complex organizational settings.

At the same time, we can see that society’s reactions to medical errors are often reductionist and focus on the attribution of personal blame. This is accompanied by a tendency to automatically resort to legal action in response to such events, a development which has gone hand in hand with the haphazard and counterproductive commercialization of the process of suing for damages. This, in turn, has led to two worrying and intractable developments: the gradual disengagement or withdrawal of the companies which provide insurance cover for health professionals and organizations; and the consolidation of what is known as ‘defensive medicine’, a clinical practice characterized by lower quality and higher costs.

The only appropriate response to medical errors is to take steps to ensure that the system systematically identifies and prevents errors, while at the same time recognizing that it is impossible to render certain clinical practices completely risk-free. The challenge is to manage the prevention of medical errors in an environment characterized by progress and uncertainty, and in which we are caring for patients and families who have become increasingly sensitive to such issues. There is clear evidence of the benefit of many of the technological advances which are applied in the clinical context. Not only have many risks been reduced, but accidents which were once common have now become far rarer. Above all with respect to the application of advanced technology, the probability of errors has fallen, as a result of the fact that the standards applied to the introduction of new technologies (and medicines, in particular) have become ever stricter. However, this progress occurs in the context of a society whose perception of these problems has changed as a result of rising expectations. While modern medicine has become less risky, society's perception or acceptance of risk has also changed, and its tolerance of errors has certainly diminished.

The complexity of our response to medical errors is reflected in the contents of this monograph, which offers a detailed analysis of the situation while refraining from offering any simple prescriptions as to how to manage and prevent such errors. The two presentations provide an extensive and to some degree complementary analysis of the issues, and this analysis is then developed further in the contributions of the invited participants, all of whom are highly-regarded health professionals who provide their own perspective and between them identify the nature and scale of the huge task faced by the health system if it is to address the problem of medical errors.

Some of the conclusions to emerge include the urgent need to improve communication between health professionals, patients and relatives, the benefits of improving the informed consent process, and of enhancing mechanisms for the internal accreditation and standardization of procedures (protocolization), so long as this is done in an intelligent manner. Another issue to be addressed is the challenge which self-regulation poses to complex health organizations if they are to succeed in eradicating the pernicious culture of

concealment typical of excessively corporatist settings. The success of our health organizations in preventing risks and errors is dependent on the degree of cohesion it achieves, the ability to build relationships across disciplines and departments, and a commitment to quality. The different protagonists in our health system should accept this new responsibility for taking specific measures designed to prevent medical errors and to create a new culture with respect to our management of risk. This monograph is therefore particularly welcome, and it will help both in the identification of possible solutions and in enabling those in our health system to come to terms with this as yet unresolved issue.

Dr Jordi Camí

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**Medical errors:
protection systems
and their paradoxes**

Jaume Aubia

Introduction

Social concern about medical errors is growing everywhere, and as a result we need to ensure that the care we offer patients is both safer and more effective. The current system of protection against medical errors has two main goals: punishment as a way of preventing future errors, and providing financial compensation to those affected. These are apparently reasonable goals, and have even been accepted as necessary and indeed essential. As doctors, we have taken them on board because we all believe in the need to make every effort to avoid errors and to ensure that those who are unfortunate enough to suffer from them receive some recompense. However, while these high principles and the values upon which they are based are laudable, I am concerned that the systems which currently exist to pursue these goals do not actually serve to achieve them. Indeed, they generate contradictions and undesired consequences which may actually impede this.

In company with many others, I therefore believe that we need to undertake a thorough review of the underlying principles of our systems for managing risks and medical errors. The existing 'error management' system is based on those two elements: civil liability insurance policies to provide financial compensation to patients for damages suffered during the course of medical and health care, and a system of punishment for individual health professionals who are shown to have been negligent or incompetent. This system has failed to deliver.

Compensation and punishment

Compensation and punishment often go hand in hand, because both issues are resolved through the courts. Where compensation is not at stake, it may be possible to address matters exclusively through the disciplinary route, applied by bodies which are responsible for ensuring professional standards and policing malpractice, but do not award financial compensation. There are major differences between countries with respect to the level of social

influence wielded by professional associations. In some countries, such as the USA, Canada, the United Kingdom and Australia, these bodies are very powerful and have the power to inspect the practice of both individuals and hospitals, and to strike professionals from their register due to poor practice. This contrasts with the situation in continental Europe, where a system based on Roman and Napoleonic law requires that procedures be based on explicit legislation.

Professional practice is very difficult to classify, catalogue and regulate through such explicit legislation, and as a result continental European legal systems are ill-adapted to cope with it. In order to ensure satisfactory levels of safety and quality in professional services, and to resolve the issue of how to control professional activity, no alternative to professional self-regulation has yet been found. However, when this self-regulation fails, the result is a lack of social trust. If this failure is total and professional bodies do not exercise their disciplinary competencies, then society or the state quite rightly seek to acquire these competencies and exercise them directly, without any input from health professionals. This is the process which the west is currently experiencing. Social trust in professional corporations is low, and society is turning to other means to solve the problem of how to control medical practice. In the English-speaking world, this reaction has been manifested primarily through the explosive growth in litigation since the early 1970s. The aim of such legal procedures is twofold: to obtain financial compensation for the damages suffered, and to 'prevent it from happening again'.

Compensation system

I should say that, in a country like the USA, where the social security system is, for all practical purposes, almost exclusively private, the importance of financial compensation is reasonable and logical. Indeed, so logical is it that it has grown spectacularly, to the extent that financial insurance against legal actions is at the very centre of the concerns of American doctors. Up to a third of the income of famous specialists in a major US city goes to meeting

insurance premiums. And the growth shows now signs of slowing. In Florida, a gynaecologist paid around 200,000 dollars at the end of 2001. The system may be unsustainable in the long term, but it is impossible to argue with its logic or vitality in the short term. The system is so powerful that, like Coca-Cola and fast food, we have adopted it almost uncritically.

But what happens when the health system which adopts the 'American model' of litigation and financial compensation has nothing in common with the American system? Firstly, our social security system already provides universal health care and social security protection which covers all of those who, under the American system, need individual compensation: the cost of medically repairing damage (new operations, rehabilitation etc.) and financial support if the damage cannot be repaired. Secondly, under the Spanish system the Civil Liability insurance of the Public Health System is paid for out of public health budgets (at national and regional level). As a result, all the money allocated to financial compensation (together with the far from negligible sums absorbed by the legal process in the form of lawyers' fees, expert opinions etc.) is diverted away from frontline care. This money could be used for other things, it comes from all of us and is, in a sense, redundant: society has already decided to 'cover' the need for health care and social security, but if these needs arise in the context of the provision of health care (note, that they are not necessarily caused by this) then we 'cover' them more generously than if they had arisen in another context. If a farm worker suffers paralysis of the hand due to an accident in the field, then he is entitled to far lower compensation than if he were to suffer the same paralysis after retirement as the result of a delay on the part of the health system in attending to post-surgical compression. This strikes me as paradoxical. I believe that we could and should have a better, more rational, and fairer system which would neither deprive people of protection nor involve impose 'double coverage' on the health system by diverting resources away from healthcare and patients.

I am aware that, speaking as a doctor, I will inevitably be suspected of using fallacious arguments designed to conceal my true intention, which is to allow doctors to avoid taking responsibility for our actions. Perhaps I am motivated by a desire to save the cost of paying for an insurance policy, or maybe what

I really want is impunity. This is untrue. I began by saying that doctors as a group share with the rest of society a desire to ensure the protection of those who are affected by medical errors. Indeed, we have the strongest motivation of all in this regard; we are in the front line, the victims are 'our' patients, we are the ones who care for them and want to resolve their health problems, and we feel responsible for them, sometimes to the extent of feelings of 'excessive' guilt. In 1974, the College of Doctors of Barcelona was the first in Spain to establish an insurance policy to pay compensation, at a time when compensation awards were practically unknown, and when the public health system did not cover this sort of risk. Of course, back in 1974 (and this was still the case in 1984 when we established the civil liability system which currently operates in Catalonia) neither health coverage nor the social security system were as extensive as they are today, and the social imperative for creating a financial system to meet such needs (one which was originally based solely on payments by doctors) was correspondingly greater than it is today. We neither wish nor seek impunity, just the opposite. But the current system is not developing in a reasonable direction. And this is despite the fact that we are still a long way from the situation in the majority of European countries, where the 'American model' has been introduced more rapidly, where insurance policies have grown spectacularly and where, it should also be said, the health system is not as fully public, less doctors are on the payroll of the health system, and as a result the tension between the economic resources allocated to covering errors and the resources to meet care needs are of a different scale.

Medical errors and punishment

I will now consider the validity of the argument which, at least implicitly, we all accept: every error should be punished because only then can we prevent such errors from being repeated. Here, error is equated with an offence, with a violation of the rules or with a crime. I don't argue that we are unable to differentiate between these categories from a legal or moral perspective. We all know that they are not the same without going into the details of the dif-

ferences between such concepts as accident, error, carelessness, negligence etc. However, regardless of these legal categories we all believe that, whatever differences there may be, the acts they describe are all deserving of punishment. In this context, professional malpractice proceedings (or even the mere mention of them) constitute a moral punishment. Arguing for the opposite course –depenalization– may seem like an act of the greatest cynicism and immorality, and if it is proposed by a doctor it may also look like an example of the worst sort of corporativism. How can anyone argue, in the face of an error which has harmed somebody’s health or even caused their death, that this should go unpunished? “Punish him, that way he won’t do it again! It will serve as an example for everyone, and we’ll all be safer.” In the legal sphere, harm or tort generates a right on the part of the victim, while in the regulation of professional practice it is the occasion for a disciplinary process. Patients and their families demand it, and society as a whole finds this both reasonable and fair. However, the question I wish to raise today is whether this approach is effective and useful. Or is there a better approach?

Safety and risk

Health systems are not as safe as they should be. Of course, it does not follow from this that total safety and zero risk are attainable, and indeed a utopian belief in such possibilities may actually have the paradoxical effect of militating against improvements and scientific progress in this area. But it still remains difficult to explain why the safety of healthcare provision is not improving.

These two issues –the fact that health systems are not safe, and the fact that safety is not improving– need to be analysed separately. Is it accurate to state that health systems are unsafe? Let us ignore for a moment the fact that the concepts of safety and risk are sociological and, therefore, relative. Each society accepts a different level of risk or danger, in accordance with a set of specific social expectations which are to some degree determined by the experience of real harm, and in part by social constructions which are not always objective. As a result, if we put this question to a grandmother who has

lived through war, periods of high infant mortality, and situations where many received no medical care for serious illnesses, she will give a very different answer than her granddaughter, a healthy, young person who is an uncritical consumer of newspapers and TV programmes. However, we should all accept that, above and beyond such subjective differences, there is a real lack of safety, even if this problem has not been the focus of much scientific study, and has generally been ignored by doctors and by the health system as a whole.

Error and failure

The simple fact that these phenomena are so little studied and that so little has been published about them should in itself give pause for thought. It is said that doctors publish 17 million articles a year across the globe, a figure which has been rising steadily for years. Despite this, the first articles on the subject of poor safety and risk only appeared a little over twenty years ago, and even today such publications are neither very numerous nor very widely referred to. But there is sufficient data to confirm that the problem exists and is very significant. As always, we turn first to scientific literature from the United States. What we may think of as the foundational study was the Harvard Medical Practice Study-1¹ which looked at New York hospital admission data in 1984 and found that 3.7% of those admitted to hospital suffered an adverse effect or injury as a result of medical care, and that 58% of these were due to some kind of ‘error’. In a parallel study performed at hospitals in Colorado and Utah conducted ten years later, the figures were 2.9% for adverse effects and 53% for error². Both studies suffer from certain defects and methodological contradictions with regard to what they define as an adverse effect or error and whether or not this error was ‘preventable’ or ‘foreseeable’. The consistency of the data may not be all it could be, but this is not the moment to analyse it in detail. It is impossible to deny that these figures reflect a real problem, and one which needs to be addressed. And this is something which the scientific community and the US Government have already begun to do. Let us put these figures in a context which makes clear their significance. If

these figures proved to be accurate, then by extrapolating from them we could attribute more deaths to medical error than to traffic accidents, to breast cancer or to AIDS. Indeed, the American figures would put them ahead of the total number of deaths from workplace accidents.

Statistics regarding the problem outside of the hospital environment are even more difficult to collect, but taken together convert the problem into a health issue of a worrying scale. Personally, I believe that these figures exaggerate the problem, that the concepts of 'adverse effect' and 'error' include many episodes which could only have been recognized *a posteriori*, and inductions which depend on the subjective opinions of those reviewing the medical record, etc. These studies have been the subject of serious criticism^{3,4}, but nobody can deny the scale of the problem. And nor can anyone deny the scant attention paid to this issue from a scientific, organizational and research perspective, above all if we compare it with the resources and research allocated to less prevalent health problems. The reason for this universal inhibition is that there is a taboo, a cultural resistance which impedes a rational, balanced approach to the problem. The very existence of controversy around the figures, the absence of an agreed perspective on the figures is, in my opinion, very significant. And we should also remember that these figures relate solely to the adverse effects or errors which appear in or can be deduced from the data recorded in the medical record, and that far from all of these incidents are errors. Nor should we think that doctors are the only ones responsible for the errors. Far more common in these statistics than the classical errors of diagnosis or carelessness are drug dispensing and administration errors, errors in treatment adherence, errors in the distribution and feedback of clinical information, errors due to inadequate resources, preventable suicides etc. This cultural resistance to identifying the problem and its scale is a collective problem of the health system, not just of individual doctors.

The second observation is that, in addition to the fact that they are high and indicate a serious problem, the figures do not appear to be improving. In ten years no clear improvement has been observed, something which is surprising in the context of scientific and technological advances in medicine as a whole which have led to major advances in the safety and efficacy of the

diagnosis and treatment of disease, and has created a host of new procedures, techniques, drugs, technologies etc. which have led to relentless improvements in the prognosis for almost all illnesses in terms of morbidity and mortality, however serious they may be. But, paradoxically, a 'pathology' which is not only very prevalent but which develops under our very noses and in the heart of the organizations which make these other advances possible, has seen no observable progress at all: the pathology of 'error'. Why? An obvious response is to deny the problem. Nobody likes to face up to their own errors. This is something which affects the daily lives of everyone, doctors of course, but also journalists (who never make mistakes, never say sorry, and never issue corrections), judges (who 'can't' make mistakes, and if they do, these are rectified by someone else), teachers (who are responsible for absentee students and educational failure?), civil engineers (who can put the 'blame' on the weather when their bridges collapse), and every profession on earth. But even if we accept that this is a basic, universal psychological defence mechanism, this does not make it ethically acceptable that medicine and doctors have not searched for a way to overcome this cultural resistance.

When we say that the problem has not improved, we must be careful to keep this in perspective. Firstly, because data is scarce and, as I have noted, that data which exists is inconsistent and recent, although it all points in the same direction. And secondly, because this statement would appear to be counter-intuitive. This is because it is beyond dispute that the individual diagnostic procedures, treatments and techniques applied by doctors are safer, more closely controlled, more precise and more effective than before. And so we ask ourselves how it can be that, if we are doing things better, the overall results have not improved.

This paradox is a superficial one, because we are not stating that the procedures are no safer, but rather that the care provided as a whole is not successful in reducing adverse effects and errors, which is a different concept. The clearest and best-documented example comes from anaesthesia. Studies in the United Kingdom and Australia show that mortality from anaesthesia has fall from 1 death for every 10,000 anaesthetics in the early 1980s to 1 death

for every 300,000 anaesthesias in 2000⁵. This represents a spectacular reduction, by a factor of 60 (or 6000%). And this is also a good example from which to draw conclusions as to the conceptual basis for addressing the problem of medical errors. Have these figures improved because anaesthetists have been sued more often or required to pay out more compensation? Clearly not. The figures have improved because the problem itself has been clearly identified, and this has made it possible to address it in a systematic, scientific way, with studies designed to improve the safety of anaesthetics and instruments, to introduce systematic monitoring, and as a result of the convergence of other types of improvements in surgical techniques and techniques to maintain plasma volume and blood circulation. It has improved because the problem has been identified and evaluated, and addressed in a systematic, cooperative manner, applying scientific methodology in a professional way. Any solution starts with identifying and evaluating the problem, not hiding from it, denying it or converting it into a taboo. Anaesthetic mortality in the 1980s was not a 'medical error' and nobody had to feel guilty because of the 'high mortality'. On the contrary, anaesthetists felt both satisfied and hopeful when they observed how much things had improved over the preceding 30 years. During the 1950s nobody could even be sure they would survive anaesthesia. The magnificent progress in safety in this field is not the work of one individual but is instead a collective effort, a consequence of how scientific optimism and systematic methodologies have brought us to where we are today. But instead of leading us into the light, we find ourselves in darkness. Anaesthetic accidents are now so rare that, when they do occur, they are seen as an 'error', an individual failure, which often results in complaint, controversy or punishment. This is poor soil in which to sow the seeds of scientific optimism, joint effort and learning. It provides a poor basis for improvement.

What has changed? Above all, the social perception of safety. When adverse effects are so infrequent, a satisfactory outcome is seen as a right and an unsatisfactory outcome as a denial of that right and, therefore, as negligence or error. Medical error is seen as an individual phenomenon which is the result of poor individual knowledge, inadequate training, carelessness or negligence. Surveys illustrate this clearly. Of the 80% of people who say they are aware of medical errors, approximately half gained their knowledge from

cases reported in the press, on radio or the TV, and the other half as a result of direct experience or from family or acquaintances. When asked what they believe to be the cause, most give responses identifying causes of a personal nature relating to the doctor, with more or less emphasis on blame. Half of the respondents put the causes down to carelessness and negligence, while the other more enlightened half believe that doctors have too much work, are stressed or other similar motives. Here I believe it is significant that society perceives error as an individual responsibility with individual causes.

Social perception of error

How can we find a solution to the problem when there is such a contrast between the social perception of error as an individual phenomenon and the reality that improvements actually spring above all from systematic, collective approaches which also provide space for individual judgement?

Within the dominant conceptions of what constitute error we are also seeing the emergence of a new notion in the spheres of management, the law and the media. This is the erroneous concept that states that not doing the 'best' is equivalent to error by omission. At first sight, this seems unimpeachable until we remember that in medicine (and science in general) there is no absolute way of determining what is optimal, either for all individuals or at all times. The information derived from controlled, scientifically robust clinical trials necessarily excludes many individuals with associated pathologies or demographic characteristics which exist in clinical reality and may even be very common. (Hypotension treatment in elderly stroke patients, cardiac insufficiency in diabetics, etc.) As a result, the 'scientific' conclusions of the clinical trial must be combined with other priorities which may mean it is reasonable to take a decision which differs from what has been defined as 'optimal'.

Consideration of the time factor is also very important, not just because scientific knowledge is not disseminated simultaneously and automatically throughout the medical community, and there is therefore necessarily a latency period separating knowledge and practice, but even more impor-

tantly because scientific certainty is always subject to review and therefore temporary. How often have we seen apparently well-established certainties undergo radical change? The use of beta-blockers in cardiac insufficiency was an 'error' which was severely criticized in reviews ten or fifteen years ago, but is now recognized as a treatment which has demonstrated its efficacy in reducing the mortality and morbidity of this disease⁶ and is therefore a required measure. And yet I am sure nobody will be surprised (or should be surprised) by the fact that in a large and well-studied series in the United Kingdom only 16% of patients received it⁷. In other words, we have to accept that at least 84% of patients with a disease which is very common (3.2 to 7.9% of the total population) and easy to diagnose receive an 'erroneous' treatment. Universal error, no less! A more reasonable and less moralistic way to view this would be to consider it as a statistic which reflects the relentless growth and rapidity of change in scientific knowledge.

I am sure one could mathematically model the impossibility of always providing an 'optimal' treatment to a patient with multiple pathologies (i.e., almost all patients), given the speed with which knowledge is generated, the barriers to its dissemination, and the continuous expansion of the concept of a treatable or preventable illness or disorder. In fact, from a philosophical perspective it could be argued that 'optimal treatment' is really the medical equivalent of the concept of 'absolute truth', and as such is incompatible with biology and empirical science. Indeed, it is somewhat surprising that such a dangerous concept has been smuggled in when, throughout the history of medicine and of science we have been satisfied with achieving better evidence of the effectiveness and applicability of scientific knowledge, and have always left absolute truth to religious and ideological dogma. Could it be that, at the start of the 21st century, as medicine and society converge, so the scientific dimension of medicine becomes incomprehensible and it is turned into social ideology?

Other approaches to error

In medicine, we find ourselves at a confusing crossroads where we appear to be caught between the dominant social demands and beliefs, on the one

hand, and remaining true to the scientific principles which have proved effective until now, on the other. Perhaps we might learn something if we turned our attention outwards and considered how other sectors have responded to the problems of risk and how to improve safety. Some analysts have looked in detail at the aviation industry, a sector which has experience of improving safety processes. The individualized approach, which is adopted by doctors when we argue that 'errors' will decline if doctors 'know more', equates error with a training deficit, and argues that better university training, continuous professional development or competency assessment are the way to resolve this problem. This assumes that error is purely a consequence of a lack of knowledge or personal skills. But this is not true. If this were the case, errors and complaints should almost never affect the most highly educated professionals, doctors working at university hospitals, heads of services, academic leaders and specialized professionals. The reality, I assure you, is very different, although for obvious reasons it is impossible to provide evidence of this on the basis of studies in Spain or elsewhere.

Indeed, simple observation of reality would appear to show exactly the opposite. If complaints were taken as an indirect index of errors, then we would have to conclude that, far from preventing errors, individual competency and expertise actually makes them more likely. Indeed, I believe I am correct in saying that it is precisely when one becomes a head of service at a large public hospital that one is most likely to be the subject of a complaint due to error and negligence. In the United States, where policies are usually individual, the amounts paid by famous doctors are much higher than those paid by 'normal' ones. This is, then, another myth which requires revision. The fact, which is surely beyond dispute, that a doctor with poor skills and inadequate training would commit more errors than a well trained one if both performed the same activity is not contradicted by the fact that, in reality, they perform different activities and procedures, that is, that they undertake risks of a different order and, more importantly, that their activity occurs in organizations which are not comparable. The results are impossible to interpret on their own. Once again, the relevant factor is not the individual but the environment and the organization. Just as risk is a

context-dependent concept, so safety is socially constructed, and different cultures accept different risks and value a given proportion of accidents differently.

The perception of what constitutes risk, and indeed the value which is attributed to human life, is not uniform. Many believe that societies have the number of accidents (and deaths) which they are prepared to accept before spending resources in order to reduce the risk. This is not to make a moral judgement, but simply to point out the fundamentally cultural component of the perception of risk. We would like to believe that safety resides in the implementation of formal control structures, protocols and standards, whereas it resides primarily in attitudes. While this may seem a statement of the obvious, protocols and standards do not work if they are in opposition to the beliefs and values shared by the groups which have to implement them, and these beliefs and values vary between cultures and over time. Risk and safety are not simply inherent properties of activities, but are also subjective and implicit processes of quantification, evaluation and acceptance of risk by the specific groups which are engaged in these activities.

However, the paradox is that this is not widely accepted in the attitudes, values and beliefs of professionals, in what we refer to as professional culture. There is an almost unanimous belief that education (or training), technological solutions, protocols and better professional conduct are the solution to the problems of safety.

Standards, and legislation in general, are always a compromise which reflect a balance between the needs of the provider (whether of industrial technology or of health services) and those of the end users. Whether this compromise is deemed acceptable or not depends on the cultural values of the society which evaluates them. We are rapidly moving towards a globalized world in which American standards, norms and procedures are accepted worldwide, but this does not mean that basic cultural values such as the value of life or our reactions in the face of extreme situations are identical, either now or in the foreseeable future. Immigration will have a significant influence on the exact balance of this compromise, and this may give rise to new tensions, but it may also make the nature of the compromise itself more explicit and there-

fore help to strengthen it, which is in effect a way of matching social expectations with results.

It is commonplace to discuss error in terms of 'rotten apples'. In this view, errors are not caused by 'good' doctors (the majority) but only by a negligent minority which may contaminate the rest. If only these individuals were removed, there would be no more errors. This view is also widely held among those registering complaints, by survey respondents (75% believe this would be a useful response), and by insurance companies (through the no claims bonus mechanism which financially penalizes those who are subject to most complaints); and it is reflected in both civil and criminal legislation and in the attitude of professional associations themselves, which place great value on precedent and repeat offences. There is obviously some truth in this belief, and I would certainly agree that some individual doctors are guilty of poor practice, have inappropriate attitudes, or suffer from a clear lack of knowledge and skills, all of which mean they should not be allowed to practise until these have been corrected. This should be the basic function of professional associations and indeed some, such as the Barcelona College of Doctors, attempt to do this despite possessing only minimal competencies and limited powers. In recent years, 28 members have been disciplined on these grounds, and several more have been disqualified by the courts for individual acts of negligence. But even if this self-regulatory and disciplinary function could be practised more effectively, something which the College wishes to achieve when its regulations are next reviewed, this would only affect a limited number of members and while this might be helpful in itself, it would have little impact on the wider problem or the main factors underlying it.

I hope I have made it clear that the current system for dealing with errors –based as it is on identifying individual blame, financial compensation, and the emerging concepts of calling for improvement by improved training of individual doctors and controlling practice by the application of protocols– is absolutely ineffective. This set of paradigms has not enabled us to detect and evaluate the problem, which is far greater than the efforts dedicated to resolving it, and is concealed by a whole layer of beliefs and perceptions which, even if they are clearly mistaken or biased, receive the nuanced but coordi-

nated support of the media, and of educational and care organizations, and are fostered by a set of dominant social beliefs which influence legal, judicial, media, corporate and economic considerations of the problem.

Given that this system clearly appears to have failed to produce tangible results and is, in fact, based on mistaken assumptions, perhaps the moment has arrived for a change of approach: to accept that error is human and inevitable and, as the cognitive sciences have shown, does not correlate closely with knowledge. And it is precisely because of this inevitability that we should not accept a situation where our organizational systems operate as if error did not exist, one where they hide from reality and continue to treat it as a problem of the individual (the agent) acting upon another individual (the patient) in which organizational responsibility is limited to censure and punishment when error is detected.

Error and systems

Even when error is incidental, simple and clearly attributable to a specific individual, very often, almost always, a whole number of different factors have converged on a place and time so that the error was not detected, either when planning the action or when the action was actually performed. Blaming an individual does not change the factors, and the error is very likely to be repeated, if not by the same individual than by another. Preventing errors and improving patient safety requires the modification of the conditions which contribute to the error.

In an organized and complex medical system like ours, where almost everything involves teamwork, it is odd that errors continue to be primarily individual. The problem is not one of bad people (bad doctors): the problem is that we need to create a safer medical care system. If an error has actually occurred, this is only because there was the potential for it to occur on multiple prior occasions, because it could have been prevented in advance and wasn't. Detecting, identifying and, if possible, preventing latent errors is the most effective way of making progress in overcoming them.

While doctors cannot always believe that someone else or 'the system' is always to blame, nor should we forget that failure is rarely attributable to a single individual but is more often a symptom of problems at the organizational level. In other words, the situation is a long way from what one might consider reasonable or rational. The system of individual blame and punishment of the last 15 to 20 years, together with the universal taboo which prevents us from examining our own failures, means that we do not have a reliable evaluation of actual accidents, and nor do we have a system (or even feel the need for one) which detects and analyses latent errors within health systems which are becoming increasingly complex and, in our case, where responsibilities and experience are becoming more and more fragmented, with the concomitant risk of converting the health system into a confusing bureaucratic labyrinth.

So what should we change? One might draw the mistaken conclusion from what I have said so far that what is required is the immediate introduction, in parallel with existing systems, of a system for monitoring medical processes, a kind of continuous inspection, perhaps under the auspices of new hospital quality control departments, in order to achieve better control of risks for patients. If to date we have neglected these issues, then what is required is to draw attention to them and monitor practice more closely, without any need to alter any of the other structural or cultural elements of the system. But this technocratic and administrative 'solution' ignores the fundamental issue of why we find ourselves in the current situation. Why has the information which underpins the complex system and the specialized procedures not been implemented? The information about the causes and context of error is not fully in the possession of any single individual but is, instead, distributed between many individuals. The only people who can act upon this information are the agents who perform the specific procedures and who are involved in the unsatisfactory processes, and if something goes wrong they are held responsible and made to answer for these shortcomings. Even if there is no formal punishment, if they are not freed from the notion of individual failure it is unlikely that they will contribute towards constructing what should be the core element of the new model: a system for the voluntary, active reporting of both active and latent errors and accidents experienced during the

course of their daily work, without anybody being either formally or morally sanctioned for this reason (neither the person reporting the event nor any of his or her colleagues).

In the United States, the Institute of Medicine proposed the implementation of a system like this a year ago, a series of error reporting systems designed so that hospitals would be required to provide standardized information which could be subjected to serial, aggregated analysis of accidents and errors⁸. Financial resources have been allocated to the implementation of these systems and for training those responsible for managing them.

However, the compulsory nature of the system for hospitals must be reconciled with the voluntary status of reporting and the need to stimulate participation. This system draws on the Aviation Safety Reporting System, and is intended to preserve its voluntary, confidential nature. The ASRS collects incidents which someone believes have affected or could affect flight safety, and acts as the basis for introducing changes to procedures. Two points: firstly, confidentiality is not the same as anonymity (anonymous complaints are not accepted) and secondly and very importantly, the body responsible for managing the ASRS is not the regulatory authority. The ASRS regularly publishes warnings and recommendations which are sent directly to the active agents, in this case, primarily to the aviation industry, although they are also made available to the regulatory authority. The ASRS maintains a database of incidents, identifies circumstances and patterns of events, issues warnings, interviews reporters and publishes a newsletter. But it has no power to decide what should be done, or to punish or reprimand anyone. Thanks to this system, over 30,000 incidents are reported every year, and since 1976 when it was introduced flight safety has improved dramatically. In economic terms, at a cost of only 2 million dollars a year it has contributed to the redesign of aircraft, air traffic control systems, airports, and the education and training of pilots, as a result of which it has helped to reduce the level of human error in the system. Other industries and countries have systems for the voluntary reporting of errors or 'near misses'⁹ and these offer lessons as to what makes them effective¹⁰. Immunity, confidentiality (so that the data cannot be linked to an institution, to patients, to a point in time, a shift or an

individual); the fact that reports are seen to come from an independent source, with data being analysed by experts; clear, rapid feedback for the informer and the interested parties; ease of use of the system, and leadership and support on the part of management.

In medicine, there is a tradition of studying past practice in order to understand how things could be done differently. However, conferences on morbidity and mortality, consensus groups and peer review all suffer from the same shortcoming: a failure to consider human factors or to think about systems other than as individual or aggregated cases; a narrow focus on individual action, to the point of excluding the support team; a bias towards searching for individual errors rather than for the multitude of causes which contribute to error, a lack of multidisciplinary integration in a wide-ranging consideration of the culture of safety. The paradigms of a medicine which is managed by means of guidelines, protocols and limits on the autonomy of the professional, far from being a guarantee against error, on the contrary appear to operate as a new source of opacity and repression in the information processes which undermine confidence within the group. The implementation of authoritarian and technocratic protocols runs the risk of becoming the fourth factor militating against greater safety, together with the three already discussed: belief in the invulnerability of the 'good, competent' doctor, blaming the individual, and a focus on active errors while neglecting latent errors.

In conclusion, I believe that it is only through a systematic, blame-free approach, based on scientific optimism and social trust, that we can begin to map out the long and difficult path towards a safer medicine. Please ignore the title of this paper. Let us start by considering and discussing safety and let us stop talking about error, because we need to understand that it is impossible to prevent errors but it is both imperative and possible for us to build safer health systems (if errors and their phantoms do not make it impossible). Thank you.

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**The management
of medical errors**

Ricardo de Lorenzo

The Current Situation Regarding Civil Liability Insurance Policies for Health Professionals and the Award of Injury and Damages Compensation Different Jurisdictions

1. Introduction

In Spain, the issue of the civil liability of health professionals, which appears inevitably to be considered in terms of the guilt or negligence of the individuals concerned, is covered by two branches of the legal system: the civil legal system, which governs disputes between individual parties, and the administrative legal system, which governs the operations of organs of the state, and handles complaints from other parties in this regard. In the Civil Code it is specifically addressed by the reform of article 9.4 of Act 6/1985, of 1 July (Basic Legislation on Judicial Power). And in the administrative legal system it is addressed by Act 29/1998, of 13 July (Regulating the Jurisdiction for Suits Under Administrative Law), giving the administrative legal system competencies in all issues regarding the liability of staff employed by the Public Health Authorities.

The introduction of this legislation has opened the way in Spain for an alternative to the civil liability system for health professionals: that of objective liability (or liability without fault), which is endorsed by the law for a series of common activities which generate certain risks, such as motor traffic and, in the health sphere, the liability of drug manufacturers (Defective Products Act and General Law for the Protection of Consumers and Users) and the Public Health Authorities (Act for the Legal Regulation of Public Administrations and Shared Administrative Procedures).

The nature of medical activity and the social context both provide a basis for the notion that objective identification of liability can be applied to the medical profession. Recently, we have seen that the First, Third and Fourth Chambers of the Supreme Court has established jurisprudence in ruling on claims for damages against health professionals in the course of treating patients which has increasingly applied objective liability criteria.

This new trend in the treatment of the liability of health professionals inevitably leads towards a reconsideration of the civil liability of doctors, given the unquestionable importance of their activity and its potentially undesirable consequences in the light of the following developments:

1. Medical science, in our society, has become increasingly sophisticated, employing ever more complex technical and scientific resources.
2. This has given rise to more effective medical practice, but also to one which is more aggressive and entails a higher incidence of risk for the patient.
3. The increased risk related to medical diagnosis and treatment has generated insecurity and fear among health professionals concerned about the potential legal and financial consequences of performing their professional duties.
4. At the same time, patients are better informed and exercise the autonomy granted to them by the law, with the result that they submit more claims for damages.
5. Finally, as a result of medical treatment, patients suffered reduced functions or disability in their daily activities as a result of medical action or treatment rather than the pathological process itself, and these are not always covered by insurance (or, when such coverage exists, it may be inadequate).

These considerations, raised by health professionals and their professional and trade union representatives on several occasions, gave rise to the agreement that the Public Health Authorities would take out a civil liability insurance policy (originally civil and subsequently employers' liability) to cover the risks deriving from the performance of health activities. (Initially this operated in the sphere covered by Spain's national health service, INSALUD, and it was then extended to all the Regional Health Services.)

The signing of these insurance policies to cover the risks involved in practising as a member of the medical profession benefited health professionals by transferring the insurance burden to their employers, something which was achieved without a concomitant relaxation in standards. Not only are these assessed by the Insurance Company as part of its exclusion clause, but in

addition, in accordance with medical and professional ethics, the individual health professional may still be held liable under criminal law. At the same time, the patient also benefits from financial compensation if he suffers injury as a result of diagnosis or treatment.

The existence of this type of insurance policy has also enabled legislators and legal bodies to extend the scope of civil liability, introducing objective elements of liability based above all on the concept of the risk inherent in medical activity. It has already been noted that the establishment of such liability insurance was the fruit of an agreement between Health Authorities and the professional and trade union representatives of health professionals, and also that the insurance premium is paid in full from the budgets of these authorities.

However, recent circumstances seem set to have a major influence on the issue of the insurance of health professionals. In the first place, civil liability insurance for health professionals is affected by the influence on insurance companies of the repercussions of the bombing of the Twin Towers on September 11, 2001. This will undoubtedly have consequences such as generalized recourse to reinsurance, the concentration of risks by means of the issue of coinsurance policies, withdrawal from the insurance of health professionals, and even, either temporarily or permanently, the refusal of insurance companies to issue insurance for objective liability.

Secondly, now that the functions and services of the Spanish national health service, INSALUD, have been transferred to Spain's Autonomous Regions, upon expiry of the current policy with Zurich S.A., each of the Regional Health Services will have to draw up an individual rather than a collective insurance agreement, and this will undoubtedly lead to an increase in the cost of premiums as compared with the current situation.

In the final instance, the aforementioned circumstances will influence the issue of who has to meet the financial cost of the insurance, and nor should we rule out changes with regard to the current situation, such as each Regional Health Service meeting only part of the cost, with medical professionals either personally or through their professional associations having to make up the shortfall.

2. The historic development of insurance contracts agreed by the Spanish national health service

As a result of the increase in legal claims against health staff since the 1980s, almost all Spain's health authorities, both national and regional, proceeded to put in place liability insurance contracts to cover any compensation rulings against their employees or other staff. In addition, when the care activity is not provided directly by the authorities but is instead supplied using an indirect arrangement such as a contract or agreement with a private entity, the public authorities insist that the administrative clauses which govern such arrangements ensure that the health centre with whom the agreement is signed holds its own civil liability insurance.

There are a number of reasons for the increase in insurance, ranging from the introduction of democracy in Spain, through a growing awareness among citizens of their rights, to the possibility of lodging claims for damages with the different branches of the legal system (civil, criminal and administrative), or the gradual shift towards the English-speaking world's system of 'patient autonomy', away from that of 'beneficent medicine'.

However, perhaps the main cause for the rise in claims for damages should be sought in Act 14/1986, of 25 April, General Health Legislation, and the inclusion therein, at the express recommendation of the Public Ombudsman, of article 10, regulating patients' rights. In this context, in 1987 Spain's National Health Service organized a workshop on the Civil and Criminal Liability of Health Professionals, and this was followed in 1990 with another course on Patients' Rights. The conclusions drawn up at the end of these highlighted, in point II. 6, the need to establish civil liability insurance for the staff of Health Institutions which depend on the Managing Entity. This conclusion was given legal backing in the Resolution of the General Department for Employment of 10 August, 1990 (Official State Gazette of 8 September), publicizing the agreement signed between the State Health Administration and the CCOO and CSIF trade unions, which included the decision of the Administration to agree a "professional liability insurance in the sphere of the nation-

al health service, subject to legal authorization and the provision of the corresponding budgetary credit”.

On the basis of this, the Additional Sixth Provision of Act 31/1990, of 30 December, on General State Budgets for 1991, established the possibility of taking out insurance policies to cover the professional civil liability of staff working for the Public Administration and the Management Bodies and Shared Services of the Social Security Department. Observe that taking out insurance cover, something which in the private sector would be very easy, in the public sector required legislation to be passed. This decision responded to demands raised both by specialists in the area and professional and trade union organizations in the health sector.

Spanish National Health Service insurance for the period 1991-1992

On 8 March 1991, as the result of a public tender process, the Spanish National Health Service signed an insurance policy with the company La Unión y el Fénix Español, and a panel of co-insurers for the years 1991 and 1992. Use of this policy was regulated by INSALUD Circular 11/1991, on instructions for the administration of the liability insurance policy signed by Spain's National Health Service, INSALUD. Upon expiry of the policy on 1 January 1993, and for reasons which were never properly explained, the service was without insurance cover during 1993 and 1994. From 1 January 1995, again after a public tender process, a new insurance contract was agreed with Mapfre and a panel of co-insurers, and this was extended until 1 March 1998. It was then replaced by a new insurance contract with Mapfre on that date, and this remained in force until 1 March 2000, the date on which the current insurance contract with Zurich, S.A. was signed.

Main conditions of the insurance policies

The original contract insured the direct and/or objective civil liability of INSALUD health staff (over 125,000 people) and related costs. The value of the contract was 225 million pesetas per year [€1.3 million] with the follow-

ing financial limits: 40 million pesetas per victim [€240,000]; 80 million pesetas per injury [€480,000]; and an annual limit of 500 million pesetas [€3 million], with an excess for material damages of 250,000 pesetas [€1,500]. The insurance included compensation for damages and expenses, legal defence, payment of legal or non-legal deposits, costs and expenses relating to the injury, and expenses and defence (lawyer and attorney) arising from medical, surgical and pharmaceutical care (both ordinary and emergency) provided with the service's own resources or through contract, and home care and transfer of patients.

The time limit on the policy covered damages caused by events occurring between 1 January 1991 and 31 December 2002, and claims submitted no later than twelve months after conclusion of the contract (that is, until 31 December 1993) for events occurring during the term of the contract and whose consequences had been observed during the period noted above, following the jurisprudence established by the First Chamber of the Supreme Court regarding the 'claim made basis'.

The financial figures for 1991 are far lower than those contained in the policy signed with Mapfre in March 1998, which were as follows: total value of policy 1,545 million pesetas [€9.3 million], limit per victim: 60 million pesetas [€360,000], limit per injury: 120 million pesetas [€720,000] and excess 500,000 pesetas [€3,000]. These, in turn, are far lower than the sums contained in the policy currently in force in the areas managed by the Spanish national health service INSALUD on 1 March 2000, signed with Zurich, S.A, valid for three years and which may be extended for a further three years. These figures are as follows: total cost of premium for period from 1 March 2000 to 28 February 2003: 9,261 million pesetas [€56 million], limit for professional/employer's civil liability: 140 million pesetas per injury [€840,000], limit for operator's/employer's civil liability 1,600 million pesetas per injury [€9.6 million], limit for employer's civil liability or workplace accident: 1,600 million pesetas per injury [€9.6 million], for all coverage, a sub-limit per victim of 66 million pesetas [€397,000] and an aggregate limit throughout the term of the contract of 12,000 million pesetas [€72.12 million], guaranteeing the expenses and imposition of deposits

within the limits stated above; finally, the excess rises to 500,000 pesetas [€3,000].

The following conclusions can be drawn from the study of these three policies:

- a) Very significant increase in the size of the premium each time a new insurance policy is signed, despite the fact that the risks insured in each of these three policies were similar and without a significant increase in the number of people insured.
- b) The insurance policy was agreed at least partly in response to the wishes of health professionals, but analysis of them reveals that the total number of claims, for each of the policies, is lower than might have been expected, both in terms of the number of individual claims and the amounts claimed.
- c) For each of the insurance policies, during the first year of its term, the number of claims submitted was low, perhaps due to the necessary period of adaptation for the health authorities together with the fact that injuries and after-effects as a result of medical treatment often only manifest themselves some time after the treatment has occurred.
- d) The areas where patients are most likely to die (emergency) or where injury is most evident (surgery, gynaecology or traumatology) are also those where there are the most claims, in common with the rest of the western world.
- e) With regard to financial compensation, it should be noted that spinal injuries (leading to paralysis etc.) are the ones which generate the most compensation awards, although injury as a result of anaesthesia resulting in coma or permanent neurological damage led to the highest individual awards.
- f) Insurance, while improving the working environment of health professionals, has also been used as a system for evaluating the quality of care and as a starting point for studying the management of health risks.
- g) It is also worth noting the large number of cases which have been solved out of court, the speed of compensation payment in such cases (and corresponding savings in interest for late payment, and legal costs) and the

benefits the entire health system derives from the fact that health professionals have the confidence to abandon 'defensive medicine'.

3. The legal position of insurance companies in administrative procedures for employer's liability

If the individual has the right to receive compensation from the authorities in the event that the latter are liable, in accordance with the administrative procedure regarding employers' liability, it is clear that if the injured party is an insurance company, then this party has the right, just like any individual, to claim compensation from the administration which has caused the injury, through the administrative liability procedure. Likewise, if the injured party holds injury insurance and the insurance company has paid out compensation, there should be no legal obstacle to the latter exercising the rights of the insured party with respect to the Administration and, therefore, initiating the corresponding administrative procedure for employer's liability as, in accordance with article 43 of Act 50/1980, of 8 October, on Insurance Contracts "the insurer, after paying compensation, may exercise the rights and take those actions which as a result of the injury correspond to the insured party with respect to the persons responsible for it, up to the limit of the compensation."

With respect to the insurance company's right to claim against the Administration, it is important to note the following:

- a) The insurer's claim is made on its own behalf, as a result of its replacement of the insured party due to payment of the compensation under the insurance contract, and there is therefore no need for a power of attorney from the insured party, because the insurer is not acting on his or her behalf.
- b) Therefore, except where the company itself is the injured party, such action can only be taken when the insurance company has paid compensation to the insured party, as these are the only circumstances under which the company assumes the insured party's rights.

- c) The insurer exercises its claim against the Administration by lodging an administrative procedure for employer's liability, in which it must demonstrate the basis on which it is acting, that is, the payment of compensation to an individual with whom it has an injuries insurance policy and who has suffered injury as a result of the operation of public services.
- d) The maximum amount the insurer can obtain from the Administration is the amount which it has paid to the insured party, as the acquisition of the rights of the insured party only applies "up to the limit of compensation". As a result, if the injury insurance establishes an excess limit where compensation is not payable by the company, the right to obtain compensation from the Administration for an amount up to this limit corresponds to the insured party, with the result that either both the insurer and the insured party jointly lodge the administrative procedure for the compensation paid and for the amount of the excess, respectively, or this is done solely by the insurer, acting both on its own behalf and on behalf of the insured party (with respect to the excess), providing evidence of the power of attorney granted by the latter.

From the above it is clear that in any other situation in which the claim for compensation is directed by an insurance company against the Administration which has caused the injury, that is, when the company is not the injured party and has not paid out any compensation to the insured party, the insurance company has no basis for launching an administrative procedure for employer's liability, as this is something that only the injured party may do, with the result that if the insurer wishes to launch such a procedure on behalf of the injured party, as often happens, then it can only do so if it shows that it has power of attorney, and this is true even where it provides legal insurance, because under such policies the insurer undertakes to meet the costs of the insured party as a result of legal action and to provide legal support services, but this does not of itself include representation of the insured party.

Insurance companies should, then, be aware of these restrictions, deriving from the particular way in which the Administration's liability is configured, whatever the legal, public or private relationship, and must avoid simply applying the same pragmatic procedures which they use when lodging claims

against other insurance companies or private individuals. When lodging a claim against the Administration, companies enter the world of administrative law and must comply with all the requirements if their claim is to be effective. Likewise, the Administration should remember that its liability is decided by this administrative procedure, with the result that, as in any other procedure, if a party (for example, the insurer) is acting in representation of another, it must demonstrate the basis on which it is acting. Should it fail to do this, the Administration must grant it a period of ten days in which to correct this failure, after which period the procedure is suspended should the failure not have been corrected. However, should the Administration, notwithstanding the failure to demonstrate the basis of the representation, settle the claim, it may not then at the appeal stage use this failure as a basis for contesting the decision or for arguing for the suspension of the procedure.

Claims for compensation against the Administration and the insurance company for employer's liability

The issue is, of course, more complicated when the injured party or its insurance company lodge its claim against the Administration and the company which insures its employer's liability, as is the case in the INSALUD insurance. We should start by repeating that the employer's liability of the Administration is configured as a direct, objective liability, distinct from civil liability, subject to a different legal system, and enforced through a different procedure, and one can only talk of the civil liability of the Health Administration, or of the staff in its service, with relation to the subsidiary or direct liability deriving from a criminal offence. Therefore, outside of this criminal context, the Administration bears no civil liability but rather the employer's liability, and for this reason there can be no civil liability insurance for the Administration, only employer's liability insurance.

However, there is no legislation which specifically regulates the Administration's employer's liability insurance as one of the forms of insurance against damages, as a result of which the regulations governing civil liability insur-

ance contained in articles 73 to 76 of the Insurance Contract Act are often considered to be applicable, and many insurance contracts agreed by the Administration even refer to them. In reality, because this is a different kind of insurance, this legislation should not apply to it. Article 73 of the Insurance Contract Act, for example, when defining civil liability insurance as that by which the insurer undertakes to compensate third parties for damages as a result of acts of the insured party covered in the contract and for whose consequences the insured party bears civil liability under the law, does not include the Administration's obligation to compensate for damages caused by the operation of public services for which it is administratively responsible.

Article 74 of the Insurance Contract Act provides that the insurer will assume the insured party's legal responsibility with respect to claims for damages, something which is not possible in the case of the Administration's employer's liability because, as stated in article 447 of the Basic Legislation on Judicial Authority, its representation and defence is the responsibility of the Lawyers of the Administration's Legal Services (State Lawyers, Legal Advisors of the Social Security Service, Lawyers of the Regional Government of Catalonia, etc.).

Article 75 of the Insurance Contract Act provides, in certain cases, for the existence of compulsory civil liability insurance, something which does not exist in the case of the Administration's employer's liability, which is designed to provide the maximum assurances to health professionals through the establishment of the direct liability of the Administration.

And article 76 of this Act attributes to the injured party the right to take direct action against the insurer, without prejudice to that person's right to claim against the insurance holder in the event of damage due to the negligence of the holder. This rule only makes sense within the context of civil liability, where the injured party is being granted an additional guarantee by being able to claim directly against the insurer or against the insured party, but makes no sense in the context of employer's liability, which is measured objectively and is claimed directly from the Administration, where the injured party, in theory, is already fully guaranteed. As a result, there is no 'direct action' in the sense of a civil action against the company providing the

Administration's employer's liability insurance. Nor is article 76 of the Insurance Contract Act applicable, and indeed its application would make no sense. This is clearer if we consider the implications of allowing plaintiffs to lodge a civil claim against the insurer without a coexisting civil action against the Administration or the staff, particularly where there is no longer the possibility of choosing the more favourable option offered by Civil Legislation, the traditional basis for making a claim against the Administration and other parties with joint liability or to make a joint claim against the Administration and its insurer. Instead, the aim has been to unify all claims regarding the liability of the Health Administration under that part of administrative law which governs disputes and claims, even when such claims involve liability which is shared with private parties.

Nor is it possible to lodge a direct civil action against the company insuring the Administration's employer's liability, if we bear in mind that this has to be declared by the Administration through the corresponding administrative procedure. As a result, even if such a civil action were admitted, it could only succeed if the aforementioned employer's liability had previously been declared either by administrative procedure or in the ruling on an administrative dispute.

Furthermore, the employer's liability insurance contract of the Health Administration is not a private contract and is not, therefore, regulated by private law, like the Insurance Contract Act, but is instead regulated as an administrative contract, covered by Royal Legislative Decree 2/2000, of 16 June, which approved the Revised Text of the Public Administrations Contracts Act, as a result of which the Health Administration has powers to interpret the contract, settle questions regarding compliance, modify it for reasons of public interest, suspend its execution, and agree its cancellation, and the Regulations on the Jurisdiction for Suits Under Administrative Law also apply to the settlement of disputes regarding the interpretation, modification, termination and effects of the contract.

In conclusion, the INSALUD employer's liability insurance contract (and, following the transfer of competencies, the contracts of Spain's Regional Health Services) is an administrative contract which is not governed by the

Insurance Contract Act. For this reason, it is not possible to launch a direct civil action against the insurance company, nor to jointly sue both the company and the Administration through the civil courts. And it must therefore be concluded that any claims for compensation against the Administration and the insurance company regarding employer's liability must be pursued through the administrative system. In other words, the company has the status of interested party in the administrative procedure with respect to the Administration's employer's liability, and is directly affected by the ruling issued by this procedure. Although this ruling may be suspended, it is in principle a firm ruling against which all of the interested parties, including the insurance party, may lodge an appeal through the administrative disputes tribunal.

Traditionally there has been a reluctance to recognize the insurance company as an interested party in administrative procedures for employer's liability, no doubt due to the difficulty of reconciling the rigid concepts of civil law with the particular nature of objective, direct administrative liability. It does not appear, however, that the intention of the legislators was to prevent insurance companies from being classified as parties to administrative procedures, as both Basic Legislation 6/1998 (Reforming the Basic Legislation on Judicial Power), and Act 29/1998, of 13 July, sought to unify all demands regarding employer's liability in the Regulations on the Jurisdiction for Suits Under Administrative Law, including those involving private parties, with the aim of preventing legal actions being spread across a range of jurisdictions and ensuring the consistency of case law, as stated in the statement of the reasons for introducing the Act.

The reference to private parties demonstrates the degree to which the legislators wished that such parties' joint liability with the Administration be resolved by the procedures for settling administrative disputes, for which purpose it is necessary that these parties have acted as interested parties in the administrative procedures for employer's liability. It is true that neither the aforementioned laws, nor Act 30/1992, of 26 November, in regulating the employer's liability of the Administration, expressly attribute to the insurance company the condition of interested party. However, the reason for doing so is the same as for interested private parties and the insurance company not

only has a legitimate interest but indeed a direct interest in so far as the insurance coverage and the administrative declaration of liability mean that it will be obliged to compensate the injured party.

Therefore, in the administrative procedure for the employer's liability of the Administration, which may be initiated either as a result of a legal ruling or at the application of the injured party, the parties will include the contractor, any joint parties (including other Public Administrations in the event of joint liability), the authorities and the staff working for the Health Administration responsible for the procedure in so far as this may have been guilty of negligence or incompetence, and the insurance companies of all of these, including the insurer of the Administration responsible for the accident in so far as this may be the object of insurance cover, and the company may be obliged to pay compensation. However, when the Administration considers that the injury is not covered by the insurance, or the amount of any compensation due is lower than the excess, there is no need to recognize the Administration's insurance company as an interested party as it has no legitimate interest in the administrative procedure.

Although the principal purpose of the employer's liability administrative procedure is for the Administration to accept or deny this liability, there is nothing to prevent the procedure also issuing a ruling as to the potential liability of the parties mentioned in the preceding paragraph. On the contrary, article 89.1 of Act 30/1992, of 26 November states that "the ruling which brings an end to the procedure will decide upon all the issues raised by the interested parties and any others deriving therefrom". Subject to its having heard the insurance company, the procedure may decide whether the injury is covered and, if so, declare the liability of the Administration and that of the insurance company by virtue of the administrative contract which binds it to the Administration.

Furthermore, the intervention of the Administration's insurance company as an interested party to the administrative procedure is desirable for the injured party, for the Health Administration and for the insurance company. The patient, if a favourable ruling is obtained, may then press its execution with respect both to the Administration and the insurance company. For the

Health Administration, a single administrative procedure may resolve both its employer's liability and the question of whether the injury is covered by the insurance contract, without any requirement for a second administrative procedure for this purpose. For the insurance company, it provides the opportunity to submit its practical experience to the administrative hearing, thereby avoiding a potentially negative decision being reached without the company having the opportunity of a hearing and, should it disagree with this decision, it may appeal against it to the administrative court system where it must, however, apply for suspension of the execution of the decision against which it is appealing if it wishes to prevent the decision from being applied to it.

By virtue of the above, a range of situations may arise, of which the following are the most frequent:

1. The Administration resolves the administrative procedure by declaring itself liable, without the insurance company being given a hearing, in which case the ruling, which is a declaratory judgement, may only be revised to the prejudice of the injured party in accordance with the strict procedures of 102 and 103 (review of void and reversible rulings) of Act 30/1992, of 26 November, and the Administration must indemnify the injured party, without prejudice to its right to demand from the insurer the amount of the indemnification through a second administrative procedure based on the competencies of the Administration with respect to the administrative insurance contract. If, after this second procedure or the corresponding appeal, it transpires that the injury is not covered by the policy, the Administration will not have been compensated by the company nor, of course, by the private individual.
2. The Administration concludes the procedure by rejecting the claims of the injured party, in which case the latter may lodge an appeal against the ruling, and the insurance company will be the co-defendant. If the patient obtains a favourable ruling, he or she may execute this ruling with respect to the insurance company and the Administration, so long as, in the case of the insurance company, the ruling has declared the injury to be covered by the insurance.
3. The Administration concludes the procedure by accepting the claim, after hearing the insurance company, which states its agreement with the coverage and the compensation, in which case the injured party may execute the ruling with respect to the Administration and the insurance company. Normally, the insurer will then pay out immediately, but if payment is made by the Administration then the latter may, in execution of the ruling, charge compensation to the company.
4. The insurer pays the injured party before conclusion of the administrative procedure, in which case, the injured party having signed a waiver as to any other claim against the company and the Administration (as usually occurs in practice), both the company and the Administration are discharged of any other liability to the injured party, except for exceptional cases of aggravated damages.
5. The Administration concludes the procedure by accepting the claim. If the insurance company does not agree with the coverage stated in the ruling or with the existence of employer's liability, or with the amount of compensation agreed, it may lodge an appeal against the Administration and the injured party, and the insurer must secure suspension of execution of the decision if it wishes to prevent the decision from being applied to it, without prejudice to whether the decision is applied to the Administration. The effects of any estimatory ruling will depend on the reason for the estimation; if this occurs due to the absence of coverage it will not give rise to the return of any moneys received by the patient, but will instead prevent the Administration from demanding compensation from the company, while if it occurs due to the absence of employer's liability or sets a lower level of compensation, this will give rise to the return of the corresponding amount by the patient and will enable the Administration to receive compensation.

4. The damages insured and competing jurisdictions

Although current Spanish administrative law has the effect of bringing all procedures involving claims of employer's liability of Public Health Authori-

ties within the sphere of the administrative branch of the law, due to the range of legal relationships existing within the private medicine sector –leasing arrangements for the provision of services and performance of works and employment contracts (temporary and permanent), in addition to the involvement of the Criminal courts in those acts which may constitute a criminal offence– it is necessary to provide at least a brief summary of the criteria which determine damages and compensation in the different jurisdictions to illustrate the complex nature of managing different insurance policies.

Claims for compensation for damages caused by the employer and employees in the context of the employment relationship

One of the most notable features of employment contracts in comparison with civil contracts is the greater degree of state intervention. The existence of a detailed regulatory framework which is far more extensive than the Civil Code constrains the range of possible agreements between employer and employee. The reason, in the employment sphere, for limiting the principle of freedom of agreement so cherished by classical Civil Law, is the socio-economic inequality which generally exists between employer and employee. This inequality means that unregulated employment contracts would actually be the expression of necessity rather than of free choice. Our legislators, following the mandate of article 2.2 of the Spanish Constitution, has issued a series of laws designed to compensate for this inequality and which guarantee certain rights which would presumably either not exist or be very rare in the hypothetical case of a completely liberal State.

As was indicated by the Constitutional Court in its Ruling 3/1983, and subsequently repeated, Employment Law, “is legislation established in order to correct and compensate for, at least in part, the fundamental inequalities” which derive, “from an underlying inequality between worker and employer which is based not only on the different economic condition of each party but also on their respective positions in the specific legal relationship which

binds them, which is one of dependency or subordination,” a subjective inequality “which is not altered by the consideration of exceptional circumstances.”

Legislative intervention in the employment contract has also affected specification of how compensation should be made for injuries incurred in the performance of this contract. In general, employment legislation indicates how much money or which clearly specified actions are required as compensation for the injury caused, without gradations for different situations, providing objective and complete compensation and leaving no space –unlike the situation which occurs in civil legislation– for a test of the damages caused which might justify a higher level or different form of compensation, irrespective of whether the offender has been guilty of serious negligence or even wilful misconduct. In this way, then, the legislation is generally governed by the principle of fixed compensation with the exception of damages and injuries caused by the health provider –or its employees– to the patients.

Indeed, in the majority of employment relationship contexts, with the exception of health damages, the jurisprudence of the Fourth Chamber of the Supreme Court has repeated the criterion of exclusive compensation for workplace injuries on the basis of the specific employment legislation which specifies the value of this compensation. An example of this doctrine is the Ruling of the Social Chamber of the Supreme Court of 3 April 1997, regarding a situation in which a worker terminates the employment relationship on the basis of article 50 of the Statute of Employment, due to a substantial modification of the employment contract affecting his personal dignity. The employee received the legally stipulated compensation of 45 days salary per year worked. The plaintiff believed that this did not compensate him fully for the damages suffered, and therefore formulated a new demand for compensation based on article 1.101 of the Civil Code, which was admitted by the Chamber of Employment Law of the High Court of Justice of the Basque Country. In its appeal ruling on this case, the Court ruled that the worker could, on the basis of employment legislation, demand that the employer comply with its obligations, or request the termination of the employment

contract, with compensation for damages in both cases. As the worker opted for the termination of the employment relationship, the compensation applicable should be set in accordance with the legislation regulating the employment relationship and, as the Employment Statute contains a specific provision (article 50) to regulate such situations of non-compliance, this must be applied and it is unlawful to have recourse to laws drawn from other legislative spheres, whose isolated application would lead, against all logic, to punishing a single act of non-compliance twice.

However, with respect to compensation for damages caused by the actions of the employer –in some cases– and more frequently by the employees or staff working for the Health Administrations, faced with the non-existence in the employment legislation of any regulations setting compensation for such situations, the body applying these laws is obliged to turn to other regulatory spheres to set the level of compensation (the scale of damages of the Private Insurance Regulation Act, or article 1.103 of the Civil Code which empowers Judges and Courts to moderate the obligation) and, furthermore, it is understood that a single act –the injury caused by the action of the employees or staff with respect to the patient– may give rise to two compensation payments, namely: a) compensation for the damages caused and b) award of a pension for the limitations which the injury imposes upon the individual's employment capacity, and this double compensation has been justified legally on the basis that the legislation, the requirements for recognition and payment of both compensations are different.

With respect to the criteria for determining and quantifying the damages suffered by the injured party, used in the employment sphere, it should be noted that, according to the usual classification, patients may suffer two types of damage: material and moral. According to the Ruling of the Fourth Chamber of the Supreme Court of 3 June 1991, the material damages include among others “those which affect the injured party's wealth and whose value can be estimated”. These are specified (article 1.106 of the Civil Code) as emergent damages (amount of wealth lost as a consequence of the offender's behaviour), and loss of income (wealth which is not obtained as a consequence of the behaviour). Likewise, material damages should include the personal,

physical damages suffered by the patient, referred to in the Ruling of the Constitutional Court 181/2000, for which compensation should be awarded so as to “leave the victim in a situation as close as possible to the situation which he would enjoy had the injury not occurred, thus rendering the traditional civil principle of full reparation a necessary element of the civil system for personal damages. As it is not possible to restore the victim's physical and moral integrity or living circumstances, the legislator must choose from among the different remedies available to provide civil reparation for physical damages that which, in each case, comes closest to providing full compensation for the damage suffered by the victim.”

Moral damages, according to the Chamber of Employment Law of the Supreme Court, are those which affect other non-financial spheres, whether of an emotional nature, such as feelings, or those of a social nature, and also include other situations which give rise to effective and far-reaching moral damages. Although these damages are necessarily of a relative and imprecise nature, jurisprudence fully accepts the need to compensate them.

The objectification of material damages is achieved, in employment law, with relative ease. With respect to loss of wealth, in the employment context the test is usually simple, as it normally equates to the lost salary which is measured using stable parameters (payments received by the patient until the moment of suffering injury, or which the patient's uninjured colleagues have continued to receive, or salaries determined by generally applicable legislation, such as a collective wage agreement). Emergent damages must be evaluated with reference to the most robust and objective scales available and specified in a precise, detailed manner by the plaintiff in the original submission.

When concerned with damage, such as that deriving from the errors of health professionals, which affects a person's physical integrity, the Constitutional Court, in ruling 181/2000 has stated that “the translation of life and personal integrity into economic terms requires the establishment of compensation guidelines which are appropriate in the sense that they respect the inherent dignity of the human being,” and must by means of this compensation attend to the integrity of the individual's entire being, without unjustified exclusion

and, as an example of a possible scale, the Judges and Courts of the Employment Law system accept appeal by analogy to Act 30/1995 (Regulation and Supervision of Private Insurance), in connection with the ruling of the General Insurance Directorate of 24 February 1998, setting out physical damage, and without prejudice to the limitations imposed upon these criteria by Constitutional Court Ruling 181/2000 with regard to ‘relevant guilt’.

Moral damage in Employment Legislation is extremely difficult to measure objectively, and the Ruling of the Chamber of Employment Law of the Supreme Court of 9 May 1984 states that the determination of this type of damage is left to reasonable legal judgement which, moreover, can only be overruled by higher courts in the case of clear error or disproportionate compensation.

Damages and criminal jurisprudence

As in Employment Law, so in Criminal Jurisprudence it has traditionally been argued that the right to full reparation is a general principle of our legal system. The 1st article of Resolution 7, approved on 14 March, 1975 by the Committee of Ministers of the Council of Europe with the aim of reducing the differences between the legislation of member states with respect to injuries and deaths, clearly defines this principle: “the person who has suffered damage has the right to compensation for this damage suffered so that he is restored to a situation as near as possible to that in which he would have been if the act for which compensation is claimed had not occurred.”

Therefore, as a consequence of the above, Spanish criminal law is governed by the principle of free determination of the compensation, autonomy of the judge to state the applicability of compensation and its amount, in accordance with the outcome of the appropriate test (article 741 of the Criminal Trials Act). Article 104 of the Criminal Code of 1973 put the method for assessing damages on the same footing as that contained in article 103 for damage to property: “reparation will be made by evaluating the scale of the damage in accordance with the instructions of the Court, in light of the price of the item, wherever this is possible, and the effect on the injured party.”

Jurisprudence, in general, had understood this legislation to grant the judge almost absolute discretion. We can also cite Supreme Court Ruling of 7 April, 1980, according to which: “... article 104, which with respect to compensation refers to article 103 which specifies that compensation will be based on an estimate of the scale of the damage as instructed by the Court taking into account among other factors the effect on the injured party. Such statements assume that Criminal Jurisdiction enjoys absolute independence in reaching a reasonable judgement as to the amount of reparation and compensation, without being bound by the rules and compensation which strictly govern employment, civil and other non-criminal legislation ...” The sole limitation came from the possibility of reviewing at appeal the basis of the compensation established in the original ruling (Criminal Chamber of the Supreme Court of 13 March, 1981) and respect for the petitionary principle (Criminal Chamber of the Supreme Court of 7 April, 1980).

Notwithstanding the above, we find ourselves facing the pre-eminence of Criminal Jurisdiction, which expresses itself in the prejudicial value of the criminal ruling over the civil action, whose purpose in this area is to avoid simultaneous procedures regarding the same actions, thereby preventing discrepant or even contradictory rulings being issued. This was the explanation given by the old Rulings of the Criminal Chamber of the Supreme Court of 21 March, 1907 and 28 April, 1917. This issue finds expression today in article 10.2 of the Basic Legislation on Judicial Power. The repealed Criminal Code of 1973, in the wording ascribed to it by the Basic Legislation of 25 June, 1983, already based liability on guilt. In similar terms, the Criminal Code of 1995 and, in particular, article 5, states very clearly that “there can be no punishment in the absence of guilt or negligence.”

It is therefore not sufficient that we find ourselves dealing with a typical, unlawful action which can be attributed to a specific individual. What is decisive, when deciding upon compensation, is whether the author of the action has acted wilfully or negligently. The requirement of criminal responsibility brings with it the civil liability deriving from the offence committed, unless the injured party renounces this or reserves the right to pursue it through the civil courts once the corresponding criminal process has been

completed, ex articles 100, 107 and 116 of the Criminal Trials Act and 109 and following of the current Criminal Code.

The jurisprudence of the Criminal Chamber of the Supreme Court has identified a set of general, guiding principles to determine the corresponding amounts of compensation, and we can note that:

- a) The ruling should apply the same levels of damages, in so far as possible, as if it were dealing with a civil action pursued independently of the criminal action.
- b) The estimation of the actual amount of damages awarded must be reasonable, taking into account all the legal circumstances (Ruling of the 2nd Chamber of the Supreme Court of 6 March, 1989).
- c) Rulings may not award more than has been applied for; in no case may the compensation awarded give rise to unfair enrichment for the injured party (Ruling of the 2nd Chamber of the Supreme Court, 25 May, 1991).
- d) Compensation covers material and damages, and rulings must specify which elements correspond to which damages (Ruling of the 2nd Chamber of the Supreme Court, 3 December, 1991).
- e) Compensation also covers the legal interests of the old article 921 of the Civil Trials Act (now, article 576 of the current Civil Trials Act).

The financial consequences of this situation gave rise to a crisis of the principle of full compensation, and there were calls from several sources for the introduction of a system of limits to the amount of compensation. The proposal that the legislators establish binding limits on compensation for the Courts has given rise to different opinions, above all when comparing the system established with the criterion drawn from the Criminal Code and articles 1.902 and 1.903 of the Civil Code and the jurisprudence applicable in this regard. In its interpretation and application, it is clear that this constitutes a restriction on reasonable legal judgement when determining compensation. However, the inequalities and disproportionality to which the setting of compensation by different judges and courts gives rise has made it clear that a legal practice typified by widely varying amounts of compensation for supposedly equivalent events justifies the imposition of criteria to be applied to the valuation of damages and injury

which are uniform in the case of events whose harmful impact on the injured party is equivalent.

At the same time, to justify the scales-based solution, recourse is made to constitutional principles. The disproportion which had been observed in compensation awards runs counter to the principle of equality before the law, endorsed by article 14 of the Spanish Constitution. But the Courts, as public powers, are bound by this principle of equality before the law which obliges them to treat all citizens equally, and this includes equal protection in the event of injury or damages due to unlawful acts.

Recently, the Second Chamber of the Supreme Court settled the controversy with respect to the issue of compensation and has issued several rulings regarding the obligatory nature of the scale, applying the Ruling of the Constitutional Court 181/2000, of which, among others, we may cite:

– *Ruling of 20 December, 2000.*

It is claimed, in the appeal application against the court ruling, that the compensation awarded is higher than that established in the Annex of the Private Insurance Regulation Act, and in the subsequent regulations which update it, and specifically than those established in Table 1 of basic death compensation.

The Chamber has issued various rulings in which it has raised the question of whether or not the scale-based system for evaluation of damages and injury caused to individuals in traffic accidents is obligatory. Act 30/95, of 8 November, on the Regulation and Supervision of Private Insurance states, in its Preamble, that this compensation system applies independently of the existence or otherwise of insurance and of the quantitative limits of compulsory insurance, and is expressed by means of a table of fixed amounts in accordance with the different categories of compensation which, taking into account the circumstances of each specific case, make it possible to specify the compensation deriving from the injury suffered. This constitutes a legal quantification of the damages suffered referred to in article 1.902 of the Civil Code.

The Civil Liability and Insurance for Motor Vehicle Traffic Act, in its general provisions, and in particular article 1.2, makes provision that the damages and injuries caused to individuals, including the value of the injury suffered and any actual, forecast or foreseeable loss of earnings as a result of the injury, including moral damages, will in any case be quantified in accordance with the criteria and within the compensation limits established in the annex of this act, which incorporates a system for the evaluation of damages to people caused in traffic accidents, except where these are the result of a criminal offence.

The Constitutional Court, in its Ruling 181/2000, of 29 June, ruled on various issues relating to the alleged unconstitutionality of elements of the Civil Liability and Insurance for Motor Vehicle Traffic Act. The Ruling recognizes that, "... the wording of the legal text gives rise to certain doubts regarding the scope of its binding nature: whether this is restricted to situations of objective liability or risk, and is not binding upon the legal system when the injury involves the relevant criminal or civil liability of the driver of the vehicle and whether, as a correlation, the reparations established are limited to the scope of compulsory insurance cover." It goes on to dispel such doubts, stating that "the legal system also applies and has full effect when the injury involves either the civil or criminal guilt of the driver, that is, that it falls within the scope of objective liability, or due to recklessness." It continues to state that, "at the same time, the scope of application of the legal system for the valuation of damages is not limited to that of compulsory insurance, because, as has been stated, this system is not tied to the compulsory insurance system, as stated in the Preamble ..." And the doubts raised regarding the binding or non-binding nature of the scale are resolved by the statement that "it must be concluded, in summary, that the scale or assessed system introduced by the disputed Act 30/95, as is proper of legislation of this nature, binds judges and courts in everything that touches on the identification and setting, both in civil and criminal courts, of compensation to be paid on the basis of civil liability to repair personal damages arising in the sphere of motor vehicle accidents."

The binding nature of the legal system for the fixed assessment of physical damage is therefore clear, and those opinions based on doctrine and case law

which argued that it was merely orientative or indicative rather than obligatory can therefore be discounted.

– *Ruling of 5 February 2001.*

This stated that the first issue to resolve, regarding the terms of debate, consisted of whether or not the scale established in Act 30/95 was to be applied on a compulsory basis, bearing in mind respect for *obiter dictum* statements of the 1st Chamber of the Supreme Court and the fact that various issues of unconstitutionality raised by different legal bodies remained pending before the Constitutional Court. And it repeats that the doubts raised regarding the binding or non-binding nature of the scale are resolved by the statement that "it must be concluded, in summary, that the scale or assessed system introduced by the disputed Act 30/95, as is proper of legislation of this nature, binds judges and courts in everything that touches on the identification and setting, both in civil and criminal courts, of compensation to be paid on the basis of civil liability to repair personal damages arising."

The panorama regarding the evaluation of physical injury in the civil jurisprudence of the Supreme Court

We note, firstly, that the *Ruling of the Civil Chamber of the Supreme Court*, of 26 March, and highlight the following section of their legal reasoning:

"... the Chamber issuing this ruling takes this opportunity to consider in depth an issue which is of great importance when deciding upon non-contractual civil liability derived from personal injury suffered in traffic accidents; the voluntary or compulsory application of scales which in the first case facilitate and in the second impose objective regulatory criteria in calculating compensation."

With respect to this issue we can draw the following conclusions:

Firstly. The function of calculating injury compensation is expressly attributed by legal doctrine to the judicial organs, who will perform this on a case

by case basis, evaluating the evidence relating to the events, without being bound by any regulatory provisions.

Secondly. That the existence of numerous scales designed to serve as a regulatory element in the widely varying fields of civil and employment liability, and specifically in the sector of injuries resulting from traffic accidents, means that we must examine the scope to be assigned to such scales when reaching a legal evaluation of the damages to be compensated.

Thirdly. The legal problems posed by the acceptance of scales by the legal organs are different depending on whether these are voluntary scales or, as is the case of the scale imposed by Act 30/95, scales of a compulsory nature.

This function of the judicial organs in setting compensation is not one which can be voluntarily abandoned and replaced by the simple application of a scale. Of course, the discretion which the Courts have when quantifying damages does not prevent them from having recourse to the scale as a guide.

However, the compulsory application of the scale would be contrary both to the wording of article 1.902 of the Civil Code and to repeated and long-standing legal doctrine which has always provided the basis for interpretation of the important regulatory principle of compensation for injury caused due to guilt or negligence providing a basis for extra-contractual liability.

The arguments against this indiscriminate and compulsory application not only in the sphere of Compulsory Insurance, as is logical, but also with regard to Voluntary Insurance, include the following:

- a) That it represents a clear limitation on the functions of the courts of justice.
- b) That it undermines the principle of freedom of agreement which informs our Civil Code and which provides the basis for the general theory of civil contracts, giving rise, furthermore, to gains for those who receive a higher premium than is due for compulsory insurance but who only have to meet the limits set by the scale set in this regard.
- c) This directly infringes one of the cardinal rules of our legislation, article 1.902 of the Civil Code.

- d) The compulsory and exclusive imposition of the scale represents an act of flagrant discrimination with respect to injuries due to other causes.
- e) Finally, the right to life and to physical integrity, expressed in article 15 of the Spanish Constitution, appear to be infringed by the compulsory application of scales.

The initial doubts regarding the jurisprudential value of *obiter dicta* considerations were dispelled following subsequent rulings of the Supreme Court, including, among others, the First Chamber:

Ruling of 24 May 1997 "... the function of calculating compensation for damages, both material and moral, is not affected by the annulment and is not subject to any scale."

Ruling of 19 June 1997 "... the function of quantifying compensation for damages is sovereign to the legal organs, which have not just the power but the obligation to evaluate the evidence."

Ruling of 21 November 1998, which was taken as indicative of a potential review of the criterion maintained until that date by the First Chamber of the Supreme Court: "... it is the repeated doctrine of this Chamber that the determination of the value of the compensation is a function attributed to the Chamber and not subject to review unless the factual basis of the decision has changed ..." Nothing prevents the application of the compensation system introduced by Act 30/95. However, it should be noted that, in the event that the judge decides that its application would unjustifiably restrict the right of an injured party to due compensation then the judge should not be bound by it.

As is clear, these rulings of the Civil Chamber of the Supreme Court were issued prior to Constitutional Court Ruling 181/2000, of 29 June, the legal doctrine of which has since been followed by the Civil Chamber of the Supreme Court, but only insofar as it refers to injuries caused by motor vehicle accidents and not to damages caused by medical actions, as is the case with this report –with respect to which the earlier doctrine contained in the legal rulings set out above continues to apply– and the Constitutional Court has declared that "it must be concluded, in summary, that the scale or

assessed system introduced by the disputed Act 30/95, as is proper of legislation of this nature, binds judges and courts in everything that touches on the identification and setting, both in civil and criminal courts, of compensation to be paid on the basis of civil liability to repair personal damages arising in the sphere of motor vehicle accidents.”

The jurisprudence of the Chamber for Administrative Law of the Supreme Court

Although in the ambit of administrative law it is not unusual for legal rulings, by analogy, with respect to injuries caused by the acts of health professionals, to apply the scale in Act 30/95, it should be noted that administrative law, in contrast with civil, criminal and company law, has specific legislation regarding employer’s liability, which is article 141.2 of Act 30/1992, of 26 November, according to which “compensation will be calculated in accordance with the valuation criteria established in the compulsory expropriation legislation, tax legislation and other applicable regulations, giving consideration, where applicable, to the predominant market valuations.”

The jurisprudence of the Chamber for Administrative Law of the Supreme Court regarding the issue which concerns us here can be summarized as follows:

- In principle not only the emergent damages but also the loss of earnings are subject to compensation, in application of the general standard of article 1.106 of the Civil Code. However, while evidence is required regarding the real nature of the damages, when it comes to emergent damages the requirements are more rigorous. This was the reason for the declaration in the Ruling of 3 February 1989 that, “in evaluating this element we are unaware not only of the earnings which could have occurred but indeed of their very existence. As a consequence, these are merely possible or potential damages which are the result of a calculation based on uncertain factors. As a consequence, this lack of certainty together with the failure to submit any proof in support of the application leads una-

voidably to the rejection of this element, as is stated in the proposed ruling.”

- In the employer’s liability procedure, compensation must be determined. Once the basis of the liability of the Public Health Authority has been established, evidence must be provided of the damages to be compensated, and the scale of the award.
- It is clear that, in order to respect the principle of equality before public offices, which constitutes the basis of the civil liability of the Public Administration, there must be complete reparation. The wealth of the injured party should not suffer, and compensation should therefore be equivalent to the loss suffered.
- The Ruling of 5 April 1989 repeats the principle which dominates the regulation of employer’s liability set out in article 106 of the Constitution, of ensuring that the injured party receives full compensation for the loss suffered.
- The Ruling of 18 July 1989, reiterating earlier rulings, establishes that compensation must correspond to the loss caused to the individual by the stated sacrifice of his or her rights and property, but without this becoming a source of gain and, moreover, indicates that “only those losses and damages supported by the actual owner of the property or holder of the rights are eligible for compensation; however, compensation may never become a source of profit or unjust enrichment for the owner of the property or the holder of the rights; therefore, it must normally be restricted to what are called ‘emergent damages’ –which in any case generate the right to compensation– and ‘loss of income’ shall only be taken into account in those cases where this is legally possible on the basis of satisfaction of the necessary requirements and circumstances from which it must derive.”
- The Ruling of 15 October 1990 refers to the principle of full compensation which informs our system for the employer’s liability of the Administration, one of the most progressive. It adds that this principle, which has deep roots which are established in law, has been explicitly formulated by this Supreme Court and consolidated as legal

doctrine, but with the complementary status assigned to it by the Civil Code within the principles of the Law (article 1.6).

- The effect of the employer's liability, states the Ruling of 11 May 1992, just as it may not unfairly impoverish the injured party due to an act or omission, nor may it lead to the party's unfair enrichment, and in this regard, "even if evidence has been provided of temporary incapacity, if this then becomes permanent then the fact that the party has already received compensation for the temporary incapacity would mean that were the claims for temporary and permanent capacity not considered together there would be a partial duplication of compensation, and this is why a joint valuation must be performed, above all if we note that the amount claimed for the consequences of the injury was not accompanied by proof –even though this could have been provided in the form of a medical report– of the degree to which the injury, deformity or other consequences had affected the party's ability to perform his or her professional activities, the irreversible nature of the effects, and the inability of the claimant to perform other jobs or roles compatible with these effects, family responsibilities which he or she was unable to fulfil, etc., for which reason this Chamber recognizes –as has been noted by the Court of the First Instance– the right of the claimant to be compensated in full for the first concept and, in contrast, to reduce by sixty percent the compensation awarded for the second concept; all of the above decisions are ones which we are obliged to take in light of the circumstances of the case and the insufficient certainty with respect to the subjective quantification of the concepts claimed by the appellant."

5. Insurance of the private medical sector

The insurance of health professionals working in private medical centres and the centres themselves is not covered by administrative law, which applies solely to public medicine. When it comes to the selection of an insurer, the

policyholder makes a choice on the basis of principles of publicity, merit and competition, and the agreement is governed by the principle of free will which applies to private law. As a result, a private professional or private health centre which may incur liability as a result of providing professional services has an incentive to take out a health insurance policy, and the basic question which arises in this regard is the maximum premium the holder is prepared to pay.

In general, when calculating the optimum insurance premium to pay, the health professional should start from the notion that the policy delivers an 'expected utility' which is calculated by determining the income or wealth of the individual with and without insurance. Likewise, it should be assumed that the insurance company will seek to maximize the expected benefit deriving from the contract. One should also take into account the question of whether nor a competitive market exists, something which is a source of uncertainty for insurance holders which is addressed if the holder obtains an optimal insurance policy: that is, a policy which covers all the risks deriving from the performance of clinical duties. However, even if such a market exists, there is still the potential for inefficiencies which we may term 'adverse selection phenomena' and 'moral hazard'.

Adverse selection in insurance processes is a consequence of an imbalance of information between insurance companies and policyholders. When signing the insurance policy, policyholders have a much better understanding of the risks to which they are exposed than the company insuring them. If the insurance company imposes a very high premium, this may discourage health professionals subject to lower degrees of risk (for example, general practitioners) from taking out a policy, on the basis that their level of risk is lower than that reflected in the policy. By contrast, health professionals who are aware of their high level of risk (for example, gynaecologists, anaesthesiologists or neurologists) would decide to take out insurance cover. If taken to its logical conclusion, the market would disappear as low-risk professionals opt out and/or high-risk professionals are excluded by the insurance companies.

There is a mechanism to reduce or even eliminate these adverse selection processes which is known as 'signposting'. Prior to signing an insurance policy with the policyholder, the insurance company may seek to detect the future risks of liability (for example, by means of the mechanisms provided in Act 15/1999, of 13 December, on the Protection of Personal Data, by exchanging information with insurance companies in order to set the level of the premium and to identify risks). These processes provide the basis for selecting future policyholders in accordance with their levels of risk, so that insurance policies reflect not only the existing, visible characteristics of the policyholder, but also those characteristics which are initially unpredictable and which are subsequently detected by means of signposting.

When we refer to the probability of a professional being made liable for damages and injuries caused by his or her clinical actions, this does not have the same meaning as when we refer to the probability of certain natural events occurring (for example, rainfall or drought). In those cases, the probability is objective and cannot be influenced by any individual. By contrast, the probability that a health risk might occur is influenced by the health professional in the sense that the risk is higher if the professional does not act with due caution, does not inform the patient properly, does not complete the informed consent document etc. For all of these reasons, the insurance company must ensure that its policyholder maximizes his or her efforts, acting in accordance with the latest professional practice in order to reduce the likelihood of an accident occurring. This establishes an agency relationship between the company and the policyholders, who each have a different set of incentives. The insurance company seeks to obtain the maximum profit from its operations, and the policyholder seeks to take as much care as possible to prevent an accident from occurring. If the insurance company provides total coverage of risk and does not monitor for the development of 'moral hazard' (that is, does not discriminate against those professionals who do not take care when performing clinical acts), then inefficiencies will appear within the insurance system.

6. Final conclusions regarding the determination of the amount of damages arising from health care in the different legal spheres and their transfer to the insurance system

As can be seen from a comparison of the systems for determining the value of compensation for injury and damages which are currently used by the different Chambers of the Supreme Court, there is no unified system to establish the amount of compensation:

1. Application of the scale of Act 30/95 is of a binding nature, after resolution of the issue of unconstitutionality raised by this Act, with relation to the damages caused by or as a consequence of traffic accidents.
2. With respect to medical acts, application of the system for assessing damages established in this scale depends on the court which is deciding upon the liability, and compensation is determined by the Court on a discretionary basis in application of the provisions of article 1.104 of the Civil Code.
3. Spain's system of Administrative Law, which is the only system other than the criminal system with competencies for ruling upon the liability of health professionals in the public sector after the legal reform introduced in 1998, has its own system for evaluating damages, contained in article 141 of Act 30/1992, of 26 November.
4. All of this constitutes an added obstacle to the efficient management of the liability insurance of the Health Services, because even though there is often agreement between the patient, the Administration and the insurance company regarding the basis of the compensation, the transaction is prevented because the parties to the procedure are unable to reach a final agreement about the amount of compensation.
5. The above situation is damaging to everyone: the Administration, the patient, and even the insurance company.

For the Administration as a result of legal challenges to the resolution declaring the existence of liability, exclusively with regard to the determination of

compensation, because this situation makes it impossible to accurately adjust the premium on the basis of results, given that in insurance policies it is common to agree that the insurer must maintain a record of the insurance account, and the balance of the account is then calculated annually taking into account a range of variables, such as: the balance of the account for the preceding year; a percentage of the net insurance premiums paid and received during the relevant years; the volume of accidents covered by the insurer during the relevant years and/or discovery period; the reserve of accidents pending, agreed with the policy holder; and interest on the annual investment.

For the policyholder who, instead of executing the compensation ruling, challenges the assessment and therefore has to wait until a final legal ruling is issued before receiving full compensation, together with meeting legal costs deriving from the challenge to the administrative ruling, and taking into account, furthermore, that with regard to late payment interest, the Administrative Court applies article 45 of the General Budget Act –which is less favourable to the injured party– and not the late payment interest system contained in the Civil Trials Act.

Finally, for the insurance company, because it is obliged to establish provisions to meet possible future liabilities, therefore making it more difficult to regulate net policy premiums, and bearing in mind that it is also common for policies to contain an agreement to the effect that the net policy premium is provisional in nature and establishing formulae for its final calculation, as occurs with the percentages which may be established with respect to accident rates.

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**Discussion and
observations**

Margarita Boladeras

I agree with the key points put forward by Dr Aubia, and propose that we go on to explore some of the issues raised in further detail. Medical errors vary widely in both their nature and their cause, and reductionist explanations which are restricted to identifying a few immediate factors or individual incompetence do nothing to help solve problems. It is clear, then, that we must find ways of overcoming this approach; as has already been noted, we need to take into account the system as a whole and, I would add, we also require a rigorous notion of what science is. The scientific method consists in detecting error, identifying explanations and alternative procedures; methodological rigour obliges us to proceed in such a way as to permit monitoring of processes and results, and to eliminate errors and unwanted deviations.

The health system should be organized in such a way as to promote the interaction of the health professionals intervening in a patient's care, reviewing cases, and evaluating their work. This is already standard practice in some health services, but it remains an exception in the health service as a whole.

Of course, healthcare procedures bear little resemblance to laboratory processes or industrial production, but are instead the result of personal relationships which are every bit as important as medical specialization itself. Rigour is not just a technical issue, but one of communication. Health care processes are based on personal interaction, and incorrect information can lead to the wrong drug being prescribed or an incorrect diagnosis being made.

The poor perception of medical errors and complaints which reach the courts could be avoided by attending to people and giving them the right explanations, at the earliest possible moment, when conflict situations arise.

Professional Colleges have been very uneven in their responses, and even those which have taken steps have not succeeded in connecting with the feelings of health service users. It is difficult to act with transparency, because doing so can meet with contradictory responses and in some cases may even have a negative impact on patient trust, but we must find ways of establishing dialogue which take account of the wide range of situations and problems encountered on a daily basis.

Montserrat Busquets

I absolutely agree with Dr Aubia that the current system of protection, based on financial compensation and professional discipline where there is negligence or carelessness, is insufficient. The safety of people whose health problems are treated by the health system requires more clear identification, and prevention which goes beyond insurance cover and legal sanctions. Without ignoring these mechanisms, I believe we need to work together with all care professionals to create an awareness of the ethical responsibility to achieve the highest possible standard of care. In this regard, the management of error is a central issue which is not just a legal question but also a professional and therefore an ethical one. My first contribution to this debate is to stress the importance of team work, primarily between doctors and nurses. In my opinion there is shared responsibility in maintaining and promoting the safety of patients and health service users, which goes beyond the 'traditional' division of work.

What do we understand by error? What type of errors are we prepared to recognize? What is the margin of safety that we can demand and that the patient is entitled to expect? There is an endless list of questions we could ask. Perhaps for this reason error is treated as an individual issue between the professional and/or the institution and the patient who has suffered injury. However, given that very few cases involve only one professional, teamwork is clearly an important tool for maintaining the safety standards which each case or situation requires. This is the key to ensuring that all health staff, with regard both to their individual practice and to the work of the team, are committed to the quality of care and the safety of the patient. In this respect, resource management and institutional policy are also key. Reducing and prevent errors requires that we ensure we have the right human, technical and material resources. In today's health sector, it is increasingly important that we include safety in the management of services rather than making it the exclusive responsibility of health professionals.

Secondly, I would like to draw attention to another group of questions, which focus on patients or health service users. We know very little about their

perception of error, and often stress the importance of the relationship between professionals and patients as a means of understanding potential errors. However, this interpersonal relationship focuses primarily on helping the patient to understand his health problem better, and to find ways of living with it. Of course, if the relationship is better then the whole process improves, but we cannot put all the weight of solving problems on the relationship between health professionals and patients. And there are also questions to which we do not know the answer.

What margin of error are patients prepared to accept? What do patients understand to constitute errors? What information do they need if they are to understand what is happening or has happened? In this respect, while I agree that we need to seek to understand the perspective of the health service user, this is not so much so that he or she comprehends the challenges of providing health care and the margins of error it involves, but rather to improve health professionals' understanding of error as seen from the perspective of the patient.

Starting from the premise that error is a human issue, except in cases of negligence where there is a clear lack of attention and professionalism, error should be managed in such a way as not to increase the distrust between professionals, institutions and patients or service users, avoiding the development of defensive mechanisms on both sides. Instead, it needs to be approached on the basis of collaboration to identify what should not happen and to provide the resources to ensure this, searching for better mechanisms for detecting errors, stressing preventive measures, and striving to bring together all of those involved, suggesting methods for evaluating outcomes, etc. In other words, we need to define as our shared objective preventing harm or reducing it to the lowest possible levels, and not creating further problems for the patient in addition to those which derive from his or her health situation.

Victòria Camps

One of the key questions which the two presentations have addressed is how to change the social perception of medical errors. I would like to identify two potential answers to this question.

Changing our language. Perhaps talking of medical errors is not the best way of approaching the problem. The first thing we need to do is change our language, and use concepts which reflect reality more accurately. An error is a mistake, something which has been done wrong, for which somebody must be responsible. Error assumes that there is also a correct way of doing things. The fact is, however, that medical practice is inseparable from a degree of risk which we must learn to accept, both as health professionals and as patients. One may, indeed should, demand a certain level of safety in response to this risk, which may be caused by accident rather than by error. But demanding safety from risk is not the same as demanding compensation for errors.

Another proposal consists of identifying foreseeable risks, establishing –as Ricardo de Lorenzo has said– a scale of health damages. This scale, however, cannot be a panacea which solves every possible conflict. Lists of this sort can never be fixed in stone. They need to be interpreted, and this requires an express desire to resolve conflicts in the most cautious, sensible manner possible. And this almost always means resolving conflicts with a degree of flexibility.

At the same time, it is important to stress the need for a voluntary rather than a compulsory approach to conflict resolution. In other words, as far as possible we must avoid legal disputes. This means that we need to educate people about the use of protocols and informed consent documents, so that they do not just become a pretext for protecting doctors from possible potential accidents or complaints. Both protocols and informed consent procedures should be seen as guidelines for how to act, not as defensive evidence that no other action was possible and that what was done was correct and had the patient's consent. During the seminar, it was noted that anaesthesia is one of the fields in which injuries have fallen most dramatically. So, does this mean that the patient's consent to undergo anaesthesia

exempts the doctor, or the centre, from compensation in the event of an unforeseen accident occurring?

The counterpart of the struggle against defensive medicine should be an acceptance by health professionals of their professional responsibility for accidents, a responsibility which will only rarely be purely individual. Health professionals are also threatened by the insecurity which arises from accidents, and for this reason they demand protection from insurance companies or the Administration for whom they work. If the cost of this protection grows as a result of poor risk management –as would appear to be happening– then it is logical that the system will become unsustainable: neither individuals, nor the Administration nor the insurance companies will be able to meet the exorbitant costs which may arise as a result of medical accidents. We have to think, then, in terms of collective responsibility, in which the organization protects the professionals involved in any damage.

Finally, the educational work necessary in order to ensure that a more rational approach is taken to risk must include the media and the way in which it reports errors, accidents and injuries. The tendency towards dumbing down and the requirement for eye-catching headlines always leads to misinformation in which the emphasis is on guilt and, as a result, confrontation between the offender and the victim. It is not possible to manage medical error or injury properly if we are not able to create a relationship of mutual trust.

María Casado

The topic of this Seminar is the focus of major concerns both in the health-care sector and in wider society. However, if the debate is to be a productive one, we must first clearly identify exactly what the title refers to, and which of the many possible perspectives we are adopting. I will therefore start by trying to clarify these issues.

Firstly, we must make it clear that when we talk of medical errors we are referring to errors which arise in the context of a complex set of health relationships where care is delivered by a team of professionals, rather than by individual doctors. This approach, together with the concept of the ‘management’ of errors, leads us to focus on organizations and prevention, rather than punishment. The aim is not so much to ensure legal and employer’s liability when a doctor commits an error which has negative consequences for a patient, but rather to understand that the set of health relationships and actions creates possibilities for error, and that our task is to find ways of minimizing these. This is why the seminar title refers to the management of errors rather than liability, even though the two issues are obviously closely linked. In my opinion, therefore, our aim is not to discuss the civil or criminal liability of the doctor, or the liability of the Health Administration; while these are both very important topics, they are not covered by the title of today’s seminar.

There is, however, one question which is related to responsibility for errors, and this is the possibility of avoiding their repetition, something which gives rise to duties with clear ethical implications. Nor should we ignore the fact that almost everyone is highly reluctant to accept their own errors, as a result of which most people almost instinctively reject their individual responsibility: ‘it wasn’t my fault’, ‘I didn’t mean to do it’, are statements which are often heard in such cases. However, the legislation recognizes objective liability, without blame, in a variety of circumstances, while dealing with the consequences of our actions and omissions is an ethical issue of the utmost importance.

One very important factor which I would like to highlight at the outset is the influence of insurance. I believe that the generalization of insurance –which

brings benefits in many fields– is transforming social relationships, and nowhere is this more evident than in the health sector. In many situations, the existence of an insurance policy covers, through financial compensation, liability for our actions, and alters the underlying personal relationships, transforming them into institutional ones. We take it for granted that payment will be met not by an individual –the person we actually know– but rather by an (impersonal) company whose business is precisely this. As a result, the pursuit of financial compensation is having a negative impact on the whole system.

I would also like to comment on something that Dr Aubia said in his presentation: the notion that correct information creates a favourable public impression. I am afraid I have to disagree with this, as there is abundant evidence to the contrary. This question has been studied carefully with regard to environmental issues, and it has been shown that groups which have better information about an issue –for example, GM crops– do not necessarily adopt a more favourable attitude. Nor does it strike me as paradoxical that there are more claims against those in more senior positions, even if we accept that these professionals are indeed the most highly trained. There are other factors involved such as, for example, the fact that the head of a team is always the most easily identifiable and, in principle, the person with responsibility for whatever occurs under his or her leadership.

In healthcare, we must take as our starting point the assumption that there are multiple causes and effects; single, linear explanations based on a few variables at most are not sufficient. Anthropologists repeatedly warn us of the need to acquire skills and attitudes which help us to manage risk and uncertainty. In this regard, it is important to remember that, in addition to controlling the risk and of errors, the social acceptability of what we do depends in a number of variables including, crucially, the issue of the justice of how such errors are distributed. I believe that, in the management of health errors, it is important to reduce the opportunities for negative episodes and adverse events to occur. But to do this we must help clarify and systematize the different processes, actions and individual contributions which together constitute even the simplest of healthcare actions.

Carles Fontcuberta

I would like to stress the need for *a priori* action to prevent the potentially serious consequences of medical error. In other words, I believe that the best way to manage error is by preventing its consequences. I will start by commenting briefly on information, communication, informed consent, the doctor-patient relationship and the ethical and professional role of doctors and (by extension) all health professionals. These, in my opinion, form the basis for the correct management of medical errors.

The doctor-patient relationship, unlike many other interpersonal relationships, is an unequal one. It is based on the contact between a professional and an individual who needs the doctor's help for reasons of health and even in order to save his or her life. In the context of this relationship, information is an essential –perhaps even the single most important– element of a very complex process. Indeed, I am absolutely baffled by the fact that we still need to explain to some medical professionals why they must inform their patients. Informing should not be an obligation in the sense of an imposition. Rather, it should be a central part of the doctor's vocation to serve his or her patients. It should be an inherent and integral part of medical practice. Information is the means of improving the relationship between doctor and patient, with all the short and long-term aspects of that.

In my experience, both as a clinical doctor and as somebody who has exercised management responsibility in various hospitals, I have seen both the positive effect of good information and the negative effect of failing to provide information or doing so incorrectly.

Informing does not mean that we will prevent error. But by informing, we are starting the process of managing potential errors. The General Health Act of 1986 represented a genuine revolution for the Spanish health system for various reasons. For a start, for the first time, Article 10 of the act introduced a patients' charter, which reflected the constitutional rights of citizens. This fact alone establishes its relevance. But perhaps the most notable feature is that several paragraphs of Art. 10 provided the basis for what we now refer to as 'the right to informed consent'.

Both the Health Administrations and health professionals ignored the existence of this charter until well into the 1990s. However, the steady increase in legal complaints against doctors, and health staff in general, raised concern about the implementation of instruments designed to ensure compliance with the regulations deriving from application of the General Health Act in general, and concentration on the issue of informed consent in particular.

For its part, Art. 10.5 states that the patient has the right “... to be told, in terms which can be understood by him and his friends and relatives, full, ongoing information, both oral and written, about the health process, including diagnosis, prognosis and treatment options.” As a result, since the General Health Law came into force, information has been an enforceable right, and failure to comply with this may lead to serious legal consequences.

And that is not all. It has been demonstrated that appropriate information significantly reduces claims for professional malpractice. We are living in an era when doctors must combine interpersonal skills with technical ability and scientific knowledge. Perhaps we are asking too much. What is certainly clear is that the interpersonal skills are losing ground to the other two areas.

Advances in medical technology appear to have greatly reduced the need to build relationships with patients. This leads to the mistaken belief that technology produces a bigger tangible impact on patients than personal contact. We should never forget the therapeutic potential of optimism, communication and moral and emotional support. The doctor is not just a scientist, a technician or an artist. He is above all a servant to the sick person and the community. And information and communication are two essential tools for the achievement of these objectives.

Narcís Mir

1. Identifying and defining the problem

We should not be surprised by the rapid growth in lawsuits as a consequence of unwanted healthcare outcomes for patients. This is due to frustration when the outcomes fall short of the patient's expectations. We do not perform a historical comparison of the advantages. If we compare electricity cuts with the level a few years ago we should be satisfied. But that it is not how it works. Both at home and at work we require a constant supply of electricity. As a result, we expect there to be no power cuts. At the same time, we have created societies where, in general, there is little tolerance of suffering, pain and death. And science, too, has contributed to this process, starting with the Enlightenment, creating expectations that any scientific and technological problem can be solved. However, irrespective of our expectations, the estimated data for the problem also show that levels of ‘errors’ are high and, what is worse, are very difficult to reduce.

2. What we can do to improve the situation

A first step would be to remove the issue of blame and talk of risk instead of error. There are two variables in the formation of risk: the probability of an injury occurring (frequency), and the scale of the effects of this event (severity). Prevention concentrates primarily on reducing probability: the best accident is one which does not exist.

And so we can ask why it is that, in industrial processes, we have achieved levels of error close to zero, but in healthcare processes there is no improvement in the level of what we call medical errors. A first response can be found in the different nature of these processes. In this regard, Mintzberg identifies five basic mechanisms for coordinating the work of organizations:

- a) Mutual adaptation: coordination occurs as a result of information communication between agents.
- b) Direct supervision: an agent is selected from among the operatives, and adopts the role of giving instructions and monitoring compliance.

- c) Standardization of operating procedures: coordination occurs as a result of routines, and the standardization of operating procedures.
- d) Standardization of results: the working process is unregulated, but outcomes are fixed.
- e) Standardization of skills: neither procedures nor outcomes are fixed, and instead the knowledge and prior training of individuals who join the organization are controlled. Teachers and doctors are a classic example of this kind of coordination.

Different organizations combine these coordination mechanisms in different ways. However, in any individual organization there is usually one method which dominates, and which typifies the organization as a whole. As a result, such methods can be used as the basis for a taxonomy of organizational forms or configurations:

- a) Simple or entrepreneurial structure. Dominated by direct supervision.
- b) Machine bureaucracy. Dominated by the standardization of work processes.
- c) Professional organization (or professional bureaucracy). Dominated by the standardization of skills.
- d) Divisionalized form. Dominated by standardization of outputs.
- e) Innovative organization (or adhocracy). Dominated by mutual adaptation.

Although I don't have the space to explore this issue in detail, I would say that the standardization of work processes facilitates the reduction of errors. This is why it has been possible to achieve substantial improvements in industrial processes. By contrast, the vertical and horizontal decentralization which is a characteristic of professional organizations works against the reduction of errors. And this is exacerbated when there is a tendency to respond to problems by exerting greater central control, establishing mechanisms corresponding to the normalization of processes (standardization, protocols etc.) and direct supervision. The results are usually disastrous: the action of poor professionals remains unchanged, while good professionals become demotivated. This is not because the work of health professionals should not be subject to supervision and protocols, but rather that these should be used

with great care and we should understand that on their own such mechanisms can never produce professional excellence.

What, then, is to be done? In my opinion, as was noted in the seminar, if there are shortfalls in training and excessive nursing workloads, then these should be corrected. There is nothing worse in a professional organization than failure of the main coordination mechanisms, that is, where there is a skills and knowledge deficit (as the result of a learning process which is too rapid). However, if our first instinct is to standardize processes, standardize outcomes or impose direct supervision, this will do little to reduce medical errors.

What mechanisms are left to us, then? Mutual adaptation (communication and searching for solutions on the basis of a two-way relationship). This, to my understanding, is the main thrust of Dr Aubia's key proposal, and some of the proposals of Dr Ricardo de Lorenzo. In first place, the issue needs to be treated as a medical one, in the sense that all health professionals are involved in searching for solutions rather than the problem being addressed solely through insurance procedures. The only effect of such an insurance-based approach would be to lead to massive growth in the insurance market. But, above all, we need to create working groups taking as their model the quality circles used in industrial settings. These use daily reports of working practices and events to identify and propose solutions designed to reduce errors without apportioning blame.

Errors can occur at any time, and the first thing that happens is that the patient generates a whole system of antibodies, which distances the patient from his healthcare team, his doctor and his nurse. The result of this lack of confidence is that the patient starts to search for somebody to blame. He feels the need to identify a guilty party, to stop the tragedy from occurring again or in order to obtain financial compensation. This distrust leads patients to seek refuge and information in associations (such as UK-based 'Patient Protect') to obtain information which some health teams are unable to give them. These associations base their philosophy on protecting the patient and seeking to prevent abuse, negligence, excessive health costs, errors and incompetence.

This should make us question whether we are really doing everything possible to prevent errors in our health teams. The first issue the team has to address is social concern at the existence of medical and nursing errors, and to put ourselves in the place of the patient and his family. To do this, we need to strive for four objectives:

1. Regaining the patient's trust, by providing patients and their families with the information they need, in a clear, comprehensible form.
2. Health education for patients is a basic element of the communication process.
3. The patient has to learn that doctor and nurse form a health team with the shared aim of ensuring that the patient recovers his health and quality of life as quickly as possible, either in hospital or in the health centre. Doctors and nurses are not in competition, but complement each other in a single team.
4. Accepting patients' concerns and understanding that patients need to be able to ask about these concerns and have access both to direct and general information which enables them to decide where to go to improve their health.

Patients ask all sorts of questions:

- Why did I have to be admitted to hospital?
- Was it really urgent?
- Do I need to have this operation?
- Why did I get this infection while I was in hospital?
- Can I choose my doctor?
- How should I choose a good doctor?
- Can I choose my hospital?
- How should I choose a good hospital?
- That went wrong, the doctors say it was inevitable, they talk about inherent risks; should I believe them?
- Was this complication normal?
- Have I been the victim of an error or of medical negligence?
- Is my hospital bill too high?
- How much do my drugs really cost?

- Are all these drugs necessary?
- Will my drugs be administered correctly?
- What should I do to reduce my risk factors?
- Is the health team able to meet patients' information needs?

In other words, we need more and better information, and we need to have enough time and enough staff to transmit it, at doctors' appointments and meetings with nurses, with the aim of achieving a clear distinction between errors which are the product of ignorance or incompetence, and adverse events which occur despite an accurate diagnosis and correct treatment.

Perhaps we need to improve our working methods. Weed recommends that patient medical records identify problems, and argues that this method should also be applied in care, teaching and research, within the framework of a scientific methodology, with quality controls to enable the prevention, detection and correction of errors. This is the purpose of evaluating the results of health teams which are committed to caring for the patient within the context of a service culture.

The scientific method is essential if we are to keep pace of technological progress, while increased investment in people is needed if we are to close the gap between patients and healthcare teams. The quality of our work and our perspective on error must change if we are to explain to our patients what constitutes a medical error and what patients can do to protect themselves. We know that 'to err is human', but if patients share their concerns, information about their health, and the decision-making process with doctors and nurses, then surely this will help to protect everyone from medical errors.

Martín Navaz

The role of the broker in transferring risk to insurance companies

The papers and discussion have been very interesting, but one issue which has not been mentioned is the fact that the insurance market is very limited, with little supply at an international level and only a handful of companies who are prepared even to engage in constructive dialogue in order to offer insurance policies which meet the demands of the policy holder while also reflecting the level of risk for the insurer.

Internationally, long before September 11, 2001, in professional circles we had already detected a current of opinion questioning the insurance of the risks of medical error which we have been discussing today. In 2001, the only companies prepared to engage in the analysis of this sort of insurance in Spain were, by alphabetical order: Mapfre, Musini (only in the Basque Country), St. Paul, Winterthur and Zurich. There was very limited price competition, based exclusively on the widespread belief among the other companies that St. Paul was practising dumping in the tender processes in which it participated.

At present, Mapfre is of the opinion that the public administrations cannot be insured within the existing legal framework for such insurance cover, St. Paul is for sale and/or is withdrawing from the Spanish market (according to press reports), Winterthur, an insurer with a long record in this area, is in the process of closing down this branch of its business before the end of the year, leaving only Zurich committed to continuing to provide such cover and Musini making occasional forays into the market in the Basque Country and potentially elsewhere. The highly concentrated and monolithic nature of the international reinsurance business does nothing to expand the market, providing instead a framework for restrictive strategies.

Clearly, the legal situation in Spain bears much of the responsibility for the position of the insurance companies which operate in our country.

Until a few years ago the role of the mediator was restricted to the placement of policies under the best market conditions available and, if possible, creating competition between the different insurance companies who submitted bids. Today, only the most imaginative of solutions will make it possible to achieve satisfactory conditions for both insurer and policyholder. Potentially valid solutions include the following:

1. Implementing a system like that used in Catalonia.
2. Establishing a system of increased excess limits, so that insurance companies only cover large claims.
3. Contracting an accident administration system which uses a self-insurance system for the efficient management of incidents, and only insures excessive losses, in the manner of a classic 'stop loss' insurer.
4. Introducing multi-annual policies, in so far as these are acceptable to both insurer and policyholder, with profit/loss sharing at the end of the period.

The last option –multi-annual policies– imposes a very high level of transparency with regard to the establishment of provisions. Indeed, whatever solution is adopted (including classic insurance policies) transparency is absolutely essential to any process of reporting incidents and establishing premiums.

It is also important that we:

- Evaluate the possibility of both health centres and professionals participating in the cost of insurance, in order to ensure that they are aware of the impact of injuries on the overall policy.
- Establish a system which makes it possible to draw on the experience of managing incidents and analysing their causes, as a basis for preventive measures which reduce the risk to policyholders.
- Ensure cooperation between insurer, policyholders and brokers to create a state of opinion in society that medicine is not a science which delivers guaranteed results, because this is the basis of current expectations and claims are often the expression of the disappointment of these expectations.

- Influence the legislature to clarify Act 30/92 so that the objective liability of the Administration does not apply in the health sector.

In this regard, the Catalan system of Civil Liability has demonstrated its capacity in responding to over 5,000 accidents. Under this system, CatSalut, the College of Doctors of Catalonia, and the College of Nurses of Catalonia jointly hold three policies under which a single insurer offers the same guarantees, thereby providing cover for the system and enabling it to work as effectively as possible. This system was created in 1993, growing out of a more restrictive agreement between the Official College of Doctors of Barcelona (COMB) and the Catalan Health Institute (ICS), and being extended five years later to the Catalan Public Health System and to the vast majority of public and private sector nurses in Catalonia.

The so-called Catalan model of Civil Liability has been a model which Spain's other Autonomous Regions have failed to copy. This failure has been due to the differences between the Catalan and other contexts in terms of institutional relationships, together with the fact that Catalonia in general and Barcelona in particular have very powerful professional colleges which have always distinguished themselves by their interest in the issue of liability cover.

The key features of the Catalan model can be summarized as follows:

- a) Insurance policies under which a single company provides joint cover for the Administration, participating health centres, doctors and nurses.
- b) A defence system which means that, irrespective of the source of the accident and its current and future repercussions for the rest of the system, the case is treated in a coordinated fashion.
- c) An integrated system which prevents those covered (health centres and doctors) from attacking each other.
- d) A system which does not duplicate the administration of financial or human resources, as the accident rate is calculated as a total and then distributed between the different parties.
- e) A system under which decisions are taken by a joint committee on which the insurer, health institutions, doctors and nurses are represented, as a

result of which cases are considered and resolved together, whatever the source of the claim.

I would like to conclude by stressing the enormous importance for this issue of raising awareness not just among the legal profession and public opinion, important as they undoubtedly are, but also among insurance companies. As I have noted, we face a crucial moment in which, due primarily to the withdrawal of two insurance companies (Winterthur and St. Paul) we may find ourselves defining medical errors only to realize that nobody is prepared to offer cover for these risks, with the danger that health professionals and centres have to meet future claims out of their own pockets.

Isabel Pera

I would like to make a few comments with respect to the title of the seminar. In the first place, the term ‘error’ itself has negative connotations, and lends itself to disparate and even questionable interpretations. I therefore believe that we need to define precisely what we understand error to mean, and to reach agreement about what it is that we are managing.

The actions to be taken and procedures to be followed differ greatly depending on whether we are dealing with an accidental error due to unforeseen circumstances deriving from the setting in which the events occurred, and are the result of natural limitations on resources and other similar conditions, or whether the mistake derives from reckless, negligent or careless conduct or a lack of the knowledge or skills required for competent practice.

It is not always easy to distinguish one situation from the other and for this reason, in my opinion and on the basis of my experience, we need to turn to professional experts. Common sense tells us that in both cases we must perform a detailed analysis of the facts and the circumstances. However, while in the first case we need to detect the weak link in the chain which has contributed to the unwanted outcome, in order to correct it and take measures to prevent it from occurring again, in the second case we must take disciplinary action, identifying those who are guilty and applying the appropriate punishment, depending on the seriousness of the events involved and their impact.

Some may argue for punishment as a means of managing errors arising from malpractice (carelessness, negligence, incompetence etc.) but I would agree strongly with those who advocate a system which accepts the possibility of accidental, random, human error, which may occur despite good practice being adhered to. In such cases, all that automatic punishment will achieve is to promote obscurantism, secretiveness, concealment and repetition. We must understand error as offering an opportunity for improvement, encouraging a clear description of the facts, analysis, correction and prevention.

On the subject of prevention, the title of today’s seminar, ‘The management of medical errors’, leads to the assumption that we are talking about what to

do only once events have already occurred. What should we do *a posteriori*? How should we act after a disaster has occurred?

At the Legal Medicine Service at the Vall d’Hebron University Hospital, our main objective is risk prevention. Avoiding malfunction, accidental incidents or errors; detecting weak points in organizational systems, structural problems, contributing to protocols, defining standards, standardizing procedures, drawing up clinical guidelines, creating accreditation systems.

This precautionary stage is the most important of all, but I would also like to stress the effectiveness of the direct advice offered to health professionals at the precise moment when the doubt, dilemma or conflict arises.

We also take follow-up action, because we recognize that it is not always possible to provide hard and fast evidence of mistakes, resources are not always optimal, and there are sometimes health professionals who fall short of competency requirements. We therefore try to ensure that our actions are based on maximum transparency, respect for service users, health professionals and other interested parties, and compliance with legislation.

Thirdly, I would like to point out that the majority of the contributions, and the presentations themselves, have taken what is primarily a biological approach to the question of the ‘Management of medical errors’, stressing the diagnosis and treatment of illness. As if there could be no defects in health promotion, education, prevention, information etc. Perhaps one day we should devote serious attention to why it is so difficult to overcome the biological model.

Finally, as far as I can see, there has been little discussion of the fact that the purpose of risk management is to guarantee the safety of the citizens who are the recipients of a healthcare which is delivered by health professionals from various disciplines, and this interdisciplinary participation is one more element in guaranteeing the safety to which we should all be committed.

Josep Prat

1. When talking of medical errors we should remember that these occur within a specific healthcare context which conditions medical actions and in which many different health professionals are involved. Medical or healthcare errors can affect individuals as citizens receiving care and as professionals providing it. And they also affect health institutions. In the first case, citizens demand protection against errors, and compensation for any injury suffered. In the second case, professionals and institutions primarily demand protection.
2. A second consideration of a general nature relates to the fact that, while errors occur with relation to professionals in all sectors of society, because healthcare is considered to be so important, healthcare errors are a focus of particular social concern.
There are two correlations we should be aware of. The first of these is the correlation which exists between risk and error, in that the greater the risk, the higher the possibility of error occurring. The second correlation concerns the relationship between error and decision-making. To put it bluntly, anyone who takes decisions also runs the risk of making mistakes. And when we evaluate the performance of individuals or organizations we need to take an overview in which we see errors in the wider context of all the decisions which the professional or organization takes. As part of this process, we must bear in mind that in the course of the care relationship and the process of diagnosis, large numbers of decisions are taken, many of which are linked together as part of a wider process.
3. Further action.
Below I have identified some possible approaches to reducing healthcare errors:
 - 3.1. Accreditation of professionals. Guaranteeing the basic skills and knowledge of health professionals.
 - 3.2. Regular assessment of skills and knowledge. The continuous development of medical science, technology and the need to keep diagnostic and therapeutic skills up to date mean that we should have a system for the regular assessment of professional practice.

- 3.3. Preventing the risk of errors. There is nothing to stop us from generating a variety of error prevention policies and strategies for implementing them, as occurs in other fields and disciplines in the world of healthcare.
- 3.4. The establishment of standards and the development of protocols for diagnosis, treatment and care procedures are error prevention strategies.
- 3.5. Improving the informed consent process. This is essential if we are to inform the patient about the risks associated with the healthcare processes he is to undergo and, just as importantly, to ensure he has confidence in the health professional.
- 3.6. Generating communication and discussion of these issues in professional and legal spheres, and also in the media, in order to prevent problems from being dealt with exclusively on a judicial basis, and informing and educating the general public.

Yolanda Puiggròs

With respect to the presentations, I would like to comment on the proposal to create a scale which would, in a similar way to the scale applied to injuries and damages caused by traffic accidents, establish the maximum compensation to be awarded in the event of injuries and damages resulting from medical errors or, in general, arising within the context of the Health Administration's employer's liability for medical procedures.

Such a scale could be very useful in avoiding the inequality which currently exists as a result of the wide variations in compensation awards for similar injuries depending on the legal body dealing with it. At present, two similar injuries may lead to very different levels of compensation not only in the different Autonomous Regions of Spain but also, on occasion, in the same region and before legal bodies with identical competencies. A scale would have the benefit of ensuring more uniform compensation awards and preventing disproportionate claims.

However, I wonder whether the establishment of a scale with the status of legislation and, consequently, subject to the requirement that it be publicized in order to ensure its efficacy, could actually lead to an increase in the number of claims. If a scale was approved and published, any citizen, advised no doubt by his lawyer, would have a degree of certainty as to what might be obtained by filing a claim and might even conclude that the scale represented an absolute right which the patient would then be unwilling to renounce.

While the establishment of a scale could have the advantage of providing legal security with respect to the application of legislation and consistency in compensation awards, we should also ask whether its mere existence might lead to an increase in the number of claims.

If the purpose of the scale is not so much to avoid claims in and of themselves, but rather to address the exorbitant sums which are sometimes awarded, it might be appropriate to establish a system of awards similar to that which operated in civil legislation for claims regarding the employer's liability of the

Health Administration before the introduction of Act 29/1998, of 13 July (regulating the Jurisdiction for Suits Under Administrative Law).

The current system only contemplates the awarding of costs against the plaintiff if the claim is ruled to have been pursued recklessly or in bad faith, or if the appeal is rejected in full.

The current legislation, together with the well-established practice in our administrative courts on the basis of the Act Regulating the Jurisdiction for Suits under Administrative Law of 1956 by virtue of which costs were only awarded against the claimant in the case of recklessness or bad faith, means that in practice costs are very rarely awarded against the claimant and this in turn means that claimants can lodge unfounded or disproportionate claims for compensation without assuming any risk whatsoever.

At the same time, I understand that injuries incurred during healthcare, whether due to medical errors in the strict sense (to repeat the title of the seminar) or healthcare actions in general, should always be considered from the perspective of the proper interests of the health service user who is deserving of protection, and who in the last analysis is the recipient of the actions and the person who benefits from the achievements of healthcare and suffers when errors occur.

In accordance with the declaration of the rights of the users of the national health system which establishes in article 10 of the General Health Act, the Charter of Rights and Obligations of Citizens with respect to Health and Healthcare in the version approved on April 2002 by the Bioethics Committee of Catalonia, the Oviedo Convention and other domestic and international legislation, the user should be the focus of all research, improvement, planning, evaluation and other efforts relating to healthcare, and just as the management of the system should centre on the service user (accessibility of services, coordination between different services to avoid unnecessary visits, etc.) so the management of medical errors should not be an exception.

Finally, I would like to stress that in the panel discussion all the participants agreed that at times claims for medical errors are the result of a lack of communication with the patient during the care process, not just by the doctor

but also by the other care and non-care staff who interact with the patient. This lack of communication may consist both of a lack of information and of impersonal treatment.

The problem of the lack of communication makes it clear that, despite its legal recognition, users are not always able to exercise their rights to information and dignified treatment in full. The duty of information of centres should extend to specific information about the channels and time periods for making claims.

Francesca Puigpelat

I would like to start by thanking the Víctor Grífols Foundation both for its choice of topic and the quality and clarity of both speakers.

With regard to the thesis advanced by Dr Jaume Aubia, I am struck by a number of thoughts, which relate to four points: a) the scope of his thesis; b) the organizational context in which error occurs; c) the health culture of the general public; d) health as a right and health as a duty.

a) The scope of his thesis. The central thesis is clear: to question the current management of risk and errors in medicine, and to propose alternative forms of management. The current approach is based on identification of individual guilt, financial compensation, improvement through better training of individual doctors, and the control of practice through the use of protocols. This assumes that errors in medical care should be resolved through legal channels. In response to this, he argues for a mere effective approach to the problem of error: seeking to replace the individual focus with a systematic, collective one which would find expression in a system for reporting both latent and actual errors without formally apportioning blame.

I am unclear, however, as to whether this new focus is a full-blown alternative to the dominant paradigm or only an addition to palliate or prevent its possible shortcomings.

Recourse to the legal system in the management of errors is not restricted to the health sector. For example, we also manage driving errors through a system of individual punishment, compensation and learning, and it does not seem that this approach should be replaced by a focus in which error is just a symptom of organizational difficulties (e.g., poorly designed roads, old cars with faulty brakes, the lack of public transport at night when people are coming back from nightclubs, lack of police at certain points of the road network, etc.). While this approach enables the detection and analysis of errors, both actual and latent, I am not clear that it represents an alternative to the law courts.

b) Organizational context in which the error occurs. The paper supports the thesis that an individual approach to dealing with error is not enough,

pointing to the apparent paradox that it is the most competent doctors, the service heads, who are most likely to be the subject of a claim. I believe, however, that there is a reasonable explanation for this. I suspect, although I have no empirical evidence of this, that the worse the patient is treated on an emotional level, the more prepared the patient is to report errors. Patients are normally prepared to be tolerant of error if the relationship with the doctor has been satisfactory from a human perspective. The greater the emotional proximity, the fewer the complaints. Perhaps many service heads are highly competent professionals but are less skilled at empathizing with the patient, although it may also be the case that the higher level of complaints simply reflects the fact that the patient is identifying that person as responsible for the service which provided poor treatment.

- c) Health culture of the general public. The presentation stressed the need to accept the fallible nature of scientific knowledge, and all the more so when its ultimate referent is the health of an individual person. In this regard, I would like to point out that it has been and continues to be the medical class which often presents itself to the public as the possessor of infallible knowledge. Campaigns to raise funds for research and the adverts for certain medical treatments seek to persuade the public that medical progress represents an infallible panacea which can resolve every problem and has no negative consequences. The medical class should, then, help to generate a health culture which is more closely in tune with the realities of scientific knowledge, recognizing both its fallibility and its provisional nature.
- d) Health as a right and health as a duty. The problem of health care must be considered in a wider context. The societies in which we live today have moved from a culture of duties to a culture of rights. Modernity represents a very important break with earlier forms of political legitimation. We have moved from solely owing the State duties, to solely demanding rights from it. Although this shift is a positive one, it may give rise to unwanted consequences if in particular social settings the idea of rights is emphasized while we forget about the notion of duties. Specifically, in the

sphere of healthcare, a robust culture of rights, which ignores the culture of duties, can create major distortions.

Dr De Lorenzo noted at the start of his contribution that he would depart from the written text which had been distributed beforehand. The reason for this was because, while the paper addressed the issue of medical errors from a strictly legal perspective, the discussion would be richer and more fluid if the presentation focused on identifying broad guidelines to guide the adequate handling of medical errors.

Despite this, I would like to refer to the written text: The current situation of civil liability insurance policies for health professionals, and the compensation awards for damages and injuries in the different jurisdictions.” I am interested above all in the section *Compensation claims regarding the Administration and the company providing employer’s liability insurance cover*.

His basic thesis is that, outside of the criminal justice system, only the employer’s liability of the Administration can be insured, not its civil liability. As a result, despite what is sometimes argued, the legislation regarding civil liability insurance, contained in articles 73 to 76 of the Insurance Contract Act, does not apply. Nor would there be the possibility of ‘private action’, as the claimant would no longer have the option of choosing the more favourable option of civil jurisdiction.

His opinion strikes me as consistent with the arguments noted in his text and summarized below. For many years, all jurisdictions were held to have competency over liability claims regarding the Health Administration. The legislators implemented a triple reform in an attempt to resolve the problem, attributing exclusive competency to Spain’s system of administrative law. To this end, they modified art. 9.4 of the Organic Law of Judicial Powers, art. 2e of the new Act 29/98 on the Jurisdiction for Suits under Administrative Law and Act 4/99 added to Act 30/92 on the Legal Regime for Public Administrations and Shared Administrative Procedure, additional provision 12.

I would be interested to know how he would assess the impact of Ruling 33/2001 of the High Court of the Special Chamber for conflicts of competency on his thesis. This states:

“As the presence of insurance companies is not expressly contemplated in the procedures for resolving administrative disputes, given its special nature, when a claim is made on the basis of the employer’s liability of a Public Administration, the reasonable course, so long as the law does not expressly specify the procedure to be applied, is to maintain the traditional and classical doctrine of allowing the more favourable option of Civil Jurisdiction, recognized in art. 9.2 of the Basic Legislation on Judicial Powers.”

Rosa Suñol

The injuries suffered by patients as a result of healthcare constitute a significant cause of morbidity/mortality, and some studies identify this as the fourth or fifth most common cause of death in various developed countries. It must be said first of all that these injuries and/or deaths rarely occur in previously healthy patients, as is often assumed, and the most recent published studies¹ have suggested that 6% (95% CI 3.4%-8.6%) of the patients who died would otherwise have been discharged from hospital alive subsequent to their stay, and that 0.5% (95% CI 0.3%-0.7%) would have survived for 3 or more months in a good state of physical and cognitive health.

For this and many other reasons, the expression ‘medical errors’ is inadequate, and promotes attitudes which encourage the apportionment of blame while doing little to improve the situation. The term ‘medical error’ brings to mind mistakes due to the negligence of an individual health professional, when the reality is that injuries mainly occur due to the design of working systems, and involve the actions of a group of both clinical and non-clinical professionals.

Here, we need to stress not the error of isolated professionals but the possibility of improving the safety of patients. This is not just a question of words; the concept of improving clinical safety entails a focus on improvement and the possibility of intervening in working systems in a global manner. Other disciplines, such as air safety, road safety and workplace safety are involved in improvement processes which are similar to the challenge faced in healthcare, without using systems which directly blame individual health professionals. Medical science itself has made great progress in improving the safety of anaesthesia, transfusions or the management of medication through the unidose system, all of which have led to significant advances in recent years.

However, it is important to establish that the issue of patient safety can be viewed from at least three different perspectives:

¹ Hayward RA, Hofer TP. Estimating Hospital Deaths Due to Medical Errors. *JAMA*, 2001; 286:415-20.

- From an epidemiological and public health perspective, injuries to patients constitute the 4th or 5th most common cause of death. We are referring here to problems in the use of medication, nosocomial infections, problems of diagnosis and treatment, etc.
- The legal perspective, and the related issue of the increased cost of civil liability insurance which, although it affects only a small proportion of health professionals, is the cause of great social concern and generates very significant costs. This is of particular importance in cosmetic surgery, obstetrics and traumatology.
- The perspective of citizens with regard to clinical safety and their trust in health professionals and care systems. Here, the issue is the change in society's perception of health services, the increasing autonomy of patients, and the modification of the social contract which promotes a belief in the right to compensation for unwanted outcomes. Although these three perspectives are related to each other, it is very difficult to address them simultaneously. In my opinion, these three perspectives must be discussed separately if we are to identify actions which can have an immediate impact.

Nor should we neglect the impact of the issue on the health profession. Coming together to promote safety could provide an example for health professionals and would be recognized by the wider society. A commitment to patient safety requires complementary approaches:

- The possibility of a right to compensation without necessarily directly blaming an individual health professional.
- Efforts at improvement headed by senior management, and included in the strategic goals of the centre.
- Efforts by professional colleges and associations to develop safe practices and to support professionals involved in difficult situations.
- The active participation of health professionals in the implementation of safe practices.
- Legal protection for risk analysis systems, in order to promote the study of this issue.
- The attitude of the media in raising social awareness and promoting dialogue.

However, the most important action of all is to recognize that improving safety requires that we engage everyone who is involved in improving and promoting the development of safe practices and the transparent information which generates social trust among citizens.

Carme Valls

The problem of safety with regard to encounters between individuals and the health system is one of growing complexity. One of the first studies carried out, by Brennan and colleagues¹, the 'Harvard Medical Practice Study' published 1991, revealed that in New York in 1984 some 3.7% of people admitted to hospital suffered from an adverse effect. Ten years later the same group published three articles^{2,3,4} in which they identified a prevalence of 2.8% for adverse effects in hospital admissions in Utah and Colorado, with a higher prevalence, 5.3%, among patients aged over 65 years.

Over the last ten years, over 300 articles have been published on the subject of medical negligence and errors. Of these, 119 considered error and negligence in the primary care services⁵.

The information system

We currently have to organize a vast amount of information. The number of articles published across the world in all areas means that we need new review methods if all the scientific evidence accumulated in the literature is to reach doctors and specialists.

In principle, the Cochrane method represents a qualitative change in an attempt to systematize evidence-based medicine and to involve users in creating the Cochrane database. The qualitative problem is this: who performs the synthesis, who provides the information? Because at present information about scientific advances comes from pharmaceutical companies and the pharmaceutical industry, that's who is creating the state of opinion.

It is also important to note that the competitive nature of the pharmaceutical industry means that there have been examples of drugs whose side effects had not been properly communicated to health professionals. (For example, the case of cerivastatin for the treatment of myopathies, or the 'Celebrex' case, in which only the first six months of the study were published, without seeing

the side effects of the drug.) Who, then, is responsible for the products investigated?

At this moment, the problem of the information system is so important in any medical errors database we may create, that we should consider the role of public health in each country in the continuous professional development of all doctors, because access to information is not an individual but a collective responsibility.

Medical and health actions

Clinical guidelines are of great importance, because the sheer volume of work means that there is no way any individual health professional can control all the different healthcare processes, and this can lead to medical errors. Scientific advances mean that protocols have to be revised, as excessive rigidity can also lead to medical errors: for example, the case of heart care in women, where the protocols were different than those used for men, leading to the false belief that women did not suffer from heart attacks. (See Yentl's Syndrome, identified by Bernadine Healy.)

Nor should protocols be reduced to high technology systems. At present the patient's medical history is not recorded systematically, including personal history and living and working conditions, as a result of which protocols are reduced to high-tech interventions, perhaps involving analysis or exploratory surgery, but not taking into account psychosocial elements (Indeed, this section has actually been removed from the new medical records proposed for Primary Care in Catalonia.)

With regard to protocols, it is also important to explain the treatment options carefully and to use the informed consent process for all treatments which could have unwanted outcomes for patients. For example, informed consent should be proposed for all treatments with side effects, and a paradigm would be the application of informed consent in hormone replacement therapy for women after the menopause, given the existence of doubts regarding this treatment.

Individual responsibility

Citizens' rights require more information and greater opportunities for participating in decision-making. We therefore need to reflect on the elements required to ensure that patients are better informed and have a more active role.

Some medical errors occur as a result of the infantilization of patients and the withholding of the information resources they need in order to be able to take decisions. It is also essential that we learn how to discuss priorities.

Legal responsibility

In this field, we should consider the need for rigorous, detailed medical records, because as soon as there is a dispute or a claim for the compensation of individuals affected by errors or irresponsible decisions, if the medical records are not rigorous and clear there can be all sorts of legal problems. In this regard, legal experts can also help doctors to be more specific. Just as surgeons advanced internal medicine by evaluating diagnostic signs to arrive at accurate diagnoses, so legal experts can help to clarify the legal aspects of medical information.

Let us consider as an example the case of people affected by exposure to pesticides at work, or cases we have seen recently in Catalonia, such as the woman whose pancreas was removed when she was actually suffering from an abdominal crisis as a result of the metabolic illness, porphyria. There are therefore problems regarding the identification of legal responsibility which should constitute part of everyday medical practice. This is why we need more careful consideration of these problems, and I thank the Víctor Grífols Foundation for enabling us to discuss them today and for stimulating the debate around issues such as how to systematize information and informed consent in all areas of medicine.

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Jordi Vallverdú

I would like to return once again to the words of Dr Aubia. At one point in his presentation he noted that “the concepts of safety and risk are sociological and, therefore, relative,” although a little later he states that, “above and beyond such subjective differences, there is a real lack of safety.” This strikes me as an example of a line of reasoning which is mistaken but nonetheless widespread in the sphere of risk evaluation. On the one hand, there is the enormous mass of individuals which constitutes civil society and which holds erroneous or biased (culturally determined) perceptions of risk, while on the other hand there is a small band of experts who know the truth and are able to offer well-founded opinions. This is not a viewpoint with which I can concur. In studies analysing scientific controversies it has been shown that the issue of risk and how it is perceived is the focus of disagreement within scientific communities (in our case the medical community). Experts do not have a unified, clear vision of the potential risk and how to identify and evaluate it, and they also disagree on technical issues such as how to evaluate the evidence produced by rival research groups or the model used for statistical calculations. Furthermore, there are clear national differences, as can be seen in the differing approaches to risk analysis in the United States and Europe. The National Research Council (in the USA) and the European Environment Agency have quite different definitions of the concepts of ‘risk’, ‘uncertainty’ or ‘ignorance’, and came from very different social and legal traditions, which advocate an adversarial model in the United States and a confidential one in Europe. Notwithstanding, the inclusion of civil society in the risk analysis models used to take scientific decisions has continued to grow, as demonstrated by concepts such as ‘risk characterization’ (created by the NRC in 1996) or points 8 and 9 of the EEA report on the precautionary principle (2002, Report 22).

The complex problem of technocracy arises when we seek to draw a clear distinction between risk perception as something which is socially constructed and risk analysis as something real and scientific. If this distinction were accurate, only the best informed individuals, with real knowledge of the case, could give a clear opinion. But matters are not so simple. Without going into

too much technical detail, we can identify some of the sources of uncertainty to be found in scientific practice: for example, epidemiology has been extremely useful in the study of infectious illnesses such as cholera, but has not reliably demonstrated its validity in the analysis of chronic illnesses such as cancer. At the same time, epidemiology has been shown to be ineffective as a preventive warning system. Moreover, if we consider the practice of epidemiology, we find disagreement regarding the use of statistical models in clinical trials: the dominance of frequency measures has been subject to systematic, if low-level opposition from Bayesian proposals, and this has been reflected in the initial phases (I and II) of trials. I could list various weaknesses in cohort and transversal studies, but this is not the place. At the same time, we find that medical experts have intrinsic difficulty in defining the concept of ‘cause’: for epidemiologists (who search for remote causes of a genetic, environmental or social nature), the notion of cause is completely different from that held by physiologists (who are more interested in the underlying pathogenic mechanism or the final development of the disease).

As a result, there can be no privileged positions in the study of medical science, but rather a broad diversity of interests and viewpoints. As Dr De Lorenzo recognized in his paper, the participation of civil society has increased massively since Spain’s transition to democracy in the 1970s. Inevitably, this change in demographic power is exercised not only through the democratic process but also in the production and consumption of goods and services. I would like to call your attention to some figures: the number of non-governmental organizations in Spain has risen from 88 in 1870, to 700 in 1939, 2296 in 1970 and over 20,000 in 2000. Civil society wishes to take part in elections and decision-making, even if this leads to an increase in legal disputes relating to ‘medical errors’.

I will end my contribution by making some suggestions regarding the study of medical errors. Firstly, I would like to quote what Dr De Lorenzo said with regard to the need for research to be led by doctors: models and protocols should arise from the medical community itself, ensuring that it stays ahead of any state or social attempt to control scientific practice. Social opinion would be far more positive if we understood that the problem had been hon-

estly identified and resolved by those involved. Secondly, the real need to include civil society in models for the analysis of medical error, as has already been done by other research bodies. Thirdly, we must accept the inevitability of error in scientific practice, without this constituting a defence of ineptitude or carelessness. Error is inherent to all human activities. Fourthly, we should make an effort to translate technical information into everyday language which is accessible to all. Social perception is determined by the source and the methods of transmitting the information: doctors have a key role to play in caring for and informing patients who are, at the same time, increasingly well-informed. Fifthly and finally, we need to consider the differences between private and public medicine, as two completely different spheres of activity, operating in different settings. The private sphere (and this also includes insurance companies) may benefit or lose out as a result of public activity, depending on the role they play and how error is managed.

Ángel Vidal

In my opinion, with respect to terminology it would be better to talk of the management of healthcare errors, rather than just medical errors, as I believe this more accurately reflects the nature of the problem, the fact that it involves professionals from a wide range of disciplines, and the fact that the system within which such errors occur is a complex one with multiple causes, making it difficult to establish whether errors are individual or organizational. My own personal interest focuses on errors deriving from health organizations.

The two presentations have considered the issue in detail, but from the very different perspectives of the law and of the health profession. Dr Aubia argued for self-regulation by the health profession, based on scientific analysis. Dr De Lorenzo analysed court rulings, and considered the crisis in the insurance sector as a result of the unpredictability of financial claims, and proposed a scale for compensation awards, together with strengthening mediation and out-of-court arbitration systems.

My own perspective is that of striving to make clinical practice as safe as possible in an extremely complex health organization. Our organizations are ill at ease with the concept of error, associating it with disgrace, and this leads to a culture of concealment which makes it difficult to identify and correct errors. We have to change this concept, and replace it with a culture of improvement and quality, separating it from its punitive associations. Health activity entails risk, and this is influenced by both individual and organizational factors. It is therefore necessary to accept and normalize it, in the sense that errors should be recorded and analysed by the organization; only if we recognize errors can we correct them. Introducing and promoting this philosophy is a task for the management of health centres.

We must provide instruments to help us identify the expected and possible outcomes, and I am thinking here of Management by Process Indicators and Clinical Guidelines. The countries of the English-speaking world are leaders in the use of Clinical Guidelines.

We also need to incorporate the perspective of citizens, with their specific experiences and any reasonable expectations they may have. Informed Con-

sent, properly used, may act as a contract between organization, health professional and service.

This is an area where we have the opportunity to reconcile the interests of different parties, as health professionals we must act safely, but without retreating into defensive medicine, following best practice wherever there is scientific evidence. Trusting in the maturity of all parties, in a society of rights, will raise more problems and create new dynamics in the relationship between professionals and service users, and it is health organizations which must perform the role of guaranteeing these rights.

Adelaida Zabalegui

The literature contains many books and articles about the quality of health care with respect to errors. It should be noted that, while the term 'medical error' is generally used, this does not mean that all errors are due to medical action. Caring for health is an interdisciplinary endeavour which is the result of action by doctors, nurses, physiotherapists, social workers, managers etc. I believe we should stop assuming that it is always the health professional who is responsible for these errors, and that instead we should talk of 'clinical errors'. We need to analyse the system within which care is provided, and realize that many of the errors which are committed are not the result of poor professional competency but rather of the lack of controls to prevent such errors, a shortfall which is associated with misguided cost control measures, which reduce the number of professionals per patient.

Nurses are the largest professional group, and the one which spends most time with patients. Recently, Needleman and his colleagues at Harvard University published an article in the *New England Journal of Medicine* (2002) on the quality of care in 799 hospitals in 11 states. The authors analysed over five million internal medicine patients and over a million surgical patients with relation to care quality indicators (nosocomial infections, prolonged hospital stay, complications, bleeding, heart failure, venous thrombosis etc.). The article concludes that the best hospital care and therefore the lowest levels of error were associated with higher levels of training for nursing staff and more hours spent by nurses caring for patients. With respect to training, it is clear that better knowledge leads to better care. With respect to time, it should be noted that nurse:patient ratios in Spain are lower than in other countries, such as the USA. In Spain, nurses are able to spend less time with each patient as they have to care for more patients, sometimes as much as three or four times more. This excessive workload prevents nurses from providing the highest standard of care, and as a result leads to an increased risk of clinical errors.

Among the most frequent clinical errors, we can highlight: medication errors, nosocomial infections, mechanical complications, falls and bedsores. At

times, these errors in clinical practice have fatal consequences, such as incorrect blood transfusions in which there is a haemolytic response due to blood incompatibilities. However, 57% of the adverse effects of healthcare are preventable (Thomas et al., 1999). Of all the different sorts of adverse effects, the most expensive are surgical complications, medication errors, and incorrect or late diagnosis or treatment.

Therefore, in my opinion, we need to implement protocols to reduce clinical risks, and we also need to improve the documentation of clinical practice in order to improve the quality of care. We also need to issue recommendations to managers and teachers with the aim of preventing high-frequency errors associated with clinical care in the context of the modern emphasis on evidence-based care. These protocols should be validated and analysed in terms of cost-effectiveness, using error reports, consideration of incident reports and medical records, and direct observation.

We also need to identify situations where there is greater vulnerability to error, such as those involving ward staff (nurse:patient ratio). The amount and experience of staff taken over the week and the year (weekends, holidays, vacations, induction of new, inexperienced staff, peak points in the day, etc.). We also need to identify those units with the greatest risk of errors (intensive care units using high-risk drugs). We also need to provide health professionals who deal with patients with more time to improve their professional practice, writing safety guidelines, building cooperation between professionals and experts in the management of clinical errors (clinical risk managers), giving clinical directors the opportunity to support a culture which goes beyond simply finding out who is to blame.

If we are to shift from a culture of blame to one of safety, it must be compulsory to report errors to a central agency, with better and more extensive legislation to enable peer review, in order to study errors and implement the necessary changes in systems so that errors do not reoccur. Secondly, we could implement a safety checklist programme, with the aim of:

- a) Encouraging every professional to view their job and their unit from a wider safety perspective.

- b) Establishing clear, concise, measurable, standardized steps that the health professional identifies and values as important safety factors, such as, for example, administering transfusions after reviewing the protocol and under the responsibility of two nurses, together with the patient receiving the transfusion.
- c) Developing a data collection method which reduces confirmation bias.
- d) Immediately correcting any possible errors identified.

For Brown (2001), knowledge is the key to preventing errors. So long as Spanish nursing education remains at undergraduate diploma level, nurses will not have sufficient training to face the challenges posed by new technology and scientific progress. Three years of education are an insufficient basis for assuming full responsibility for the professional care of patients, their families and the community. It is now twenty-five years since Spain introduced undergraduate nursing diplomas, and it is now time that we put ourselves on the same level as the United States, Canada, the United Kingdom, the Netherlands, Finland and Greece, where nurses are able to make a greater contribution to patient care, and education is at degree, postgraduate and Ph.D. level in Nursing Science.

List of participants

Speakers

- Jaume Aubia, Vice President of the Official College of Doctors of Barcelona
- Ricardo de Lorenzo, President of the Spanish Association for Health Law

Chairperson

- Jordi Camí, Director of the Municipal Institute for Medical Research and member of the Board of Trustees of the Víctor Grífols i Lucas Foundation

Invited specialists

- Margarita Boladeras, Professor of Moral Philosophy at the University of Barcelona
- Montserrat Busquets, Nurse and Senior Lecturer in Ethics and Legislation at the School of Nursing, University of Barcelona, and member of the Board of Trustees of the Víctor Grífols i Lucas Foundation
- Victoria Camps, President of the Víctor Grífols i Lucas Foundation
- María Casado, Director of the Bioethics and Law Observatory at the University of Barcelona
- Carles Fontcuberta, Managing Director of the Fundació Unió Catalana d'Hospitals
- Narcís Mir, Director of the Risk Observatory, Institute of Safety Studies

- Vicens Molina, Supervisor of the Pharmacy Service at the Bellvitge Hospital, and Lecturer in Pharmacology at the School of Nursing at the University of Barcelona
- Martín Navaz, Managing Director of Confide, Correduría de Seguros, S.A.
- Isabel Pera, Head of Legal Nursing at the Vall d'Hebron Hospital, Barcelona.
- Josep Prat, Director of the Catalan Health Service
- Yolanda Puiggròs, Legal Advisor to the Hospital Consortium of Catalonia
- Francesca Puigpelat, Dean of the Faculty of Law at the Autonomous University of Barcelona
- Rosa Suñol, Director of the Avedis Donabedian Foundation and Director of the Avedis Donabedian Chair for Quality at the Autonomous University of Barcelona
- Carme Valls, Deputy in the Catalan Parliament for Grup Parlamentari Socialistes-Ciutadans pel Canvi
- Jordi Vallverdú, Lecturer at the Department of Philosophy at the Autonomous University of Barcelona
- Àngel Vidal, Director of Programmes and Quality at the Catalan Institute for Oncology
- Adelaida Zabalegui, Director of the School of Nursing at the International University of Catalonia

Publications

Bioethics Monographs

20. *Ethical Challenges of e-health*
19. *The person as the subject of medicine*
18. *Waiting lists: can we improve them?*
17. *Individual good and common good in bioethics*
16. *Autonomy and dependency in old age*
15. *Informed consent and cultural diversity*
14. *Considering the problem of patient competency*
13. *Health information and the active participation of users*
12. *The management of nursing care*
11. *Los fines de la medicina* (Spanish translation of *The Goals of Medicine*)
10. *Corresponsabilidad empresarial en el desarrollo sostenible* (Corporate responsibility in sustainable development)
9. *Ethics and sedation at the close of life*
8. *Uso racional de los medicamentos. Aspectos éticos* (The rational use of medication: ethical aspects)
7. *The management of medical errors*
6. *The ethics of medical communication*
5. *Problemas prácticos del consentimiento informado* (Practical problems of informed consent)
4. *Predictive medicine and discrimination*
3. *The pharmaceutical industry and medical progress*

2. Ethical and scientific standards in research

1. Freedom and health

Reports of the Foundation

4. Las prestaciones privadas en las organizaciones sanitarias públicas (Private provision in public health organizations)

3. Therapeutic cloning: ethical, legal and scientific perspectives

2. An ethical framework for cooperation between companies and research centers

1. Social perceptions of biotechnology

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1. What should we do with persistent sexual offenders?

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