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Articolo di ricerca

L'epidemiologia dell'"errore medico" in una città di medie dimensioni del centro Italia: un'indagine sulle denunce per responsabilità medica tra il 1997 e il 2004

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Abstract

Rationale. In the last 30 years in western countries there has been an exponential increase in malpractice claims, in the amount of compensations and in media attention on malpractice, with considerable consequences on human, economic, socio-cultural, insurance, professional, legal and ethical context. However in Italy there is a substantial lack of studies and data.

Objectives. To analyze malpractice claims in Terni, a city of 111000 inhabitants, and to shed some light to the patient compensation process.

Methods. Data concerning patients, accidents and compensation processes were provided by a group of medical-legal experts involved in malpractice claims, filed by residents in Terni, period 1/1/1997 – 31/12/2004. Fundamentally this work is an observational study; though we adopted the binomial test and a Bayesian approach to analyze the correlation between age and gender and malpractice.

Results. A number of 363 malpractice claims were filed, with a rate of 0.41 per 1000 of the general population and 0.75 of inpatients. The patients' age was significantly associated with an increase in the claim rate; no significant difference between genders. The average time between accident and conclusion was 3yrs 7mos; between claim and conclusion 1yr 7mo; the average amount of compensation was ⇔ 101490.00.

Conclusions. Our data greatly address the need, particularly in Italy, to perform detailed studies on adverse events and malpractice claims. Some fundamental innovation in legislation regarding medical liability is also necessary.

Keywords. Medical errors, patient safety, malpractice claim, population rates, risk management, compensation process.

INTRODUCTION

In the last twenty years, the issue of medical errors and patient safety has gained ever growing momentum in medical literature. From the cornerstone Harvard Medical Practice Study [1-2] to the "2000 Institute of Medicine report" [3] and a number of studies on drug adverse events listed in Medline from 1995 to date, research regarding incidence, causes and prevention of adverse events is one of the major concerns in current medical practice. However, current research is almost exclusively based on studies in Anglo-Saxon countries [4-6], with a few exceptions [7-8]. In Italy, there is a substantial lack of data, since no systematic studies, except from theoretical articles, single or multiple case descriptions [9-10], personal casistic reports [11] and a non-clinical report by Lombardia Region, edited by an economical newspaper [12], have been carried out to date. Here we investigate malpractice claims in Terni, a middle-sized city in Central Italy of about 110000 inhabitants, for the period 1997-2004. Even though major attention has been devoted to "adverse events" (defined as "an injury caused by medical management rather than by the underlying disease or condition of the patient" [3]), and several studies [13-14] have pointed out a poor correlation between malpractice claims and adverse events, in our opinion the issue of malpractice claims deserves scientific attention in itself since:

1. whether correctly or incorrectly, it involves a multitude of patients which healthcare organizations should be providing an answer to; in our opinion, the quality of the process of compensation for malpractice claims and iatrogenic damages is one of the aspects of quality in healthcare;
2. historically, in Anglo-Saxon countries the first epidemiological studies used malpractice claims as a source of data as well [15-18];
3. the economical burden of compensation for malpractice has a great impact on healthcare systems: the "insurance crisis" that occurred in the US in the 70's and 80's represented a prompt for the above-mentioned multitude of research, probably not much less than scientific, professional or ethical interest by doctors;
4. litigation claims "may also be a good source for information" to identify high risk processes to be studied using proactive risk assessment tools such as FMEA or similar and to establish a priority among them [19].

Therefore, our study aims to investigate malpractice claims in our city and shed some light on the patient compensation process as well as to point out, as far as possible, any similarities and differences with the results of studies in other countries.

METHODS

This study is based on a survey on the residents in the city of Terni in the period 1997-2004. Terni had one teaching hospital: Azienda Ospedaliera "S. Maria", with an average of 694 beds (of which 93 Day-Hospital beds), 113 general practitioners, 14 paediatricians, and 34 specialised doctor's rooms during the observa-

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tion period. In our survey, Terni residents at the time of the event were taken into account, disregarding the location where the treatment was given. For each malpractice claim filed in this period against any healthcare facility (in Terni or elsewhere in Italy) we obtained data regarding the following three areas of interest:

- the patient: sex; age; diagnosis upon hospital admission (or upon the doctor's room examination for outpatients); diagnosis upon discharge; presence/absence of comorbidities; consequences of the event (temporary disability; percentage of permanent impairment; reduction in life expectancy; death);
- the accident: setting (hospital, first aid care, GPs' rooms; specialised doctor's rooms); area (surgical or medical); discipline involved; day of the week when the accident occurred (weekday; weekend and/or public holiday); time of the day in which the accident occurred; ordinary or day-hospital admissions, urgent/emergency or elective admissions, DRG and MDC were also recorded where possible; data on informed consent (whether or not the informed consent process was questionable in the opinion of the claimants', the defendants' and the Courts' consultants) and the quality of medical records;
- the compensation process: time from accident to claim, from accident to conclusion (compensation or compensation denial) and from claim to conclusion; outcome of the claim; amount of compensation (if any); drafter of the medical-legal report.

The data was extracted from personal records of cases of a group of medical-legal professionals working in Terni that had been appointed by complainants, plaintiffs, healthcare facilities and insurance companies. Only residents at the time of the claim were taken into account. Each medical-legal professional provided anonymised data to the coordinator of the research (GB). Population and hospitalisation data were requested from the local section of Italian NHS, that provided anonymised data, thereby fully respecting the Italian privacy law (T.U. 196/2003).

We used the binomial test to compare gender rates by age class.

In order to take parameter errors into account, we adopted a Bayesian approach and computed the Bayesian *p-value* against the following models:

1. the model consisting of a unique claim rate that is common to each gender and age class;
2. the model in which there is a specific rate for male and a specific rate for female, common to each age class;
3. the model consisting of an equal claim rate for male and female, but specific to each age class.

The Bayesian *p-value* [20], unlike the classical *p-value*, is computed on a predictive distribution. So, in this case, the *p-value* is the probability of a more extreme event than the observed frequency according to the (posterior) Beta-Binomial distribution (instead of the Binomial). It follows that a small Bayesian *p-value*, a san example P<0.01, still indicates a model that cannot be verified because it seems to be unable to predict the observed anomaly. As a prior distribution, we consistently used a non-informative uniform Beta (1,1), which gave a more prudent (wider) acceptance region. We found that when all the age classes are assumed to have the same claim rate (either under model 1 or 2), the Bayesian and classical *p-values* are quite similar, indicating small parameter errors (due to adequate sample size). The sample size is reduced, however, when rates are assumed to be specific to ages.

RESULTS

In the observation period (since 1997 to 2004), a number of 363

Table 1 - a) Claims by age in Terni's Population; b) Claims by age in inpatients

a)

		Males				Females				All		
Age Class	no. claims	Population	Incidence Rate per 1000	p-value	no. claims	Population	Incidence Rate per 1000	p-value	no. claims	Population	Incidence Rate per 1000	p-value
0-1 yr	6	4.808	**1,25**	30,7%	3	4.184	**0,72**	21,0%	9	8.992	**1,00**	40,2%
2-14 yrs	3	43.184	**0,07**	13,0%	7	40.784	**0,17**	22,2%	10	83.968	**0,12**	39,1%
15-45 yrs	72	175.416	0,41	41,6%	74	171.976	0,43	41,4%	146	347.392	0,42	47,7%
46-64 yrs	46	110.800	0,42	23,4%	61	120.008	0,51	27,7%	107	230.808	0,46	46,1%
65-75 yrs	29	50.728	0,57	21,0%	26	63.824	0,41	21,1%	55	114.552	0,48	44,9%
> 75 yrs	18	36.872	0,49	14,5%	18	61.040	0,29	20,1%	36	97.912	0,37	47,4%
Total	174	421.808	0,413	44,4%	189	461.816	0,409	41,8%	363	883.624	0,411	42,7%

b)

		Males				Females				All		
Age Class	no. claims	No. admissions	Incidence Rate per 1000	p-value	no. claims	No. admissions	Incidence Rate per	p-value	no. claims	No. admissions	Incidence Rate per	p-value
0-1 yr	6	9.693	0,62	29,3%	3	8.480	0,35	21,7%	9	18.173	0,50	40,9%
2-14 yrs	3	12.801	0,23	16,3%	5	9.297	0,54	20,9%	8	22.098	0,36	38,6%
15-45 yrs	51	35.696	**1,43**	30,2%	58	60.454	**0,96**	14,7%	109	96.150	**1,13**	29,3%
46-64 yrs	37	42.955	0,86	13,8%	53	41.697	1,27	20,6%	90	84.652	1,06	43,0%
65-75 yrs	23	43.267	0,53	42,0%	20	35.268	0,57	42,6%	43	78.535	0,55	44,6%
> 75 yrs	13	36.524	**0,36**	40,2%	13	41.551	**0,31**	36,6%	26	78.075	**0,33**	43,7%
Total	133	180.936	0,735	44,4%	152	196.747	0,773	37,6%	285	377.683	0,755	40,2%

malpractice claims against healthcare facilities or single doctors were filed, with an average of 39 per year. The last year registered a much higher frequency of claims (92). The date of the accident covers a period of around 20 years. The period since accident to claim is 2.03yrs (740.7 days) on average (SE of the mean 53.18 days), but it may have taken as long as 14 years. The mean for the period since claim to conclusion and for the overall period since accident to conclusion are 1yr and 7mo and 3yrs and 7 mo respectively. The claim rate of the residents was 0.41 per thousand for an average population of 110453 people in the eight year period. We used the binomial test to compare gender rates by age class and found a significant difference between age classes but not between genders. Using the Bayesian approach reported in the paragraph "Methods" we obtain the following results. Table 1 shows the rates that are 0.01 significant under model 1 (incidence rate of the total) and model 2 (male and female incidence rates) in bold print. Moreover, most of the non-significant classes are in a grey area, eg became significant at 0.05 level. It is worthy to note that the same classes were identified when using the Binomial test. According to table, while age plays an important role in discriminating claim rates, especially for inpatients (Tab. 1b), claim rates of males and females of the same age are quite similar. Age seems to play an important role, especially in the classes of ages 2-14 and 0-1. Only a milder difference was detected for age classes 46-64, 65-75 and over 75, with non-significant variability between genders. The low claims rate is to be expected in youngs 2-14 years old; the rate in inpatients over 75 years is to be remarked, being less than half than average (0.33 *versus* 0.76). The result is quite different to the statistics of the prominent studies on adverse events quoted in the introduction, in which age over 65 years as well as the presence of comorbidity and a low social status (i.e. no health care insurance) tended to be associated with adverse events. This difference is confirmed to a certain extent by the result indicating that in our study, coexisting pathological conditions are present in only 58.6% of claiming patients.

Death as a consequence of the presumed medical malpractice accounted for more than 20% of the cases and 25% resulted in a permanent impairment of >20% (Tab. 2); the mean permanent impairment was 21.4% (SE 1.6%).

Regarding to the accident, this study shows that the events that generated claims occurred predominantly in hospital settings (85.3%), on Sundays and on public holidays or on the day before.

Table 2 - Consequences of the presumed medical malpractice

	Nr.	%
Consequences		
Temporary inability only	25	9,2%
Permanent impairment 1 to 5%	20	7,4%
Permanent impairment 6 to 10%	45	16,6%
Permanent impairment 11 to 20%	49%	18,1%
Permanent impairment 21 to 50%	53	19,6%
Permanent impairment 51 to 100%	19	7,0%
Reduction in life expectancy	4	1,5%
Death	56	20,7%
Total	271	
Missing/unknown	92	
Minimum	1	
Maximum	100%	
Average	21,9%	

Surgical disciplines were involved in 216 of the 316 cases (68.4%). In 53 cases (17.3%), professionals other than physicians were involved (37 nurses, 2 of which were ward sisters, and 16 technicians). Regarding to the type of hospitalisation, the very low incidence of claims for Day-Hospitals in comparison to ordinary admissions is not surprising (20, equal to 10.5%; p<0.00001); the low complexity of cases and the absence of urgent/emergency cases play an important role. The tendency is even more pronounced for elective admissions with respect to urgent/emergency admissions, where the latter involved 109 claims (64.5%; p<0.0001). The distribution of cases, according to the Major Diagnostic Categories, shows the high percentage of MDC 21 («Injuries, Poison & Toxic Effect of Drugs»); this concurs with the general data regarding the higher incidence of claims involving urgent/emergency admissions. In 86 cases (23.4%), the opinion of the claimant/plaintiff's expert(s) concurred with the one of the defendant's expert(s) regarding to the existence of a negligent error. Therefore, in about one fourth of the cases, differences were, at worst, related to the extent of physical permanent impairment and consequently the amount to be paid by the Insurance Company. The most recurring errors were related to therapy and 195 (45.3%) thereof involved a surgical operation, either in the decision to perform or not to perform it, in the surgical

Table 3 - Time since event - claim to claim - conclusion (compensation denied/dismissal of case)

	Event-claim		**Event-conclusion**		**Claim-conclusion**	7,4%
	no.	**%**	**no.**	**%**	**no.**	**%**
<1 to 6 months	14	14,4%	0	0,0%	6	6,2%
7-12 months	24	24,7%	1	1,0%	9	9,3%
1 to 3 years	37	38,1%	20	20,6%	46	47,4%
4 to 5 years	14	14,4%	38	39,2%	19	19,6%
6 to 10 years	6	6,2%	35	36,1%	17	17,5%
> 10 years	2	2,1%	3	3,1%	0	0,0%
Total	**97**		**97**		**97**	
Missing/unknown	266		266		266	
	10 dd.	**Minimum**	**11mo.**	**Minimum**	**11mo**	**Minimum**
	13yrs. 11mo.	**Maximum**	**18yrs. 8mo**	**Maximum**	**8yrs. 5mo**	**Maximum**
	2yrs. 2mo.	**Average**	**3yrs. 7mo**	**Average**	**1yrs. 7mo**	**Average**

Table 4 - Outcome of claim

	no. claims	%
Settlement before trial	66	54,5%
Compensation awarded to the claimant	14	11,6%
Dismissal of the claim (including compensation denied)	17	14,0%
Out-of-court settlement during trial, after Court-appointed medico-legal expert opinion	24	19,8%
Total	**121**	
Missing/unknown	242	

technique selected or eventually whilst performing the intervention.

Table 3 deals with the claim and compensation process: the time gap between the event and the claim (2yr 2mo on average) is not surprising, considering the time that usually elapses between the adverse event and the first signs of the consequent disease as well as the cost of the legal process. Since 49.8% (156) of the claims were filed in the last three years and claims involving major impairments/major compensation tended to last longer than the average length, it results on the average period since claims to conclusion (1yr 7mo). In just 14% of the cases, the patients were unsuccessful in their claims and more than half of the claims were settled before going to trial (Tab. 4).

Table 5 indicates that the average amount of compensation detected from the available information is a little more than € 100000, a very considerable amount when referring to the overall phenomenon, with the highest figures for Neurosurgery (~ € 425000), Pathologic Anatomy (~ € 270000) and Obstetrics and Gynaecology (~ € 176000). The remarkable difference between the amount claimed and the amount awarded (3:1 ratio) indicates an incorrectly excessive calculation on the part of the claimant that could have relevant negative consequences for all the parties involved.

In less than 70% of the cases, expert reports were not drawn up by medico-legal specialists; in just 19 cases (6.6%) there was a form of collaboration between a medical-legal specialist and specialist(s) in the related field(s). It must be negatively pointed out that in 7 cases (8.6%) even the Court appointed "inappropriate" specialists. The quality of the medical records was poor in 77 (24.6%) of the cases, as either implicitly or explicitly mentioned in the medical-legal reports.

Serial errors

One of the most important results of our study is the detection of at least 6 "critical matters", corresponding to 6 clinical pathways burdened by a high rate of claims: 6 cases of endocarditis and/or sepsis (6 deaths), 5 cases of pulmonary embolism (4 deaths), 8 cases of appendicitis (2 deaths, 6 major impairments), 7 cases of mistakes in the diagnostic and therapeutic approach to breast cancer (mainly mammography readings; 2 deaths, 5 reductions in life expectancy) and differences in calibration in two laboratories of the same healthcare facility for common haematological tests (Hb, rbc, etc.; 1 death). Another very frequently raised complaint concerned informed consent (109 cases, 107 surgical and 2 medical); it is worthy to note that in 52 cases the defendant's consultant admitted that there had been a failure in the informed consent procedure, and in 12 cases it was decided by the Court.

DISCUSSION

Collected data confirm that malpractice litigation is quite a remarkable phenomenon, considering that Terni can be regarded as a sample of a large part of Italy (excluding big cities and rural areas, i.e. more than 65% of total Italian population) both in terms of the human suffering it implies (involving 0.41 per thousand of the general population) and in economical terms (€ 9900000 known compensation; around € 31000000 estimated compensation; i.e. around € 40/year for each Terni resident).

In 1996, Prof. F. Introna, one of the most distinguished profes-

Table 5 - Amount awarded

	Requested by claimant/plaintiff		**Settlement/ compensation**	
	no. claims	**%**	**no.**	**%**
None	0	0,0%	16	33,3%
Up to 5000 Euro	8	5,0%	9	18,8%
> 5.000 to 10.000 Euro	5	3,1%	12	25,0%
> 10.000 to 25.000 Euro	18	11,3%	27	56,3%
> 25.000 to 50.000 Euro	23	14,5%	8	16,7%
> 50.000 to 100.000 Euro	19	11,9%	10	20,8%
> 100.000 to 250.000 Euro	**33**	20,8%	18	37,5%
> 250.000 to 500.000 Euro	18	11,3%	12	25,0%
> 500.000 to 1.000.000 Euro	24	15,1%	2	4,2%
> 1.000.000 < 2.000.000 Euro	7	4,4%	1	2,1%
>2.000.000 Euro	4	**2,5%**	0	0,0%
TOTAL	**159**		**115**	
Missing/unknown	204		148	
	363		363	
4	€ 377,00	minimum	€	minimum
4	€ 3.615.198,00	maximum	€ 1.500.000,00	Maximum
4	€ 310.374,00	average	€ 101.490,00	Average

sors in Italian Legal Medicine, when referring to the Harvard Medical Practice Study [1], said that "such research probably cannot be repeated in Italy" [9]. In our opinion, the time has come, even in Italy, to overcome this limitation and face the problem of medical errors by performing systematic studies on adverse events, possibly on a nationwide scale, as a first step. The literature quoted in the introduction gives many excellent methodological models.

In this context, it would be greatly desirable to carry out studies on malpractice claims as well, since it offers information useful in improving not only the quality of healthcare services but also the quality of the compensation process in terms of length, fairness and equity.

The average time that elapsed since the claim to the conclusion of the compensation process (1yr and 7mo) represents the most important result of the study from this point of view, especially when considering that one fourth involved patients with a 20% impairment and 7% thereof were above 51%; needless to say, this led to obvious difficulties in working and/or to loss of income, not to mention care expenses. It also has to be kept in mind that this result, as previously mentioned, is a "minimum value". Furthermore, the socio-economical environment of our study represents many middle-sized towns and quite a large part of overall Italian population, but certainly not the largest cities (≥ 500.000 inhabitants). It is easy to imagine that the average time from claim to conclusion is far longer for the latter, especially when a case goes to Court and a trial ensues. Thus, it seems that the time has also come for innovation within the legislative framework, to facilitate a reduction in the patient's waiting period for compensation, which is due in more than 85% of the cases. Data shown in Table 3 indicates that in around one fourth of the cases, the consultants of the claimant and those of the defendant agreed about the occurrence of a negligent adverse event, the quantum being the possible source of disagreement. More than half of the claims were settled before trial. Therefore, 20% of the cases in which the claim was settled only after the Court-appointed medical-legal expert opinion, represents the first area of possible improvement. An answer could be to implement arbitration proceedings, to be held by a Permanent Expert Commission appointed by the Province's Medical Order with precise time limits, adopting the same criterion used for damages compensation in motor vehicle accidents (D. Lgs. 7/9/2005, n. 209), with obvious wider time limits due to the average complexity of malpractice cases. Another legislative matter that needs to be faced is the conflict between the "duty to warn" (the duty of any public officer, such as a doctor working for the NHS, to inform a judiciary when a crime like culpable homicide comes to their attention; sec. 331 Penal Proceedings Code) and any activity involving an analysis of the quality of care given [21], solved elsewhere since the 80's [22]. Otherwise a precious quality tool such as a clinical audit would be heavily impaired and any kind of incident reporting system, which is of vital importance in a risk management context as well-known worldwide (see JCAHCO), would be hindered. Moreover, the field experience of the Authors as consultants in penal and civil (assumed) malpractice cases allowed them to verify the real truth behind the phrase defining «the doctor [as] the second victim» [23]. Since claimed medical mishaps are only the "tip of the iceberg" of systematic organisational failure, once again the time has come to intervene in existing penal laws by means of valorising organisational failure and managerial responsibility to levels higher than (or at least, equal to) the failure of those at the "sharp end". The British control assurance and recent legislation passed in France on iatrogenic damage provide extremely valuable suggestions.

Regarding quality factors in the malpractice compensation process and in order to guarantee both the patient and the doctors, it seems that a more professional approach to medical-legal consultancy as well as an improvement in the quality of medical records [24-27] is needed, in accordance with the guidance given by sections 62 and 26 of the Italian Medical Ethics Code.

Assuming that the greater incidence of malpractice claims is to be expected in more accident-prone cases (e.g. in elderly people with underlying chronic comorbidities, suboptimal general conditions, etc.), which however was not observed in our data, the above quoted notion of a poor correlation between adverse events and claims seems to be confirmed. If so, along with some other factors, the patient-doctor relationship is in need of major attention. From this point of view, our data indicating poor quality in the informed consent procedure again represent only a hint of the need to address major cultural change by doctors and healthcare workers aimed at a systematic, organisational patient-safety oriented culture, in which any effort that facilitates a more empathetic approach in the doctor-patient relationship is to be considered a priority.

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Epidemiology of medical errors in a medium size town of central Italy: an investigation of malpractice claims in the period 1997-2004

Razionale. Negli ultimi 30 anni si è registrata nei paesi occidentali una crescita esponenziale delle controversie per responsabilità medica e dell'entità economica dei risarcimenti, nonché della risonanza mediatica rivolta alla cosiddetta malasanità, con conseguenze importanti e spesso preoccupanti a livello umano, economico, socio-culturale, assicurativo, professionale, giurisprudenziale, etico. In Italia, nonostante ciò, si assiste ad una sostanziale carenza di dati e di studi volti all'analisi del fenomeno.
Obiettivo. Lo scopo di questo lavoro è quello di analizzare le denunce per responsabilità professionale medica nella città di Terni, 111.000 abitanti, e di far luce sul procedimento di risarcimento del danno al paziente.
Metodologia. I dati analizzati riguardano i pazienti, l'evento e il procedimento di risarcimento e sono stati estrapolati dalle consulenze medico-legali in tema di responsabilità medica effettuate da un gruppo di specialisti in Medicina Legale e riferite al territorio della città di Terni tra il 1997 e il 2004. Lo studio è essenzialmente di natura osservazionale. Tuttavia sono stati utilizzati il test binomiale e il teorema di Bayes allo scopo di analizzare la correlazione esistente tra l'età e il sesso dei pazienti e l'incidenza delle denunce.
Risultati. Sono stati riscontrati 363 casi di denuncia per responsabilità medica, con un tasso dello 0.41 per 1000 abitanti e dello 0.75 per 1000 degenti. L'età dei pazienti risulta significativamente associata ad un incrementato tasso di denuncia, mentre non si sono dimostrate differenze tra i sessi. Il tempo intercorrente tra l'errore medico e la sentenza è in media di 3 anni e 7 mesi, mentre quello tra la denuncia e la sentenza di circa 1 anno e 7 mesi. L'ammontare del risarcimento è in media di ⇔ 101490.00.
Conclusioni. I nostri risultati indicano la necessità, soprattutto in Italia, di implementare indagini scientifiche incentrate sullo studio degli eventi avversi in campo sanitario e delle denunce per responsabilità professionale medica. Necessarie inoltre riforme legislative in tema di responsabilità medica.

Parole-chiave. Errori medici, sicurezza del paziente, contenzioso giudiziario per responsabilità professionale medica, qualità della prestazione sanitaria, gestione del rischio clinico, risarcimento del danno.