

The clinical legal medicine: a need for quality of care and patient's safety. A single center five-year experience

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Summary. *Introduction.* Clinical legal medicine is a branch of legal medicine that takes place in a clinical setting approaching the patient's bedside and using a particular attention not only for conceptual or normative references but also for every possible medical and social aspect. *Material and methods.* The requests of medico-legal opinions received by the Department of Legal Medicine of a large university hospital were retrospectively collected over a 5-years period. The analysis focused on the recurrence rate of the requests and the most common medico-legal issues to be solved in a clinical context, differentiating between adult and minor patients. *Results.* The collected medico-legal advices amounted to 448. The most clearly involved clinical area was Medicine (54%) followed by Gynecology and Obstetrics (15.6%), Pediatrics and Surgery (10.7%). The requests concerning patient's self-determination in therapeutics choices, including refusal of proposed treatments, covered almost one-half of total casuistry. The designation of support administrator represented also a relevant issue (20.5%). In case of minors, the queries related to reporting crimes were three times higher than in adults, while the appointment of a support administrator was never requested. *Conclusion.* Clinical legal medicine, through medico-legal advices, plays a primary role in contributing to the safeguarding of health and to the decision-making process of clinicians. (www.actabiomedica.it)

Keywords: Clinical legal medicine; medico legal advice; medico-legal evaluation; patient's safety.

Introduction

The right to health, based on principles of universality and solidarity, has been recognized since implementation of Italian Constitution, in 1948. Article 32 declares the interest of nation to safeguard health as a fundamental right of the individual and as a collective interest. The first realization of this principle dates back to the end of the sixties when hospital reforms (Law n.132 of 12th February 1968; Decrees of

the President of the Republic n. 128, 129, 130 of 27th March 1969) established hospital institution, defined as public institutions directed to hospitalization and treatment of patients. In the same historical period, the discipline of legal medicine received in Italy the first official recognition. In fact, the article 25 of D.P.R 27th March 1969 declared "a medico-legal and social insurance service has to be established in regional hospitals (...)". Law n. 833 of 23rd December 1978, that established the National Health System with the aim

of protecting physical and psychological health of the individual and community, defined a new dimension of legal medicine. Article 19 states “The Local Health Units provide prevention, treatment, rehabilitation and legal medicine services”, without explaining the exact meaning of “legal medicine” [1]. Before the entry in force of the aforementioned law, the medico-legal intervention detained a more technical connotation, as a useful instrument to facilitate the administration of justice. After 1978, a new concept of legal medicine started to take hold, permitting to overcome the dichotomy, already expressed in 1937 by Cazzaniga [2] and still surviving in a few international countries [3], between juridical legal medicine, with a doctrinal dimension, and forensic legal medicine with a practical dimension.

As Benciolini wrote in 2005 [4]: “It names clinical legal medicine because, first of all, it takes place in the clinical setting, caring for the single citizens who address the Health System as patients or because of prevention. (...). Moreover, the clinical dimension of legal medicine operating in National Health System refers to a direct approach to the patient-citizen where the attention has to be pointed not only to conceptual or normative references, but also to every possible implication”. Of peculiar importance in clinical legal medicine is the physician-patient relationship, that provides for the presence of physician to the “patient’s bed side”.

It’s hard to list the possible practical activities of clinical legal medicine, as they can extremely vary according to the several needs and challenges introduced by scientific innovations and medical technologies. Anyway, a concise list is contained in the Ministerial circular n. 30 of 10th February 1970 that conferred specific responsibilities to medico-legal service in hospitals [5]: providing expert opinion to Emergency Room specialists for writing medical reports; expert opinion in matter of hospitalization and dismissal or consent to medical and surgical treatments; support in litigation between hospitals and insurances; medico-legal assessments aimed to safeguard the hospital institution in professional liability lawsuits; intervention in issues associated with organ donation and transplantation from a cadaveric source; collaboration in clinical and forensic toxicology assessment.

Many innovative aspects should be added; however, the activity of providing an intra-hospital advice plays a role of primary importance and necessity. Medico-legal advice may be defined as the “determination of the relationship between biological events and legislation or the application to the healthcare of general or special legislative provisions” [6].

Although organizational aspects may differ among hospitals, the process that ends up requesting an expert opinion usually starts when a physician or another health professional asks a question on medico-legal issues. Medico-legal experts may answer to this question in an oral form or by telephone in simple cases and in a written form – after having visited patient - in more difficult cases. In our hospital the medico-legal service offers a 24 hour clinical support and the questions raised inside the various medical wards are taken in charge by the expert on duty. The on-call medico-legal experts may be directly contacted through the service mobile or the administrative office which is appointed to receive the request forms for medico-legal opinion. Because of the close collaboration that has been emerging among physicians and medico-legal experts, some of them may be also directly requested by colleagues to whom they have formerly provided an advice in a similar case.

It is noteworthy that the requests of medico-legal advices about specific problems are addressed to specialists who belong to the medical equip of the hospital and, for this reason, detain a great experience about the issues that most commonly need to be solved in the hospital itself. Suspected cases of child abuse represent an example. In fact, in these cases, where a highly specific knowledge about the lesions which may be observed is extremely important, the possibility to tap into large case series, as the ones that a hospital have available, is fundamental in order to make a correct diagnosis of child abuse and to establish the time of its occurrence [7]. Thanks to this experience, some gray cases are finally understood as related or not to child abuse [8-10].

Reflection about issues which lead physicians to ask a medico-legal opinion is substantial in order to comprehend the need of clarity, requested by both patients and health professionals, about relation between medicine and law [11,12].

Materials and Methods

An informatic database was developed to store and analyze the advices requested to the medico-legal service of the university hospital of Padua, which counts 60.0000 hospitalizations and 7 million outpatient visits per year about. The request of medico-legal opinion implies the completion of a specific form with the medico-legal query and personal data of both the patient and the health professional who makes the request. On-call medico-legal specialists receive the request and may answer by telephone or by written opinion, depending on difficulty of the specific case.

Data were collected over a period of 5 years from 01.01.2013 to 31.12.2017.

Collected data were analyzed in order to study the recurrence rate of the queries in respect of the requesting ward and the medico-legal issue. Finally, the requested opinions on issues concerning minor patients were separately analyzed in order to compare them with the general casuistry.

The wards which the requests of advice come from we divided in the following 9 areas:

- Anesthesia and Resuscitation (including Intensive Care Unit and Semi-Intensive Care Unit);
- Surgery (including General and Specific Surgery Units);
- Health management (including Health Management Office, Clinical Governance, General and Administrative Management Office);
- Gynecology and Obstetrics (including Gynecology and Obstetrics, Delivery room, Gynecology Emergency Department);
- Medicine (including General Clinical Medicine, Specialized Clinical Medicine, Geriatric Unit, Long Term Care Unit);
- Pediatrics (including Pediatrics Emergency Department, Pediatric Intensive Care, various Medicine and Surgical Pediatric Divisions, Child Abuse & Neglect Unit, Pediatric Day Hospital, Neonatology);
- Emergency Room;
- Psychiatry;
- Others, when the request comes from a ward out of the list.

The medico-legal queries were classified into 13 fields:

- Consensus to medical treatment. In these situations, medico-legal specialists are usually asked to verify the patient's capacity to make decisions about diagnostic ascertainments or therapeutic treatments. The most delicate cases involve psychiatric or minor patients and the patients with clouding or loss of consciousness in medical/surgical emergency or urgency contexts. In some cases, the request of evaluating the subject's capacity is due to social and organizational reasons. More general questions refer to the form the consent needs to be obtained, regardless of the patient capability.
- Refusal of medical treatments. This kind of query was considered separately from the former one in order to highlight its significance in all the casuistry.
- Support administrator, interdiction, incapacitation. In this field, medico-legal specialists are asked to evaluate the opportunity, according to Law n. 6 of 9th January 2004, to design a support administrator, in order to assist - through temporary or permanent sustain - people who are dependent in activities of daily living because of physical or psychical impairments. More uncommon questions regard the interdicted or incapacitated people.
- Professional liability. Medico-legal evaluation is commonly requested in cases of suspected malpractice.
- Mortuary policy and death assessment, where the medico-legal specialists give advices about the procedure for declaration of death and determination of brain death.
- Investigations about drug and alcohol addiction for forensic purposes.
- Deontology, in cases with not only legal but also deontological and ethical implications.
- Voluntary termination of pregnancy, according to the provisions of Law n. 194 of 22nd March 1978;
- Other issues regarding contraception, sterilization and in vitro fertilization, commonly related

- to the use of contraceptives by minors and the provisions of Law n. 40 of 19th February 2004;
- Reporting crimes. In these cases, medico-legal specialists are asked to assist other physicians in the identification of a criminal activity and in the writing of a medical report for the offences that are prosecutable *ex officio*;
 - Reporting sexual crimes. This kind of query was considered separately from the other crimes former due to their preponderance and peculiarity;
 - Abandonment of child or disabled person;
 - Compulsory health treatment. In this field, medico-legal opinion is necessary to begin an involuntary treatment of mentally ill patients or other kind of patients.

Results

The medico-legal opinions, analyzed in the considered temporal range, amount to a total of 448. **Table 1** shows an overall upward trend over time of medico-legal advice requests.

Wards. As reported in **Table 2**, the wards that resulted to most often ask for medico-legal opinions are, in decreasing order, Medicine (242), Gynecology and Obstetrics (70), Pediatrics and Surgery (48), which contributed, respectively, to 54%, 15,6% and 10,7% of the total amount.

Queries. The distribution of queries during the considered period is reported in **Table 3**. The main reason that led physicians to ask for medico-legal opinions is the refusal to medical treatments, that recurs in more than 25% of the casuistry. Other common queries concern the procedure to design a support administrator (20,5%), issues related to the validity of

Table 1. Medico-legal advices requested during a 5-year period

Year	Number of medico-legal opinions
2013	68
2014	100
2015	82
2016	87
2017	111
Total amount	448

consent to medical treatment (17%) and the procedure that regulate the voluntary termination of pregnancy (10,7%). Medico-legal support is also frequently requested when the commission of a crime is suspected in order to identify clinical situations that meet mandatory reporting requirements (7%). This result is even more significant when adding the opinions offered in case of suspected sexual crimes, that represent a conspicuous percentage of the casuistry (7,8%). The recurrence of the other queries is less than 5% of the total amount.

Minors. 79 medico-legal opinions (17,6%) concern issues that involve minor patients (**Table 4**). Compared to the totality of the patients, in this sample a few queries are more represented as the consent to medical treatment (21,5% vs 17,4) and the activity related to reporting crimes (except for sexual ones) whose rate is three times higher (21,5% vs 7%). When considering reporting sexual crimes, this query is two times more frequent in minor patients than in adults (17% vs 7,8%). On the contrary, other queries are less common when minors are compared to adult patients, as the ones concerning refusal of medical treatments (7,5% vs 25%) or the appointment of support administrator that is never requested below 18 years of age. Interestingly, the voluntary termination of pregnancy has a quite similar recurrence rate in the two groups (12,6% vs 10,7%).

Discussion

When giving an opinion in a clinical context, medico-legal specialists go beyond the forensic purposes of their activity. This peculiar dimension implies not only a sound juridical knowledge but also the awareness that law needs to be adapted to a specific person.

The direct conversation with the patient and the health professionals (medical and not medical) who have asked for technical support makes unique every medico-legal advice that, in fact, is the result of legal, deontological, ethical and clinical aspects.

Sometimes the physicians may request medico-legal opinion as a strategy of defensive medicine in order to avoid from getting involved in legal disputes.

Table 2. Medico-legal advices distribution by wards

Wards	2013	2014	2015	2016	2017	Total	Total (%)
Anesthesia and Resuscitation	1	2	3	0	3	9	2
Surgery	8	14	8	7	11	48	10,7
Medicine	37	54	44	51	56	242	54
Hospital Management office	0	3	0	0	0	3	0,6
Gynecology and Obstetrics	10	11	18	20	11	70	15,6
ER	0	4	1	0	4	9	2
Psychiatry	3	5	1	2	7	18	4
Pediatrics	9	7	7	7	18	48	10,7
Others	0	0	0	0	1	1	0,2
Total	68	100	82	87	111	448	

Table 3. The content of queries directed to the medico-legal service

Query	2013	2014	2015	2016	2017	Total	Total (%)
Consensus to medical treatment	10	15	16	15	22	78	17,4
Refusal of medical treatment	21	24	14	19	34	114	25,5
Support administrator, interdiction and incapacitation	17	22	17	14	22	92	20,5
Professional liability	0	0	1	2	3	6	1,3
Mortuary policy and death assessment	1	2	2	3	1	9	2
Investigations about drug and alcohol addiction	1	1	2	2	3	9	2
Deontology	0	0	1	2	1	4	0,9
Voluntary termination of pregnancy	5	8	13	15	7	48	10,7
Other problems concerning contraception, sterilization, in vitro fertilization	0	3	1	2	1	7	1,5
Reporting crimes	4	13	7	5	3	32	7,1
Reporting sexual crimes	5	10	5	4	11	35	7,8
Abandonment of child or disabled person	1	2	0	2	2	4	1,6
Compulsory health treatment	3	0	1	2	1	7	1,5
Total	68	100	82	87	111	448	

When this intent is clear, the medico-legal specialist should remind the clinician of the positive acceptance of responsibility, defined as the “attentive and conscientious presence of health care professional, before being charged of inappropriate behavior”. Through this approach, it is possible to prevent adverse effects before they happen [13].

Concerning the reasons for which physicians request medico-legal opinion, the most frequent issue relates to the capability of patient to self-determination

in therapeutics choices, which is fundamental to prove validity of medical activity.

These kinds of queries together the ones that concern the refusal of treatments amount to almost one-half of total casuistry and show a constant increasing trend during years. Similar considerations may apply to the group of minor patients. In fact, however minors are subjected to parental responsibility, they have the right to receive correct information in order to accept a certain treatment.

Table 4. The content of queries directed to the medico-legal service in case of minor patients

Query	2013	2014	2015	2016	2017	Total	Total %
Consensus to medical treatment	3	2	2	3	7	17	21,5
Refusal of medical treatment	0	1	0	2	3	6	7,5
Support administrator, interdiction and incapacitation	0	0	0	0	0	0	0
Professional liability	0	0	1	0	0	1	1,2
Mortuary policy and death assessment	1	0	0	0	0	1	1,2
Investigations about drug and alcohol addiction	0	0	1	1	0	2	2,5
Deontology	0	0	1	0	0	1	1,2
Voluntary termination of pregnancy	0	2	2	5	1	10	12,6
Other problems concerning contraception, sterilization, in vitro fertilization	0	1	0	0	0	1	1,2
Reporting crimes	2	7	4	2	2	17	21,5
Reporting sexual crimes	3	6	3	0	2	14	17,7
Abandonment of child or disabled person	1	1	0	2	1	5	6,3
Compulsory health treatment	0	0	1	2	1	4	5
Total	11	13	15	17	23	79	

In this background, clinical legal medicine promotes the process for an adequate information of the patient, assuring a correct communication among health care professional, patient and family. Through a qualified opinion about patient's capability to express a valid consent, the process of obtaining informed consent is not reduced to an aseptic filling out of forms.

Collected data, together everyday experience, show an increasing number of patients who refuse medical treatment, including blood transfusion, amputations, tracheotomy, etc.

The recent Law n. 219 of 22nd of December 2017 is likely to be helpful to resolve many conflicting situations related to this topic, because it provides the physician with the indications to get the patient's consent and the patient with the tools for self-determination in health care decisions through advance directives and shared care planning [14].

Concerning blood transfusions, the implementation of Patient Blood Management [15], even though the introduction of guidelines developed by the National Blood Centre [16], represents a revolutionary scientific element [17] that will greatly limit the use of allogeneic transfusions, reducing their risks and conflicts between physicians and patients who refuse them.

The period of time chosen for the present study does not go beyond 2017 really because of the aforementioned news; in fact, the impact of the latter in clinical practice, evaluating how they affect the queries directed to medico-legal service, will be the object of a future separate study.

Among the other queries, the designation of support administrator for people with total or partial loss of autonomy according to Law n. 6 of 9th January 2014 is also relevant.

In the presented casuistry this figure is often appointed to assist old people who suffer from cognitive impairment without decreasing their residual autonomy.

A greater use of this instrument is predictable and desirable in future, since Italy has one of the oldest population in the world and in 2030 the median age will be more than 50 years old and a large part of the population, almost one third of the total, will be over the age of 65 [18]. For this reason, the queries from Medicine, Geriatric Unit, Long Term Care Unit - which are already the majority- are expected to increase. Through a direct intervention, medico-legal specialists become aware of patient's needs and autonomy, verifying whether the law requirements regulating designation of support administrator are satisfied

and, finally, drawing up the correct reporting to the judge supervising a guardianship.

Medico-legal opinion is also necessary for reasons of justice in case the suspicion of a crime, particularly sexual crimes, arises. This kind of query is particularly delicate in case of minor patients, who, according to collected data, represent a relevant proportion of the total patients suspected to be victims of a crime.

Finally, great attention is paid by physicians in safeguarding the patient's choices, not just in terms of legal liability, now regulated by law n. 24/2017 [19], but also according to an ethical and deontological point of view.

Even though the medico-legal opinions that were requested in a non-formal manner may not have been included in the casuistry, producing an underestimation of the real number, the presented sample is a useful representation of this specific medico-legal activity.

Conclusions

Medico-legal advice permits a reflection in a context of interaction among clinicians and medico-legal specialists, representing a valid tool for safeguarding the patient's health and freedom of choice.

For these reasons the role assumed by clinical legal medicine in every hospital is fundamental for prevention activity, health safety and support to other colleagues.

Health administrators, who decide about economics and managerial decisions, must be aware of the importance and peculiarity of this medical branch, reserving to it the right recognition and a sufficient staff.

Moreover, academic training has to be embedded with clinical legal medicine; the teaching of legal principles and classic topics of legal medicine, together with the reflection on the activity of giving medico-legal opinions in a clinical context, should be offered in every school of specialization in Legal Medicine, even in order to accomplish with the ministerial provisions concerning the educational profile which justifies the allocation of specialization grants covering the needs of National Health System.

Contributions

All the authors have co-operated in every phase of the work, each one contributing mostly to some aspects. **MB** has made substantial contributions to the conception and design of the study; **MR** and **MS** has collected and contributed to the data analysis; **DR** has made a substantial contribution to the drafting of the manuscript and to its critical revision, adding important intellectual content; **AA** has designed and conceptualized the study.

All the authors have given their final approval of the version to be published.

Competing Interests

The authors declare that they have no competing interests.

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