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# Defensive Medicine and Defensive Bureaucracy

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**Abstract**

Defensive medicine has been described as a "bane" for healthcare. It occurs when a medical practitioner performs (or not performs) treatment or procedure to avoid liability, placing second the real needs of patients. Defensive medicine increases the healthcare costs and hinder the efficiency and efficacy of the health Administration. The essay analyses defensive medicine as a form of defensive bureaucracy, pointing out lessons that can be learned from the health care sector about assessment techniques and the role of law facing the problem. The article concludes that the role of law facing this kind of phenomena must be "resized" suggesting focusing on tailored solutions for each sector.

*Keywords:* defensive medicine, defensive bureaucracy, medical liability, doctor-patient relationship

**Riassunto.** *Medicina difensiva e burocrazia difensiva*

La medicina difensiva è stata descritta come una "rovina" per la sanità. Si verifica quando un medico esegue (o non esegue) un trattamento o una procedura per evitare di incorrere in responsabilità, mettendo al secondo posto le reali esigenze dei pazienti. La medicina difensiva aumenta i costi di sanità e ostacola l'efficienza e l'efficacia dell'amministrazione di salute. Il saggio analizza la medicina difensiva come una forma di burocrazia difensiva, mettendo in luce le lezioni che possono essere apprese dal settore sanitario sulle tecniche di valutazione e sul ruolo della legge di fronte al problema. L'articolo conclude che il ruolo del diritto di fronte a questo tipo di fenomeni deve essere "ridimensionato", suggerendo di concentrarsi su soluzioni su misura per ogni settore.

*Parole chiave*: medicina difensiva, burocrazia difensiva, responsabilità sanitaria, relazione medico-paziente

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## 1. Definition of defensive medicine (DM)

Malpractice and the associated legal medical litigation led to a practice, in the medical and health field, which is intended to limit the autonomy of the doctor and the clinical decisions, so that it can be protected from judicial consequences (Iadecola e Bona, 2009; Fineschi, Pomara and Frati, 2001). This practice is commonly referred to as defensive medicine (DM).

DM refers to all medical care by physicians, aimed primarily at preventing the risk of litigation (Agarwal, Gupta A. and Gupta S., 2019). When doctors order tests, procedures, or visits, or avoid certain high-risk patients or procedures, primarily (but not necessarily solely) because of concern about malpractice liability they are practicing DM (US Congress,

1994; Fiori, 1996).

The phenomenon of DM is complex, that's why the concept involves heterogeneous behaviours. It includes all medical actions that physicians do (or not to do) without considering them the standard of care according to their clinical knowledge[1]; these actions (or inactions) are meant to shield the best physicians from negligence or malpractice lawsuits filed by patients or their families (Toraldo D.M., Vergari and Toraldo M., 2015).

DM has two dimensions: it may supplement care or reduce care. Thus, the phenomenon is generally divided into two categories: "positive" DM when physicians prescribe unnecessary or repetitive tests, referrals and/or procedures (over diagnosis and caesarean section operations are the most common examples) and "negative" DM when physicians refuse care to high-risk patients or avoid risky procedures (US Congress, 1994, p. 13)[2].

DM is not always bad for patients (US Congress, 1994, p. 13). The multifaceted nature of the phenomenon means that DM does not always result in harm to the patient, as it sometimes results in greater attention, even if not necessary, but without risk (Manna, 2014, p. 13).

Most importantly, in all cases, DM still has a negative impact on healthcare costs and on the quality and functionality of services.

## 2. History of the concept and diffusion of DM

DM is a concept originating in the USA in the early 1970s and later extended to other continents, including Europe (Garattini and Padula, 2020).

The very first mention of DM in a public speech was probably that of the General Counsel of the American Medical Association in 1974, who recommended it after provocatively suggesting that his colleagues should do no medical action at all as the only

[1] It is worth noting that the broad definition of DM that is accepted here includes defensive medical practices that may be medically justified and appropriate.

[2] Some authors refer to negative DM also the difficulty of finding medical staff in the specializations considered to be at risk (emergency medicine, surgery, etc.), also due to the increasing costs of insurance premiums.

way to avoid malpractice lawsuits (Berlin, 2017).

Interest in DM as a strategy for deterring patients' lawsuits for medical negligence and malpractice has increased in recent decades because of the growing number of litigations in many countries.

Many studies have consistently observed that doctors operating in high-risk specialties (in particular: emergency medicine, surgery, anaesthesia etc.) believe that the increase in litigation is the main cause of the emergence of defensive attitudes (Studdert *et al*., 2005; Hiyama *et al*., 2006). According to these surveys, more and more operators are changing their behaviours in response to the concern of being sued by patients.

Among recent factors affecting the amount of DM, it is worth mentioning new technology. Perceptions of increasing risk may arise from the continual development of new diagnostic techniques and improved therapies for serious conditions. Both of these technological trends could make the consequences of not testing more serious. The availability of more accurate or early tests or new therapies changes a natural risk into a "preventable" risk and places a new burden on the physician to correctly interpret the results of the test. When a medical technology is new, physicians may retain greater uncertainty about the appropriate indications for its use and therefore more conscious concern about the potential for liability (US Congress, 1994, p. 9).

The discussion on DM is part of a more general debate in the medical literature on the role of modern medicine and it is an upward trend. The flowcharts below are based on the trend of articles with «defensive medicine» in the title published in PubMed (Garattini and Padula, 2020, p. 166)[3].

[3] PubMed is a free resource supporting the search and retrieval of literature on biomedical, health fields, and related disciplines.

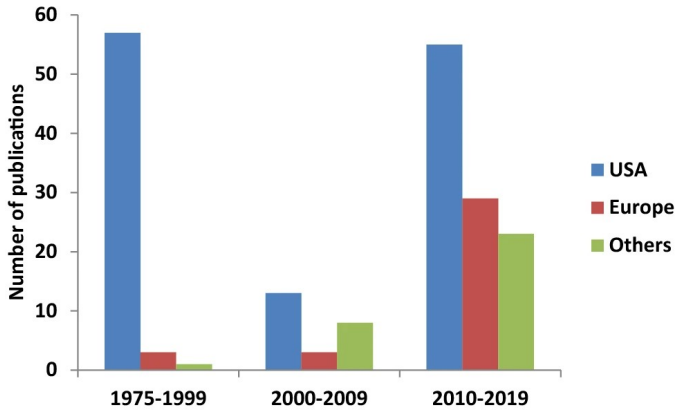


Fig. 1: Trend of articles with «defensive medicine» in the title

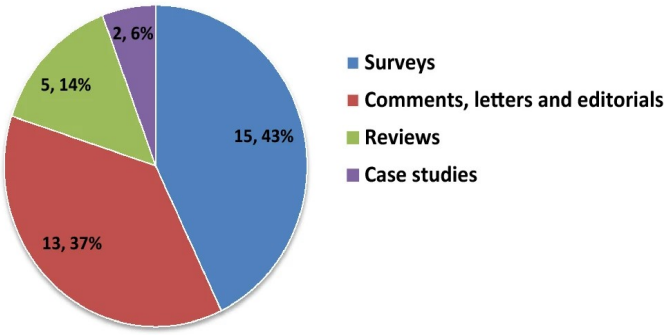


Fig. 2: Articles with «defensive medicine» in the title published in Europe by type of publication

The magnitude of the problem is staggering.

It has long emerged that accurate measurement of the overall level and national cost of this phenomenon is virtually impossible (US Congress, 1994, p. 1). The best that has been done is to develop a rough estimate of the upper limits of the extent of certain components of DM.

The medical liability system, including defensive medicine, has been estimated to cost the United States more than $55 billion annually, or between 2.4%-10% of total healthcare spending (Kessler and McClellan, 1996).

In Italy, the parliamentary committee of inquiry appointed to evaluate medical malpractice and to investigate the reasons for regionals' health services deficit estimated that DM costs to the public healthcare system more than 10 billion euros per year or 10.5% of its overall expenses (Commissione parlamentare d'inchiesta sugli errori in campo

sanitario e sulle cause dei disavanzi sanitari regionali, 2013). It is a conservative estimate, based only on ineffective allocation of human and public financial resources (for over-diagnosis and over-treatment). The same amount has been confirmed by the Italian National Agency for Regional Healthcare Services (AGENAS) in 2014 (AGENAS, 2015)[4].

Due to its impact on NHS expenditure, DM soon became also a driver of new policies and reforms in many countries (Forti *et al*., 2010)[5].

## 3. Health professionals' liability in Italy

If DM is primary a strategy for deterring patients' lawsuits for medical malpractice, it is worth focusing on the health professionals' liability regime.

A central goal of the tort system is to deter negligent behaviours and hence improve the quality of medical care.

Having regard to the Italian experience, medical malpractice crossed different phases: some scholars thought of "Swinging malpractice" (Castronovo, 2020).

Initially, we passed from physicians' immunity from liability to the "error hunting".

This reflects the redefinition of the doctor-patient relationship in the welfare society. We witnessed the transition from a paternalistic relationship, where the doctor represented the undisputed *dominus* of therapeutic choices and their execution, to a "consensualistic" relationship (so-called therapeutic alliance) where the doctor remains the dominus of the execution of therapeutic choices, which, however, unlike the past, are the result of a co-decision. The phenomenon, in turn, reflects the greater awareness of their rights on the part of the patients (as citizens) and of the importance of their health in an economic context of well-being.

In the late 1970s the case law[6], supported by scholars, obtained a paradigm shift: health

[4] AGENAS is a technical and scientific body of the Italian NHS carrying out research activities and supporting the Ministry of Health, the Regions and Autonomous Provinces of Trento and Bolzano.

[5] For the description of Italian legislative reforms aimed to tackle DM see *infra* the next paragraphs.

[6] See Cass. civ., December 21, 1978, no. 6141. With this ground-breaking decision the obligation on the physician was defined no more as an "obligation of means" but as an obligation to deliver a specific result in absence of

professionals, initially perceived as "genius loci"[7] immune from liability, become liable and, then, pray of litigation.

Interpreters lowered the bar for the claimants to prove causation through the assertion that physicians have an obligation to deliver a specific result (patient's health) in the absence of highly difficult technical problems.

The same phenomenon involved other European jurisdictions: courts found different ways to alleviate the burden of proving causation on the patient because deemed weaker than in typical cases (Koch, 2011).

In Italy, we registered a growing number of litigations for medical negligence and malpractice and the multiplication of overlapping liability regimes (civil liability; criminal liability; administrative accounting liability; managerial liability; disciplinary liability). Ultimately, it leads to the spreading of DM.

In a recent phase, some legislative acts (adopted in 2012[8] and 2017[9]) took a step back, mitigating the health professionals' liability and fighting DM. The legal doctrine agrees that the primary purpose of these reforms is, in fact, to reduce DM (Alpa, 2017; Gelli, Hazan and Zorzit, 2017; Hazan and Zorzit, 2017)[10].

Those reforms amended all the basis of liability: civil law liability; criminal liability and administrative - accounting liability.

From the civil liability perspective, the main evolution was, in a nutshell, the qualification of the liability of these professionals no more as contractual but as tortious, in order to mitigate the burden of proof arising from malpractice (Castronovo, 2020). Liability concerning structures (both private and public) though keeps on being contractual.

highly difficult technical problems.

7 See Cass. civ., October 16, 2007, no. 21619.

8 The so called Balduzzi Decree (Decree Law no. 158/2012, converted into Law no. 189/2012) aimed to tackle DM (in the case law, the refom is described as «inteso a contenere la spesa pubblica e arginare la "medicina difensiva", sia attraverso una restrizione delle ipotesi di responsabilità medica (spesso alla base delle scelte diagnostiche e terapeutiche, "difensive", che hanno un'evidente ricaduta negativa sulle finanze pubbliche), sia attraverso una limitazione del danno biologico risarcibile al danneggiato in caso di responsabilità dell'esercente una professione sanitaria», see Trib. Milano, July 17, 2014).

9 The so called Gelli-Bianco Law (Law no. 24/2017) *Disposizioni in materia di sicurezza delle cure e della persona assistita, nonché in materia di responsabilità professionale degli esercenti le professioni sanitarie*.

10 Many scholars argued that the 2017 reform's goal was to fight DM. See also the annual report of the First President of the Supreme Court of Cassation of 2018.

For our purpose, it is worth focusing on the administrative tort perspective. In fact, the problem of DM has an administrative tort dimension in the case of health professionals operating in public structures (Villamena, 2019).

According to the current Italian law, the patient entitled to compensation for damage faces a so-called *double track* scenario.

The damaged party may act against the structure (or its insurance company, with a "direct action" that will be applicable from the date of entry into force of the Ministerial Decree establishing minimum requirements of insurance policies for health facilities) on the basis of contractual liability (i) for damages related to its own errors (e.g., related to structural and organizational choices) or (ii) for damages caused by intent (willful misconduct) or gross negligence of professionals employed.

The other path is to act against the physician, who is now liable for damages towards injured third parties according to the tortious liability (general principle *neminem laedere*).

In the first scenario, once the public structure is sentenced to compensate the damage caused by the physician and it is demonstrated that it caused damage to the treasury (so called *danno erariale*), the Court of Auditors is entitled to act against the professional who caused it.

According to the special rules on administrative – accounting liability (Fracchia, 2007) the damages caused by ordinary negligence are only on the public structure (not *culpa levis* principle) and the public prosecutor of the Court of Auditors has the competence to file the above-mentioned "redress claim" against the physician[11].

[11] To complete the picture it is worth mentioning that latest reforms in the field of administrative – accounting liability reduced the financial exposure of legal representatives of public administrations (public health structures included) in case of settlement of disputes with a conciliation agreement. According to the amendment introduced by Legislative Decree no. 149/2022, the Italian Law about the Court of Auditors (Law no. 20/1994) now states that legal representatives of public administrations can be deemed liable only in case of willful misconduct or gross negligence «arising from a serious breach of law or misrepresentation of the facts of the case». It confirms the goal to limit the liability fighting "defensive" behaviours related to the uncertainty of the legal framework (promoting, in the meanwhile, disputes resolution by means of agreement).

## 4. The main features of the latest reform

The latest reform aimed, first, at facilitating actions against public structures rather than against physicians. The contractual liability regime facilitates the party entitled to file the damage claim both from the perspective of the burden of proof and from one of the limitation periods (10 years vs. 5 years). Therefore, while affirming the tortious nature of the liability of health professionals, the reform incentivised direct actions against structures. The flip side is that the tortious nature of the liability implies that the health professional can be required to compensate for the damage which is "unforeseeable" in the time in which the obligation arose (unlike the structure which, by responding contractually, is required, in the absence of willful conduct, to compensate only for the damage which is "foreseeable" according to Art. 1225 of the Italian Civil Code) (Granelli, 2018).

The reform also imposed to consider «situations of particular difficulty, including organisational difficulties, of the public structure» (Art. 9, par. 5, Law no. 24/2017) in the quantification of damages in redress claims. Such provision aims to promote efficiency. As organizations run the risk of being held liable for damage caused by their servants' misconduct (without any possibility of being relieved of the obligation to compensate the injured person), they are encouraged to use every means available to them in order to avoid inefficiency, disorganization, illegality and – more generally – the negligence of their servants (Fracchia, 2007, p. 366). The mentioned provision also aims to lower the financial exposure of physicians.

In the same perspective, it can be mentioned the introduction of a cap for health professionals' payment in case of redress claims (art. 9, par. 5, Law. no. 24/2017). It is worth noting that the Court of Auditors has, in general, a discretionary power to reduce the amount of the payment to the civil servant (so called "reductive power"). The reform of 2017 fixed a maximum threshold for the payment related to the value of the total gross earnings in the reference year (up to three times such value).

On the other hand, the reform established a connection between the final judgment of liability and the health professional's career. Such measure promotes accountability and

performance, prohibiting access to promotions for three years and stating that the definitive judgment of liability is «specifically evaluated in public procedures for promotions» (art. 9, par. 5, Law no. 24/2017).

To complete the picture, it is worth mentioning a (more sectorial) legislative intervention of 2015 that introduced specific sanctions to fight DM[12]. In order to counteract the phenomenon of "positive" DM and the associated waste of public resources, Italian legislator provided for financial penalties (in form of reduction of economic treatment) against the doctor who, without sufficient justification, has to "*prescribing behaviour*" that does not comply with standards of "*prescriptive appropriateness*" subsequently specified by a Ministerial Decree[13]. The ineffectiveness of the measure was demonstrated by the need for a new legislative intervention, that occurred only two years later.

While we have no evidence to assess the concrete effects of the application of the reform enacted in 2017 on DM, we can say that at least two conditions must be met for the tort system to effectively deter poor quality care: first, the malpractice system must provide physicians with information as to what care is acceptable; second, physicians must be able to improve the quality of care they offer. The sending of a clear signal to physicians about the standard of care the legal system demands is key to a proper malpractice system.

## 5. Lessons learned from DM

### *5.1. Factors influencing DM*

DM is a phenomenon that modern democracy knows, studies, and has tried to address from half a century.

[12] Decree Law no. 78/2015, converted into Law no. 125/2015, devoted Art. 9-*quater* to *Riduzione delle prestazioni inappropriate* (measures to reduce inappropriate prescriptions and actions).

[13] See the Decree of the Ministry of Health of the 9th December 2015, named *Condizioni di erogabilità e indicazioni di appropriatezza prescrittiva delle prestazioni di assistenza ambulatoriale erogabili nell'ambito del Servizio sanitario nazionale*.

Much effort has been put into determining predictors and motivators of DM practices, with the end goal of eliminating incentives for physicians to practice defensively, reducing wasteful spending, and protecting high-risk patients.

Concerning the "malpractice reform policy option" the main problem with using the traditional reforms to reduce DM is that they risk not to target the practices that are likely to be least medically beneficial. In reducing physicians' general anxiety about being sued or having unlimited financial exposure, they may also weaken whatever "deterrence" value the current malpractice system provides, with no quality assurance system offered in its place to hold physicians accountable for the care they render. Some traditional tort reforms, particularly those that limit potential compensation (e.g., caps on damages), resulted in affecting the very small minority of plaintiffs who receive high damage awards (US Congress, 1994, p. 17 and 75 ff.).

Recent literature concluded that the debate on DM is confusing, giving no clear guidance in practice to policymakers for potential action based on robust evidence and rational logic (Kapp, 2016).

However, in this complex framework, it is worth trying to shed light on the characteristics influencing DM.

The fear of litigation is undoubtedly the main factor influencing DM.

DM practices are likely to be more common in nations with high recourse to tort lawsuits and a density of lawyers (for instance Italy has by far the highest proportion of malpractice lawsuits settled in courts among the largest mainland European countries: 90% in 2014 compared to 60% in France and 40% in Germany) (Toraldo D.M., Vergari and Toraldo M., 2015). Some scholars talked about a sort of "luxury tax" paid in wealthy countries with tort-based legal systems (Fronczak, 2016).

It is worth underlining that the presence of alternative remedies with non-judicial character seems to influence the phenomenon. In Northern European countries (such as Denmark, The Netherlands, and Sweden), where patients' complaints can be addressed earlier in alternative sites (e.g., medical disciplinary boards) before arriving in the courts, physicians are less financially liable for non-gross negligence and DM seems to be

perceived as a less pressing issue at present (Garattini and Padula, 2020).

Another important lesson learned is that environmental factors influence DM more than individual factors (Prabhu, 2016).

Some studies explored the association between perception of medicolegal environment and defensive practice. Comparing the self-reported defensive practices of neurosurgeons in two US states with starkly different medicolegal environments (having regard to average malpractice insurance premiums and total malpractice coverage), one study demonstrated that physicians operating in high-risk states were 1.5 times more likely to practice DM compared to neurosurgeons in low-risk states (Cote *et al*., 2016).

Having regard to the risk perception, it is worthwhile to notice that in Italy (as well as in other countries)[14] the perceived risk seems to be way higher than the real one. Considering the latest data available, the cost of malpractice in Italy in 2016 (obtained adding the refunded damages paid by insurance for malpractice to the cost bared by structures to create insurance funds) is less than 1 billion euro (Granelli, 2018), ten times lower than the estimated annual costs of DM.

Concerning the availability of liability insurance, economic studies demonstrated that it can effectively deter DM (Antoci *et al*., 2019). Moreover, one study suggests being cautious about the effects of the availability of liability insurance on DM because it can lead to opposite results[15].

We cannot affirm that in general the introduction of a medical malpractice insurance can completely discourage the practice of defensive medicine. However, the availability of such a further choice for physicians introduces many new scenarios, which, in turn, can suggest a broad range of strategies that a policymaker may undertake to pursue the goal of a fair and efficient public health care (Antoci *et al*., 2019, p. 430).

Other studies focused on the reputational perspective.

[14] It is the same, for instance, in the US, where physicians result to be concerned about the professional, financial, and psychological consequences of litigation but, on balance, they tend to overestimate the risk of these effects as well (US Congress, 1994, p. 37).

[15] In sum, the effect of reducing DM is possible when the price of insurance is calculated according to its actuarially fair value, plus a loading charge (either proportional or fixed). The result changes with the premium calculation principle: when the price of insurance is market-dependent is possible to have the co-existence of all the strategies and the permanence of all the possible behaviors by physicians and patients.

Some authors did not relate DM solely to the fear of litigation but extended it to being perceived as a low-profile physician among colleagues (Berlin). It is not surprising if we consider that the problem of blame is meaningfully addressed in the framework of EU policies promoting patient safety and quality of care[16].

DM seems to be closely related also to media effects: a social culture oriented to individual "blame" can boost a "witch-hunt" aimed at identifying physicians who are personally responsible for medical errors and blame them publicly (ToraldoD.M., Vergari and Toraldo M., 2015). It may increase DM practices.

### *5.2. Possible solutions to DM*

In the framework of a vast literature where is possible to find everything and its opposite, one can draw at least one sound lesson from the DM debate: the role of law seems to be "resized" by such studies.

If the need to streamline existing rules of liability is widely stressed as important, having regard to adaptations and amendments to existing liability rules it is worth considering the compliance costs related to the introduction of new rules (Clarich, 2020).

Therefore, it seems better to focus on organizational measures, such as enacting shared operating protocols to assist practitioners and to integrate models of conduct to prevent professional and organizational liability implications. We cannot but agree on the fact that an organizational culture aimed at limiting both extreme severity in punishing clinical errors and full discretion in medical practice should be highly recommended in health care systems (Garattini and Padula, 2020).

Last but not least, the vast majority of research and surveys in the field converge affirming that the most effective reaction to DM is to focus on the restore of trust with patients (Garattini and Padula, 2020; Vento, Cainelli and Vallone, 2018).

[16] See Council conclusions on patient safety and quality of care, including the prevention and control of healthcare-associated infections and antimicrobial resistance emphasizing the need to «Develop measures that allow just and blame-free reporting by health professionals or patients and support blame-free handling of errors and adverse events as well as learning from them» (European Council, 2014/C 438/05, Art. 28 f).

DM seems to be closely related to the creeping crisis of trust in the modern physician–patient relationship. In the last few decades, patients' trust in physicians has been undermined mainly because doctors have drastically cut the time spent to discuss with each patient. In this scenario of lack of patient face-time the burden of administrative tasks plays a crucial role (Sinsky *et al*., 2016)[17]. It is alarming if one considers that diseases vary a lot depending on the individual, so the physician-patient relationship is still crucial. Caring is not only about examining patients, ordering tests, and prescribing drugs. It is about spending time with patients, being at their side, talking to them without hurrying, showing a sincere interest in their condition and its social implications, answering their questions, and addressing their concerns. If this relationship is lost or diminished to unacceptable levels, then DM is the logical consequence (Vento, Cainelli and Vallone, 2018).

The problem has a more general social dimension considering the new approach to science: modern society is changing the attitudes and expectations of people towards the way healthcare is delivered due to scientific progress. Physicians seem to be able to make more accurate diagnosis and better therapy, so any illness seems potentially curable in a scenario of a widespread "zero-mistake" culture.

In such environment, the use of internet search by patients increases their fear of receiving substandard care instead of the best care available if the outcome is adverse (Garattini and Padula, 2020, p. 168).

Paradoxically, the litigation phenomenon was fuelled by an expectation of perfection even as the technical quality of medical care increased (Wiet, 1989).

## 6. First conclusions

The study of DM as a form of defensive bureaucracy may give some important insights into well-experienced assessment techniques and new approaches to solving the problem.

[17] In the United States ambulatory practice, for each hour doctors give direct clinical face time to patients, approximately two further hours are spent on electronic health records and desk work in the clinic day.

At the same time, it is clear from the outset that no one-size-fits-all solution can (or should) be offered.

In respect of DM cost assessment, it is worth considering that it refers to redundant practices artificially increasing healthcare expenditures, while defensive bureaucracy is mainly related to the "signature phobia". If the need is to fight inaction, assessment techniques must be tailored to the negative character of the phenomenon.

In addition, the estimate of DM's costs seems to be conservative because it does not consider costs on the public agents (such as insurance fees) and costs on the customers of public health service (both "bureaucracy costs" related to more difficult procedures and "psychological costs").

Secondly, we must consider that the doctor-patient relationship plays a pivotal role in the health sector. Focusing on personal relationships is key to solve the problem of DM but it could not be decisive for defensive bureaucracy.

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