

The duty of being a medical conservative. When in doubt, for the patient

CAMILLA ALDERIGHI¹, STEFANO DEL PACE², RAFFAELE RASOINI¹

¹IRCCS Fondazione Don Carlo Gnocchi, Firenze; ²Dipartimento Cardioracovascolare, Azienda Ospedaliera Universitaria Careggi, Firenze.

Pervenuto il 16 aprile 2019.

Summary. Recently, John Mandrola et al. established the tenets of medical conservatism. We endorse this approach to patient care, and we believe that, in order to have this perspective incorporated into medical reasoning, the foundations for being medical conservatives should be taught since medical school. In this Perspective, through an analogy between medicine's and criminal law's approaches to uncertainty, we suggest that the precautionary principle of *in dubio pro reo* could be adapted to medicine as a decisional strategy for medical conservatives. This principle would represent a cognitive and decisional filter that allows physicians to counterbalance the currently widespread propensity toward interventions with a conservative and precautionary attitude.

Il dovere di essere medici conservativi. In caso di dubbio, a favore del paziente.

Riassunto. Recentemente, John Mandrola et al. hanno stabilito i principi del conservativismo medico. Noi condividiamo questo approccio alla cura del paziente e riteniamo che, per far sì che i medici lo facciano proprio nel loro modo di ragionare, dovrebbero esserne poste le basi fin dai primi anni dell'università. In questo articolo, attraverso un'analogia tra l'approccio all'incertezza della medicina e quello del diritto penale, suggeriamo che il principio di precauzione *in dubio pro reo* potrebbe essere adattato alla medicina come strategia decisionale per i medici conservativi. Questo principio rappresenta un filtro conoscitivo e decisionale che consentirebbe ai medici di controbilanciare la propensione attualmente diffusa verso l'intervento con un atteggiamento conservativo e precauzionale.

Introduction

Recently, John Mandrola et al. established the tenets of medical conservatism¹. We endorse this approach to patient care, and we believe that, in order to have this perspective incorporated into medical reasoning, the foundations for being medical conservatives should be taught since medical school.

From uncertainty to intervention bias

In medicine, the difficulty of differentiating between abnormalities of low relevance and those that are clinically meaningful pushes many decisions into the realm of uncertainty.

Physicians routinely come across patients with a wide range of abnormalities of uncertain significance, such as a renal incidentaloma detected on chest CT scan, hypercholesterolemia in an elderly patient without a history of cardiovascular disease, or severe aortic stenosis in a symptomatic patient whose symptoms can, nevertheless, be reasonably attributed to one or more coexistent disorders.

However, although providing recommendations about diagnostic or therapeutic choices can be challenging in similar cases, when faced with uncertainty most physicians tend to opt for action over more conservative choices².

Starting in medical school, physicians' education is shaped toward action. This results from the learning

and the rewarding of an investigative attitude guided by the principle of not neglecting any diagnostic or therapeutic option³. This education is strengthened, during practice, by the systematic targeting of omission errors.

It is self-evident that physicians are required to have this ability mastered in situations requiring it, such as the management of many acute or life-threatening conditions. However, in recent decades, an amplification of this attitude has been witnessed to the extent that "intervention bias" has been proposed as a term to describe physicians' prejudice to intervene, with diagnostic tests or therapies, even when non-intervention strategies would be equally reasonable⁴.

Financial pressures, medical-legal concerns and increasingly "prescriptive" clinical practice guidelines have all contributed to lowering decisional thresholds when recommending interventions, and the same has been derived from cultural factors, both on the side of physicians and of patients³.

Furthermore, as the sensitivity and availability of diagnostic tests have considerably increased, a parallel over-detection of potentially "actionable" abnormalities of uncertain significance has been observed⁵. For example, in patients with suspected pulmonary embolism undergoing chest computer tomographic angiography, detection of incidental findings requiring diagnostic follow up has been reported to be more than twice as likely to be detected than the pulmonary emboli for which the test had been requested⁶.

Finally, the biomedical model still represents a strong and implicit theoretical base of physicians' reasoning



Primum non nocere, deinde curare.

and biased-to-action decision making. According to this model, diseases are equated with deviations from the norm of quantifiable biological variables so that any corrective action to restore the norm may be considered a solution⁷. Physicians' adherence to the biomedical model, particularly in the current technology-driven drift of abnormalities of uncertain significance, has contributed to a widespread assignment of disease labels that are often the starting point of corrective actions.

All the above factors have established fertile grounds for doctors to increasingly assign blame to abnormalities of uncertain significance, often by raising them to the rank of disease – even to the point where normality is eroded – and to eventually over-recommend diagnostic tests or treatments⁵.

The oxymoron of sound benefit-risk estimations in the swamp of uncertainty

Before recommending any medical act, physicians are required to consider the risk of harm from any diagnostic or therapeutic intervention and balance it against the expected benefit.

Indeed, a fundamental precept of medical code prioritizes the principle of non-maleficence over beneficence: *primum non nocere, deinde curare* (“first do no harm, then cure”). It follows that adequate understanding of interventions' potential adverse consequences is a prerequisite for doctors to accomplish sound harm-benefit risk estimations.

However, unlike interventions' benefits, the reporting of safety issues in clinical trials and systematic reviews has resulted to be widely inadequate⁸⁻¹⁰. Furthermore, due to patient complexity or lack of evidence, in many clinical circumstances both the harms and benefits of interventions are scarcely measurable and definable.

Many patients with multimorbidity, as well as many elderly and frail patients, exemplify this challenge. These patients are largely excluded from clinical trials, have high incidence of abnormalities of uncertain significance, and go through frequent interactions with health care providers. These factors can contribute to putting these patients at risk and lead them to experience more harm than benefit from many diagnostic or therapeutic interventions¹¹.

Especially when patient complexity and lack of evidence generate uncertainty, application of the *primum non nocere* principle is not always straightforward and intervention bias can amplify the risk of harm; therefore, medical decision-making needs to be safeguarded so not to betray any interventionist prejudice.

The need for a “presumption of innocence”

In this respect, medicine could receive inspiration from criminal law. Law and medicine share a deci-

sion-making process that is based on the contextual analysis of evidence. In criminal law, the attribution of guilt has been historically linked to the need to apply a protective precaution, symbolized by the *in dubio pro reo* principle (“[when] in doubt, for the accused”). Given the frequent uncertainty about the path to the truth, and about truth itself, and given the seriousness of the conviction of an innocent defendant, reasonable doubt – that is, a doubt that allows for the configuration of a plausible alternative hypothesis to the prosecution's – underlies a protective system in which it is even accepted to let guilty parties go free in order to avoid the conviction of innocent individuals. Because every verdict holds the power to restrict individual freedom, this is a fundamental principle of criminal law.

Although moved by beneficial intent, physicians also hold a restrictive power over individual freedoms. Whether the physician is requesting a diagnostic test, prescribing a therapeutic intervention, assigning a label of disease or even of disease risk, these acts can prompt a metamorphosis from person to patient. The potential adverse consequences of this process often extend beyond physical issues, like drugs' or interventions' adverse effects, to other spheres of life, including the psychological, social and financial, along with the daily need of dealing with treatments' burden¹².

At the same time, many medical decisions are subtended by doubt: indeed, the knowledge underpinning many routinely performed medical interventions is often lacking or unreliable, especially for patients facing multiple health challenges, and, even when robust evidence favors interventions, the expected health benefits are often marginal¹³.

When the risk-benefit ratio of an intervention is uncertain, and no urgent need for action is deemed necessary, incorporation of the *in dubio pro reo* principle into medical decision-making highlights that a precautionary attitude can be a reasonable alternative to immediate action.

Rebalancing expectations through shared understanding

To apply the *in dubio pro reo* principle in medicine is not a renunciation to take care, nor is it to deny the possibility of a cure. Rather, it means acknowledging and disseminating the counterintuitive truth that not all interventions, even if recommended with beneficent intent, result in benefit.

Conservative strategies like watchful waiting, choosing a less invasive option, and deprescribing are all examples of medical acts arising from the “presumption of innocence” in uncertain terrain where the risk of harm may be relevant.

Unlike criminal law, where the application of the *in dubio pro reo* principle in a judgment implies the

closure of the relationship between a defendant and the system, to apply this principle in medicine is only the beginning of a path in which a patient will be followed up about the outcomes related to this choice.

For doctors, to apply the *in dubio pro reo* principle implies to courageously take chances: whether a conservative choice is pursued, even a slightly higher risk of a missed diagnosis or omission to recommend a potentially effective treatment could pave the way to blame or even to malpractice proceedings.

However, as the introduction of the *in dubio pro reo* principle was required in the late Roman period to rebalance a criminal law system that was skewed toward accusation, also in contemporary health care systems dominated by intervention bias and prone to overuse, physicians' approach to decision-making should be required to incorporate a precautionary attitude in order to rebalance health decisions.

Fear of malpractice proceedings arising from omission errors has contributed to stigmatize the misleading analogy between intervention and cure. Therefore, in order to disseminate medical conservatism, it would be necessary also for the medical-legal systems to adopt this beneficent principle and consider it while judging physicians' conduct.

Patients also can be biased toward intervention, either as a result of unrealistic expectations¹⁴, or for the desire to have their symptoms legitimated through an intervention, which is often surrogate of a poor doctor-patient communication¹⁵. Nonetheless, a balanced doctor-patient communication that is aimed at eliciting patients' preferences has been observed to often result in patients opting for conservative choices¹⁶. In this respect, "reasonable doubt" is a cognitive filter able to mitigate intervention bias and help deliver uncertainty to patients as a balanced sharing of the available imperfect medical knowledge.

Were the learning of this principle included and mastered during medical school and training, it would allow physicians to counterbalance the current attitude toward intervention with an opposite perspective that focused instead on the "presumption of innocence".

Whenever uncertainty dominates the clinical picture, it can simply be unfeasible to define *a priori* on what side of a decisional threshold, whether more conservative or interventionist, the real benefit for a patient lies. Nonetheless, it is precisely when physicians share their imperfect knowledge with patients and support them, in a "maieutic way," to have choices and values superimposed, that physicians' role rises above mere action and reaches its highest objective, that is to care.

Acknowledgements: the authors are grateful to Silvia Governatori (Ordinary Judge, Court of Florence) and Michele Papa (Full Professor of Criminal Law, University of Florence) for the fruitful talks about the relationship between medicine and criminal law.

Conflict of interests: the authors have no conflict of interests to declare.

References

1. Mandrolia J, Cifu A, Prasad V, Foy A. The case for being a medical conservative. *Am J Med* 2019 Mar 6. pii: S0002-9343(19)30167-6.
2. Kiderman A, Ilan U, Gur I, Bdoiah-Abram T, Brezis M. Unexplained complaints in primary care: evidence of action bias. *J Fam Pract* 2013; 62: 408-13.
3. Emanuel EJ, Fuchs VR. The perfect storm of overutilization. *JAMA* 2008; 299: 2789-91.
4. Foy AJ, Filippone EJ. The case for intervention bias in the practice of medicine. *Yale J Biol Med* 2013; 86: 271-80.
5. Brodersen J, Schwartz LM, Heneghan C, O'Sullivan JW, Aronson JK, Woloshin S. Overdiagnosis: what it is and what it isn't. *BMJ Evid Based Med* 2018; 23: 1-3.
6. Hall WB, Truitt SG, Scheunemann LP, et al. The prevalence of clinically relevant incidental findings on chest computed tomographic angiograms ordered to diagnose pulmonary embolism. *Arch Intern Med* 2009; 169: 1961-5.
7. Engle GL. The need for a new medical model: a challenge for biomedicine. *Psychodyn Psychiatry* 2012; 40: 377-96.
8. Pitrou I, Boutron I, Ahmad N, Ravaut P. Reporting of safety results in published reports of randomized controlled trials. *Arch Intern Med* 2009; 169: 1756-61.
9. Parsons R, Golder S, Watt I. Over a third of systematic reviews did not fully report the adverse events outcome. *J Clin Epidemiol* 2018 Dec 13. pii: S0895-4356(18)30816-3.
10. Gyawali B, Shimokata T, Honda K, Ando Y. Reporting harms more transparently in trials of cancer drugs. *BMJ* 2018; 363: k4383.
11. Scott IA, Guyatt GH. Cautionary tales in the interpretation of clinical studies involving older persons. *Arch Intern Med* 2010; 170: 587-95.
12. Spencer-Bonilla G, Quiñones AR, Montori VM; International Minimally Disruptive Medicine Workgroup. Assessing the burden of treatment. *J Gen Intern Med* 2017; 32: 1141-5.
13. Ioannidis JPA. Why most clinical research is not useful. *PLoS Med* 2016; 13: e1002049.
14. Hoffmann TC, Del Mar C. Patients' expectations of the benefits and harms of treatments, screening, and tests: a systematic review. *JAMA Intern Med* 2015; 175: 274-86.
15. Newton EH. Addressing overuse in emergency medicine: evidence of a role for greater patient engagement. *Clin Exp Emerg Med* 2017; 4: 189-200.
16. Rothberg MB, Sivalingam SK, Kleppel R, Schweiger M, Hu B, Sepucha KR. Informed decision making for percutaneous coronary intervention for stable coronary disease. *JAMA Intern Med* 2015; 175: 1199-206.