

UNNECESSARY MEDICINE, AN ISSUE WITH MAJOR ETHICAL IMPLICATIONS

Gabriel Ungureanu, Ioana-Dana Alexa, Maria-Christina Ungureanu

U.M.F. „Gr.T. Popa”, Iași

Correspondence address: mariachristina1105@gmail.com

Abstract

The authors discuss an important chapter of iatrogenic pathology – unnecessary medicine, by reviewing epidemiological aspects and financial impact and identifying such elements in no less than 10 areas: surgery, interventional medicine, diagnostic investigation, substitute procedures, shared medical appointments, preventive medicine, drug therapy, aesthetic surgery, unconventional medicine, medicine on political demand. We shall review the causes, motives and mechanisms of unnecessary medicine such as one's hyperprudence to cover oneself with diagnosis arguments or to prevent potential complications through preventive therapies (defensive medicine), weak functionality of the institutionalized inspection bodies, onerous motivation. The respect for the fundamental principles of medical ethics (the primum non-nocere principle doubled by the principle of doing good), the use of practice guidelines, the proper functioning self-control mechanisms in exercising the medical profession, a different management of error and the existence of a consistent protective legislation for both the patient and doctor would be key-elements to avoiding unnecessary medicine.

Keywords: unnecessary medicine, types, causes, mechanisms, solutions

One of the most controversial areas in medicine is the recommendation of an investigation, medication or surgery when the benefit / risk ratio is not high enough, as recent years have witnessed increasingly insistent debates about unnecessary medicine. Such suggestive terms as *overprevention, overdiagnostic, overtreatment, overprescription, unnecessary or unjustified surgery,*

unnecessary hospitalization or, more general terms, such as *unnecessary health care*, are nowadays being used.

A. The epidemiological and economic dimensions

Although the existence of unnecessary practices in medicine has long been detected, in the last 30 years the interest in



INTERNAL MEDICINE

General Reviews

iatrogenic pathology and unnecessary medicine was boosted by the explosive growth of health care costs. If initially the phenomenon appeared more visible in the spectacular area of surgery⁽¹⁾, subsequently particular attention was given to the costly investigations in invasive procedures, interventional therapy and chronic substitutive procedures⁽²⁾. The data about the epidemiological and economic dimensions of this phenomenon are controversial. More sources of documentation can be identified:

- studies presented by medical professionals
- studies carried out by governmental agencies
- studies carried out by insurance companies
- figures often unverified /unverifiable, exaggerated by extrapolation, taken/ submitted by people concerned in the increasing of the media rating of the publication or of the TV-shows by means of sensational allegations.

But even some figures may seem exaggerated, there is a hard core of truth that medical professionals should not ignore, nor hide, but to evaluate it properly and intervene concretely to limit it if not eradicate it. Based on the high consumption of drugs, their side effects and cost, upon the request of Senate Finance Committee, US Congress mandated the Centers for Medicare

and Medicaid Services to sponsor the Institute of Medicine (IOM) to conduct a study on the incidence and costs of medical errors. IOM Report 1999⁽³⁾, by using numerous sources, attested the iatrogenic pathology impact both on mortality and on the costs of medical care, considering it as the 4th leading cause of mortality in the USA, which prompted President Clinton to establish the "US Task Force to find ways to reduce medical errors". An important chapter in iatrogenic pathology considering the consequences on patients (over 30,000 deaths / year) as well as the financial impact (around \$ 122 billion) would have been the unnecessary medicine (H-CUP Data); the current malpractice regulatory frame, created to protect the patient, caused further substantial increases in costs, leading to increased investigations and interclinic appointments (shared medical appointments), questionable whether needed, most doctors recognizing the practice of defensive medicine as a mean of self-defense; although the sources and methodology are questionable, it is estimated that the costs of unnecessary medicine would reach 34% (Gallup Survey) of the money spent in the system⁽⁴⁾.

IOM Report results were much publicized, exaggerated and distorted not only by the sensation-hungry press with shocking headlines, but by some practitioners of alternative medicine methods that present

conventional medicine as a real wound upon human health ruining the finances of the state, although there are simple, cheap natural means of health preservation and healing of diseases, unconventional medicine offers.

B. Types of unnecessary medicine

We will try an overview of the types of the unnecessary medicine and of the causes that generate them. We identified no less than 10 such chapters:

- unjustified surgery
- unjustified interventional medicine
- over-investigation
- unjustified substitute procedures
- excessive interclinic specialist checkups
- overprevention
- unnecessary medication (medication overprescription);
- aesthetic surgery
- unconventional medicine
- medicine on political demand

1. Unjustified Surgery

In the twentieth century there have been an impressive number of fashionable surgeries, with prophylaxis **aim**, without considering the risks and consequences, subsequently considered to be excessively and unnecessarily recommended in a significant number of cases, such as appendectomy, tonsillectomy, cholecystectomy, circumcision (without religious motivation), caesarean section and sometimes hysterectomy and mastectomy⁽¹⁾.

2. Unjustified Interventional Medicine

Includes interventional procedures such as carotid endarterectomy, coronary revascularization (percutaneous translu-

minal angioplasty), placement of catheters (including central venous catheters, idle catheters)^(5,6,7).

3. Overinvestigation

It refers to investigational procedures in particular imaging (coronarographies, mammographies, computer-tomographies, MRI, radioisotope investigations)⁽⁸⁾ or endoscopic recommended excessively, often without the prospect of a therapeutic decisions.

4. Unjustified substitute procedures

The decision to implant pacemakers or cardioverters in questionable situations or the choice of models of very sophisticated, expensive pacemakers, with unnecessary performance in the present case⁽⁹⁾. ACC/AHA/NASPE Guideline for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices as well as ESC Guidelines for management of arrhythmias were elaborated specifically to combat overprescription.

5. Excessive interclinic checkups (shared medical appointments), practiced either for minor symptoms for fear of assuming decision responsibilities (defensive medicine) or for the mutual profitability of medical practices (onerous medicine) that can achieve a real windmill of unjustifiable checkups generating overinvestigation.

6. Medication overprescription

We quote a few examples of well-known unnecessary medicine therapy:

- **antibiotics:** the use of antibiotics, especially new and with broad spectrum is considered to be excessive and abusive, e.g. in upper respiratory infections (in 90% of cases



INTERNAL MEDICINE

General Reviews

of viral etiology) as in postoperative prophylactic administration; the misuse of antibiotics has led to the creation of drug-resistant microbial strains, the rate of occurrence of which exceeds the capacity of research laboratories in the field to find solutions;

- **oral long-term systemic corticotherapy** in the bronchospastic chronic respiratory diseases (COPD) or in rheumatology can generate severe side effects (consecutive osteoporosis fractures, cortisone diabetes, corticod dependence, hypertensin, peptic ulcer, psychosis, etc.) with no obvious benefits over other therapeutic approaches;
- **antidepressants** (e.g. fluoxetine) used increasingly more frequently and sometimes in combination with cerebral stimulants (e.g. methylphenidate);
- **benzodiazepines** the overprescription of which generate addiction;
- **chronic replacement hormone therapy** in postclimax
- **proton pump inhibitors** especially in i.v administration (often **unjustified** – except for bleeding ulcer)^(10,11,12).
- **antipsychotics and sedatives** excessively used, e.g in care homes for elderly⁽¹³⁾.

7. Overprevention

Preventive antibiotic therapy used postoperatively in aseptic pathology or in the therapy of viral diseases without superimposed bacterial infection is one of the controversial practices; such is the antibiotic prophylaxis, practiced in particular during winter in the intercritical management of COPD. The last flu epidemic (AH1N1), the scale and severity of which were widely publicized seemed exaggerated to many medical professionals, leading to suspicion of artificial creation of panic designed to increase sales of influenza vaccine. Suspicions were cast including on the WHO-makers who would be in conflict of interest. Were the epidemic proportions limited precisely by the measures taken or we face a case of over-prevention? The fact that most doctors and nurses have refused vaccination, even under the threat of sanctions, materialized the force of this suspicion. The epidemiologist Dr. Wolfgang Wodarg, president of the Council of Europe's Health Commission, accused the pharmaceutical companies of influencing the WHO's decision to declare a mild AH1N1 flu as pandemic by creating a "campaign of inducing panic" and a "false disaster"⁽¹⁴⁾.

8. Aesthetic surgery

A special chapter could be devoted to aesthetic surgery which in many cases can

be considered medically unjustified. The risks are not negligible and there is legislative tendency to move responsibility from the obligation to use the best means towards the obligation to obtain the best results.

Lifestyle current models and aesthetic canons insistently promoted by the media now make us sail in the twists and turns of unnecessary medicine, oscillating between the dangers of morbid obesity and mental anorexia. Doctors should be more involved in shaping modern aesthetic standards of the human body, in promoting a healthy lifestyle and diet, in condemning practices harmful for health and risky aesthetic corrections.

9. Unconventional Medicine

Modern medicine considers as alternative medicine all those practices that are not part of conventional medicine, practices that are based on tradition or on the spiritual experience of practitioners and not scientifically sustained nor supported by evidence-based medicine. Complementary medicine includes about the same methods as alternative medicine however used not instead of but along with conventional medicine. Complementary medicine and alternative medicine are designated together as unconventional medicine.

Proponents of conventional medicine do not resign themselves to the status of tolerated, but often violently attack conventional medicine in media presenting it as dangerous, harmful, costly and unnatural, unlike unconventional medicine that would be accessible, cheap, efficient (including in case of failure of conventional medicine) and therefore strongly require the reimbursement of methods by health insurance. Alternative medicine practitioners require complete abandonment of

conventional therapy as a prerequisite. It seems outrageous that in some situations when the fight with the disease is performed against time, to delay starting the adequate therapy program and suggest illusory methods to a patient inadequately informed and confused; the patient's right to choose can not be questioned, but we wonder whether the treating physician did everything in his/her powers to inform the patient on the nature and condition of the disease and on the treatment options.

Indifference or even encouragement (tacit or clearly expressed) by governments of these methods might be explained by the need to reduce health consumer pressure on an overloaded system or by lobbying pressures of people (co)interested and influential materially and politically. The economic weight of the industry producing OTC drugs, food supplements and (pseudo)dietetic preparations somehow explain the laxity in legislation. Less explicable seems the indifference of medical professional associations.

In 1998, the Swiss government starts PEK (Programm Evaluation Komplementärmedizin / Program for Evaluating Complementary Medicine) to study the role and effectiveness of complementary medicine that is increasing now in Swiss healthcare system: five of the methods most commonly used in complementary medicine were evaluated: homeopathy, neural therapy, phytotherapy, traditional Chinese herbal therapy and anthroposophic medicine. In 2005, after completing the study and evaluating the results, the five complementary therapies evaluated have been struck off the list of services covered by Swiss health insurance system (KLV).

In 1992, the US Congress established the Office of Alternative Medicine within the



INTERNAL MEDICINE

General Reviews

National Institutes of Health to evaluate alternative remedies. Consequently, in 1993, they started 30 research grants; the results were absolutely unconvincing and unacceptable by the evidence-based medicine criteriologia.

In 2015, the Report of National Health and Medical Research Council (NHMRC) of Australia (Paul Glasziou) after the analysis of 57 systematic reviews containing 176 individual studies on 68 different diseases found no difference between homeopathy and placebo. It is morally imperative that every medical method, besides the undeniable "primum non nocere" principle to also satisfy the desire of "the principle of doing good", a certain effectiveness, well documented and with minimal risk.

Critics of alternative medicine believe that alternative medicine ideology usually ignores biological mechanisms, is defamatory of modern science and often relies on ancient practices and natural remedies axiomatically considered to be more potent and less damaging than conventional medicine. Consequently, herbs and mixes of herbs are considered superior to the active components isolated in laboratory and alternative therapeutic methods are fervently promoted despite the obvious lack of clinical efficacy and in the virtue of reasons that violate fundamental scientific laws⁽¹⁵⁾. But even herbal therapy

can be dangerous; e.g. the most dramatic case of herbal nephrotoxicity occurred in Belgium (over 100 cases of death or renal failure in people who ingested a Chinese herbal weight loss/slimming remedy containing aristolochic acid⁽¹⁶⁾).

There are some less categorical voices, especially in oncology, which believe that complementary therapies used together with conventional methods to control symptoms and improve quality of life should be differentiated from alternative therapies used instead of conventional medicine (ablation surgery, radiotherapy, chemotherapy). Some complementary therapies are considered beneficial for the symptomatic therapy of cancer (hypnosis, relaxation therapy, massage, music therapy, acupuncture), since some major cancer therapy centres tend to integrate complementary medicine methods together with conventional medicine methods both clinically and academically in "integrative oncology" programs⁽¹⁷⁾.

10. Medicine on political demand

It represents one of the most serious ethical slippages in both medical research and medical practice. We quote as examples:

- Pseudo-scientific experimental medicine (notorious in concentration camps, practiced by totalitarian regimes)

- Pseudo-scientific argumentation of food austerity
- Penitentiary medicine, practiced for non-medical purposes:
 - obtaining information (truth serum)
 - making people more obedient
 - punitive medicine.

C. Causes, motives, mechanisms

Unnecessary medicine practices can be determined by:

- limits of knowledge in a certain stage of medicine (which can cause errors even in the practice of the time);
- the influence of a dominant opinion trend which requires a certain therapeutic fashion;
- abusive recommendation of a new method for training purposes;
- hyper-caution to be covered with diagnoses arguments or prevent potential complications through preventive therapies; the spectrum of malpractice charges and the explosive growth of malpractice insurance costs has dangerously amplified the phenomenon leading to an increasing practice of defensive medicine;
- temptation to directly use the most sophisticated methodology which is the gold-standard method (sometimes the most risky such as the angiography in pulmonary embolism) instead of going through a diagnostic algorithm that selects only a minority for it;
- ineffectiveness of ethical control committees;
- onerous medicine - a special case is the onerous way of using costly procedures without potential utility

and with risks to the patient only for purely lucrative purpose - in controversial situations or even in the absence of any necessities - (following the hospital benefit and / or personal benefit); we propose this term to situations where the patient is subjected to an investigation or therapeutic interventions consciously unnecessary (with risks for patients) to differentiate onerous medicine (connectable to iatrogenic pathology) from strictly financial fraud in healthcare such as such as reporting inflated costs of medical procedures or outstanding and costly, but nonperformed procedures (the patient is not involved and we cannot speak of iatrogeny); addressing health management in general and hospitals in particular through excessive economic approaches, terrorized by self-financing needs and by the boosting of profitability at any cost may generate reprehensible ethical deviations.

One must not neglect issues such as:

- The impact of advertising and the use of media to promote drugs or procedures that generate stressful requests from patients, that some doctors lack the strength to resist, although with no solid scientific arguments to recommend. It is also mentioning the pressure of medicine and medical equipment factories, importers and distributors on health providers (possibly stimulated by substantial sponsorship) whose options can be therefore influenced.
- The pressure of patients: we can only wonder if only doctors (some doctors?)



INTERNAL MEDICINE

General Reviews

are to blame or patients (some patients) are also guilty of complicity in unnecessary medicine? We know a number of situations such as caesarean surgery under the pressure of the pregnant patient/ her family for fear of pain / natural childbirth complications, pressures for recommending biological analysis or unnecessary investigations (echocardiograms, coronarography, CT, MRI, etc.) or pressure to prescribing some medicine. The doctor may give in upon the patient's pressure for various reasons: for kindness, for fear of losing the patient in favour of a more compliant colleague (e.g. concurential medicine and family doctor's list of patients), because of the lack of time to convince the futility of the drug investigation requested or uncertainty about the diagnosis (generated by the deficient training or examination).

Even in these circumstances, the responsibility still lies with the doctor!

C. Corectives of unnecessary medicine

Preventing unnecessary medicine is a very difficult challenge that requires the conjugation of several directions out of which we quote bellow^(3,18-21):

1. Respecting the fundamental principles of medical ethics:

the principle of *primum non-nocere* doubled by the principle of doing good, and the use of mandatory and informal informed consent, the use of the right to a second opinion in risky investigations / therapies and the promotion of evidence-based medicine.

2. Changing the management of error

(from person-approach to system-approach) and improving the legal framework of medical practice are mandatory to ensure patient's and doctor's protection, both potential victims of medical failure⁽²²⁾; increasing the practice of defensive medicine has negative consequences not only indirect on patients (by draining funds for investigations of questionable utility), but also by the tendency to avoid facing cases with higher risk; moreover young doctors will tend to avoid choosing specialities with frequent allegations of malpractice.

The management of error is essential to prevent its repetition and retracting; it requires more appropriate, more flexible, more nuanced legislation, differentiating fault from error, allowing the patient compensation in both cases, but limiting the escalation of the amounts that can be claimed.

3. Structuring, launching and effective functioning of the self-control mechanisms of medical research and of

the medical profession (quite numerous, but not sufficiently operant):

- Ethics committees of hospitals and medical research institutes
- Professional societies of medical specializations (able to formulate, apply and control professional standards)
- College of Physicians (able to detect and correct ethical deviations).

4. Compliance with practice guidelines

based on trials carried out under rigorous conditions for scientific substantiation and research ethics that synthesizes the principles of best practice of the moment, however allowing the doctor enough freedom of movement to individualize therapeutic conduct according to the concrete peculiarities of the patient (medical judgment should remain sovereign) without fear of allegations of malpractice to paralyze his/her initiative and block the advancement of medicine; in the same sense it is considered that it is time for the scientific community to stop giving free rein to alternative medicine as assertions, speculation and testimonials cannot take the place of evidence, while "alternative therapies" should be subject to the same rigorous criteria as "conventional" medicine⁽¹⁵⁾.

A reserved attitude on Evidence based medicine (EBM)?

Trying to tackle the issue in a manner more open to critical reflection, we should wonder whether the huge pressures of the extremely powerful pharmaceutical industry, the main financing of pharmaceutical research and manufacturing of medical devices industry influences the results of trials and modulates the concepts of modern strategy. The boundary between health and disease is always moving, the targets of primary

prevention have a more precocious approach, constantly expanding the scope of potential beneficiaries of preventive medication (eg new criteria for the definition of the chronic kidney disease tend to encapsulate most of the elderly population), indications of interventional medicine and surgery are becoming wider and wider, equipment is becoming more sophisticated, more efficient and more expensive, and the doctor becomes more dependent on it. Medicine is becoming increasingly aggressive and the therapeutic targets lower and lower (BP, glycemia, cholesterolemia and LDL-cholesterolemia) (Lower is better, isn't it?).

There was a reflux of this trend (also generated by EBM) such as the abandoning (in diabetes) of optimal BP as target or of glycemic hypercontrol, both extremely difficult to carry out, risky and with no obvious benefits. Evidence based medicine provides the scientific foundation of modern medicine and the conditions for achieving the trials are increasingly draconian (criteria for the inclusion and exclusion of casework, research methodology, equipment performance, ethical requirements, exclusion of conflicts of interest, etc.).

But we cannot explain why in a certain period all the evidence converge to a certain opinion and afterwards all should support the contrary view (see beta-blockers in heart failure, the advantages of erythropoietin therapy in renal disease, the target BP values in diabetes, heart impact of hormone replacement therapy administered post-climax). Could we then argue whether the medical research progress justifies the so frequent change of Practice Guidelines (ESC / EHS Guidelines for hypertension management: 2003, 2007. update 2009, 2014) ?

However, although the guidelines are neither the Bible nor the Koran of medicine, they



INTERNAL MEDICINE

General Reviews

remain the best tool that we have to outline and implement Best Practice of the Moment. We believe that the guidelines must be of further indicative, not normative value and the medical judgment should remain preponderant.

References

1. Leape L. Unnecessary surgery. *Ann Rev Public Health*. 1992;13:363-383
2. Leape LL. Error in medicine. *JAMA*. 1994 Dec 21;272(23):1851-7.
3. Kohn LT, Corrigan JM, Donaldson MS, eds. 1999 Institute of Medicine(IOM) report :To Err Is Human: Building a Safer Health System. Washington, DC: National Academy Press; “).
4. Hettrich Carolyn, Mather III RC, Sethi MK, Nunley RM, Jahangir AA, and the Washington Health Policy Fellows- The costs of defensive medicine- *AAOS Now*, 2015,9:7.
5. Parenti CM, Lederle FA, Impola CL, Peterson LR. Reduction of unnecessary intravenous catheter use. Internal medicine house staff participate in a successful quality improvement project. *Postgrad Med J* 2004 80(939);
6. Lederle FA, Parenti CM, Berskow LC, Ellingson KJ. The idle intravenous catheter-*Arch Intern Med*. 1994 , 22;154(16):1829-32. *Ann Intern Med*. 1992 May 1;116(9):737-8
7. Herrero GS, Martinez de Albornoz Torrente P, et al. Use and abuse of intravenous catheters in conventional hospital -*An Med Interna*. 2006 Oct;23(10):475-7
8. Miron S-D, Labar A, Gutu M, Astarastoe V: Ethical issues of excessive use of medical imaging investigation of patients with previously established diagnostic-*Rev Rom Bioetica*, 2014, 12:4.
9. Greenspan AM; Kay HR; Berger BC et al: Incidence of unwarranted implantation of permanent cardiac pacemakers in a large medical population. *N Engl J Med* 1988 ,318 158-163.
10. Craig DG, Thimappa R, Anana V, Sebastian S. Inappropriate utilization of intravenous proton pump inhibitors in hospital practice--a prospective study of the extent of the problem and predictive factors *QJM*. 2010.
11. Gupta R, Garg P, Kottoor R, et al. Overuse of Acid suppression therapy in hospitalized patients. *South Med J*. 2010 ;103(3):207-11.
12. Murphy CE, Stevens AM, Ferrentino N et al. Frequency of inappropriate continuation of acid suppressive therapy after discharge in patients who began therapy in the surgical intensive care unit. *Pharmacotherapy*. 2008 ;28(8):968-76.
13. Simoni-Wastila L, Yang HK. Psychoactive drug abuse in older adults. *Am J Geriatr Pharmacother*. 2006 ;4(4):380-94.
14. Wodarg W et al: Faked Pandemics - a threat for health- Doc. 12110/ 18 December 2009 Parliament Assembly of the Council of Europe (PACE)
15. Marcia Angell J P Kassirer: Alternative Medicine- The Risks of Untested and Unregulated Remedies *NEJM*, 1998, 339:839-841)
16. Combest W, Newton M, Combest A, Kosier JH - Effects of Herbal Supplements on the Kidney -*Urol Nurs*. 2005;25(5):381-386.
17. Vickers A - Cancer Cures: “Unproven or Disproven” *CA Cancer J Clin* 2004;54:110-118
18. Eldar Reuben: Understanding and Preventing Adverse Events-*Croatian Medical Journal*, 2002, 43(1):86-88,
19. Soubrie C, Lebrune-Vigne B: Iatrogenie. Diagnostic et prevention *Rev Prat*, 2005, 55, 209-216.
20. Reason J - Human error: models and management - *BMJ* 2000;320:768-770
21. Helmreich RL. On error management: lessons from aviation. *BMJ* 2000; 320: 781-785
22. Wu AW: Medical error: the second victim *BMJ* 2000;320:726-727.