

Iatrogenesis: analysis, control and prevention

Document of the SESPAS-OMC working group on iatrogenesis

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Presentation

SESPAS and the OMC have signed a collaboration agreement on the analysis, control and prevention of iatrogenesis, in view of the importance of this problem and the manifest need to minimise its impact. These concerns form part of the social legitimisation of the two institutions, the first, as a confederation of professional associations in the field of public health working to improve the health of the population, and the second, as a public law entity providing support for the exercise of medicine to the benefit of the population as a whole.

Accordingly, a working group has been constituted (as detailed in the Annex) to contribute to reducing, as far as possible, the consequences of iatrogenesis. To properly address this issue the problem must be considered in political, social and professional terms, with the involvement of the areas of society best equipped to collaborate in this task. In consequence, this position paper, the first of a series, is presented, with the following content:

1) A conceptual definition of the problem, its basic types and their potential scope; 2) The areas of iatrogenesis: general and specific; 3) Estimates of its potential impact and social costs; 4) A preliminary inquiry into its causes and possible determinants; 5) Considerations regarding its prevention and control, including short and medium-term recommendations. The paper also includes a glossary of related terms, a bibliography and information on documentary sources.

The aim of this paper is to communicate the position of SESPAS and the OMC, and of associate bodies, that iatrogenesis presents a public health problem in Spain, and to raise awareness of this question through publication as an article in a peer-reviewed journal such as Gaceta Sanitaria. Beforehand, the question should be discussed and, if necessary, views exchanged with all concerned, including other scientific societies, particularly those that have long been actively involved in the deployment and consolidation of the Patient Safety Strategy of the Spanish National Health System, together with other professional corporations (colleges of nursing, dentistry, pharmacy, veterinary science, etc.) and other institutions and elements of civil society interested in collaborating.

Introduction

Because of its high degree of complexity, during healthcare there are numerous *incidents*, that is, unintended or unexpected circumstances or acts that can cause or have caused harm. Some do not impact on the patient (*near-miss*), others do, but do not cause harm (*harmless incident*), while others both affect the patient and cause harm.

Strictly speaking, the latter category, known as an *adverse event* in health intervention, is defined as any harm caused by medical care, without necessarily implying error, negligence or low quality of care. The term merely indicates that an undesirable clinical result has occurred as a result of an element related to diagnosis or treatment, and not to the underlying disease affecting the patient (1).

It is not always easy to distinguish *avoidable* adverse events from *unavoidable* ones. Some may be attributable to medical errors, when something wrong is done (error of commission) or when what is necessary is not done (error of omission). However, other problems, as we discuss below, are almost inseparable from diagnostic processes, treatments, preventive interventions and rehabilitation.

In consequence, it is vital to understand that, fortunately, errors and negligence do not always cause harm and that a proportion of the harm attributable to medical care is both inevitable and inseparable from it. These considerations underlie the classical definition of *patient safety*: reducing the risk of *unnecessary* harm associated with health care *to a minimum acceptable level* in accordance with collective cultural values, current knowledge, available resources and the context in which care is provided, always taking into account the risk involved in not providing a particular health care or in providing an alternative (2).

Adverse events in medical and health care interventions are believed to have a very significant impact on health, health service organisation, the economy and the society in general. Without exaggeration, this can be described as a priority problem for public health worldwide. Nevertheless, no comprehensive information systems exist with which to accurately monitor the harmful events associated with medical and health care practice.

Over the last two decades, awareness and concern for patient safety have increased throughout the world, as clearly evidenced by the many international actions undertaken, some in a positive sense, to *improve patient safety* by raising health care quality, and some facts as the rise of *defensive medicine*.

However, the concept of *patient safety* does not cover all areas of health care-related harm. Patients may be affected not only by diagnostic actions and treatments, but also by preventive interventions such as population screening, early treatment, vaccination programmes, health protection and promotion, road safety campaigns, safety in the workplace initiatives, food quality regulations, and many more. All them can be associated to adverse events. Hence, we propose to use an older, and perhaps more provocative term, *iatrogenesis*.

1. Background

Iatrogenesis is an alteration, usually negative, in a patient's health status resulting from a medical intervention. The term was first used in the Manual of Psychiatry by Eugen Bleuer, in 1924, to refer to the symptoms that the therapist may induce in a suggestible patient. The neologism is constructed from the Greek terms *iatros* (healer, physician) and *genesis* (origin),

and expresses the concept of harm provoked by medical treatment, that is to say, an *adverse effect*.

It is debatable whether the term iatrogenesis is really the most appropriate for considering the possible harm caused by health care, since it is associated with a great many interrelated concepts, most of which have negative connotations and have generated a provocative cloud of terms, such as adverse effect, unintentional, complication, error, negligence, failing, risk, incompetence, malpractice, carelessness, inappropriate, incident and adverse event. This type of charged vocabulary merely adds noise to a problem that calls for a calm, proactive approach. For example, in the judicial sphere, iatrogenesis is often (and not always correctly) associated with negligence.

The etymology of the term *iatrogenesis* highlights the fact that all medical and health interventions have pros and cons, *risks and benefits*, and that their safety cannot be absolutely guaranteed. An appropriate intervention (the administration of a properly-indicated, effective drug), correctly implemented (by the right route and at the right dose) may nevertheless provoke a harmful (adverse) reaction as a result of its own primary pharmacological action (side effect). Moreover, an inappropriate intervention (in terms of diagnosis, treatment or follow up) whether by commission or by omission does not always cause harm¹.

Some adverse events are serious, unequivocal, measurable and, often, preventable. These *never events* should not occur, but do. For example, *sentinel events* (performing an intervention on the wrong patient or one affecting a healthy limb) are clearly unacceptable and often reflect serious problems in health service organisation or procedure. In this respect, there exist *trigger signals* that alert to the possibility of health care-induced harm (the administration of vitamin K following an overdose of anticoagulants) (1). No human activity is free of errors, and the context of iatrogenesis well reflects the dictum: *to err is human* (3).

Any analysis of medical interventions and decisions must take into account their risks and benefits, and at the same time accept that the knowledge obtained is never absolute and therefore that there will always be some associated uncertainty. For all these reasons, iatrogenesis should be analysed from a standpoint that encompasses all forms of harm arising from medicine and health care, including that which is potential, that which is avoidable and that which is unavoidable, and incorporate factors causing mild, moderate or severe harm. The level of knowledge that can be achieved about iatrogenesis will largely depend on our ability to extract significant, relevant information from studies of incidents, near misses, adverse events, sentinel events and triggers, as well as from other information and monitoring systems.

In view of the above considerations, the Hippocratic aphorism *Primum non nocere* (First, do no harm) should be understood as a guiding principle, not as a precept, since from *First, do no harm* it might be deduced *Therefore, do nothing*, which could be worse. Although the legitimate purpose of medical intervention is to cure or alleviate ill health, to improve the prognosis of disease and to promote and protect health – which at a population scale is termed the collective promotion and protection of health – the consequences of any

¹ When the cost is in the numerator and the denominator contains the benefit minus the harm, these interventions have a denominator that either tends to zero, in which case the cost per unit of benefit tends to infinity and the activity can be termed adiabatic, or the denominator is negative, i.e. the benefit is less than the harm, and then the intervention is directly unacceptable (see: <http://evalmedicamento.weebly.com/varios/competencia-mision-vs-culto-al-tramite-actividades-adiabaticas-y-pseudociencia>)

<http://evalmedicamento.weebly.com/varios/un-modelo-explicativo-de-las-intervenciones-sanitarias-mediante-las-teorias-de-tipos-logicos-y-de-la-comunicacion-humana-galo-a-sanchez-grupo-evalmed-grade>)

intervention may be beneficial, detrimental or a combination of the two, or there may be no effect at all. Just as the disappearance of a disease or the relief of its symptoms is not always the consequence of a medical intervention (*vis medicatrix naturae*- the healing power of nature), nor should a worsening of the patient's condition or the appearance of complications and sequelae necessarily be attributed to the physician's actions.

In addition to the above types of harm that are associated with prevention, diagnosis, treatment and rehabilitation, which can be classified as *clinical iatrogenesis*, other forms of harm can arise from *medicalisation*, particularly that which is related to unjustified or exaggerated interventionism (as also occurs in the broad area of public health), and from the expropriation of every individual's responsibility for their own health, via *cultural and political iatrogenesis*, which tends to strike down autonomy and resilience, two characteristics that are strongly associated with positivity vis-à-vis health; in this respect, see Illich (4).

2. Aspects of iatrogenesis

Iatrogenesis affects diverse areas of health and of the health care system. Firstly, regarding individual clinical care, in areas such as disease prevention (immunisation, screening, etc.) and health promotion (advice on hygiene, exercise, diet, etc.). Secondly, at the population level, i.e. the institutions involved in public health issues (environmental protection and improvement, safety in the work place, road safety, etc.). Moreover, iatrogenesis occurs at all levels of health care, including primary, specialised attention and socio-health care.

In addition, and no less important, many public policies (related to education, employment, town planning and housing, among others) can have an impact – positive or negative – on the health status of individuals and communities. These considerations underlie and justify the *Health in all policies* initiative, according to which private and public health should be addressed through policies generated in all sectors that affect health, especially in view of the magnitude of population effects (i.e., the policies adopted, or otherwise, may affect very large numbers of people).

A complementary view of iatrogenesis is provided by the *iceberg image* (5). The most severe and striking adverse events (their visible zone) constitute only one ninth of the overall problem. The submerged area (the remaining eight ninths), which often goes unnoticed, contains the incidents, near misses, mild adverse events and *latent factors and circumstances* whose structure and potential for interaction can and do favour the appearance of major adverse events. Such latent factors may include a culture prioritising medical interventionism, or prone to technological fascination (giving rise to unfounded expectations in the possibilities of medicine and prevention), overdiagnosis, diagnostic errors, unnecessary or inappropriate treatment, deficiencies in health service organisation, inadequate incentives, insufficient or skewed training, information gaps among health care professionals, communication problems and inappropriate human resource policies.

Another part of the iceberg that has been insufficiently explored is that of the harm that can occur in disease prevention and in health promotion and protection (6). Preventive measures are not immune from unanticipated adverse outcomes, often lack the scientific evidence necessary for them to be recommended to all, and may be based on commercial interests, promoting an unnecessary medicalisation of daily life and what might be called, by extension, a 'preventive siege' lacking the ethical considerations that the actions of the health system in general, and public health care in particular, should incorporate (7, 8). As well as the effect on patients, there is a further impact on the population at large, when large sectors of society are

improperly converted into 'patients' or are labelled as such, and thus become statistical candidates to suffer harm but not benefits.

The iceberg metaphor reflects the difficulties of analysing the causes of iatrogenesis (which are almost always multiple, and hardly ever isolated), their real impact on the health of patients (*first victims*), on health care personnel (*second victims*) and on the organisation and the health system in general (*third victims*), and the (avoidable) health expenditure it provokes, including litigation and legal complaints, as well as the influence on the institutional, cultural and moral values of society as a whole (9-12).

3. Quantification and impact of iatrogenesis

Estimating the magnitude of iatrogenesis as a public health problem depends to a great extent on how it is measured. Thus, the identification criteria must be closely defined, together with the procedures required to obtain, validate and analyse information on the phenomenon, this being a fundamental aspect of all epidemiological methods. In this respect, a broad-based approach as proposed in this paper poses a significant challenge, because not even the simplest approaches, i.e. those restricted to adverse events, have proven capable of giving precise estimates of the incidence, morbidity-mortality or disease burden associated with iatrogenesis (1, 13-15).

Although in recent years the number of adverse events reported in Spain has steadily increased, for various reasons, a significant degree of underreporting persists, which poses a major obstacle to a good understanding of the causes and magnitude of iatrogenesis, to equipping us to learn from mistakes made and to the implementation of effective measures to reduce it, on the basis of information compiled. Nevertheless, and in spite of the difficulties involved, the strengthening of notification has long been recognised as crucial to improved patient safety (2, 16-18).

As part of its World Alliance for Patient Safety, the World Health Organization proposed that iatrogenesis be systematically studied, through a five-stage cycle: 1) determine the magnitude of the harm and the number and types of adverse events; 2) understand their causes; 3) find solutions to make health care safer; 4) evaluate the impact of solutions in real life situations; 5) translate them into practice (19,20). Although much progress has been made in its implementation, the results of this initiative, in terms of practical, effective improvements in patient safety, are clearly very insufficient.

3.1. Methodological aspects: from data to knowledge

The terminological imprecision of the concept of iatrogenesis need not prevent us from considering how its magnitude and repercussions, and those of its determinant factors in different areas of health care, might be estimated accurately and effectively. In transforming the available data on iatrogenesis into information and knowledge, three prior questions must be addressed: what do we seek to measure, how, and what information is needed to do so?

Depending on what we wish to discover (the clinical or economic burden of iatrogenesis; its risk factors; a long-term outlook on the harm caused and its evolution; institutional, organisational or human factors; associated latent factors) a wide variety of methods can be brought to bear, with different types of study design and of qualitative and quantitative methods, derived from various disciplines, such as statistics, epidemiology, operations

research or economics, and from various sources and data records, since no single approach allows us to measure iatrogenesis specifically and directly, and all have limitations (1, 2, 19-23).

In considering patient safety, two complementary perspectives – collective and individual – should be adopted, based on a detailed analysis of specific cases viewed as useful for reflection and learning. Studies focused on individuals and on isolated cases can be undertaken either proactively, before they occur, in order to forestall adverse events (for example, by a failure mode and effects analysis) or retrospectively, to analyse a major adverse event that has taken place, seeking to prevent its reoccurrence (for example, by root cause analysis) (1).

The active identification and management of *potential risks* has the obvious advantage of *preventing* the occurrence of adverse events, in comparison to *reacting* after the event has taken place. This approach also avoids the barriers to understanding that can be provoked by *hindsight bias* and the fear of *everything coming out*, and of blame and punishment following an adverse event (24).

Detailed investigation of adverse events, especially those that have caused or may cause significant harm, represents both an opportunity for improvement and, if the results obtained and useful measures for improvement are adequately communicated, an opportunity for learning and the translation of knowledge to other areas of health care, where this kind of population-based research is often lacking.

3.2. Sources of data on iatrogenesis

In studies of the magnitudes and determinants of iatrogenesis, different sources of data can be used. Clinical-administrative data (for example, the Minimum Basic Data Set (CMBD, Spanish initials) and the analysis of morbidity-mortality, from certain causes, provide useful information and an overview of iatrogenesis. Focusing on clinical safety, the Agency for Healthcare Research and the Organization for Economic Co-operation and Development (15) have both published lists of indicators to identify and control *sentinel events* and *trigger* indicators.

Indicators of the use of health care resources (surgical interventions, diagnostic tests), including those of low-value technologies (i.e., those which are less effective, or safe or cost-effective than available alternatives, or which are merely cosmetic), and their geographic variability, together with studies assessing the adequacy or otherwise of their indications, provide valuable information, especially of overuse or of inappropriate use, and this is extremely useful for detecting and quantifying iatrogenesis and its costs (25-36).

Both as a data collection instrument for population-based studies and for individual case analysis, the clinical history constitutes a valuable resource. Indeed, despite foreseeable shortcomings in the information contained, the clinical history is still considered the gold standard for information about the health care provided and its consequences.

Systems for the voluntary reporting of incidents and adverse events and for learning from them, the direct *in situ* observation of the organisation and development of health care activity, reasons for complaints, demands and litigation, the opinions of patients and professionals and the ongoing evaluation of health services are other, complementary sources of relevant data and information, and their triangulation is of invaluable assistance for a better understanding of the associated and latent factors determining iatrogenesis, both in general and that which is specific to cases and care centres.

4. The impact of iatrogenesis

4.1. Impact on patients and the general population

According to recent estimates, adverse events may be the third leading cause of death in the United States (13). Although these events are often attributed to errors or negligence by doctors and other health personnel, this ignores the fact that perceptions of medicine have evolved. Once, it was simple, ineffective and assumed to be safe; now, health care is complex, effective and known to be potentially dangerous (although less so than ever before) (37).

In Spain, the frequency and distribution of adverse events has been analysed in several studies promoted by the Ministry of Health, Social Services and Equality, located in hospitals (the ENEAS study), in primary health care (the APEAS study), and in social/health care centres (the EARCAS study), as well as in more specific settings, such as incidents and adverse events in intensive care medicine (the SYREC study), and the EVADUR study (Adverse Events in Hospital Emergency Services in Spain), promoted by the Spanish Society of Emergency Medicine (38-43). In the ENEAS study, the observed incidence of patients with adverse events was 9.3%; in APEAS it was 11.2%, in SYREC, it was 40% and in EVADUR it was 7.2% (38-43).

4.2. Impact on health care professionals and on the health system

Serious adverse events also have consequences for *second victims*, i.e., health care providers who are involved in an unanticipated adverse patient event, because the professionals involved are concerned for the patient's progress and must also take into account possible legal and professional repercussions. The commonest emotional consequences in these second victims are anxiety, bewilderment, confusion, difficulties of concentration and attention, depersonalisation, frustration, feelings of guilt, sadness, mood swings, insomnia, repeated re-experiencing of the event, doubts about one's own professional ability and fear of legal consequences and loss of reputation. In addition, health organisations and centres (*third victims*) may suffer loss of prestige, reputation and, therefore, confidence as the result of an incident related to patient safety (9-12).

A problem frequently associated with the occurrence of an adverse event and its management is the immediate search for "culprits", together with the taking of hasty, compulsive decisions that may unleash a disproportionate level of resource mobilisation, which is often reversed as soon as the initial social alarm has dissipated.

5. The costs of iatrogenesis

Several recent studies have been undertaken to estimate the costs of health-related harm. In one, it was conservatively estimated that 15% of hospital spending and activity in OECD countries is attributable to patient-safety failings (22). A literature review of this question estimated that over 40 million hospital adverse events occurred worldwide each year, causing an annual loss of 23 million disability-adjusted life years (DALYs). Of these, two-thirds affected countries with low levels of GDP (32). Another review, based on data for 30 European countries for the year 2015, concluded that of the 3.5 million DALYs lost, approximately 1.5 million were avoidable (33).

Notwithstanding these studies, there remains a need for comprehensive, accurate estimates of the costs imposed on health systems and society by iatrogenesis, taken in the broad sense referred to in this report. On the other hand, partial approximations of the costs of iatrogenesis – due to adverse events, specific medical errors, adverse drug effects or surgical complications – have been made in a number of countries, including Spain (13, 15, 34).

To Err is Human, the influential report published by the Institute of Medicine in 1999, advised that a broad approach should be taken to cost evaluation, recalling that in addition to accounting costs, “Errors are also costly in terms of opportunity costs. Dollars spent on having to repeat diagnostic tests or counteract adverse drug events are dollars unavailable for other purposes. Purchasers and patients pay for errors when insurance costs and copayments are inflated by services that would not have been necessary had proper care been provided”. The report also emphasised that the relevance and magnitude of indirect costs (loss of productivity) and of intangibles should be taken into account, observing, “But not all the costs can be directly measured. Errors are also costly in terms of loss of trust in the system by patients and diminished satisfaction by both patients and health professionals. Patients who experience a longer hospital stay or disability as a result of errors pay with physical and psychological discomfort. Health care professionals pay with loss of morale and frustration at not being able to provide the best care possible. Employers and society, in general, pay in terms of lost worker productivity, reduced school attendance by children, and lower levels of population health status” (3).

Some estimates have been made of the costs of “no safety” in hospitals, i.e. the *incremental costs* associated with the diagnosis, treatment and rehabilitation of harm caused by avoidable adverse events with respect to the cost of attention in their absence. Nevertheless, as in other areas of health care, insufficient economic assessments have been made to determine whether a given action, programme or set of measures aimed at improving safety are efficient, that is, whether they are *worth what they cost* (34). Furthermore, as the above-mentioned studies were circumscribed to local circumstances, caution should prevail in any attempt to extrapolate their findings to other settings. On the other hand, there is no need at all for caution in reiterating the need for more and better studies of this type to be conducted in Spain.

It is therefore evident that, despite the limitations of these studies and in spite of the acknowledged knowledge gaps regarding the costs of iatrogenesis, the information currently available is sufficient for both iatrogenesis and patient safety to be viewed as an international priority, even though this information is very far from being sufficient to properly determine the costs of iatrogenesis to the Spanish national health system.

6. Latent causes of iatrogenesis: the health environment, culture and social values

As is also the case in studying the aetiology of diseases and the determinants of health, in seeking to understand and control iatrogenesis it is necessary to take into account certain key elements of the health environment that exert a decisive influence on the appearance of adverse reactions. These *latent factors* in the health system concern the organisation of services; the appropriateness, effectiveness and safety of the medical services provided; information systems; the physical condition and maintenance of facilities and equipment; the design and implementation of routine checks; the competence and training of health care professionals; information, schedules and working conditions; professional satisfaction, leadership and professionalism; communication; human resources policies; currently applicable incentives; and the periodic evaluation of the system and of the good governance of

institutions, whether directly or indirectly related to health care. In fact, most adverse events have a systemic aetiology and are influenced by several of the above factors; only rarely can a single cause be identified (3, 35, 36, 44).

Much of medicine's capacity to provoke harm arises from the avid willingness of the population to undergo all kinds of tests, examinations, interventions or treatments, and to accept all kinds of recommendations or information without realising or acknowledging their potential harmful effects, or without considering that the incidence of adverse events increases in line with the size of the population exposed to the risks.

As detecting the causes and consequences of adverse events also depends on the context, social and cultural factors must be evaluated in the specific historical and cultural context of the society in question, paying special attention to the knowledge available and to the medical technologies employed.

In addressing the aetiology of iatrogenesis, we must also examine the origins of the behaviour of those involved in actions with iatrogenic potential, because this potential is rooted in the values and beliefs that make up today's socially accepted "medical culture", as well as in the cultural and social devices upon which this culture relies. A notable factor in this regard is the default tendency of professionals and the public at large to overestimate the benefits and underestimate the risks of medical technologies and health interventions (45). It is therefore essential to conduct a collective, in-depth exploration of the determinants and causes of iatrogenesis.

One of the indisputable drivers of our current exposure to iatrogenesis is the synergy between the prevailing interventionist medical culture and the irrepressible advance of medicalisation. The widespread belief in the supposed infallibility of medical science underpins expectations of a perfect outcome and tends to increase the risk of errors and failures. Such expectations, which are generally exaggerated, can lead to the unnecessary provision of health care, and thus multiply the risk of iatrogenesis (27-30, 35).

These beliefs and expectations are accompanied by popular fallacies and ideas that although highly questionable are rarely questioned, such as "more is better", "information is power", "technology can solve all our problems" and, even, "death is avoidable". These attitudes fit perfectly within the inherited medical culture, presided over by the myth of perfection (46), by an impossible, quixotic quest for certainty, by feelings of failure, guilt and shame when patients are harmed (47) and by an unfounded belief that punishing those who make mistakes will make health workers in general more careful and less liable to err in the future.

In addition to the above, there exist professional, institutional and social incentives and pressures that, on the one hand, stimulate, or even "reward", overdiagnosis and overtreatment, and, on the other, dissuade professionals, both individually and corporately, from taking effective, recognised measures to improve safety. These factors are complemented by disincentives such as the fear of public shaming and of possible legal action whenever a diagnostic test is omitted or an indicated treatment is rejected.

The presence and impact of these elements in health clinics and institutions is compounded by self-serving commercial interests that promote 'healthism' and stimulate unfounded preoccupations on the basis of which lifestyles and diets are modified, with questionable effectiveness and safety.

"Mediatrogenesis", or the ill effects to health provoked by professional, individual or collective sources, amplified through the mass media, is another contributory factor, which fosters and

endorses practices and behaviours of doubtful benefit, while silencing their potential for associated harm.

Awareness of the risks associated with medical interventions has risen dramatically, but, despite the benefits accrued from this growing concern, there is a risk of blinding oneself to the reality of iatrogenesis by unequivocally associating it with error and its avoidance. Narrowing the management of iatrogenesis by simply addressing the *adverse events* of current practices is a short-sighted and unfocused approach to the problem. In order to confront the complexities of iatrogenesis, it is also necessary to redefine the ways in which the social acceptability of health practices – preventive, diagnostic and therapeutic – is assessed and to reexamine the socially accepted point of equilibrium between risks and benefits. In this respect, a systemic approach should always be adopted.

Health care professionals and society as a whole must understand and accept that it is much easier to put a man on the moon than to prevent each and every possible failure of the organism; that misleading information (whether so intended or otherwise), which is obtained other than from an appropriate clinical context, or information which is simply not understood, is more likely to cause harm than good; that launching a seek-and-destroy operation against “early warning illness” does not always produce a better outcome for the patient; and, last but not least, that more is not always better.

7. The paradoxes of “defensive medicine”

Defensive medicine is coming to be viewed as an apparently paradoxical cause of the iatrogenesis that the medical profession claims it wishes to avoid. Some forms of iatrogenesis give rise to claims and lawsuits that automatically provoke defensive clinical attitudes and, hence, more iatrogenesis. Nevertheless, malpractice liability systems, as are found in the United States and elsewhere, insist on the sterile path of establishing a culture of guilt, despite the fact that this policy not only fails to alleviate the problem but in fact contributes to the overuse of medical procedure, thereby aggravating iatrogenesis.

Some physicians have claimed that defensive medicine – defined as a deviation from good medical practice for fear of litigation – is the leading cause of medical excesses. In the United States, over 90% of physicians in “high-risk” medical specialities recognise having practised defensive medicine, mainly in the form of requests for unnecessary diagnostic tests and procedures, by prescribing more medication than is indicated and by referring patients more frequently than is necessary. In the Spanish health service, action should be taken to oppose the creeping contagion of medical liability systems and their undesirable consequences.

8. Proposals

Some of the measures that need to be implemented to reduce iatrogenesis and to continue improving patient safety will inevitably require structural changes in the health system. The difficulties involved in this, however, should not be taken as a pretext for excluding proposals or silencing recommendations. Our medical ethics oblige us to make them explicit. Doing nothing and maintaining the status quo can also lead to socially inadmissible adverse events and opportunity costs.

The pre-eminence of a medical and health culture that is strongly influenced by consumerism tends to generate excessive and even chimerical expectations about the possibilities of

medicine. In this context, there is no leeway for self criticism, and professionals are at the mercy of the short-term interests of lobbyists and corporations. The lack of political visibility on the determinants of iatrogenesis and its consequences limits the possibilities for its prevention and control. This situation clearly justifies the urgent inclusion in the health policy agenda of iatrogenesis as a an element of outstanding importance, especially since it is not currently referred to as an explicit priority in health policy, in research or in training programmes.

Questions should be raised about the current health culture, in which a certain banalisation of medicine coexists with exaggerated expectations about its possibilities, which encourages overdiagnosis and overtreatment. Attention should also be paid to establishing incentives, both explicit and tacit, to persuade health professionals that openly confronting possible mistakes is worthwhile and that, on the contrary, concealing mistakes for fear of public embarrassment and possible lawsuits may be the worst personal choice.

Medical malpractice law is in need of reform and is currently insufficient to prevent overdiagnosis and overtreatment. As well as continuing to press for such reform, additional ways of overcoming the drivers of medical excess must be investigated. Further efforts are needed to change the culture of medicine, and even culture in a broader sense, and this will require us to be more willing to accept the inevitability of occasional failure, and even of error.

A culture of evaluation should be established in medicine, including the assessment of clinical results and the detection of iatrogenesis in regular clinical practice. As recommended by the OMC and SESPAS, such a culture should also ensure the full, reliable, transparent and appropriate assessment of medical technologies before their real-world application, thus improving the process by which health technologies are adopted and promoting their appropriate use.

It is vital to rigorously evaluate the effectiveness and efficiency of all medical interventions that are currently being implemented in our country, including those aiming improvements in patient safety. However, although few such assessments have been made to date, inaction cannot be justified by drawing attention to the absence of interventions of proven efficacy and cost-effectiveness.

It is essential to know whether, as we suspect, insufficient resources are being applied to the prevention and control of iatrogenesis. If this is so, the necessary level of resources must be determined and the authorities urged to allocate them efficiently and to evaluate and account for the actions taken, in an appropriate and timely way.

All those responsible for patient safety in the regional health services and their bioethics committees, as well as the universities responsible for undergraduate and postgraduate training in the field of health sciences, and of course the agencies promoting and financing medical and health research, should include iatrogenesis as a matter of priority in their agendas and act accordingly in their respective fields of action.

At the same time, the problem of iatrogenesis must be brought to the attention of public administrations (national, regional and local) and legislative bodies (Congress, Senate and Regional Parliaments), and commitments in this respect demanded of political parties, social partners and the media.

Finally, and as proposals for specific interventions are drawn up and agreed, the administrations responsible for health, research, justice and the economy should be called upon to adopt them.

Recommendations

The following recommendations are made by this working group.

1. Health authorities (national, regional and local) must recognise that iatrogenesis is a large-scale public health problem and explicitly include it among health policy priorities, in order to meet stated objectives regarding patient safety and iatrogenesis.
2. Given their potential, the achievements made to date and the need to implement newly-agreed actions, health authorities at all levels should contribute the necessary resources, prioritised towards intensifying the rigorous, independent deployment and evaluation of the *NHS Patient Safety Strategy*, and periodically report to society the results obtained.
3. The health authorities should, without further delay, prioritise the design and implementation of specific incentives of different types. Those incentives should be effective and congruent with the goals of the *NHS Patient Safety Strategy*. Besides that, other incentives recommended in this document pay particular attention to strengthening information systems related to patient safety and existing systems for reporting incidents and adverse events.
4. All health professionals must take decisive action to reduce the marked non-compliance of the recommendations of various international organizations such as WHO on effective interventions for the prevention of nosocomial infection and bacterial multiresistance, such as adequate hand hygiene, and overprescription, underprescription and inappropriate prescription of antibiotics. Spain has a remarkable low adherence to these norms, compared to European countries.
5. The results of periodic evaluations should be published, regarding both the strategic lines of action set out in the *NHS Patient Safety Strategy* and additional actions taken independently of this Strategy. Competence should be fostered through comparisons and action taken to strengthen existing sources of information on good practice, nationally and internationally.
6. A long-term policy of promoting research into the causes and determinants of iatrogenesis should be designed, implemented, financed and maintained, together with an independent evaluation of preventive and control measures, and systems to ensure accountability and the publication of results obtained.
7. The necessary legislative reforms should be undertaken to protect professionals from the potential impact of reporting and acknowledging incidents and adverse events, considering the reforms undertaken by other European countries.
8. To promote these recommendations, an active coordinated front should be created, with the participation of health authorities, health-related professional corporations and scientific societies, bioethics committees, universities offering health science degrees, civic associations, patient and consumer organisations and society at large.
9. A yardstick of health-care-related harm should be adopted, in order to increase legal certainty and to reduce unjustified variability in the determination of compensation awards in judicial and extrajudicial processes of health care liability, thus helping reduce litigation and combating the practices of defensive medicine.

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