[Translation:]

"Primum non nocere"

Preventing Overdiagnosis, the Quaternary Prevention


[Original Latin text]
“Primum non nocere” Preventing Overdiagnosis, the Quaternary Prevention

A bibliographic research

Bachelor’s thesis

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ABSTRACT

Primary Care is the main scenery where promotion of health and various levels of prevention take place. Overdiagnosis and overtreatment are a major health, social and economic problems, both regarding its incidence and its morbimortality. Is at this point where Quaternary Prevention acts and has begun to gain importance, a concept of prevention that tries to avoid unnecessary or excessive diagnosis, interventions and treatments; and that is increasing its value in Family Doctors clinical practice. The purpose of the current bibliographic research is to analyze, through medical articles and grey literature, the state-of-the-art of this new way of prevention.

Keywords: preventive healthcare, quaternary prevention, overdiagnosis, overtreatment.
DESCRIPTION OF THE TOPIC

1. Importance and consequences of iatrogenia

Iatrogenia (from the Greek "brought forth by the healer") is defined as any adverse consequence in a patient resulting from treatment by a physician, nurse or health professional or from products or services beneficial to health. Among the causes of Iatrogenia are included: side effects of possible drug interactions, complications arising from a procedure or treatment, medical error, negligence, unexamined instrument design, anxiety or annoyance in the physician or treatment provider in relation to medical procedures or treatments, unnecessary treatment for profit.

Globally it is estimated that 142,000 people died in 2013 from adverse effects of medical treatment up from 94,000 in 1990. An earlier Institute of Medicine report estimated 230,000 to 284,000 iatrogenic deaths annually. The epidemiology of iatrogenic disease in the elderly has not been precisely reported; however, it is possible to make estimates from previous publications related to iatrogenic disease, a recent meta-analysis showed the incidence of iatrogenic disease to be between 3.4% and 33.9%.

Related to the social and cultural iatrogenesis, the 20th century social critic Ivan Illich named the concept of medical iatrogenesis in his 1974 book Medical Nemesis: The Expropriation of Health by defining it at three levels: first, clinical iatrogenesis is the injury done to patients by ineffective, unsafe, and erroneous treatments. He described the need for evidence-based medicine 20 years before the term was coined. Second, at another level social iatrogenesis is the medicalization of life in which medical professionals, pharmaceutical companies, and medical device companies have a vested interest in sponsoring sickness by creating unrealistic health demands that require more treatments or to treat non-diseases that are part of the normal human experience, such as age-related declines. He argued that medical education of physicians contributes to medicalization of society.
because they are trained for diagnosing and treating illness therefore they focus on disease rather than on health. Third, cultural iatrogenesis refers to the destruction of traditional ways of dealing with, and making sense of, death, suffering, and sickness.\textsuperscript{16}

It’s sure that Ivan Illitch, as one of the least polyvalent philosophers has been the great thinker, before everybody to see the problem with medicine. But one have to consider the influence of Paul Feyerabend (against method) and his anarchism in sciences, Donabedian and the way to quality as well as Conrad the sociologist who first has addressed the “medicalization” process and which definition is still at MeSH. And there are certainly more influences which have paved the way to our currents thoughts.

2. Overdiagnosis and overtreatment

Medicine’s much hailed ability to help the sick is fast being challenged by its propensity to harm the healthy. A burgeoning scientific literature is fuelling public concerns that too many people are being overdosed\textsuperscript{17}, overtreated\textsuperscript{18}, and overdiagnosed\textsuperscript{19}. This literature suggests several broad and related pathways to overdiagnosis: screening in people without symptoms, overdiagnosis resulting from use of increasingly sensitive tests in those with symptoms, etc.\textsuperscript{20,21}

Overdiagnosis occurs when people without symptoms are diagnosed with a disease that ultimately will not cause them to experience symptoms or early death. At the clinical level, a key aim is to better discriminate between benign “abnormalities” and those that will go on to cause harm. Sensitive diagnostic technologies identify tiny “abnormalities” that generally will remain benign, and although screening saves lives in some cases, in others it may turn people into patients unnecessarily and may lead to treatments that do no good and perhaps do harm.\textsuperscript{22}

Evidence is mounting that medicine is harming healthy people through ever earlier detection and ever wider definition of disease.\textsuperscript{20}
More broadly defined, overdiagnosis refers to the related problems of overmedicalisation\textsuperscript{20,23,24} and shifting thresholds, all processes helping to reclassify healthy people with mild problems or at low risk as sick.\textsuperscript{21,25}

With estimates that more than 200bn $ (160bn €) may be wasted on unnecessary treatment every year in the United States\textsuperscript{20,26}, the cumulative burden from overdiagnosis poses a significant threat to human health. The downsides of overdiagnosis include the negative effects of unnecessary labelling, the harms of unneeded tests and therapies\textsuperscript{27}, and the opportunity cost of wasted resources that could be better used to treat or prevent genuine illness. Because most people who are diagnosed are also treated, it is difficult to assess whether overdiagnosis has occurred in an individual. It is only certain when an individual remains untreated, never develops symptoms of the disease and dies of something else. The most of the inferences about overdiagnosis comes from the study of populations.

The forces driving overdiagnosis\textsuperscript{20} are embedded deep within the culture of medicine and wider society, underscoring the challenges facing any attempt to combat them. A key driver is technological change itself; as Black described in 1998\textsuperscript{28}, the ability to detect smaller abnormalities axiomatically tends to increase the prevalence of any given disease. Other drivers are the commercial and professional vested interest, conflicted panels producing expanded disease definitions and writing guidelines, legal incentives that punish underdiagnosis but not overdiagnosis and cultural beliefs that more is better; faith in early detection unmodified by its risk. New technologies mean that ever more sensitive tests can detect “abnormalities” and “incidentalomas,” while widening definitions of disease and falling treatment thresholds capture more and more previously unmedicalised people in their net.\textsuperscript{29} The pharmaceutical industries that benefit from expanded markets for tests and treatments reach wide influence within the medical profession and wider society, through financial ties with professional and patient groups and funding of direct-to-consumer
advertising, research foundations, disease awareness campaigns and medical education.\textsuperscript{25,30} Most importantly, the members of panels that write disease definitions or treatment thresholds often have financial ties to companies that stand to gain from expanded markets.\textsuperscript{31} Similarly, health professionals and their associations may have an interest in maximising the patient pool within their specialty, and self-referrals by clinicians to diagnostic or therapeutic technologies in which they have a commercial interest may also drive unnecessary diagnosis.

Avoidance of litigation and the psychology of regret is another obvious driver as professionals can be punished for missing the early signs of disease, without generally face sanctions for overdiagnosing. Quality measures focused on doing more may also encourage overdiagnosis in order to meet targets for remuneration incentives.\textsuperscript{21,32}

Although the approach has reduced suffering and extended life for many, for those overdiagnosed it has needlessly turned the experience of life into a tangled web of chronic conditions.\textsuperscript{33} The cultural norm that “more is better” is confirmed by recent evidence suggesting patient satisfaction flows from increased access to tests and treatments, even though more care may be associated with greater harm.\textsuperscript{30,34,35}

\begin{figure}[h]
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\includegraphics[width=\textwidth]{infographic.png}
\caption{Infographic of the things that drive ‘too much medicine’ and some of the counterbalancing things that propel us towards more appropriate care, or ‘the right amount of medicine’.\textsuperscript{36}}
\end{figure}
3. **Preventive Healthcare and the Quaternary Prevention**

Disease and disability are affected by environmental factors, genetic predisposition, disease agents, and lifestyle choices. Health, disease and disability are dynamic processes which begin before individuals realize they are affected. Preventive healthcare, preventive medicine or prophylaxis, consists of measures taken for disease prevention, as opposed to disease treatment. Disease prevention relies on anticipatory actions that can be categorized historically as Primary, Secondary, and Tertiary Prevention.\(^{27,33,37,38}\) But clinical prevention, under the influence of public health, has been organised in a chronological manner since the middle of the 20th century.\(^{10}\) A paradigm shift from a chronological to a constructivist relationship-based preventive pattern of care offers new insight into the practice of doctors, and brings to light the new concept of Quaternary Prevention.

<table>
<thead>
<tr>
<th>Level of prevention</th>
<th>Leavell &amp; Clark (1940s)</th>
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<td>Quaternary</td>
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*Table 1. Two prevention frameworks.*\(^{39}\)

During the WONCA International Classification Committee (WICC) annual meeting in Durham, North Carolina in 1999, the international committee endorsed a new concept: Quaternary Prevention, also known as P4. It is a new term for an old concept, *first, do not harm (primum non nocere).*\(^{12,33,40,41}\) The Quaternary Prevention is a set of health activities that try to mitigate or avoid the consequences of unnecessary or excessive intervention of the health system as the mongering disease (the creation of new diseases)\(^{10,11,15,41,42,43,44}\), it has to be understood as a taxonomic approach; it is a movement, a foundational idea, that seeks to re-found the ethical values of medicine so that it becomes an activity for humans exercised by humans and in contact with life.\(^{42,45}\)
The concept was made up by the Belgian general practitioner Marc Jamoulle\textsuperscript{33,42,44,46} and it is defined as the action taken to identify a patient or a population at risk of overmedicalisation, to protect them from invasive medical interventions and provide for them care procedures which are ethically acceptable by the WONCA dictionary of Family Medicine.\textsuperscript{9,10,38}

The main idea is to avoid patient overdiagnosis and overtreatment\textsuperscript{43,47}, but there is another main thought or idea that defines this concept, cited from Dr. Jamoulle: “Family Medicine is related to persons and this to the “to be” aspect of the work. Despite the fact that the initial thinking was about prevention, the core concept of Quaternary prevention deals with relationship and mutual influence of human beings. In this model the patient as the doctor are responsible of their way to deal with anxiety of death and suffering and the way they attempt to escape the human fate”. The hypothesis is focusing on the patient instead of the disease will reduce unnecessary medicine.\textsuperscript{27,48}

In terms of education and raising awareness among both the public and professionals, more honest information is needed about the risk of overdiagnosis, particularly related to screening.\textsuperscript{20,49} The Archives of Internal Medicine’s feature “Less is More” now regularly augments the evidence base\textsuperscript{50}, high level health policy groups in Europe are debating ways to tackle excess.\textsuperscript{51}

The challenge of this issue is to articulate the nature and extent the problem more widely, identify the patterns and drivers, and develop a suite of responses from the clinical to the cultural.\textsuperscript{31} Other policy reforms could review the permanency of some diagnostic labels, address calls for increased independence in the design and running of scientific studies\textsuperscript{52}, and adjust the structural and legal incentives driving overdiagnosis.\textsuperscript{20}

To do quaternary prevention is to say “no” to many considerably indecent proposals, and to offer prudent and scientific alternatives (“ethics of negation”, “ethics of ignorance sharing”).\textsuperscript{30}

To do quaternary prevention is the feeling of knowing that what matters is the quality of life. Concern about overdiagnosis does not preclude awareness that many people miss out on much
needed healthcare. On the contrary, resources wasted on unnecessary care can be much better spent treating and preventing genuine illness.

The challenge is to work out which is which, and to produce and disseminate evidence to help us all make more informed decisions about when a diagnosis or treatment might do us more good than harm. The intent of quaternary prevention is not to eliminate but rather to moderate the medicalization of the daily life, is acting in order to achieve the goal of Medicine that aims for “the maximum quality with the minimum quantity, as close to the patient as possible”.

“To prevent is better than healing, when preventing is less harmful than healing”, every doctor-patient meeting should include quaternary prevention in order to avoid/limit the damage caused by the activity of the health system.

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**Figure 2.** Four fields of the patient-doctor encounter based on relationships. The doctor looks for diseases. The patient could feel ill. Timeline is obliquely oriented from left to right, from alpha to omega, from birth to death. Anyone will become sick and die, doctors as well as patients.

**Figure 3.** The patient-doctor relationship is at the origin of the four types of activities. The arrow shows that the P4 attitude is impacting all the activity (Jamoulle & Roland 1995, WONCA dictionary 2003).
The consultation, meeting between two human beings, is also a meeting between knowledge and feelings or between science and conscience and could induce a considerable range of products and derived costs, from zero expenditure to the most implausible ones.

The understanding of the organization and economy of healthcare shows how the three dimensions of prevention, clearly included in the daily work, are complemented with the fourth dimension, quaternary prevention or prevention of medicine itself, whose understanding could help to control the economic and human costs of healthcare. Parodying the Chi² we can establish four fields which represent four different medical action areas.

The P4 is the least intuitive. The patient feels sick, the doctor is asked to find the problem. Doctors are supposed to detect false positive cases. But they are also prone to create false positives by lack of attention, lack of listening, lack of knowledge, inadvertence, anxiety, defensive behaviour or interest. Any uncontrolled or unconscious medical act could throw the patient into the fourth field.

The critique of the biomedical model (Mc.Whinney) or hegemonic (Menendez) requires the construction of alternatives. One of them is the biopsychosocial model whose practice demands periodic updates such as the People-centered Clinical Model. P4 manifest, in this way, along with the own proposals of those mentioned, postulates a model characterized by being: inclusive; reductionist, integral and integrated; tolerate uncertainty; involve the human, social and political dimensions; avoid and denounce the naturalization of hunger, exclusion, manipulation, inequality, violence, racism, exploitation, which harm health more than "diseases". The enthusiasm generated around this topic shows that this concept is used as a framework for a multifaceted repositioning of current questions and limitations of medical practice: Attention Deficit Hyperactivity Disorder market extension, transformation of risk factors, symptoms or problems of life into disease, osteoporosis marketing, breast cancer epidemiology and screening, incidentaloma issues, flu & HPV immunisations, drug
marketing in mental health, hypertension or dyslipidaemia, as well as empathy and communication or the value of the symptoms including when medically unexplained. This concept of prevention involves a sort of permanent quality control on behalf of the consciousness of the harm they could, even unintentionally, do to their patients. And it also involves the ideas that medicine is based on a relationship and this relation must remain truly therapeutic by respecting the autonomy of patients and doctors, and that bringing the best health outcomes to patients, and in so doing, lay the foundation for a wise and sustainable system for future generations.

Quaternary Prevention is particularly relevant in the elderly, whose comorbidity is associated with increased fragility. Clinicians have ethical obligations to protect patients at risk of harm from excessive interventions. This would place equal value on the art of “not doing”—making complex decisions not to give treatments, not to order tests, and to stop current treatments when in the best interests of the patient. If patients with chronic comorbidity are to get the best from medical care, there is an urgent need for these different ways of thinking—beyond diagnoses. In the words of William Osler: “It is more important to know what type of person has the disease than to know what type of disease the person has”.

4. Quaternary concept expanding worldwide

Expanded by WICC, the P4 concept has spread worldwide but especially in South America, Asia, but also in Europe and North America. This is no coincidence; it is on the fringes of the centrality of the hegemonic thinking of modernity (Europe and USA), where its failure is most noticeable and where the suffering consequences of poverty, exclusion, inequality are greater and all directly impact over the health, and where better spaces for creative solutions are generated.
Astonishingly, quaternary prevention has lain dormant for two decades; nevertheless, nowadays, with the expansion of Internet and social networks and facing the worldwide overdiagnosis movement, Primary Care is starting to be familiarized with the idea.

Endorsed by the Society of Brazilian Family and Community doctors (SBMFC), Quaternary Prevention has been proposed as a core concept of the Brazilian health system and has induced an international move in the whole of South America.\(^5\)

There are also Family Medicine networks around the world\(^6\) focused on the concept of overmedicalisation such as PRO-PRICARE, a practice network of six academic institutions from Bavarian.\(^4\)

4.1 Preventing Overdiagnosis Conferences and Symposia

An international scientific conference called Preventing Overdiagnosis born in 2013 aims to provide a forum for learning more, increasing awareness, and developing ways to prevent the problem of overdiagnosis (www.preventingoverdiagnosis.net).\(^2\)\(^0\)\(^2\)\(^1\) Although still young character of this international initiative (in 2017 will be the fifth conference in Québec), it is increasingly attractive: in Barcelona, Spain (2016) there has been a 30% increase in the number of submissions compared to the previous year (Bethesda, USA) and more than 500 registered, that is, with great Anglo-Saxon dominance.\(^6\)\(^2\) There were several interesting works about how you can reduce the number of unnecessary tests, referrals to other levels of care and drug treatments if primary care physicians had more time in their clinics. The works were done in other countries, not Spain, and they were based on medical visits that last fifteen minutes per patient.\(^6\)

A characteristic of the conference is the complete absence of the drug industry, medical devices or ICTs to its organization and sponsorship. This is unthinkable in any medical congress and this lack of industry support certainly has implications for the costs of registration. However, there are many institutions that support this initiative as medical
journals (BMJ²⁹, PLoS), universities, scientific societies and other organizations such as the Dartmouth Institute or the Iberoamerican Cochrane.⁶²

To avoid low-value practices, a number of initiatives, such as the Do not recommendations of the National Institute of Clinical Excellence of the United Kingdom or Choosing Wisely²⁰,⁶⁴ of the American Board of Internal Medicine, have been emerging.²¹ In this way, some governments support also this new point of view, the Scottish Government through the presence of her Chief Medical Officer, Catherine Calderwood, in the last conference that took place in Barcelona. She is the lead author of the governmental document Realistic medicine⁶⁵ which discuss medical challenges such as the current attention focused on the person and their active role in decisions that affect them, reducing variation in care processes and results, the necessary loss the damage (iatrogenic) and waste of resources; and on a more local scale, the Government of Catalonia carries out the project Essencial⁶⁶.

Also, there have been and there are important Family Doctor’s Conferences which are focused somehow on this issue¹⁰,³³,⁴³, on one hand the Costa Rica’s conference Cumbre de Medicina Familiar de San José de Costa Rica 2016⁶⁷,⁶⁸ and on the other hand 1st European Forum on Prevention and Primary Care organized by WONCA Europe.⁶⁹

Research on this issue is now recognised as part of the future scientific direction of the National Cancer Institute’s division of cancer prevention in the United States.²⁰,⁷⁰ And at the level of clinical practice new protocols are being developed to bring more caution in treating incidentalomas.⁷¹
STATE-OF-THE-ART

Results related to this issue have to be focused on papers and conferences. In this way, it is certainly relevant the presence that this concept of health is acquiring in WONCA and other family doctor’s conferences, and also through its “own” conference which is increasing their numbers of participants year by year.

This prevention focus is very broad and involves ethical issues, shared decision making, person focused care, conflict of interest, crisis in evidence based medicine, and research financing. One of the main tools we have to face this turbulence is educating new generations with a new paradigm based on critical thinking and the actual ones through motivational interviewing, which has been developed as an effective method to promote behavior changes in patients.

Healthcare systems need to start to value and provide adequate support for the kind of generalist care that focuses more on the person than on the disease entity. Quaternary Prevention is a new concept for a lot of Family Doctors, but its presence in their clinical practice has already started to gain, somehow, importance.

CONCLUSIONS

In the 21st century, developed countries have the healthiest and longest-lived populations in the history of humanity. However, the demand for health and the supply of health activities (attention intensity, medicalization of life and mongering disease) achieve the perverse effect of dissatisfaction with health and with the services received. It is the "paradox of health", the contrast between objective data, quality of life and mortality, and subjective data, the results of health satisfaction surveys, and health services.
This dissatisfaction should be solved through Quaternary Prevention, the prevention of unnecessary medical interventionism, which is based in one of the cornerstones of medicine: *primum non nocere*. The best way to accomplish this is to listen better to our patients, to focus more on them, in their ill mood, in their anxiety; avoiding overdiagnosis and overtreatment, and reducing iatrogenia. We need a strong and lasting relationship with the patient and trust in our honesty and medical knowledge.

The idea is not to crush against medical technology and progress but to show a reasonable approach to the use of medical procedures. We have to talk about it openly, we have to make it a research theme, we have to teach it.
“Primum non nocere” Preventing Overdiagnosis, the Quaternary Prevention

BIBLIOGRAPHY


25. Moynihan R, Cassels A. Selling sickness: how the world’s biggest pharmaceutical companies are turning us all into patients. Nation Books. 2005.


40. The quaternary prevention concept has been endorsed by WICC [Internet]. WONCA. [cited 13 February 2017]. Available from: http://www.ph3c.org/4daction/w3_CatVisu/en/the-quaternary-prevention-concept-has-been-endorsed-by-wicc-.html?wDocID=103


47. González de Dios J, Ochoa Sangrador C. Ectasia piélica perinatal, efecto cascada y prevención cuaternaria.


50. Grady D, Redberg R. Less is more; how less health care can result in better health. Arch Intern Med. 2010;170:749-50.


69. I European Forum on Prevention and Primary Care [Internet]. EUROPREV. WONCA. [cited 14 February 2017]. Available from: http://www.mgfamiliar.net/EUROPREV/index