DOI: 10.1590/1413-81232023287.13292022EN

Genealogical analysis of Quaternary Prevention: between the use of Evidence-Based Medicine and care reformulation in Primary Health Care

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Abstract *We conducted a genealogical analysis of quaternary prevention, an instrument of primary health care to address overmedicalization and iatrogenesis, based on related statements and interviews with the creators of this concept. This tool has been used in the reformulation of care and the doctor-patient relationship, but limited to the risk-benefit assessment by using current scientific evidence. In this study, we analyze the paradoxes of evidence-based medicine (EBM) and discuss the relationship of EBM and quaternary prevention and primary health care (PHC). Finally, we suggest questioning the truth of the evidence for the development of other health paradigms.*

Key words *Quaternary Prevention, Evidence-Based Medicine, Risk, Primary Health Care, Family and Community Medicine*

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Introduction

Quaternary prevention (P4) is a tool used in primary health care to address excessive medicalization and iatrogenic interventions[1-3]. The concept of P4 has been discussed in the international literature[4-6], with relevant participation of Brazilian researchers in the debate[7-11], both as an "action taken to identify patient at risk of overmedicalization, to protect him from new medical invasion, and to suggest to him interventions, which are ethically acceptable"[8], and as an "action taken to protect individuals from medical interventions that are likely to cause more harm than good"[4]. In Brazil, it has special emphasis of the scientific-institutional field of the Brazilian Society of Family and Community Medicine[12].

In this article, we present results of a genealogical analysis of P4 aiming to contribute to the debate around tool qualification and care qualification in PHC. We describe its formulation and different debates and contemporary perspectives in national and international literature, recognizing several meanings and uses of the concept. We discuss aspects and paradoxes of evidence-based medicine (EBM) and, finally, highlight issues for reformulation of care and the doctor-patient relationship in PHC.

Methods

We conducted a genealogical analysis of statements related to the debate around quaternary prevention. Besides selected technical documents, scientific articles, and academic books that define and contextualize the concept, we used two interviews about this tool – with Marc Jamoulle, a Belgian family physician and appointed as the creator of the concept, and Miguel Pizzanelli, a family physician in Uruguay and member of the Quaternary Prevention Committee of Wonca - World Organization of Family Physicians. This study was approved by the Research Ethics Committee of UNICAMP.

We see genealogy[13,14] as a specific procedure that analyzes certain statements seeking to denaturalize the regimes of power and truth in social practices and display their grids of intelligibility. Instead considering natural objects as data, it observes how certain statements and devices become rationalizable and operable through their own norms and how true discourses should not be considered universal and atemporal, but the result of specific historical contexts. It has no intention to understand the phenomenon as the mere development of its origins nor the necessary achievement of its purposes, but identify its heterogeneous trajectories of discourses, practices, events, and internal connections, without using regimes of truth as natural laws or global needs.

Such methodological analysis attempts to discuss concepts generally seen as data and question discontinuous branches that constitute familiar phenomena and are often used by us – when we talk, for example, about prevention, risk, and scientific evidence. It investigates how certain authorities were allowed to speak about these concepts; how they were classified, trained, legislated, theorized, and which principles, goals and objectives are considered in their government plans.

Here, we address the concepts not from canonical and normative perspectives, but taking as a starting point their own operability and their potential uses for the resolution of contingent situations. A genealogical analysis does not assess the validity or necessity of P4, neither tries to change its definition or terminology, but seeks other ways of thinking and acting in the field of health care based on gaps and possibilities in its own formulation and development.

Definitions of quaternary prevention

"Quaternary prevention" is a term originally proposed by Belgian physician Marc Jamoulle in 1986[15]; in 1991 it was integrated into the Wonca dictionary, described an "action taken to identify patient at risk of overmedicalization, to protect him from new medical invasion, and to suggest to him interventions, which are ethically acceptable" to objectively respond to excessive intervention and medicalization in clinical practice, both in diagnostic and therapeutic procedures[1,2].

According to Jamoulle, the idea for this term came up in a class on epidemiology, in which the occurrence of two situations was analyzed. In this adapted diagram, the physician's assessment regarding the presence or absence of a disease is correlated with the patient's own assessment, with four possible alternatives: 1) patient feels sick and the physician assesses that they are really sick; 2) patient feels well, but the physician assesses that they are sick; 3) patient feels well and the physician concludes that they are not sick; and 4) patient feels sick, but the physician assesses that there is no disease.

Quaternary prevention would be useful in the fourth hypothesis: "quaternary" prevention would be precisely not intervening in a situa-

tion that has no disease or that does not require a specific medical action, to avoid unnecessary and potentially iatrogenic risks. Texts about this concept often mention the Hippocratic principle of "first, do no harm" (primum non nocere), that is, avoid unnecessary potentially iatrogenic interventions in patients[1,3,12].

In general, the idea of prevention is linked with preventing future damage and enabling temporal modification of certain events. Based on the natural history of the disease, prevention means using epidemiological knowledge to control and to reduce the incidence of specific illnesses and complications[16]. The original debate on the levels of prevention was conducted in the 1950s by North American epidemiologists Hugh Leavell and Edwin Clark[17]. Primary prevention would use specific guidelines to prevent the development of diseases, secondary prevention would identify and intervene in the initial and asymptomatic stages of a disease, and tertiary prevention would promote rehabilitation actions for diseases that had been identified.

In the Brazilian Treaty for Family and Community Medicine, Jamoulle and Gusso[3] mention the work of Leavell and Clark and highlight a previous use of the "quaternary level of prevention" to designate "palliative care", which is different from P4. According to them, this definition would restrict preventive practice to the chronology of the health-disease process. The unprecedented formulation of P4 visually rearranges the classic levels of prevention by Leavell and Clarke – originally restricted to the disease progress over time – and proposes "a new relational perspective of prevention"[8].

P4 is also mentioned in the reflections by epidemiologist Geoffrey Rose[10,18] about prevention measures. He categorizes the strategies into reductive measures, intended for all population, such as reducing the use of tobacco, saturated fats, salt, pesticides; and additive measures, including the use of medication, vaccines, screening measures, and specialized intervention. Unlike reductive measures that globally affect social determinants of the health-disease process, the additive measures may involve iatrogenic actions, which is a central issue for P4, without significant benefits to the population.

A recent bibliometric study[19] assessing the term "quaternary prevention" and its international relevance to public health found only 124 records of quaternary prevention in the main health and medical databases. For the authors, it was a relatively small amount when compared to the term "medical overuse," which had 100 times more results than "quaternary prevention" in the PubMed database.

Jamoulle addresses this differentiation in an interview, highlighting that, while clinical epidemiologists "developed the concept of overmedicalization", family physicians "developed the concept of quaternary prevention based on [...] patient-centered medicine". He adds: "we talk about the human being and clinical epidemiologists talk about the process. It looks the same, but it is not".

When asked about this distinction, Miguel Pizzanelli also values a shift of P4 from an instrument that measures risks based on scientific evidence to a new rationale for the doctor-patient relationship. According to him, the group he coordinates at Wonca has sought to reformulate this concept based on three pillars: a paradigmatic pillar, which refers to the crisis of the hegemonic biomedical model and the need for new paradigms; an ethical pillar, which disappeared from the original definition in its contemporary application; and a cultural pillar, since the concept should not be exclusively medical or related to health professionals, but to the medicalization debate and forms of sociability as a whole. Finally, he highlights the desire to rename the name of the working group, in an attempt to move it closer to new paradigms for family medicine.

This distinction is repeated in different articles and texts about P4[3,8,20,21], emphasizing that its originality started to occupy a place at the intersection between public and individual health, shifting from the hegemonic disease-centered paradigm to an organization based on the doctor-patient relationship that would bring new perspectives to the physician's work. Also, the formulation and execution of the concept would involve an "extraordinary development of the 'art of healing', based on the doctor-patient relationship, practical wisdom, and existential contextualization, which is developed with improved practice of care"[9].

In another perspective, Martins *et al.*[4] suggest excluding the category of medicalization from the concept, seeking to define the practice of P4 as "actions taken to protect individuals (persons/patients) from medical interventions that are likely to cause more harm than good". The removal of "medicalization" and "overmedicalization" and the inclusion of "more harm than good", potentially calculable from evidence-based medicine, aim to bring quaternary prevention closer to clinical decisions that scientifically consider a

statistical view around screening exams, routine procedures, check-ups, and introduction of medications that are considered ineffective.

In support of this conception, an article by the Brazilian Society of Family and Community Medicine published as a manifesto[12] is favorable to P4 and medicine "without conflict of interests", offering "the best for the patient" based on a constant search for "the best and most adequate scientific evidence, free of conflicts of interest, to promote health with minimal intervention". According to the manifesto, physicians must "empower the population with the most reliable information for joint decision making regarding diagnosis or therapy, without manipulation or coercion". The document reinforces this approach to P4 with EBM, operating around the risk-benefit calculation of clinical interventions in PHC.

Tesser and Norman[7] have debated this connection between PHC and the language of EBM. They claim that P4 is a well-structured concept that incorporates three main points: risk of overmedicalization, patient protection, and ethical alternatives, whose definition is broader than the recent initiative to redefine it with the inclusion of the "more harm than good" statement[7]. Therefore, they support the idea of maintaining the concept of medicalization in the definition of P4 and argue that the proposed change "blurs Jamoulle's original emphasis on the doctor-patient relationship, highlighting the harm-good relationship through evidence-based medicine (EBM)"[8]. In addition, they indicate[11] that medical practice in PHC "requires simultaneity between the critical spirit towards EBM, as well as (its) mastery and increasing use" and that the "initiative to limit the definition of P4 to the language of EBM should be rejected"[11].

In this sense, Santos[22] criticizes the expansion of profit through excessive medicalization in health and highlights it in the practice of P4, more than a "strategy", a "mandatory clinical attitude" for the construction of the identity of family physicians and for the production of a holistic care that is able to fulfill all dimensions of one person.

We understand that a genealogical analysis of P4 requires placing it in a dispute between the updated application of evidence-based medicine and new proposals and debate about care reformulation in primary health care.

Paradoxes of Evidence-Based Medicine

Generically described as the "process of systematically discovering, evaluating, and using research findings as a basis for clinical decisions"[23], EBM emerged in the 1990s from clinical epidemiology studies that sought to ensure the best possible treatment according to the scientific evidence available.

The first documented report of a randomized clinical trial was published in 1948 by the BMJ[24]. In 1972, Archibald Cochrane published the book titled Effectiveness and Efficiency: Random Reflections on Health Services, which systematizes the experimental approaches to find out which clinical methods were more effective and efficient and which ones were inefficient. The result of the hierarchical sum of meta-analyses and systematic reviews of these pieces of "evidence" from local and specific clinical studies would create a kind of current library of the best evidence available.

EBM has been promoted by a small group of researchers from specialized medicine and related areas, who have access to technical and methodological resources to perform research that will define protocols on a large scale[25-27]. With the promise of rationally effective, cost-effective, and safe interventions, it changes the conduct and autonomy of the medical profession, changing the relationship between clinicians and their own tools and technical knowledge[28].

In the hegemonic approach to EBM, scientific evidence is essentially supported by the calculation of risks, that is, a scientifically calculable probability of the effectiveness of a clinical intervention or event. This calculation is the basis for "risk factor" in health, a measurable and comparable attribute between different groups and populations[29,30].

There is special importance in the fact that a truth, such as risk, can be translated into a number and a probability. Reducing complex phenomena to numbers produces an image of "merely technical" objectivity, regardless of the judgments of those who calculated it. Numbers convey results and information in a way that is known and automatically translatable anywhere in the world. They standardize subjects and objects of statements and ensure interchangeability around different situations, without revealing different influences and contexts affecting them, presenting critical certainty, apparently detached from moralities or hidden interests[31].

This quantitative language that naturalizes risk, as discussed in another article[29], received

relevant criticism. Risk, just like any other social phenomenon, should not be considered as something static and objective, but involving a set of values and rationalities in dispute, as part of a network of social interactions and production of meanings and truths.

Regarding risk factors in the context of P4, according to Gérvas and Fernandes[32], when physicians define risk factors and convert them into diseases that require diagnosis and treatment, many unnecessary medical interventions are justified: "The medical power to define the line between health and disease makes the definition of the risk factor a boundary that almost always tends towards the disease"[32].

Castiel supports this understanding when he indicates[33] that risk has a temporal paradox: it always measures a difference between two chronologically distinct ideas and judgments. In the course of time, a plausible judgment is found. But he highlights the calculation of risk makes it an "autonomous and objectifiable" entity, independent of contexts, creating a kind of "ontological status" of risk and scientific evidence.

This evidence ends up linked with some aspiration for certainty and a reliable medical promise, even if it often frustrates both professionals and patients. The clinical definition based on sophisticated technologies and randomized double-blind studies, without conflicts of interest, ends up assuming a biological "truth" of illness, with a specific way of viewing it. But what drives EBM tests are questions that are difficult to answer based on individualized and singular knowledge. In other words, a clinical trial is only justifiable when there is a real doubt about whether a treatment is actually effective (or more effective), so that no one can be sure of which alternative will produce better results.

Therefore, conducting a clinical trial does not separate effective from ineffective treatments in advance, but seeks estimates of treatment effectiveness, since all treatments are at some level abstractly effective and the calculation of effectiveness does not imply an obvious and straight clinic decision making[25].

This debate is particularly seen in breast cancer screening in women in Brazil, promoted by the Pink October campaign, disseminated every year in the PHC in Brazil. The Cochrane organization, with pioneer work for the dissemination of scientific evidence, recognizes that:

If we assume that screening reduces breast cancer mortality by 15% after 13 years of follow-up and that overdiagnosis and overtreatment is at 30%, it means that for every 2000 women invited for screening throughout 10 years, one will avoid dying of breast cancer and 10 healthy women, who would not have been diagnosed if there had not been screening, will be treated unnecessarily. Furthermore, more than 200 women will experience important psychological distress including anxiety and uncertainty for years because of false positive findings. To help ensure that the requirements for informed choice for women contemplating whether or not to attend a screening programme can be met, we have written an evidence-based leaflet for lay people that is available in several languages[34].

Ultimately, the evidence shows that screening has more potential to generate iatrogenesis in healthy women than prevent deaths. This paradox produces the demand for the "leaflet" and the shared decision between the physician and the patient based on the best "evidence", that is, based on the dissemination of specialized knowledge to women.

Therefore, EBM ends up producing a new area of indetermination. In the space between the evidence-based clinical trial and the practice, which is crucial for the development of P4, there is an open dispute regarding the power of the physician and the patient. According to these criteria, the harm and the good of an intervention are permanently balanced and the clinical uncertainty is renewed and expanded.

Furthermore, the gold standard of evidence – such as randomized clinical trials – is linked with a specific theory of statistical inference and does not assess or describe explanatory and causal mechanisms for situations in health care. As discussed by critics of EBM[26,35], its theoretical structure can be "quite dull", without any kind of theoretical grouping or paradigmatic debate. None of the evidence-based tests simply measures "an objective reality of risk for health or disease", but intervenes to represent the disease in certain ways; for example, delimiting the line between what is considered normal and what is considered pathological[36]. In this sense, scientific evidence is not a pre-existing and stable body of knowledge that can simply be translated into practice; on the contrary, it is a product of specific scientific processes historically and culturally situated, with almost constant loyalty to a specific procedure and community for truth production.

When discussing such conceptual limits of EBM, Ashcroft[35] suggests that, as a patient, he would like to be treated according to the best clinical evidence. But, as a philosopher, he has

some "certain skepticism" around EBM statements and highlights the lack of methodological modesty and philosophical debates, which are inherent to any type of production and validation of scientific statements.

However, the growing claim of "evidence-based" physicians ends up producing a professional judgment guided by professional associations and institutions with economic and scientific resources to produce and to validate them in the scientific literature. Then, the following questions come up: Who will be responsible for the production and interpretation of these data? How to define acceptable values to consolidate a decision at population and individual levels?

Lambert[26] emphasize the existence of "Trojan horses" embedded in the generalized insertion of EBM in health practices: potential loss of professional autonomy, ethical and clinical questions regarding whether patients are receiving the best care for their specific needs, limitation and standardization of health interventions disregarding local realities, and economic and political prioritization of health problems with the "best evidence" to the detriment of historically neglected diseases.

These considerations reinforce the idea that practice depends not only on evidence-based scientific propositions – whose production is the main purpose of EBM – but also includes operational knowledge linked with judgment and recognition skills for specific unique situations. Despite that, EBM is usually considered a synthesis of the current health knowledge, and not as a contingent manner to systematize and index statements that are potentially verifiable through certain statistical methods.

In a similar perspective, Greenhalgh *et al.*[37] analyzed the crisis of this hegemonic EBM from five aspects: a) the evidence-based "quality mark" has been misappropriated by vested interests; b) the volume of evidence, especially clinical guidelines, has become unmanageable; c) statistically significant benefits may be marginal in clinical practice; d) inflexible rules and technology-driven prompts may produce care that is management driven rather than patient centered; and e) evidence-based guidelines often map poorly to complex multimorbidity.

They propose "real evidence-based" medicine that makes the ethical care of the patient its top priority; demands individualized evidence in a format that clinicians and patients can understand; is characterized by expert judgment rather than mechanical rule following; shares decisions with patients through meaningful conversations; builds on a strong doctor-patient relationship and the human aspects of care; applies these principles at community level for evidence-based Public Health.

Diana Rose *et al.*[28] also discuss the fragilities of EBM and propose a "multiple perspective" paradigm to integrate various sources of evidence in mental health care. They suggest consistent inclusion of perspectives on evidence from service users and exclusion of the monolithic and hierarchical discourse of EBM around "universally true" knowledge, which does not recognize the historicity and asymmetries of power in the production of such knowledge.

This criticism reminds us of the feminist perspectives that have discussed how scientific "objectivity" has been marked by a hegemonic capitalist and patriarchal rationality, depreciating local knowledge that questions the status quo. Feminist epistemology has suggested that so-called universal and objective truths have some kind of "God trick", generated by disembodied scientists with visions from all places but, at the same time, visions not starting from any specific place[38].

These critical postures involve doubts around stable categories such as gender, body, subject, sex, etc. We can include, in the case of P4, "prevention", "evidence", "risk", and "medicalization". According to Adams *et al.*[39], such categories are not self-evident entities that exist in the world like "trees or rocks", but are mutable and synergistic concepts that play a complex role in helping us understand the human experience.

Challenges in care reformulation in PHC

In our genealogical analysis of P4, we identified that it has been proposed as an important reformulation of care and the doctor-patient relationship, but limited to the risk-benefit assessment by using current scientific evidence. Its formulation has properly highlighted the importance of going beyond prevention and the statistical calculation of evidence-based risk and make health professionals reflect on what type of "lens" they are using to problematize iatrogenesis and medicalization[40].

In this sense, we believe it is essential to correlate P4 with critical debates around medicalization, risk, and the use of scientific evidence, since its uncritical incorporation may reduce or even become opposed to its original objectives.

We argued above[29,41] that such concepts should be seen without content and value defined in advance, but as an open field of dispute in the social body, involving a detailed and heterogeneous investigation of how more and more "experts" have created and performed diagnostic and therapeutic procedures to visualize and intervene on the disease.

Cholesterol, blood pressure, diabetes, exercise, work, leisure, stress, anxiety levels – human behavior has been measured and diagnosed based on indexes, behavior patterns, and risk factors. This finding demands a deep analysis of the concept of normality, beyond a statistical average that is considered ideal and desirable for the prevention of diseases.

This paradigm shift will also involve considering illness as a singular event, which always happens in the totality of life, and not as a specific disorder that can be restored to the pre-illness condition, independent of the system of intelligibility that recognizes it. More than risk prevention, PHC has to incorporate the idea of health as mastery and openness to danger and risks, as a bold confrontation with the inexorable danger of living[42].

In agreement with Hacking[43] in the context of mental health, the categorization of diseases and risk factors (hypertension, diabetes, hypercholesterolemia, fibromyalgia, gastritis, depression, anxiety, etc.) also has a retroactive effect on the illness experience itself, creating patterns and kinds of suffering prenamed by biomedical science. To critically address the hegemonic medical paradigm, first it will be necessary to discuss about illness by actively including the environment, social relations, and culture, not just as psychosocial appendices of a crystallized biological reality.

Finally, PHC must radically search for collective forms of life, care, and resistance in the face of adversity, seeking to explore and give importance to the experiences of the subjects involved while exploring and investigating the relationships and contexts of production of health and illness, without reducing "people/patients" to constructions that are totally determined and incapable of resistance. In addition, it will be crucial to develop multiple perspective paradigms in the production of truth, which can recognize our health categories as devices in constant renewal, which are able to invent lives that are worth living.

Collaborations

HS Andrade and SR Carvalho participated equally in the conception, writing and revision of the article.

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Article submitted 09/12/2021
Approved 12/12/2022
Final version submitted 14/12/2022

Chief editors: Romeu Gomes, Antônio Augusto Moura da Silva