Psychiatry and Evidence-based Medicine

A Psiquiatria e a Medicina Baseada em Evidências
Psiquiatría y Medicina Basada en la Evidencia

RESUMO
A Medicina Baseada em Evidências (EBM) surgiu nos anos 1990 para tornar a prática médica mais científica, substituindo decisões baseadas em autoridade por escolhas fundamentadas em dados empíricos e estudos rigorosos. Definida como o uso criterioso da melhor evidência disponível, a EBM propõe integrar pesquisa científica, experiência clínica e valores do paciente, promovendo decisões compartilhadas e redução de erros. Apesar de seu impacto positivo, enfrenta críticas quanto à influência de interesses econômicos e ideológicos, especialmente na psiquiatria, onde pode contribuir para a patologização da vida. Assim, o artigo conclui que é necessário retomar o espírito crítico original da EBM, exigindo maior rigor e reflexão diante das evidências, especialmente na área da saúde mental.
PALAVRAS-CHAVE: Medicina baseada em evidências, patologização da vida, psiquiatria, saúde humana.

ABSTRACT
Evidence-Based Medicine (EBM) emerged in the 1990s to make medical practice more scientific, replacing decisions based on authority with choices based on empirical data and rigorous studies. Defined as the judicious use of the best available evidence, EBM proposes to integrate scientific research, clinical experience and patient values, promoting shared decisions and reducing errors. Despite its positive impact, it faces criticism regarding the influence of economic and ideological interests, especially in psychiatry, where it can contribute to the pathologization of life. The article concludes that a return to EBM's original critical spirit is needed, with more rigor and reflection when evaluating evidence, particularly in mental health.
KEYWORDS: Evidence-based medicine, pathologization of life, psychiatry, human health.

RESUMEN
La Medicina Basada en la Evidencia (MBE) surgió en la década de 1990 con el objetivo de hacer más científica la práctica médica, sustituyendo las decisiones basadas en la autoridad por elecciones fundamentadas en datos empíricos y estudios rigurosos. Definida como el uso juicioso de la mejor evidencia disponible, la MBE propone integrar la investigación científica, la experiencia clínica y los valores del paciente, promoviendo la toma de decisiones compartida y reduciendo errores. A pesar de su impacto positivo, enfrenta críticas respecto a la influencia de intereses económicos e ideológicos, especialmente en psiquiatría, donde puede contribuir a la patologización de la vida. Por lo tanto, este artículo concluye que es necesario retomar el espíritu crítico original de la MBE, exigiendo mayor rigor y reflexión ante la evidencia, sobre todo en el ámbito de la salud mental.
PALABRAS CLAVE: Medicina basada en la evidencia, patologización de la vida, psiquiatría, salud humana.

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INTRODUCTION

Evidence-*based medicine* (EBM) began as a movement in the early 1990s, with the aim of optimizing clinical care by educating physicians in the understanding and use of published literature, including systematic reviews and meta-analyses. According to David Sackett et al.[1], EBM is the "conscious, explicit, and judicious use of the best current evidence in making decisions about the care of individual patients."

EBM emerged as a critical response to traditional medical dogmatism—which often relied on the opinions of authorities, tradition, or unproven pathophysiological mechanisms—and proposed an epistemological revolution: replacing the hegemony of "it is so because it has always been so" with a practice anchored in reproducible empirical data; establishing hierarchies of evidence to qualify decisions[2].

EBM sought to transform medical practice into a rigorous discipline, supported by reliable data and well-conducted studies. In this sense, it contributed to the development of science by producing reliable clinical practice guidelines, initiated by researchers in the 1980s. More recently, however, EBM has progressed to recognize the limitations of evidence alone and has increasingly emphasized the need to combine critical evaluation of evidence with patient values and preferences through shared decision-making[3].

According to Freddi and Romàn-Pumar[4], EBM is not a "cookbook" medicine perpetrated by arrogant individuals to serve the financial interests of economic groups and suppress clinical freedom, that is, an imperative, deterministic, and totalitarian practice of medicine that ignores patient preferences and limits humanistic/individual medicine. EBM is a benchmark of excellence for guiding clinical decisions, integrating one's own expertise with that of others and patient preferences in order to improve clinical practice and limit variability and errors.

As its name implies, EBM consists of identifying, evaluating, and applying the best scientific evidence to inform clinical decision-making**.** EBM employs a hierarchical system of evidence classification known as "levels of evidence." The lowest level of evidence is personal communication, while the highest level of evidence includes meta-analysis of double-blind randomized studies. Physicians are encouraged to find the highest level of evidence to answer clinical questions[3,4,5].

The clinical-methodological paradigm of EBM guides medical decision-making based on a threefold integration: the best available scientific evidence (prioritizing studies with methodological validity and meta-analyses); the clinical expertise of the professional; and the individual values and preferences of the patient[1].

The decision-making process in EBM generally follows a structured approach, which includes:

1. Formulating a relevant clinical question: For example, "What is the best treatment for hypertension in elderly patients?"
2. Searching for the best evidence: Looking for relevant scientific studies to answer the question.
3. Evaluate the evidence: Examine the quality and applicability of the studies found.
4. Integrating the evidence with clinical experience and patient preferences: Making decisions that consider the context and specific characteristics of the patient.
5. Evaluate results and adjust decisions: Monitor the effects of treatment and revise the approach as necessary.

EBM helps reduce variability in medical practice and promotes more effective, safe, and personalized care. It also encourages physicians to question old practices that may no longer be supported by scientific evidence and to adopt new, more effective approaches.

EBM, even when applied to general medical practice, faces substantial criticism. Its advocates present it as a tool to "bridge the gap between clinical research and medical practice," but its critics argue that this gap is, in fact, an insurmountable philosophical divide—since EBM often neglects the complexity of the individual in favor of statistical generalizations.

Furthermore, although population studies are relevant when it comes to public health, their application to each individual subject is problematic, to say the least, as it minimizes the importance of the intangible physical, emotional, and spiritual aspects of the disease. Moreover, not all such evidence is equally good, because there are differences in randomized studies in terms of design, sample size, and

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even statistical significance. Not to mention that the evidence is often contradictory[4]. Finally, Holmes et al.[6]suggest that "the evidence-based movement is outrageously exclusionary and dangerously normative [...] and constitutes a good example of microfascism at play in the contemporary arena." In other words, "the evidence-based movement is outrageously exclusionary and dangerously normative [...] and constitutes a good example of microfascism at play in the contemporary arena."

In summary, EBM presents several fundamental problems. First, biomedical reductionism: population studies, although useful for public health policies, fail to capture subjective dimensions (physical, emotional, and spiritual) of disease, which are essential in individualized care. Second, the hierarchy of evidence is questionable because not all "evidence" is equally valid: there are considerable methodological variations (sample size, study design) that compromise direct comparisons. The statistical significance obtained in studies does not mean clinical relevance (in this regard, psychiatry provides a good example by observing minimal differences in depression scales without a real impact on patient well-being). There are also contradictions and publication bias, as evidence is often inconsistent or conflicting, and positive studies are published more often than negative ones[7]. Finally, EBM can impose a single standard of "scientific truth" that delegitimizes other forms of knowledge (e.g., patient narratives), constituting microfascism[6].

Evidence-based psychiatry

When applied to psychiatry, however, EBM seems to encounter another, even more serious problem: the absence of scientific evidence. According to psychiatrist Emmanuel Stip, "*if we want to ground psychiatry in evidence-based medicine, we run the* real risk of *taking a* closer *look at what has* long been considered a reality." He concludes:

> *Psychiatrists must above all continue to doubt and remain critical. We must also militate in favor of the publication of negative results, because their inaccessibility modifies our body of knowledge as a whole, typically introducing a bias in favor of the new drugs. [...] Celebrating the 50th anniversary of neuroleptics and thinking about their efficiency, one cannot resist quoting Umberto Eco (apparently quoting Boscoe Pertwee, an 18th-century author) in Kant and the Platypus: "I used to be indecisive, but now I am not so sure.* Freely translated, "Psychiatrists must, above all, continue to doubt and remain critical. We must also advocate for the publication of negative results, because their inaccessibility modifies our body of knowledge as a whole, typically introducing a bias in favor of the new drugs. [...] Celebrating the 50th anniversary of neuroleptics and thinking about their efficiency, one cannot fail to quote Umberto Eco (apparently quoting Boscoe Pertwee, an author) in Kant and the Platypus: "I used to be indecisive, but now I am not so sure.

Unlike the advances seen in areas such as antibiotic therapy, cardiovascular and renal pharmacology—where research funded by public-private partnerships often results in new therapeutic agents with a measurable impact on reducing morbidity and mortality—psychopharmacology presents a different scenario. In these established medical specialties, pharmacological development is guided by precise biochemical markers and an established understanding of pathophysiology, which allows for continuous improvement of treatments (e.g., new oral anticoagulants have a lower risk of bleeding); more accurate diagnoses (e.g., there are biomarkers for chronic kidney disease); and the objective reduction of adverse outcomes (e.g., reduction in mortality from acute myocardial infarction with kininase 2 enzyme inhibitors).

In psychopharmacology, however, the absence of validated biological markers and the etiopathogenic complexity of mental disorders challenge this paradigm. While in cardiology a new drug can demonstrate superiority in trials with clear outcomes[9] (e.g., 20% reduction in deaths from HF), antidepressants often show clinically irrelevant differences compared to placebo[10] .

Psychopharmacology is hampered precisely by the absence of such biological or neurochemical markers and the lack of understanding, to date, of the proclaimed pathophysiology of mental illnesses[11]. Several theories have been proposed to try to explain the pathophysiology of schizophrenia and depression, to cite two examples. The dopaminergic hypothesis of schizophrenia, later replaced by the glutamatergic hypothesis, is a good example. In the first case, schizophrenia would be related to increased dopaminergic activity in the mesolimbic pathway, and in the second case, it would be related to the hypoexpression of glutamatergic NMDA receptors in GABAergic neurons that regulate the mesocorticolimbic dopaminergic system. These hypotheses would explain the use of dopamine D_2 receptor antagonists as antipsychotics[12].

The monoaminergic hypothesis of depression—which postulates a causal relationship between reduced serotonergic activity (and other monoamines) and the onset of depressive symptoms—served as the main justification for the development and massive prescription of selective sero-

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tonin reuptake inhibitors (SSRIs)[12]. However, this hypothesis, widely disseminated from studies in animal models[13], has proven insufficient to explain the etiological complexity and clinical heterogeneity of mental disorders[11,14].

As Steve Hyman, former director of *the National Institute of Mental Health (NIMH)*, pointed out, all psychotropic drugs—including antidepressants and antipsychotics—essentially act by disrupting neurotransmitter functions[14]. This statement raises a fundamental paradox: if there is no consensus on the neurobiological basis of mental illness, nor validated biochemical markers, how can psychiatry claim to be a truly evidence-based practice?

Furthermore, recent meta-analyses have questioned the clinical efficacy of SSRIs, revealing that their benefits are often modest and inconsistent when compared to placebo. Meta-analyses reveal that the average difference between SSRIs and placebo on the HAM-D (Hamilton Depression Rating Scale) is only 1.8 to 2.2 points—below the clinical threshold of relevance (3 points)[10,16] . Other critical findings from meta-analyses: about 80% of the antidepressant effect is replicable by placebo; in cases of mild to moderate depression, the SSRI-placebo difference is statistically insignificant; the selective publication of positive studies artificially inflates the perception of efficacy.

Given this scenario, it is worth asking: to what extent does the monoaminergic theory reflect scientific progress or a convenient simplification to justify pharmacological interventions?

Given this scenario, it is urgent to ask whether psychiatry has used the discourse of EBM as a smokescreen to practice “cookbook” medicine (in this case, the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders), perpetrated by arrogant individuals to serve the interests of financial groups, suppress clinical freedom, ignore patient preferences, and limit humanistic/individualized medicine. Or, in other words, has psychiatry used the discourse of EBM to rely on the opinions of authorities, tradition, or unproven pathophysiological mechanisms that have been propagated in pharmacology and psychiatry textbooks? This scenario represents exactly what Evidence-Based Medicine (EBM) has sought to overcome since its inception.

Psychiatry permeated by neoliberalism-

As Kenneth Rochel de Camargo Júnior[18]demonstrates, the phenomenon of medicalization transcends the psychopharmacological sphere, revealing intricate relationships between science and capital. The pharmaceutical industry directs massive investments not only to the development of new drugs but, above all, to the construction of scientific evidence that legitimizes their use. This strategy is summarized in Sackett's observation: *"New types of evidence are being generated which, when known and understood, create frequent and important changes in the way we care for our patients."*

The result in numbers is quite emblematic. In the US, pharmaceutical companies spend US$ 20 billion/year on direct marketing to physicians alone (including free samples and "educational" events)[19]. For every dollar invested in clinical trials, two are spent on promotion, i.e., advertising and marketing[20]. This phenomenon results in a virtuous circle for the industry: the accelerated production of drugs is accompanied by an equally intense flow of research that justifies their clinical adoption. The pharmaceutical industry has invested heavily in the development of "*me too drugs*" — drugs with minor molecular variations from existing drugs, but without significant therapeutic advances. A study by *the National Institute for Health Care Management* (2002) revealed that, among 1,035 new drugs approved in 12 years, only 15% represented true innovations[21].

At the same time, clinical trials published in high-impact journals — often authored by renowned researchers and rigorously peer-reviewed — have frequently served as marketing tools. Their goal? To validate the use of new drugs, even when their superior efficacy has not been proven[18]. Added to this is the strategy of "*disease mongering*," a practice whereby the industry amplifies or even "creates" new diseases to expand markets[21].

This dynamic, however, raises critical questions about the extent to which this "evidence" reflects real therapeutic needs or strategic commercial interests. In short, *Big Pharma's* commercial interests directly influence the production of medical knowledge, shaping everything from diagnostic criteria to therapeutic approaches. Therefore, it is possible to say that part of what is considered evidence-based medicine is, in fact, based on distorted or questionable evidence[22]. The results have been extremely lucrative for *Big Pharma*: sales of Clonazepam (Rivotril), Bromazepam (Lexotan), and Alprazolam alone reached 19.3 million boxes in a single year. The antidepressant Fluoxetine recorded sales of 3.5 tons in 2011[11]. And these numbers continue to rise[23]. Given this scenario, it is inevitable to return to the central questions of this study: are these drugs, which generate exorbitant profits for the pharmaceutical industry, really effective? Can we really talk about evidence-based psychiatry?

CONCLUSIONS

Evidence-based medicine seeks to revive the use of the scientific method, based on radical criticism of

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pre-existing knowledge and a subsequent tireless search for empirical evidence in clinical practice. Protocols and guidelines need to be validated and supported by the entire scientific community, based on randomized studies and meta-analyses. Neurobiological psychiatry has sought to achieve scientific status by adopting the precepts of evidence-based medicine. However, considering that scientific knowledge is influenced by economic, social, cultural, and ideological factors, and that the production of knowledge can be influenced by powerful economic *lobbies*, there are glaring flaws in what has been considered "evidence-based." In psychiatry, these flaws have contributed to the mechanisms of pathologizing life through the construction of diagnoses that are followed by inappropriate prescriptions.

The solution may be to demand more evidence from EBM. In this sense, the academic community in general, and mental health professionals in particular, need to be parsimonious in relation to the scientific findings that support certain protocols and guidelines. In other words, health professionals need to be properly trained to be radically critical, as EBM has advocated since its inception.

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