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Evidence-Based Medicine and Its Limitations: Toward an Expanded Clinical Epistemology

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ABSTRACT: Objective: *To discuss the philosophical foundations and epistemological limits of Evidence-Based Medicine (EBM), proposing pathways toward an expanded clinical epistemology.* ***Methods:*** *An interdisciplinary narrative review was conducted, covering literature published between 2004 and 2024 in PubMed, SciELO, and Web of Science. The review included theoretical and reflective texts addressing the philosophical assumptions of EBM, its criticisms, and proposals for epistemological improvement, with emphasis on philosophy of science, bioethics, narrative medicine, and social studies of science.* ***Results:*** *Three main axes of epistemological tension were identified: (1) the primacy of positivist empiricism, which tends to marginalize tacit knowledge and individual clinical judgment; (2) the insufficient integration of qualitative evidence and patient values into clinical decision-making; and (3) the limitations of algorithmic standardization in addressing the complexity of real-world clinical practice. Several authors propose a more pluralistic and interpretive clinical epistemology that values the art of care, clinician experience, and patient uniqueness.* ***Conclusion:*** *Medical rationality can be enriched by interpretive and humanistic approaches, integrating scientific evidence, context, clinical expertise, and patient values in a balanced way, thus fostering a more effective, ethical, and humanized model of care.*

KEYWORDS: *Clinical Decision-Making, Epistemology, Evidence-Based Medicine, Narrative Medicine, Philosophy of Science.*

I. INTRODUCTION

Evidence-Based Medicine (EBM) has established itself over the past few decades as the dominant paradigm in clinical practice, emphasizing the systematic use of the best available scientific evidence in decision-making regarding patient care. Its proponents argue that EBM enhances the quality of care by reducing reliance on personal opinions and unproven traditions, promoting clinically grounded decisions【9】. However, since its inception, EBM has also been the subject of critical analyses that question its philosophical foundations and epistemological limitations【10】【11】. Critics point out that the near-exclusive emphasis on evidence

from randomized clinical trials and meta-analyses reflects an empiricist-positivist view of medical knowledge, which may be inadequate to capture the complexity of real-world clinical practice【12】【13】.

Authors such as 【5】【6】and【7】suggest that medicine must be reclaimed as an interpretive art, in which technical-scientific knowledge is complemented by the hermeneutic understanding of health and illness experiences【5】【6】【7】. This perspective brings medicine closer to the humanities, recognizing that the doctor-patient relationship, the clinical narrative, and the context have a decisive influence on the application of scientific knowledge in individual cases. In this sense, medical practice would involve not only the application of evidence-based protocols but also a dimension of clinical judgment that escapes strictly defined algorithms【6】【12】.

In parallel, Greenhalgh【8】*et al.* (2014) argue that EBM, in its original form, is facing a "crisis" due to its reductionist appropriation, which neglects contextual factors and patient values【8】. The EBM community itself has acknowledged the need for reformulation: for example, there is a movement to incorporate qualitative evidence and patient preferences into clinical recommendations, as seen in methodological updates (e.g., the GRADE initiative) aimed at making guidelines more patient-centered. Still, the debate persists as to the extent to which the current model can reconcile scientific evidence with individualized care.

In light of this scenario, a central question arises: what are the epistemological limits of EBM, and how might they be overcome toward a more comprehensive clinical epistemology? Addressing this issue requires an interdisciplinary dialogue involving philosophy of science, ethics, sociology, and other fields. In this article, we explore the philosophical foundations of EBM, mapping its core critiques and examining proposals to expand its epistemological framework. Our goal is to reconfigure the understanding of clinical rationality to integrate different forms of knowledge – quantitative and qualitative, general and particular, scientific and experiential – into health decision-making.

II. METHODOLOGY

This is a narrative review with an interdisciplinary approach. We chose this methodology due to the theoretical nature of the problem under investigation, which involves philosophical concepts and reflective analyses that are not amenable to quantitative synthesis. The construction of the theoretical corpus involved searches in the PubMed, SciELO, and Web of Science databases, covering the period from 2004 to 2024. We used descriptors such as "evidence-based medicine," "philosophy of science," "epistemology," "narrative medicine," and "clinical judgment," combined using Boolean operators in both English and Portuguese.

We included relevant articles, theoretical essays, book chapters, and full books that addressed: (1) the philosophical and historical assumptions of EBM; (2) epistemological critiques of EBM; and (3) proposals for expanding or revising clinical epistemology. We excluded purely empirical studies (e.g., meta-analyses of clinical trials) that did not contain epistemological reflection, as well as duplicate publications found in multiple databases.

We initially conducted an exploratory reading of titles and abstracts for material screening. Next, we performed a full reading of the selected texts, extracting key ideas and cross-referenced citations. Data processing was qualitative and interpretative, following these steps: (a) identification of recurring themes in critiques and proposals related to EBM; (b) thematic grouping of ideas (e.g., evidence hierarchy, role of subjectivity, integration of knowledge forms); and (c) narrative synthesis of each thematic category, linking authors and converging or complementary perspectives.

To facilitate visualization of the results, we created Table 1, which summarizes the main authors identified, their contributions, and respective critiques or proposals regarding the epistemology of EBM. This systematization highlights both convergences and specificities within the various argumentative lines. It is worth noting that, given the broad scope of the topic, this study did not aim to exhaust the entire existing literature, but rather to highlight representative and influential contributions to the ongoing debate.

This study did not involve patient data or human interventions, as it is a theoretical investigation based on secondary sources. Therefore, approval by a research ethics committee does not apply. Nevertheless, academic rigor and respect for copyright were maintained throughout the use of bibliographic references.

III. RESULTS

General characterization of critiques and proposals:The literature analysis revealed that, although EBM has enhanced objectivity and reproducibility in medicine, its epistemological foundations have been questioned along three main axes. First, there is criticism of EBM's strict empiricism, grounded in a rigid hierarchy of evidence that privileges randomized studies and meta-analyses, potentially at the expense of clinical experience and individual context【11】【12】. Second, the insufficient consideration given to qualitative evidence and patient values in standardized recommendations is emphasized, which may limit the practical application of evidence to the unique reality of each case【8】【15】. Finally, the challenge of clinical complexity is highlighted, where general algorithms and guidelines are not always capable of addressing the nuances and variability present in real-life care situations【14】.

Identified authors and perspectives: The **Table 1** presents a synthesis of the main authors and works that contribute to this discussion. Each of them focused on distinct yet complementary aspects concerning the limitations of EBM and pathways for its improvement.

Table 1– Key Authors on the Foundations and Limits of EBM, with Their Contributions and Proposals

Author(s)	MainContribution	Critique orProposal
Tonelli [1–3]	Advocates for epistemological pluralism and the integration of evidence, experience, and values.	Criticizes the reductionism of EBM and proposes a more interpretive and plural clinical epistemology.
Solomon [4]	Analyzes how medical knowledge is produced and contested among different rationalities.	Proposes a contextual and situated epistemology for clinical decision-making.
Gadamer [5]	Introduces hermeneutic understanding and the art of listening in clinical practice.	Argues that medicine should be understood as an interpretive, not merely technical, practice.
Montgomery [6]	Examines clinical reasoning as a narrative and moral process, not purely technical.	Values medical intuition and prudence as legitimate components of clinical decision-making.
Mattingly [7]	Explores narrative in medical practice and the meanings attributed to the experience of illness.	Emphasizes the importance of active listening and meaning-making as essential elements of care.
Greenhalgh *et al.* **[8]**	Criticize the crisis of EBM due to its complexity and loss of clinical context.	Advocate for a new integrative approach that values experience and clinical judgment.
Guyatt*et al.* **[9]**	Structured the methodology of EBM based on a hierarchy of evidence.	Despite criticisms, they defend standardization and clinical safety as strengths of EBM.
Hutchisone Rogers [10]	Question whether clinical knowledge can be entirely derived from science.	Value tacit knowledge, experience, and individual interpretation in clinical practice.
Ashcroft [11]	Questions the validation criteria of evidence within EBM.	Criticizes the rigid hierarchy of evidence and suggests more context-sensitive approaches.
Cartwright eHardie [16]	Analyze the limits of generalizing evidence to individual decisions.	Warn against extrapolating statistical data and advocate for contextualizing clinical guidelines.

Source: The authors, based on references [1–3, 4–11, 15].

As evidenced in **Table 1**, different authors have approached the issue from distinct angles. Tonelli【1】, for instance, argues in favor of epistemological pluralism, in which scientific evidence is only one

of the pillars of clinical decision-making, alongside the physician's experience and the patient's preferences【1】【2】【3】. In this alternative model, no single form of knowledge holds absolute hegemony, and it is up to the clinician to contextually integrate these diverse domains. Similarly, Cartwright【16】 and others emphasize that evidence derived from population-based studies does not always directly translate to the individual without proper adaptation. Policies or guidelines based solely on aggregated data may fail if local and individual circumstances are not considered【15】.

The influence of the medical humanities is also evident in many of the proposed revisions to EBM. Montgomery【6】, a scholar of narrative in medicine, argues that clinical practice is fundamentally interpretive, not a mechanical application of rules【6】. This entails recognizing that subjective aspects - such as empathy, intuition, and understanding the meaning of illness for the patient - are inherent components of good medical care. Mattingly【7】, in turn, studying clinical reasoning from an anthropological perspective, shows how healthcare professionals construct "therapeutic plots" to make sense of clinical situations, emphasizing the importance of narrative and lived experience in decision-making【7】. These perspectives contribute to an epistemological critique of EBM: by privileging only what is measurable and replicable, there is a risk of ignoring essential but less quantifiable dimensions of medicine.

Another set of critiques focuses on the practical application of guidelines and protocols. Hutchison and Rogers【10】question the notion that science alone can generate all the answers required for clinical care【12】. They argue that, at the point of care, physicians often face evidence gaps, ambiguities, and individual particularities that require flexibility and personal judgment. In this context, a rigid adherence to impersonal protocols may clash with the need for personalized treatment. This tension is exemplified in discussions on guideline adherence: even when robust evidence is available, the final decision often requires tailoring to the specific case, taking into account comorbidities, patient preferences, and other variables not captured in standard studies.

The issue of complexity and automation:In recent years, with the rise of clinical decision support systems and artificial intelligence tools, a new layer of debate has emerged. On one hand, such technologies promise to enhance the application of EBM by providing clinicians with instant recommendations based on the most up-to-date evidence. On the other hand, concerns have been raised that an overly algorithmic practice may lead to dehumanization and loss of professional autonomy. Recent studies (Greenhalgh【8】【12】) suggest that automation can exacerbate the dehumanization of medical practice by reinforcing linear models of thinking that fail to accommodate the adaptability and creativity needed in complex scenarios【14】.

In this regard, Solomon【15】warns that mere adherence to protocols, without critical thinking or patient dialogue, may result in clinical alienation—turning the physician into an executor of guidelines rather than a decision-maker attuned to the nuances of care【15】. She advocates for the explicit incorporation of patient-centered care into the core of evidence-based practice, which implies, for example, engaging in shared decision-making and respecting patient preferences even when they diverge from generic recommendations.

Synthesis of findings:Overall, our findings indicate that EBM, as a methodology, does not fully capture the complex reality of medical knowledge. There is a broad consensus among critics that a broader understanding of what constitutes "evidence" is needed, as well as a reconsideration of how it is applied. This includes: recognizing the value of qualitative studies and case reports (especially in situations where controlled trials are unfeasible or insufficient); valuing the professional's experiential knowledge as part of applicable evidence; and actively incorporating ethical considerations and patient preferences into the decision-making equation【6】【7】.

It is important to note that the proposals for an expanded epistemology do not call for abandoning scientific evidence, but rather for repositioning it within a more complex framework. The idea of narrative medicine, for example, does not oppose biomedical findings but asserts that patient care goes beyond disease—it also involves the person's story, expectations, and social context. Gadamer【5】already argued that the art of healing requires practical wisdom(*phronesis*, in Aristotelian terms), that is, the ability to apply general

knowledge to particular circumstances in a prudent and ethical manner【5】. This practical wisdom is precisely the element not captured by evidence manuals, but developed through experience and reflective practice.

IV. DISCUSSION

The findings of this review suggest that reconfiguring EBM toward a broader clinical epistemology is not only desirable but perhaps necessary to ensure the relevance and effectiveness of contemporary medicine. The identified epistemological limitations—empiricist reductionism, neglect of qualitative data, and algorithmic rigidity—converge on a central point: clinical rationality is richer and more multifaceted than what was envisioned in EBM's original model.

One of the most debated aspects is the hierarchy of evidence. Initially designed to classify the methodological reliability of studies, this hierarchy has inadvertently established a hierarchy of knowledge valuation, in which clinical experience and pathophysiology have been subordinated to data from clinical trials【10】【12】. However, as Ashcroft【11】points out, the definition of "clinical effectiveness" cannot be fully captured by average outcomes from population studies. Each patient presents a unique set of circumstances that modulate outcomes—factors that range from genetic and environmental variables to personal beliefs and family support.

Another crucial point is the recognition of subjectivity as inherent to medical practice. Montgomery【6】emphasizes that medicine deals with people and meanings—not merely with organs and data—and must therefore balance science and humanism. This view echoes the Hippocratic tradition, in which the art of medicine resided precisely in tailoring treatment to the individual patient. Today, this is reflected in the practice of adapting clinical recommendations to informed patient preferences—an approach aligned with the model of shared decision-making.

The incorporation of qualitative evidence and mixed methods emerges as a response to the limitations of strict positivism. Greenhalgh *et al.*【8】highlight that combining quantitative and qualitative methods offers a more comprehensive and contextualized view of healthcare. In contemporary practice, EBM increasingly acknowledges that qualitative studies complement quantitative data by providing context, meaning, and insights into human experiences.

This reductionist model is symbolically illustrated in the classical anatomy derived from René Descartes, represented in Figure 1 (insert image after this paragraph). The diagram, adapted from neurophysiological treatises of the 17th and 19th centuries, exemplifies the stimulus-response logic and the centralization of clinical decision-making in the brain. This symbolic configuration reinforces a standardized, decontextualized, and mechanistic medical practice, as discussed by authors such as Hutchison【10】and Rogers【12】, Greenhalgh【8】, Papoutsi【14】, and Zacks【13】.

Next, Table 2 presents a critical reading of the visual elements of the image, based on these same sources, highlighting the epistemological limitations of the Cartesian paradigm.

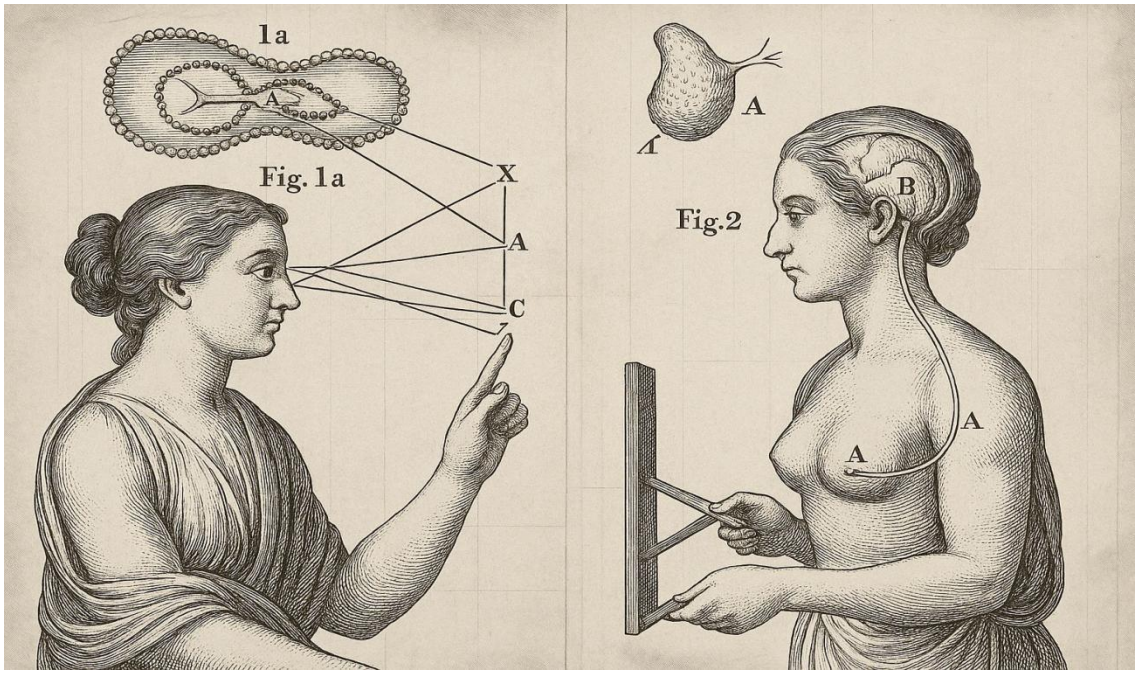

Figure 1– Visual representation adapted from René Descartes, illustrating the stimulus-response model and centralized control.

Table 2– Critical Interpretation of the Cartesian Image.

Letter / Symbol	ImageLocation	Visual Meaning	CriticalInterpretation
X, A, C	Fig. 1a	Visual focus points	Reduction of clinical complexity to discrete pathways [10,13].
1a	Fig. 1a (upperstructure)	Nervecell / synapse	Algorithmic translation of clinical perception; critique of decontextualization [13].
A (body nerves)	Fig. 2	Linear stimulus-response pathways	Excessive standardization of clinical responses [10].
B (brain)	Fig. 2	Processing center	Centralized decision-making, neglect of tacit knowledge [10].
A (uppergland)	Fig. 2	Symbolic representation of central regulation	Mechanistic and Cartesian view of medical practice [13].
□ **(intersection)**	Fig. 2	Optic chiasm or neural decussation	Neural integration challenges algorithmic linearity [10].
λ (lambda)	Fig. 2	Visual field crossover	Symbolizes the interpretive complexity of the sensory system [10,13].

Source: The authors, based on Hutchison and Rogers [10], Zacks [13], Greenhalgh [8].

Regarding automation and algorithms, our review suggests caution. Decision-support tools based on artificial intelligence are rapidly expanding, promising personalized and real-time updated recommendations. However, authors such as Greenhalgh【8】and Papoutsi【14】warn that complex systems—such as healthcare—do not adapt well to purely algorithmic solutions.

Montori【15】uses the term *"industrialization of care"* to criticize excessive standardization processes that reduce the medical act to a sequence of protocol-driven steps. He argues that restoring the patient's protagonism—through dialogue and shared decision-making—is a way to counterbalance this trend.

Our work also aligns with proposals like that of Solomon【4】, who advocates for a pluralistic view of medical knowledge. According to her, contemporary medicine encompasses a variety of explanatory models—biomedical, epidemiological, psychosocial—that must be integrated to build a more comprehensive clinical epistemology.

This perspective is compatible with the notion that the clinician's experiential knowledge is not only valid but essential for real-world decision-making, as argued by Tonelli【1】and Shapiro【2】.

V. CONCLUSION

Based on the review conducted, we conclude that Evidence-Based Medicine (EBM), while having brought undeniable methodological advances to clinical practice, presents intrinsic limitations when regarded as an exclusive epistemological paradigm. The philosophical foundations of EBM—rooted in empiricism, objectivity, and experimental control—do not encompass the full richness and complexity of the medical knowledge required to care for human beings in real and unique situations.

By reconfiguring EBM from a broader epistemological perspective, we propose: (1) Recognizing the interpretive nature of medicine – acknowledging that clinical practice involves both art and science, facts and values, general evidence and personal narratives; (2) Valuing the integration of knowledge – combining high-quality quantitative evidence with qualitative insights, experimental knowledge with clinical experience, and general guidelines with contextualized judgment; (3) Incorporating subjectivity and ethics into decision-making – understanding that healthcare is an encounter between subjects (physician and patient), guided by ethical principles, individual preferences, and mutual communication; and (4) Embracing complexity as a premise – developing conceptual and methodological tools capable of engaging with complex systems, rather than reducing them to simplified linear models【14】.

This reformulation does not imply abandoning the valuable contributions of EBM. On the contrary, it means deepening and contextualizing evidence-based practice, avoiding its transformation into a "recipe book" disconnected from reality. It means, for instance, that clinical guidelines should serve as flexible references, not rigid mandates; that final decisions must always consider *"this concrete person, with this condition, in their unique circumstances"*, rather than an abstract average patient. It also means that therapeutic success should be measured not only in biomedical terms, but also in terms of relief of suffering, restored function, and patient satisfaction with care.

In short, we advocate for an expanded clinical epistemology that repositions medical science in dialogue with experience and ethics. This view reinforces the legitimacy of different ways of knowing in medicine—the know-what of general evidence and the know-how of clinical practice—without imposing an absolute hierarchy between them. We believe such integration will make medicine more coherent, humane, and effective, by combining the strength of the best available evidence with the relevance and sensitivity of the best possible practice. Ultimately, it is about enhancing medicine's capacity to fulfill its essential purpose: to care for people, in all their complexity, in the most informed and compassionate way possible.

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