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EBM analysis



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Adapt or die: how the pandemic made the shift from EBM to EBM+ more urgent

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Abstract

Evidence-based medicine (EBM's) traditional methods, especially randomised controlled trials (RCTs) and meta-analyses, along with risk-

and—in some—prolonged sequelae. Effective and safe vaccines were produced rapidly, but uptake has been patchy and highly transmissible variants continue to spread and mutate. Coordinated disin-







“EBM+ is “an approach which systematically considers mechanistic evidence (studies which aim to explain which factors and interactions are responsible for a phenomenon (Parkkinen et al., 2018)) on a par with probabilistic clinical and epidemiological studies” (Tresker, 2022; Aronson et al., 2021).

Methods and tools in traditional EBM were primarily focused on answering simple, focused questions in population-intervention by PICO outcome comparison format, searching for RCTs for study evidence, critically appraising studies for risk of bias using tolls and checklist, and combining them using meta-analysis. While EBM+ investigates extended broad and complex contacts of questions in thorny clinical and policy questions, that are evolving over time, a more flexible and quick-witted approach is needed in the form of modification of EBM's hierarchy of evidence into EBM+. This paper proposes the tools and framework for integrating mechanistic evidence -known as “EBM+” with traditional EBM to form an interdisciplinary evidence-based medicine to better inform clinical and health practices such as for mitigating the COVID-19 pandemic. It integrates a wide range of study design, complexity science, engineering research, and the social sciences with variable quality and definitiveness into a fast decision making. In the paper, Greenhalgh et al. (2018) stated that there is a need for a shift in EBM into EBM+ due to its limitation of evidence hierarchies (validity of study types), which put RCT and meta-analysis on top of study selection and rejecting all other study types as less trustworthy. These limitations of the traditional EBM approaches exposed during the COVID-19 pandemic especially those needed evidence was characterized by a combination of complexity, urgency, and threat in patients' management and decision making. Thousands of lives are likely to have been lost as a result of what was incorrectly claimed as an absence of evidence through the "evidence-based" approach that dismissed or downgraded mechanistic evidence, but exaggerating findings from poorly designed or irrelevant RCTs. The authors introduce some conceptual tools and quality frameworks from various fields involving what is known as mechanistic evidence, where modifications being made to the hierarchy evident by using the Systematic Review/Meta-Analysis as a lens through which primary evidence is interpreted based on grading (Level 1 (Strongest)- Level 5 (Weakest)).

The scenario of using the traditional biomedical versus complex systems paradigms.

The use of the traditional biomedical paradigm versus the complex systems paradigm are different depending on the features of the system where the intervention is set to be tested. It is not referring to the characteristics of the intervention itself (Shiell et al., 2008) (Hawe et al., 2009). In simple trials such as drug and vaccine efficacy, it may only need simple-planned intervention with one unchanged health component, while complex interventions such as study improvement of health and system may need multiple interacting components in trial and adaptive to changes to fit with the environment. An example is given by Greenhalgh & Papoutsi, 2018, an intervention that involved a multi-component public health program that aims to prevent Type-2 Diabetes in the complex system of deprived, multi-ethnic inner-city communities with limited leisure facilities, multiple fast-food and street-food outlets, and a variety of existing faith-based community support programs. It needs inter-related and mutually interacting within components. The scenario can be understood based on the difference between these two paradigms as shown below where the process of the research and decision-making differ in direction of the planned intervention.

Table 1 shows 6 over 9 aspects of paradigm comparison between traditional biomedical versus complex system paradigms approaches to researching health services and systems. (reproduced and adapted from (Greenhalgh & Papoutsi, 2018))

| | EBM Traditional Biomedical Paradigm | EBM+ Complex Systems Paradigm |
|---|--|---|
|  Scientific truth | Singular (Objectively focused questions to answer uncertainty with specific research methods. | Multiple (Integrating multiple research methods from multiple disciplines to answer complex interactions between components in intervention). |
|  Goal of research | Establishing the truth which can be used as a universal and generalized source of information. | Exploring tensions; generating insights; revealing multiple perspectives from multidisciplinary. |
|  Assumed model of causality | Linear, cause, and effect with determining the effect size from the input factors. | Linear, cause, and effect with the determination of the magnitude of the effect based on input factors. |
|  Good research | Is based on strictness, precision, and standardization in research methodology. | Provide strong theory, flexible research methods, and openness to adaptation and modification in shift circumstances. |
|  Data Collection Approach | Need complete dataset to support powered study. | Decisions are made based on incomplete datasets when needed. |
|  Analytic focus | Dualisms: comparing 2 factors of A and B; finding the influence of A and B. | Dualities: inter-relationships and tensions between many factors in shift circumstances. |

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