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Evidence-B(i)ased Medicine: Limitations and Non-Superstition-Based Alternatives

Joshua Green, M.D., Ph.D. (PGY4)

"I often say that when you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind."

Lord Kelvin

"How did Lord Kelvin know *that*?"

Elio Fratarolli

Introductory Remarks

The Evidence-Based Medicine (EBM) movement crystallized in the early 1990's at McMaster University in Canada (3). The movement originally challenged practitioners to validate their treatments based on reasoning and clinical studies rather than personal authority (9). In this essay, I will argue that, contrary to this wholesome intention, EBM is authoritarian in spirit and actually constricts discourse about how to make clinical decisions.

Epistemological Biases of EBM

The phrase "evidence-based" implies that EBM has the sole right to define what evidence is and that the alternative must be superstition-based medicine. EBM uses this authoritarian stance to uphold an evidence hierarchy by which to assign how much weight to give clinical studies. From highest to lowest in standing, the ranking of studies is: systematic reviews of randomized controlled trials (RCTs), meta-analyses of RCTs, individual RCTs, nonrandomized or uncontrolled trials, and expert opinion (e.g. see table 1 in ref 5). There are some variations in the schemata proposed but two factors are constant: 1) RCTs and reviews of RCTs are at the top of the hierarchy and 2) clinical sources other than formal studies are either not mentioned or appear at the bottom of the hierarchy as expert opinion.

One of EBM's most famous statements vividly describes the implications of the evidence hierarchy (3):

Evidence-based medicine de-emphasizes intuition, unsystematic clinical experience, and pathophysiological rationale as sufficient grounds for clinical decision-making, and stresses the examination of evidence from clinical research.

Thus, clinical experience (including subconscious knowing and intuition) and theory-based reasoning are ejected from discourse or are relegated to the bottom of the hierarchy. Moreover, even within the clinical study category, the use of randomization and control groups is favored over all other conceivable characteristics that could make a study good (e.g. study size, similarity of study to target population, quality of outcome measures). I often ask myself the question: is this way of viewing evidence the only valid perspective and is it even a reasonable perspective? In the following sections, I consider some problems with a strict EBM approach with special focus on psychiatry.

Problem 1: Assumption that treatment and physician are readily separable

The technology of RCTs presupposes that the treatment can neatly be separated from the treater. Although this may be true for pills that affect the same receptors no matter who prescribes them, I believe that in psychotherapy, the therapist matters as much as the treatment approach. Specifically, therapist attributes such as degree of self-acceptance, comfort with the range of human emotions, and emotional attunement are likely to matter immensely in outcomes. Imagine, for example a patient who suffered great humiliation in childhood and therefore acts in rejecting ways towards others so as not to risk humiliation. Common countertransference enactments with such patients include acting overly indulgent or defensive; both reactions result from the therapist's struggle to acknowledge and/or make use of their own anger in useful ways. Another example of the importance of the therapist's capacities is in the ability to experience intimacy; a therapist fear of intimacy could result in sending a patient subtle cues not to reveal feelings towards the therapist. If we restrict our attention to RCTs that typically study one variable per study at great cost in time and labor, we will likely wait decades or centuries before considering the rich

interactions between therapist, patient, and theoretical framework that are likely to exist.

Problem 2: De-emphasis of inner experience

A second problem with EMB in psychotherapy is that the implicit denigration of inner experience and intuition robs the psychotherapist of important tools. The value of a therapist's inner experience is eloquently described by psychoanalytic author Nancy McWilliams (6):

Differentiating between an essentially depressive and an essentially self-defeating individual . . . turns on the therapist's noticing that instead of feeling sympathy for a suffering person, he or she is feeling a sadistic inclination to criticize. The realization that one may be dealing with a psychopathic person may come via the therapist's noticing that he or she feels duped or contemptuously bested. The appreciation of a paranoid core under an ostensibly depressive presentation may emerge from the therapist's noting an anxiety-filled fantasy that the patient will file a malpractice suit.

The point is that our subjective reactions to patients can direct us to important understandings about patients in ways that external observations and statistical analysis may miss.

Problem 3: Limitations of numerical scales

A further limitation of EBM in psychotherapy is that commonly-used symptom-focused scales do not reflect the potential richness of outcomes. Consider, for example, the following vignette told by a psychodynamic therapist (2): a middle-aged woman presented with anxiety and panic attacks that began after she and her family moved to a new city. Her husband, who had a new job, was away from home much more than he had previously been. Her husband's absences triggered anger which was rapidly covered up by anxiety. Through the therapist's persistence, the patient began to allow herself to experience anger. Soon after, the patient was able to associate her anger with childhood experiences of a sick mother who was in and out of hospitals until dying when the patient was 12. In fact, she had stomped out of her mother's hospital in anger one day before her mother's death; her mother's unresponsiveness had elicited the patient's fury. The guilt was too much and the memories of her mother's death and funeral were repressed until initiating psychotherapy. As a result of the therapy process, the patient saw that, "she had nothing to do with the death and . . . was able to feel compassion for the little girl who had to face her mother's death alone." The

patient was also able to “face all the grief she experienced while her mother was alive but chronically sick and unavailable.” This vignette illustrates the kind of gains that are not easily captured by simple numerical scales such as the Beck Depression Inventory. EBM in its current form is therefore unable to distinguish between the above treatment and symptomatic improvements from lorazepam or fluoxetine. In theory, one could devise scales to “measure” these deeper changes. However, until cumbersome studies are conducted, such observations are considered hearsay and are off the radar of EBM.

Problem 4: Under-emphasis on descriptive research

Many findings of great clinical relevance do not come from RCTs. Consider, for example, the landmark work of attachment theorists such as John Bowlby, Mary Ainsworth, and Mary Main. These researchers teach us that children adopt very specific strategies in order to maximize the likelihood of receiving care from their caregivers; the strategies are called secure attachment, avoidant attachment, ambivalent attachment, and disorganized attachment (4). An avoidantly attached child, for instance, shows few signs of distress in distressing situations because he or she has learned that showing the appropriate emotions actually elicit negative responses from the caregiver. This developmental experience could undoubtedly harden into fixed attributions about others as the child becomes an adult. The relevance of this understanding for psychotherapy seems transparent yet the absence of RCTs in attachment research means that EBM offers little reason to take note of the important findings.

Problem 5: Sanitized RCT Populations

RCTs are usually designed to study a single intervention in a single condition. Potentially confounding conditions (i.e. comorbidities) are therefore excluded. This approach has the advantage of good internal validity: the intervention can more easily be shown to affect the condition. However, the omission of comorbidities also raises the question of whether external validity is thereby compromised: in other words, do the results apply to individuals who are unlike the patients in RCT study populations (in that they have multiple conditions which may interact in complex ways)? For example, numerous RCTs show that antidepressants are effective in treating symptoms of major depression in people *without* comorbid personality disorders. Are antidepressants effective for patients with major

depression and personality disorders? Does the answer depend on the particular personality disorder? Most of the data on antidepressants do not address such issues.

Problem 6: Combinatorial issues

Systematic reviews of RCTs, the favorite technology of EBM, are most helpful in evaluating single interventions for discrete problems. To the extent that clinical situations usually involve multiple problems with multiple potential interventions, the number of options is large. Accordingly, the number of RCTs that would be required to create a truly “evidenced-based” world could be staggering. Saver and Kalafut (2001), for example, based estimates of necessary comparison trials on the number of agents approved or in late phase III clinical trials for Alzheimer’s disease or ischemic stroke (7):

Possible combination regimens number 128 (2^7) for Alzheimer disease and 32 (2^5) for ischemic stroke. Hierarchical, serial clinical trials would permit identification of the optimum combination of these agent classes for Alzheimer disease through 127 trials, enrolling 63,500 patients, requiring 286 years; for ischemic stroke through 31 trials, enrolling 186,000 patients, requiring 155 years.

The impracticality requires no further comment.

CONCLUSIONS

Evidence obtained from clinical experience, basic theories of health and disease, and clinical studies is crucial to making good clinical decisions. EBM tends to narrow the field of inquiry to RCTs and thereby discourages discussion of complex questions of how and when to apply evidence from a broad range of sources. In place of EBM’s doctrines, I suggest robust discussion of difficult epistemological issues and recognition that there are probably many valid perspectives about how to make clinical judgements.

SOURCE INFORMATION

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