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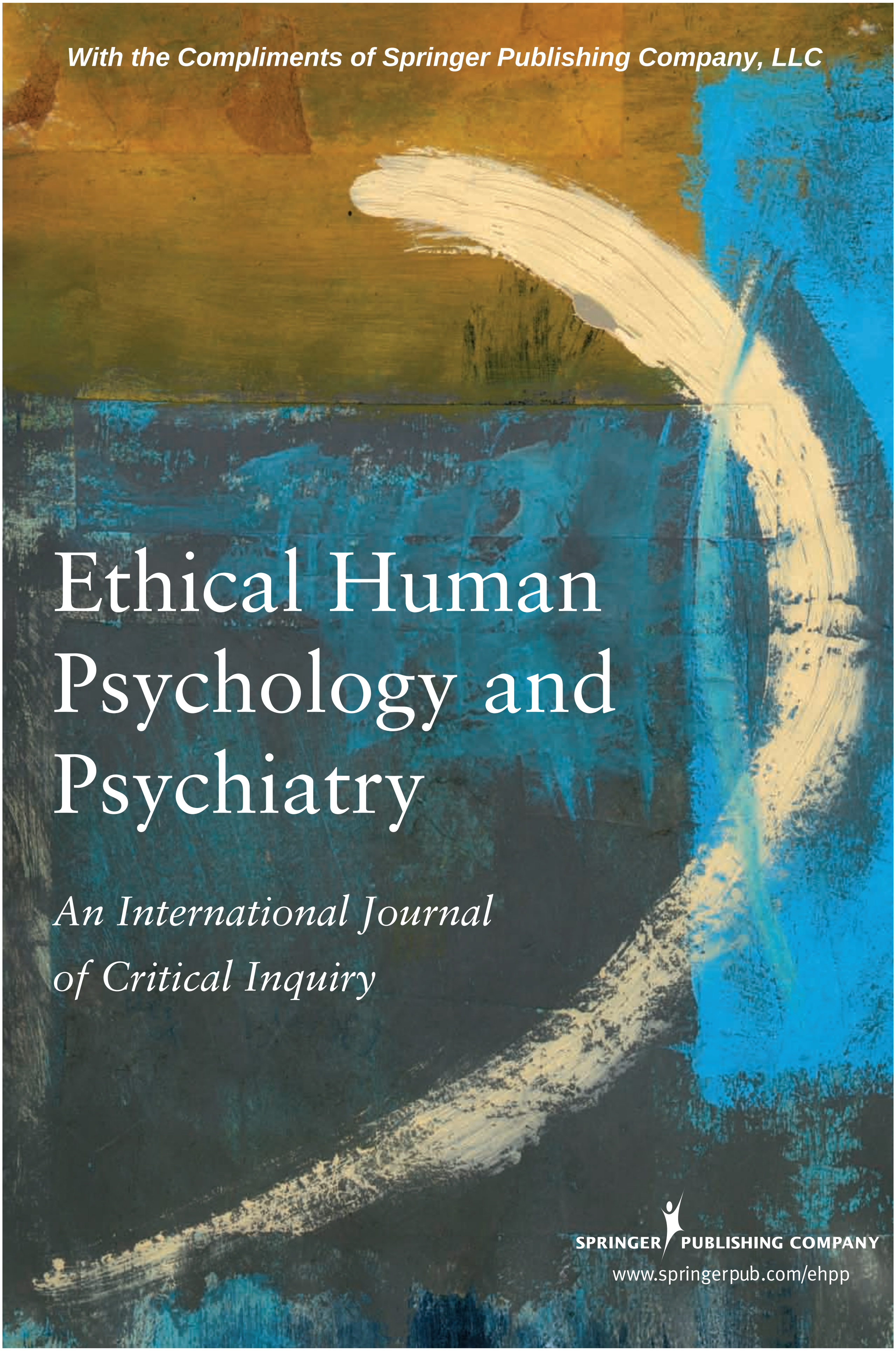

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The Limits of Evidence-Based Medicine and Its Application to Mental Health Evidence-Based Practice: Part One

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The present article outlines the major limitations of evidence-based medicine (EBM) and through a close review demonstrates that the three component EBM process model is a pseudoscientific tool. Its "objective" component is the collection, systematic analysis, and listing of "effective" treatments applying a research hierarchy from most rigorous (systematic reviews of randomized controlled trials [RCTs]) to least rigorous (expert opinion). Its two subjective components are the clinical judgment of helping professionals about which "evidence-based" treatment to select and the specific and unique relevant personal preferences of the potential recipients regarding treatment. This procedural mishmash provides no more rigor in choosing "best practice" than has been provided by good clinical practitioners in the past because both turn out to be subjective and authority based. The article also discusses EBM's further methodological dilution in the National Institute of Mental Health (NIMH) endorsed Evidence-Based Mental Health Practice (EBP) movement. In EBP, the allegedly rigorous EBM protocol is altered. Instead of systematic expert protocol-driven EBM reviews of RCTs, NIMH sanctioned expert consensus panels decide "evidence-based practices." This further problematizes the development of best practices in mental health by converting it to a political process. The article concludes with some observations on these issues. In a second article (part two) forthcoming, assertive community treatment (ACT) is examined as an example of an EBP that fails as a scientifically effective treatment despite its EBP certification and general popularity among practitioners.

Keywords: clinical practice; evidence-based medicine; evidence-based practice; mental health; social work

> *No profession is free of dogmatic clowns.*
>
> —Jacobsen, 2009, p. 19

The relatively recent phenomena of evidence-based practice (EBP) in mental health is derived analogically from the dramatic growth and resulting assertion of legitimacy of its parent movement, evidence-based medicine (EBM). Mental health EBP as a result depends on the concept of disease as the target of amelioration and presumes its validity in understanding and responding to the complex human existential travails that are the problems addressed in mental health. As Thomas Insel (2007), the director of the National Institute of Mental Health (NIMH), tells us, "as [mental health] research during the Decade of the Brain (1990–2000) forged the bridge between the mind

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and the brain, research in the current decade is helping us to understand mental illnesses as brain disorders" (p. 757). In 2010, the NIMH budget was $1.5 billion, most of it earmarked for research on the severely mentally ill (SMI) and their treatments. Almost a third of the funding, about $400 million, was spent on brain and basic behavioral research (NIMH, n.d.) designed to verify NIMH's institutional assumption that mental illnesses are brain diseases.

This bald-faced declaration by the director of the NIMH, the institution that disburses the overwhelming majority of mental health research dollars and outlines the direction of all acceptable mental health research programs in the United States, in the absence of any physiological markers or identified lesions that would be diagnostic of even a single currently listed mental disorder within the *Diagnostic and Statistical Manual of Mental Disorders* (*DSM*; American Psychiatric Association, 2000) seems to be putting the cart well before the horse but has not disturbed the mental health helping professions and their EBP (Gomory, Wong, Cohen, & Lacasse, 2011).

This article will first briefly describe EBM and then identify its problems. Then it will describe its reworked version as EBP applied to mental health in the United States and discuss its problems. Another article (part two) forthcoming in this journal will provide a specific example of how it can all go wrong by reviewing assertive community treatment (ACT) perhaps the most well documented EBP certified by the NIMH that has been around for more than 40 years.

WHAT IS EVIDENCE-BASED MEDICINE?

It is not new. EBM is clinical epidemiology on steroids. Dr. Sackett (2002), EBM's most well-known developer, explains:

> Clinical epidemiology has played a central or major role in five recent evolutions (some say revolutions) in healthcare: in evidence generation, its rapid critical appraisal, its efficient storage and retrieval, evidence-based medicine, and evidence synthesis. . . . As more and more clinicians, armed with the strategies and tactics of clinical epidemiology, cared for more and more patients, they began to evolve the final, vital link between evidence and direct patient care. Building on the prior evolutions, and manifest in clinically useful measures . . . and often incorporating the patient's own values and expectations . . . the *revolution of Evidence-Based Medicine* was introduced by Gordon Guyatt. Since its first mention in 1992, its ideas about the use (rather than just critical appraisal) of evidence in patient care and in health professional education have spread worldwide and have been adopted not only by a broad array of clinical disciplines . . . but also by health care planners and evaluators. (p. 1164)

EBM is defined formally by its developers as follows:

> [T]he conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights,

> and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient-centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996, pp. 71–72)

It is extremely difficult to resist the allure of a protocol that proposes (a) combining the best objectively derived evidence of treatment effectiveness, with (b) the application of caring and sensitive clinical expertise of individual clinicians, to (c) choose those specific treatments that mesh with particular patients' "predicaments, rights, and preferences" while simultaneously (d) ameliorating specific patients' illnesses. Perhaps the popularity of the EBM idea is because of this seductive linguistic combination of all that scientific medicine ideally aims to accomplish as a healing enterprise and for suggesting that this utopian research program is actualizable. Clinical epidemiologist Dr. Feinstein wrote with a colleague in a 1997 article raising a warning about EBM, "[h]ardly anyone can disagree with the goal of getting clinicians to make 'conscientious, explicit, and judicious use of current best evidence' for decisions in patient care" (Feinstein & Horwitz, 1997, p. 529). The devil is in the details.

Evidence-Based Medicine's Difficulties

Unfortunately, despite its popularity, EBM has come under serious criticism. Here are the most problematic issues. First, the RCT that EBM identifies as the gold standard research model for determining effective outcomes uses *group-aggregated averages* in the data analysis and as a result provides little useful information on how to select an effective treatment for *any* particular individuals, the goal of all clinical practice. Dr. Feinstein, credited by Sackett (2002) with putting clinical epidemiology on the scientific map, notes that "randomized trials were not intended to answer questions about the treatment of individual patients" (Feinstein & Horwitz, 1997, p. 532).

Second, even if we were to ignore the earlier-mentioned important problem in order for RCTs to be validly used, the sample of patients must be a random sample selected from a population of individuals who all have the same underlying disease. This proves well nigh impossible in psychiatric samples because psychiatric diagnoses are neither reliable (Kirk & Kutchins, 1992) nor valid (Boyle, 2002) and therefore cannot be used as a method to identify people with the same mental disorder necessary for RCT research (Wolf, 2000). As the *DSM* states, "In the *DSM-IV* there is no assumption that each category of mental disorder is a . . . discrete entity . . . dividing it from other mental disorders or from no mental disorder. . . . [T]herefore . . . individuals sharing a diagnosis are likely to be heterogeneous even in regard to the defining features of the diagnosis" (APA, 2000, p. xxxi). This assertion of unreliability and invalidity may strike some readers as unduly harsh, yet it is recognized and so stated by numerous authors, including prominent *DSM* architects. For example, psychiatrist Allen Francis, one of the chief editors of the *DSM-IV*, in a 2011 interview bluntly states that "there is no definition of a mental disorder. It's bullshit. I mean, you just can't define it" and further asserts that "these concepts are virtually impossible to define precisely with bright lines at the boundaries" (as quoted in Greenberg's 2011 online article in *Wired Magazine*). And, the earlier identified director of the NIMH Thomas Insel writing with other colleagues from NIMH confirms the after some 40 years of effort, the empirical failure of the DSM declaring that the,

> [d]iagnostic categories based on clinical consensus fail to align with findings emerging from clinical neuroscience and genetics. The boundaries of these categories have not been predictive of treatment response. And, perhaps most important, these categories, based upon presenting signs and symptoms, may not capture fundamental underlying mechanisms of dysfunction. (Insel et al., 2010, p. 748)

Third, although RCTs may be very useful in deciding if an active drug is better than placebo (i.e., a nonactive pill or process also known to influence the outcome being researched) to treat, say, an infection, they may not be the best way to evaluate the effectiveness of socially complex service packages usually provided by public social welfare and mental health systems. These services include various components, such as case management, psychiatric medication monitoring, cognitive-behavioral treatment, employment training, activities in daily living, and budgeting classes. Depending on a particular agency's philosophy and funding requirements, each service package and each component therein may be organized and implemented differently across agencies and even within a single agency. The resulting "lack of precision makes it difficult to model the causal pathways of interventions, which is central to the RCT model" (Wolf, 2000, p. 101). To further complicate the portrait: If attempts are made to test the various components' separate effects on the patients, that is, to *unbundle* bundled services, the strong possibility exists that some important elements of the *bundled* intervention will be overlooked because they are hard to measure or so idiosyncratic that they cannot be standardized and transferred uniformly to another setting. For example, it may be that the most "highly effective aspects of the intervention are those unmeasured aspects that are associated with highly stylized characteristics of the staff, say their interactional style or level of motivation" (p. 101).

It should be noted that some information derived from RCT research, such as the known numbers of individuals needed to treat (NNT) calculated in a particular past trial, may offer some help to both individual treatment recipients and their clinicians for deciding among possible "effective" treatment options because we operate under conditions of uncertainty in our daily lives (see particularly, Gigerenzer, 2002). For example, if in one treatment only 2 people need to be treated to have one receive the benefit of it versus another treatment where 100 people have to receive treatment for one person to benefit that may be a useful basis for comparison although by no means definitive. After all, no prior research sample can be assumed to mirror the person about to be treated.

RCTs may also, if rigorously implemented help to rule out useless (e.g., those psychiatric drugs that do not separate from placebo statistically or clinically) or harmful interventions (those drugs that have worse adverse effects than therapeutic effects; Kirk, Gomory, & Cohen, 2013, especially Chapters 6 and 7). For cogent arguments on the deep problems of RCT research in mental health, see Cohen and Jacobs (2010) and Lacasse (2011).

Fourth, comprehensive evaluations of treatment outcomes from multiple studies carried out by combining data from all the studies have their own limitations. Such systematic pooling of study results, known as a meta-analysis, has come to be seen as the gold standard for deciding on an intervention's effectiveness. Meta-analyses now number in the thousands in the psychiatric outcome literature alone. Yet the limitations of meta-analyses need closer scrutiny. One such limitation is that meta-analyses often take the information given in individual RCT studies as factually accurate. As many scholars have pointed out, those who conduct meta-analyses do not necessarily assess independently how well each individual RCT was implemented or evaluate the impact of potentially bad implementations on the quality of the data gathered (Bailar, 1995; Feinstein, 1995; Feinstein & Horwitz, 1997; Oakes, 1986; Rothman, Greenland, & Lash, 2008, p. 682; Williams & Garner, 2002) and no meta-analysis considers the impact of the administrative organization of an intervention program and its rules and regulations that, as will be argued in the forthcoming article mentioned earlier on ACT, are primarily responsible for programmatic success not its hypothesized clinical[1] interventions (the foci of analysis for such systematic reviews). The American statisticians Richard Berk and David A. Freedman go further and advise:

> [W]ith respect to meta-analysis, our recommendation is simple: just say no. The suggested alternate is equally simple: read the papers, think about them, and summarize them. Try our alternative. Trust us: you will like it. And if you can't sort the papers into meaningful categories, neither can the meta-analysts. (Berk & Freedman, 2001, p. 21)

The conceptual analysis suggested by Berk and Freedman relies instead on inferential reasoning of another sort. It is the "traditional methods of reflection, tracing of connections, [and] reaching tentative conclusions" (Bauer, 2000, p. 20).

A formulaic reliance on statistical significance testing and arbitrarily aggregated statistical findings can be harmful for good scientific work (McCloskey, 1985; Oakes, 1986) and may obscure or mask deeper methodological problems such as the erroneous construction of the variables used for a study's statistical analysis or the ignoring of the historical development of ideas, concepts, or theories fundamental to a research project (e.g., see Gomory, 2002 for the history of the idea of ACT and its relation to coercion). As the distinguished economist Peter Bauer has suggested in another context:

> The acceptance of quantitative methods as the most respectable [scientific] procedure has permitted the burgeoning of incompetent and inappropriate econometric studies, including those based on flawed data. Conversely, studies based on direct observation or detailed examination of slices of history are apt to be dismissed as anecdotal, unscholarly or unscientific. . . . In short, preoccupation with mathematical and quantitative methods has brought with it regrettable atrophy of close observation and simple reflection. . . . This type of reasoning . . . has retreated not because it has been proved less informative . . . [but] because it has been castigated as . . . less rigorous than its more modish successors, largely because it less resembles the procedures of the natural sciences, especially physics. (Bauer, 2000, p. 20)

In fact, an editorial introducing a very recent (January 2012) series of articles in the *BMJ* (formerly known as the *British Medical Journal*) dedicated to research on missing clinical data and their impact on the methodology of EBM had this to say on the flaws of quantitative findings in systematic reviews of clinical trials for EBM:

> These articles confirm the fact that a large proportion of evidence from human trials is unreported, and much of what is reported is done so inadequately. . . . What is clear from the linked studies is that past failures to ensure proper regulation and registration of clinical trials, and a

> current culture of haphazard publication and incomplete data disclosure, make the proper analysis of the harms and benefits of common interventions almost impossible for systematic reviewers. (Lehman & Loder, 2012)

A fifth issue regards what kind of evidence is best for determining if the treatment is effective. Should we rely strictly on statistical analyses of numerical data as EBM advocates urge or should we more broadly incorporate other systematically reviewed empirical evidence currently disallowed under EBM? Some doctors argue that "the general priority given to empirical evidence derived from clinical research is not epistemologically tenable" (Tonelli, 2006, p. 248) but should only be considered as one source along with others. These others could be evidence obtained from well conducted observational and naturalistic studies, gathering of individual case studies into a searchable database (sometimes referred to as experience-based evidence), studies on human and animal physiology, as well as evaluations of patient goals, values, and specific features of the delivery system relevant to practice (Tanenbaum, 2006; Tonelli, 2006). Even assuming that expanding the sources of evidence should be undertaken the question of how to weigh objectively what form of evidence to consider as telling and in what order in selecting better from worse interventions would still remain. (A methodological conundrum that may have no possible resolution because each form of evidence may be derived from different and irreconcilable theoretical perspectives.)

Sixth, the part of the EBM definition urging the need to consider clinical judgment (i.e., the subjective calculation of the helping professional regarding the problem) as well as the patient's personal wishes when choosing the proper EBM treatment, greatly appeals to common sense. EBM proponents, however, have consistently admitted that they have not a clue about how to incorporate these two subjective elements into the protocol of EBM (Cohen, Stavri, & Hersh, 2004; Haynes, 2002). Without a formal systematic procedure for selecting, organizing, and integrating the best research evidence, best clinical judgment, and patients' preferences, the EBM approach for choosing an effective treatment for a given individual presenting with a given illness is no more "scientific" and arguably cannot be caused by the highly personal nature of such interactions than the approach used by ethical clinicians in the past. These clinicians carefully weighed the best information available to them from multiple sources to choose the best care to recommend to their patients based on their education, training, experience, and positive therapeutic alliance with their patients. Feinstein and Horwitz (1997), long students of medical practice, note "most good clinicians have regularly assembled evidence when they reviewed their own experience, developed clinical judgment, read the medical literature, attended medical meetings, and had discussions with one another. This activity seems entirely compatible with the . . . practice of EBM" (p. 529). The attitude and approach of a caring clinician has always entailed a concern for the person seeking help. In fact, the relatively new term "shared decision making" seems to reflect the approach described by Feinstein and Horwitz used for decades by good doctors:

> In shared decision making, both parties share information: the clinician offers options and describes their risks and benefits, and the patient expresses his or her preferences and values. Each participant is thus armed with a better understanding of the relevant factors and shares responsibility in the decision about how to proceed. When more than one viable treatment or screening option exists, clinicians can facilitate shared decision making by encouraging patients to let clinicians know what they care about and by providing decision aids that raise

> the patient's awareness and understanding of treatment options and possible outcomes. Decision aids, which can be delivered online, on paper, or on video, can efficiently help patients absorb relevant clinical evidence and aid them in developing and communicating informed preferences, particularly for possible outcomes that they have not yet experienced. (Barry & Edgman-Levitan, 2012, p. 781)

EBM is not unique or original in wishing to more fully integrate patients into making decisions regarding their care.

A seventh crucial issue is that deciding what constitutes the scientific evidence to be used for EBM requires experts "certified" as authorities in the subject. Such an EBM certification of proper methodological capability must be done by authorities who themselves were certified in such expertise by some prior certified authorities, who where themselves in need of certification prior to being anointed, and so on. This infinite regress indicates that such certification can only be an arbitrary process based on conventionally agreed on requirements. So, rather than dramatically reducing or eliminating arbitrary or authority-based individual medical decision making, or rather than substituting an objective for a subjective decision-making process in choosing best practices as some have argued (Gambrill, 1999), EBM has turned out to represent merely another form of expertly justified *authority* now more likely based on the authority of so called expert consensus processes (using methodological criteria also consensus derived [i.e., the 2011 and latest version as of this writing of the *Cochrane Handbook for Systematic Reviews of Interventions* edited by Julian Higgins and Sally Green]). The subjective judgment of individual clinicians now becomes the subjective judgment of the authorized EBM evaluators who are expected to come to consensus regarding which studies meet the consensus protocol for systematically evaluating RCTs[2] regarding the choice of best practice (see especially, Feinstein & Horwitz, 1997; Gupta, 2003), leading to a new "orthodoxy" promoted now as scientific and objective (Williams & Garner, 2002). To best illustrate this authority and consensus-driven process, let me quote from the 2011 Cochrane Systematic Review on Intensive Case Management where the authors explain:

> The authors of this review do include an active pioneer of developing and implementation [*sic*] the experimental intervention model across the scientific community and clinical world (MM) and one included study is his (Marshall-UK). As a team, we have tried to ensure that decisions are made by rational consensus and not to have an expert in the team would have been an inadvisable omission. In some cases, protocol rules were not clear enough and need for subsequent clarification arose and post-hoc decisions had to be taken. (Dieterich, Irving, Park, & Marshall, p. 50)

Finally, and perhaps most problematically, the effectiveness of EBM itself has never been fully tested according to its own principles. Do clinicians who practice EBM achieve better outcomes than those who don't? Nobody knows. That question has never been put to an EBM-favored test, for example, by conducting an RCT of comprehensively EBM-trained clinicians versus those not so trained to assess an ability to select and implement effective treatment to help their patients. That is, the optimistic claims of EBM effectiveness are not themselves evidence-based (Cohen et al., 2004). The latest research, however, corroborates prior findings regarding EBM training efforts on doctor behavior and patient outcome done on a smaller scale. A 2007 controlled trial comparing doctors taking an EBM workshop with doctors who did not found "no statistically significant differences . . . between intervention and control doctors' test-ordering performances, and their patients' drug utilization" (Shuval et al., 2007, p. 581). So the whole EBM project is formally untested even though it has been promoted and marketed for more than 20 years and where more limited evaluation has occurred, EBM training has not proved superior in the training of clinicians for selecting or providing effective treatment. As Dr. Martin Tobin, the former director of the Division of Pulmonary and Critical Care Medicine at Loyola University of Chicago's Stritch College of Medicine in his concise 2008 evaluation of EBM comments:

> EBM founders have never undertaken an RCT of the effects of EBM on patient outcome. So EBM does not satisfy its own basic requirements, which it demands of everyone else. (Hypocrisy or what?) . . . EBM founders say clinical decisions should be based on empirical evidence but EBM founders have never subjected EBM to empirical testing. Instead, EBM . . . is solely based on expert opinion. Thus if EBM tenets are true, then EBM should not be trusted. (Tobin, 2008, pp. 1072–1073)

Such uncertainty regarding the validity of EBM would suggest caution in marketing its wholesale adoption. Unfortunately, there is little doubt that it has been heavily marketed with resounding success, judging from its adoption as an organizing, pedagogical, and practice principle in Western medicine and the helping professions.

These criticisms throughout the medical literature have not gone unnoticed and recent warnings have come directly from some EBM developers. Haynes (2002), one of the original inventors, wrote that "accelerating the transfer of [EBM] research findings into clinical practice is often based on incomplete evidence from selected groups of people, who experience marginal benefits . . . raising questions of the generalizability of the findings" (p. 1) and that at *best* it should be "an adjunct to healthcare decisions" (p. 6). Haynes has also concluded that "EBM has long since evolved beyond its initial (mis)conception that EBM might replace traditional medicine. EBM is now [instead] *attempting* [emphasis added] to augment rather than replace individual clinical experience" (Haynes, 2002, p. 1). This more modest contemporary stance of the EBM creators about EBM's "adjunct" role in medical decision making based on the practical failure of their entirely overblown original programmatic claim that EBM represents "[a] NEW paradigm for medical practice" (the Evidence-Based Medicine Working Group [1992, p. 2420]) should have served to tone down the enthusiasm for it by other helping professions as a research panacea, but institutional inertia often distorts the transfer of new information to other specialty fields.

Evidence-Based Medicine and Evidence-Based Practice in Mental Health

EBM and its methodology is now claimed to be the "best practice" approach used in the broad field of mental health, albeit under a slightly altered name, EBP. Some leading American psychiatric researchers (composed of academics from the fields of psychology, psychiatry, and social work) working with those labeled the SMI explain:

> Over the past two decades, we have witnessed amazing strides in the development of effective service models for people with SMI . . . in 1998 . . . a national consensus panel identified six practices . . . attaining the status of EBP. . . . EBP in mental health is part of a larger evidence-based medicine movement which quickly has become a dominating influence in medicine . . . following the model of evidence-based medicine, EBPs are founded on the meta-principles of (1) using

> the best available evidence, (2) individualization, (3) incorporating patients' preferences and (4) expanding clinical expertise. (Bond, Salyers, Rollins, Rapp, & Zipple, 2004, pp. 576–577)

Relying on the professionals' and perhaps the general public's resonance to the simplicity and commonsense appeal of the EBM idea, implementations of evidence-based mental health practices[3] for the SMI have been moving full steam ahead, its promoters blithely ignoring the deep questions raised (summarized earlier in the article) concerning the construct and the application of EBM.

The supporters of EBM have developed a sophisticated research infrastructure, including prominently the Cochrane Collaboration mentioned earlier. This enterprise solicits groups of volunteer medical professionals and academics to constitute expert work groups conducting systematic rankings and reviews of the numerous RCTs of treatments (occasionally also reviewing the findings of less rigorous research) available for many physiological problems, some psychiatric problems, and some more general behavioral issues such as the effectiveness of smoking cessation programs. These systematic reviews are used to determine which treatments should be considered as "evidence-based." This is how the Collaboration's website explains it:

> Each systematic review addresses a clearly formulated question; for example: *Can antibiotics help in alleviating the symptoms of a sore throat?* All the existing primary research on a topic that meets certain criteria is searched for and collated, and then assessed using stringent guidelines, to establish whether or not there is conclusive evidence about a specific treatment. The reviews are updated regularly, ensuring that treatment decisions can be based on the most up-to-date and reliable evidence. (downloaded September 2, 2012 from http://www.cochrane.org/cochrane-reviews)

As the quote mentioned earlier suggests the Collaboration expects that treatment decisions will be made based on the Collaboration's recommendations regarding what may be evidence based and what may be not. These reviews are stored in a researchable electronic database available by paid subscription. The evidence base for mental health interventions that have been subjected to these procedures is far more limited and generally lacks the kind of consistent methodological scrutiny that physiological medical interventions have usually been subjected to (Drake et al., 2001).

What has not been commented on in the literature till the present article is that even with the deep difficulties just outlined earlier for EBM, there is another complicating issue that further undermines the scientific value of mental health EBP. That is, that a fundamental difference characterizes how EBM and EBP determine their recommended interventions. Mental health EBP, the one receiving support from American psychiatric science's key political patron, the NIMH, uses expert *consensus* to identify its effective interventions rather than formal protocols as originally recommended by EBM: "[strict] rules for designating a practice as an EBP . . . were not imposed in the Implementing EBPs Project; rather panels of research scientists were asked to review controlled studies" (Mueser, Torrey, Lynde, Singer, & Drake, 2003, p. 389).

Usually, in reaching consensus, a group, regardless of its purpose or membership, must get all members to agree to one expressed [or explicit] understanding. This is not a scientific but rather a social and political process. Unless explicit procedural and methodological criteria of the process are agreed to before starting, consensus reaching is arbitrary and may be captured by those in the group who are most persuasive rhetorically rather than scientifically. How the expert consensus agreement for the EBPs was reached is not described in the published literature, but it is noteworthy that this process was carried out with the sanction of NIMH under the auspices of the Robert Wood Johnson Foundation (Mueser et al., 2003), funded by the family fortune derived from Johnson & Johnson, the eighth largest pharmaceutical company in the world (five former executives of which sit on the foundation's board of trustees as of this writing).

Because the identification of EBPs is meant to reduce clinicians' uncertainty in choosing effective treatments, the certification of certain treatments as evidence based by a consensus vote of approved experts should be based on consistently demonstrated success of the intervention. If, however, the evidence used to make the certification is weak, faulty, or ambiguous, then the certification can have the unintended consequence of institutionalizing coercive, ineffective, or even harmful treatments with almost no possibility of reversing those decisions. Statistician Kenneth J. Rothman observes:

> Many of the commonly used modes of causal inference are fallacious . . . one such method of inference, the method of "consensus," has been embraced, presumably for political reasons, by the National Institutes of Health. . . . The National Institutes of Health regularly convenes Consensus Development Conferences to address specific questions and draw inferences. . . . Were consensus a correct basis for inference, then a once flat earth must have become spherical . . . Consensus itself requires no further justification, and may be based on shared beliefs that are irrational. (Rothman, 1988, p. 6)

This difficulty is illustrated by the fact that among the certified EBPs, some are considered more valid than others: "[A]mong EBPs identified by the RWJ conference . . . three practices (supported employment, ACT [Assertive Community Treatment], and family psychoeducation) have strong and convincing evidence for effectiveness whereas the evidence is weaker for the remaining three" (Bond et al., 2004, p. 580). Unfortunately, whether based on strong or weaker evidence, once an intervention is labeled an EBP, its authority has immeasurably increased.

The distortion of the original EBM approach as the framework of EBPs in American mental health practice can be seen by the rhetorical turn taken in two articles published 5 years apart with the same lead author, psychologist Gary Bond, a leading replicator/evaluator/promoter of ACT. As we have earlier noted, Bond et al., stated in 2004 that mental health EBPs were founded explicitly on the EBM process and its key "meta-principles of (a) using the best available evidence, (b) individualization, (c) incorporating patients' preferences, and (d) expanding clinical expertise" (pp. 576–577). In 2009, however, Bond, Drake, McHugo, Rapp, and Whitley declared that those explicit principles were unnecessary for EBPs:

> *Evidence-based medicine* sometimes refers to a process—the judicious use of the best scientific evidence, combined with clinical expertise and consumer preferences in making decisions in health care. . . . The term EBP, has been used similarly in the mental health field. . . . The term EBPs also refers to specific evidence-based (or empirically supported) interventions . . . (usually randomized controlled trials). Thus the acronym, EBP, is used throughout this article to refer to *specific interventions* and not to the *process* of clinical decision making. (pp. 569–570)

Explaining that EBP can now refer to specific interventions and ignoring the process of how they were identified (i.e., by a consensus vote of experts, a method completely unacceptable for EBM) allows Bond and his colleagues to change the scientific rules of the game for mental health EBPs. Talking about EBP as if it is a derivative form of EBM gives the impression that mental health determined EBPs have the same scientific credibility as EBM process (weak although it may be to informed observers) identified EBPs. But the reality is that mental health EBPs are not identified through the same procedures (EBM necessitates systematic reviews of RCTs, not expert consensus) and cannot be considered as analogs to EBM-derived treatments. Instead of addressing the methodological differences, Bond and colleagues in Essock et al., 2003 accuse their critics of being ignorant of science:

> Some people misunderstand research and some simply reject the methods of science . . . Most of the authors of this paper have been involved in the evidence-based medicine movement believe that these concerns are based on misconceptions and poor application of some practices. (Essock et al., 2003, pp. 936–937)

The various problems regarding EBM and EBP discussed in this article have not been adequately addressed or solved by the EBP experts. These experts are well aware of most of the problems, an awareness that prompted at least one meeting to gather and summarize the concerns regarding mental health EBPs "voiced by members of diverse stakeholder groups; consumers, family members, policy makers, administrators and researchers" (Essock et al., 2003, p. 920). The resultant report was authored by 14 of the self-styled leaders of the EBP mental health movement who magnanimously state that they, in "the spirit of science being transparent and welcoming a public discussion . . . offer this collection of concerns [regarding EBPs] . . . hop[ing] that these summaries will be useful to others" (Essock et al., 2003, p. 921).

This report is a confirmation that the criticisms raised in this article are shared by many who are affected by EBPs. But, this sort of mea culpa exercise seems to be geared for public relations more than anything else, because after admitting that there are many problems with EBPs, the authors do not suggest revisiting the procedures and methods used to name EBPs or reevaluate their selections by more rigorous means. Instead, they praise their original choices, saying that the "National Evidence-Based Practice Project study groups identified six EBPs for community mental health treatment of persons with severe mental illness . . . [which] provide a strong foundation for defining minimal services for people with severe mental disorders" (Essock et al., 2003, p. 932) without offering any scientific evidence for the claims. Furthermore, insisting that these EBPs are characterized by "sensitivity to individual differences, by attention to choices and preferences, by client centeredness, by empowerment, by diversity of methods, and by reliance on clinical skills and judgment" (Essock et al., 2003, p. 937), all admirable characteristics but are claims impossible to accurately evaluate globally.[4]

CONCLUSION

Perhaps much like any idea whose time has come, EBM is just too attractive to be fatally bruised by the hundreds of critical articles launched at its putative evidence-based core. This article may be another quixotic attempt to convert the EBM convinced to skepticism and educate the as yet unconvinced or uninformed regarding the problematic nature of the EBM/EBP enterprise. The back story so to speak. This article attempted to lay out what EBM asserts it is, then marshaled the many limitations to its methodology identified in the extant literature while adding a few not often addressed. Then the article detailed the further loosening of scientific rigor in the conversion of EBM into the EBP of mental health by the political involvement of the NIMH.

The result of this analysis suggests that EBM is a fallible and limited trial-and-error process as all human enterprises relying on individual human beings' decisions must be. The empirical component of EBM, that is the effort to ascertain systematically whether various treatments or practices have been subjected to critical tests regarding their effectiveness and have passed such tests, is a good thing. But this sort of falsificationary procedure is the essential component of science and its progress toward scientific truth generally (see Popper, 1989) and does not in any way rely on systematic reviews per se or is special to EBM practice.

As Taleb (2012) in his important new book *Antifragile* observes,

> medicine today remains an apprenticeship model [as are the other helping professions such as social work and clinical psychology which generally use internships to learn their crafts] with some theoretical science in the background, but made to look entirely like science (p. 224)

and what is labeled EBM is just the added technology of "the cataloging of empirical regularities" (p. 224), making information more convenient in some sense for review but empirically no more scientific. (Keeping in mind all the caveats of such information listed in the present analysis.) For example, two renowned clinical epidemiologists report that

> when insulin first achieved a rapid reduction in diabetic acidosis and when penicillin first eradicated bacterial endocarditis, the results in both instances came from observational rather than RCT research, and each set of results were reported in a single study. Despite the extraordinary efficacy of both treatments and their dramatic impact on clinical practice, neither study, if newly reported today would be included in the Cochrane collection of authoritative evidence. (Feinstein & Horwitz, 1997, pp. 534–535)

More specifically in mental health research, psychiatrist David Healy (2007) who has examined the problems with antidepressant RCT research for years recently has argued that not considering case studies may actually do harm. According to him, since the late 1950s:

> the pendulum has swung in favor of RCTs. The leading journals in medicine devote their space to RCTs and all but refuse to take case reports. . . . The dominant factor is a perception that the evidence from RCTs trumps all . . . evidence, especially that from case reports. This is the case, even when case reports come from the most senior clinicians in the field and outline effects that follow challenge-dechallenge and rechallenge paradigms and when these effects are explicable in terms of known pathological mechanisms. . . . In preferentially accepting RCTs . . . over case reports, journals risk privileging the experiences of the 1 specific drug responder over the 9-fold larger pool of other responders or nonresponders. . . . [W]e see [since placebo replicates 80% of the effect of an active drug] that of 5 people responding to an antidepressant 1 responds specifically to the drug while the other 4 would have responded to placebo. . . . But now driven by evidence that is less generalizable than commonly thought, clinicians rapidly take up the

> newest treatments. Faced with patients who turn suicidal, for instance, they consult the RCT evidence base that will commonly not list such effects, or may list them under codes such as emotional lability, which few clinicians will realize means suicidality. Failing to see evidence of a hazard, the clinician in this case may even double the dose of the new agent. (Healy, 2007, pp. 133–135)

About the use of the two subjective components of the EBM model regarding the individual choices about treatment that the clinician and the patient must make, a more melancholy conclusion is reached. At best, the clinician makes her selection based on her current understanding of the research (much is dependent on her intellect, analytic and clinical skills, and her comfort and familiarity with some basic statistical concepts and procedures) and her knowledge of her patient (including the patient's personal preferences, psychosocial particulars, level of comfort, ethical perspectives, etc.). All of these various attributes, capabilities, and skills of the clinician have been given the honorific of "clinical judgment." Feinstein (1967) in his book *Clinical Judgment* devoted entirely to this topic notes that

> [t]he clinician's approach to evaluating the patient exclusively as a person is still an artful aspect of care that depends on human perception and understanding. These components of clinical care are properties of heart and spirit, of instinct and psyche, and cannot be easily identified, assessed, or quantified by ordinary methods of reasoning. (pp. 28–29)

As a result, the clinician's selection of treatments to offer her client is a guess, perhaps educated perhaps not. Furthermore, she can after selecting what she considers a potentially effective treatment for the client, through the use of various tactics such as calculating relative and absolute risk reduction (mathematical calculations determining proportional reduction in the rates of adverse outcomes between the experimental and control groups of the research on selected treatments) and the numbers needed to treat (the total number of people that must receive the selected treatment in order for one person to have a positive outcome) help inform the client about what the available RCT research on the particular treatment impact has been. But regrettably, these tools say very little about what the actual impact of the treatment on the person contemplating that treatment will be because these studies are always assessing average treatment effects (that is all that statistical methodology allows). Some members of the treatment group may have benefited, some may have been unaffected, and some may have been harmed by the treatment (Horwitz, Singer, Makuch, & Viscoli, 1996). So an outcome demonstrating an average overall effectiveness on the experimental group can say little, specifically, about what the impact of the treatment on a particular patient or client may be because none is the hypothetical average person. This uncertainty unfortunately leaves the client with limited meaningful information for choosing a treatment. Making his selection either authority based (going along with the clinician's interpretations or preferences especially if a good therapeutic alliance is in place) or arbitrary, because little if anything the client could learn from the EBM/EBP process will indicate anything reliably about the treatment effect specifically on him. And possibly it could be both. Pretty much what historically has always been the case. This is what the evidence regarding EBM and EBP has led me to conclude.

NOTES

1. *Clinical treatment effect* is defined as some specified nonadministrative clinical/biological/behavioral component(s) of a treatment program that can motivate or cause internalized/volitional change, or the "acquisition of coping skills" by clients, which leads to clients' improved functioning that results in reduced hospital stays and greater "independent" community tenure in a community mental health program such as ACT, for example.

2. The Cochrane Collaboration is the leading organization carrying out and maintaining a database of EBM systematic reviews. It does this through voluntary work groups whose members apparently are only cursorily checked for expertise before joining. As their website informs the curious:

> *Note*: Membership of a Cochrane group is not based on formal qualifications. There are no membership fees. The key requirements are that you:
>
> - have suitable skills (and willingness to learn new ones);
> - can volunteer some of your time over an extended period;
> - work as part of a team;
> - support the aims of the Collaboration; and
> - share the Collaboration's spirit of goodwill.

3. There is what I believe to be a pseudo or rhetorical debate, principally in one mental health profession, social work, about whether we can call individual interventions/treatments/therapies EBPs. For example, is it legitimate to label the application of apparently effective set of exposure-based therapies for anxiety EBPs or only recognize a singular technical process of evidence-based mental health practice with no well tested individual treatments permitted to be called EBPs? Some social work academics have even titled their work, "Evidence-based *Practices* Do Not Exist" (Thyer & Pignotti, 2011). Stating emphatically that "[t]here are no scientifically justifiable lists of evidence-based practices (as a noun)" (Thyer & Pignotti, 2011, p. 333). To test this very provocative but perhaps widely held belief, I undertook a search of the relevant literature in the ProQuest databases of MEDLINE and PsycINFO on October 2, 2012, using "evidence-based practices" as either the subject term or as the title term. Surprisingly, there were, from 1999 to 2012, 687 scholarly works published on these "non-existent" practices. Interestingly, every EBM originator discusses such evidence-based entities in their oeuvre (see, e.g., Crites et al., 2009; Ellis, Mulligan, Rowe, & Sackett, 1995; Glasziou, 2002; Gray, Haynes, Sackett, Cook, & Guyatt, 1997; Randolph, Haynes, Wyatt, Cook, & Guyatt, 1999; White et al., 2011). In fact, Dr. Haynes (2004), perhaps EBM's foremost publicist, recently emphasized as he urged more inclusive contributions to EBP that "policy makers and managers are essential to the provision and organization of services so that evidence-based practices and procedures are available and accessible when needed" (p. 407). Regarding specifically the social work domain, there were 74 publications using the term *evidence-based practices*. The social work journal publishing most such articles was *Research on Social Work Practice* with 11 articles. The take away from this little exercise, I believe, is that perhaps some confusion exists among some academics about terminology, semantics, and meanings regarding EBP and its technology. But both EBM practice as a conceptual process model and specified evidence-based treatments/therapies/interventions/policies as EBPs are conventionally accepted as useful concepts by most of those interested in these issues and, most importantly, the creators of the EBM enterprise themselves also see it that way. Although these sorts of academic imbroglios can be entertaining, reminiscent of the schoolmen's discussions in the Middle Ages of how many angels may fit on the head of a needle, this is a distracting academic semantic sideshow to the real question of what the helping professions can effectively do to ameliorate difficult human travails.

4. I will review ACT, the most well promoted of *validated* NIMH mental health EBPs that has also been found to be so by the Cochrane Collaboration (Marshall & Lockwood, 2004), in detail in the second article in a forthcoming issue of this journal uncovering what has not been uncovered by the current tools of both the EBM and EBP processes regarding the nature of that treatment.

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