

From chapter 1:

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A Critical Look at ESTs.

The RCT design was developed in medicine to establish whether new drugs are superior to placebo or current treatments, and psychology has imported that design for its EST protocols as a way of testing effectiveness of psychotherapy. Drug companies assure purity of the physicians prescription of medication, but there is no such explicit, uniform way of characterizing psychotherapy interventions. The problem is addressed under the EST model by requiring psychotherapies be manualized, and by assessing therapists for adherence and/or competence in delivering the treatment before they begin (and sometimes during) participation in a study. ESTs are established by experiments that conform to medicine's randomized control trials (RCTs). Subjects are assigned to an experimental or a control group, and the proof of effectiveness is a significant difference at the .05 level in a reasonably large sample. Replication of results at different sites provides the strongest evidence of effectiveness.

The reason treatments for non responders cannot emerge from the EST paradigm is that nonresponders are not eligible to participate in EST (or RCT) research protocols. A survey of psychiatric and psychological treatment

studies (Benjamin, 2006) provided examples showing nonresponders are directly or indirectly excluded. EST studies rule out patients who: are chronically or acutely suicidal; repeatedly hospitalized; have been “nonresponsive to comparable treatments,” or qualify for several diagnoses (i.e. are highly comorbid). Unfortunately, these exclusionary rules are major markers of the nonresponder population. Not only does selection of subjects for ESTs screen out severely disordered nonresponder patients, but the EST reports rarely provide detail about noncompliance or withdrawal from protocol in their estimates of effectiveness. If, for example, a patient has to be removed because of deterioration, he or she often is classified as a non completer, reducing the sample size, but not affecting the estimate of effectiveness¹. Most ESTs drop subjects if they miss a specific small number of sessions; nonresponders are notably irregular and even if allowed to begin treatment in an EST protocol, are likely to be dismissed for noncompliance.

If compared to treatments for cancer, it appears that in enthusiasm for ESTs, psychology has decided that therapy can be delivered only for stage one, or at most, stage two psychological “cancers.” More severely disordered

¹ This problem was reviewed by LaValley (2003), who noted that “intent to treat” analysis inherent in RCT trials means there must be an outcome report for every subject assigned at the time of randomization. He found that 13% of 249 medical studies described as “intent to treat designs” were not analysed properly. Fifty – five % of the remaining “intent to treat” studies did not provide detail adequate to assess whether withdrawals or noncompliance affected the findings.

cases are not to be addressed by service, training or research because they cannot come under the umbrella of EST and RCT² practices.

Effectiveness studies of IRT

An IRB approved research protocol has been in place for the past three years at the IRT clinic. Subjects are consenting participants drawn from a population of patients referred by their physicians for clinical purposes. The IRT treatment consisted simply of a 90 minute consultative interview with Benjamin (described in Benjamin, 2003, chapter 2) followed for a few inpatient sessions conducted by closely supervised IRT graduate student trainees. During the consultation, the patient and the interviewer develop a case formulation that addresses the presenting symptoms, including suicidality. A small percentage (10 to 15%) of consultative patients go on for long term outpatient IRT with a trainee.

A pilot report (Critchfield, Benjamin & Dillinger, submitted) shows important changes when the prior year is compared to the year following the consultation. Significant decreases in annual means were observed in number of suicide attempts (1.91 dropped to 0.36), number of days in hospital (21.73 days dropped to 5.45), and number of hospitalizations (2 dropped to 0.73). Despite the apparent severity of the cases, so far, a careful scan of public records suggests we have had no deaths in any patients seen in the 3 years the clinic

² Of course nonresponders could be randomly assigned to different treatment groups. But the RCT design also requires a pure sample and relatively large N. Non responders are almost always highly comorbid, and, when treated by psychotherapy, likely to be so time intensive and difficult to hold in treatment, that is it hard to collect large N, even if highly adherent, competent therapists are available.

has been operative. This can be interpreted in the context of a relatively recent survey (Bostwick & Pankratz, 2000, p.1928) that reported the lifetime mortality rate for hospitalized psychiatric inpatients in general is over 8%, and the fact that most deaths by suicide occur within 3 months of discharge (McKenzie & Wurr, 2001). If the mortality rate is this high for all inpatients, it likely is higher for the subset of nonresponder patients who usually have high risk features such as recurrent suicidal acts, repeated hospitalizations, and large prior numbers of days in hospital. These results suggest that the brief IRT intervention helped reduce suicidal behaviors and deaths. Nonetheless, we do not imagine there was personality reconstruction of the sort we have seen in the (relatively few) long term clinic outpatient treatments conducted by trainees, or in our private practices³.

³ Ken Critchfield, Ph.D., Research director at the IRT clinic, and Kathleen Levenick, M.D., director of the Madison, Wisconsin IRT training program, and I, all have private practices specializing in IRT. There, we usually see people who are functioning reasonably well, but who have tried many therapies to deal with intractable depression that can include private, chronic suicidality, or unremitting anxiety, and/or difficulties with aggression that bring them to the court's attention.