Healing or stealing: Ethical issues surrounding subjectivity and "fudging" in clinical trials in dermatology

***Dear Dr Dermatoethicist:* During a screening visit for a clinical trial, I found the patient's skin assessment score borderline for enrollment into the trial. Just as I was about to inform him that he is slightly below the severity score needed to enroll into the study, he expressed his desperation to be enrolled. He asked if I could "fudge" the scores to "make them work." He explained that Food and Drug Administration-approved treatments are too costly and that this trial is his only hope at living a normal life again. What is my ethical obligation?**

— Dr Conflicted

***Dear Dr Conflicted*:** Assessment of disease severity in clinical trials in dermatology depends upon inherently subjective, rater-dependent scoring systems. These scoring systems are used as a means of collecting data throughout the study and to determine eligibility for study inclusion. Within the construct of the scoring system, there is substantial room for the evaluating dermatologist to adjust assessments by exploiting subjectivity in the evaluation of a patient's disease severity. These adjustments occur when an assessor believes that he or she could reasonably choose between 2 different severity scores, and then choses the score that most benefits the assessor's intentions for the patient. This action differs from lying, in that there is no intent to deceive, only conscious bias.

Patient enrollment is the lifeblood of clinical trials, and investigators often feel pressure to meet enrollment goals. Falsifying data to facilitate enrollment is unethical,[1] and owing to the exchange of money involved, deliberately enrolling ineligible patients could be viewed as fraud. However, it is important to note that although compensation might be a motivating factor, there is an altruistic, patient-centered underpinning to enrolling patients in clinical trials. Many patients are desperate for effective therapies and cannot afford available alternatives. Likewise, future patients depend on therapies that can only become available if a trial shows safety and efficacy. Consequently, it could be argued that investigators are adhering to the ethical principles of autonomy and beneficence by exploiting subjectivity in assessments to ensure that a patient receives treatments that he or she desires, and the public gains access to novel therapeutics.

This argument is countered by a deeper understanding of the pernicious effects of subjectively adjusting clinical trial data and how this action relates to the core values of medical ethics, namely nonmaleficence and truthfulness.[2] Truthfulness underpins the entire drug-approval process, and laxity with truthfulness compromises scientific integrity. The minimal benefit that might be gained by altering an individual patient's assessment is far outweighed by the potential detriment to the patient, investigator, sponsor, scientific community, and the public.

Although it might be tempting to see inherent subjectivity as an opportunity to justifiably influence a certain outcome, every effort should be made to adhere to the standards established by the designated skin assessment system. It is therefore important for investigators to be particularly aware of the subjectivity associated with skin assessments and to remain vigilant about biases and influences to avoid compromising the ethical principles essential for clinical trials.

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