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Editorial Open Access

Selection Criteria in Clinical Trials: A Clinical Conundrum

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Editorial

Imagine that for the past two years, you have been caring for a previously healthy 45 year old patient with metastatic genitourinary carcinoma. After exhibiting only a partial response to first and second line combinations of chemotherapy and radiation therapy, several bony metastases re-emerge begin to show signs of aggressive expansion. You have determined he would be the perfect candidate for a Phase 2 randomized controlled trial (RCT) at a nearby academic center and, with cautious optimism, explain the potential of the new agent being investigated. You are nearly set to proceed when suddenly you are informed that the patient does not qualify for the study on the grounds that they do not satisfy one small detail of study's numerous enrollment criteria. You carefully review the inclusion criteria, and it turns out that patients with a remote history of vague seizure-like activity after a sports related concussion as a youth and therefore must be disqualified. Frustrated, you argue that his seizure-like activity was remote, not straight forward, not unusual after an acute head injury, and in no way associated with chronic epilepsy, and has no clinical impact on his underlying fitness to participate in an RCT. But these arguments will ultimately be made in vain, as seizure disqualifies the patient regardless of etiology. These criteria are set in stone.

This has become an increasingly frequent occurrence for clinicians as we are faced with an ever expanding number of inclusion and exclusion criteria in RCT protocols. It raises both ethical and academic questions. While the ethical dilemma of restricting treatments to only the most robust and fit patients can be justified by the need to amass a data set with a minimal number of confounding variables, there is also the question of external validity. With an ever increasing number of exclusion criteria included in RCTs, are we reaching the point where these sample populations no longer represent the real-world clinic patients that these drugs are intended to treat?

This is not to say that standardized recruitment to RCTs isn't essential. Strict inclusion criteria maintains high internal validity, minimizes any confounding variables, and helps ensure that a causal relationship can be established between the interventions and outcomes at hand. However, as the criteria for what should make up an RCT sample population become increasingly restrictive, several troubling phenomena arise. It should be apparent that patients that are ineligible for RCTs have significantly worse outcomes than trial-eligible patients. But how do we manage these patients? With an absence of any well-established studies, these patients can often be relegated to choosing between dubious, potentially dangerous therapies lacking any real scientific data for their populations, or palliative, end-of-life measures.

Fortunately, several potential solutions have gained momentum in recent years to address the increasingly restrictive environment of larger RCTs. Individual providers, for example, have the ability to longitudinally track treatment responses in their own patient populations, without the constraints present in a larger RCT. Retrospective real-world data may not be as robust as RCTs, but certainly provides insights for patient populations who would never be eligible for trials. Other alternatives include extracting data from expanded access programs, single center studies, community networks, national registries, international chart reviews, and insurance company databases, among other big data solutions.

In a world where the outcomes of RCTs can make or break major pharmaceutical companies, it is unlikely that cherry-picking of RCT subjects via restrictive inclusions/exclusion criteria will improve. Therefore, clinicians must be saavy as they evaluate data and extrapolate findings to apply to their own patients that may be very different that those who were enrolled in pivotal studies.