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"Clinical Trials Design in Operative and Non Operative Invasive Procedures"

By Kamal M.F. Itani and Domenic J. Reda, editors, 2017, 495 pages, Springer, $149

Review by Norman M. Goldfarb

"Clinical Trials Design in Operative and Non Operative Invasive Procedures" is a solid handbook for clinical researchers plus content tailored for surgical studies, such as the following chapters:

- Quality Control in Procedural Studies
- Pilot Studies
- Surgeon Training and the Learning Curve
- Using a Placebo or Sham Procedure as a Control: Ethics and Practicalities
- Patient Recruitment and Retention in Procedural Trials
- Equipoise in Interventional Trials

The chapter on surgeon training includes the following excerpt:

Introduction

With every intervention, procedure, interpretation of a test, or even new medical treatment, there is a learning curve. This learning curve differs among providers based on background, training, skills, environment and available support, as well as the similarity of the new intervention to older ones. In addition, moving beyond the learning curve to experienced provider in a new intervention is open to interpretation based on the observer, his/her background within the field, and the observer status on the learning curve for that intervention.

When testing a new intervention in a prospective randomized trial, the investigators will have to decide on the level of expertise of each participating investigator, their standing on the learning curve, the level of expertise that each has to achieve prior to enrolling patients, how it is measured, and ethical considerations related to patients and society. This chapter will discuss each of these points and how to address them within a large prospective randomized clinical trial.

Definition

The learning curve has been defined as the time it takes and/or the number of procedures an average surgeon needs to perform independently in order to reach a reasonable outcome. Others have represented the learning curve as the variable, such as operating time, complication rate, hospital stay, or mortality. A learning curve may also be operationally defined as an improvement in performance over time. It therefore implies a baseline performance, an improvement over time, which can happen at various rates of speed, and a plateau in performance afterwards. The speed with which a plateau is achieved is dependent on the initial performance level and the rapidity with which the improvement occurs up to the plateau. Depending on the learning-curve phase, lack of investigator equipoise might exist, favoring

traditional interventions during the baseline or improvement phase and possibly favoring the newer intervention during the plateau phase.

(a) Baseline performance

Baseline performance depends on the individual baseline skills and familiarity with similar interventions or exposure to similar interventions in the past. For example, an orthopedic surgeon performing hip or knee replacements might be comfortable with one or two prostheses that are commonly used. However, when a new prosthesis is introduced into practice, it might require a new set of skills, some of which overlap with the old ones and some which are totally new. The level of overlap is also dependent on the type of prosthesis the surgeon was using.

(b) The improvement phase

The improvement phase is also dependent on each individual surgeon's background with the technology, learning abilities, as well as the environment in which they practice. The environment might have other experts able to provide feedback about progress, a larger volume of patients to be treated the newer intervention, the availability of cadavers, animal labs, or simulators to practice. All of these will factor into the speed at which the plateau is reached.

(c) Plateau phase

During the plateau phase, the individual is considered familiar, comfortable and experienced in performing the newer intervention and should be able to teach it to others interested in acquiring these skills. The assessment that the individual is at the plateau phase is arbitrary and can be a function of reported volume, time, observation or a combination of all the above. Any auditor of this new technology should be at the plateau phase.

The book includes 54 chapters, by 45 contributors, in 11 sections:

- Basic Principles
- Study Designs
- Statistical Considerations
- Ethical Considerations
- Considerations Specific to Surgical or Procedural Trials
- Regulatory Considerations
- Common Errors
- Adjuncts to Clinical Trials
- Budgeting
- Funding
- Publication

Reviewer

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