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"Manual for Clinical Trials Nursing, 3rd Edition"

Angela D. Klimaszewski, Monica Bacon, Julia A. Eggert, Elizabeth Ness, Joan G. Westendorp, and Kelly Willenberg, editors, 2015, 644 pages, Oncology Nursing Society, $140

Review by Norman M. Goldfarb

"Manual for Clinical Trials Nursing, 3rd Edition" is a comprehensive handbook for clinical research nurses, study coordinators, clinical investigators, and others involved in the conduct of clinical trials, especially complex oncology studies.

The following excerpt illustrates the sophisticated yet practical content in the book:

Physician/Nurse Adherence Issues

Armed with all of the knowledge and interventions, patients' chances of being nonadherent are diminished. Clinical trial nurses (CTNs) are the hub of the wheel. Physicians, patients and ancillary staff should work closely with CTNs who guide all through the trial. If a patient calls a physician and is given permission to change his or her next appointment, or to take less than the number of pills required to maintain adherence, then the issue is lack of CTN involvement and physician education. Educating physicians regarding the protocol and protocol requirements is vital to the successful completion of a study. CTNs should make every effort to see patients with the physician to avoid errors. But, with all of the patients and multiple protocols, mistakes can still occur. To prevent inadvertent physician nonadherence, patients should be taught to call their CTN if they have problems with making appointments or need to change an appointment, taking the prescribed treatment, or with any other aspect of the clinical trial.

CTNs should make physicians aware of required laboratory tests and scans and ensure they are ordered appropriately. Chemotherapy orders are written or entered in the electronic medical record by CTNs at some institutions and reviewed and signed by a physician. This provides a double-check mechanism to ensure that the treatment dosages and modifications, if required, are correct. CTNs should see each on-treatment patient to ensure that medications, performance status, and side effects are documented and that patients are monitored closely following institutional guidelines.

CTNs may be nonadherent to the protocol because of a lack of training and serving in multiple roles, such as a staff nurse or nurse navigator. Clinical trials are becoming increasingly complicated and require strong attention to details. Many trials have companion studies embedded within the primary study, adding to the complexity. Most studies now incorporate quality-of-life questionnaires that need to be done at specified time points. As protocols become more complex, it is important to review the components of each study. The majority of studies are opened at an institution based on the request of a physician, and this is especially true in the community setting. CTNs should be able to review the study prior to it being opened and verify that the necessary resources are available to conduct the study at that institution.

The book includes 62 chapters by 97 contributors in 11 sections:

- History and Foundation
- Clinical Trials: Fundamental Information
- Product Development, Review and Approval Process
- Financial Factors
- Recruitment and Retention
- Clinical Trial Participants
- Genetics and Genomics
- Documentation and Data Management
- Quality Assurance
- Professional Development of Clinical Trial Nurses
- International Clinical Trials Research

The book is available in bookstores.

Reviewer

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