Category: Training & Quality Assurance – Work in Progress

Peer-to-Peer Quality Chart Review

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1. Background

Regulatory audits and inspections can happen at any time and the onus is on the study team to always be 'audit ready'. While addressing findings in monitoring reports is an important step in the audit preparation process, deficiencies and subsequent responses are seldom shared outside the study team and rarely inspire organizational quality improvement initiatives. The Helen Diller Family Comprehensive Cancer Center (HDFCCC) at the University of California San Francisco (UCSF) developed and implemented an internal peer-to-peer chart review process aimed at not only improving data accuracy, but building a culture of quality improvement and higher standards.

2. Goals

The chart review process was designed with the following objectives:

1. Ensure patient safety and quality data;
2. Ensure workflows, policies and regulations are followed;
3. Identify training gaps; and
4. Develop corrective and preventative action plans.

Additionally, the peer-to-peer review process is an opportunity for clinical research staff development.

3. Solutions and Methods

A comprehensive checklist was developed by a working group from each program at the HDFCCC. Each month, clinical research staff in each program review a pre-defined number of study charts, including charts completed by new staff, new studies and a random selection of active patients. All CRCs have at least one chart reviewed per year.

The results of peer-to-peer chart reviews are reviewed in two phases: monthly at program specific internal reviews where individual personnel training gaps and program specific workflows can be identified and addressed; and quarterly at HDFCCC wide reviews where common oversights and omissions are identified and overall process improvement can occur across the entire organization. The two step review of findings ensures communication and immediate action first within the program, then organizational training and workflow gaps are discussed in groups with representation across the entire HDFCCC.

4. Outcomes and Future Directions

In the first 12 months of implementation, 182 charts were reviewed using the comprehensive checklist. The most common findings were documentation of eligibility and timeliness of investigator review. Sponsors have anecdotally commented that study charts are cleaner and staff doing the chart reviews

have developed a better understanding of processes, workflows and the purpose of clear and concise documentation.

Clinical research staff buy-in into the process and its objectives was fundamental in the success of the initiative. The focus of the initiative is continuous improvement and education, and not another onerous, ineffective and inefficient process.

As the initiative moves into the second year, efforts are underway to examine the trial portfolio in each program and tailor the chart review based on the external oversight already in place. Additionally, a system for a cross-program review of charts is being developed to ensure high standards are consistent across all programs.

Policy review is a key component of the review process, and while policies have been updated overtime, older trials were following old policies at their inception. The version of the policy at the time of procedure execution, and the implication of changes in the new policy, need to be considered in future chart reviews.