UCSF Helen Diller Family Comprehensive Cancer Center

Peer-to-Peer Quality Chart Review

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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 improving data accuracy, and building a culture of quality improvement and high standards.

Methods

A comprehensive checklist (Figure 3) was developed by a working group with representation from each clinical research program at the HDFCCC. Each month, clinical research staff in each program review study charts with a focus on:

- Charts completed by new staff;
- New studies; and,
- 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 within each HDFCCC clinical research program. Programmatic reviews identify individual training gaps and areas for process improvement in program specific workflows.
- Quarterly HDFCCC wide reviews. Center wide reviews identify common oversights and omissions across the organization, and areas for overall process and training improvement.

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.

Outcome

In the first 12 months of implementation, 182 charts were reviewed (21% of all therapeutic accruals) using the comprehensive checklist. The number of findings per chart decreased from 2.6 to 2.1over the year. 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 need for clear and concise documentation.

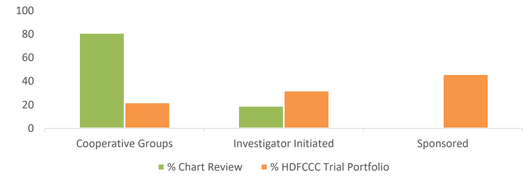
Policy review is a key component of the review process, and while policies have been updated over time, older trials were following older policy versions when they first started. The version of the policy at the time of procedure execution, and the implication of changes in the revised policy, need to be considered in the review process.

Clinical research staff buy-in into the process and its objectives was fundamental in the success of the initiative.

Future Directions

As the initiative moves into the second year, efforts are underway to:

- Examine the trial portfolio in each program and tailor the chart review priorities based on the external oversight already in place.



- Establish a system for a cross-program review of charts to ensure high standards are consistent across all programs.
- Formalize the quarterly review of findings and update policies, guidelines and training based on findings.

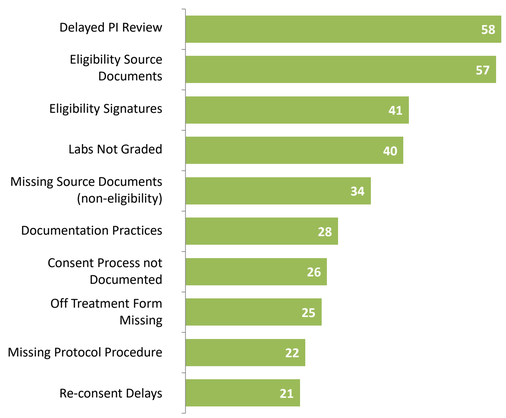


Figure 1: Top 10 Observations by Category
Primary observations found in first year of chart review implementation. The most common findings were documentation of eligibility and timeliness of investigator review.

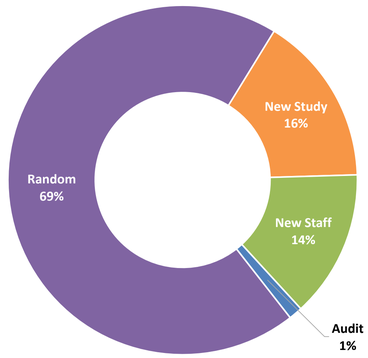


Figure 2: Reason for Chart Review
Most charts were selected at random and unexpected, 1% were selected as part of sponsor audit preparations.

Figure 3: HDFCCC Chart Review Checklist