Development of a Competence-Based Quality Assurance Program

R. Kingsford, J. Espinosa, S. Sharry, J. Moehle, L. Lujan, T. Werner

Huntsman Cancer Institute, University of Utah

1. Background

One of the largest challenges plaguing cancer centers is turnover among coordination staff. Oncology clinical trials are becoming increasingly complex in an industry that is already highly regulated. In our experience, it is difficult to recruit coordinators who have previous experience in oncology. Over the past 5 years, we have focused on developing a robust and comprehensive training program to get new coordinators able to function in their roles as soon as possible. Given the volume of information in the form of regulations, standard procedures, and institutional policies relayed in the training program, it is not possible for new staff to retain all of the necessary concepts. In order to address gaps in retention, Huntsman Cancer Institute (HCI) Clinical Trials Office (CTO) leadership is in the process of developing a competence-based quality assurance program.

2. Goals

There are 4 primary goals of the HCI CTO's competence-based quality assurance program:

1. Create a culture shift of proactive process improvement rather than reactive corrective action plans.
2. Identify retention gaps to provide re-training.
3. Highlight necessary modifications to the training program.
4. Provide opportunities for professional development for our coordination teams.

3. Solutions and Methods

The Competence-Based Quality Assurance Program consists of 3 phases:

1. Administration of a general competence exam. The competence exam will be administered to new employees at approximately 3 months from hire. The exam is delivered in an open-book, proctored, online format and consists of general questions surrounding key concepts of Good Clinical Practice, HCI CTO standard operating procedures, and institutional policies. The exam is mapped to the individual training courses. If a coordinator misses the majority of the questions on a specific content area, the coordinator will be required to attend the associated training class again with additional mentorship in this area.
2. Task-based competency assessments. New staff will be required to demonstrate competence on individual tasks (i.e., scheduling a monitoring visit, conducting and documenting informed consent, etc.) prior to being authorized to complete them autonomously. Competence assessments for new staff will be completed by senior staff who have demonstrated competence.
3. Quality assurance chart reviews. New coordinators will have 5 charts per month reviewed for months 3-6 of the new employee's hire. All coordinators past the 6-month mark will have 2 charts per month reviewed on a continuing basis. Chart reviews consist of review of the database including metrics such as number of queries, data completion percentage, etc. The

reviews will also include assessment of adherence to departmental documentation and Good Clinical Practice standards.

4. Outcomes

Development and refinement of this important project is ongoing. Determining the important concepts and procedures considered to be essential for coordinator competence has led to some modifications of the training program.

5. Lessons Learned

Identification of staffing resources to create and maintain this program is challenging, but the HCI CTO is committed to the investment. As the program is further developed, adjustments will be made to the training program to address deficiencies as they are identified. We look forward to reporting progress on this critical project in a future abstract.