Category: Trial Recruitment & Study Conduct (IIT) – Work in progress

Improvement in Adverse Event (AE) Review Times: Piloting the Epic AE Module and New AE Collection Workflow

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1. Background

At Weill Cornell Medicine Meyer Cancer Center (MCC) Cancer Clinical Trials Office (CCTO), paper adverse event (AE) logs are used for collection, grading, and attribution review. The logs are completed by research coordinators who extract AE information from clinic notes in the electronic medical record. Completed paper logs are brought to the investigator for grading, attribution, and wet-ink signature. Data are transcribed from the AE logs into the electronic data capture (EDC) system. This process is redundant and prone to delay and error. To streamline procedures and improve AE review times, the CCTO piloted the use of the electronic Epic AE Module with the Lymphoma Research Team.

2. Goals

The Lymphoma pilot set out to evaluate the impact of the new AE collection workflow and the Epic AE Module on average time to collect and review AEs. The goal was to decrease the average number of days to capture AEs and have them reviewed, graded, and attributed by treating investigators within five days by shifting AE collection from a task performed after visits by research staff outside of clinic, to one performed by clinic staff.

3. Solutions and Methods

Clinic staff were instructed to capture AEs using the Epic AE module on the day they were reported. AEs were routed in Epic to treating investigators for review. Investigators were instructed to complete review within five days of AE collection.

Forty-five subjects with visits in the six months prior to the pilot and 47 subjects with visits after the pilot were reviewed for AEs. Forty-three AEs reviewed using paper and 39 AEs reviewed using Epic were identified. The date each AE was reported in clinic and the date of investigator review were collected. Difference in days between the date AEs were reported and the date of investigator review was calculated. Mean Days to Review was calculated for both paper and Epic.

4. Outcomes

Mean days between study visit and paper and Epic review were 61 days and 11 days, respectively. The ranges for paper and Epic were 184 days and 47 days, respectively. Figure 1 shows days to review for each group. One out of 43 paper AEs and 13 out of 39 Epic AEs were reviewed within five days.

5. Lessons Learned and Future Directions

The new AE workflow and use of the Epic AE module decreased review timelines. Despite the reduction, AEs were not reviewed within the targeted five-day timeline. Further evaluation of research coordinator and investigator timelines will help identify bottlenecks and direct education and oversight to help bring review of AEs closer to the five-day goal. It was unclear how much improvement in timelines was due to establishing expectations and moving the workflow into clinic versus being due to using the electronic Epic system instead of paper. The MCC CCTO plans to roll out the new AE capture workflow and use of the Epic AE module across all research teams. An analysis following the broad roll out is planned to measure the impact of the new workflow and Epic AE Module across the entire MCC CCTO.

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