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Streamlining the Collection of Adverse Event Data

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Introduction

Adverse Event (AE) data collection and reporting are key components of any clinical research study. To protect subject safety, research sites should report AEs to the sponsor and IRB in a timely manner. However, these reports are often delayed when the data are incomplete or there are conflicts between documents, wasting staff time tracking down and reconciling the data. If correct data are not obtained quickly, it may never be available. To address these issues, we therefore conducted a small experiment to improve AE report accuracy and timeliness, while also increasing staff efficiency in a consistent process.

Methods

We modified our existing process with two interventions:

- We replaced two paper source document forms with one consolidated electronic "research note" in our electronic medical records (EMR) system. This form included AE reporting. (See Figure 1.)
- In the old process, the study coordinator frequently left the exam room after conducting the visit, leaving the subject to wait for the investigator for a discussion of AEs, concomitant medications, treatment plan, etc. In the new process, whenever possible, the study coordinator remained in the exam room until the investigator arrived and then participated in a three-way discussion.

Figure 1. Research Note Adverse Event Line Item

AE (CTCAE)	Dates	Grade	Relatedness	Alternate Etiology	Action Taken:	Comments
	Start: End:	[ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5	[ ] Unrelated [ ] Unlikely [ ] Possible [ ] Probable [ ] Definite	[ ] None [ ] Study Disease [ ] Pre-Existing [ ] External Factors	[ ] None [ ] Withheld [ ] Reduced [ ] CC Med/Procedure:	

In our oncology unit, we observed 11 pre-intervention subject visits and eight post-intervention subject visits, collectively conducted by five of the six study coordinators and six of the 12 oncology investigators at our site. We considered AE reporting complete when the study coordinator received the electronic AE report signed by the investigator, which included diagnosing each AE and assessing it with the Common Toxicity Criteria (CTC) for severity and relatedness. During the experiment, we collected data on over 160 AEs, none of them Serious Adverse Events (SAEs).

Once the pre-intervention data were collected, a small group that included three study coordinators, individuals from our compliance and contracting departments, and representatives from the Medical Center's information technology (IT) department met for two days to discuss the best approach. Based on our conclusions, we created a standard visit and AE collection process, along with an electronic visit template that incorporated all the data elements required at each visit. (Note: This template is not yet fully structured with fields for all individual data elements.) Using this template, we created electronic forms for each study visit during the experiment.

New Process

The new, standard process for AE data collection and reporting consists of the following steps:

Coordinator creates list of potential AEs

1. At the beginning of study, create list of potential AEs using the informed consent form or package insert for reference.

Coordinator prepares for subject visit

2. Update research note form based on AEs observed to date. Identify AEs requiring attention with red highlighting.

Coordinator conducts subject visit

3. Record study data in research note, updating any continuing AEs and adding any new AEs, along with concomitant medications and any other pertinent information.
4. If AE(s) have been reported and the investigator is not already present, wait until he or she arrives to assess the AE(s).
5. If the primary coordinator cannot stay, obtain presence of back-up coordinator and brief on AE(s).
6. Optionally, review AE(s) with investigator outside exam room.
7. Discuss AE(s) with investigator and subject in exam room.
8. During discussion, complete research note with AE diagnosis, severity and relatedness assessments per the investigator.
9. Obtain investigator's electronic signature (with date stamp) on the electronic research note.
10. To avoid discrepancies, investigator dictates his or her standard clinic note using AE data from the research note.

Results

Using the new process and forms did not increase the time spent with subjects during visits, since the primary change was the presence of the study coordinator during a three-way discussion. The wait time for the investigator averaged six minutes (0 to 21 minutes range). In some cases, the study coordinator left the exam room during this period to complete other tasks. The entire discussion time averaged 36 minutes, with a range of 14 minutes (low complexity) to 82 minutes (high complexity), typical for oncology studies. During this discussion, the average individual AE was covered in 1.1 minutes, with a range of 7 seconds to 10.5 minutes, and all the AEs were covered in an average of 7.5 minutes, with a range of 2.3 to 22.4 minutes.

These discussions improved the quality of the data, for example, by resolving ambiguities in terminology, e.g., "cold" vs. "upper respiratory infection." In most cases, final AE reports were available immediately to submit to the sponsor and IRB. In addition, the wait time was

more than by offset by the time previously consumed in following up on and reworking the typical AE report (based on fading memories). Also, the investigator left the exam room with complete data for dictation of a consistent clinical note.

The time required to obtain the investigator's assessment of AEs decreased from an average of 17 days to only 45 minutes (including the discussion of concomitant medications, treatment plan, etc.) (In some cases, although the AE report was complete, it took up to 15 hours to obtain the investigator's eSignature.)

Study coordinator and investigator satisfaction increased because the new process saved everyone time and aggravation. Study subjects also appreciated hearing the discussion and contributing when appropriate. They also had more confidence in the care they were receiving.

Conclusion

Although the experiment tested two interventions simultaneously and did not generate statistically significant results, the results justified implementation of the new, standardized process, which has been well accepted by investigators, study coordinators, and subjects.

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