Module 7: Quality Control and Assurance

Introduction to Quality Control and Assurance

Welcome to the seventh module in the Social and Behavioral Research Best Practices course. Here we'll cover the basics and importance of good quality control throughout the course of a study. Let's get started by hearing from Morgan, a principal investigator. During a recent study she needed to apply for grant funding after she had already collected some data and, as a result, encountered a few challenges along the way.

Morgan's Grant Process

My team and I were in the middle of an exercise study to address pain and physical function in adults with symptomatic knee osteoarthritis. We got to a point where we were nearly out of money, and needed to find more funding in order to complete the research.

We had a grant mechanism identified, but the grant agency was asking for a lot of detail about our data. Unfortunately, we had had a lot of staff changes and computer problems at the time, so we were behind on our data entry and the quality of data procedures were lacking. This was making it harder to compile and report our results.

A Difference in Questioning

During this study, we had one person, Marisa, who was responsible for conducting the walking tests with participants. Unfortunately, at one point Marisa was out sick for a couple of weeks and another team member had to take on her responsibilities. Marisa had been asking participants how they felt AFTER they finished the walking test, as the protocol required. But, since Marisa had been out, another team member, Sam, was asking participants how they felt BEFORE the walking test…and the responses were

radically different. Participants interviewed by Marisa often responded as feeling fatigued, where participants interviewed by Sam generally felt less fatigued at the time of questioning.

Kilograms or Pounds?

Another difficulty we encountered during this study was a discrepancy in the units of mass we used to weigh participants. Some of the data was recorded in kilograms and other data was recorded in pounds.

Course Study Manual

Take a minute to explore the Resources section in the top right corner of your screen. Here you'll find your Social and Behavioral Research Course Study Manual for this module covering quality control. Be sure to print this before you continue.

Throughout this module you'll be able to pause the course and take notes specific to your institution. In the end, you'll have a roadmap to a successful social and behavioral research study.

Overview of Quality Control and Assurance

Quality assurance is defined as "All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented ad reported in compliance with Good Clinical Practice and the applicable regulatory requirements."

So what does this mean? In general, quality assurance refers to the planned actions during a trial which make sure you are doing the right things in the right way.

Quality control refers to the actions that stem from a quality assurance plan. It's formally defined as "The operational techniques and activities undertaken within the quality assurance system, to verify that the requirement for quality of the trial-related activities have been fulfilled." In other words, quality control makes sure the results of what you've done throughout a study are what you expected.

Developing and sticking to your procedures manual is key. This helps ensure that the right people are performing a task and have been trained to do so. Just as you probably don't want your accountant to fix your broken refrigerator, you don't want an untrained team member collecting data. Once quality procedures are put in place, accountability is vital. Every team member has to be held to a high standard.

The Roles

At the end of the day, data quality is everyone's responsibility. It's about being a proactive member of your research team. Consider this Golden Rule of Research: everyone has their own duties, but everyone is responsible for ensuring quality. Typically, team members are responsible for making sure that proper procedures are outlined in the clinical protocol and procedures manual, and that everyone on the study team has access to them. If a study team includes a coordinator, this role can often fall to him or her. Additionally, team members can take actions to ensure quality data is collected. Often times, research assistants collecting data from participants and team members responsible for data entry play this role by checking that the collected data is accurate and complete. Sometimes these roles are performed by the same person.

Importance of Systematic Controls

Systematic controls are a great way to periodically take stock of how well data and processes are being maintained. Take a moment to remember the most successful study

you've ever been involved with. Did everyone know their roles? Were there regular training sessions to make sure everyone was on the same page? Did everyone know how data would be collected? If you answered yes to all of these questions, it's likely that your successful study had systematic controls in place. If you answered no to all these questions … let's fix that. In the next few minutes we'll review some pre, mid and post study strategies for good quality data management.

Reporting Guidelines

Not surprisingly, the data collected during a study should be as accurate as possible. This can be done in a few different ways. A study team should make sure that a standard has been established for all data that will be collected.

Data can be captured electronically which will help to avoid any transcription errors. On the other hand, paper data collection can easily be checked at the moment of completion to review for any missing or incomplete responses. If surveys are collected online, this may not be possible. When using surveys for data collection, it is recommended to use validated surveys that have been rigorously vetted. These will yield data that is responsive to change in your population, and be more generalizable to other studies.

As study procedures are administered, any oddities in the data should also be recorded according to indications made in a Procedures Manual. For example, if a participant is physically unable to perform a strength test during their study visit, that field should not be left blank, but should be marked as N.C. or Not Collected, along with the reason why. This will let anyone reviewing the data at a later time get a clearer picture of the participant visit. Not Applicable or Not Valid designations can also be used. These

classifications, while not a requirement, will ensure proper data collection and recording while also providing a first step toward data quality.

Random and Systematic Error

Bias in research studies may influence raw data or the interpretation of data. Whether in the study design, data collection, or analysis phase, bias can lead to errors, which makes it harder to evaluate the true association between an intervention and study outcomes.

Errors might be random or systematic. Random errors occur in all research studies and measurements, and are due to implicit and unpredictable variations in the sample or measurement process. When designing research studies and protocols, attempts should be made to minimize random errors as much as possible. For example, a random error can occur during range of motion measurements that use a goniometer and an anatomical landmark, which may vary between participants. Landmark variations occur naturally, are unpredictable, and therefore random. Another example of random error is a walking test in which some participants feel fatigued or depressed and, as a result, walk more slowly than other participants. Again, this kind of error includes variability in the participant sample and cannot be controlled or predicted by a study team.

Systematic error, however, occurs when every data point within a study is exposed to the same set of errant circumstances. This type of error is usually related to imprecise calibration of study equipment, or differences in observations and measurement by either study staff or participants. A good example of this is an uncalibrated scale which affects all participants in the same, consistent way. As a result of this error, all the participants appear to weigh five more pounds than they actually do. This type of error

can be mitigated with proper and diligent calibrating processes and continual education of staff.

A common source of systematic error is that of participant self-selection into a study. Participants who agree to be in studies may be characteristically different than those in the general population a study team is trying to sample. For example, in an exercise study which requires frequent in-person sessions, people who choose to participate may be more motivated and are able to travel to the center easily, which may not be the intended population of interest.

Overall, random error happens in every study and can cause noise in the data. On the other hand, systematic error may result in the study sample misrepresenting the population for whom the research team wants to generalize their findings. Although it's difficult to eliminate all errors, in order to minimize them, proper protocols and procedures should be put in place before a study begins.

Measurement Error

One type of error that can be minimized is measurement error. Measurement errors can affect the quality of the data. For example, say a survey question asks a participant to assess their pain severity. Does this mean pain right now or pain over the course of a day or week? Is it overall pain or pain in a particular area of the body? How participants interpret this question will lead to bias if clarifications aren't made to prevent it.

Influence of Time

For the most part, instances of bias are unintentional and can often stem from a lack of time. During a participant visit, the highest priority should be placed on the safety of the participant, followed by data collection. For example, perhaps to get the most out of a

participant's limited time, it is decided that altering the order of activities will make the process more efficient. This rearrangement could have an effect on your data. It won't be surprising that participants asked to complete a strenuous exercise test and then answer a question about fatigue will respond with a higher rating than other participants completing the same activities, but in a different order.

Any situation where the clinical protocol is not adhered to - even in the slightest way - should be documented and, depending on reporting requirements, reported to your I.R.B.

Additionally, the time of day or year during which data is collected can affect answers provided by participants and should be considered when planning the study.

Take a moment to pause the course and make note of an instance of bias you have experienced in your Course Study Manual. How could you address something like this in the future to avoid bias?

Transcription Errors

Typing or transcription errors are common. Very often the person entering data can mistype and hit the four key when they meant to hit a seven.

Encourage team members to slow down and take their time when entering data. This will help to minimize mistakes and an incorrect analysis later on. Additionally, it's a good idea to keep all source documents from a study, in case there is a need to verify any possible transcription errors.

During a study, a team member might need to read someone else's handwriting and derive meaning from it. However, not everyone has the same level of legible handwriting.

Your data management plan should include strategies for checking the data for typos, out-of-range data, and information that has been read differently by study team members.

Avoiding Bias

In the Research Protocol module of this course, we discussed the importance of treatment fidelity. Remember, treatment fidelity involves making sure that the actual intervention of a study is conducted as the clinical protocol specifies and that the intervention is received by the participant as intended. As part of this effort, procedures manuals are written to help minimize bias by describing specifically how tasks must be completed. So, it stands to reason that if you deviate from a protocol, you're opening yourself up to bias and potential issues when interpreting data.

To minimize this, provide team members with continual training and communication to help prevent deviations and ensure that everyone understands the importance of data integrity. Also, if frequent clinical protocol deviations, such as a repeatedly missed study visits or incomplete assessments occur, this can be an indication that there are problems with the protocol and that an amendment may be needed.

All in all, maintaining treatment fidelity over the course of a study will help minimize the risk of bias that can result from both systematic and random errors.

Quality Control and Assurance Strategies

It's rare that a study will go off without a hitch. The best a research team can do is be proactive and implement controls to prevent and anticipate issues before they arise and learn from them when they occur. What are some good strategies to avoid the pitfalls we've just discussed? Click each strategy on screen to learn more.

Create Structured Procedures Manuals

Begin with a structured procedures manual that outlines the activities of a study. In this document, try to anticipate any unexpected circumstances that might come up and provide a solution.

Develop a Data Management Plan

Data management plans are a part of every study. This document should be readily available to all team members and clarify how data will be selected, collected, analyzed, handled and published. Teams should also have statistical procedures in place to handle any missing or outlying data.

Develop Standard Rules for Recording Data

Within the procedures manual, there should also be an outline for standard reporting rules. This will help study members understand the data they should be capturing and how it should be recorded. For example, make note of how many decimal places a value should be recorded or what unit of measurement should be used. These rules should also outline where data is to be stored. A secure, designated server is often the best place.

Check Your Work

Create a checklist to ensure that interventions are carried out as stipulated in a clinical protocol document and in as consistent a way as possible. These checklists should include a data check to make sure that all questions and answers have been received from the participant before he or she leaves.

Sign Your Work

Minimize questionable data by having the team member who is collecting data write their name or initials on any source documents so they can be asked about something later.

Audit Data Collectors

Periodically check in with team members who are collecting data to ensure that they are following protocols and maintaining treatment fidelity. Data should be clean and reliable.

Audit Participant Files

Routine checks of participant files for completeness and accuracy are always a good idea. Additionally, double data entry significantly lowers the error rate in a data set, but it isn't enough to enter data twice without comparing the two sets. It's recommended to audit your data regularly.

Make Decisions

As part of a double data entry process, there will be discrepancies. In these situations, who gets to decide what is "correct"? This decision should be made by someone who is not actually entering the data - usually the P.I. or data manager. Once a decision is made, it should be documented in a place that is accessible to all team members.

Communicate as a Team

Communication is key. When there is open communication among team members and with participants, everyone is on the same page and better data can be collected. A great time to communicate as a team about potential quality issues is during a regular team meeting. This is also a good time to share raw data with the team.

Learn from Every Study and Everyone

So how do you implement all these strategies from here on out? Quality control and assurance is a skill that is learned and improved over time. All study teams should make it a priority and because of this, we can all learn from ourselves and each other.

Throughout the course of a study, make note of lessons learned and how you should do things differently. Also, take advantage of those who have gone before you. Mentors and colleagues are a great resource! Chances are you work in an institution with someone who has encountered the exact same situation. Ask them questions! Two or three brains are always better than one.

Course Study Manual Check-In

By now you should have filled in the Quality Control and Assurance section of your Course Study Manual. If you haven't, take some time to complete this job aid. And don't forget to check out the Resources section for additional information and links, as well. When you're ready, click Next to move to the final assessment for this module.

Lessons Learned

Now that our team has been through the process of gathering data for the grant proposal, we're definitely aware of some of our deficiencies in data management and collection. Moving forward, we're going to strive to be the epitome of quality.