

## **SUMMARY OF MODERATOR NOTES FOR OFFICE OF RESEARCH AND DEVELOPMENT (ORD) TELECONFERENCE**

Date: June 3, 2004  
Time: 1430 to 1520 (EST)  
Dial in Code: 1-800-767-1759  
Access Code: 32976  
Moderator: C. Karen Jeans, MSN, CCRA, CCRN

*(This represents an informal summary of the above-noted teleconference. Some statements may have been left out inadvertently; this is not intentional. The summation is written in the first person with exceptions as noted.)*

### **Purpose of Monthly NCQA Teleconferences**

Let's get started. My name is Karen Jeans, and I am a part of COACH (the Center of Advice & Compliance Help within ORD) and I would like to thank you all for taking this hour out of your incredibly busy schedules to take part in this teleconference which is sponsored by the Office of Research & Development. We hope that you will find this useful. This is the first of a planned series of monthly teleconferences which are specifically designed to accomplish two purposes: (1) disseminate useful information to assist VA institutions in preparing for the NCQA accreditation process, and (2) provide an avenue for networking.

In terms of getting out useful information concerning NCQA accreditation issues, this teleconference is a progression of different mechanisms that are being utilized to help. The first mechanism was the ACE! Training workshops that were held in October and November of last year and February of this year. Workshops of that nature are great ways to get large volumes of information out, but it's not practical to do a workshop every six months.

The second mechanism is the frequently asked questions (FAQs) located on the NCQA website. How questions get posted is that I keep a log of every contact concerning an NCQA issue. There are questions that are consistently asked by a variety of people. I contact NCQA or they contact me if the same thing is happening on their end, and we write a series of questions. Once the questions and answers are agreed upon by NCQA and ORD, there is a sign-off process and NCQA posts them on the website.

The third mechanism is the ACE! Tools. This will be discussed in a few minutes on the agenda when we discuss the PRIDE website; this is the fourth mechanism is these teleconferences. In terms of frequently asked questions, one question that I get asked frequently is where do we currently stand in terms of VA sites that

have gone thru their surveys and what is the plan for the next months in terms of sites that are going thru. So, to answer that, I am going to ask Paula Schlichter to talk to us about this.

### **Current Status of Site Survey Visits**

Paula's initial comments were to commend all of the VA institutions for their hard work and to convey Dr. Cates' appreciation of their {VA institutions} work. Paula discussed that a total of 24 VA sites are NCQA accredited. Seven (7) are accredited for a period of two (2) years and 17 are accredited for three (3) years. NCQA plans to conduct surveys of VA institutions at a rate of four (4) a month and the schedule is completed through March of 2005. The seven (7) VA sites that have two (2)-year NCQA accreditation were accredited under Version 1.1. A question was asked if there was a location where VA sites could find out who had received their accreditation decisions; Paula discussed that this was located on the NCQA website.

### **PRIDE Website**

I want to talk about the PRIDE website and tools that are on the website. To get to the PRIDE website from the VA R&D website, just go to "hot topics" and there's PRIDE. You can go thru the VA R&D site and click under "hot topics. Once you're in the PRIDE website, there are two key topics in the toolbar at the top of the page that I want to tell you about. (1) If you enter the "NCQA Accreditation" section, you will find the link to the FAQs that are on the NCQA website as well as a copy of some of the conference materials used during ACE training and the NCQA Standards. If you go to the top of the navigation section and click on the word "resources", you will find a variety of items. Specifically under the word "tools" you will find three (3) NCQA tools that are based on what was presented during ACE training. However, they are not exactly the same tools that we used; they been tweaked and modified to make them more useful.

Together, these three (3) NCQA tools are similar to the NCQA Data Collection tool and are called the (a) Individual Study File tool, (b) Documented Processes and Reports tool, and (c) Pharmacy Review Tool. Instructions for completing each form within each tool are included.

One (1) of these tools is something that was developed after the ACE workshops, and that is the investigational pharmacy evaluation tool. This pharmacy evaluation tool in particular is unique in that it contains a lot of information in the comments section that is not in the NCQA Accreditation Standards and represents information that reflects the evolution of how the pharmacy elements are being evaluated. This tool in particular will be modified within the next two (2) weeks because I want to include some of the information that I'm going to give you today. All of the tools have version dates. The version date of the pharmacy evaluation tool is May 18, 2004. The feedback that I have

received from sites that have used the pharmacy tool has been positive, but it {pharmacy tool} still needs some minor modifications.

### **Key Issues in NCQA Accreditation Preparations**

So, before I address these questions on the agenda, I still want to spend a few minutes hearing from you on this topic: what do you see as the biggest obstacle or issue in terms of the NCQA Accreditation Process?

Comments from teleconference participants included the following:

1. Concerns on NCQA evaluation of minutes from VA IRBs using MIRB.
2. NCQA evaluation of the 12-month documented processes criteria for sites already accredited and preparing for renewal.
3. Clear guidance on content of the Memorandum of Understandings (MOU) for non-affiliated institutions merging with small VA Human Research Protection Programs.
4. Clear guidance on content of Memorandum of Understandings (MOU) for VA institutions working with other institutions.
5. Lack of communication with small VA institutions on NCQA scheduling and arrangements necessary to undergo accreditation (consolidation).
6. Waiver processes for a non-affiliated IRB.

Paula discussed that there has been extensive work by ORO and ORD on the MOU issues, but that this is a very complex document with issues that are being worked on by numerous individuals. I also discussed that while it is very frustrating to not have this guidance that is needed today, it is more important to get clear guidance out on the MOU than guidance that doesn't make sense just to get it out. However, this information will be conveyed to Dr. Cates and we will get work to get these issues addressed and put these on the agenda for next month's NCQA teleconference. These issues need to be addressed and this is why this teleconference is being held.

### **Key Issue #1: On-Site Pharmacy Survey for Evaluation of Category INR, Elements 4B and 4C**

The reason that I have put these questions down concerning the pharmacy evaluation for this teleconference is that these questions are continuing problems. Based upon the written standards, you can't find the answers. Each one of these questions will become a frequently asked question on the NCQA website. So, let's start with the first two questions because they bleed into each other. These questions deal with on-site investigational pharmacy evaluation, which are addressed in Category INR, Elements 4B and 4C on pages 16-18 on the NCQA Standards Version 2.1.

*Question A: What is an “active” investigational drug study?*

*Question B: What is the current methodology NCQA uses to select investigational drug studies for the on-site investigational pharmacy evaluation?*

Initially, NCQA used a convenience sample to figure out which studies would be selected during the on-site investigational pharmacy evaluation. They went to the site, and selected at the site. That is not what is being done now. Instead, there has been a column added to the application form that asks the site on the Protocol Listing Worksheet to indicate if the protocol involves drug; this in and by itself is not a sufficient screen. Based on my conversation with both Maureen Amos and Debbie Dasguta this week, they indicated that after NCQA receives your application, your contact person from NCQA will be talking with the site contact person and the pharmacist to figure out which studies are eligible for evaluation during the on-site visit.

When you read INR Element 4B and it states that NCQA selects three (3) active studies, the question is what an active investigational drug study is. For practical purposes, an active study is one in which subjects may be enrolled. For NCQA purposes, an active study is one in which a subject has been enrolled in the look-back period and was dispensed study drug during the look-back period. It narrows the numbers of studies that are eligible for pharmacy evaluation. The surveyors know which studies will be evaluated for the investigational pharmacy prior to actually getting to the pharmacy, which is the appropriate way to do this.

Discussion was held concerning clarification of the word “enrolled” vs. “dispensed” for NCQA purposes. Discussion was also held on how NCQA randomizes pharmacy studies vs. IRB files for those sites undergoing a full NCQA survey. Unlike the IRB file reviews, at the present time NCQA is not going back in three-month increments and choosing the three (3) pharmacy studies for the on-site NCQA evaluation based on when study drug was dispensed to the subject. All investigational studies which are eligible for NCQA evaluation are randomized based on the 12-month look-back period.

Clarification on which entries NCQA will be evaluating will also be discussed. Because the entire NCQA evaluation is theoretically based on a 12-month look-back period, pharmacy entries on an investigational log for subject dispensing that occurred outside of the look-back period will not be evaluated. This is consistent with information that was received from NCQA in December of 2003 and has been verified through both information from NCQA and information from sites that have undergone NCQA pharmacy evaluation in 2004. If there are only two (2) subjects enrolled who were dispensed investigational drug in the look-back period, the study is still eligible for NCQA evaluation if the investigational drug is targeted stock. NCQA is not using criteria of a minimum of five (5) subjects per investigational drug study for NCQA pharmacy evaluation.

Another query that was asked concerned the status of revision of M-2. While there is a concerted movement towards revision of M-2, I do not know the current status of this revision, although this was discussed at the AO meeting in Washington, D.C. in February, 2004. This will be put on next month's agenda to allow time for getting factual information on the current state of the revision.

*Question C: In ACE! Training, NCQA explained to all sites that the investigational pharmacy must keep the most current version of the protocol in the investigational pharmacy. How is this evaluated during the on-site investigational pharmacy survey?*

Question C references INR, Element 4C. It was made very clear by NCQA (both Marianne Smith and Jessica Briefer French) at ACE! Training and at the AO meeting with the investigational pharmacy sessions that the VA Pharmacy Service must keep the most recently approved version of the protocol in the pharmacy. The question becomes this: How are the surveyors validating approved protocol versions in the investigational pharmacy? In reality, they are not going back to the IRB files and validating that the protocol in the pharmacy is the most recently approved version. Per Debbie and Maureen, they are looking for some type of documentation that will allow them to validate that protocol as an approved protocol. They both suggested that a copy of the R&D approval letter be in the pharmacy file to help the surveyors. Some sites put the version of the protocol on their 10-1223. But NCQA is not looking that the pharmacy has all of the amendments.

Discussion of whether amendments constituted a current protocol was held. NCQA does not care if the VA Pharmacy Service has the amendments; it needs to evaluate whether the copy that the VA Pharmacy Service has is indeed valid. Although they (Jessica Briefer French, Marianne Smith, and Michele Straus) have stated for consistency's sake that the VA Pharmacy Service should have the most recently approved protocol, what has been previously explained a few minutes ago is how NCQA is evaluating the factor. Questions were asked concerning how the pharmacy could consider itself having an approved protocol if it did not keep have a copy of the amendments in their files. I discussed that there is a difference between amendments and protocols and that the local VA can do whatever it wants to do concerning interpretation of this Factor. If the local VA HRPP wants to require the VA Pharmacy Service to keep every amendment as well as revised protocols, that is fine. It is not necessary for NCQA. The purpose of this teleconference is to explain what NCQA is evaluating and what sites should be prepared for to get past this Factor evaluation.

Questions were also asked concerning an opinion of whether the IRB letter or R&D letter should be included in the VA Pharmacy Service file. Form 10-1223 is required to be sent to Pharmacy Service and some sites are including information concerning the protocol in the comments sections. However, per

INR, Element 4B, the approved protocol date that NCQA uses in its evaluation of the Investigational Drug Log is the R&D approval date. Therefore, in my opinion, it would be advantageous for the R&D approval letter to be in the VA Pharmacy Service. Again, this is not a requirement; the purpose of this teleconference is to relay information on what NCQA is seeing and what they would suggest sites to do to prepare; this is one of those recommendations that sites can do or choose not to do.

*Question D: How are informed consent documents evaluated during the on-site investigational pharmacy survey?*

Question D is simple and references again INR, Element 4C. How NCQA evaluate the informed consent forms during the on-site pharmacy evaluation? This is the method that is currently being used as per Debbie and Maureen: They already know that subjects have been enrolled. They will ask the investigational pharmacist how many subjects have been enrolled, and then look at all of the subject informed consent forms. They are only looking for subject signature and dates. They are not looking for signatures of anyone else; including the individual who conducted the consent process. However, they are looking to see what version that subject signed. Because of that, both Debbie and Maureen stated to me that they recommend that for this evaluation of informed consent forms, that the investigational pharmacist keep the entire executed subject informed consent form copies in their files. This is just a recommendation. As they stated and I confirmed again, the investigational pharmacist can keep the last page with the subject signature and date as long as a version number or something that allows tracking to occur is there, but this one of their suggestions.

*Question E: What can be entered as “control numbers” on investigational drug logs for purposes of NCQA evaluation during the on-site investigational pharmacy survey?*

Question E is a short and simple question, but very frequently asked. What can be used as a control number for NCQA evaluation purposes? They don't care what you use, as long as it is an identifier that allows for tracking of what drug was given to which subject. You can use a patient number, just don't leave it blank.

*Question F: What suggestions have NCQA made for sites preparations of the on-site investigational pharmacy survey?*

1. Make sure your investigational pharmacist has been given a copy of the standards during the site preparation process.
2. Be able to produce a list of “active” studies where a subject has been enrolled with dispensed investigational drug during the look-back period.

3. Keep a copy of the R&D and IRB approval letter that confirms the protocol within the VA Pharmacy file is approved with the study file documents in the Pharmacy.
4. Keep all pages of the executed subject informed consent forms in the investigational pharmacy if you are not using a log method.

Questions were asked concerning the most common problems that NCQA has encountered in prior pharmacy on-site evaluations. The most common problem that NCQA relayed to me {Karen Jeans} was lack of documentation concerning the expiration date for evaluated drug logs. NCQA stated that this was a problem in the initial evaluations of Version 2.1, but has improved dramatically as information has been conveyed about the importance of having an expiration date or having a letter or confirmation through e-mail from the sponsor that the sponsor is keeping up with the expiration date.

To end this up, I have a list of items that are key issues, but I would like to know what you think is a key issue for next month. My list includes different methods institution can use to evaluate investigator compliance per INR, Element 5A without hiring auditors. Comments from teleconference participants included:

1. HRPP auditing techniques,
2. Affiliate IRB issues,
3. Small VA site issues,
4. ACE! Tool does not have Exempt Reviews, and
5. Guidelines for investigational devices.

The call concluded at 1520 hours (EST).