

## **MCHB/EMSC Webcast**

### **Intra-Abdominal Injury Trial Room DB**

March 18, 2008

JENNY WADE: Hello and welcome to the Intra-abdominal Injury Trial Room DB and if you're watching this you're a new study coordinator to the study. We're here at the CDMCC in Salt Lake City, Utah and you'll be hearing talks from myself and Anna Davis. Anna Davis is the data manager for the study and you'll be receiving quite a few emails from her and myself regarding data entry quality or changes to our data, or pretty much anything that has to do with the study you'll be hearing from us. Today Anna will be talking about trial DB. If you have a computer with Internet access with you, you can follow along. And she'll also be talking about the query manager. Here is Anna Davis.

ANNA DAVIS: Hello. I just would like to first introduce the website that we're going to use for data entry for the ab. trauma study. It will be in the link I send you with your username and password. And that website looks like this. To log in, you enter your username, and then your password. And you'll be asked to change it the first time you log in. If you have any problems with that, you can email me. It also has links at the bottom that allowed you to change your password at any time as well. The studies that you have access to will appear in this white window to the left of the screen. I have access to the intra-abdominal injury study. If you're involved in other studies in the network, they'll be listed here. To access this particular study you can click -- double click it or click it and press select. Once you're in the database, the patient I.D. window, which is the first one here, shows you the patients that you've entered into the database.

Our site, this is a test site, begins with EM20 and every site begins with this acronym. It refers to the network EM, emergency medicine 20, which is the protocol number for this study. Every site has a four-character acronym, since we're in Utah our four character acronym is UTAH and a four-digit patient number that begins with 1 and sequentially numbers down as you add patients to the study. If you request a patient be deleted that patient number will no longer appear in this list. You may see it jump -- for example, if I requested that Utah patient 4 be deleted, once that was done, you would see this list say 1, 2, 3 and skip to 5. So to enroll a patient in the study, you have to first click on the view demographics button, which is right here at the bottom. These are all buttons that you'll use to create new forms and add new patients, etc. Actually, you're going to add a new patient so you're going to actually click on this button right here. If you want to view data on existing patients, you can click on that patient, show all forms for the study, new data, and below displays a list of patient forms that have been entered for that patient. To view that form, you click on the view/edit button and that form will show up. To close the form, you just select close and it will take you back to the main screen where you can navigate to other forms. You can also move this box around by hovering your arrow over the whitish gray bar so you can see more buttons. The screen resolution I'm using a pretty large. If you'd like to adjust your screen resolution so you can see more on your screen, you can do that. That's just with your computer setting. So to view the demographics for this patient, which aren't contained on form 1, they are on your paper form 1 but the demographics are actually a separate component in the electronic data that we use, the data system. You were still selected on patient 1 and you can see that it's kind of a grayed-out box here. That's the patient that you're on. And you can view the demographics that were entered for that patient. You can also change demographics if you need to by going into this screen. You can view the enrollment data for this patient by selecting view enrollment and see what the enrollment data looks like. To go back you're

always going to just say enter or edit or clinical data, which is essentially back. That just means you're going back to the clinical data so that's everything aside from demographics and enrollment.

So I'll show you how to create a new patient. Notice that the last patient we've entered is Utah patient 36. To add a new patient you don't have to be selected any patient in here, you can just click this button, add new patient and the first screen it brings you to is the demographics. Notice it says auto generated for patient I.D. It is not going to let you generate your own patient I.D. It will do that automatically. Just enter a birthday and the 6. If you've selected it -- what is listed here on other you'll need to enter that there and an ethnicity. Once you've done that, you can generate the I.D. and enroll the patient. This is just a box that comes up saying you'll delete your entered I.D. but you haven't done that. It will always pop up and you'll press okay. Now it's brought us to the enrollment screen and it says that our patient -- we're enrolling the patient Utah 37, which was the last number that which was the next number due to be created. You'll enter the investigator at your site. I'm just going to randomly select one and select enrollment and the date that you're entering the data. You're going to save your enrollment. And then go back to entering your clinical data. Now when you look at the list and scroll to the bottom you see the new patient you've created at the bottom of the list. Sometimes when you're creating a patient, if you miss a step, you won't see the patient at the bottom of the list and the step that you would have missed is the enrollment screen. And I'll just briefly show you how to find that if that happens for you. So I'm going to act like I'm adding another new patient. You can enter your dates in a short year format, I believe. So if you're on the screen, the demographic screen and you click this interedit clinical data instead of proceed to enroll, you see it with patient 38, but you can't see patient 38 in your list. That's because you hadn't completed the enrollment for that patient yet. So to find that patient so that you can

enter enrollment you need to search. And you can type in EM20, your site number and then just a wild card and search. It will show you every patient that doesn't have an enrollment completed yet. You click on that patient and now you can view the demographics if you want. Just make sure it's the patient you thought you were looking at. Or you can just go to enroll patient and then it will bring you to that screen that you had missed before. Once you're done, just make sure you save your enrollment and go back to your clinical data main page. So to create forms for this study, you have to click on your patient that you've created first. And then you're going to start navigating around these event buttons.

There is different events for the study and different forms associated with those events. So the first event is the E.D. visit. Within the E.D. visit you have two forms that you can complete. The first one is a form 1 which is the E.D. data form. That's the form that the physician has filled out in the E.D. and given to you to enter in. The other form is a KAPPA form. Another physician filling out a form that has similar questions to the form 1 on the same patient to just verify assessment-type questions and compare two physicians' assessments of the same patient.

The next event phase is the double data entry. There is only one form associated with that. That's called the E.D. form DDE standing for double data entry. That form needs to be filled out and completed for every patient that has a form 1. So I'm just navigating back to the E.D. visit screen where I can see the form 1 and then the double data entry where we can see the form 1 double data entry. If you have not enrolled a patient, if you need to enrolled a missed eligible patient, that's where you'll just create the missed eligible form and no other forms need to be created because that patient was missed. But we do want

some basic information about the missed eligible and that's why you'll need to create a form 3. And note that if you create a form 3, you shouldn't have any other forms created.

The next phase -- these are the forms that the research coordinator or assistant at each site is going to be abstracting from the patient chart. The first one is a laboratory data form and that's form 5. That should be filled out starting using all laboratory data that is collected on that patient from the first seven days after E.D. triage. So you can start filling that out at any point but you should at least have started to fill it out by day eight. Because all the data is captured in the first seven days.

The next one is the imaging data. This is all the imaging reports, CTs, ultrasounds, MRIs, x-rays, any type of imaging done on the patient will be captured on this imaging form.

That's abstracted and entered by the research coordinator. The last form is the outcome data and there are three forms under -- that you will see -- actually, you may not see form 6C. I'm able to see it because I have access to that. That will be entered here at our site so if you do see it, you probably may just have view access rights and not entering rights for that form. But there are two forms that you're going to be entering as a research coordinator. But only one form that you're going to actually be gathering the information for. That's 6A and as you can see it has an RA after it, which stands for the research assistant. And that's the form that they fill out. The PI is the PI at your site. The site PI for the study at your site who fills out a 6B if certain questions are answered yes on 6A. You can refer for further details on which questions on 6A warrant a 6B being filled out by your PI. If your PI needs to fill out that form you're going to go into trial DB and click on 6B and enter that form here.

The last phase is the follow-up and there is just one follow-up form. It's telephone and mail survey. And that's what you'll be filling out for patients who are not hospitalized. If they're hospitalized you don't have to fill out this form. This is a brief form that just kind of wraps up data collection for that form, for that patient. And also if you had attempted to do follow-up on a discharged patient but they were lost to follow-up you'll fill out a few details on this loss of follow-up on the final status form as well.

That covers the forms that are eligible to be entered and that should be entered for each patient in trial DB. Now I'll show you how to create those forms. The process is the same no matter what form you're creating. If I'm going to begin at the beginning, I'll go to my ED visit and once I've got it clicked in this event box, I'll have to go to the actual form that I want to create and select it. So you just need to make sure you selected a patient. Patient 37 and a form. Once you've done that, you can open a new form and that's the button at the bottom left. You start entering your information and you can tab between fields.

Anything that is grayed out is a skip because I didn't enter other down here, this -- had I needed to enter a certification that wasn't on this list I would have selected other and this box would have lighted up and allowed me to enter information there. You'll need to enter the injury date and like I said, you can enter just a brief month, day, year format. And once you press tab it stores it as March 19, 2008. If you know the time of injury, you need to select whether you know it or not. And you'll be able to enter that. Times need to be entered in a military format without a colon. So if they were injured at 1:00 p.m. you'll need to enter 1300 like that. If you accidentally enter a colon, you'll get an error. And that's just to remind you to enter it in the format specified. You can proceed down and just enter information in. This history of injury I've skipped over entering a lot of data here for time's sake but I did want to point out a few other skip patterns that exist. Since there are many different types of injury mechanisms, we've attempted to collect things regarding the injury

mechanism using as few questions as possible. So depending on what you select as your injury mechanism, the fields below will light up if you need to enter anything else.

Examples, I select object struck abdomen. I won't be able to enter any of the motor vehicle collision things that apply but I will be able to enter specifics about the object that struck the abdomen. And I'm always able to enter a comment in this field below. This could be anything the physician wrote in the margin regarding the injury, but if it is truly an other category, an other mechanism, you'll need to enter that other mechanism in this other mechanism field right here. You can also enter a comment but it's recommended you describe the other mechanism as succinctly as possible in this box and if you need to add more information you can do so in the comments. And then these fields that come next will -- once you -- once I've answered yes to a particular parent question, the two child questions, 2A and 2B will now be able to -- they're grayed out now but as soon as I've selected yes and click out of that box, they'll light up for me to enter. Had I selected no, they would have remained grayed out. And when you get down to the score you can choose to just enter the components of the score and the totals will add up automatically or if you maybe don't have a component, but know maybe one or two but don't have all three, actually it would only apply if you only knew one, and you could enter an aggregate score. Please just enter all three or an aggregate score. For the vital signs you'll need to say whether the physician recorded a vital sign or they recorded unknown. Or not documented. Not documented is for you if you've looked in the chart. Vital signs can be abstracted by the RA or RC at the site. If you should only use not documented if you've looked in the chart and they aren't documented in the chart. Once I've selected yes, you can see the box lights up for me to enter systolic blood pressure. And if you enter a respiratory rate that's out of range you'll get a warning giving you the expected range. You're able to bypass this warning and leave it at that but please note you'll get a query if it's way, way out of range. The other fields on this form follow this -- the format of the

paper form and have the same type of skip patterns that I've mentioned earlier. That is if the parent question is negative or no, it's going to gray out everything that would follow that.

I just want to briefly show you how to enter more than one answer. For example, if you say yes to thoracic trauma, and want to enter more than one, more than one thoracic abnormality is checked on your form you'll want to enter more than one of those, you can do that by selecting the first one and then adding a record. And you can select as many as you need to. You can even select the same one twice. However, you'll get a query if the same one is selected more than once. If you accidentally added that last one, all you do is highlight it, select delete record, continue with the warning and it will be deleted. Once you're done with the form, you can either choose to mark it as pending if you need to complete some more data on that form or completed. Since I haven't completed entering data on this form I'll see if I can save it with it just being appending. This particular case, on form 1, it won't let me save this form as pending because I've missed entering some mandatory questions. So please don't start entering this form until you've entered all the mandatory questions and actually most all the questions on this form are mandatory. So it will tell you one by one which questions are mandatory but it's better just to, since those aren't in any particular order, the one that's lit up in pink here is the one that's telling me it's mandatory. But it's only going to tell me one mandatory field at a time. It won't light up all the mandatory ones at one time so I would be doing this for quite a while if I tried to save it each time. The next one it shows me that's mandatory is this one. So it's not in any particular order. So just to get out of this screen real quick I'm going to X this box and it's just going to let me know my changes aren't going to be saved and that's because I didn't complete all the mandatory questions and I'm going to say okay. And you'll just notice that for this patient that I've just tried to enter a form, it was -- it did store that form but none of

the data that I entered was saved. That's because, again, there were mandatory questions I didn't complete and it wasn't allowing me to save without completing them. So that is trial DB, I guess, in a nutshell.

Other forms are created in the same fashion by selecting the event and then the form on the right and opening a new form. Other forms aren't quite as long as the first form and don't have as many mandatory fields so they're easier to complete. For example, the laboratory form, there may be times when you just don't have any lab results to record and if you select no and click off of that all the subsequent lab types are grayed out and you're able to mark your form as completed and save it. Once it's saved it will refresh and you're able to close that screen. If you at any time want to see all the forms you've entered for a patient, click on -- make sure you're on that patient, click on show all forms and view data and it will show you the two forms you've created for that patient. And what their status is. Who entered the form and then the date and then when the last modification of that form was made. If you need to print the forms for any reason, you're able to print them using these buttons to the right. And those will just not send directly to a printer but bring up a form that is then printable. For example, this is what the form would look like. And as you can see, it has all the questions listed but all the data is blank because that form didn't have any data in it.

So I'll briefly show you the lost to follow-up form. I think trial DB has just logged me out so I'm going to log back in. I'm not sure why it -- actually -- I'm not sure what happened there. Okay. There is the form. That must have been just a little glitch in the system but as you can see I went back into the main page and I still appear to be able to get into the forms. As I mentioned before, this form is required for all patients who are not missed eligible. If they're hospitalized or not sent home there is only really one button that you need to

answer and that is this first button, which is -- question, which is what is the final status and you'll complete this after you've completed all the forms. And you've selected they were admitted. Once you select that, the questions that pertain to lost follow-up are all grayed out and you can complete your form, save it and you'll be finished. If, however, your patient was discharged and you need to complete follow-up with the parents, you can select whatever the outcome of that follow-up was. Whether you were able to conduct that survey, whether the parents refused the survey, or whether the patient was lost to follow-up. Once you select that, then other options will be available. So if I've conducted the survey it's essentially the same as if I've completed all forms and the patient was hospitalized. There are no more questions to answer.

If parents refused the survey, I'll need to do lost to follow-up procedures and I need to select whether I've done those and what the outcome of them were -- was. And the same thing would apply to patients who you've not been able to conduct the follow-up survey by phone. You've sent a mail survey and you're not getting any response, they're also lost to follow-up and you'll need to complete the same questions. Looks like this particular form allows you to save even though you haven't completed all the data. In this case, you'll just get a query when you have missing fields. Now I would like to show you how to log out. And just pressing the red button. If you need to log in again there is a link to it here and these are the links I spoke about initially, which you can click if you forgot a password or you need to change your password. Here is a telephone number of support person at our site, at our center that will help you if you're having any technical difficulties with the webpage and the web system.

The next system I would like to show you is the query management system. You'll be getting an email with a link to this system as well. This system is separate from the trial

DB but they both work together and this system actually looks at data that has been entered in a trial DB and generates queries when data is not consistent within a patient. So if you've said that a patient was injured, after they were triaged you'll get a query. Or if you say that you -- that a patient had certain labs done but you haven't entered those labs or any number of things that could be wrong with your data, this system is designed to find and let you know about. And this is where you can manage all the queries that get sent to you. And your log-in will be the exact same log-in as you used to log in to trial DB. If you change your password in trial DB it will be synced to this system and changed in this system. When you log in it brings you to the first screen and these buttons -- the black button and the rest are blue, will change. These are -- you can think of these as tabs to navigate around this website. Since I'm on the search query tab that's in black. If I wanted to go to the search results query details, query reports, query review, any of these, once I select on that tab the rest of the tabs are the hyper links.

Your site, I have my test count I have access to three of our test sites here. And that's why I'm just able to see all of those. But yours -- if you have access to just one site will disappear here and you won't be able to change that. You can look at queries by what their status is, whether they're resolved or unresolved and also by like a sub status if you want to look at all your automatically-resolved queries versus your manually resolved and your pending and non-pending queries. Pending ones are all the ones you've requested a manual resolution for and haven't been resolved yet by the study data manager, who is me.

So for this site there is another quick way to look at all those queries. That's down at the bottom here. You've got the list of your total number of queries. The total number of your resolved queries, and the total number of your unresolved. And these are all hyper links

which allow you to just click on them and that brought me to my search results screen where I have essentially done a search for all my unresolved queries. And it's telling me that 105 queries have been returned and it's going to show me two pages of data if I've selected -- depending on how I've selected it to -- how many queries I've selected to show per page. Since I have 105 queries and I only have showed 100 results that's why it's showing me two pages of two available pages. I can change this setting here at any time. If I want to see 200 results per page, I can just type that in and select change and now I'm just going to get one page of data that I just need to scroll down to get, you know, to navigate around. There is a few columns of data here that show you details on the query. And again hyper links to get to the specific query. I click on the query I.D. and these are all unique I.D.s. And it will show me the query term and some boxes where I can add a note or request a manual resolution if I need to do so. You can always select back or you can select these buttons here to navigate around. If you select on the rule ID, you can go to just what the rule is that this query had violated. And this particular rule is rule ID704. And this is the rule that says the ED form has been pending for more than three days, please verify the information and save it as completed. If you want to look at all the queries you have for that particular rule, you can go back to your search results. You can actually go to your search query and specify that rule. I believe it was 740. I'm not positive. Make sure that you've selected all queries here unless you just want to see the unresolved ones and search. Maybe it was 704. And then it will bring up a list of all your rules, all the queries you have that were generated from that particular rule. To go another way to look at that is to select a report by rules. And I've done that by going into this query report tab and asked it to give me a query report by rules, which is -- this is telling me I selected that. And then I can select all rules or any particular rule that I'm interested in. If I were to just be interested in this same rule for demonstration purposes, I'll select that and select get report. And it will bring up a screen that shows me that I have seven queries. Actually, I'm sorry, I have

149 queries for that particular rule. Seven of them are unresolved and 142 are resolved. At any point you're able to go to user configuration and just change the appearance of your fonts and default number of queries per page, etc. So I would change my default to show me 100 queries per page. You can change that here to whatever number you want. Your fonts are changed here. Whether or not you want to view the grid or not, just -- that option just took away a grid. That will appear. If you have any questions navigating around this website email or call me. I don't mind calls whatsoever. I think it's helpful that we can talk through any problem that you're having.

There are lots of other little useful filtering options that you can play around with and sort of create and I think that's the best way to just sort of learn how to navigate. Please remember when you're done to log out and close your browser. Now I'm going to turn it back over to Jenny and she is going to explain a few helpful tools to get information through E-room and wrap up our city training for today. Thanks.

JENNY WADE: Hi, this is Jenny Wade again and I'll be going over E-room. If you haven't received an E-room account, please contact me. This is -- E-room is essentially a locked, password protected filing cabinet, essentially. All studies have an E-room so if you're involved in more than one PECARN study make sure you have access to each E-room. This is my main page after I've been logged in. This is the first page that I'll see. I'm going to go to the study abdominal trauma since I'm the coordinator for the CDMCC for the site. As you can see there are various other E-rooms that I could go to that help me with my job function. Okay, so this is the page that -- the main E-room you're going to see. And there are all these various I cons, if you want to learn more there is a link to the website and you can click on that and also find our newsletter and it will also describe all the other research that is going on in PECARN. This is helpful especially if you're new to the network, not just

new to the intra-abdominal injury study. There are a few files in here that you'll use more than others. Some you really won't use at all. I would say that the most important filing in here is the FAQ database. The frequently asked questions. I receive quite a few emails every day asking about eligibility, if a question is about how to fill in a form. Really anything to do with the study. If I receive a question that I think that other sites might also have, I will put it in the FAQ database. So here is the database, as you can see, you want to see what the status is of the question, make sure it's active if you're going to be using it to help guide you through the study. The topic and DCF, this first one is inclusion/exclusion criteria, DCF1 general. It will list a question and answer, date that it was entered, and if it's a question that is really -- a really important question, a new rule that we just created, then I may flag it. And then I've also just added a recent column called date reviewed.

Quarterly we'll be reviewing FAQs to make sure they're current. Here you may or may not see initials of who entered this frequently asked question. This question is what should an RA do if a clinician left an entire page blank and it's too late to go back and ask him or her to fill in the data? So here you just check to see if there are any questions that are retrospective variables in the room. You may or may not have become familiar with retrospective variables. We have a few that are able -- that you may complete after the clinician has finished. If they have left it blank. You want to enter the data into trial DB. The data that was actually completed. And for all blank fields choose physician did not answer. So those blank fields would be fields that don't have retrospective variables and the physician left it blank. You also want to send an email to Anna. Her email is listed here with the patient number and note stating that the fields were left blank. So that's just an example of an FAQ that's in there. If you want to, say, look for all the FAQs on DCF5 you can actually search for those and I am going to -- you'll want to come up to this search

field and I'm going to look for DCF5. I'll go into this search and click here. And scroll down. I'm going to uncheck everything. Except for DCF5. And there it is right there. Make sure nothing else is checked and then I'm going to press okay. So nothing has happened yet, so I need to hit find and that will activate the search. So now when I look down here in the topic, all of them should have DCS5 in them. This topic, for example, has inclusion, exclusion, DCF5, microscopic urine analysis and urine dipstick. That's the FAQ. This tool bar up here is great because you can just click on abdominal trauma E-room and it will take you directly back there. Another important folder is the move. The CDMCC will update the latest one. As you can see I have an open section and a hidden item section. We just have that here to keep track of old MUE archives. It will not appear on your screen. I'll close that down. So this is what will appear in your MUE. You have some sections that are quick links to your MUE. Torso diagram. If you click on it, it will automatically appear and you can get a quick look at what the torso diagram is if you would like to. And there you go. All right. Also it's separated into sections. It's over 400 pages and this tool really helps for you to go to specific sections especially if computers are a little slow. If I just want to look at protocol data collection, go into this folder and I want to just look at data collection forms and click it there. And then here it will just show me all the data collection forms from the MUE. There is DCF1, etc.

Okay. Go back into the main ab trauma page. Study updates and reports. Every two weeks the CDMCC will update the enrollment reports. The enrollment report form status organ injury and outcome report will be updated every two weeks. This is updated March 19th, so the next one should be around April 4th. There is also some older reports here that you can access. Every so often we'll run different reports than our regular scheduled reports. If you would like to access those, the demo graphics reports it's helpful doing your RIB renewals, we can run demographic reports for specific sites as well as the whole

study. That's a good tool. All right. Data collection forms, this is a folder that has all the data collection forms that you'll be using for the study. They're all PDFs and available here as well as Spanish telephone follow-up, surveys and mail surveys. Okay. There is section here RA tools. There is a few cheat sheets, guidelines at determining race and ethnicity. This is a good one if your ED clinicians are struggling to figure out what the race or ethnicity of a patient is. Missed eligible document. This is just -- it gives you -- I'll show you -- it gives you a rundown of possible -- I'm sorry, this is a letter regarding missed eligibles and the criteria. So we also have cheat sheets. Forms if you have an equivocal CT. So any form you really need to use for the study should be in this RA tools folder. We also have an IAI study directory. It's divided up by site of the study personnel. If you're wondering who the PI -- site PI for UC-Davis is, there you go. And also who is research coordinator is. It also at the bottom will give you CDMCC links, personnel as well as other co-investigators such as the study radiologist, Dr. Gorgeous. Back to the main ab trauma page. Protocol, we'll give you the latest protocol if we have any amendments. We'll provide you with track changes and a summary of changes. Quality assurance folder, this will provide you with quality assurance audits that we're currently doing. So essentially I'll send out on email telling you about the quality assurance and if -- I will put the results in this area. The quality assurance we have going on right now is of normal CTs and I'm having each site uphold three normal CTs in the trial DB. This is a really safe and secure area to look at this sort of data. Okay. There is the data management folder. This will give you trial DB startup guides and links to trial DB and the query manager.

Database deletion so you can see if your site -- how many patients have been deleted from your site as well as you can fill out a new trial DB user agreement if you're new to the study. Okay. There are various other folders which I'm not going to go into all of them. One good thing to check up on is essential documents finder. This folder will give you all

the information you need to put in your essential documents finder as well as a checklist. Conference call agenda and minutes. This will give you all previous called minutes, agendas from meetings, conference calls, etc.

Okay. Just take some time to go through and search through the folders. If you're having a hard time accessing certain folders, let me know. We do only give access to -- if it's site-specific material we only give access to that specific site. So that may be a reason why you can't get in. That is the basic trial DB. If you have any questions -- sorry, E-room. If you have any questions about it email me at any time.

Okay. Well, that is about it for our training. Thanks so much for taking the time to sit through and learn about trial DB, the query manager and E-room. Like Anna and I said before if you have any questions before, we're here to answer those questions and to help guide you in the study. So we look forward to talking with you and welcome to the Intra-Abdominal Injury Study.