

ProTECT III

BYOLECT III



Second Annual Investigators' Meeting
April 2011

Training QA Process of
Neuropsychological Outcomes

ProTECT III

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Initial GOSE, DRS and NOS-TBI certification

- **Who has to get certified?**
 - Anyone who will do the test
 - Must keep certification active by doing ≥ 2 every 6 months
 - Primary Site Investigators (GOSE only)
 - Can change yourself to “Waived” in WebDCU following initial certification if you will not/no longer administer the GOSE
 - Primary Site Coordinators (All 3)
 - Can change yourself to “Waived” in WebDCU following initial certification if you will not/no longer administer the GOSE
- **When should I get certified?**
 - We recommend you wait until about 1-2 months prior to your first outcome visit.
 - NIHSS 2 years

Initial GOSE, DRS and NOS-TBI certification

- Advice?
 - Don't take it too early. You will forget what you learned and expire.
 - It's hard (Especially the GOSE), take it seriously
 - Warning: If you fail, you have to talk to us before you can try again
 - Don't take it "just for fun"
 - We strongly recommend only maintaining certification for the number of people your enrollment can support. One primary and 1 back up is probably good (more on this later).

Training and Initial Certification Procedure for all NP Raters

- For NP, primary training was at the October 2010 Outcomes Meeting
- Those unable to attend will need to
 - Observe video of meeting
 - In person training by
 - Someone who did attend or
 - Dr. Felicia Goldstein or Dr. Angela Caveney
- Pass “test out” at site visit or send mock video ahead of time
 - Dr. Caveney or Goldstein will visit your site as close to your first testing as possible
- Receive Testing Certificate

Quality Plan (GOSE, DRS and NP)

- All Testing will be digitally recorded
 - Forms from selected visits will be requested for review
 - The first 5 visits for each Rater
 - A 10% sampling throughout the trial
 - Recordings, forms and data entry will be reviewed centrally
 - Feedback will be given for all reviewed tests (even if no errors)
 - Feedback
 - By email if less than 3 minor errors
 - If more than 2 minor errors or a major* error is found (within a single visit), a phone call may be arranged to discuss the problems
- *Major error = Any error that indicates a lack of understanding of the proper standardized administration of the test OR a scoring/data entry error that is large enough to change the interpretation of the data.
- GOSE major error = Any error that changes the final score

Remediation

- If more than 2 minor or any major errors are found on the 5th (of the first 5) tests reviewed or on any one of the randomly selected tests, the next test conducted by the same Examiner will be evaluated. Previous tests may also be requested depending on the nature of the error.
- If any Examiner continues to make multiple or major errors despite feedback, the outcomes team may discuss de-certification of this individual.

What is the source?

- DVD of the session or the paper forms?
- Because, as the consent stands now, we cannot keep the videos past 3 months, the paper must be considered the source.
- We have revised the consent to be able to keep the DVDs longer, so they may be used as the source.
- This will result in a change in the kind of feedback we can provide you and also whether we need to see corrections made to the paper forms.
 - This means less work for you and better feedback with the new consent
- So...the sooner you implement the new consent the better!
 - For those of you doing the video consent prior to the 6 month visit, consider re-consenting those people you test after you have IRB approval to use the update.
- We'll need you to tell us who falls under the new vs. old consent prior to our review.

Certification Expiration (GOSE & NP)

- If you do not test twice in 6 months, your certification will expire
- We will use the dates of May 1st and November 1st as static expiration dates
 - Therefore, the first period may be shorter (or longer) for you, depending on when you certify initially
 - 90 day grace period
- Re-training may also be required if you make repeated errors
- If you will not test another patient or will not “test out” a trainee, you can allow your certification to expire
- You do not need to re-certify until you need to do testing or training again (but, please plan ahead)

Avoiding Expiration of Certification

- As May 1 or Nov 1 approach, if you have not done 2 evaluations since the last static expiration date, you can either:
 - (Includes NP) Test real or “dummy” patients (record) before expiration date
 - Total of 2 (i.e., do either 1 or 2 more depending on how many you have done so far)

OR

- (GOSE/DRS only) Re-do online training

Retraining Following Expiration

- NP re-training includes
 - Observation of videotaped sessions (website)
 - Additional review of materials
 - “Test Out” with certified individual (or video submitted to Angi or Felicia)
 - Potentially additional site visits in a few cases
- GOSE/DRS re-training includes
 - Re-do online training modules

Update on Quality Reviews

April 29, 2011

Pass Rates for GOSE and NP Exams

	# Videos Reviewed	Pass Rate
GOSE	N=39	N=35 (90%)
NP Exams	N=34	N=28 (82%)

Common Reason for Questioning Validity of GOSE

- Interview not performed with an informant in order to verify the patient's self-rating
- Neuropsychological results are not consistent with the rating

Solutions

1. Make attempt to interview a collateral source
2. Speak with NP rater

Common Reason for Questioning Validity of GOSE

- Interviewer does not probe reason for patient being unable to perform an activity such as return to work (cognitive vs. physical vs. other such as not released by physician)

Solution

- Be sure to find out the reason: Could patient work, for example, from a cognitive perspective?

Most Common Reason for Failure of a NP Exam

- Incorrect test administration that affects the interpretation of the results

Gentle Reminders

- Please don't film patient's face
- Leave identifying information off the forms you mail to us (e.g., name, DOB)
- Put Patient ID# on every form
- Fill in all blanks on source documents (___: 003 vs 3)

Thanks



Questions?

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GOSE

Hints & Suggestions



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General Recommendations

...regarding the Glasgow Outcome Scale – Extended (GOSE)





Re-read the original training GOSE intro transcript presented by Joy Pinkerton

- That description is excellent and better than anything we can discuss here in the few minutes that we have.
- Re-reading that introduction again now that you've given the GOSE a few times may be even more helpful than when you read it originally.



Don't Be Afraid to ask too many follow-up questions

- They know this is research, so unless you're 100% certain, ask another question.
- As we feel pressure to make no mistakes, there is often a tendency to do 'less,' rather than 'more' (that way, we have less opportunity to do something wrong). It is OK to ask the same question repeatedly in different ways. We're not trying to win their vote.



Take Time and Build a Little Rapport

- We're all busy, but getting it right is important!
- While redirection is at times necessary to focus their answers, letting the participant go on a tangent can also be helpful by giving you greater insight into how they think.
- Don't worry about the GOSE taking an extended period of time. With practice, the time will decrease automatically.



Go Back and Slowly Read Through the Form Right After They Leave

- When you're so focused on the interview, it's easy to check the wrong box by accident.
- Sometimes it takes a little time for our brains to digest the information we received.
- Is the information consistent with what you already know about this participant from other sources?



*Go Back and Forth Between Participant
and Caregiver –they may disagree...*

GOSE – Participant
GOSE & DRS – Caregiver
DRS – Participant

- Beware of deficits to self-awareness
 - Take notes, but don't check the box...yet.
- Even if no awareness issues, some may be embarrassed about pre-TBI status: income, working history, education, etc.



Specific Recommendations

...Regarding GOSE Questions 5, 6 & 7



Q5 – Are they Currently Able to Work to Their Previous Capacity?

- Beware those that feel they are ready to return to full-time work, but have not yet entered the workplace.
 - Because they haven't yet returned, this question is hypothetical. They likely have not thought through all aspects of what returning to work means. You need to ask specific questions to get them thinking about it.
 - Inquire about fatigue and if they feel it would interfere with their returning to work full-time at this moment (reduced work capacity).



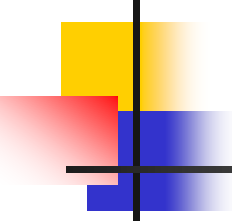
Q5 – Are they Currently Able to Work to Their Previous Capacity? continued

- Differentiate physical changes caused directly by the TBI, from peripheral injuries (amputation, compound fracture) sustained in the same accident. We're only interested in the TBI (central nervous system damage)
 - *"Let's say your leg and hip were all healed, do you think..."*
 - *"Would you/he/she need extra help, supervision..."*
 - *"What about fatigue, would that interfere with..."*



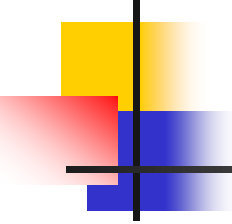
Q5 – Are they Currently Able to Work to Their Previous Capacity? continued

- Make sure they understand that this question is unrelated to them actually going back to work.
 - If applying for disability, they may feel obligated to say they cannot work.
 - They may feel they are ready, but simply waiting to get physician's clearance.



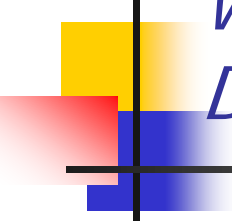
Q6 – Are They Able to Resume Regular Social and Leisure Activities Outside Home?

- We can't judge changes to social and leisure activities until we know what they were before the TBI.
 - Start by asking open ended questions about pre-TBI activities (“How did you spend your time when you weren't working?”)
 - Social activities with other people
 - Hobbies and other interests



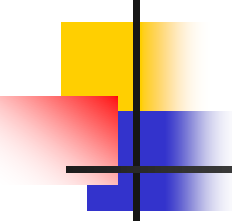
Q6 – Are They Able to Resume Regular Social and Leisure Activities Outside Home?

- Make sure the reason for change (if any) is related to problems caused by the TBI.
 - If he decided to stop hanging out with his old friends because they drank alcohol and used drugs, and he has decided to turn over a “new leaf”, then this is NOT due to TBI, even though the decision to make the change is related.



Q7 – Have There Been Psychological Problems Which Have Resulted in Ongoing Family Disruption or Disruption to Friendships?

- I like to preface this question with a statement about TBI:
 - “Many people say that after a TBI, they notice changes to behavior or personality. Some may become calmer while others may become more irritable, or more easily angered. Have you noticed any changes?”
 - Notice that I try not to influence their response in only one direction, but give them the option that the TBI may affect personality in different ways.



*Q7 – Have There Been Psychological Problems
Resulting in Ongoing Family/Friend Disruptions?
continued*

- Then after they respond I ask about how this has affected their relationships with friends and family.
 - It is very important to specify how often these “disruptions” occur, and to learn how often they occurred prior to the TBI.



Questions?



How the brain works.

Key Points and FAQs

6 Month Outcome Visit

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General

Q: Can I let my (GOSE, NP) certification expire if I will not be doing any testing or Training of new staff at my site?

A: Yes, but you must be certified again to train or test in the future.

Q: How does expiration of certification work?

A: Certifications expire on the static dates of May 1st and November 1st of each year. You must conduct 2 tests (whether with a mock patient or real Study Participant) over the previous 6 months to stay active.

General (2)

Q: What should I data enter if only part of a neuropsychological test was administered?

A: Leave the item blank. For example, do not enter the total number of words on the COWAT if only one or two letters were administered. Similarly, do not enter the time to complete the Grooved Pegboard Test if the test is prematurely terminated. Entering partial scores in these examples will skew the interpretation of the test results.

In some cases, it may be appropriate to record a partial score. For example, if Digits Forward was completed (but not Digits Backwards) you can enter both the score and the span for Digits Forward. You could also enter the score for one hand of the Grooved Pegboard test even if the test was not completed with the other hand.

General (3)

Q: The outcomes manual [Section 4.0] mentions that "The SC/SI and NP Examiner at each site will double score the tests and enter the data into the WebDCU™ " What does this mean?

A: It is best if each site can work out an arrangement where the SC double checks the math and some (limited) scoring of the NP Examiner before he or she enters the data into WebDCU™.

Another option is to have a second NP Examiner (or technician) review the forms before they are submitted to the coordinator.

In all instances, the person conducting the NP testing should recheck his or her administration and scoring (possibly viewing portions of the videotape for verification of the Study Participant's responses) before giving the forms to the SC for data entry.

General (4)

Q: Can I write the Study Participant's name or birthdate on the forms anywhere?

A: No. The forms cannot link the Subject ID to any information that could potentially identify the Study Participant. Therefore, on the GOAT, you should simply write "correct" rather than writing what the Study Participant actually says for items where the answer contains personal identifying information.

Watch the FrSBe forms carefully for this as well. Write the Subject ID at the top of the form to help keep the Study Partner from writing in the name. If the Study Partner does write the name on the form, black it out completely.

General (5)

Q: Should the Study Participant use pen or pencil to complete testing?

A: Whenever possible use pen

Q: How do I burn a DVD from the Flip Video Player?

A: Follow these steps:

- Plug camera into usb port

- Insert a blank DVD into the drive

- Select Roxio from popup menu

- Select Data, then Data Disc

- Click on Add Data at the top, then Add Folder

- Click on My Computer, then FlipVideo, then DCIM, then 100VIDEO, then Ok

- Click on the orange button in the bottom right

- The DVD is now burning. The CD drawer will open when it is done.

- *Use a sharpie to write on the DVD

GOSE

Q: Can I use other information (like the Npsych testing or NOS-TBI information) to help me score the GOSE?

A: Yes. You can use any information available to you to help get the most accurate evaluation possible.

NOS-TBI

Q: If a Study Participant refuses to complete the NOS-TBI, should I enter any of the scores or just say “not done”?

A: On this test, since individual items are entered, you should enter any of the information you were able to obtain.

Q: How do I do the sniff test?

A: Place drops of the scent onto strips of paper. This helps bring out the odor.

Q: When do I use the multiple choice card for the sniff test?

A: The multiple choice card should be used if the Study Participant indicates he or she does not know the answer, or gives an incorrect answer when naming any of the four smell items.

NOS-TBI (2)

Q: My Study Participant today was very impaired and not able to indicate to me whether he could hear or smell and so on. How do I score this? Is this “UN” for “untestable”?

A: As a rule of thumb, use the worst score for items where you cannot tell what the score would be due to severe impairment. Using “UN” essentially removes this item from the total score, causing Study Participants who are very impaired to have artificially low scores. Only use “UN” when a Study Participant is truly only untestable due to a physical barrier or disability, such as a Study Participant who probably could speak if it were not for being intubated or in the case of amputation.

Q: If a person cannot do even the modified GOAT, how do I document this on the CRF?

- Item 1: Reliability of Galveston Orientation and Amnesia test administration.
 - Relatively standard procedure, reliable results
 - Highly irregular procedure, unreliable results
 - Not done

- Item 2: Specify the reason: (e.g. study participant too cognitively impaired, study participant too physically impaired, study participant refused to begin/continue, examiner discontinued administration, etc.)

FORM IS ENDED HERE

GOAT

Q: Can I give full credit for recall of any event before or after the injury, no matter how far it is from the injury?

A: YES

6 Month Follow Up Form

Q: Should I still collect the 6 Month Follow Up Form if a Study Participant is unable to be tested?

A: Yes. Although this form should be completed by the NP Examiner, any study team member can complete it (i.e., no certification is necessary).

6 Month Follow Up Form

Q: Some Study Participants are uncomfortable answering questions about alcohol and illicit substances while being recorded. Is it ok if I ask these after the camera is turned off?

A: YES

6 Month Follow Up Form

Q: A Study Participant denied drug use in the year prior to her injury, yet her drug screen was positive at the time of the accident. What do I do?

A: Score what you know to be the truth on this item. Be sure to also add a comment regarding this.

6 Month Follow Up Form

Q: A Study Participant was underage at the time of his injury. He told me that he drank alcohol. Should I include alcohol as an illicit drug/controlled substance?

A: No

6 Month Follow Up Form

Q: Is ADHD considered a learning disability for purposes of filling out the 6 Month Follow Up Form?

A: No. However, be sure to further question about LD as they are often comorbid.

Q: Can I score the education level as "Associates" if a Study Participant has attended "trade school" for 2 or more years?

A: Yes. Education that would be roughly equivalent to an Associate's Degree can be considered here. This education would typically result in some kind of "certificate" or "license" for a particular profession or skill.

FrSBe

Q: I mailed the FrSBe to the Study Participant's significant other, and it will be a few days before the form is returned. Do I need to wait to get the form back before I submit the other test scores?

A: No, go ahead and submit all other test scores. The FrSBe should be entered separately within five calendar days of receiving the ratings.

Q: Do I use the FrSBe Excel Scoring Program for both English and Spanish scoring?

A: Yes.

FrSBe

Q: Should I enter into the scoring program the original numbers circled in ink or the numbers on the carbon copy?

A: Enter the original numbers that were circled in ink. The scoring program will automatically reverse the score when needed.

Q: How do I enter unanswered FrSBE items in the Excel Scoring Program?

A: Skip that item entirely (regardless of any scores that were answered for either part).

PHQ-8

Q: Do I have the Study Participant fill out the PHQ right on the CRF itself?

A: Yes. The Spanish version, however, uses a separate form and scores will need to be transferred.

Q: Can I read this questionnaire to Study Participants who are unable to do it on their own?

A: Yes.

Buschke Selective Reminding

Q: How long is the delay period?

A: 20 minutes \pm 5 minutes.

Questions?

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