

# *Outcome Ascertainment*

Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial  
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# Objectives

- What is the HOBIT trial's primary outcome
- Be able to identify the Glasgow Outcome Scale-Extended (GOSE) scoring system
- Be familiar with the GOSE structured interview
- Know how and when subjects will be interviewed
- Know how blinded assessors will be trained to do the GOSE

# Primary Outcome

- The HOBIT trial utilizes Glasgow Outcome Scale-Extended (GOSE) as the primary outcome scale for cognitive, behavioral, and disability measures, because of its increased sensitivity to “real world” performance and functional changes over time.

# GOSE

- The GOSE employs an eight-point scale, with higher scores associated with better outcome

# GOSE

1	Dead	
2	Vegetative	Condition of unawareness with only reflex responses but with periods of spontaneous eye opening
3	Lower severe disability	Patient fully dependent for all activities of daily living. Requires assistance to be available constantly. Unable to be left alone at night
4	Upper severe disability	Can be left alone at home for up to eight hours but remains dependent. Unable to use public transport or shop by themselves
5	Lower moderate disability	Able to return to work in sheltered workshop or non competitive job. Rarely participates in social and leisure activities. Ongoing daily psychological problems (quick temper, anxiety, mood swings, depression)
6	Upper moderate disability	Able to return to work but at a reduced capacity. Participates in social and leisure activities less than half as often. Weekly psychological problems
7	Lower good recovery	Return to work. Participates in social and leisure activities a little less and has occasional psychological problems
8	Upper good recovery	Full recovery with no current problems relating to the injury

# GOSE

- Categories are subdivided into upper and lower stratifications for the outcomes of
  - “Severely disabled” (three, four), “Moderately disabled” (five, six) and “Good recovery” (seven, eight)
- “Death” is scored as one, and “persistent vegetative state” as two.

# GOSE Scoring

- Favorable outcome in the HOBIT trial will be defined based on the sliding dichotomy methodology
  - Subjects whose initial GCS scores are 6-8 are considered to have a favorable outcome if their 6-month GOS-E score is upper good recovery to lower moderate disability
  - Subjects whose initial GCS scores are 3-5 are considered to have a favorable outcome if their 6-month GOS-E score is upper good recovery to upper severe disability

# GOSE Structured Interview

- One key is to make ask and record what subject was at baseline throughout interview
- Do not consider changes that result from other types of socio economic problems resulting from the injury, for example, financial difficulties keeping the subject from engaging in social activities



# GOSE Structured Interview

- **Consciousness**
  - Is the subject able to obey simple commands, or say any words
- **Independence at Home**
  - Is the assistance of another person at home essential every day for some activities of daily living
  - The key to this question is to determine the maximum length of time the subject can be left alone: 8 versus 24 hours

# GOSE Structured Interview

- Independence outside of the Home
  - Is the subject able to shop without assistance
  - Can the subject travel locally without assistance

# GOSE Structured Interview

- Work or School
  - Is the subject currently able to work/school to previous capacity
  - If not working to previous capacity, how restricted is the subject at work/school?
    - Reduced work/school capacity
    - Able to work only in a sheltered workshop or non-competitive job, or currently unable to work.

# GOSE Structured Interview

- Social and Leisure Activities
  - Is the subject able to resume regular social and leisure activities outside the home?
  - What is the extent of restriction on social and leisure activities?
    - Participate a bit less, but at least half as often as before injury
    - Participate much less, less than half as often
    - Unable to participate: rarely, if ever, take part.

# GOSE Structured Interview

- Family and Friendships
  - Have there been psychological problems that have resulted in ongoing family disruption or disruption to friendships?
    - This question is regarding the disruption of relationships rather than on changes in personality in general
  - What has been the extent of disruption or strain?
    - Occasional - less than weekly.
    - Frequent - once a week or more, but tolerable.
    - Constant - daily and intolerable (If the subject has become very withdrawn and socially isolated, this also constitutes as “constant disruption.”).

# GOSE Structured Interview

- Return to Normal Life
  - Are there any other current problems relating to the injury that affect daily life?
    - Symptoms such as headaches, dizziness

# GOSE Testing

- Consistent with the recommendations of the Outcome Measures Subcommittee of the NIH/NINDS Head Injury Centers, total interview and testing time should not exceed 75 minutes in order to enhance subject compliance and minimize subject fatigue.

# GOSE Testing

- The GOSE testing will be performed at hospital discharge, 30 days post-injury, 3 months post-injury, and 6 months post-injury.



# GOSE Testing

- The 30 day and 3 month post-injury assessments may be done by telephone interview, although in person interviews would be preferred.
- The subject/family member should be interviewed in person rather than by telephone for the 6 month GOSE assessments except for unusual circumstance.

# GOSE Testing

- A family member must be interviewed in addition to the subject
  - Patients with severe TBI often lack insight and are likely to deny psychological problems. It is important to also speak separately with someone close to the subject.
- Please remind the subject/family member not to talk about treatment arm to blinded assessor

# GOSE Testing

- The testing must be done by trained and certified site personnel who are blinded to the treatment arm
- Would recommend having at least 2 trained and certified assessors at each site
  - Assessor should be a neuropsychologist, physician, or nurse

# GOSE Testing

- After the GOSE interview is completed, the outcome CRF will need to be completed and entered into the WebDCU website

# GOSE Training

- Study personnel who will be performing the GOSE will be required to successfully complete the online training and certification available on the study website.

# GOSE Training

- The training will consist of an instructional video with examples followed by a certification test.
- A certificate is automatically generated upon passing the test.

# GOSE Training

- If the test is failed the assessor will be contacted to discuss the incorrect responses and re-train the important principles that were missed.
- Once this is complete the individual will be given approval to take the certification test again.

# GOSE Training

- There will be ongoing quality and reliability checks of the data performed across hubs/spokes



# Conclusions

- The blinded 6 month GOSE will be the primary outcome for the HOBIT trial
  - The blinded GOSE will also be conducted at 1 and 3 month
- The GOSE uses a structured interview with both the subject as well as a family member (done separately)
- The blinded assessor must be trained and certified which is done on the study website