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INFORMATION PAPER

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SUBJECT: Patient Global Impression of Change (PGIC): Recommendations for Scoring and Serial Administration for Concussion Health Care Outcomes Standardization

1. PURPOSE

Five domains of outcome and five measures were recommended for consideration of DOD stakeholders in the Military Health System (MHS) by the Office of Outcomes and Assessment (OOA) at the Defense and Veterans Brain Injury Center (DVBIC) for serial assessment of health care outcomes of military personnel diagnosed and treated for concussion. The PGIC was selected as one of the two core measures for concussion health care outcomes. This paper provides a survey of the literature and best practices in scoring and measurement frequency for the PGIC, a measure of domain of global outcome. This review informed the recommendations for standardization by the OOA at DVBIC. The paper was disseminated to stakeholders to summarize consensus on the use of the PGIC in serial assessment of concussion health care outcomes.

2. BACKGROUND

Many measures used to assess the health care system are overly reliant on administrative data whereas direct feedback from the patient is a more meaningful measure of health care system performance (CPDP, 2011). A patient rating of change measure asks the person receiving health care services to evaluate the effectiveness of treatment. Global rating of change scales are recommended for improving the applicability of information from clinical trials to clinical practice. There is strong correlation between patient completed global rating of change scales and patient self-rated importance of change, clinician measures of global patient change, and patient satisfaction measures (Farrar JT, Young JP, LaMoreaux, L et al., 2001; Fisher, 1999).

In practice, clinicians routinely ask their patients whether they are better, worse or the same but not many quantify the magnitude of this change or consider the reliability of the information (Kamper, Maher, and Mackay, 2009). A global rating of change scale is commonly used in clinical research to reliably and accurately assess the patient's own impression of change in health related status (Middel et al., 2001; Wyrwich et al., 1999). By tailoring the question in global impression of change measures, the scale is made relevant to whatever health condition a patient presents with and is presented explicitly in the question. Explicitly mentioning the health condition in the question is important to avoid ambiguity and is particularly important for those conditions that frequently present with co-morbidities that are not the target of intervention (Kamper, Maher, and Mackay, 2009).

There is variability in the title and design of global rating of change scales with few described in detail. The PGIC is the most commonly used anchor based method of assessing clinically important change in which the external judgment of meaningful change is made by the patient (Amirfeyz, Pentlow, Foote, and Leslie, 2009). The PGIC scale is described in a 2004 paper by Hurst and Bolton, "Assessing the Clinical Significance of Change Scores Recorded on Subjective Outcome Measures." The PGIC is particularly suited to capturing clinically meaningful change that makes a difference to the patient (Bolton, 2014) and has been used extensively in studies of musculoskeletal conditions. The PGIC was used as an outcome measure in DoD sponsored hyperbaric oxygen trials (Miller, personal communication) upon the recommendation of the Food and Drug Administration (FDA). The FDA requested the inclusion of the PGIC in clinical trials with military personnel with persisting post-concussion symptoms to serve as an anchor for determining clinically significant change on the NSI (Bahraini, 2014).

Consisting of one question rated on a seven point Likert scale, the PGIC offers a quick and simple method of quantifying clinical progress. The patient is asked to describe the change in activity limitations, symptoms, emotions, and overall quality of life related to the concussion. The PGIC scale is displayed in Figure 1.

Figure 1: PGIC

Since beginning treatment at this facility, how would you describe the change (if any) in ACTIVITY LIMITATIONS, SYMPTOMS, EMOTIONS and OVERALL QUALITY OF LIFE related to your post-concussive condition?

Choose ONE.

- No change (or condition has gotten worse) (1)
- Almost the same, hardly any change at all (2)
- A little better, but no noticeable change (3)
- Somewhat better, but the change has not made any real difference (4)
- Moderately better, and a slight but noticeable change (5)
- Better and a definite improvement that has made a real and worthwhile difference (6)
- A great deal better and a considerable improvement that has made all the difference (7)

3. OVERVIEW

The PGIC was selected by stakeholders as a core measure for global concussion health care outcome to capture the patient perspective regarding the achievement of clinically important benefit from concussion care treatment. Standardization of the definition of clinically meaningful change and measurement frequency are important so that data can be aggregated across settings to produce meaningful results.

4. INTERPRETING THE PGIC

PGIC values of 6 or more are reported to correlate best with actual change (Amirfeyz et al, 2009). Hurst and Bolton (2004) use an a priori definition of clinically significant improvement of PGIC categories of either “a great deal better” or “better”. These categories equate to a noticeable, worthwhile, and meaningful change. Patients scoring either 6 or 7 on the PGIC scale were categorized as “improved”.

5. SERIAL ADMINISTRATION OF THE PGIC

How the passage of time affects global ratings of change is largely unknown. There is no empirical evidence to support a recommendation regarding the maximum or minimum length of time over which the measure should be administered. In clinical trials, the PGIC is typically administered at the conclusion of treatment. However, in clinical care of concussion, there is often not a defined end point for treatment. Furthermore, clinicians may be interested in tracking the progression of when in the course of treatment improvement begins or deterioration occurs.

6. SERIAL ADMINISTRATION RECOMMENDATIONS

The score from the PGIC will inform the discussion by the provider with the patient about their progress and be reported in the provider note.

The PGIC will be completed at the second through fifth concussion visits. Thereafter, the PGIC will be administered concurrent with follow-up visits at two week intervals.

The PGIC is an anchor based method in which the external judgment of meaningful change is made by the patient (Amirfeyz, Pentlow, Foote, and Leslie, 2009). For purposes of aggregated data interpretation, all seven categories of clinical improvement will be reported as treatment outcome metrics with scores of 6 and 7 interpreted as clinically significant improvement.

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