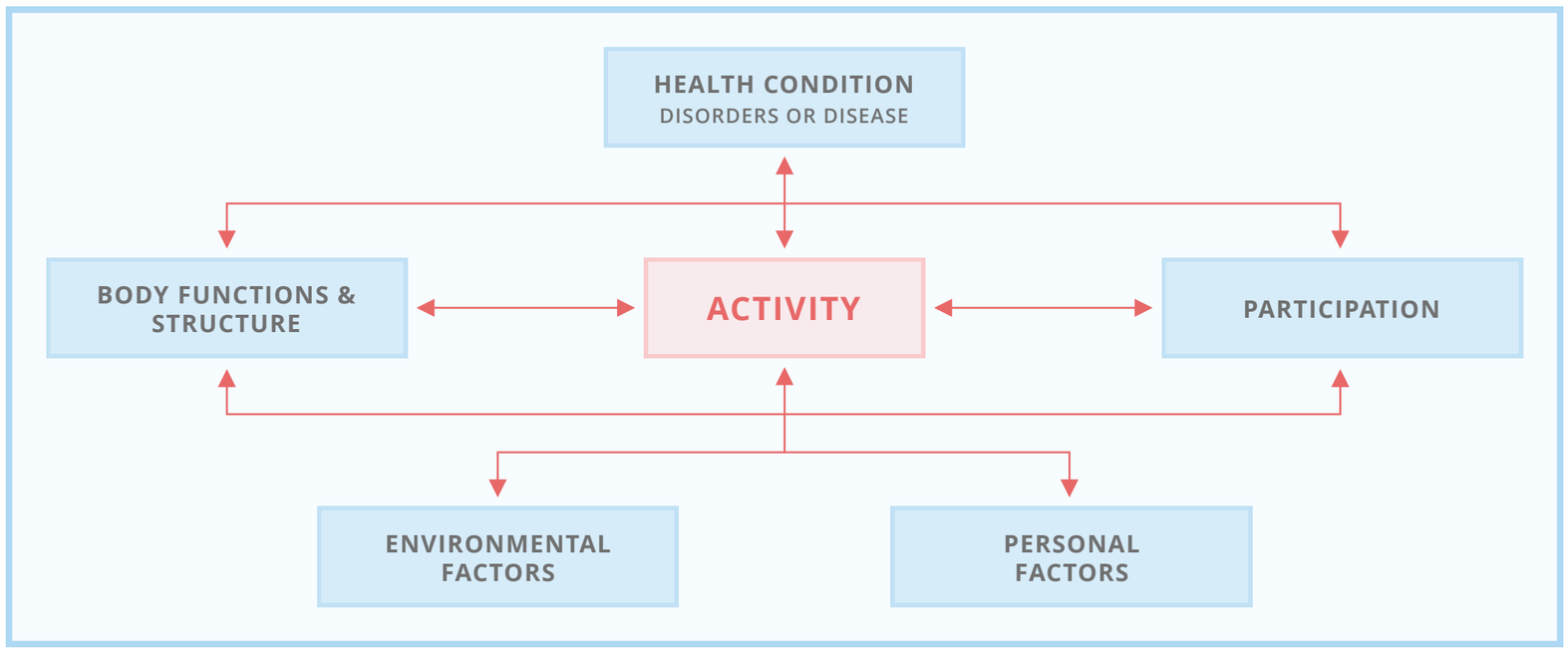
Standardized Assessments for the Management of Children with Motor Disorders

PHYSICIAN GLOBAL ASSESSMENT (PGA)

Description of Assessment

Purpose: Assessment of overall treatment response to intervention(s).

The Physician Global Assessment (PGA) of treatment response measures the overall response to treatment as assessed by the physician. The PGA is a well accepted and commonly used scale for evaluating treatment response in clinical trials both in adults and children. PGA is a simple instrument and the result is easily understood. However, assigning a score for PGA requires a very detailed evaluation. To perform this assessment a physician/health care provider would use extensive data from every aspect of ICF.



Overall response to treatment should be based not only on achievement of treatment goals but also change in impairment, activity and participation. When scoring PGA in children with motor disorders, a physician/health care provider should consider all data on the history from parents/caregivers/therapists about response to intervention(s), physical examination for assessment of passive range of movement (PROM), active range of motion (AROM), muscle strength and selective motor control, hypertonia, pain or sleep disturbance, tolerance to therapeutic procedures like stretching exercises, splinting or casting, functional assessments like bilateral hand usage or gait, changes inactivity limitations, participation restrictions and quality of life.

Assessment Details

The physician/health care provider should answer first the question on how the patient is doing in his or her life since receiving the intervention(s) and

- Make an assessment of the change as improvement, no change or worsening.
- For improvement or worsening decisions choose a score that best indicates his or her assessment about therapeutic efficacy of the intervention(s).

The physician/health care provider should not consider the overall picture but the overall **response** to treatment. Evaluation of a patient for PGA is an individualized approach based on clinical characteristics and treatment objectives of that patient.

Investigators of this educational program suggest physicians/health care providers to complete the appropriate evaluations in all ICF domains in objective terms as much as possible to describe the changes referring to pre-intervention status of the patient.

Information from multiple sources to be considered for PGA in children with movement disorders may include:

- History from parents/caregivers/therapists

- Subjective symptoms of the patient like pain, sleep disturbance
- Tolerance to therapies like
    - OT/PT/stretching, etc.
    - Splint/orthotics
    - Casting
- Physical examination
    - PROM
    - AROM
    - Muscle strength/selective motor control
    - Spasticity/dystonia measurements
- Body functions like gait
- Treatment objectives
- Activity limitations
    - Restrictions in participating to life situations
    - Quality of life

Rating System

All physician global assessment ratings will be performed with input from the physical examination, interim medical history, any available videotape of upper limb and/or gait function, assessment of objectives of treatment, changes in activity and participation restrictions, use of splints/braces & assistive devices, and parent & patient interviews).

+4	Markedly Improved
+3	Much Improved
+2	Improved
+1	Slightly Improved
0	No Change
-1	Slight Worse
-2	Worse
-3	Much Worse
-4	Markedly Worse

Background / History

Development of the Assessment

The literature reveals an assortment of “global assessment scales”. These scales differ in various ways:

- Who completes the scale varies (patient, parent, physician, therapist, and/or trained observer).
- When the scale is completed (baseline, and/or after intervention).
- What is rated (pain, wrinkles, headaches, or other problems or an overall health or disease rating).
- The rating format (5, 7, 9, or 10-point scale, 0 to 9, -4 to +4, etc or a 100mm VAS).
- Which aspects of the condition are being considered (symptom severity, symptom frequency, problem duration, disease activity, anatomical area, or overall health or overall disease activity).
- The scale can be phrased to assess current status (impression of a disease at a single point) [Static] or change in status (assessment of the global improvement from baseline [Also referred to as a Dynamic or Relative form of the scale].
- The timeframe over which the rater should consider the status also varies and must be clearly defined.

For the purposes of this educational website, we will be discussing the use of a 9 point scale to evaluate response to treatment.

The Global Assessment Scale is a simple instrument with a 9 point ordinal scoring system ranging from -4 indicating very marked worsening to +4 very marked improvement. This scale provides a subjective overall evaluation of treatment response by the patients/ caregivers or physicians/health care providers. This scoring of global improvement (+1 to +4), no change (0), or global worsening (-1 to -4) is performed with respect to the pretreatment status of the patient, there are no baseline measurements.

The Global Assessment Scale of 9 points was used by Naumann et al. (2002) in a randomized, double blind clinical efficacy and safety botulinum toxin-A (BONT-A) study for the treatment of cervical dystonia. Comparable scales of different categories had been used in other previous investigations. In a double blind placebo controlled trial of BoNT-A for the treatment of spasmodic torticollis, Greene et al. (1990) used the Results of Injection Scale in which patients were asked to evaluate the change in the torticollis relative to baseline as +3=markedly improved, very happy with the results, +2=moderately improved, happy with the results, +1=slightly improved, but not significantly, 0= no change, -1= slightly worse, but not significantly, -2=definitely worse. In idiopathic cervical dystonia patients treated by BoNT-A, Tarsy (1997) compared clinical rating scales for dystonia using global physician rating of improvement on a scale of 0 to 3, 0 indicating no change, 3 indicating marked reduction in pain and dystonia. In a retrospective analysis of children with cerebral palsy treated by BoNT-A for spastic equinus foot, Pascaul et al. (2011) used a global assessment scale scoring from -2 to 4: -2 (severe worsening), -1 (mild worsening), 0 (no change), +1 (mild improvement in tone), +2 (moderate improvement in tone), +3 (moderate improvement in tone and function), +4 (significant improvement in tone and function).

Physician versus Patient/Caregiver Global Assessment Scale

The global assessment of treatment response by a physician is assumed to be more objective compared to patients/caregivers. A physician can consider additional aspects of the condition (like physical examination, outcome assessment methods, laboratory work outs, radiology) focusing on objective measures which are not assessable by the patients or caregivers as well as the history from the patients and caregivers and may have an insight into whether they tend to amplify or minimize the response to treatment. Patients assess subjective phenomena and even under ideal goal setting environments patients and parents may have unrealistic expectations and different objectives or perception.

Reliability

The PGA is a bipolar, accurate, well labeled, continuous, and logical Likert scale of 9 points. By definition Likert scales are survey questions that offer a range of answer options-from one extreme attitude to another typically including a neutral midpoint. Likert scales are quite popular because they are one of the most reliable ways to measure opinions, perceptions, and behaviors. Although there are several inter-rater and intra-rater reliability studies, especially in the fields of dermatology and rheumatology, the authors of this website could not locate any reliability studies specifically for PGA in children with neurologic conditions.

Validity

Although there are multiple validity studies in the fields of dermatology and rheumatology, the authors could not locate any clinical studies directly aiming to explore the validity of PGA as an outcome assessment tool in children with neurologic conditions. However, in randomized phase 3 international multicenter clinical trials on efficacy and safety of abobotulinumtoxinA in both children and adults with neurologic conditions, the PGA was used as a secondary outcome measurement tool in conjunction with a large set of validated outcome measures on muscle tone/spasticity to function/quality of life. In the double blind placebo controlled phase of these trials improvements in PGA paralleled the improvements both in muscle tone/spasticity and/or function. In the repeated open label extension periods of the clinical trial with children with spastic equinus foot deformity a sustained efficacy was obtained by PGA in parallel to other valid outcome measures like MAS, Tardieu Scale, and GAS. However, in adult upper limb and lower limb studies progressive improvements were obtained by PGA parallel to functional improvements by walking speed, Disability Assessment Scale (DAS), Modified Frenchay Scale (MFS) and quality of life.

Pros & Cons

Pros

- Simple instrument.
- Results easily understood.
- Used in adults and children.
- Used in many neurologic conditions to evaluate treatment response to intervention(s).
- An individualized assessment.
- Detailed assessment to score PGA will provide the physicians/heath care providers to understand the outcome of intervention(s) within the ICF concept. Understanding the complex interactions between a health condition, change in impairment, it's relevant positive or negative effects on functioning, activity and participation level of the patient in the context of his or her personal and environmental factors would guide the clinicians to delineate the factors positively or negatively influencing the goals of treatment and complex interactions within all ICF domains. This would further provide better planning of the treatment approach.

Cons

- Subjective tool.
- Requires training.
- Improvement in some parameters, worsening in others can be an obstacle to hinder assessors decision.
- Changes in impairment/activity/participation/treatment objectives not due to the intervention(s) but to personal/environmental factors or associated conditions may complicate the assessment of overall treatment response.
- Adverse events which are negatively influencing the treatment objectives can be a limitation for assessment.