

PRIMARY MEASURES IN FOTO

In the FOTO¹ Patient Outcomes system, a *primary measure* is the standard *patient-reported outcome measure (PROM)* used for a particular patient's body part/condition or impairment.

Patient-level results for primary PROMs are reported on the Patient Specific Report which typically include the following values or scores at intake and/or status:

- Patient-level primary PROM score
- Patient-level primary PROM score change and interim/discharge scores
- Risk-adjusted predictions: PROM change score, number of visits and duration of episode in days.
- Additional clinical interpretation estimates: risk-adjusted statistical FOTO (mean FOTO database) score, reliability (MDC or SEM), minimal clinically important change (MCII), and functional staging.

Clinician- and/or Clinic-level reporting for FOTO primary PROMs use comparative benchmarking based on risk-adjusted performance.

Primary PROMs in FOTO represent the best available science of measurement, usually based on itemresponse theory (IRT) methods and administered using either computer adaptive testing (CAT) or short form. While most IRT-based primary PROMs are FOTO-originated, other sources of modern science measurement may be considered, such as those in the PROMIS² and NeuroQoL³ measurement systems.

All clinicians and staff using FOTO are expected to uphold the validity and reliability of the measurement by adhering to the *Standards of Administration for FOTO Measures*. The Standards of Administration is *required reading* and available <u>here</u> or by submitting a request to support@fotoinc.com. Users are also encouraged to complete a short certification video course that is available on the FOTO Learning Center. (*Not yet signed up for the FOTO Learning Center? Contact support@fotoinc.com*)

Questions in FOTO PROMs are to be answered independently by the patient, without coaching or other influence by the staff or therapy team. If the patient is unable to answer the questions independently, the provider must select **Proxy or Recorder** on the Episode Details page in the FOTO system. More information about the Proxy/Recorder functionality is available <u>here</u>.

¹ FOTO Patient Outcomes = Focus on Therapeutic Outcomes [®] <u>www.fotoinc.com</u> <u>www.fotoinc.com</u>



PRIMARY PROMS IN THE FOTO SYSTEM

FOTO PROMs		Other PROMs
Balance Confidence	Lower Extremity Physical Function	Neuro-QoL Communication
Bowel Constipation	Lower Quadrant Edema	Neuro-QoL HDQLIFE Swallowing
Bowel Leakage	Neck	Difficulties
Dizziness Functional Status	Pelvic Floor Dysfunction Index	Neuro-QoL ² Pediatric Cognitive Function
Dizziness Positional Status	Urinary Problems	PROMIS Cognitive Function
Elbow, Wrist, Hand	Upper Quadrant Edema	PROMIS ³ Pediatric Mobility
General Orthopedic	Shoulder	PROMIS Pediatric Upper Extremity
General Physical Function	Stroke Upper Extremity	
Jaw Functional Status Scale	Stroke Lower Extremity	
Low Back		

PRIMARY PROMs BY CARE TYPE

Orthopedic, Industrial, and Pain Management

- Elbow, Wrist, Hand
- General Orthopedic
- Jaw Functional Status Scale
- Low Back
- Lower Extremity Physical Function
- Neck
- Shoulder

Neurological

- Balance Confidence
- Dizziness Positional Status
- Dizziness Functional Status
- General Physical Function
- Jaw Functional Status Scale
- Stroke LE
- Stroke UE

² PROMIS = Patient-Reported Outcomes Measurement Information System[®] <u>www.healthmeasures.net</u>

³ Neuro QoL = Quality of Life in Neurologic Disorders[®] <u>www.healthmeasures.net</u>



Cardiopulmonary

- General Physical Function ("FOTO Med Neuro")
- Lower Quadrant Edema
- Upper Quadrant Edema

Pelvic Floor

- Bowel Constipation
- Bowel Leakage
- Pelvic Floor Dysfunction Index ("FOTO PFDI")
- Urinary Problems

Pediatric

- Neuro-QoL Pediatric Cognitive Function
- PROMIS Pediatric Mobility
- PROMIS Pediatric Upper Extremity

Speech

- Neuro-QoL Communication
- Neuro-QoL HDQLIFE Swallowing Difficulties
- PROMIS Cognitive Function

ABOUT THE FOTO PROMs

The FOTO *patient-reported outcome measures (PROMs)* were developed using advanced measurement methods known as *Item-response theory (IRT)*. PROMs developed using such modern methods hold advantages over classical methods including valid assumptions for interval scaling, optimal scale coverage (minimal or no floor and ceiling effects), and uni-dimensionality. An additional advantage of IRT is that it allows for administration of PROMs by either *computer adaptive testing (CAT)* or *short form* for reduced patient burden (fewer questions) while maintaining high measurement precision.

A separate *risk adjustment model* was developed for each FOTO primary PROM using regression analyses that considered multiple patient characteristics and medical/health factors as predictors of outcomes. All patient factors included in the FOTO risk adjustment models are statistically significant



and contribute to explaining variance in predicting outcomes. Patient baseline characteristics used **to** *risk-adjust the outcomes are considered non-modifiable i.e., outside of the providers' control*. Riskfactors include: intake primary PROM score; age; biological sex; acuity as number of days from onset of the treated condition; type of payer; number of related surgeries; exercise history; use of medication at intake; previous treatment for same condition; post-surgical procedures or surgical types; and 32 specific medical comorbidities. The risk-adjustment model is used to calculate a predicted PROM score at discharge (or a predicted change score).

FOTO PROM SCORING BASICS BY CARE TYPE

All FOTO PROMs and risk adjustment models generally target patients aged 14 and older. Younger patients may be administered FOTO PROMs so that clinicians may utilize patient-level outcomes data, but ages 13 and younger are not included in benchmarked comparative reporting.

Orthopedic, Industrial, and Pain Management

With respect to the FOTO PROMs used in the Orthopedic, Industrial, and Pain Management care types, (i.e., the FOTO Low Back, FOTO Neck, FOTO Shoulder, FOTO Elbow/Wrist/Hand, FOTO Lower Extremity Physical Function, Jaw Functional Status Scale, and FOTO General Orthopedic), each of these FOTO PROMs assesses physical functional status (FS). Scores are reported on an approximated 0 to 100 continuous scale except for the FOTO Jaw Functional Status Scale which uses scoring is based on the *T*-score metric and with patients centered on a mean of 50 and a standard deviation of 10. Higher scores indicate better function.

Neurological

The *FOTO Stroke Upper Extremity and Stroke Lower Extremity* PROMs assess physical functional status (FS) for patients after stroke. Scores are reported on an approximated 0 to 100 continuous scale with higher scores indicating better FS.

The *FOTO Jaw Functional Status Scale (JFSS)* assess physical functional status for patients with orofacial disorders. Scoring is based on the *T-score* metric, with patients centered on a mean of 50 and a standard deviation of 10. Higher scores represent better function.

The *FOTO Balance Confidence* PROM assesses a patient's perceived balance confidence for patients with balance impairments. Scoring is based on the *T-score* metric, with patients centered on a mean of 50 and a standard deviation of 10. Higher scores represent better perceived balance confidence.

The FOTO Dizziness Positional Status (DPS) and FOTO Functional Status (DFS) PROMs assess the impact of dizziness on the patient's perceived positional and functional status respectively. Both the DPS and DFS are administered for patients set up under the Vestibular impairment. Scoring is based on the *T*-



score metric, with patients centered on a mean of 50 and a standard deviation of 10. Higher scores represent better positional and functional status. The FOTO system will select the DFS or the DPS as the primary PROMs based on the DPS score at intake i.e., if the intake DPS *T-score* \leq 55 the DPS is the primary PROM; if the intake DPS *T-score* > 55 the DFS is the primary FOTO PROM. Both the DPS and DFS scores at intake are taken into account for risk-adjustment, regardless of which measure was selected as he primary PROM.

The *FOTO General Physical Function (also known as Med Neuro)* PROM assesses general physical functional status and is used for other impairment categories in the Neuro care type. Scores are reported on an approximated 0 to 100 continuous scale with higher scores indicating better FS.

Cardiopulmonary

The FOTO Upper Quadrant Edema and Lower Quadrant Edema PROMs assess physical functional status for patients with lymphedema and other causes of regional swelling (i.e., swelling that is not limited to a particular joint). Scores are reported on an approximated 0 to 100 continuous scale with higher scores indicating better FS.

The *FOTO General Physical Function* PROM assesses physical functional status and is used for patients with cardiopulmonary impairments not related to edema. . Scores are reported on an approximated 0 to 100 continuous scale with higher scores indicating better FS.

Pelvic Floor

The FOTO Pelvic Floor module is unique in that it provides a discreet mode for the patient to specify which pelvic floor conditions apply to them (i.e., urinary, bowel leakage, bowel constipation, pelvic pain, pelvic organ prolapse). The patient selections drive the selection of PROMs in the following manner:

- 1. Urinary Problems PROM is administered using computer adaptive testing. The FOTO Urinary Problems PROM assesses urinary-related problems such as leakage, frequency, and control. The FOTO PFDI is also administered; only the FOTO Urinary Problems PROM score is used for risk adjustment.
- 2. If bowel constipation problem is selected by the patient, The FOTO *Bowel Constipation* PROM is administered using computer adaptive testing. This PROM assesses constipation-related problems such as frequency, difficulty, and use of assistive measures. In addition, the PFDI is also administered; only the FOTO Bowel Constipation Problem PROM score is used for risk adjustment.
- 3. If bowel leakage problem is selected by the patient, The FOTO *Bowel Leakage* PROM is administered using computer adaptive testing. This PROM assesses bowel incontinence-related problems such as frequency, leakage, and control. In addition, the PFDI is also



administered; only the FOTO Bowel Leakage Problem PROM score is used for risk adjustment.

4. The FOTO Pelvic Floor Dysfunction Index (PFDI) is a static, 6-item measure in which 6 items are administered (i.e., not administered via CAT). The 6 PDFI items pertain to household chores, physical activities such as walking, swimming, or other exercise; entertainment activities; traveling by car or bus; social activities, and sexual activities. FOTO PDFI is administered for all patient-designated pelvic floor problems (i.e., urinary, bowel constipation, bowel leakage, pelvic pain, and/or pelvic organ prolapse). FOTO PFDI scores are reported on an approximated 0 to 100 continuous scale with higher scores indicating greater <u>dys</u>function while higher scores on the Urinary and Bowel PROMs indicate better function. The FOTO PFDI results are not risk adjusted at this time.

Pediatric

The *PROMIS Pediatric Mobility and Upper Extremity* short forms contain items from the full PROMIS Physical Functioning item bank to target ages 5-17. Scores are reported as T-scores where the mean is 50 and the standard deviation is 10. The possible range of T-scores is 14 to 59 for the PROMIS Pediatric Mobility and 10 to 57 for the Upper Extremity short forms available in FOTO, respectively, with higher scores meaning better function.

The *NeuroQOL Pediatric Cognitive Functioning* v2.0 8-item short form contains items from the full NeuroQOL Pediatric Cognitive Functioning item bank and targets ages 8 to 17. Scores are reported as T-scores where the mean is 50 and the standard deviation is 10. The possible range of T-scores for the is 21 to 65 with higher scores meaning better cognitive function.

Parents/caregivers may respond to questions on the pediatric patient's behalf; this must be documented in FOTO under the Proxy/Recorder functionality.

Speech

The *HDQLIFE Swallowing Difficulties* 6-item short form targets adults (ages 18+). Scores are reported as T-scores where the mean is 50 and the standard deviation is 10. The possible range of T-scores is for the is approximately 41 to 77 with higher scores representing greater difficulty swallowing.

The *PROMIS Cognitive Function* 8-item short form targets adults (ages 18+). Scores are reported as T-scores where the mean is 50 and the standard deviation is 10. The possible range of T-scores is for this short form is approximately 23 to 64 with higher scores representing better cognitive function.

The *Neuro-QoL Communication* 5-item short form targets adults. Scores range from 0 to 100 with higher scores indicating better communication ability.



SCORE INTERPRETATION FOR FOTO PROMs

Scoring and scaling

Most FOTO IRT-based PROMs are reported on an approximated scale of 0 to 100 where a higher score may indicate better functional status, better perceived balance confidence, and better dizziness positional and functional status depending on which PROM is primary. The JFSS, DPS and DFS are reported on t-scales where the mean is 50 and the standard deviation is 10.

About 0 and 100

- 0 and 100 do not mean anything specific; 100 does not mean perfect or normal, and 0 does not mean bedbound or zero function.
- By the same logic, it is incorrect to think of a 0 to 100 scale as meaning 0% to 100%.
- This applies to most or all PROMs used in healthcare today.
- Some lowest or highest scores may even be below 0 or above 100.

Comparing scores between PROMs

- Scores between different PROMs are not directly comparable. E.g., a score of 50 on one PROM does not mean the same thing as a score of 50 on a different PROM.
- Scores between different PROMs cannot be aggregated and interpreted as a single outcome score.

FOTO has developed crosswalk functionality ("score-linking") between related traditional or legacy measures that assess the same construct, allowing to mathematically link a score from one scale to the other. Cross walk functionality is available in FOTO for the following legacy tools: modified ODI, DASH, NDI, LEFS, HOOS Jr, and KOOS Jr. More information on cross-walks is available <u>here</u> and <u>here</u>. In addition, more detailed information about the methodology by researchers at Northwestern University to develop crosswalks is available <u>here</u>.

Predicted Change Score

The Predicted Change Score is a risk-adjusted estimate that accounts for multiple non-modifiable patient characteristics and medical health factors known to influence outcomes independent of treatment rendered.

- It is the first choice for clinical interpretation because it is scientifically robust and pertains to either functional status, balance confidence, or dizziness impact outcomes at discharge.
- On the individual patient level, Predicted Change is an important guide in that it represents what typically happens from treatment rendered for similar patients.

- If a patient has the potential to exceed the Predicted Change, care should not be stopped once the patient achieves the Predicted Change, and FOTO re-assessments (status) should continue. The greater the actual change, the better it is for the specific patient!
- On the group level, the PROM results from all patients for a specific body part/condition or impairment are aggregated and used to make comparisons between providers (clinicians or clinics) and to compare outcomes over time for a specific provider.

Standard Error of Measurement (SEM) and Minimal Detectable Change (MDC)

- SEM and MDC are reliability estimates used determine the error associated with the primary
 PROM scores (point estimate) and the amount of score change needed to exceed statistical
 measurement error. The clinical application of these reliability estimates is to know that a
 change in score is above or below the measurement error. MDC does not necessarily imply that
 an improvement is important to the patient. In addition, MDC estimates used in FOTO are
 specific to the intake PROM score so as to provide an MDC that is individualized to the patient's
 baseline level of perceived function or status. It is known, for example, that intake PROM
 scores, regardless of whether the measure was developed by FOTO or other research groups,
 are likely to have larger standard errors at the extremes of the scale's range (i.e., highest and
 lowest possible scores).
- Typically for most FOTO PROMs, the SEM is < 4/5 points out of 100 scale.

Minimal Clinically Important Improvement (MCII)

- MCII represents the minimal amount of score improvement that is likely clinically important to the patient. Like MDC values, MCII estimates used in FOTO vary based on the intake PROM score. It is common that the lower (less ability) the intake score is, the more improvement is needed to achieve MCII.
- MCII values were determined using an external anchor from patient ratings of 3 or greater on a 15-point Global Rating of Change (GROC). The GROC scores range from -7 to +7 with +3 defined as "Somewhat Better."
- Although MCII values have some limitations including patient recall bias and specificity to the anchor selected, they are a useful interpretation guide to assess improvement or change that is clinically important to the patient.
- Since MCII values are 1) not risk-adjusted and do not take into account patient characteristics other than the initial score at intake and 2) represent minimally important improvement or change. MCII does not replace the risk-adjusted estimate of predicted change. MCII values should only be used as an intermediate estimate of improvement during the episode of care, not a patient discharge outcome goal or target.

FOTO PATIENT OUTCOMES



Functional Staging

- Functional Staging models are currently available for FOTO orthopedic, pain management, and industrial care types.
- Functional staging provides clinicians with yet another tool for clinical interpretation of an individual patient's functional status score.
- Functional Staging provides a visual display of a clinically logical classification system based on Item Response Theory methods.

More information about the functional staging models available for FOTO PROMs is available <u>here</u>.

UNDERSTANDING COMPUTER ADAPTIVE TESTING (CAT)

One of the advantages of using as item response theory (IRT) is reduced patient and clinical burden by administering a PROM using computer adaptive testing (CAT). Instead of requiring a patient to answer a long list of questions from the full item bank, CAT enables a scientifically precise *score estimate* based on patient responses to only a handful of questions or items from the PROM's item bank. On average, most CATs in FOTO administer 5-7 questions before achieving a reliable score estimate.

Here are some of the key components of CAT and how they work:

- Item Bank and the Metric
 - Each patient-reported outcome measure (PROM) has a UNIQUE item bank.
 - The term *item* means the functional questions, together with the patient response options and patient instructions.
 - The PROM's *item bank* is the full set of items that assess a single concept (e.g., physical functional status).
 - The *metric* is the measurement continuum on a scale that ranges from low to high values. A ruler or tape measure is a good image to think about as an example of a metric.
 - Using IRT, the items, including their response categories, have been mathematically calibrated (placed) along the metric.
 - Because IRT considers the difficulty of each item, the different items become aligned along the metric by order of the level of difficulty each item represents.
 - Starting question
 - Each CAT has a specific "average ability" question that has been pre-assigned as the *starting question*.
 - Once the patient has answered the starting question, the IRT math starts to get information about the patient's ability and calculates a *provisional estimate* of the patient's current status with its associated measurement error.
- Selection of Subsequent Questions

- The IRT math uses the information gained from the patient's response to the starting question to select the next question. The IRT math looks for the next question as the one that will be most informative as to the patient's current status, given the initial *provisional estimate*.
- After each question, the score estimate is re-calculated, and then the IRT math selects another item that is most informative given the last provisional estimate.
- Stopping Rules
 - The IRT math continues to select questions until 1 or more of the stopping rules are satisfied.
 - Stopping rules for FOTO PROMs include some or all of the following criteria:
 - 1) The pre-determined minimum number if items was administered.
 - 2) Mean absolute change in the provisional estimate over a certain number of consecutive question responses (usually 3) is less than a pre-defined value.
 - A pre-determined level of measurement error (SEM) has been achieved. [Typically, SEM < 4/5 points out of 100.]
 - 4) The CAT reached the maximum pre-determined number of items, or all items from the item bank have been administered (the latter is very rare).
 - The last provisional estimate after the CAT stops becomes the patient's final score.

When administering PROMs via CAT, measurement is thus tailored to the individual's ability, with fewer items administered i.e., less burden, compared to classical PROMs while maintaining measurement precision. For example, the Oswestry (ODI) is a fixed survey requiring administration of all 10 items, compared to the FOTO Lumbar CAT which administers only 6 items on average.

UNDERSTANDING SHORT FORMS

In addition to CAT, short form is another way to administer and IRT-based item bank. Both CAT and short form provide a precise score estimate based on responses to a small number of items from the full bank. Whereas CAT is dynamic, administering items in an individualized or "tailored testing" approach, a short form administers a static, pre-determined set of items that were selected from the full bank based on statistical and clinical content factors.

An advantage of short form over CAT is that patient respond to the same questions every time, an option preferred by some clinicians. Because short form mode does not allow for individualized questions, reliability (precision) may be relatively lower (but still within acceptable ranges) when using short form rather than CAT.

PATIENT OUTCOMES



Importance of Patient-Reported Outcomes for Clinicians

Patient-reported outcome measures (PROMs) are increasingly advocated as a necessary component of patient-centered care. The overall strategy for administering PROMs is to engage patients as active participants in goal setting, to improve healthcare outcomes,^{1,2} and foster improved communication between the patient and his or her provider (i.e., therapeutic alliance⁵). PROMs also promote family/caregiver engagement and communication with the provider.

Placing risk-adjusted PROM data directly into the hands of the provider and sharing that information with their patients/family during the healthcare visit embodies the definition of patient-centeredness advocated by the National Quality Forum's vision to achieve best performance improvements and accountability through patient-reported outcomes.³ In addition, use of PROMs is recommended in clinical practice guidelines as a standard component of evaluation and management for multiple provider types, including physical therapists.⁴

Other modes of measurement such as clinician-rated tests and measures are also important. However, the <u>single most important indicator</u> of the impact of healthcare on a patient's life is the patient's perception or voice. ¹⁻³

References:

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- 3. National Quality Forum. Patient Reported Outcomes (PROs) in Performance Measurement. January 10, 2013. https://www.qualityforum.org/publications/2012/12/patient-reported_outcomes_in_performance_measurement.aspx Accessed March 21, 2019.
- 4. Guide to Physical Therapist Practice 3.0. Alexandria, VA: American Physical Therapy Association; 2014. Available at: http://guidetoptpractice.apta.org/. Accessed August 13, 2019.
- 5. Ferreira PH et al. The Therapeutic Alliance Between Clinicians and Patients Predicts Outcome in Chronic Low Back Pain. Phys Ther 2013 (March issue)

For More FOTO PROM Information

More information on FOTO PROM development and clinical applications is available <u>here</u>. References published on the psychometric development and clinical application of FOTO PROMs can be accessed at <u>https://fotoinc.com/peer-reviewed-articles/</u> For PROMIS and NeuroQoL measures check out <u>https://www.healthmeasures.net</u>.