

The Feasibility of Systematic Goal Quality Assurance During Goal Attainment Scaling in a Rare Disease

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Objectives

Goal attainment scaling is a personalized, patient-centered clinical outcome assessment that quantifies the effects of an intervention based on individualized goals.¹

Clinicians and/or disease experts work with patients and/or caregivers to identify personal goals (symptoms and challenges) and develop goal scales that are meaningful to them.

As an individualized approach to the assessment of treatment response, the process of constructing goal scales is needs to be standardized and significant methodological rigor is required for its standardization.

Goal quality assurance ensures that clinicians are setting high-quality goals that follow the SMART (Specific, Measurable, Achievable, Relevant, and Time-bound) criteria.

Here we investigated the feasibility of using a goal quality assessment inventory to ensure a standardized approach to high-quality goal development across patients with heterogeneous symptoms.

Methods

Four clinician experts (GAS interviewers) were trained in setting goals with caregivers of individuals with SCN2A-associated developmental and epileptic encephalopathies.

Two assessors independently evaluated the goal scales using a goal quality inventory (n=20) developed pre-study to facilitate real-time goal quality assurance within a fast-paced clinical trial environment.

The goal quality inventory included items which expanded on the SMART criteria along with other items such as language specificity, outcome orientation, and the use of patient-friendly language.

The GAS experts gave the goals overall ratings based on their assessment: excellent, acceptable, needs improvement.

Interrater reliability (IRR) was evaluated with Cohen's kappa (95% confidence intervals, CI) and Scott's Pi. Percentage agreement between the two raters was also calculated.

Methods

How Goal Attainment Scaling Works:



Clinician facilitates the interview for subject or caregiver to identify goals

Together, they set the 5-point goal attainment scale for each goal

Each rates during follow-up whether the goals have been attained

The Goal-Setting Visit



The Follow-Up Visits



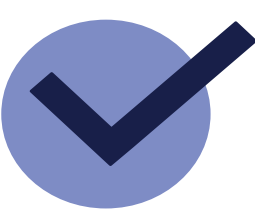
Results

Goal Quality Inventory



Goal Title

- » Concise title
- » Reflects content of the goal scale



Scale

- » All 5 levels complete
- » Concise attainment levels



Specific

- » Attainment levels include only one outcome each
- » Outcome clearly stated



Measureable

- » Quantifiable change described
- » No overlap between attainment levels



Achievable

- » Potentially achievable (0 level)
- » Sufficiently challenging (not too easy)
- » Realistically achievable (not too hard)



Relevant

- » Directly or indirectly related to patient's condition
- » Directly or indirectly related to intervention



Timebound

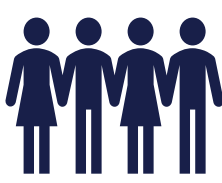
- » Realistically expected to change by primary endpoint
- » Possible to evaluate at each time point



Other

- » No use of vague language (e.g. gets better, improves)
- » Outcome oriented (not a process goal)
- » No clinical jargon
- » Written from the patient's perspective
- » Present tense

Results



10 participants and their caregivers participated in goal-setting interviews with four GAS interviewers.



Two GAS experts independently completed goal scale evaluation for 30 goals.



The overall percent agreement between raters was 88.8%.



IRR was evaluated based on the responses that the GAS experts gave for each item on the goal quality inventory for each of the participants goals (Table 1).

Table 1: Calculated IRR coefficients

IRR	Coefficient
Cohens Kappa	0.395 (95% CI: 0.275 - 0.515)
Scotts Pi	0.319

Conclusions

There is a critical need to standardize implementation of personalized endpoints like goal attainment scaling to ensure consistency across sites/patients.

A two-step goal setting process, whereby goals are reviewed by two independent reviewers using the inventory following each initial visit (screening) is recommended. GAS interviewers can then work with the patients at the subsequent visit (baseline) to incorporate the feedback on each goal scale and finalize the goals and goal scales.

As such, goal quality inventories may be utilized to standardize to goal-setting in clinical development.

Acknowledgements & References

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¹ Kiresuk, T. J., Smith, A., & Cardillo, J. E. (Eds.). (2014). *Goal attainment scaling: Applications, theory, and measurement*. Psychology Press.

