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Evidence Notes

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Goal Attainment Scaling – a useful individualized outcome measure for clinical studies?

Welcome to the third issue of Evidence Notes, the monthly newsletter from Bridge Medical. Our aim with this newsletter is to write short, informative articles about interesting aspects in the evidence space. The content will be jargon free as we aim to stress the applicability of each area to our Clients day to day work. In this issue we explore the concept of **Goal Attainment Scaling**, a clinician/patient generated personalised outcomes scale. Whilst the concept has been around for several decades, given the heightened interest in PROs, we are starting to see increased interest in its application, and we have recently worked with two asset teams to incorporate the approach into Phase III / IIIb clinical trials. We hope you find this short article interesting – next time we will be examining statistical approaches to handling bias and confounding in non-randomised data sets.

Previous articles have described alternative approaches to pragmatic clinical trial design. In this article we highlight a "real-world" approach to outcome measurement, the Goal Attainment Scale (GAS).

The problem with traditional scales in clinical research is that they assess a standardised set of questions regardless of the relevance of specific items to each individual patient; this is true even of many patient-reported outcome measures (PROs). Moreover, item response to PROs may vary with clinical status; those with severe illness may be more concerned with symptoms or drug side-effects, whilst less severely ill patients may be more interested in recovery-oriented goals such as social relations, employment etc[1].

The GAS, however, is a PRO which overcomes these weaknesses because it is an individualised assessment based on achievement of goals **which are personal** to each patient[2]. Whilst the goals (i.e. what is measured) are individual to each patient, there is a standardized approach to assessment that is quantifiable and applicable across different conditions and severities. In essence, it is a measure of "achievement of expectation" rather than a measure of outcome *per se*[3].

The GAS was first developed by Kiresuk & Sherman (1968)[2], has been cited widely in the academic literature (over 800 publications mostly in the psychology literature[4]) and has been shown to have high reliability, variable validity & excellent responsiveness[5,6,7]. Use in drug intervention studies, however, appears to be limited to dementia in Alzheimer's disease (AD[8,9,10]) and Parkinson's disease (PDD[11]).

There are no definitive schedules for application of GAS as this will vary depending on the clinical condition under study[5]. Helpfully, there are several detailed guides available on ways to operationalise GAS[7,12,13,14]. Below is a summary of the basic steps. To illustrate the process we use a simple clinical example of an elderly male patient with COPD who is entering a clinical study and one of his goals is to improve his walking distance.

1. **Goal setting –** At the start of the study goals are carefully selected by interviewing the patient and/or caregiver to identify specific problem areas, usually a minimum of 3 and a maximum of 5-6.

- **Clinical example:** The patient articulates 3-4 functional goals that they would like to improve during the course of the study, one of which is related to improving walking distance.

2. **The "expected" outcome –** For each identified goal, an outcome is predicted and agreed that is **achievable within study constraints** This is called the "expected outcome".

- **Clinical example:** Currently the patient can walk around the ground floor of his house, but cannot walk up the stairs unaided. In this case the "expected outcome" agreed between clinician and patient is to walk up the stairs unaided.

3. **Attainment Levels –** The GAS is typically based on a 5-point scale and each goal will have its own GAS scale (Figure 1). The expected outcome is usually scored 0, there are two "attainment levels" below (- 1, - 2) and two above (+ 1, + 2).

   Each of these attainment levels need to be very carefully described a priori in a way that is meaningful to the patient, relevant to the condition being studied, consistent with treatment duration, likely to be influenced by the proposed intervention and, most importantly, can be observed and measured.

- **Clinical example:** Figure 2, over the page, shows descriptors for each attainment level for our example.

  It should be noted that, in this example, -1 represents the baseline status to

Figure 1: The GAS 5-point Scale

-2	-1	0	+1	+2
A lot less	A bit less	Expected Outcome	A bit more	A lot more

allow for potential deterioration (to -2). In certain clinical circumstances, where substantial deterioration is expected and maintenance of baseline may be a desirable outcome of treatment, baseline may be set to 0 (e.g. AD)[15].

4. **Scoring –** a standardized statistical formula is used to sum achievement of goals to provide a measure of overall goal attainment. Different ways of expressing the results can be found in the literature[5], the most common being the use of a T-score[2]. Some argue that this enables GAS scores to be normalized and then analysed with parametric statistics; others believe GAS scores are ordinal (i.e. the "distance" between levels is not equal) and non-parametric statistics apply[5,16].

A number of modifications and improvements to the basic principles of GAS have been described over the years[5]. One of the key ones is the introduction of published standardised goals or "item banks"[13,17]. For example, in Alzheimers Disease a "Symptom Guide"[15,18] provides patients and caregivers with a range of plain-language descriptors for each problem across the full dementia severity range which, it is argued, will help them determine how each problem might worsen or improve. Such approaches may also overcome the perceived non-linearity of the scale, although others believe their use may undermine the personalized nature of GAS.

As with all scales, there are a number of challenges with GAS. In Table 1 we list some of the advantages and disadvantages.

Figure 2: Example Attainment Level Descriptors

	Attainment Level	Descriptor for attainment level
+2	A lot more	Patient can walk to the local shop unaided
+1	A bit more	Patient can walk up the stairs unaided two times within a one hour period
0	**Expected Outcomes**	**Patient can walk up the stairs unaided**
-1	A bit less	Patient can still only walk around the ground floor of his house
-2	A lot less	Patient cannot walk between rooms on the ground floor unaided

Table 1: Advantages and Disadvantages

Advantages	Disadvantages
Relatively easy to understand and use	Risk of bias (raters may set some patients easier goals)
Individualised goals relevant to each patient; no redundancy of items	Success depends on teams ability to select appropriate goals & predict outcome; observable changes may not correspond to pre-defined outcomes
Assesses multiple domains	Time consuming – especially at baseline
Quantifiable – provides a single overall score linked to functional improvement	Little used in pharmacological intervention studies
May provide a more sensitive measure than traditional psychometric scales	Independent GAS assessors may be required for blinded trials but will not be familiar with patient's usual attainment; may also require "control" GAS i.e. goals not affected by treatment
Psychometric properties generally established	Unresolved statistical issues around single overall score

With the increasing use of PROs, their potential use to support claims in approved medical product labeling[19], and their importance for value assessment of a medicine by HTA & payers, the GAS might be overdue a widespread resurrection and a modern application in capturing those outcomes which are truly important to each individual patient i.e. not simply patient-*reported* outcomes but patient-*generated* outcomes.

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