

Beyond Patient Journals - Using GAS to Capture the Patient Voice

Ardea Insights Webinar Series

January 28th, 2021



ARDEA

OUTCOMES

Ardea Insights Webinar Presenters



CEO

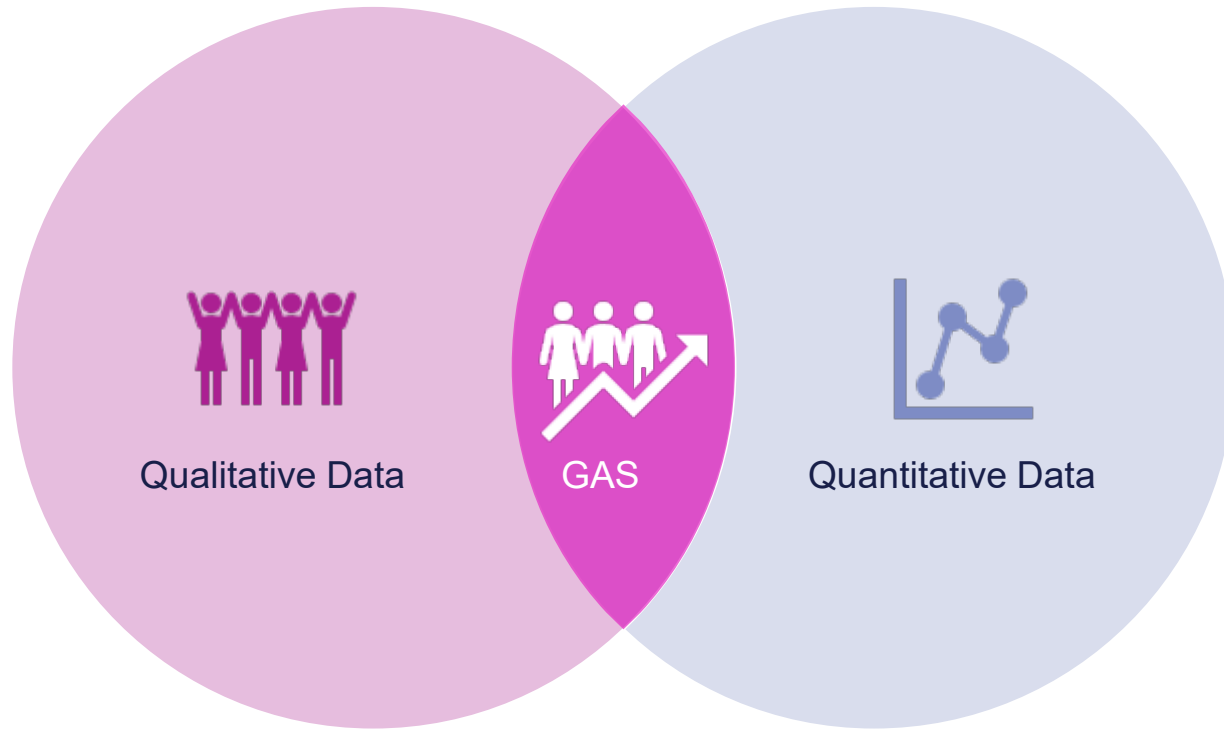
Chere Chapman



Biostatistician

Taylor Dunn

Interpreting GAS Data



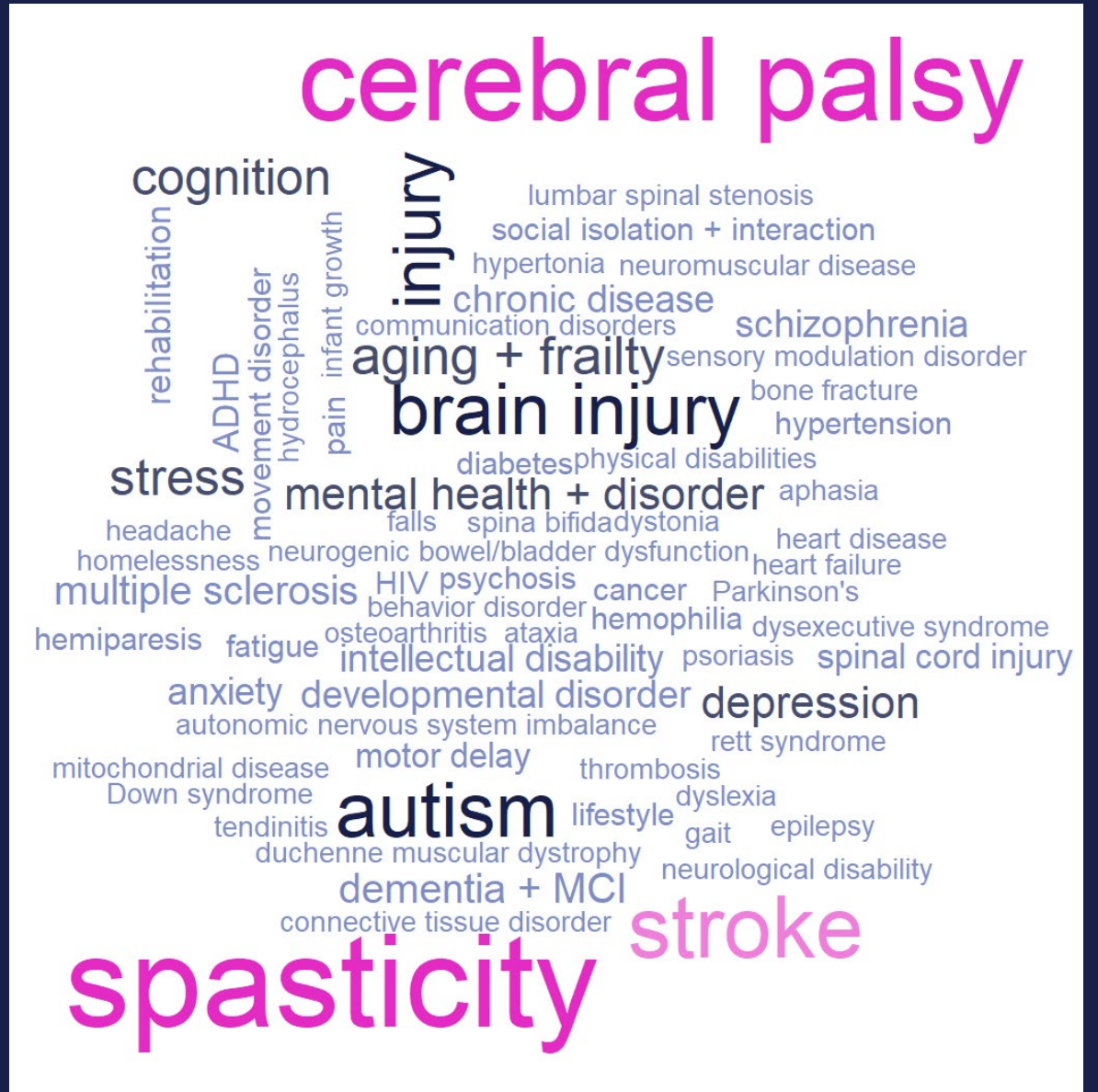
Where quantitative and qualitative meet to measure efficacy and effectiveness

Agenda

- **Overview of Goal Attainment Scaling**
 - **GAS Value as an Endpoint**
 - **Basics of the GAS Method**
- **Example: GAS and PROMs in Kidney Disease**
- **Questions**

GOAL ATTAINMENT SCALING
MEASURES THE EXTENT TO WHICH A
PATIENT'S INDIVIDUAL GOALS ARE
ACHIEVED WITH INTERVENTION.

APPLICATIONS OF GOAL ATTAINMENT SCALING IN RESEARCH.



GAS Method and Data Value

PHASE 01

PHASE 02

PHASE 03

PHASE 04

➤ GAS is a **Patient-Centric Outcome Measure**

➤ GAS may be used Phase 1B onward

Phase 4 → Reported by patients as a PRO/RWE

Phase 1→4: GAS is facilitated by a Clinician: some similarities to a Clin-RO but coming the patient

Best **introduced early**
in clinical development

Data shows **efficacy**
and **effectiveness**

Data is **inherently**
clinically meaningful
and relevant

Modified GAS data
captured direct from
patients or caregivers

✓ Changes the nature of the
dialogue between patient and clinician

✓ GAS data is meaningful to patients,
caregivers, sponsors and regulators

✓ Promotes shared decision-making
✓ Incorporates wishes and concerns of
patients or caregivers

✓ GAS is motivating
✓ GAS can promote adherence

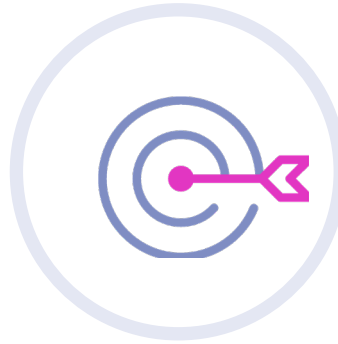
How Goal Attainment Scaling Works:

THE BASICS



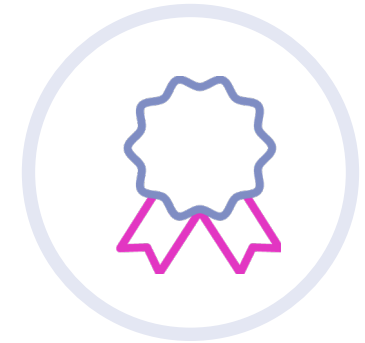
IDENTIFY GOALS

Clinician to facilitate interview for subject or caregiver to identify goals



BUILD GAS SCALES

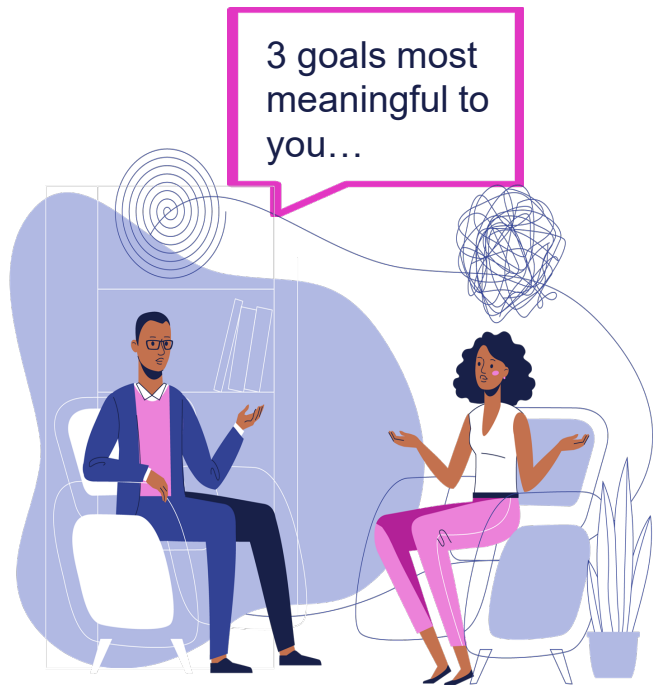
Set the 5-point goal attainment scale for each identified goal



MEASURE ATTAINMENT

Rate during follow-up whether the goals have been attained

The Goal-Setting Visit



Goal Title



Much Better than the Goal



+2

Somewhat Better than the Goal

+1

The Goal

0

Baseline Status

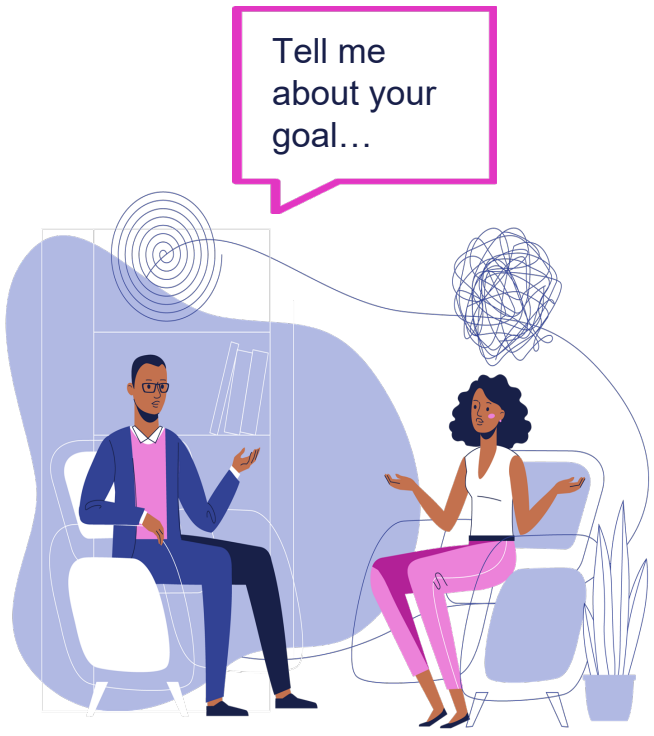
-1

Much Worse than the Goal

-2

The Follow-Up Visits

	Subject Rating	GAS Interviewer Rating
Much Better than the Goal Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat.	<input type="radio"/> +2	<input type="radio"/> +2
Somewhat Better than the Goal Ut enim ad minim veniam, quis nostrud exercitation ullamco laboris nisi ut aliquip ex ea commodo consequat.	<input type="radio"/> +1	<input type="radio"/> +1
The Goal Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Ut enim ad minim veniam, quis.	<input type="radio"/> 0	<input type="radio"/> 0
Baseline Status Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor.	<input type="radio"/> -1	<input type="radio"/> -1
Much Worse than the Goal Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor.	<input type="radio"/> -2	<input type="radio"/> -2



Common pitfalls with PROs:

A kidney disease example

**Heterogeneity is hard to capture with
standardized measures.**

Individuals with kidney disease experience a wide variety of symptoms and challenges

GAS embraces heterogeneity of disease expression.

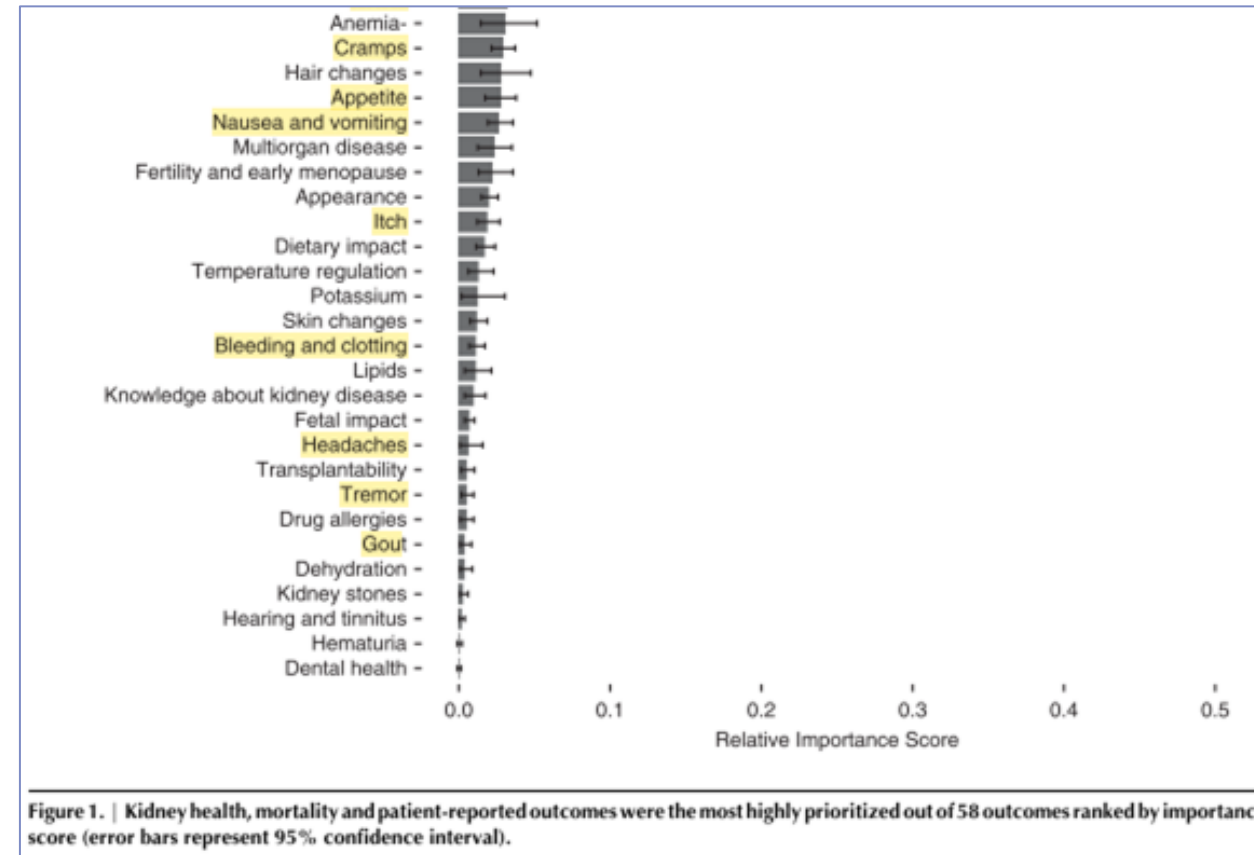
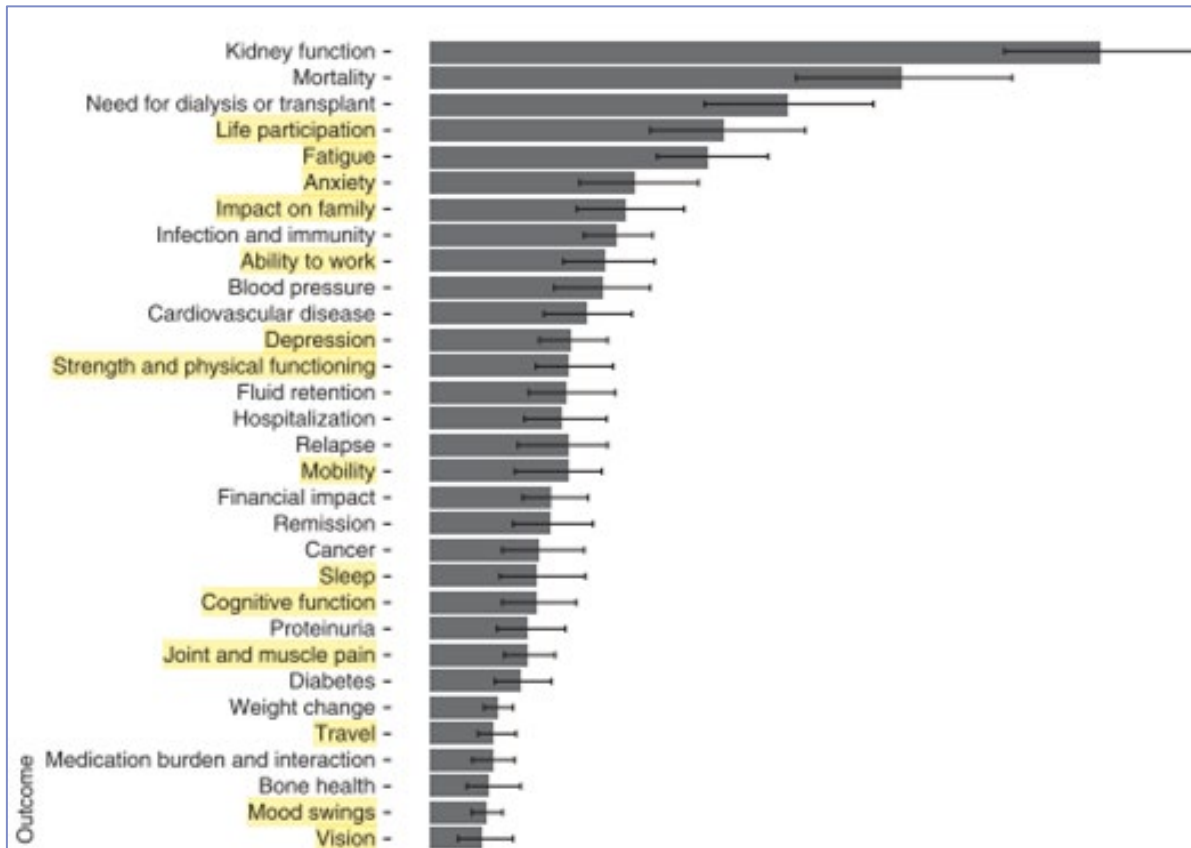


Figure 1. | Kidney health, mortality and patient-reported outcomes were the most highly prioritized out of 58 outcomes ranked by importance score (error bars represent 95% confidence interval).

**Existing PROs have important
limitations.**

There are limitations to existing PROs used in kidney disease

GAS can avoid some psychometric issues found with PROs used in CKD.

Psychometric issues:

- Floor and ceiling effects are common
- Evidence of responsiveness is limited

Instrument version	Population
Agarwal [32]	Pre-dialysis
KDQOL-36 [33, 34, 37, 38, 40–42]	Pre-dialysis
	Dialysis
KDQOL-SF [35, 36, 39, 43–48, 76, 85–96, 102]	Pre-dialysis
	Dialysis
	Transplant
CDQOL [49]	Dialysis
CHEQ [50, 51]	Dialysis
DSI [52, 53]	Dialysis
ESAS [54, 55]	Dialysis
KDQ [56, 57]	Dialysis
KDQOL (D)[58]	Dialysis
KDQOL (M)[59]	Dialysis

NHP [60, 61]	Dialysis
SF-12 [62]	Dialysis
WHOQOL-BREF (D) [63]	Dialysis
QLI 3.0 [64–67]	Dialysis
SF-36 v2	Dialysis [68]
	Transplant [69]
ESRD-SCL [70–72]	Transplant
EQ-5D [73]	Transplant
GIQLI [75]	Transplant
GSRS [75]	Transplant
KTQ [77–79, 84]	Transplant
MTSOSD [74]	Transplant
RTQ v1 [80, 81]	Transplant
RTQ v2 [81]	Transplant
TTO (modified) [83]	Mixed (D & TX)
CKD-SBI [82]	Mixed (D & Pre-D)

**Standardized PROs can be
cumbersome and may not capture what
is truly important to the patient.**

Standardized measures lack nuance and can miss important issues.

By allowing the patient to identify their meaningful issues, GAS is both focused and comprehensive by design.

GAS avoids “looking for a needle in a haystack”.

GAS focuses on a few clinically meaningful goals versus standardized outcomes which ask dozens of questions (e.g. **KDQOL-36**).

During the past 4 weeks, to what extent were you bothered by each of the following?

	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
17. Soreness in your muscles?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
18. Chest pain?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
19. Cramps?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
20. Itchy skin?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
21. Dry skin?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
22. Shortness of breath?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
23. Faintness or dizziness?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
24. Lack of appetite?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
25. Washed out or drained?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
26. Numbness in hands or feet?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
27. Nausea or upset stomach?	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
28 ^a . (Hemodialysis patient only) Problems with your access site? ...	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
28 ^b . (Peritoneal dialysis patient only) Problems with your catheter site? ..	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

GAS embraces heterogeneity of disease expression.

There are limitations to existing PROs.

GAS is focused and inherently clinically meaningful.

Discussion

Thank you.
Ardea Outcomes.

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