

Phase I Study Protocol To Develop A Short-Form Patient-Reported Outcomes Measure For Gender-Affirming Surgery

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BACKGROUND & PURPOSE

- Gender-affirming surgery (GAS) is increasingly available as a treatment for gender dysphoria.
- Patient reported outcomes are particularly important for evaluating GAS outcomes because the dissonance between sex assigned at birth and gender identity are closely related to both external reactions to physical appearance and internalized self-perception
- Currently available patient reported outcomes measures (PROMs) for GAS are either unvalidated or limited in scope.

PURPOSE: To develop a short-form PROM to assess the impact of GAS

METHODS

- Best practice guidelines in survey design and scale validation were followed in the development of the Vanderbilt Mini-PROM-Gender (VMP-G).
- Deductive and inductive methods were used to combine qualitative patient experiences with existing data on patient outcomes to create conceptual themes and frameworks relevant to the clinical context.
- A three-phase mixed methods approach was used to develop the VMP-G (**Fig. 1**). Our recruitment methodology ensured a diverse sample – all adult patients seeking GAS at Vanderbilt University Medical Center were eligible to participate.
- Classical test theory approach was used for psychometric analyses (acceptability, reliability, and validity).

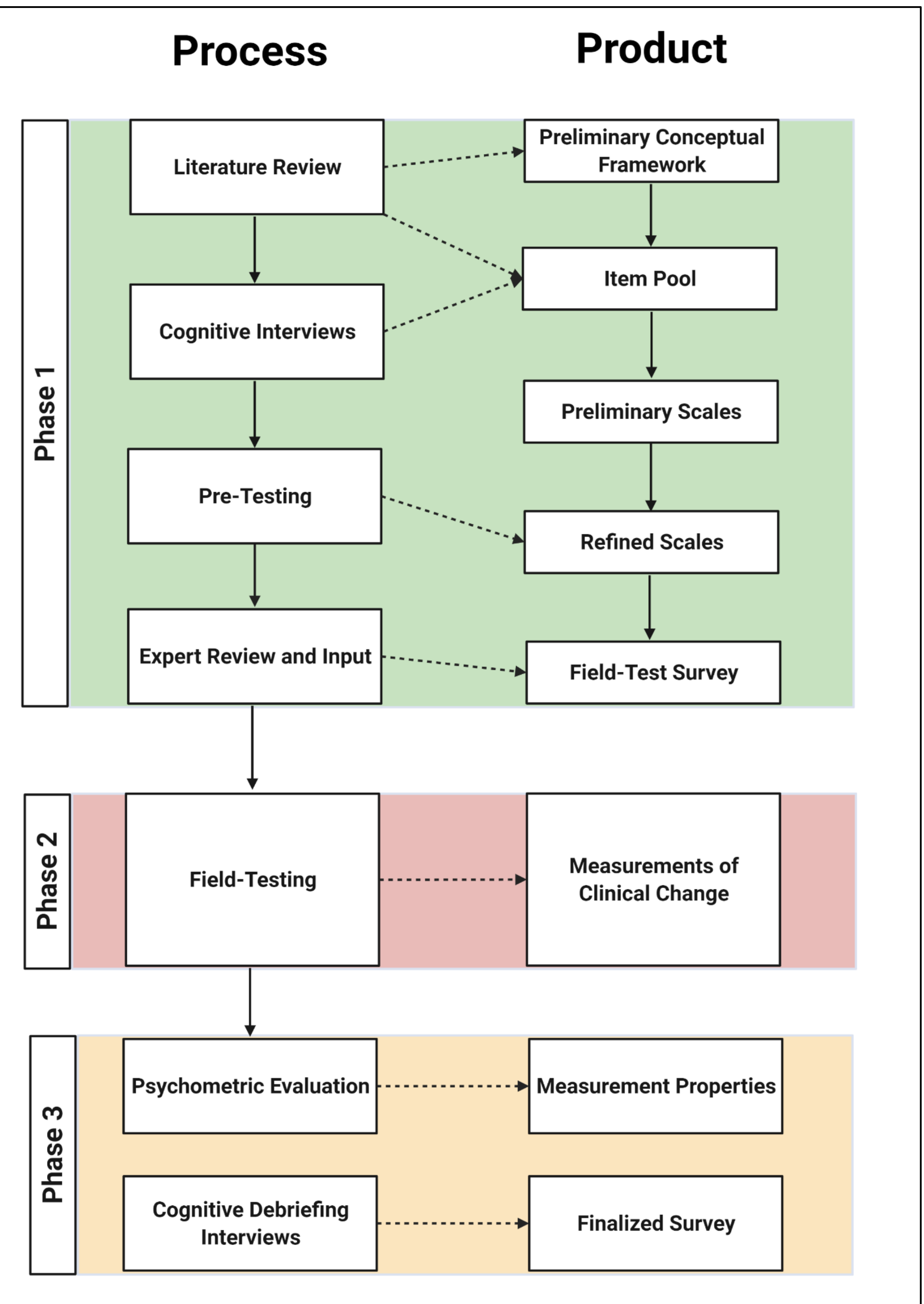


Figure 1. Flow diagram illustrating the 3-phase mixed methods protocol for developing VMP-G

VMP-G SURVEY

Table 1. VMP-G Items Grouped by Scale

Scale: Quality of Life (physical and psychosocial)

How would you rate your overall quality of life?

How would you rate your physical function (e.g., mobility, strength, bladder, bowel, etc.)?

How often do you experience negative feelings about yourself?

How often are you misgendered?

How safe do you feel in your daily life?

How comfortable are you in public settings?

Scale: Self-Concept

I accept my physical appearance.

I feel my body aligns with my gender identity.

Scale: Satisfaction

Your overall health?

Your personal life?

Your professional life?

Your sex life?

The care you receive from your healthcare providers?

Scale: Gender Dysphoria

Face/neck

Chest

Genitals

Hips/buttocks

Voice

How often do feeling of gender dysphoria disrupt daily life?

Non-Scale: Regret

Based on my current knowledge and experiences, I would receive gender-affirming surgery.

Table 2. Summary of VMP-G Psychometric Evaluation

Cronbach's α	Test-Retest (Intraclass Correlation Coefficients)	Item-Total Correlation (mean, range)	Inter-Item Correlation (mean, range)
0.774	0.895	0.530, 0.333-0.660	0.373, 0.173-0.598
0.777	0.897	0.640, 0.640	0.640, 0.640
0.705	0.797	0.478, 0.301-0.724	0.339, 0.102-0.580
0.680	0.786	0.420, 0.296-0.556	0.271, -0.006-0.492

Table 3. Effect Sizes of VMP-G Scales

Scale Scores	Effect Size (g)
Quality of life	1.21 (0.62-1.78)
Self-concept	1.68 (1.06-2.30)
Satisfaction	0.86 (0.30-1.42)
Gender Dysphoria	1.24 (0.65-1.82)
Total Score	1.44 (0.84-2.03)

- VMP-G includes four scales: quality of life, self-concept, satisfaction, gender dysphoria, and one non-scale item (regret) (**Table 1**).
- All scales exceeded criteria for acceptability, reliability, and validity, with the exception of the gender dysphoria scale (**Table 2**).
- All scales had large effect sizes (**Table 3**).

RESULTS

Table 4. Comparison of Preliminary VMP-G Scores

Scale Scores	Overall (n=67)	Pre-operative (n=17)	Post-operative (n=50)	p
Quality of life	23 (20-25)	17 (16-22)	24 (22-26)	<0.001*
Q1	4 (4-5)	4 (3-4)	4 (4-5)	0.002*
Q2	4 (4-5)	4 (4-5)	5 (4-5)	0.712
Q3	3 (3-4)	3 (2-3)	4 (3-4)	<0.001*
Q4	4 (2-4)	3 (2-4)	4 (3-4)	0.029*
Q6	4 (3-5)	3 (3-4)	4 (4-5)	0.005*
Q8	4 (3-4)	3 (2-4)	4 (3-4)	0.001*
Self-concept	7 (5-8)	4 (3-6)	8 (6-8)	<0.001*
Q7	4 (3-4)	2 (2-3)	4 (3-4)	<0.001*
Q19	4 (2-4)	2 (1-2)	4 (3-4)	<0.001*
Satisfaction	19 (17-22)	17 (15-20)	20 (18-22)	0.003*
Q9	4 (3-5)	4 (3-4)	4 (4-5)	0.019*
Q10	4 (3-5)	4 (3-4)	4 (4-5)	0.030*
Q11	4 (3-5)	3 (3-4)	4 (3-5)	0.005*
Q12	3 (2-5)	3 (2-4)	3 (2-5)	0.709
Q13	5 (4-5)	4 (3-5)	5 (4-5)	0.033*
Gender Dysphoria	20 (16-22)	15 (12-20)	21 (18-23)	<0.001*
Q5	3 (3-4)	2 (2-3)	4 (3-4)	<0.001*
Q14	3 (2-4)	3 (2-4)	3 (2-4)	0.928
Q15	4 (2-4)	1 (1-2)	4 (3-5)	<0.001*
Q16	4 (2-5)	3 (2-4)	4 (3-5)	0.005*
Q17	3 (2-5)	3 (2-4)	3 (2-5)	0.381†
Q18	3 (2-4)	3 (2-4)	3 (2-4)	0.382†
Regret (non-scale)				
Q20	5 (4-5)	5 (5)	5 (4-5)	0.224
Total Score	74 (64-82)	58 (53-71)	78 (70-82)	<0.001*

- VMP-G scores were collected for 67 patients including 17 pre-operative patients and 50 post-operative patients. Each item was scored on a 5-point Likert scale with total possible scores ranging from 20 to 100.
- Post-operative patients scored significantly higher on all scales and total score compared to pre-operative patients (78 vs. 58, p<0.001) (**Table 4**).

CONCLUSION

- The VMP-G is an effective, validated PROM to evaluate GAS outcomes for transgender and gender non-binary (TGNB) patients.
- As a short form, VMP-G has the potential to decrease respondent burden for a population that has traditionally faced discrimination and limited access to healthcare.
- Characterization of the benefits and harms of GAS has wide-ranging potential impacts for the TGNB population – from changing policy and access to care, to providing much needed outcomes data for patient-centered care.