Validation of a New Clinical Outcome Assessment: the Vaccination Experience Questionnaire (VEQ)

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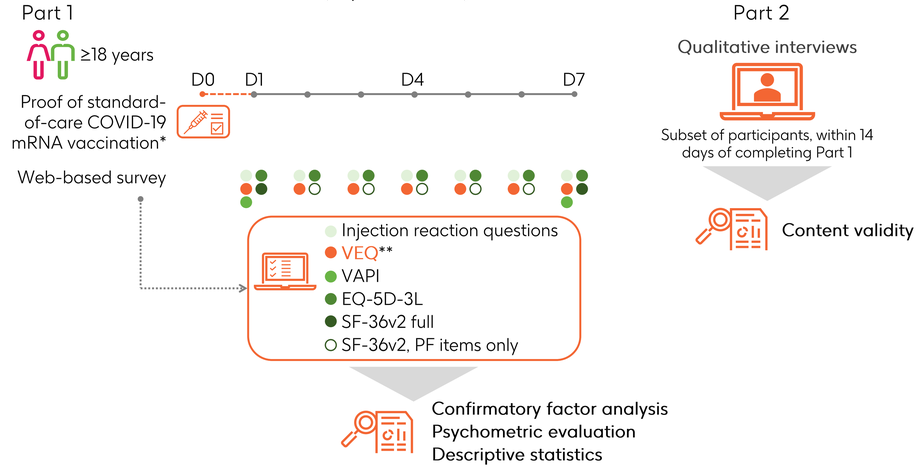
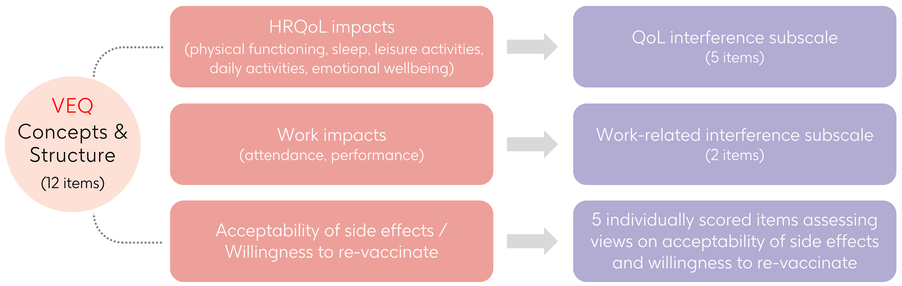
Background

- Information about the acceptability and impact of side effects on daily life as perceived by study participants is generally not collected in vaccine trials.
- The Vaccination Experience Questionnaire (VEQ) is a novel, self-report clinical outcome assessment (COA) designed to capture vaccine recipients' experiences beyond traditional adverse event reporting.
- By assessing the impact of post-vaccination side effects on health-related quality of life (HRQoL) and work, as well as perceptions of side effect acceptability and willingness to re-vaccinate, the VEQ aims to address a data gap in vaccine trials. Data from the VEQ may inform strategies that support vaccine confidence, which may be especially relevant for newer vaccines with limited real-world experience.
- We evaluated the structure, performance, and content validity of the VEQ.

Study design

Non-interventional, mixed-methods study in the US (Sep–Dec 2022)





*The vaccine was administered outside of the current study and consistent with US CDC recommendations for the indicated population at the time of study conduct. Proof of vaccination was required; **VEQ items 1–8 from D1 to D6 and all 12 items on D7.

Conclusions

The VEQ is a psychometrically sound, fit-for-purpose measure that provides a comprehensive evaluation of the acceptability and impact of vaccination-related side effects on daily life, as well as willingness to re-vaccinate. These features support its use in vaccine trials and potentially real-world studies.

The VEQ was designed to be vaccine-agnostic and can be readily integrated into clinical trials alongside traditional adverse event assessments administered via eDiaries.

VEQ data may inform healthcare professionals and advisory bodies in developing patient-centered vaccination strategies to improve vaccine coverage.

Digital poster Supplementary material — SCAN ME

Narrated summary — SCAN ME

Results

Study participants (Part 1*)

Part 1: N=210

Age
Mean: 39.8 years (SD 15.9)
≥65 years: 7.6%

Race**
White: 71.0%
Black/African American: 19.0%
Asian: 9.5%
Other: 8.1%

Web survey compliance
≥98.6% across 7 days

*Part 2 demographics are not presented as Part 2 participants (N=22) are a subset of Part 1 participants; **≥1 category possible.

Confirmatory factor analysis (D1–D3)

Predefined 2-factor model
TLI=0.978; CFI=0.985 (D1 data)
Acceptable model fits

This analysis supports the 2-factor structure of the VEQ with the QoL and work-related interference subscales. The non-weighted scoring approach based on this structure was therefore justified.

Psychometric evaluation (D1–D7)

Internal consistency reliability
Cronbach's α 0.67 to 0.92
Subscales are reliable measures and produce consistent results

Item-to-item correlations
r=0.3–0.7 (moderate), except for the leisure activities item and daily activities item with r>0.7 (strong)
Moderate relationship of most items among each other

Item-to-subscale correlations
r≥0.7 for most items
Strong relationship of most items within each subscale

Convergent validity
r=0.3–0.7 (D1 data) between VEQ subscales and related measures*
Accurately measures the intended constructs

Discriminant validity
r<0.3 (D1 data) between VEQ subscales and unrelated measures*
Measures constructs different from other constructs

Responsiveness
Mean subscale scores declined as side effects resolved from D1 to D7
Responsive to change

Thresholds for acceptable model fit: TLI ≥0.95, CFI ≥0.95. Internal consistency thresholds: Cronbach's α <0.70: weak, α ≥0.70: strong. Correlation thresholds: r <0.3: weak, r between 0.3–0.7: moderate, r between 0.7–0.9: strong, r >0.9: very strong.
*Related measures include VAPI domains, EQ-VAS, and SF-36v2 physical component summary, physical functioning, role physical, bodily pain, and role emotional. Unrelated measures include SF-36v2 mental component summary, general health, vitality, social functioning, and mental health.

Descriptive statistics

- On D1 post-vaccination, >80% of participants reported in the VEQ that their side effects in the last 24 hours were perceived as "mostly" or "completely" acceptable, increasing to >90% by D7.
- Minimal interference with QoL and work was observed across 7 days.

Qualitative interviews (Part 2)

- Qualitative interviews (N=22) confirmed strong content validity of the VEQ and led to minor editorial refinements to improve clarity.

Limitations

- The study population was US-based, with limited representation of adults ≥65 years of age and certain racial/ethnic groups, restricting generalizability.
- The narrow response range (due to mild, short-lived effects) may limit sensitivity to differences in acceptability.

Abbreviations

CDC, Centers for Disease Control and Prevention; **CFI**, comparative fit index; **D**, day; **N**, number of participants; **PF**, physical functioning; r, Spearman correlation coefficient; **SD**, standard deviation; **SF-36v2**, 36-Item Short-Form Health Survey version 2; **TLI**, Tucker-Lewis index; **US**, United States; **VAPI**, Vaccinee's Perception of Injection questionnaire (injection-site reactions).

Disclosures

BMC, WHC, EkB, IJ, EZ, ShaB, and EIB are or were employees of GSK at the time of the study design and/or conduct. BMC holds financial equities in GSK and Thermo Fisher. WHC holds financial equities in GSK and AstraZeneca. EkB holds financial equities in GSK and Moderna, Inc. IJ, ShaB, and EIB hold financial equities in GSK. DAA, DNR, IB, and ShwB declare consulting fees from GSK paid to their institution for the conduct of the study. The authors declare no other financial or non-financial interests, relationships, or activities.

Author contributions

BMC, DAA, WHC, EkB, DNR, IB, ShwB, EZ, and EIB contributed to the conceptualization. BMC, DAA, WHC, EkB, DNR, IB, ShwB, IJ, EZ, ShaB, and EIB contributed to the validation. DAA, DNR, IB, and ShwB contributed to the formal analysis and investigation. BMC and ShaB contributed to writing the original draft. All authors contributed to the writing (review & editing) of the poster and approved the final version.

Data sharing statement

The datasets generated during and/or analyzed during the current study are not publicly available due to participants consenting to data being published in anonymized form and full interview recordings/transcripts only being available to the project team responsible for conducting the research..

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