

evidation

Equitable research drives equitable health care:

The power of patient-reported outcomes (PROs)

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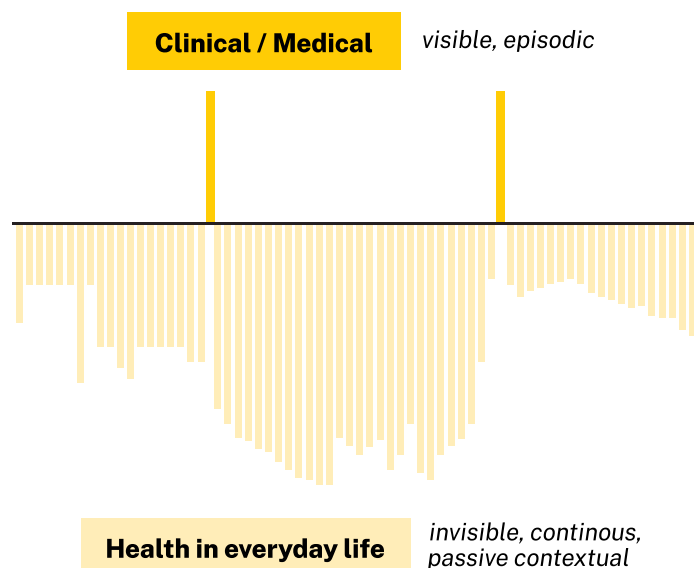
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PROs show a more complete picture of individuals' health journeys

In clinical and health research, patient-reported outcome (PRO) data capture information about the when, how, and why of individuals' health – and how they feel and function in real life.

PROs offer even more value — with continuous insights between visits

By collecting data between clinic visits, PROs highlight experiences missed during episodic clinic visits or in-person research assessments. This is especially true for electronic PROs (ePROs). They also enable researchers to reach a broader population, including individuals who may not have regular access to health care.



Pairing PROs with social factors reveals deeper insights

Combining PROs with demographic and **social determinants of health (SDOH)** characteristics helps uncover individuals' health experiences across a range of characteristics – and can identify disparities in access to care, treatment outcomes, and satisfaction with health care.

PRO data is often missing in research findings due to challenges with how to incorporate it

PRO data is often underutilized due to researchers' challenges with how to select, develop, use, and interpret PROs – particularly for diverse populations.



The following sections describe strategies to collect and interpret PRO/ePRO data in research, within the context of SDOH, to improve health equity.

Inclusive data collection is critical to advance health equity

Ensuring that your study is representative of the population affected by your research outcomes is critical to equitable health care. Developing, validating, and using PROs must embrace diversity across SDOH—like education, economics, community, culture, and discrimination. This helps in selecting and designing the best-fit PRO for the motivations and barriers specific to your study population—as well as the **validated instrument for the study population**.

Strategies to choose fit-for-purpose PRO/ePRO instruments for your study population

STRATEGY	EXAMPLES OF ACTIONS	BENEFITS
<p>Use clinically and culturally validated instruments</p> <p>Select questionnaires and surveys that reflect the survey population</p>	<ul style="list-style-type: none"> Interview participants during PRO selection to understand their viewpoints, motivations, and barriers Involve a diverse group of participants—across race/ethnicities, gender identities, ages, socioeconomic status (SES), education levels, and ableness—in your PRO selection 	<ul style="list-style-type: none"> Overcome barriers to participation and minimize SDOH confounders Increase your chances of enrolling and retaining a representative sample Collect more clinically and culturally relevant data Better understand how the product or program will perform in the real world
<p>Ensure instruments are free of bias</p> <p>Inherent clinician or researcher bias, which could be reflected in how the questions are asked, significantly impacts how individuals answer them</p>	<ul style="list-style-type: none"> Include questions relevant to the participants’ culture, age, and gender Choose instructions or questions phrased inclusively to avoid implicit biases such as “women with breast cancer” or “men with prostate cancer” 	<ul style="list-style-type: none"> Ensure PRO instructions, questions, and answers are relevant for all potential participants Show participants they are seen and valued Increase the likelihood of capturing everyone’s voice

STRATEGY	EXAMPLES OF ACTIONS	BENEFITS
<p>Implement PROs electronically (ePROs)</p> <p>Some of the actions we propose should be done in conjunction with licensing guidelines and/or researcher input</p>	<ul style="list-style-type: none"> • Deliver PRO content and questions on a digital platform, i.e. apps, web, patient portals 	<ul style="list-style-type: none"> • Reduce in-person visits • Reach a larger, more representative population • Minimize the effect of researcher bias on the results
<p>Utilize digital platforms to engage participants</p> <p>With ePROs, harness the full potential of digital platforms to effectively engage participants</p>	<ul style="list-style-type: none"> • Use various formats — like text, images, and video — for instructions • Send notifications, alerts, and reminders to complete a PRO • Offer unbiased, uniformly applied rewards or games to encourage PRO completion • Provide multiple options to complete PROs — for example, tablet-based PROs in the clinic might be more suitable for lower SES populations, including racial minorities • Make thoughtful choices about reducing the burden of participation — for example, scheduling the assessment during a healthcare appointment • Incorporate inclusivity in the design, such as a read-aloud option for individuals with visual impairment or neuromuscular disorders 	<ul style="list-style-type: none"> • Support different learning styles and education levels • Achieve more complete data sets • Reduce participant drop-off during follow-up • Offer flexibility to complete PROs when it's convenient

Interpretation and sharing of findings determine the use of PRO/ePRO data for equitable health

Analyzing aggregated data alone can obscure SDOH-related differences that help make healthcare equitable. Here are strategies to make the interpretation of PRO data more impactful:

- **Stratify your cohort by SDOH or demographic variables to eliminate any confounders that may skew results.**

Example: In a study of **respiratory conditions** conducted online with 1,888 participants, women and individuals with COPD reported more frequent symptoms and greater impact on physical activity and psychosocial function compared to the participants with asthma and/or nasal polyps.

- **Conduct analysis to generate hypotheses about what is causing health disparities – and identify potential SDOH-related mechanisms for further exploration.**

Example: In a study of **chronic pain** conducted on the Evidation platform, race-based analyses found higher pain severity and interference reported by African American individuals with chronic pain than non-Hispanic White individuals — even after holding objectively measured activity levels constant. This highlights a disproportionate burden of chronic pain for African American individuals and could guide future research on potential underlying factors, such as experiences with the healthcare system.

Example: Higher observed rates of **breast cancer** and other health conditions such as **stroke**, **heart disease**, and **uterine leiomyoma** in Black women spurred the research strategy for a **follow-up longitudinal cohort study** of 59,000 Black women in the United States. The Black Women's Health Study (BWHS), started in 1995, uses biennial questionnaires to identify social constructs underpinning racial differences in health. Data analysis over the years has found:

- Higher **hysterectomy rates** in the South and for women with a lower education level — which could explain lower endometrial cancer rates in Black women than non-Hispanic White women

- Higher **rates of type 2 diabetes** for women living in low-SES neighborhoods regardless of personal education and income levels
- Lower rates of breastfeeding likely due to **racism, cultural norms**, and lack of parental leave

These results highlight the importance of incorporating the social context of health disparities into research.

→ **Pair PRO data with more objective data — like wearable-generated sleep and activity data — to identify “hidden” trends.**

Example: The **American Life in Realtime (ALiR) registry** aims to create a nationally representative data set to inform equitable health programs. **Using the ALiR data set**, including biometric data from provided Fitbit devices, researchers were able to model and predict COVID-19 infections for men, minority populations, and less-educated individuals more effectively than a model trained on data obtained from individuals using their own wearable device. Ensuring equitable participation by providing wearable devices to those who might not be able to afford them is crucial for representative data collection.

→ **Share findings widely to ensure the insights will be useful for the people they impact — as well as the organizations funding research and shaping treatment guidelines and social interventions.**

Although researchers typically share findings through scientific publications, conferences, and organization websites, making them widely accessible in lay language via patient registries, patient groups, and other publicly available domains promotes equity in knowledge. This approach to knowledge sharing builds trust in the research process and encourages diverse participation.

Visibility around PRO findings has also spurred programs to address inequities. For instance, the **2015 U.S. Transgender Survey (USTS)** findings on disparities that transgender women of color experience led to the introduction of a **congressional resolution** calling for non-discrimination protections in healthcare and beyond.



Utilize PROs to drive health equity and inform your research

Ensuring that a representative sample completes PROs is key to advancing health equity. Doing so provides a deeper and more accurate understanding of individuals' health experiences — including nuances driven by SDOH. These insights can shape public policy decisions, guide the development and commercialization of therapies, and ultimately impact health.

To read more about how to select, design, and analyze PROs in clinical research, take a look at these resources:

- [Statistical analysis of patient-reported outcomes in clinical trials](#)
- [Validity arguments for patient-reported outcomes: justifying the intended interpretation and use of data](#)
- [Chapter 18: Patient-reported outcomes: Cochrane Handbook for Systematic Reviews of Interventions](#)



To learn how Evidation engages individuals in order to characterize and quantify disease progression, treatment experience, and quality of life, **connect with a member of our commercial team.**