

A guide to Patient-Reported Outcome Measures

Part three: Examples of PROMs and PREMs

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This brief explores examples of PROMs being used for different diseases, and periods of care. It further explores the different outcome measures introduced in the previous brief while placing various measures within the context of healthcare priorities in the Western Cape. Specific focus is placed on how general PROMs should, and can, be adjusted to be context specific and useable.



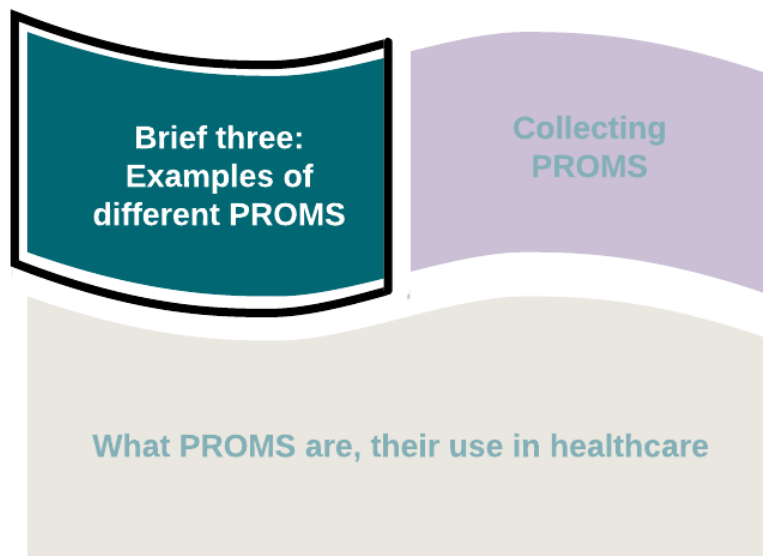
Introduction

The collection, analysis and reporting of patients' experience of healthcare, and of their self-reported health outcomes, is now a feature of more advanced healthcare systems around the world. This information is valuable for delivering, evaluating, and improving patient-centred healthcare.

Incorporating this type of measurement into the South African healthcare system can facilitate shifts to value-based care. It sharpens the focus on patients' perspectives and priorities, producing data that can be utilised by frontline clinicians and by managers to improve both the healthcare system and patients' quality of life.

This third brief in the series explores examples of PROMs.

Figure 1: This brief in the context of the PROMs briefs series



The Western Cape's priority areas

Five healthcare value streams have been prioritised by the Western Cape Department of Health and Wellness (WCDoHW): diabetes, violence and trauma, maternity, mental health, and tuberculosis (TB). Each of these priorities call for robust primary care services and may be ideal sectors in which to consider the introduction of patient-reported outcomes and experience measures.

With PROMs and PREMs in the toolbox, clinicians, managers, and policymakers would be equipped with useful new metrics to incorporate in specific existing and future initiatives aimed at improving quality and results.

Diabetes

Diabetes is a major, and rapidly growing, threat to public health in South Africa and a large burden on primary care services. Most public sector patients with diabetes don't get to see specialists (endocrinologists) until they have reached a severe or even end stage of the disease. An approach emphasising prevention and early treatment is needed.

The treatment focus has been on glycaemic (blood sugar) control, but new guidelines recognise that glucose levels on their own provide limited insight into outcomes that matter, both to clinicians and patients, such as heart, vascular, and kidney complications, and into the daily experiences, effects and challenges faced by patients living with and managing this chronic, deadly disease. Despite its magnitude, the significant treatment



burden that patients take on, and that is needed to keep the disease in check, is often invisible to clinicians.

A 2017 study in Chilean community health centres gave insights into the difficulties faced by patients living with diabetes.¹ The major burdens for patients were gaining access to clinicians, implementing complex medication regimens, and changing lifestyles (food and physical activity). To cope, patients drew support from their family, social environment, lay expertise, and spirituality. Clinicians caring for these patients faced significant administrative tasks, limited formularies, and protocol rigidity. The study authors called for "[minimally disruptive medicine](#)" that incorporates assessment of treatment burden into routine care, modifies clinical protocols based on patient workload, and improves patient capability through individual and social support. They suggest this collaborative approach will lead to better-fitting treatment programs, reduced burden, and improved adherence and outcomes.

Measuring diabetes outcomes

Numerous PROMs with good measurement properties and specific to diabetes have been developed, such as the Diabetes Distress Scale ([DDS](#)), Problem Areas in Diabetes ([PAID](#)) scale, Diabetes Quality of Life ([DQOL](#)), Summary of Diabetes Self-Care Activities ([SDSCA](#)), and Diabetes Treatment Satisfaction Questionnaire ([DTSQ](#)). The International Consortium for Health Outcomes Measurement ([ICHOM](#)) measurement set for diabetes includes non-disease specific measures such as [PHQ-9](#) and [PHQ-2](#) (depression) and [WHO-5](#) (a short, self-reported measure of mental wellbeing).

Less formalised PROMs were explored in the PROTECTOR diabetes telehealth. The pilot used a ten-question assessment administered at the patient's entry and graduation from a diabetes care program. The questions measured factors such as ability to manage diet, and PREMs measures such as ease of disease management. The measures were easy to collect for the given cohort size, and well understood by patients who showed general improvements on these measures throughout. Establishing these measures at baseline could also be used as a guide on what educational interventions were included in each patient's care plan.

Trauma and violence

South Africa is struggling to cope with an epidemic of trauma and violence. In trauma care, experience with patient-reported outcomes is reported from research studies in which over 100 different PROMs have been used. Introduction of PROMs into the routine care of these patients may help target and manage the needed clinical services.

- Despite the magnitude of prevalence of trauma and violence, the impact of trauma on health may be unappreciated. In urban Ethiopia, telephone-administered surveys found that 22% of trauma patients had significant persistent functional disability after six months, with many injuries having an ongoing financial impact²
- In a review of outcomes of tibial (lower leg) injuries in LMICs, no PROMs were used, but a study reported that only 20% of patients employed before injury were working 12 months post-injury³

In these studies, lack of documented telephone numbers and difficulty contacting subjects at recorded telephone numbers were the major obstacles to data collection. Language barriers and respondent participation rates were not significant limitations.

Surgery plays a vital role in managing the effects of trauma and violence. A recent review of "global" hand surgery* (i.e., in LMICs) emphasised the importance of PROs "throughout the care cycle" in understanding the consequences of limited surgical access, in evaluation of improvement initiatives, for prioritising cost-effective procedure and enabling shared decision-making. The authors point out that PROMs offer consistent, validated ways to measure trauma-relevant symptom severity including physical function, pain, general well-being, and quality of life. They note also that trauma-specific measures were used in fewer than 5% of studies.⁴ This is important because if the measurement does not focus on what's important to the patient, then it loses its

*'Global' is often used as a synonym for lower- and middle- income countries (LMICs)



usefulness. e.g., [EQ5D](#) is sensitive only to major trauma (loss of mobility) etc.

“Only through assessing a patient’s pain, function, and satisfaction before and after an intervention can we truly understand the benefit of the care we provide and the impact of surgical capacity-building initiatives on the quality of patient care.”

Measuring trauma- and violence-related outcomes

The specific PROs used may vary depending on the type and severity of the traumatic injury being treated, as well as other factors such as patient age and comorbidities.

Pain intensity is often assessed using a numerical rating scale ([NRS](#)) or a visual analogue scale ([VAS](#)). Patients are asked to rate their pain on a scale from 0 to 10 or to indicate the intensity of their pain on a line.

Functional status measures assess a patient's ability to perform activities of daily living, such as walking, dressing, and bathing. Examples of functional status measures include the Activities of Daily Living Scale ([ADL](#)) and the Functional Independence Measure ([FIM](#)).

Quality of life ([QOL](#)) measures assess a patient's overall well-being and satisfaction with life. Examples of QOL measures include the Short Form-36 ([SF-36](#)) (too lengthy for routine use) and the EuroQol-5 Dimension ([EQ-5D](#)).

Traumatic injuries can lead to **depression and anxiety**, so it is important to assess these symptoms. Examples of measures used to assess depression and anxiety include the Patient Health Questionnaire ([PHQ-9](#)) and the Generalized Anxiety Disorder ([GAD-7](#)) scale.

Traumatic injuries can also lead to **post-traumatic stress disorder (PTSD)**, so it is important to assess this condition as well. Examples of measures used to assess PTSD include the Posttraumatic Stress Checklist ([PCL](#)) and the Impact of Event Scale ([IES](#)).

Maternity

Maternal outcomes are important not only to mothers but their newborn and older children, their families and to society in general. As with all PROs, the domains and items that matter to patients should be defined, taking into account individual and community differences and circumstances.

A recent project, in Kenya, run by PharmAccess,⁵ demonstrated the feasibility of using mobile technology to track women through pregnancy and collect PROMs data to measure and address gaps in access and provision of high-quality care to pregnant women. PROMs were collected at least twice during pregnancy and twice after labour and delivery. **Information Box 1** shows an example of a patient journey through the maternal care pathway as the patient experiences the collection of PROMs.



Information Box 1: PROMs use case

Let's follow Sarah, 23 years old from Khayelitsha, who is pregnant for the first time, through antenatal care, labour and delivery, and postpartum care.

1. Pregnancy:

At her first antenatal clinic appointment, eight weeks pregnant, Sarah uses her cellphone, connected to the clinic's free Wi-Fi, to complete a questionnaire that includes a Health-related Quality of Life measure (the PROMIS Global10). This helps the clinic team understand her individual needs and preferences and develop a personalised care plan. Throughout her pregnancy, Sarah is periodically prompted to record and respond to any emerging issues or changes in her condition, helping identify potential risks, offering tailored support and advice, and adjusting her care plan as needed.

2. Labour and delivery:

After delivery, and before going home from the Midwife Obstetric Unit (MOU), Sarah is asked to complete questions about her birth experience (assessed via the BSS-R), to record her satisfaction with the results of care, confidence as an active participant in healthcare decisions, and confidence in healthcare providers. These responses, in aggregate, help the team review how well they are supporting Sarah and other patients like her and ensuring they feel heard and understood.

3. Postpartum period:

In the days and weeks following delivery, Sarah responds to questions that help the clinicians identify any challenges she may be facing and provide appropriate support and interventions: incontinence (tracked using the ICIQ-SF or Wexner scale), pain with intercourse (tracked using PROMIS SFFAC102), success and confidence with breastfeeding (the BSES-SF), mother-infant attachment (the MIBS), confidence with her role as a mother, and postpartum depression (assessed via the PHQ-2 with optional follow-up with the EPDS).

The PROMs data is added to the patient's folder by clerical staff each morning and is also available on the patient's phone.

Sarah's clinic team use the collected PROM data to evaluate the effectiveness of her postnatal care plan and make any necessary adjustments to support her ongoing recovery and adaptation to motherhood.

Throughout Sarah's pregnancy journey, the PROMs provide valuable insights into her experiences, needs, and preferences, enabling more personalised and patient-centred care. The ongoing collection of PRO data supports continuous quality improvement in maternity care services, ensuring that Sarah and other expectant mothers receive the best possible care.

Measuring maternity outcomes

The **International Consortium for Health Outcomes Measurement's (ICHOM)** Outcome Measures for Pregnancy and Childbirth⁶ standard set includes no fewer than nine patient-reported outcomes. These are shown in Figure 2.

The **postpartum period** tends to be a major focus of maternal health PROs, with infant health often underrepresented. Useful maternity-specific measures include the Obstetric Quality of Recovery ([ObsQoR-11](#) and [ObsQoR-10](#)) and Postpartum Quality of Life ([PQOL](#)) instruments.

Most existing childbirth-related PROMs were developed in high-income countries, potentially limiting their applicability in LMICs but a condition-specific PROM for assessing care quality in maternity services in LMICs has recently been published.⁷ A single comprehensive PROM, while useful for overall assessment and comparison of quality across facilities, is not needed to begin assessing outcomes and working to improve them. Additionally, PROMs have to be context specific, a factor that has shown measure sets, such as the ICHOM set, be adapted for local context to reflect what patients within a given context value. Previous work by Percept for example used stakeholder interviews, interviews with mothers, and literature reviews, to establish that a measure set to maternal outcomes in the South African context should include additional factors such as how well the patients felt their supporters were received during antenatal care appointments.



Figure 2: The International Consortium for Health Outcomes Measurement's (ICHOM) Outcome Measures for Pregnancy and Childbirth



Mental Health

Measurement of mental health using PROs is useful for screening and could help improve mental health outcomes in LMICs where awareness is low and access to professional mental health services is limited.

A study in Kenya used electronic data collection of [PHQ-2](#) to screen for depression, demonstrating the relevance of measurement in addressing mental health issues. Community health workers and nurses were trained to offer basic mental health screening and support to pregnant women, along with standard operating procedures for referral to specialised psychological care. Group-based interventions helped patients to understand that these issues are common and encourage early health-seeking when needed.

Measuring mental health

Perinatal depression and anxiety are alarmingly common in LMICs but often undocumented and underdiagnosed. In Kenya, for example, nearly one in every three pregnant women suffer from perinatal depression symptoms. Screening tools for perinatal depression is recommended, using tools such as the Edinburgh Postnatal Depression Scale ([EPDS](#)) and the Patient Health Questionnaire-9 ([PHQ-9](#)) but because they were developed in Western contexts, they may need validation in local settings; the Perinatal Depression Screen ([PDEPS](#)) is an example of a tool developed in and for a different setting (Kenya) with better measurement properties than the EPDS and PHQ-9. Mental health conditions often coexist with major physical conditions like heart failure and diabetes.

Tuberculosis

Tuberculosis (TB) is South Africa's second leading cause of death. TB initiatives have emphasised biomarkers for diagnosis and for gauging treatment success, and clinical outcomes do feature in TB outcome measurement sets. The patient's point of view however has been largely overlooked. PROs can be used to evaluate the efficacy of treatment, assess program performance, foster improved dialogue between patients and healthcare providers, and keep track of long-term outcomes.



Information Box 2: PROMs use case

Jane Hendricks is a 35-year-old woman who has had a persistent cough, weight loss, and fatigue for several weeks. Jane visits the clinic, where she is diagnosed with TB based on her history, chest x-ray findings and a positive sputum sample. The team at the clinic decides to use PROMs to monitor and support Jane's care throughout her TB treatment journey. They expect it will help with initial assessment, ongoing monitoring, communication, and evaluation of treatment effectiveness.

1. Before beginning her TB treatment, Jane completes an adapted, Afrikaans language version of the SF-12 questionnaire. This helps her team understand her baseline symptoms, quality of life, and any potential barriers to treatment adherence.
2. At monthly intervals during her six-month treatment course, Jane completes a subset of questions from the ? which allows her team to monitor her progress and identify any new or worsening symptoms. This information helps them tailor her care plan to address her specific needs and concerns.
3. The PROMs data facilitates communication between Jane and her healthcare team by providing an additional, structured way for her to report her symptoms and concerns.
4. At the end of her TB treatment, Jane completes the full questionnaire one more time. Her healthcare team compares her responses to her baseline assessment, which gives them important information to evaluate the overall effectiveness of her treatment and assess any need for further treatment.

PROMs data collected from Jane and other TB patients can be used by clinicians, managers and policymakers to identify trends, evaluate program performance, and implement targeted interventions to improve the quality of TB care in the healthcare system. Jane's treatment is more patient-centred. She becomes empowered to take an active role in her care and helps her healthcare team address any issues that may impact her treatment adherence or overall wellbeing.

Measuring TB-related outcomes

SF-12 is a general-purpose quality of life questionnaire that has 12 items grouped into domains of physical functioning, social functioning, psychological functioning, role functioning, cognitive functioning, and vitality. Afrikaans, isiXhosa, isiZulu, Sesotho, Setswana versions are available. Question items uncover limitations in physical activities, social activities and role activities, bodily pain, general mental health (psychological distress and well-being), emotional problems, and vitality (energy and fatigue).

The St. George's Respiratory Questionnaire ([SGRQ](#)) is an instrument used to measure health-related quality of life in patients with respiratory disease, including TB. SGRQ question items are grouped into three domains: symptoms, activity, and impact. Question items in the SGRQ include:

- "During the past 4 weeks, how often did you cough?"
- "During the past 4 weeks, how much sputum did you bring up?"
- "During the past 4 weeks, how much did your breathing problems interfere with your daily activities?"
- "During the past 4 weeks, how much did your breathing problems interfere with your social activities?"
- "During the past 4 weeks, how much did your breathing problems affect your overall quality of life?"

Treatment Satisfaction Questionnaire for Medication ([TSQM](#)) and EuroQol 5-Dimension ([EQ-5D](#)), are additional non-TB specific measurement tools that may be useful.

After the 2019 '1st International Post-Tuberculosis Symposium' in Stellenbosch, a report explored post-TB outcomes including mental health, physical functioning and the impact of stigma, noting that despite microbiological cure, TB can continue to negatively affect an individual's quality of life.⁹ 20-50% of survivors



experience lung impairment post-treatment, with persistent symptoms, economic losses, and impaired social life. Rates of depression and anxiety are twice as high in TB patients than in the non-TB-infected population. Mental health issues correlate with the severity and duration of TB, and are linked to loss of income, social role disruption, hopelessness, and stigma. Untreated depression can result in reduced treatment adherence and poorer TB outcomes.

People with lived experience of TB describe debilitating after-effects which can effectively be identified with PROMs.

*“Unfortunately, many individuals, like myself, suffer for years after treatment completion to battle against side effects of the medication. The toxicity of the medication is overlooked, and more care should be given to post-TB health and well-being of every TB survivor.
(Female TB survivor, 24 years)*

*Nowadays, I cannot walk long distance as I used to do, my legs are weak as well as my whole body is weak. I agree that I am healed because they tested me and said I don't have TB – but my whole body is still weak. During cold it is worse I feel pain all over my body.
(Female TB survivor, 40 years)*

The effects are really serious. Once you get TB it impairs your health as well as your ability to carry out your daily activities. (Male TB Survivor, 54 years)

*However, as you can see now I am healthy and OK although I am not yet to my normal life like before, but for me I see my progress is good and I have started doing my activities.
(Female TB survivor, 35 years)”*

Conclusion

In this third brief, we have provided practical examples of PROMs for the Western Cape's priority areas. These can be used a starting point for small pilots or testing in particular contexts. The examples are just that-helpful suggestions for effective, easy to scale PROMs. The examples also illustrate that for any PROMs to be used effectively, it is important to develop culturally appropriate and linguistically validated instruments that are sensitive to local contexts and patient needs. Additionally, clinicians and program managers should be trained on how to interpret PROs and use the data to inform clinical decision-making and program planning.



References

1. G SB, Ar Q, Vm M. Assessing the Burden of Treatment. *J Gen Intern Med.* 2017;32(10). doi:10.1007/s11606-017-4117-8
2. Laytin AD, Seyoum N, Azazh A, Zewdie A, Juillard CJ, Dicker RA. Feasibility of telephone-administered interviews to evaluate long-term outcomes of trauma patients in urban Ethiopia. *Trauma Surg Acute Care Open.* 2018;3(1):e000256. doi:10.1136/tsaco-2018-000256
3. Schade AT, Hind J, Khatri C, Metcalfe AJ, Harrison WJ. Systematic review of patient reported outcomes from open tibia fractures in low and middle income countries. *Injury.* 2020;51(2):142-146. doi:10.1016/j.injury.2019.11.015
4. Rosenberg GM, Stave C, Spain DA, Weiser TG. Patient-reported outcomes in trauma: a scoping study of published research. *Trauma Surg Acute Care Open.* 2018;3(1):e000202. doi:10.1136/tsaco-2018-000202
5. Al-Shammari I, Roa L, Yorlets RR, et al. Implementation of an international standardized set of outcome indicators in pregnancy and childbirth in Kenya: Utilizing mobile technology to collect patient-reported outcomes. *PloS One.* 2019;14(10):e0222978. doi:10.1371/journal.pone.0222978
6. Nijagal MA, Wissig S, Stowell C, et al. Standardized outcome measures for pregnancy and childbirth, an ICHOM proposal. *BMC Health Serv Res.* 2018;18(1):953. doi:10.1186/s12913-018-3732-3
7. Field J, Holmes MM, Newell D. PROMs data: can it be used to make decisions for individual patients? A narrative review. *Patient Relat Outcome Meas.* 2019;10:233-241. doi:10.2147/PROM.S156291
8. Promising pilot to improve mental health for pregnant women in Kenya. PharmAccess Foundation. Accessed May 16, 2023. <https://www.pharmaccess.org/update/promising-pilot-to-improve-mental-health-for-pregnant-women-in-kenya>
9. Glossary. YHEC - York Health Economics Consortium. Accessed May 16, 2023. <https://yhec.co.uk/resources/glossary/>