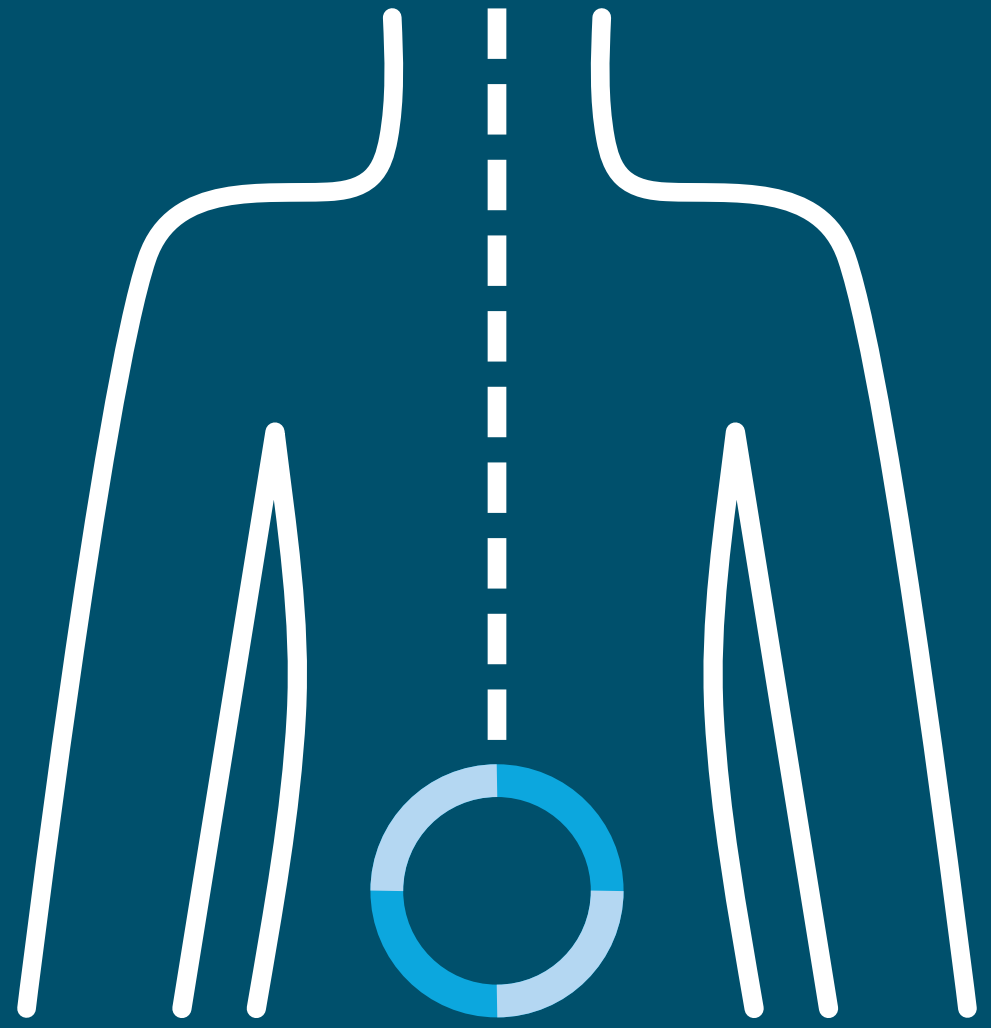
AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE



Patient-Reported Outcome Measure Recommendations for Low Back Pain

September 2024

The Australian Commission on Safety and Quality in Health Care acknowledges the traditional owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

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Contents

Abbreviations

Term	Definition
COSMIN	COnsensus-based Standards for the selection of health Measurement INstruments
DASS-21	Depression Anxiety Stress Scale – 21 items
EQ-5D-5L	EuroQol – 5 Dimensions – 5 Levels
HRQoL	health-related quality of life
MK-K5	Mayi Kuwayu Modified Kessler 5
NPRS	Numerical Pain Rating Scale
ODI	Oswestry Disability Index
PROM	patient-reported outcome measure
RMDQ	Roland Morris Disability Questionnaire

Quick guide – PROM recommendations for low back pain

This two-page quick guide summarises the recommendations. It may be used and adapted to support communication and implementation of PROM recommendations.

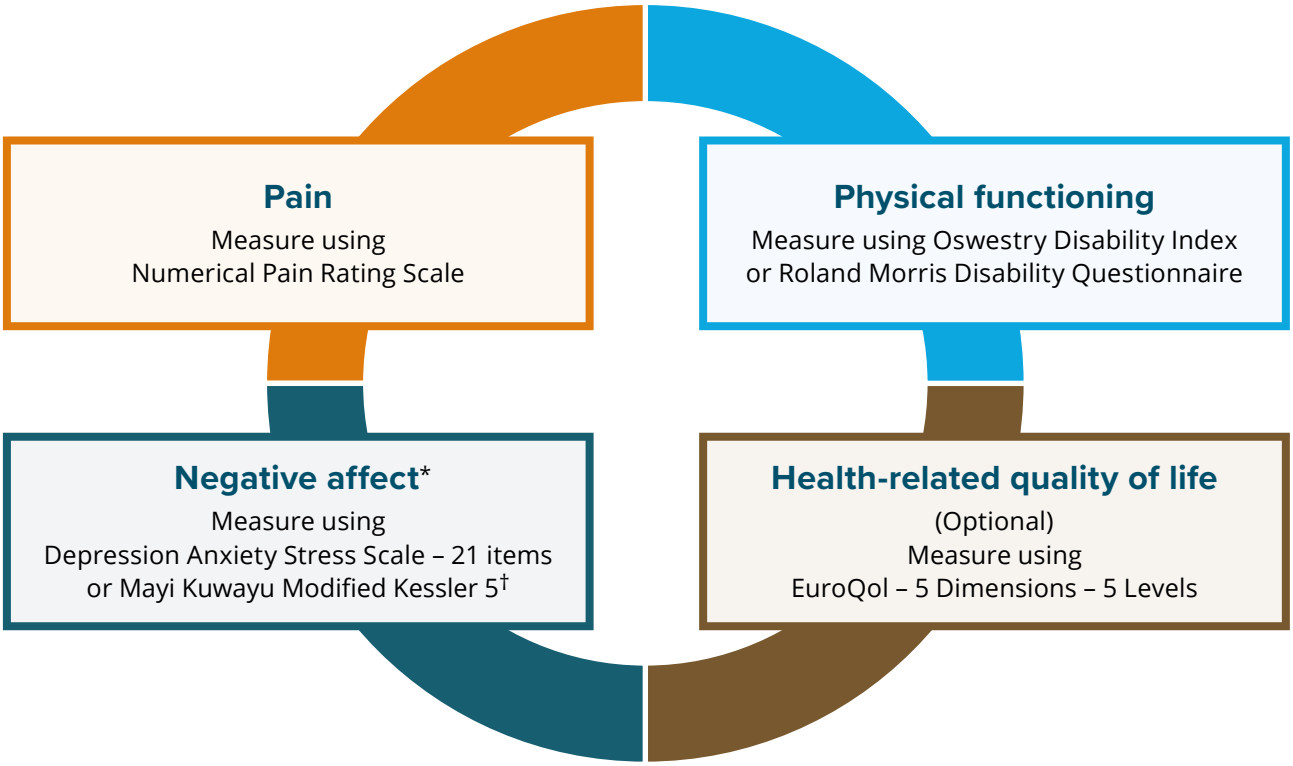
Low back pain affects most people at some point in their lives.[1] It often leads to psychological distress and poorer quality of life[2], and is the leading cause of disability worldwide.[1,3]

Using patient-reported outcome measures (PROMs) can support clinicians to:

- Partner with patients in the management of their pain
- Assess and monitor the progress of low back pain and interventions from the patient's perspective.

The Australian Commission on Safety and Quality in Health Care (the Commission) has developed evidence- and consensus-based recommendations for the use of PROMs for low back pain. These recommendations are intended to maximise the clinical usefulness of PROMs and minimise survey fatigue. Figure 1 shows the recommended PROMs for measuring the outcomes important to people with low back pain receiving either non-surgical or surgical interventions.

Figure 1: Overview of recommended PROMs for low back pain in patients receiving non-surgical or surgical interventions, for people aged 16 and over



* For patients with chronic low back pain, or who are at risk of developing chronic back pain.
† For Aboriginal and Torres Strait Islander people.

Summary of recommendations

There are many outcomes that are important to people who present with low back pain, including improving pain and being able to participate in daily activities. PROMs can be used to measure these outcomes to help assess and monitor progress from a patient's perspective. For some outcomes, more than one PROM has been identified, and implementers can select one of these. Table 1 provides a summary of the recommended PROMs to use concurrently for low back pain.

Table 1: Summary of recommended PROMs for low back pain

Outcome	Measure	Number of items	Time to complete	Licensing, fees and distributor	How to score
Pain	Numerical Pain Rating Scale (NPRS)	1	Less than 1 minute	▪ Licence not required ▪ Free in public domain	Not applicable
Physical functioning (choose one of either)	Oswestry Disability Index (ODI)	10	3–5 minutes	▪ Licence required ▪ Free for clinical practice ▪ Fees may apply to healthcare organisations ▪ MAPI Research Trust ePROVIDE™	Scoring guide at MAPI Research Trust ePROVIDE™
	Roland Morris Disability Questionnaire (RMDQ)	24	5 minutes	▪ Licence not required ▪ Free in public domain ▪ www.rmdq.org	Scoring guide at www.rmdq.org
Negative affect	Depression Anxiety Stress Scale – 21 items (DASS-21)	21	Not assessed in any study	▪ Licence not required ▪ Free in public domain ▪ Psychology Foundation of Australia	Scoring key provided at DASS downloads and explained in DASS FAQ #30
	Mayi Kuwayu Modified Kessler 5 (MK-K5) (Suitable for Aboriginal and Torres Strait Islander people)	5	Not assessed in any study	▪ Licence not required ▪ Free ▪ Mayi Kuwayu Modified Kessler 5	Scoring guide within Mayi Kuwayu Modified Kessler 5
Health-related quality of life (optional)	EuroQol – 5 Dimensions – 5 Levels (EQ-5D-5L) (Suitable for Aboriginal and Torres Strait Islander people)	5	Less than 5 minutes	▪ Licence required ▪ Fees may apply ▪ EuroQol Group	Scoring guide in *EQ-5D-5L User Guide*

Detailed information on the recommended PROMs, including samples for review, is provided in **Appendix A**, and guidelines for their use are in **Appendix B**. The development of the PROM recommendations is detailed in Appendices **C**, **D**, **E** and **F**.

Equity considerations when using PROMs

Accessibility of PROMs

Patients with disability, low literacy skills or cognitive impairment, or those from diverse linguistic and cultural backgrounds may experience barriers with completing PROMs. The Commission aims to provide recommendations that are accessible. This includes identifying PROMs that have validated translations or that have been validated in specific population groups, and providing advice for using PROMs in specific groups.

Where the Commission has not given advice for a specific patient group, clinical judgment should be used to assess whether the recommended PROMs support clinician–patient communication and shared decision making.

Cultural safety

The development of many PROMs is underpinned by Western biomedical models of health and wellbeing. Many PROMs may not be applicable to the needs of Aboriginal and Torres Strait Islander people[4], or compatible with their conception of health and wellbeing.[5] Other factors that may affect a PROM's acceptability for Aboriginal and Torres Strait Islander people are the PROM's length, language, wording and use of scales.[4]

Some research has engaged with communities on the cultural modification of PROMs and development of PROMs for Aboriginal and Torres Strait Islander people. Further work is needed to translate and culturally validate existing PROMs and design high-quality PROMs with and for Aboriginal and Torres Strait Islander communities.[4]

Where there is evidence of validity and reliability, the recommendations will highlight alternative PROMs that are suitable for Aboriginal and Torres Strait Islander people.

Caveat for data analysis

If a healthcare service is using data from PROMs for service-level analyses, accommodating the diverse needs of patients may introduce measurement bias and affect the reliability and validity of responses.[6] Analysis methodology should assess the impact of the potential bias and develop an approach to accommodate limitations.

See Agency for Clinical Innovation resource on **Analytic principles for patient-reported outcome measures**.

PROM recommendations for low back pain

Context

Low back pain is a leading and increasing cause of disability and loss of productivity worldwide.[7,8] It is associated with poor health-related quality of life in comparison to that of the general population, and limitations to mobility, self-care, employment, and social participation. In Australia, one in six people report back problems.[2]

Data from the **Australian Atlas of Healthcare Variation Series** identified significant service variations across Australia related to low back pain:

- In 2013–14, the number of Medicare-funded services for computed tomography imaging of the lumbar spine was 11.8 times higher in the areas with the highest rate compared to the area with the lowest rate.[9]
- Between 2015 and 2018, there was a 12-fold difference between the highest and lowest rates of lumbar spinal fusion surgery, and over a seven-fold difference in rates of lumbar spinal compression surgery.[10]

In response to these findings, the Commission developed the ***Low Back Pain Clinical Care Standard***. The standard consists of eight quality statements that describe the key components of care that a patient presenting with a new acute episode of low back pain should receive. This includes early clinical assessment, management, and review and referral. The standard also applies to patients with an acute episode, recurrence, or exacerbation of chronic low back pain.[11]

The ***Third Australian Atlas of Healthcare Variation*** (2018) also found a 5% increase in opioid prescribing nationally between 2013–14 and 2016–17.[12] Opioids, which are commonly prescribed for acute low back pain[13], are high-risk medicines with potential to cause harm, such as misuse, dependence and overdose. The ***Opioid Analgesic Stewardship in Acute Pain Clinical Care Standard*** was developed to provide guidance on the appropriate use and review of analgesics for managing acute pain, to optimise patient outcomes and reduce the potential for opioid-related harm.[14]

The ***Fourth Australian Atlas of Healthcare Variation*** (2021) recommended addressing the identified service variations by using high-quality research and outcome monitoring, including PROMs, to identify patients who would benefit from spinal surgery rather than more conservative interventions for low back pain. This prompted the Commission to develop recommendations on validated PROMs for low back pain.[10]

There are many outcomes that are important to people who present with low back pain, such as improving pain and being able to participate in daily activities.[15,16] Several PROMs can be used to measure these outcomes, to assist with assessing and monitoring progress from a patient's perspective.[16-18]

Patients with low back pain may consult more than one type of clinician and receive multiple interventions for their pain. They may also transition between surgical and non-surgical points of care and can progress to recovery or chronicity. Recommending a set of PROMs for use across clinical areas to collect outcomes from patients with low back pain promotes consistency and a shared understanding between clinicians of a patient's journey of care.

Goal

To support clinicians to use PROMs to:

- Partner with patients in the management of their low back pain
- Assess and monitor the progress of low back pain and interventions from the patient's perspective.

Pain

Numerical Pain Rating Scale (NPRS)

- **Number of items: 1**
- **Time to complete:** Less than 1 minute

Recommendation

Reducing pain is the most important outcome reported by patients seeking clinical care for their low back pain.[15,18,19] The NPRS is recommended to assess pain intensity. It is a commonly used and comprehensible tool, and it is easy to administer either graphically or verbally.

Recall period

The recommended recall period for pain PROMs differs for patients with acute low back pain and chronic or persistent low back pain as follows:

- **For patients presenting with acute low back pain, measuring pain 'right now' and 'in the past 24 hours' will provide clinicians with a baseline to aid monitoring of the patient's progress.**
- **For patients presenting with chronic or persistent low back pain, measuring pain 'in the past 24 hours' and 'in the past week' will provide clinicians with more information about the patient's experience of pain over time.**

Rationale

Pain intensity is consistently identified as the most important pain domain in low back pain literature and consensus-based development of core outcome domains for low back pain.[18-21] The NPRS is the most frequently used PROM to measure pain intensity in people with low back pain in clinical practice, clinical trials and clinical quality registries.[3,22]

Consensus-based studies and initiatives have also selected the NPRS to measure pain. For example, it is used in an updated core outcome set for low back pain clinical research[18], the International Consortium for Health Outcomes Measurement standard set for low back pain[21], the National Institutes of Health Research Task Force's set of standards for research on chronic low back pain[23], and the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials recommendations for chronic pain clinical trials.[20]

A systematic review conducted using the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) guidelines found that the NPRS had low or very low quality of evidence for content validity.[19] However, it is still recommended for its simplicity and wide use in clinical practice. For more information and a sample of the NPRS, see **Appendix A**.

Physical functioning

Oswestry Disability Index (ODI) or Roland Morris Disability Questionnaire (RMDQ)

ODI:

- **Number of items:** 10
- **Time to complete:** 3–5 minutes

RMDQ:

- **Number of items:** 24
- **Time to complete:** 5 minutes

Recommendation

Physical functioning is measured to assess the effect of low back pain on activities of daily living, such as walking or moving around, personal care and sleep.[24] Both the ODI and the RMDQ are recommended to measure this outcome. Although the ODI is the preferred tool, clinicians and healthcare services may choose to use the RMDQ if cost is a barrier.

Rationale

Low back pain can affect the ability of patients to participate in day-to-day activities, such as walking, self-care and socialising.[2,24] In conjunction with reducing pain intensity, increasing participation in everyday activities is an important outcome and rehabilitation goal for low back pain interventions.[15] The ODI and RMDQ are the most frequently used PROMs to measure physical functioning in people with low back pain in clinical practice, clinical trials and clinical quality registries.[3,22,25]

A systematic review conducted using the COSMIN guidelines assessed the psychometric properties of the ODI and RMDQ in people with low back pain and did not find adequate quality evidence for content validity.[25] The ODI provided marginally superior results in terms of its psychometric properties compared with the RMDQ. The ODI also has the advantage of being shorter and more widely used.[26]

In the absence of sufficient evidence to support the use of alternative PROMs to measure physical functioning, the ODI and RMDQ are considered to be useful tools to understand how low back pain is affecting a patient's day-to-day activities.

ODI or RMDQ?

The ODI is the preferred tool for assessing physical functioning. This is because the ODI captures more in-depth information, with multiple domains of daily living across 15 items, which patients can rate along a scale of impact. In comparison, the RMDQ has 24 items with a binary response, which can limit the amount of information that can be collected about the patient's physical functioning. Additionally, the ODI is the selected PROM to assess physical functioning in standardised outcome sets for both research and clinical practice.

However, licensing requirements for the ODI may be a barrier for some clinicians and healthcare services, where fees may apply according to the conditions of use. The RMDQ is given as an option that is free in the public domain. For more information and samples of the ODI and RMDQ, see **Appendix A**.

Implementation tip

The low back pain PROMs recommended in this document can be applied as an entire questionnaire set. However, to minimise survey burden and maximise clinical usefulness, clinicians can prioritise measuring pain and physical functioning to assess and monitor a patient's progress.

Clinician communication tip

Patients with low literacy skills may be unable to complete a PROM themselves due to sentence length and unfamiliar words.[6] Although PROMs are designed to be completed by the patient without interpretation of the patient's response by a clinician or anyone else, clinicians may consider supporting patients with low literacy by reading through each item. This can be used as an opportunity to educate patients about the nature of low back pain, and how their pain experience may affect their mood and quality of life.

Related resource: Supportive resources on health literacy

Negative affect

Depression Anxiety Stress Scale – 21 items (DASS-21)

- **Number of items: 21**
- **Time to complete:** Not assessed in any study

Recommendation

Negative affect refers to the subjective experience of negative emotional states, such as anxiety, depression, stress, sadness, worry and anger. There is a link between negative affect and chronic low back pain. Low back pain can affect mood, and mood can increase the likelihood of chronicity.[27] The DASS-21 can be used to measure three categories of negative affect: depression, anxiety and stress. It can be used in people who present with a history of chronic low back pain, and in people with ongoing management of low back pain persisting more than 12 weeks beyond initial management of an acute exacerbation.

Rationale

There is a reciprocal relationship between mood and the experience of pain, and people with chronic low back pain are reported to have higher incidences of mental health comorbidities.[11,27,28] Measuring a patient's emotional state, or more specifically their negative affect, in conjunction with measuring pain intensity and physical functioning, can provide clinicians with a biopsychosocial understanding of a patient's experience of pain, and assist in assessing and managing low back pain.

In Australia, the DASS-21 is commonly used in patients with chronic low back pain who present to specialist pain services. A persistent pain collaboration that collects a standard set of data from specialist pain services in Australia and New Zealand includes the DASS-21 to measure patient outcomes as a result of treatment.[22,29]

At the time of publishing these recommendations, no systematic review had been conducted to assess the psychometric properties of the DASS-21 or other mood/distress PROMs using the COSMIN guidelines in people with low back pain or chronic pain. However, for the general population, the DASS-21 has sufficient evidence for content validity and has been assessed to be psychometrically robust.[30]

The DASS-21 was developed with no specific population in mind and has wide applicability to different patient populations.[30-32] It is recommended for use with people who have or who may be at risk of developing chronic low back pain. For more information and a sample of the DASS-21, see **Appendix A**.

Cultural consideration

The **Mayi Kuwayu Modified Kessler 5 (MK-K5)** is a measure of psychological distress that has been culturally modified and validated for Aboriginal and Torres Strait Islander people.[33] It was modified from a five-item Kessler Psychological Distress Scale, which was adapted from the 10-item version by Aboriginal and Torres Strait Islander representation at a social and wellbeing workshop. It was modified to be culturally sensitive and short for use in the National Aboriginal and Torres Strait Islander Health Survey.[34]

The MK-K5 can be used as a culturally sensitive and shorter alternative to the DASS-21 for Aboriginal and Torres Strait Islander people.

For more information and a sample of the MK-K5, see Appendix A.

Psychosocial assessment tools

Psychosocial factors are associated with an increased risk of developing disability in people presenting with low back pain. These factors and emotional responses to pain are associated with delayed recovery, and their presence indicates the need for further assessment and appropriate intervention.[35]

Assessment tools used to identify unhelpful beliefs about pain and other psychosocial factors are clinically useful, but these tools are not PROMs.

For more information about using 'yellow flag' assessment tools, see **Quality statement 2 – Psychosocial assessment** in the *Low Back Pain Clinical Care Standard*.

Clinician communication tip

Explaining negative affect to patients

There is a risk that patients may misinterpret a negative affect PROM as the clinician believing the pain is 'all in their head', and so may disengage.

Before completing the questionnaire, explain to the patient that pain can affect both the body and the mind, and vice versa. Some simple questionnaires can help identify their concerns and help in developing the best treatment and support for them. For example:

> 'Pain can cause us to feel stressed or sad, and feeling stressed or sad can make us feel more pain. It is like the volume is turned up on pain and other symptoms. Filling in this questionnaire can help me understand how the pain is affecting the way you feel and help figure out the best way to help you.'

Listen to the patient, and validate that their thoughts and feelings are understandable, and the pain they are experiencing is real.

For more useful communication tips, see the *Low Back Pain Clinical Care Standard*.

Health-related quality of life

EuroQol – 5 Dimensions – 5 Levels (EQ-5D-5L)

- **Number of items: 5**
- **Time to complete:** Less than 5 minutes

Recommendation

Low back pain is associated with poor health-related quality of life (HRQoL) in comparison to the general population.[15,36] HRQoL may be measured if there is an interest in global health outcomes. However, to minimise survey burden, clinicians should prioritise measuring pain and physical functioning as they are the most immediately important outcomes for patients with low back pain. The EQ-5D-5L is recommended to measure HRQoL in people with low back pain.

Rationale

Low back pain is associated with poor HRQoL in comparison to the general population.[15,36] HRQoL is a commonly recommended outcome in clinical trials, but is less commonly used in clinical settings.

There is sufficient but very low-quality evidence for the relevance, comprehensibility and comprehensiveness of the EQ-5D-5L in people with low back pain. All other measurement properties have not been assessed in people with low back pain.[36]

Despite the lack of evidence of other psychometric properties of the EQ-5D-5L in people with low back pain, it is still recommended by the International Consortium for Health Outcomes Measurement for the low back pain standard set due to its large evidence base for other patient populations and the general population, and the extensive availability of validated translations.[21] In addition, the EQ-5D-5L is shorter and relatively inexpensive compared with other commonly used HRQoL tools.

For more information and a sample of the EQ-5D-5L, see **Appendix A**.

Psychometric evaluation of EQ-5D-5L in Aboriginal and Torres Strait Islander people

At the time of publishing these recommendations, there is no culturally appropriate HRQoL instrument available that has been designed by and validated specifically for use by Aboriginal and Torres Strait Islander people. Measurement of HRQoL within the Aboriginal and Torres Strait Islander framework of health and wellbeing must include domains of family and community, and constructs of connectedness beyond the individual.[37]

To determine whether meaningful data on HRQoL could be captured in this population, a study assessed the construct validity and reliability of the EQ-5D-5L in 1,012 Aboriginal adults across several distinct language groups. It found adequate reliability and good discriminant validity, and concluded that the EQ-5D-5L is a suitable tool for measuring HRQoL in Aboriginal and Torres Strait Islander people.[38]

Collection time points

The time frames for collecting data from PROMs will vary depending on the acuity of the low back pain presentation, the goals of the patient and the clinician, and the intervention.

To assess the effect of an intervention, it is recommended that, at a minimum and where practical, clinicians use PROMs to collect information from patients at the start and end of treatment (for example, at the first or second visit, and when the patient returns for follow-up appointments). If it is practicable, collecting at least three data points will establish a trend to determine whether a patient's outcome score improves in response to an intervention.

Acute presentation

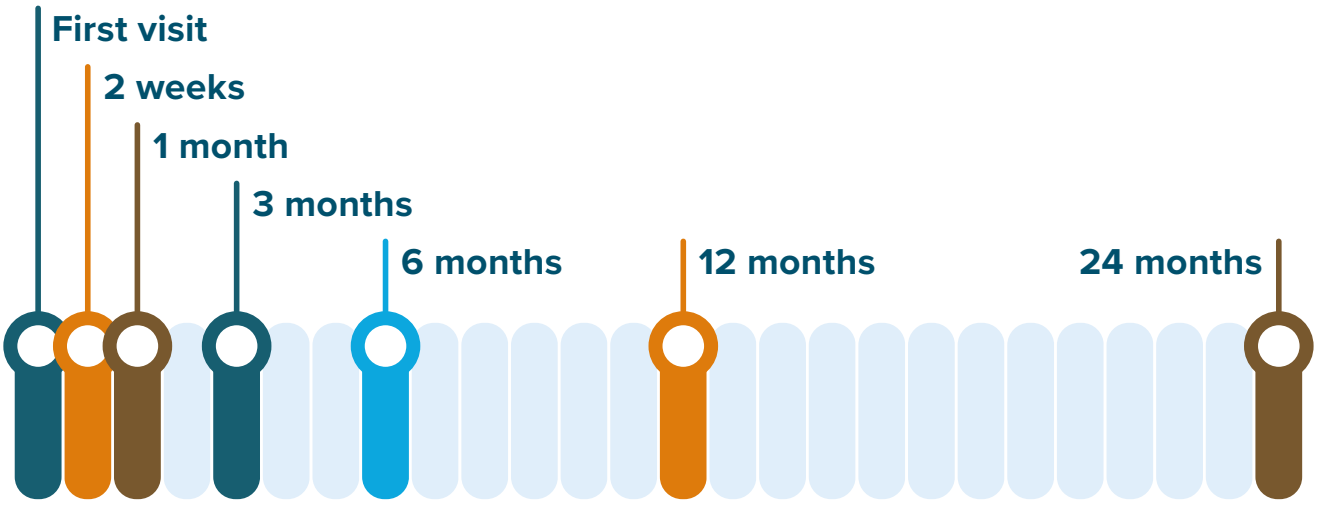
Acute presentations of low back pain or interventions that provide short-term relief (such as analgesics) may not require extensive follow-up administration of PROMs. PROMs may be used in the short term (such as when the patient returns for a follow-up visit) to ensure an intervention is effective.

Longer-term collection

Regular and longer-term collection of patient-reported outcomes using PROMs is recommended for patients with longer-term rehabilitation goals, for example, after surgical intervention or an episode of multidisciplinary care for chronic low back pain. If resources are available and patients are not lost to follow-up, continued use of PROMs for more than six months after treatment is recommended to assess the longer-term outcomes of the intervention.

See Figure 2 for recommended collection time points for longer-term rehabilitation goals.

Figure 2: Recommended collection time points for low back pain PROMs for longer-term rehabilitation goals



Not to scale

Risk factor for persistent spinal syndrome

It is recommended that patients receiving surgery have their pain measured two weeks after surgery to identify those who are experiencing severe pain. Patients with unidentified and unmanaged severe pain two weeks after surgery may have an increased risk of developing persistent spinal syndrome (formerly failed back surgery syndrome[39]).

Appendix A: Detailed information about recommended PROMs

Please note that all versions of PROMs included in this appendix are samples and are for information purposes only to determine suitability for clinical use. Unless it is specified that the PROM is free in the public domain, the samples cannot be used without respective authorisation from distributors, copyright holders or developers. Refer to the licensing requirements for information on how to obtain authorised clinical use of PROMs.

Numerical Pain Rating Scale (NPRS)

PROM description

The NPRS (detailed in Table 2) is a self-reported pain rating along an 11-point Likert scale, ranging from 0 (no pain) to 10 (pain as bad as you can imagine or worst pain imaginable; see **Figure 3**). The descriptors of the anchor statements that refer to pain intensity vary. Patients are asked to circle a number that best represents their pain intensity. There may be introductory questions with or without recall periods. The most common recall variations include asking patients to report their pain currently, in the last 24 hours or in the last week.[19]

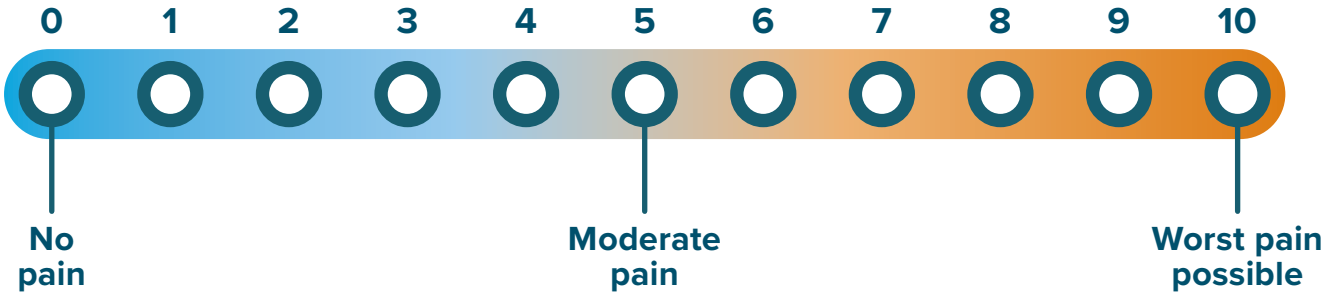
Development

No publications were found with information about the development of the NPRS.

Table 2: Detailed information about Numerical Pain Rating Scale

Characteristic	Details
Name	Numerical Pain Rating Scale
Abbreviation	NPRS
Country developed	Not known
Year validated	Not known
Short summary	Subjective measure for acute and chronic pain. It is a segmented, numerical version of the visual analogue scale.
Domains/dimensions	Unidimensional
Number of items	1
Time to complete	Less than 1 minute
Response type and range	11-point Likert scale, from 0 (no pain) to 10 (pain as bad as you can imagine or worst pain imaginable)
Scoring guide	Not applicable
Translations	Minimal language translation is required
Licence required	No
Fees	No – free in public domain
Copyright	No copyright
References to the original papers	Not applicable

Figure 3: Numerical Pain Rating Scale – Pain score 0–10



Oswestry Disability Index (ODI)

PROM description

The ODI 2.1b (detailed in **Table 3**) consists of 10 sections (pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, travelling), each containing six statements ranging in intensity (scored from 0 to 5); patients select the statement that best represents their situation (**Figure 4**). Scores on each of the 10 sections are summed, giving a maximum score of 50. The total score is then converted into a percentage (index) by multiplying it by two. Scores are stratified into severity: 0–20, minimal disability; 21–40, moderate disability; 41–60, severe disability; 61–80, crippling back pain; 81–100, patients are either bed-bound or have an exaggeration of their symptoms. A change in the patient's score of 10% or more is considered a clinically significant result.

Development

The ODI was first developed by specialist clinician John O'Brien in 1976 and later published by Jeremy Fairbank in 1980. The ODI was originally developed through patient interviews to identify the disturbance to activities of daily living caused by chronic back pain. It was designed for use with client groups that had acute, subacute or chronic back pain. The ODI was later modified by a Medical Research Council group in the United Kingdom, removing references to medication from the pain and sleeping items to improve the relevance of these items to people not taking medication. In 2000, the original ODI developer made additional modifications that led to version 2.0 (an option was added for 'no pain' in the pain intensity section), and then version 2.1 (alteration made to the travel section) and 2.1a (one-word adjustment to the opening statement).[40] ODI 2.1b was developed with a one-word alteration made to the personal care section.

Table 3: Detailed information about Oswestry Disability Index

Characteristic	Details
Name	Oswestry Disability Index
Abbreviation	ODI
Country developed	United Kingdom
Year validated	1980
Short summary	Measures pain-related disability for low back pain and spinal disorders more generally and is the preferred choice in severe disability when compared with the Roland Morris Disability Questionnaire. It is available in multiple versions and its items are included in the Patient-Reported Outcomes Measurement Information System® (PROMIS®).
Domains/dimensions	Unidimensional
Number of items	10
Time to complete	3–5 minutes
Response type and range	Six-point Likert scales with various anchors
Scoring guide	**MAPI Research Trust ePROVIDE™**
Translations	**45 translations, including English for Australia**
Licence required	Yes
Fees	▪ Free for clinical practice ▪ Fees may apply to healthcare organisations
Distributors | Weblink	ODI Contact information and permission to use: ▪ Mapi Research Trust, Lyon, France ▪ **eprovide.mapi-trust.org**
Copyright	ODI © Jeremy Fairbank, 1980. All rights reserved.
Author(s)	Fairbank JC
References to the original papers	Fairbank JC, Couper J, Davies JB, O'Brien JP. The Oswestry low back pain disability questionnaire. Physiotherapy 1980;66(8):271–3.

Figure 4: Oswestry Disability Index Version 2.1b

Oswestry Disability Index (ODI) version 2.1b

This questionnaire is designed to give us information as to how your back (or leg) trouble affects your ability to manage in everyday life.
Please answer every section. Mark one box only in each section that most closely describes you today.

Section 1 - Pain intensity

- ☐ I have no pain at the moment.
- ☐ The pain is very mild at the moment.
- ☐ The pain is moderate at the moment.
- ☐ The pain is fairly severe at the moment.
- ☐ The pain is very severe at the moment.
- ☐ The pain is the worst imaginable at the moment.

Section 2 - Personal care (washing, dressing, etc.)

- ☐ I can look after myself normally without causing extra pain.
- ☐ I can look after myself normally but it is very painful.
- ☐ It is painful to look after myself and I am slow and careful.
- ☐ I need some help but manage most of my personal care.
- ☐ I need help every day in most aspects of self care.
- ☐ I do not get dressed, wash with difficulty and stay in bed.

Section 3 - Lifting

- ☐ I can lift heavy weights without extra pain.
- ☐ I can lift heavy weights but it gives extra pain.
- ☐ Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, e.g. on a table.
- ☐ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can lift only very light weights.
- ☐ I cannot lift or carry anything at all.

Section 4 - Walking

- ☐ Pain does not prevent me walking any distance.
- ☐ Pain prevents me walking more than one mile.
- ☐ Pain prevents me walking more than a quarter of a mile.
- ☐ Pain prevents me walking more than 100 yards.
- ☐ I can only walk using a stick or crutches.
- ☐ I am in bed most of the time and have to crawl to the toilet.

Section 5 - Sitting

- ☐ I can sit in any chair as long as I like.
- ☐ I can sit in my favourite chair as long as I like.
- ☐ Pain prevents me from sitting for more than 1 hour.
- ☐ Pain prevents me from sitting for more than half an hour.
- ☐ Pain prevents me from sitting for more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

ODI - United Kingdom/English - Mapi.
ODI_AU2.1b_eng-GBori.doc

(continued)

Figure 4: Oswestry Disability Index Version 2.1b (continued)

Section 6 - Standing

- ☐ I can stand as long as I want without extra pain.
- ☐ I can stand as long as I want but it gives me extra pain.
- ☐ Pain prevents me from standing for more than 1 hour.
- ☐ Pain prevents me from standing for more than half an hour.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

Section 7 - Sleeping

- ☐ My sleep is never disturbed by pain.
- ☐ My sleep is occasionally disturbed by pain.
- ☐ Because of pain I have less than 6 hours sleep.
- ☐ Because of pain I have less than 4 hours sleep.
- ☐ Because of pain I have less than 2 hours sleep.
- ☐ Pain prevents me from sleeping at all.

Section 8 - Sex life (if applicable)

- ☐ My sex life is normal and causes no extra pain.
- ☐ My sex life is normal but causes some extra pain.
- ☐ My sex life is nearly normal but is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is nearly absent because of pain.
- ☐ Pain prevents any sex life at all.

Section 9 - Social life

- ☐ My social life is normal and causes me no extra pain.
- ☐ My social life is normal but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sport, etc.
- ☐ Pain has restricted my social life and I do not go out as often.
- ☐ Pain has restricted social life to my home.
- ☐ I have no social life because of pain.

Section 10 - Travelling

- ☐ I can travel anywhere without pain.
- ☐ I can travel anywhere but it gives extra pain.
- ☐ Pain is bad but I manage journeys over two hours.
- ☐ Pain restricts me to journeys of less than one hour.
- ☐ Pain restricts me to short necessary journeys under 30 minutes.
- ☐ Pain prevents me from travelling except to receive treatment.

ODI - United Kingdom/English - Mapi.
ODI_AU2.1b_eng-GBori.doc

Roland Morris Disability Questionnaire (RMDQ)

PROM description

Patients completing the RMDQ (detailed in Table 4) are asked to place a check mark beside a statement if it applies to them 'today' (**Figure 5**). This approach was chosen to make it suitable for observing short-term changes in back pain. The score is calculated by adding up the number of items checked, with total scores ranging from zero (no disability) to 24 (maximum disability).

Development

The RMDQ was first published in 1983, and was originally designed and tested for use in primary care settings for low back pain. It has since been used in a variety of other settings (for example, research, healthcare specialists).

Multiple versions of the RMDQ have been developed; however, the content between the different versions of the RMDQ varies considerably. These deviations make comparisons across studies challenging, with international experts calling for use of the original 24-item version because of its widespread use and benefits in standardisation.[41]

Table 4: Detailed information about Roland Morris Disability Questionnaire

Characteristic	Details
Name	Roland Morris Disability Questionnaire
Abbreviation	RMDQ
Country developed	United Kingdom
Year validated	1983
Short summary	A short measure of disability, particularly caused by low back pain. It is primarily recommended for mild to moderate disability, and focuses only on physical problems. It is available in a number of forms and uses a checklist format. 24-, 18- and 11-item questionnaires are available.
Domains/dimensions	Unidimensional
Number of items	24
Time to complete	5 minutes
Response type and range	Respondents select from a list only those items that describe current function.
Scoring guide	**www.rmdq.org**
Translations	**57 translations, including English for Australia**
Licence required	No
Fees	No – free in public domain
Distributors | Weblink	**www.rmdq.org**
Copyright	Available in public domain and can be used without permission
Author(s)	Morris R and Roland MO
References to the original papers	▪ Roland M, Morris R. A study of the natural history of back pain. Part I: Development of a reliable and sensitive measure of disability in low-back pain. Spine 1983;8(2):141–4. ▪ Roland M, Fairbank JC. The Roland–Morris disability questionnaire and the Oswestry disability questionnaire. Spine 2000;25(24):3115–24.

Figure 5: Roland Morris Disability Questionnaire

QUESTIONNAIRE ON LOW BACK PAIN

Australian English version of the Roland-Morris disability questionnaire. MAPI 2005.

The cultural adaptation process is described at section 1.2 of translation details at end of the questionnaire

When your back hurts, you may find it difficult to do some of the things you normally do.

This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe your situation *today*. As you read the list, think of yourself *today*. When you read a sentence that describes your situation *today*, put a tick against it. If the sentence does not describe your situation, then leave the space blank and go on to the next one. **Remember, only tick the sentence if you are sure that it describes your situation *today*.**

1. I stay at home most of the day because of the pain in my back.
2. I change position frequently to try and get my back comfortable.
3. I walk more slowly than usual because of the pain in my back.
4. Because of the pain in my back, I am not doing any of the jobs that I usually do around the house.
5. Because of the pain in my back, I use a handrail to climb stairs.
6. Because of the pain in my back, I lie down to rest more often than usual.
7. Because of the pain in my back, I have to hold on to something to get out of a lounge chair.
8. Because of the pain in my back, I ask other people to do things for me.
9. I get dressed more slowly than usual because of the pain in my back.
10. I only stand up for short periods of time because of the pain in my back.
11. Because of the pain in my back, I try not to bend or kneel down.
12. I find it difficult to get out of a dining chair because of the pain in my back.
13. My back is painful most of the time.
14. I find it difficult to turn over in bed because of the pain in my back.
15. I do not feel like eating much because of the pain in my back.
16. I have trouble putting on my socks (or stockings) because of the pain in my back.
17. I only walk short distances because of the pain in my back.
18. I sleep less than usual because of the pain in my back.
19. Because of the pain in my back, I get dressed with help from someone else.
20. I sit down for most of the day because of the pain in my back.
21. I avoid heavy jobs in the house because of the pain in my back.
22. Because of the pain in my back, I am more irritable and bad tempered with people than usual.
23. Because of the pain in my back, I climb stairs more slowly than usual.
24. I stay in bed most of the time because of the pain in my back.

Depression Anxiety Stress Scale – 21 items (DASS-21)

PROM description

The DASS-21 (detailed in Table 5) is a measure of negative emotional states of depression, anxiety and stress (**Figure 6**). The patient indicates the presence of a symptom over the previous week. Each item is scored from 0 (did not apply to me at all over the last week) to 3 (applied to me very much or most of the time over the past week). The essential function of the DASS-21 is to assess the severity of the core symptoms of depression, anxiety and stress.

Although the DASS may contribute to the diagnosis of anxiety or depression, it is not designed as a diagnostic tool. Indeed, symptoms typical of depression, such as sleep, appetite and sexual disturbances, are not covered by the DASS and will need to be assessed independently. The DASS is not meant to replace a comprehensive clinical interview.

Development

The DASS was developed in 1995 by Lovibond and Lovibond, who identified a broad range of core symptoms of depression and anxiety, and identified stress as a separate factor with a different range of core symptoms. Based on these findings, Lovibond and Lovibond developed the DASS to assess the core symptoms of depression, anxiety and stress, and a brief 21-item version, the DASS-21.[42]

Table 5: Detailed information about Depression Anxiety Stress Scale – 21 items

Characteristic	Details
Name	Depression Anxiety Stress Scale – 21 items
Abbreviation	DASS-21
Country developed	Australia
Year validated	1995
Short summary	A 21-item measure to assess the negative emotional states of depression, anxiety and stress. The DASS-21 is a shorter version of the DASS-42.
Domains/dimensions	3: Depression, anxiety, tension/stress
Number of items	21
Time to complete	Not assessed in any study
Response type and range	Four-point Likert scale, from 0 (did not apply to me) to 3 (applied to me very much or most of the time)
Scoring guide	Scoring key provided at **DASS downloads** and explained in **DASS FAQ #30**
Translations	**57 translations**
Licence required	No
Fees	No – free in public domain
Distributors | Weblink	**Psychology Foundation of Australia**
Copyright	Available in public domain and can be used without permission
Author(s)	Lovibond PF and Lovibond SH
References to the original papers	Lovibond PF, Lovibond SH. The structure of negative emotional states: comparison of the Depression Anxiety Stress Scales (DASS) with the Beck Depression and Anxiety Inventories. Behav Res Ther 1995;33(3):335–43.

Figure 6: Depression Anxiety Stress Scale – 21 items

DASS21

Name: *Date:*

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:

0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of time
3 Applied to me very much, or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (eg, in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3
20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

Mayi Kuwayu Modified Kessler 5 (MK-K5)

PROM description

The MK-K5 (detailed in **Table 6**) is a culturally modified and validated version of the Kessler Psychological Distress Scale 5 (K5) for Aboriginal and Torres Strait Islander people, which assesses psychological distress (**Figure 7**).

Development

The Kessler Psychological Distress Scale 10 (K10) was developed in 1992 by Ron Kessler and Dan Mroczek. Kessler and Mroczek reviewed approximately 500 psychological distress items from various sources, reducing these to 45 items. Based on United States surveys, the scale was further refined to 32 items, and then two sets: one with six items (K6) and one with 10 items (K10).

In 2003, Aboriginal and Torres Strait Islander stakeholders at a social and emotional wellbeing workshop raised concerns about the cultural appropriateness of the word 'worthless' in the K10, which might be considered offensive to some Aboriginal and Torres Strait Islander people. Professor Kessler and state and territory health authorities gave support for the inclusion of five questions to measure psychological distress among Aboriginal and Torres Strait Islander people.

Alterations were also made to two items to improve cultural comprehension: feeling 'hopeless' was changed to feeling 'without hope'; and feeling 'restless or fidgety' was changed to feeling 'restless or jumpy'.[34] However, there was a lack of robust evidence for the validity of the modified version in Aboriginal and Torres Strait Islander peoples, especially younger adults, and for those residing outside of New South Wales.[33]

The MK-K5 was developed and validated with further modifications to support comprehensibility in the Aboriginal and Torres Strait Islander population.

Table 6: Detailed information about Mayi Kuwayu Modified Kessler 5

Characteristic	Details
Name	Mayi Kuwayu Modified Kessler 5
Abbreviation	MK-K5
Country developed	Australia
Year validated	2021
Short summary	A culturally modified Kessler 5 instrument that can be used to assess the psychological distress levels of Aboriginal and Torres Strait Islander people.
Domains/dimensions	Unidimensional
Number of items	5
Time to complete	Not assessed in any study
Response type and range	Five-point Likert scale, from 1 (none of the time) to 5 (all of the time)
Scoring guide	Scoring guide within **Mayi Kuwayu Modified Kessler 5**
Translations	Unknown
Licence required	No
Fees	No
Distributors | Weblink	**Mayi Kuwaya – The National Study of Aboriginal and Torres Strait Islander Wellbeing**
Copyright	Can be used without permission
Author(s)	Brinckley M, Calabria B, Walker J, Thurber KA and Lovett R
References to the original papers	Brinckley M, Calabria B, Walker J, Thurber KA, Lovett R. Reliability, validity, and clinical utility of a culturally modified Kessler scale (MK-K5) in the Aboriginal and Torres Strait Islander population. BMC Public Health 2021;21:1111.

Figure 7: Mayi Kuwayu Modified Kessler 5

Mayi Kuwayu Modified Kessler 5 (MK-K5)

Background:
The Kessler Psychological Distress Scales are population and individual-level tools designed to measure general psychological health status. The MK-K5 is a culturally modified Kessler-5 instrument which can be used to assess the psychological distress levels of Aboriginal and Torres Strait Islander peoples.

MK-K5:

In the last 4 weeks, about how often did you feel…

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
Nervous?	O	O	O	O	O
Hopeless (have no hope)?	O	O	O	O	O
Restless or jumpy?	O	O	O	O	O
Everything was an effort (have no energy)?	O	O	O	O	O
Sad?	O	O	O	O	O

MK-K5 Scoring:
Response options are scored as: "none of the time" = 1, "a little of the time" = 2, "some of the time" = 3, "most of the time" = 4, and "all of the time" =5.

A total MK-K5 score is created by summing responses to all five items. The total MK-K5 score is recoded to missing if a participant does not respond to one or more items. Scores range from 5-25, with higher scores indicating higher level of psychological distress.

The MK-K5 categories and cut-offs are:

- Low psychological distress (scores: 5 to <8)
- Moderate psychological distress (scores: 8 to <12)
- High psychological distress (scores: 12 to <15)
- Very high psychological distress (scores: 15 to 20)

In the Aboriginal and Torres Strait Islander population, MK-K5 cut-off scores of **11 or above** indicate referral for further clinical assessment for risk of depression and/or anxiety.

Reference:
Brinckley, M., Calabria, B., Walker, J. Thurber, K.A., Lovett, R. (2021). Reliability, validity, and clinical utility of a culturally modified Kessler scale (MK-K5) in the Aboriginal and Torres Strait Islander population. BMC Public Health 21, 1111. https://doi.org/10.1186/s12889-021-11138-4

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EuroQol – 5 Dimensions – 5 Levels (EQ-5D-5L)

PROM description

The EQ-5D-5L is a measure of health-related quality of life (HRQoL). The first part of the EQ-5D-5L consists of five items measuring mobility, self-care, usual activities, pain/discomfort and anxiety/depression, with five descriptive response options each corresponding to severity. The second part consists of a 0–100 vertical visual analogue scale that scores self-rated health from the best imaginable health state to the worst imaginable health state (**Figure 8**).

Development

The EQ-5D was developed by the EuroQol Group in the 1980s as a HRQoL measure to be used in large-scale surveys to enable cross-national comparisons of health state valuations. Each dimension had three response options corresponding to severity (the EQ-5D-3L). In 2011, the EuroQol Group developed and tested a new five-level severity description system to improve sensitivity and reliability, which was renamed the EQ-5D-5L.[43]

Table 7: Detailed information about EuroQol – 5 Dimensions – 5 Levels

Characteristic	Details
Name	EuroQol – 5 Dimensions – 5 Levels
Abbreviation	EQ-5D-5L
Country developed	Europe: Denmark, England, Italy, the Netherlands, Poland and Scotland
Year developed	2011
Short summary	Group of instruments that have been developed to describe and value health across a wide range of disease areas. A visual analogue scale records self-rated health on a vertical scale with two end points.
Domains/dimensions	5: Mobility, self-care, usual activities, pain/discomfort, anxiety/depression
Number of items	5
Time to complete	Less than 5 minutes
Response type and range	Descriptive system comprising five dimensions. Respondents check the box corresponding to the level of severity that describes their health state in the given dimension.
Scoring guide	Scoring guide in ***EQ-5D-5L User Guide***
Translations	More than 150 translations, including English for Australia
Licence required	Yes
Fees	▪ Yes – fees may apply ▪ Licensing fees are determined by the EuroQol Office based on the user information provided in the registration form. You are not obliged to purchase the EQ-5D by registering.
Distributors | Weblink	**EuroQol Group**
Copyright	© EuroQol Research Foundation. EQ-5D™ is a trademark of the EuroQol Research Foundation.
Author(s)	The EuroQol Group
References to the original papers	Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, Bonsel G, Badia X. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res 2011;20(10):1727–36.

Figure 8: EuroQol – 5 Dimensions – 5 Levels – Health Questionnaire – English version for Australia

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems with walking around ❑
I have slight problems with walking around ❑
I have moderate problems with walking around ❑
I have severe problems with walking around ❑
I am unable to walk around ❑

PERSONAL CARE

I have no problems with washing or dressing myself ❑
I have slight problems with washing or dressing myself ❑
I have moderate problems with washing or dressing myself ❑
I have severe problems with washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

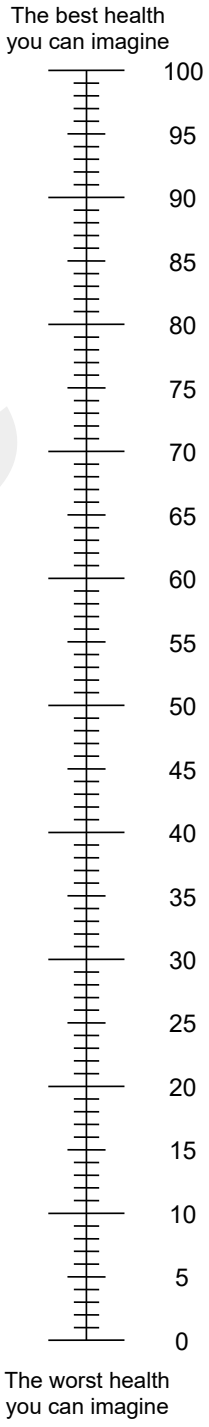
2

(continued)

Figure 8: EuroQol – 5 Dimensions – 5 Levels – Health Questionnaire – English version for Australia (continued)

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
  0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



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Appendix B: Using PROM recommendations

Measurement for improvement

Healthcare services and clinicians can implement PROM recommendations as part of localised quality improvement. To monitor quality improvement, it is recommended that PROMs are used at specified and standard time points (see **Collection time points**). This will enable comparative analysis and reporting, such as by intervention and by provider.

Using PROMs to meet national standards and accreditation

Implementing PROM recommendations for quality improvement can also support healthcare services to meet the requirements for the following criteria:

National Safety and Quality Health Service Standards

- Action 1.08: Safety and quality systems – Measurement and quality improvement
- Action 1.28: Clinical performance and effectiveness – Variation in clinical practice and health outcomes

National Safety and Quality Primary and Community Healthcare Standards

- Action 1.03: Patient safety and quality systems – Measurement and quality improvement
- Action 1.21: Clinical performance and effectiveness – Variation in care delivered and health outcomes

PROMs in clinical quality registries

The routine collection, analysis and reporting of patient-reported outcomes is increasingly being adopted by clinical quality registries (CQRs). CQRs systematically monitor the quality of health care within specific clinical domains. The information generated can be used to improve care of an eligible population, and risk-adjusted reports can be generated in a format that can be used for quality improvement activities. Clinicians and healthcare services may consider participating in national and/or international CQRs to inform quality improvement activities.

See the **Australian Register of Clinical Registries** to search for Australian CQRs by condition.

Clinical care standards

PROM recommendations are aligned with and can be used to complement relevant **clinical care standards**. Clinical care standards contain quality statements that provide guidance on the delivery of evidence-based care, and sometimes include advice on using validated tools to assess and monitor a patient-reported outcome. Clinicians and healthcare services may choose to implement PROMs from these recommendations or consider suggestions within the relevant standard as part of developing a systematic approach to using PROMs.

Appendix C: Approach to developing condition-specific PROM recommendations

There are numerous resources that support the selection of the most suitable PROMs to use in clinical practice. Key considerations when selecting a PROM include its psychometric properties, its acceptability to patients and its feasibility in clinical practice (see the Commission's advice on **selecting PROMs** for a list of resources and key considerations for selecting PROMs).

There are hundreds of validated PROMs available for clinicians and healthcare services to select from, and the development of new PROMs is increasing. The Commission aims to support clinicians and healthcare services with selecting PROMs for specific conditions, to promote consistency across clinical areas and types of interventions. We do this by developing evidence- and consensus-based recommendations on:

- Outcomes that are relevant to people with a specific condition
- Existing and validated PROMs that best measure those outcomes
- When to use PROMs to collect these outcomes.

To develop the recommendations, the Commission conducts a literature review and environmental scan to identify existing PROMs for a specific condition. Candidate PROMs are selected based on their psychometric properties, which are assessed using definitions and gradings adopted from the COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) guidelines.[44-46] A panel consisting of clinicians and consumers with lived experience consider the evidence to build consensus on which PROMs to use for the specific condition.

See **Figure 9** for details on the approach to developing PROM recommendations.

Figure 9: Approach to developing condition-specific PROM recommendations

Appendix D: Definitions and COSMIN grading criteria for psychometric properties of PROMs

Definitions and grading standards in Table 8 below were adopted from the COSMIN guidelines.[44-46] The table provides the definitions for each of the psychometric properties, together with the COSMIN grading criteria. Each criterion was rated as positive (+), indeterminate (?) or negative (−). If no information for the property was available, a rating of zero (0) was applied.

Table 8: Definitions and COSMIN grading criteria for psychometric properties for PROMs

Psychometric property	Definition	Rating	Rating criteria
Internal consistency	The extent to which the PROM (sub)scale items are correlated (homogenous), and thus measure the same concept.	+	At least low evidence for sufficient structural validity **and** Cronbach's alpha(s) ≥0.70 for each unidimensional scale or subscale
		?	Criteria for 'at least low evidence' for sufficient structural validity not met
		–	Low evidence for sufficient structural validity **and** Cronbach's alpha(s) <0.70 for each unidimensional scale or subscale
Reliability	The consistency of scores over a time span of no clinical change; quantified through repeated administrations of the PROM in a time period when patients are not expected to experience clinical change.	+	ICC/weighted kappa ≥0.70
		?	ICC/weighted kappa not reported
		–	ICC/weighted kappa <0.70
Measurement error	The systematic and random error of a patient's score that is not attributed to be true in the construct measured.	+	SDC or LoA < MIC
		?	MIC not defined
		–	SDC or LoA > MIC
Structural validity	The degree to which the scores of a PROM are an adequate reflection of the dimensionality of the construct to be measured.	+	CFA/IRT/Rasch: CFI or TLI or comparable measure >0.95 or RMSEA <0.06 or SRMR <0.08
		?	CFA/IRT/Rasch: Not all information for '+' reported
		–	Criteria for '+' not met

+ = sufficient, – = insufficient, ? = indeterminate, AUC = area under curve, CFA = confirmatory factor analysis, CFI = comparative fit index, COSMIN = The COnsensus-based Standards for the selection of health Measurement INstruments, ICC = intraclass coefficient, IRT = item response theory, LoA = limits of agreement, MIC = minimal important change, PROM = patient-reported outcome measure, RMSEA = root mean square error of approximation, SDC = smallest detectable change, SRMR = standardised root mean residuals, TLI = Tucker–Lewis index.

Psychometric property	Definition	Rating	Rating criteria
Criterion validity	The degree to which the scores of a PROM are an adequate reflection of a 'gold standard'. The COSMIN panel reached consensus that no gold standard exists for PROMs. The only exception is when a shortened instrument is compared to the original long instrument.	+	Correlation with gold standard/ AUC ≥0.70
		?	Not all information for '+' reported
		–	Correlation with gold standard/ AUC <0.70
Construct validity	The extent to which an instrument's scores relate to other measures in a manner that is consistent with theoretically derived hypotheses regarding the concepts being measured.	+	Correlation with an instrument measuring the same construct ≥0.50 **or** ≥75% of the results are in accordance with hypotheses **and** correlation with related constructs is higher than unrelated constructs
		?	No hypotheses defined **or** reported correlations solely with unrelated constructs
		–	Correlation with an instrument measuring the same construct <0.50 **or** <75% of the results are in accordance with hypotheses **or** correlation with related constructs is lower than with unrelated constructs
Responsiveness	The ability of a PROM to detect change over time when clinically relevant change is expected to occur. Recommended metrics include standardised measures of effect size and the Norman's responsiveness coefficient.	+	The results are in accordance with hypotheses
		?	No hypotheses were defined
		–	The results are not in accordance with hypotheses

+ = sufficient, – = insufficient, ? = indeterminate, AUC = area under curve, CFA = confirmatory factor analysis, CFI = comparative fit index, COSMIN = The COnsensus-based Standards for the selection of health Measurement INstruments, ICC = intraclass coefficient, IRT = item response theory, LoA = limits of agreement, MIC = minimal important change, PROM = patient-reported outcome measure, RMSEA = root mean square error of approximation, SDC = smallest detectable change, SRMR = standardised root mean residuals, TLI = Tucker–Lewis index.

Appendix E: Summary grading of psychometric properties

Table 9: Summary grading of psychometric properties of recommended PROMs for low back pain

Measurement properties		NPRS[19]	ODI[25,26]	RMDQ[25,26]	EQ-5D-5L (utility)[36]
Content validity	Relevance	? Low	? Very low	+ Very low	+ Very low
	Comprehensiveness	? Low	– Very low	– High	+ Very low
	Comprehensibility	+ Very low	+ Very low	+ High	+ Very low
Structural validity		N/A	? Moderate	– High	
Internal consistency		N/A	+ Moderate	+ Moderate	
Test–retest reliability		? Low	+ Moderate	+ Moderate	
Measurement error		– High	+ Moderate	+ Moderate	
Construct validity		? Very low	+ Moderate	+ Moderate	
Responsiveness		? Moderate	? Moderate	? Moderate	

+ = sufficient results, – = insufficient results, ? = indeterminate results, EQ-5D-5L = EuroQol – 5 Dimensions – 5 Levels, ODI = Oswestry Disability Index, N/A = not applicable, NPRS = Numerical Pain Rating Scale, RMDQ = Roland Morris Disability Questionnaire.

Empty cells represent measurement properties not assessed in any study.

Cross-cultural validity was not assessed for any instrument.

Appendix F: Panel consensus criteria

Table 10: Panel consensus criteria to assess candidate PROMs

Criterion	Definition
Interpretability	The score and change in score are easy to calculate and comprehensible
Clinical relevance and actionability	The domains and score are clinically useful and provide information that supports clinical practice, patient–clinician communication and shared decision making. Factors include: ▪ Scores for individual domains are actionable for clinical practice ▪ Changes in score over time are clinically useful
Consumer acceptability	The PROM addresses domains that are important to consumers and is comprehensible. Factors include: ▪ Reading age ▪ Required mental and physical ability level ▪ Completion time ▪ Length of instrument
Cost	The PROM requires licensing or payment of a fee for usage
Accessibility	Validated translations of the PROM are available in the most spoken languages other than English in Australia
Level of agreement	There is evidence of national and international use of the PROM in clinical practice

Glossary

Term	Definition
Acute low back pain	Low back pain that lasts less than three months. The term 'acute' indicates the duration of symptoms and is not a diagnosis.
Australian Atlas of Healthcare Variation	A series developed by the Commission that explores the extent to which the use of health care in Australia varies depending on where people live, how their care is funded and their level of socioeconomic disadvantage. The aim is to prompt further investigation into whether the observed variation reflects a response to differences in people's healthcare needs or in the informed choices they make about their treatment options.
Biopsychosocial (also known as socio-psycho-biomedical) framework	A framework that helps clinicians understand the complexity of their patient's experience and lays a foundation for assessment and more effective pain management. The way a person processes nociceptive signals in their brain, and their resulting pain experience, depends on their developmental stage (for example, infancy, adolescence, adulthood), the social and cultural context (socio-), their emotional state (psycho-) and their biological health (-biomedical). A biopsychosocial approach considers the bidirectional relationship between these factors and the person's pain experience to determine strengths and areas that may need support during management.[47]
Chronic low back pain (also referred to as persistent pain)	Low back pain that is present for more than three months. The term 'chronic' indicates the duration of symptoms and is not a diagnosis. Chronic low back pain may have a specific cause, or may be non-specific – that is, no cause has been identified.[35,47]
Clinical care standards	Standards developed by the Commission to help support the delivery of evidence-based clinical care and promote shared decision making between patients, carers and clinicians. Clinical care standards aim to ensure that people receive best-practice care for a specific clinical condition or procedure, regardless of where they are treated in Australia.
Clinician	A trained health professional who provides direct clinical care to patients. A clinician may be a registered or non-registered practitioner, and may provide care within a healthcare service as an employee, a contractor or a credentialed healthcare provider, or under other working arrangements. Clinicians include nurses, midwives, medical practitioners, allied health professionals, paramedics and other professionals who provide health care, and students who provide health care under supervision.
Content validity	A psychometric property that indicates the degree to which the content of a PROM is an adequate reflection of the construct to be measured. It is considered to be the most important measurement property of a PROM. A PROM with sufficient content validity indicates that all items of the PROM are relevant to a specific population and context of use (relevant), capture concerns of the patient (comprehensive) and are understood by the patient (comprehensibility).[44]
COSMIN	The COnsensus-based Standards for the selection of health Measurement INstruments initiative that aims to improve the selection of PROMs in research and clinical practice by developing tools for selecting the PROM that is most fit for purpose. This initiative has established quality standards for reporting and grading of reliability and validity in PROMs.

Term	Definition
Health-related quality of life (HRQoL)	The 'health aspects of quality of life, generally considered to reflect the impact of disease and treatment on disability and daily functioning. HRQoL also reflects the impact of perceived health on an individual's ability to live a fulfilling life.'[48]
Multidisciplinary approach	An approach to chronic pain management that simultaneously addresses all biopsychosocial factors affecting the patient's pain, and helps patients achieve their goals sooner than approaches that address only some contributors to the patient's pain.
Negative affect	The subjective experience of negative emotional states, such as anxiety, depression, stress, sadness, worry and anger.
Pain	An unpleasant sensory experience associated with, or resembling that associated with, actual or potential tissue damage.
Patient-reported outcome measures	PROMs are questionnaires that help patients to report on outcomes relating to their health. These questionnaires focus on various aspects of health, such as symptoms, daily functioning and quality of life. PROMs are usually used to measure outcomes on two or more occasions to enable comparisons to be made over time.
Physical functioning	The ability to participate in daily activity and movement, such as walking, sleeping and socialising.
Psychometric properties	The validity and reliability of PROMs. Many PROMs have undergone rigorous psychometric development. Careful design and testing of PROMs increase confidence that they measure what they have been developed to measure (they are valid) and do so in a consistent manner (they are reliable).
Recurrent pain (also referred to as episodic pain)	Pain that occurs episodically over three months or more. Each episode is similar in presentation – it may be recurrent acute nociceptive pain or episodes of a chronic pain condition.
Reliability	The degree to which the measurement is free from measurement error. Three properties of reliability can be evaluated for a PROM: internal consistency, test–retest reliability and measurement error.
Responsiveness	Captures the ability of a PROM to detect change over time when clinically relevant change is expected to occur.
Validity	The degree to which a PROM measures the construct(s) it purports to measure in terms of structural, construct and criterion validity.

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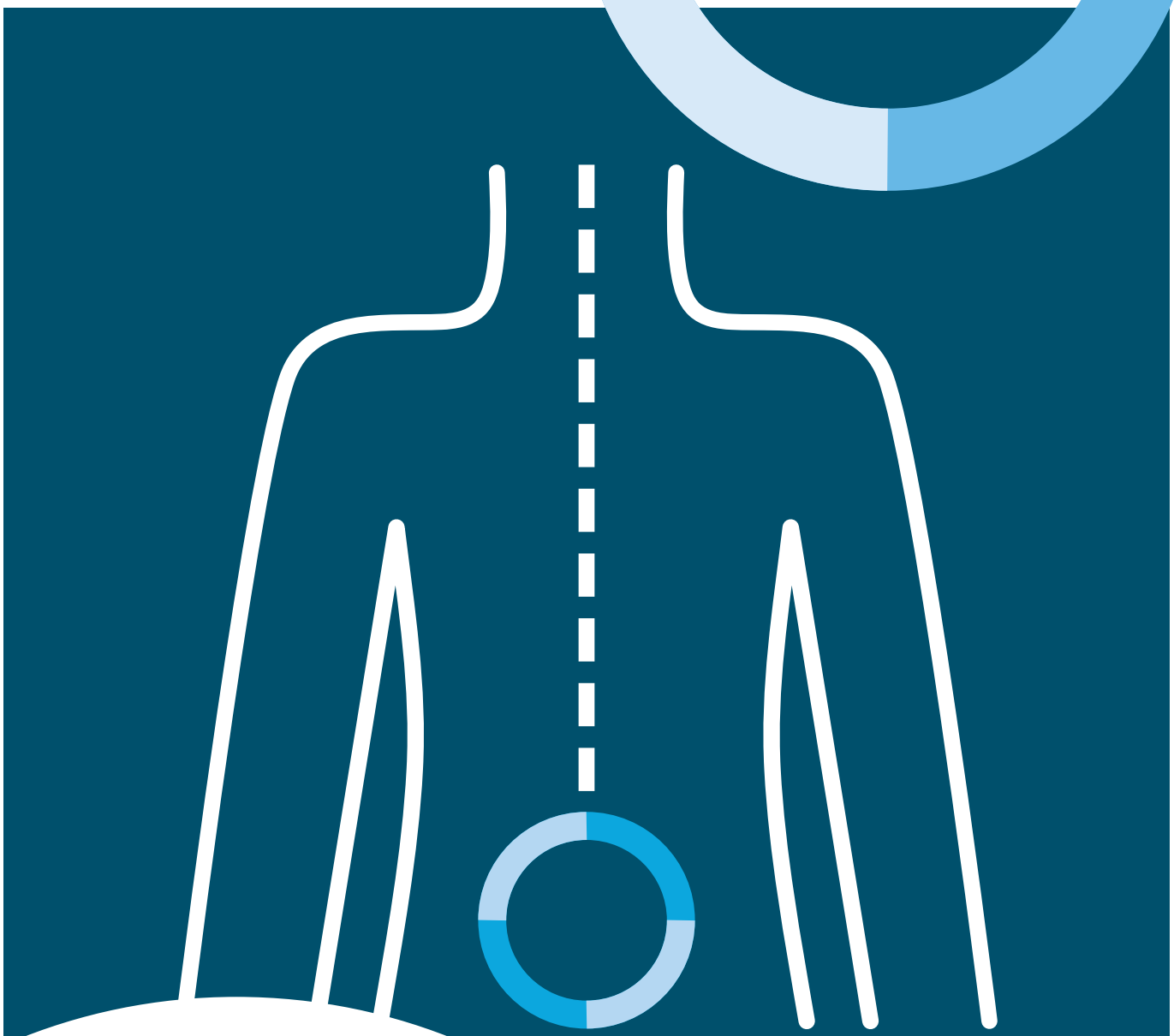

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