Patient-Reported Outcome Measures

PROM

THE IMPORTANCE OF PATIENT-REPORTED OUTCOME MEASURES

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PROMs
- ➤ **WHAT** are they ?
- ➤ **WHY** are they used ?
- ➤ **WHAT** are they used for?

WHAT ?

- Patient reported Outcomes **(PRO's)** are outcomes known only **to the patient**

- Patient reported outcome measures **(PROM's)** are **tools** we use to measure patient reported outcomes.

Quality is measured from **RECIEVER'S PERSPECTIVE & NOT FROM PROVIDER**

If **QUALITY** is to be at the heart of everything we do, it must be understood from the **perspective of the patient (receiver)**

The **effectiveness of care from the patient's own perspective is** measured through **patient –reported outcome measures**

"Outcomes remain the ultimate validators of the effectiveness and quality of medical care."

-Avedis Donabedian

Donabedian, A. (1966). Evaluating the quality of medical care.
The Milbank Memorial Fund Quarterly, 44(3),

- Measurement of the **patient's health status** or **health-related quality of life (HRQoL)** at a single point in time.

- Measures **outcomes of specific interventions.**

- **Changes in health status at two different points in time** (e.g. before and after an operation at different intervals)

- Which is the **best treatment** for the condition & is patient's condition improving ?

- Is **subgroup** of population sicker than others ?

- Certain PROMs are suitable for purposes of **economic evaluation** (e.g., estimation of quality –adjusted life years – QALYs)
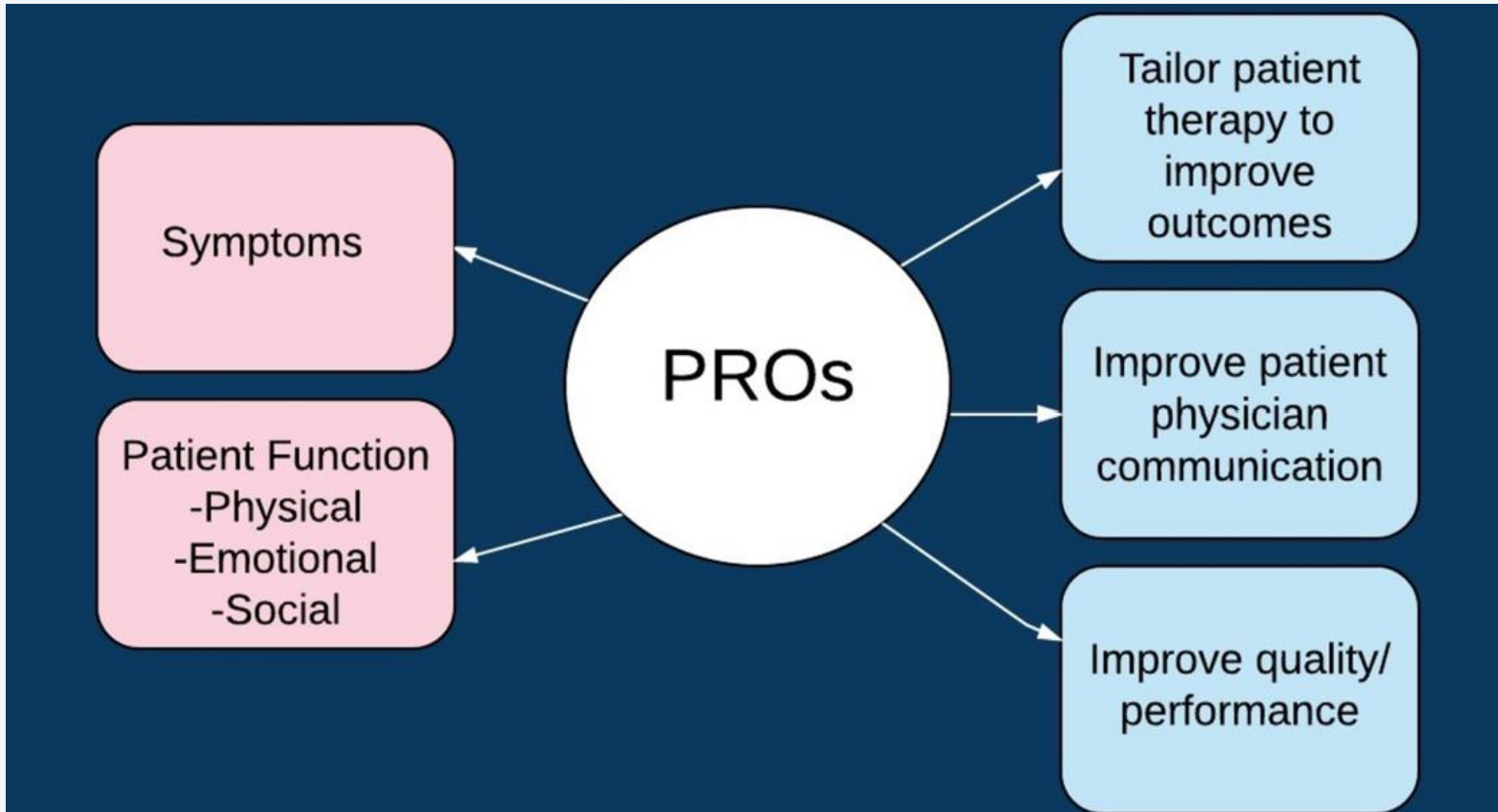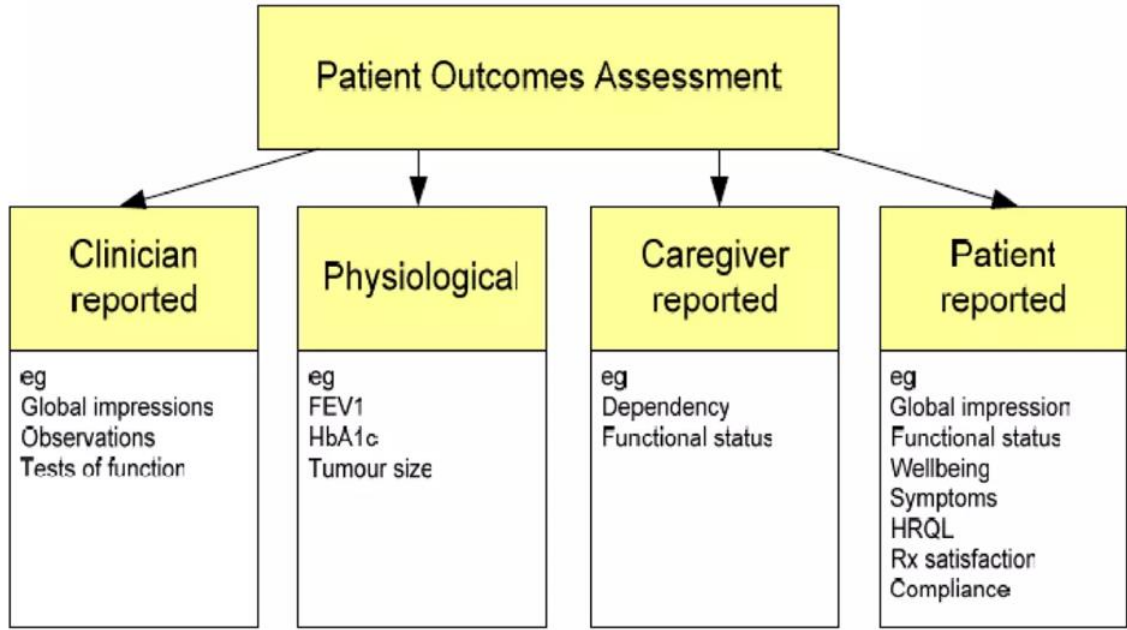
- **PRO instrument**
  - PRO instrument is a questionnaire reported voluntarily
  - It captures PRO data used to measure treatment benefit or risk in medical product clinical trials

Patient-reported outcomes	Clinician-reported outcomes
Pros • Inexpensive • Capture patient's experience • Flexible administration modes • Computerized/ algorithmic assessment	Pros • Summative assessment by clinician • Standardized activity and setting
Cons • High respondent burden • Variable performance in demographically- defined subgroups • Low response rates	Cons • Rater bias • Inter/intra-rater variability • Does not capture patient experience

Using patient reported outcomes

Patient Reported Outcome
- Identify issue and population of interest
- Identify domains of importance to patients

Patient Reported Outcome Measure
- Identify existing PROMS
- Test for reliability, validity, responsiveness
- Test feasibility of use

Patient Reported Outcome Performance Measure
- Aggregate PROM data, benchmark
- Evaluate threats to validity. E.g. exclusions, missing data, poor response rate

| Concept	e.g. Person with clinical depression
PRO Patient-reported outcome	Feeling depressed
PROM patient-reported outcome measure	PHQ-9
PRO-PM patient-reported outcome performance measure	% patients score > 9 by 3 weeks

Instrument selection	• Does the PROM address the study aims? • Will the PROM respond to changes in health status during the study period?
Instrument administration	• How and when will the PROM be administered? • What is the overall burden on the patient and clinicians? • Considerations: standardize time points, training for individuals administering the instrument, mode of administration
Data analysis and interpretation	• Will the results be presented as statistical change, clinically meaningful change, or both?
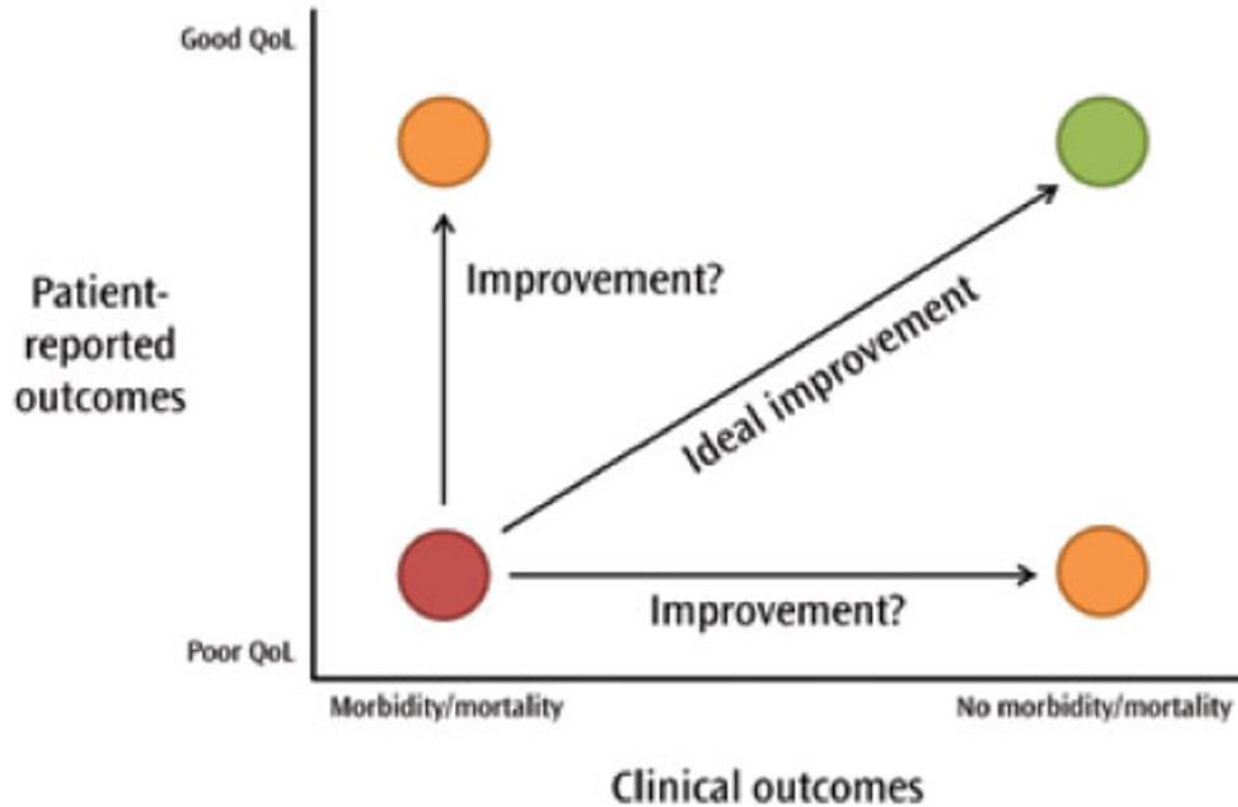
Surgical Outcome – 2 perspectives

- Clinician's perspective
- Patient's perspective

Ideal : go hand in hand –
🔴 **red circle** to 🟢 **green**

- **HAVING AGREED TO EMBARK ON JOURNEY TO IMPLEMENT PROM ……..**

- **WHAT ARE THE NEXT STEPS …….**

- **Does the PROM measure what you want to measure from patient's perspective ?**
- **C**heck the information we **GET** and **DON'T** get from a PROM

CHOOSING THE RIGHT PROM ………

Implications of choosing the wrong PROM

- Fail to identify significant outcomes

- Mislead clinical practice

- Misrepresent treatment and disease impact

- **Content validity** - does the content reflect the concept/construct measured ?

- **Face validity** - do the individual items look as if they are measuring what they should?

- **Criterion validity** - can the construct be measured accurately?

- **Construct validity** - Is the content understandable to the patient

- **Reliability** - are the results stable over time when applied to the same people at different time periods?

- **Precision** - does the measure discriminate between different patient groups, health states, treatments etc?

- **Responsiveness** - is the measures responsive to change when change is present ?

- **What to measure may be obvious given the condition being treated.**
  - For ex: treatment on pain

- **When it is not obvious, it is based on literature reviews and expert opinion.**

- Subsequently, **patient interviews** ensures **understanding and completeness of the concepts** contained in the items.
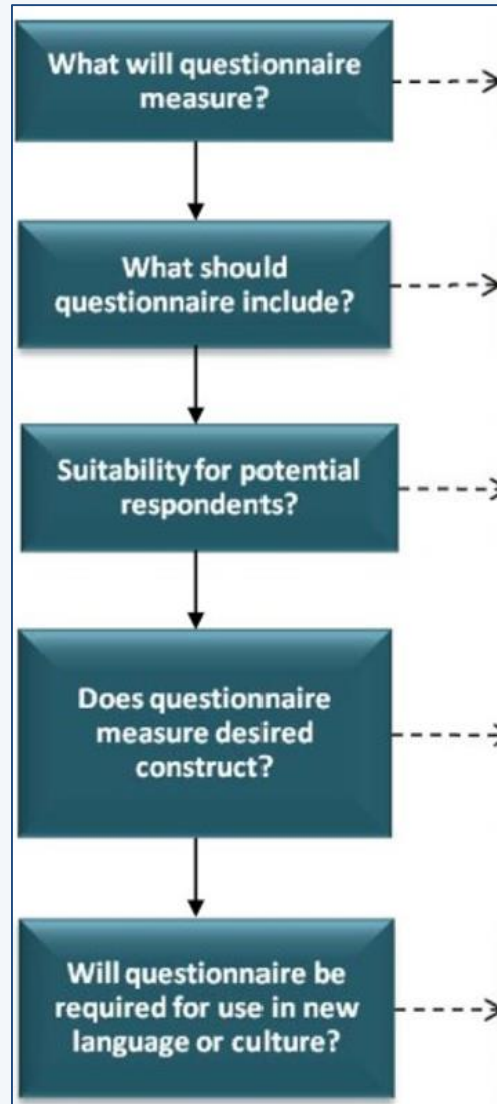
- What content should be measured?

- How should content be defined
- How is best item set selected

- Does it appear to measure appropriately (face validity)?
- Is content a reasonable representation of patient experience (content validity)?

- Do items measure intended content (construct validity)?
- Can item scores be added together (scalability)?
- Is level of measurement error acceptable (reliability)?
- Is scale able to measure real change in construct (responsiveness)?
- Are data collected free from biases

- Have appropriate translation methods been employed?
- Have new language versions been tested ?

Flowchart boxes:
- What will questionnaire measure?
- What should questionnaire include?
- Suitability for potential respondents?
- Does questionnaire measure desired construct?
- Will questionnaire be required for use in new language or culture?

- Acceptability - will people fill it in?

- Any language barrier ?

- Response rates

- Item completion rates

- Missing cases

- Take an evidence-base approach in selecting the PROM

Feasibility – how easy will it be to use?

- Cost
- Time
- Ease of scoring
- Interpreting scores
- Supporting documentation (Manual, norm-reference scoring etc.)

1. **Children and Adolescents**
   For patients who cannot respond for themselves (e.g., infant patients), we encourage observer reports that include only those events or behaviors that can be **observed**

2. **Patients Cognitively Impaired or Unable to Communicate**
   we encourage observer reports that include only those events or behaviors that can be **observed.**

3. **Culture or Language Subgroups**
   To translate and culturally adapt the instrument for populations that will use them.

Generic and condition specific - strengths and weaknesses

Generic

- Suitable for the general population

- Comparisons with other conditions/disease groups

- Content may be redundant for certain condition/illnesses

- Not sensitive to detecting disease-specific issues

Condition-specific

- Specific to disease group

- Sensitive to detecting clinically significant changes

- Content relevant to target group

- Cannot compare with general population

'Go for a combined approach ?'

Factors that can contribute includes the following:

• **Length of questionnaire** or interview & Inadequate time.

• Formatting, font size too small to read easily

• **New instructions** for each item and typical style

• **Requirement that patients consult records** to complete responses

• **Privacy** of the setting

• **Questions that patients are unwilling to answer**

• **Need for physical help** in responding (e.g., turning pages, holding a pen, assistance with a telephone or computer keyboard)

Analyze Patient Outcomes

I Physical function
Mobility, dexterity, range of movement, physical activity Activities of daily living: ability to eat, wash dress

II Symptoms
Pain, Nausea, Appetite, Energy, vitality, fatigue, Sleep and rest

III Psychological well-being
Psychological illness: anxiety, depression
Coping, positive well-being and adjustment, sense of control, self-esteem

IV Social well-being
Family and intimate relations
Social contact and social opportunities Leisure activities

V Cognitive functioning
Cognition, Alertness, Concentration,   Memory, Confusion, Ability to communicate

VI Role activities
Employment , Household management, Financial concerns

VII Personal constructs
Satisfaction with bodily appearance
Life satisfaction
Spirituality

VIII Satisfaction with care

Mobility (M)
I have no problems in waking about (Level 1)
I have some problems in walking about Level 2)
I am confined to bed (Level 3)

Self Care (SC)
I have no problems with self-care (Level 13
I have some problems washing or dressing myself (Level 2)
I am unable to wash or dress myself (Level 3)

Usual Activities (UA)
(eg, work, study, housework, family, or leisure activities)
I have no problems with performing my usual activites
I have some problems with performing my
I am unable to perform my usual activities

Pain/Discomfort (PD)
I have no pain or discomfort
I have moderate pain or discomfort
I have extreme pain or discomfort

Anxiety/Depression (AD)
I am not anxious or depressed
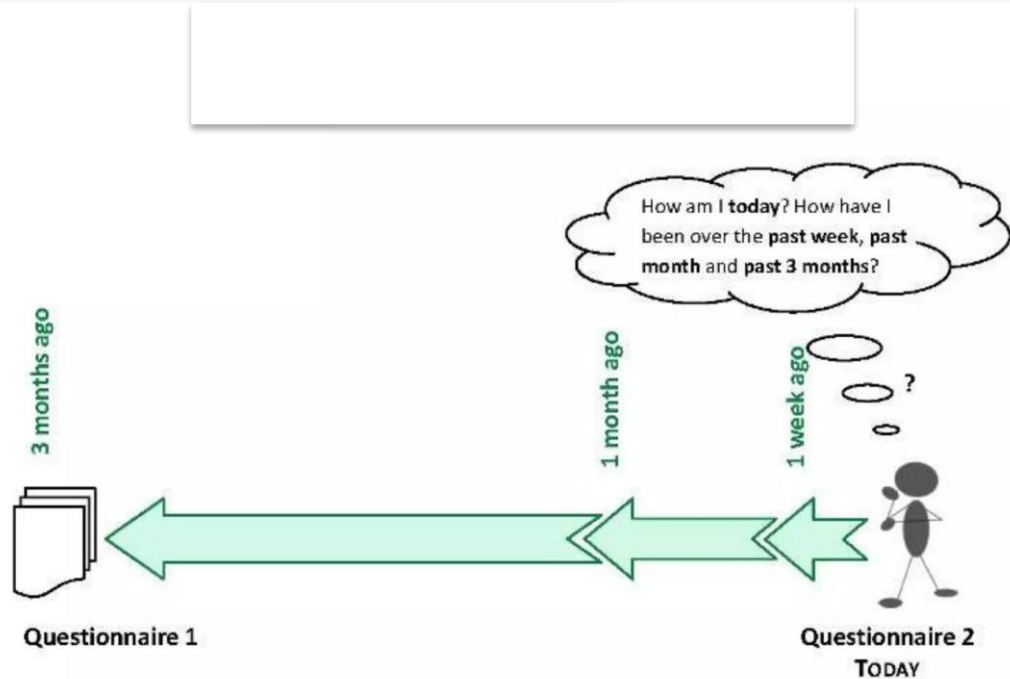I am moderately anxious or depressed
I am extremely anxious or depressed

Scoring of items and Domains

	Score	Description
Pain	P1 P2 P3 P4 P5	Unbearable Severe Moderate Mild None
Functional Status	F1 F2 F3 F4 F5	Total incapacity Can do activities at home Activities outside home with limitation Limitations with strenuous activity Able to do everything
Economic Status	E1 E2 E3 E4 E5	Unable to do tasks around home Able to do tasks around home but unable to perform paid work Able to do sedentary capacity Able to work at moderate capacity Able to work at heavy capacity or previous job
Medication	M1 M2 M3 M4 M5	>10 tablets or equivalent 6-9 tablets or equivalent 3-5 tablets or equivalent Regular NSAIDs or occasional None or occasional

-
    Obtain **patient input**

- Generate **items**

- Select **recall period, response options and format**

- Select mode/method of administration

- Conduct patient cognitive interview

- Pilot test **draft** instrument

- Document **content validity**

How am I **today**? How have I been over the **past week, past month and past 3 months**?

3 months ago

1 month ago

1 week ago

Questionnaire 1

Questionnaire 2
TODAY

- The choice of recall period that is most suitable **depends on the instrument's purpose, Disease or condition's characteristics, duration, frequency.**

- **Short recall periods** or items that ask patients to describe their current or recent state are usually **preferable.**

- If detailed recall of experience over a period of time is necessary, we recommend make use of a **diary for data collection**).

- **Response** is likely to be influenced by **the patient's state at the time of recall.**

STEPS TO START
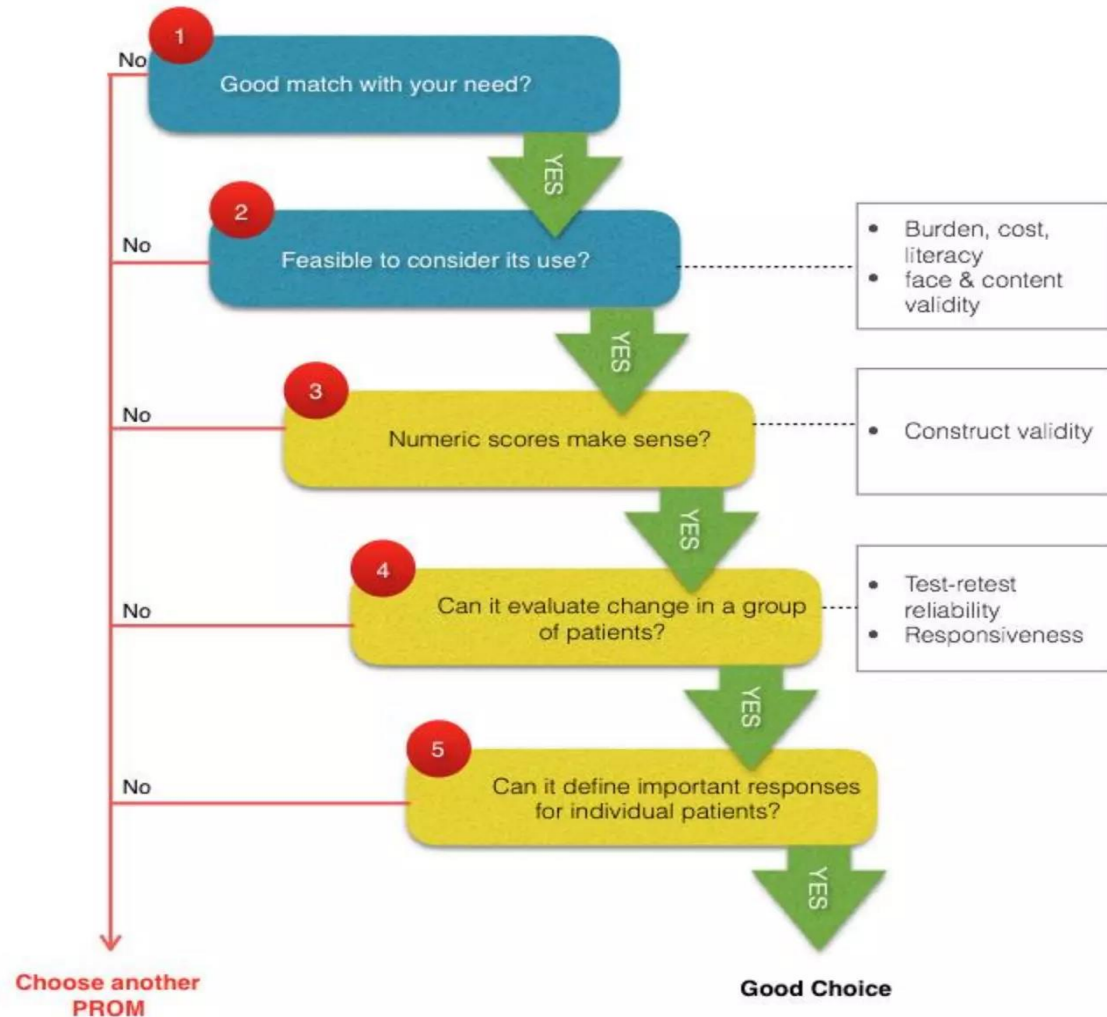
Administration

Types of PRO Administration

- Self-administered
- Interviewer-administered

Mode of PRO Administration

- Paper and pencil
- Electronic (PDA, websites)
- Telephone recording (IVRS)
- Interviewer-administered
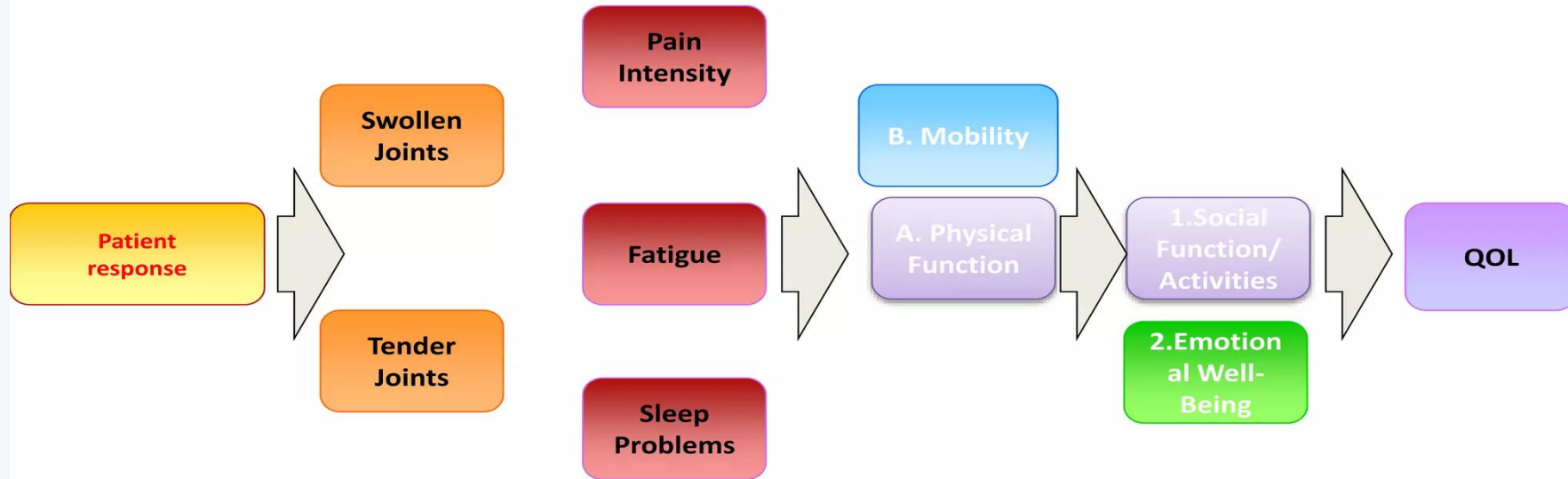
Endpoint Model: Treatment of Symptoms Associated with Disease Y

Concept	Endpoints
Indication Treatment of symptoms of Disease Y ⟶	**Primary** Total Disease Y symptoms score (PRO assessment)
Supportive Concepts Other treatment benefit	**Secondary** Physical performance (PRO or non-PRO assessment) Disease Y-related physical limitations (PRO assessment)
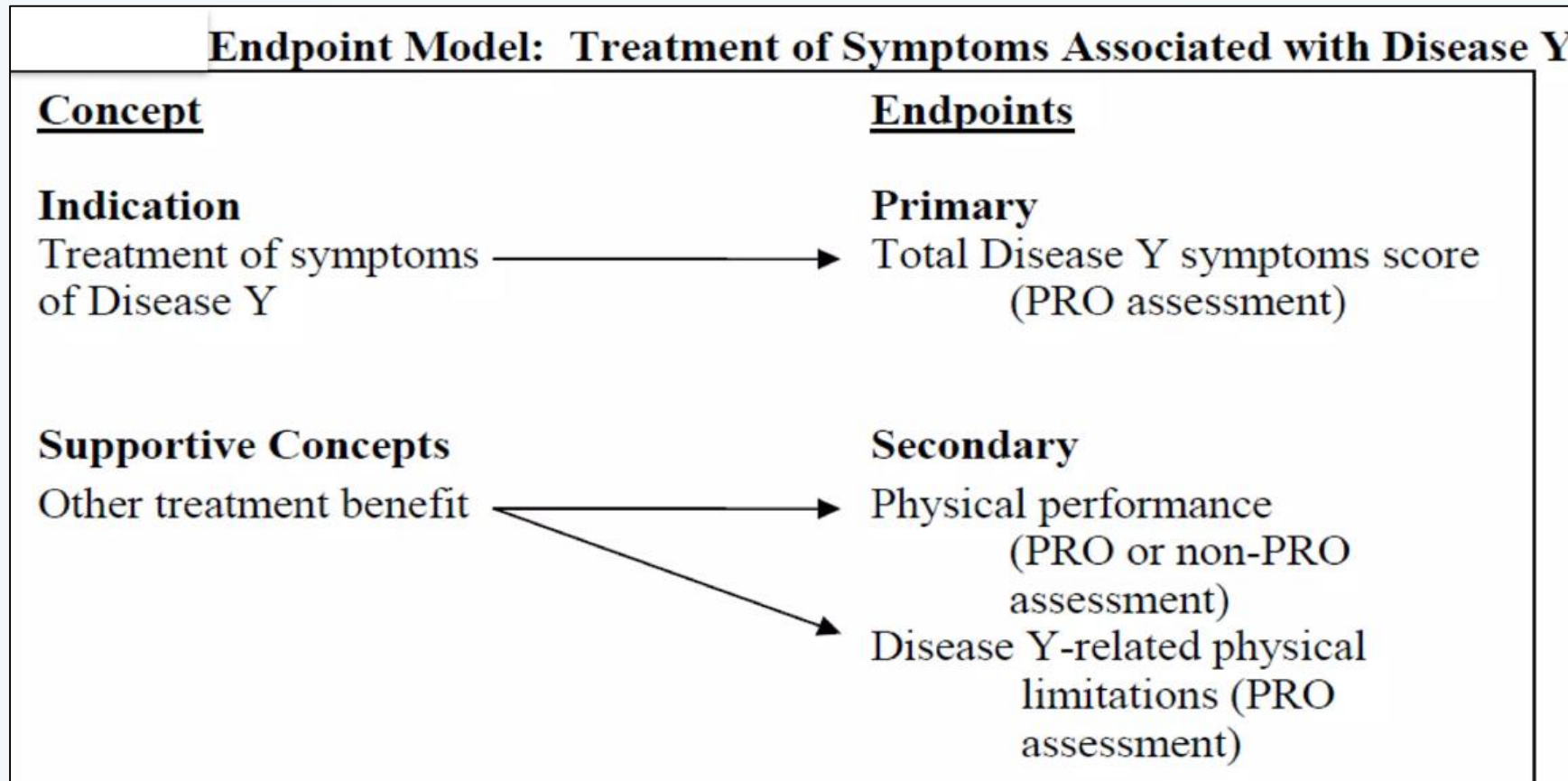
Objective tests

- Disabilities of the arm, shoulder and hand (DASH)
- QuickDASH
- Patient-rated wrist evaluation (PRWE)
- Short form 36 (SF-36)
- Patient-reported outcome measurement information
- system- upper extremity (PROMIS-UE)
- Oxford elbow score (OES)
- Oxford shoulder score (OSS)
- Oxford hip score: OHS
- Oxford knee score: OKS
- Knee Society score: KSS
- American shoulder and elbow score (ASES)
- Shoulder function index (SFINX)
- Mayo elbow performance index (MEPI)

Subjective tests

European quality of life five dimension (Euro-QoL 5D)
EQ-5D visual analog scale: EQ-VAS

Patient-reported outcome measure	Key construct covered
Assessment of Quality of Life instrument	Health-related quality of life
Pain numerical rating scale	Shoulder pain
Oxford Shoulder Score	Shoulder function
QuickDASH	Shoulder function
Kessler Psychological Distress Scale	Psychological distress
Modified Parenting Disability Index*	Shoulder-related parenting disability
Work Productivity and Activity Impairment Questionnaire	Shoulder-related work productivity

*Modified from the Parenting Disability Index initially developed for rheumatoid arthritis.[28]

CASE STUDIES – EXAMPLES

Case Study : Cancer Care

- **Background :** Oncology clinic introduced PROMs to assess the impact of cancer treatments.
- **Outcome:** Early detection of treatment side effect and improved symptom management.
- **Results: 15% decrease in hospital readmissions, highlighting proactive care.**

Case Study : Mental health Intervention

- **Background :** A mental health clinic incorporated PROMs to assess the well-being of patient.
- **Outcome:** Facilitated early identification of psychological distress and treatment adjustment.
- **Results: 25% reduction in reported anxiety and depression scores, demonstrating the effectiveness of tailored interventions.**

Case Study : Chronic Disease

- **Background :** A primary care practice implemented generic PROMS for patients with chronic conditions.
- **Outcome:** Streamlined monitoring of overall health, promoting preventive care.
- **Results: 30% decrease in hospitalizations related to unmanaged chronic conditions, emphasizing the role of continuous monitoring.**

Case Study : Rheumatoid arthritis
- **Background** : hospital implemented PROM for Arthritis
- **Outcome** : Improved patient – physician communication, leading to personalized treatment plans
- **Results** : **20 % reduction in reported pain levels & increased patient satisfaction**

Item Property	Reason for Change or Deletion
Clarity or relevance	• Reported as not relevant by a large segment of the target population • Generates an unacceptably large amount of missing data points • Generates many questions or requests for clarification from patients as they complete the PRO instrument • Patients interpret items and responses in a way that is inconsistent with the PRO instrument's conceptual framework
Response range	• A high percent of patients respond at the floor (response scale's worst end) or ceiling (response scale's optimal end) • Patients note that none of the response choices applies to them • Distribution of item responses is highly skewed
Variability	• All patients give the same answer (i.e., no variance) • Most patients choose only one response choice • Differences among patients are not detected when important differences are known

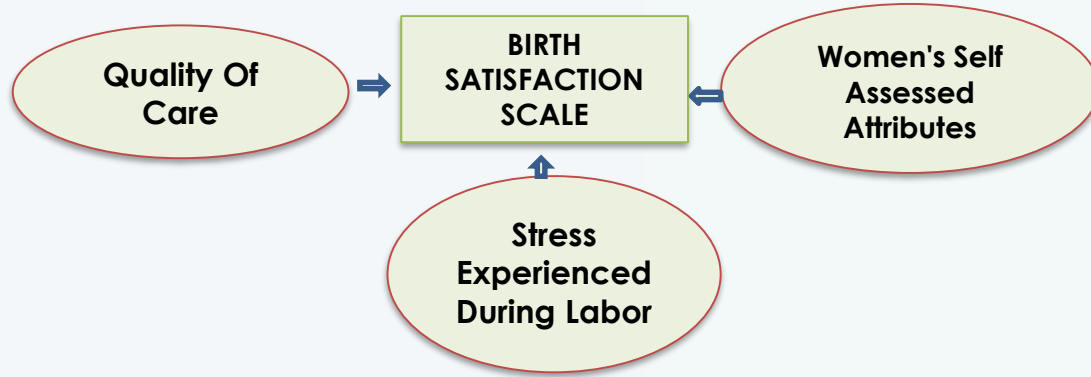| Reproducibility	• Unstable scores over time when there is no logical reason for variation from one assessment to the next
Inter-item correlation	• Item highly correlated (redundant) with other items in the same concept of interest
Ability to detect change	• Item is not sensitive (i.e., does not change when there is a known change in the concepts of interest)
Item discrimination	• Item is highly correlated with measures of concepts other than the one it is intended to measure • Item does not show variability in relation to some known population characteristics (i.e., severity level, classification of condition, or other known characteristic)
Redundancy	• Item duplicates information collected with other items that have equal or better measurement properties
Recall period	• The population, disease state, or application of the instrument can affect the appropriateness of the recall period
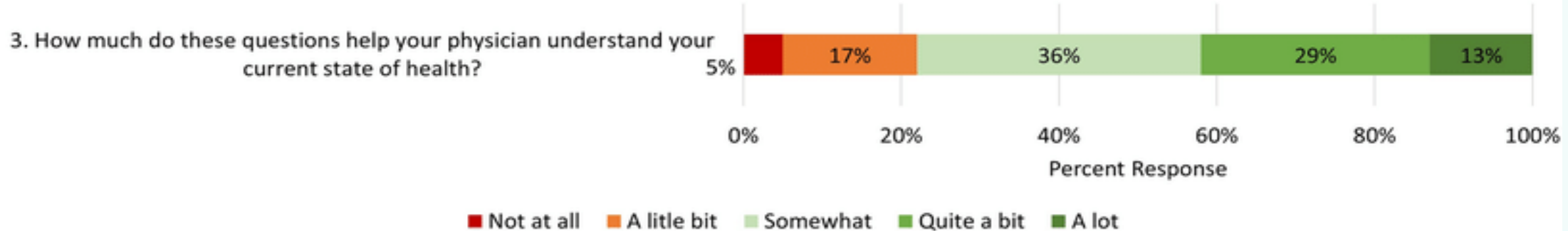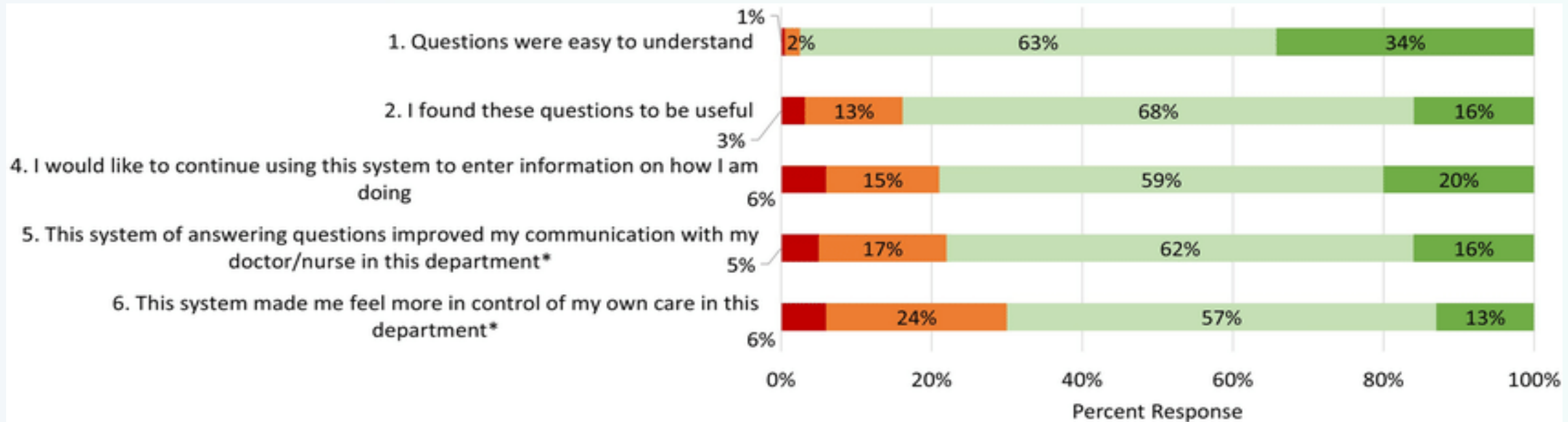
- ❑ Birth Satisfaction Scale (BSS)

- ❑ Knee Injury and Osteoarthritis Outcome Score (KOOS, JR)

- ❑ Gastroesophageal Reflux Disease Questionnaire

- ❑ International Prostate Symptom Score (IPSS)

- ❑ Hemorrhoidectomy Scale

- ❑ Sino-nasal outcomes test-22

- ❑ The Dizziness Handicap Inventory (DHI)

- ❑ The Headache Impact Test-6 (HIT-6

Birth Satisfaction Scale (BSS)

Quality Of Care → **BIRTH SATISFACTION SCALE** ← Women's Self Assessed Attributes

↑ Stress Experienced During Labor

SEGMENT	Sl No	Questions
Quality of care	BSS I	I came through childbirth virtually unscathed
	BSS V	I was not distress at all during labour
	BSS VII	I thought my labour was excessively long
Women's self assessed attributes	BSS II	The delivery Room staff encouraged me to take decisions about how I wanted my birth to progress
	BSS III	I felt well supported by staffs during my labor and birth
	BSS IV	The staff communicated well with me during labor
	BSS VI	The delivery room was clean and hygienic
Stress Experienced during the labour	BSS VIII	I felt very anxious during my labour and birth
	BSS IX	I felt out of control during my birth experience
	BSS X	I found giving birth a distressing experience

Birth Satisfaction Score

Category	MWCH	Aster Hospital
Quality of care	89	76
Women's self assessed attributes	97	97
Stress Experienced during the labor	17	40

(Y-axis: Percentage, 0–120)

Legend: ■ MWCH ■ Aster Hospital
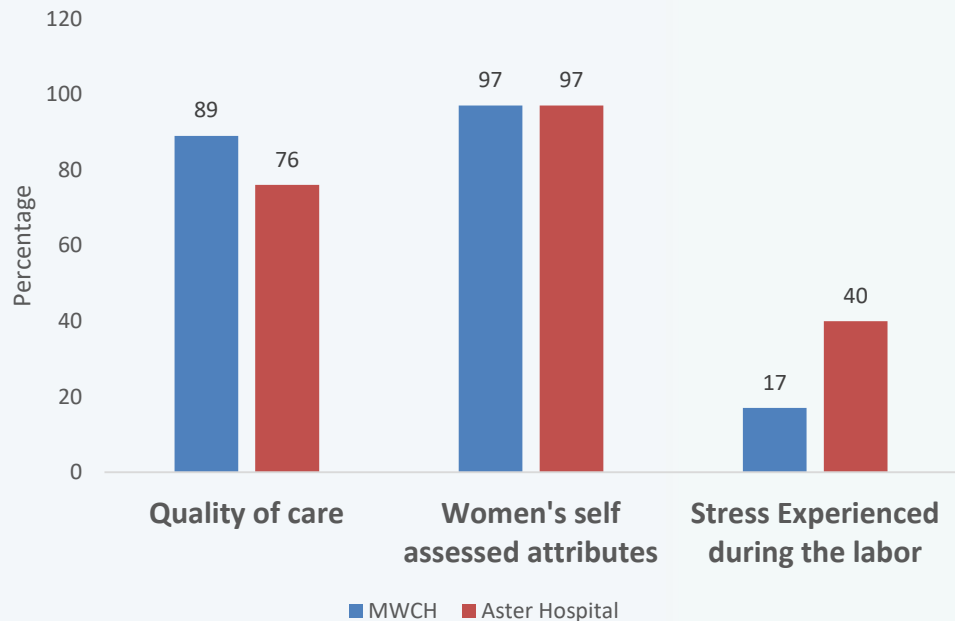
PATIENT REPORTED OUTCOME MEASURES (KOOS)

(KOOS, JR)

Interval Mean Score

33.9 — Baseline (Pre-operative)
56.7 — Post operative 6 weeks)

Score (0, 20, 40, 60) — Interval Score

■ Baseline (Pre-operative)
■ Post operative 6 weeks)
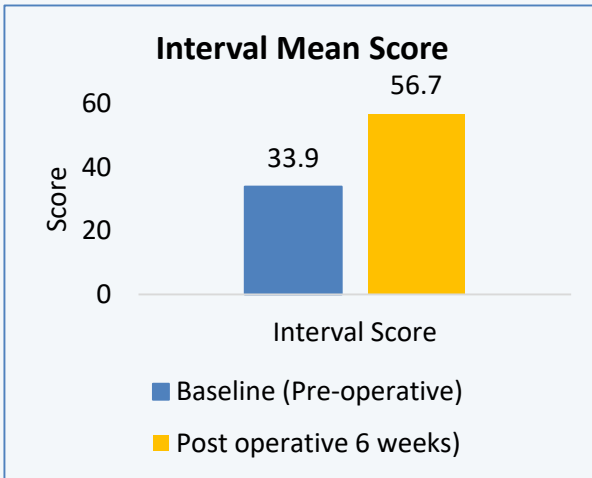
The interval score :0 to 100
0 represents total knee disability
100 represents perfect knee health.

Attribute wise Analysis

Stiffness: 3.3 / 2.0
Pain: 12.9 / 8.1
Function Daily Living: 3.5 / 2.1

■ Baseline (Pre-operative)
■ Post operative 6 weeks)
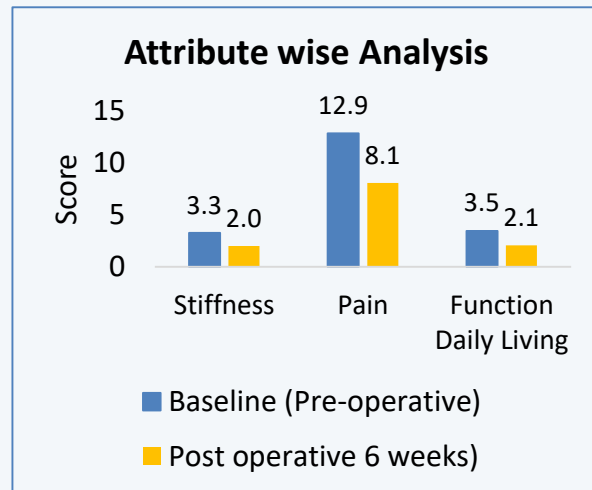
Higher the attribute score worse the symptoms

Instructions:
This survey asks for your opinion about your knee and helps us understand how well you are able to complete your usual activities. Answer each question by ticking the appropriate box (only one box for each question). If you are uncertain about how to answer a question, please give the best answer you can.

I. Stiffness
Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint. What amount of knee stiffness have you experienced the last week during the following activities?

S1. How severe is your knee stiffness after first wakening in the morning?

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

II. Pain
What amount of knee pain have you experienced the last week during the following activities?

P1. Twisting/pivoting on your knee

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

P2. Straightening knee fully

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

P3. Going up or down stairs

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

P4. Standing upright

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

III. Function, daily living
This section describes your ability to move around and to look after yourself. For each of the following activities, please indicate the degree of difficulty you have experienced in the last week due to your knee.

A1. Rising from sitting

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

A2. Bending to the floor/pick up an object

☐ None (+0) ☐ Mild (+1) ☐ Moderate (+2) ☐ Severe (+3) ☐ Extreme (+4)

Table for converting raw summed scores to interval level scores

Raw summed score (0-28)	Interval score (0 to 100 scale)
0	100.000
1	91.975
2	84.600
3	79.914
4	76.332
5	73.342
6	70.704
7	68.284
8	65.994
9	63.776
10	61.583
11	59.381
12	57.140
13	54.840
14	52.465
15	50.012
16	47.487
17	44.905
18	42.281
19	39.625
20	36.931
21	34.174
22	31.307
23	28.251
24	24.875
25	20.941
26	15.939
27	8.291
28	0.000

Gastroesophageal Reflux Disease Questionnaire

Each question is scored from 0 to 3 where 3 denotes worsening of symptoms

- ❖ **Scope: Anti-reflux surgery** Fundoplication surgeries
- ❖ **Survey collection:** Pre-surgery and post-surgery after 1 month.
- ❖ Response rate is **70%**
- ❖ Collection method: Microsoft Form and QR code

1 How often did you have a feeling behind your breastbone (heartburn)?
Pre-Score :2
Post Score : 1.1

2 How often did you have stomach contents (liquid or food) moving upwards to your throat or mouth (regurgitation)?
Pre-Score :2.1
Post Score : 1.2

3 How often did you have pain in the center of the upper stomach?
Pre-Score :1.9
Post Score : 1

4 How often did you have nausea?
Pre-Score :1
Post Score : 0.4

5 How often did you have difficulty getting a good night's sleep because of your heartburn and/or regurgitation?
Pre-Score :1.7
Post Score : 0.4

6 How often did you take additional medication for your heartburn and /or regurgitation, other than what the physician told you to take.(such as Tums, Rolaids and Maalox)?
Pre-Score :1
Post Score : 0.5

Pre Surgery Score and Post Surgery Score

Month	Pre Surgery score	Post Surgery score
May-23	7.5	4
Jun-23	11.3	6
Jul-23	9	4.6
Aug-23	12.6	6

■ Pre Surgery score ■ Post Surgery score

The Total score ranges from 0 to 18 where higher the score worse are the symptoms

Hemorrhoidectomy Scale

EuroQol **Scale**

International Prostate Symptom Score (IPSS)

Parameters	Score
Total Responses	58/ 102
No Bleeding	81.4%
No Fever	100%
Bowel Movement	53.4%

Attributes
- Incomplete emptying
- Frequency
- Intermittency
- Urgency
- Weak Stream
- Straining

	Mild	Moderate	Severe
	41	47	13
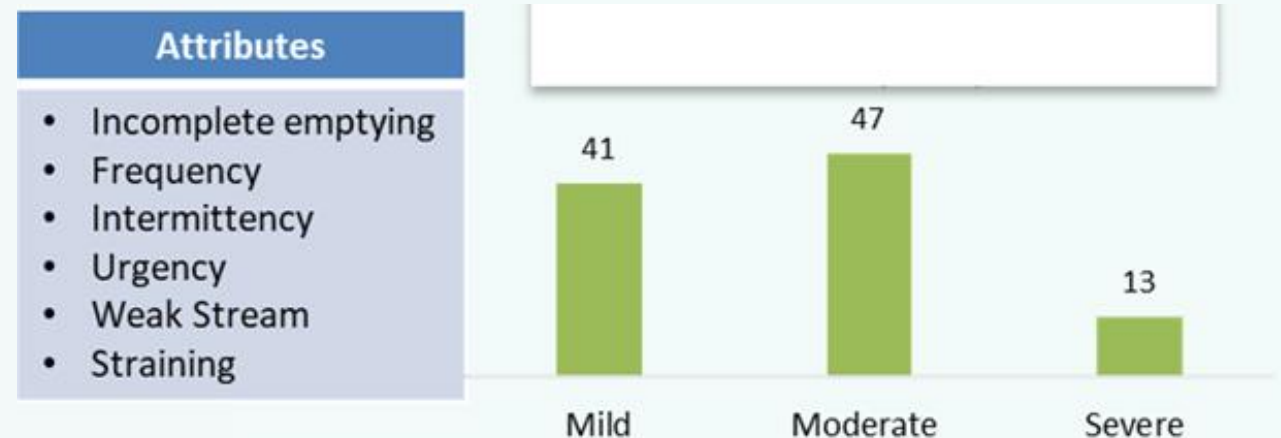
- **Mildly** -Conservative Management and Life style modification
- **Moderate** -Medication and Life style modification
- **Severely** -Medication and Surgery
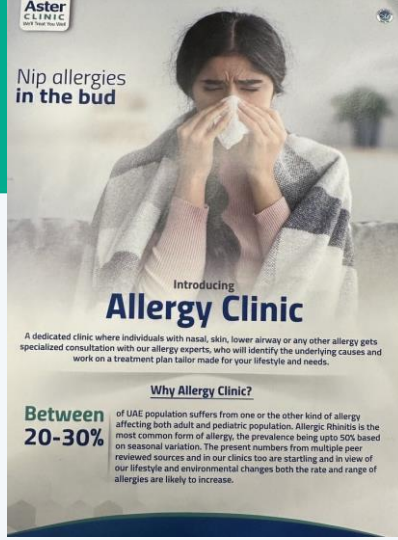
The **Sino-nasal outcomes** test-22 (SNOT-22) represents the reference questionnaire to assess patients with chronic rhinosinusitis (CRS).

SNOT 1- first visit,
SNOT 6, after 6 weeks

SNOT 1	SNOT 6
35	12

The Dizziness Handicap Inventory (DHI) is used in to assess & quantifies the impact of dizziness on quality of life.

Measures self-perceived handicap.

PRE	POST
31	10

The Headache Impact Test-6 (HIT-6) Measures contributing to headache & impact on
• social functioning,
• role functioning,
• vitality,
• cognitive functioning
• psychological distress.

• little or no impact (49 or less),
• some impact (50–55),
• substantial impact (56–59),
• and severe impact (60–78).

Quality is never an accident. It is always the result of intelligent effort.

JOHN RUSKIN

Intelligent effort in this context is understanding quality and outcome from PATIENT'S PERSPECTIVE

Thank you!