

Should PROMs and PREMs be standard in clinical care and available for clinical trials?

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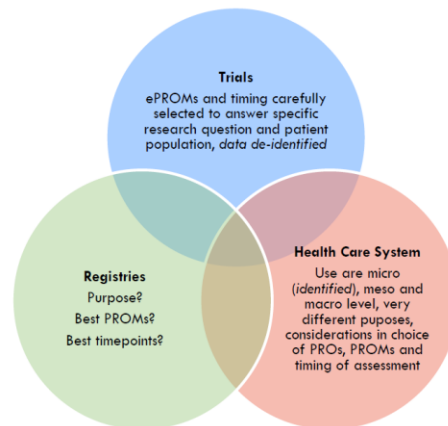


This work was carried out with the support of the Grant provided by the Cancer Research Trust



Embedding trials within health care system, clinical quality registries

Choice of PROM and timing of assessment is determined by purpose - what will the PRO data be used for?



Key issue/ difference: Are patients identified, identifiable?

- Patient privacy & confidentiality
- Shared with clinicians?
- Does this affect how patients respond?



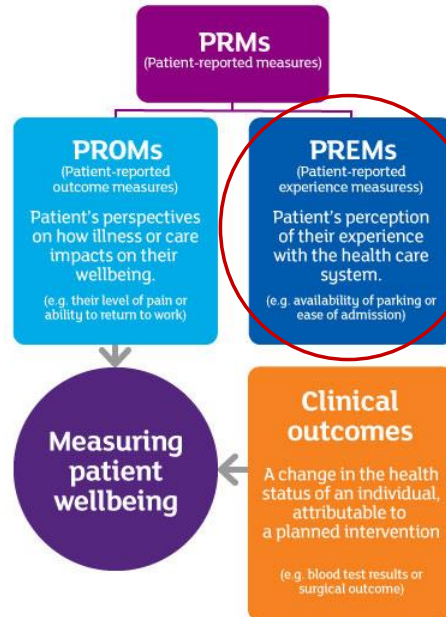
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2018 ACTA Summit, ePROMs: Considerations and challenges in using electronic patient reported outcome measures, The University of Sydney



PREMs vs PROMs

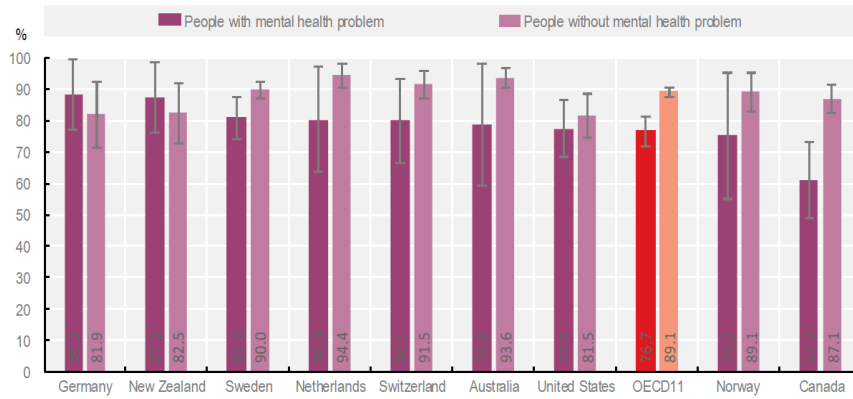
- © Patient-reported experience measures (PREMs) allows patients to provide direct feedback on their perception of their experience with health care or service
- © Recent Deloitte research: hospitals with better patient reported experiences even perform better financially



Why measure patient experience?

- "Real-World Data" produces "Real-World Evidence" - estimate the value of our care and so strive to improve both efficacy and effectiveness of treatments.
Prof Maarten Ijzerman UoM
- In addition to outcomes, *how* people are treated also matters
- A positive care experience is a strong signal of quality care and is instrumental in outcomes achieved, especially for those who manage multiple chronic conditions
- ...despite considerable progress in some specific cases, the care experience is not captured systematically. This needs to change, given the growing importance of this dimension of service delivery
OECD 2019, *Health at a Glance Report*

Figure 6.27. Share of people who were treated with courtesy and respect by doctors and nurses during hospitalisation, 2016



Source: Commonwealth Fund International Health Policy Survey 2016.

Figure 6.41. Doctor spending enough time with patient during consultation, 2010 and 2017 (or nearest year)

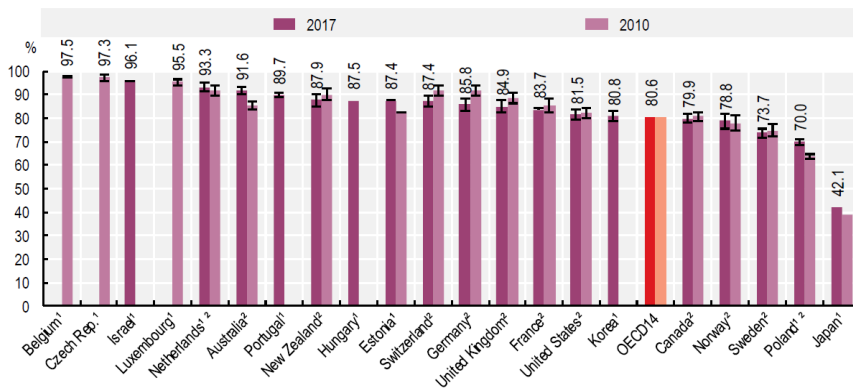
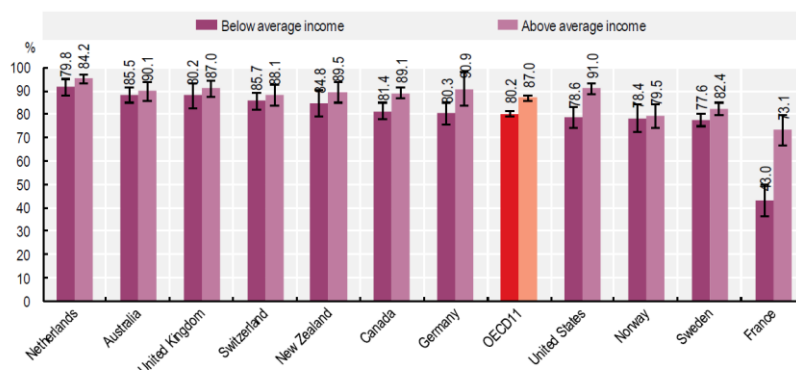


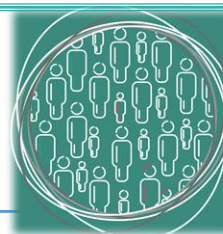
Figure 6.44. Regular doctor involving patient in decisions about care and treatment by income, 2016



Source: Commonwealth Fund International Health Policy Survey 2016.

The All.Can patient survey 2018 –

Understanding efficiency in cancer care



First-ever international survey to gather patients' insights on inefficiencies that occurred in their experience of care

- **Current and former patients** with any type of cancer and their carers
- Questions asked about **personal experiences** with waste and inefficiency throughout cancer care – where things could have been improved
- International **literature review**, and in-depth patient **interviews**
- Final results were published internationally **on 24th July 2019**
- The findings are aimed at governments, policymakers, patient organisations and healthcare providers



Swift, accurate and appropriately delivered diagnosis:

When detected outside a screening program:

	Overall	Breast cancer	All other tumours
Cancer was diagnosed as something different – either initially or multiple times	28%	18%	43%
Diagnosed within three months		91%	69%
Waited more than six months to be diagnosed with cancer	12%	5%	22%

Source: Patient Insights on cancer care. All.Can 2019



Information, support and shared decision-making

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'My cancer nurse was, and still is, the most amazing support we could have asked for. She has a wealth of knowledge and helped us out and at any time of the day or night!'

	Overall
Did not feel involved enough in deciding which treatment options were best for them	35%
Not given enough information (in a way they could understand) about their cancer care and treatment	28%
Did not receive enough support to deal with ongoing symptoms and side effects – including beyond the active phase of their treatment	50%
Did not receive enough information (in a way they could understand) about the signs and symptoms indicating that their cancer might be returning or getting worse	41%
Not given information about patient groups, charities and other organisations that might be able to support them	31%

Source: Patient Insights on cancer care. All.Can 2019



Integrated multidisciplinary care



'Some initial psychological assistance might be useful, even if the patient doesn't request it – sometimes one doesn't realise one needs it!'

	Overall
Did not have access to a specialist cancer nurse, either immediately after their diagnosis or during treatment	30%
Support from allied health professionals was not available when they needed it	19%
Not offered complementary therapies (e.g. massage, meditation, acupuncture, aromatherapy and/or other non-traditional therapies) as part of their cancer treatment	63%
Needed some sort of psychological support during/after their cancer care	64%
<i>Of those, psychological support during/after their cancer care was not available</i>	35%

Source: Patient Insights on cancer care. All.Can 2019



The financial impact of cancer

	Overall
Experienced out-of-pocket costs	79%
Experienced travel costs	32%
- <i>had to travel for 1–2 hours to attend appointments or receive treatment</i>	11%
- <i>travel more than 2 hours</i>	7%
- <i>overnight stay because it was too far from home</i>	9%
Loss of employment	27%
Loss of insurance	8%
Childcare costs	4%

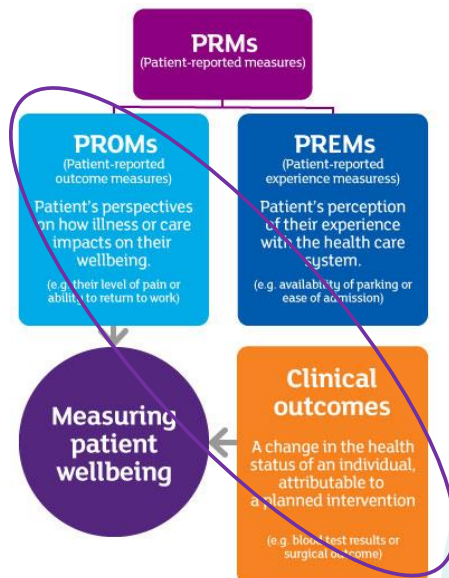
Source: Patient Insights on cancer care. All.Can 2019

So how can we then use this routinely collected PREMs data in clinical trials?

- Implementation of trials evidence
- Regulatory approvals
- Health economics
- Health outcomes/comparative effectiveness research



PROMs vs PREMs

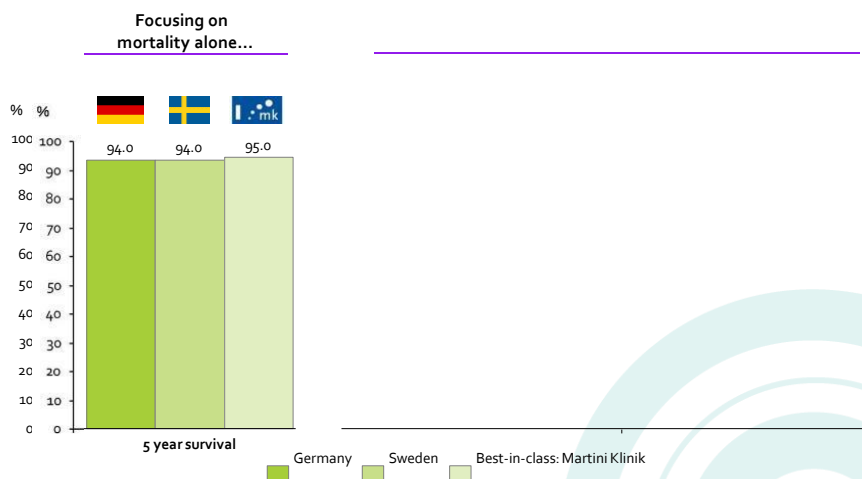


- © Patient-reported outcome measures (PROMs) capture a person's perception of their health

Why do we need to measure PROMs in clinical care?

1. To help us in better detecting disease and therapy related symptoms and so improve QoL Basch et al JCO 2016
2. To counsel patients better in regard to the long term consequences of treatment
3. To facilitate communication and decision making during and after treatment Velikova et al EJC 2010
4. To identify "unmet needs" for the individual patient and for subgroups of patients

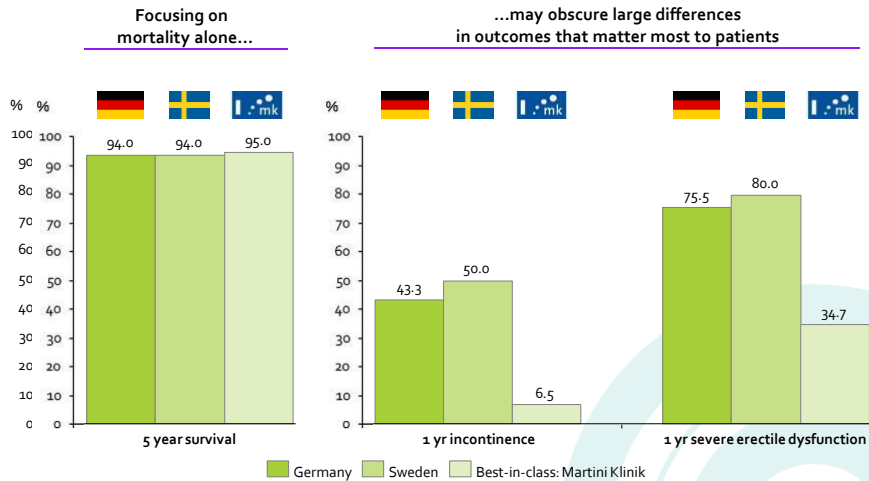
Variability in outcomes...



Swedish data rough estimates from graphs; Source: National quality report for the year of diagnosis 2012 from the National Prostate Cancer Register (NPCR) Sweden, Martini Klinik, BARMER GEK Report Krankenhaus 2012, Patient-reported outcomes (EORTC-PSM), 1 year after treatment, 2010

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Variability in outcomes...

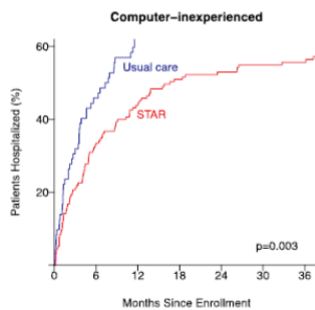


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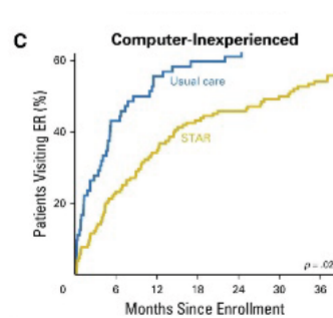
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Monitoring with PRO led to a significant reduction in unplanned emergency room visits and hospital admissions in the computer inexperienced group

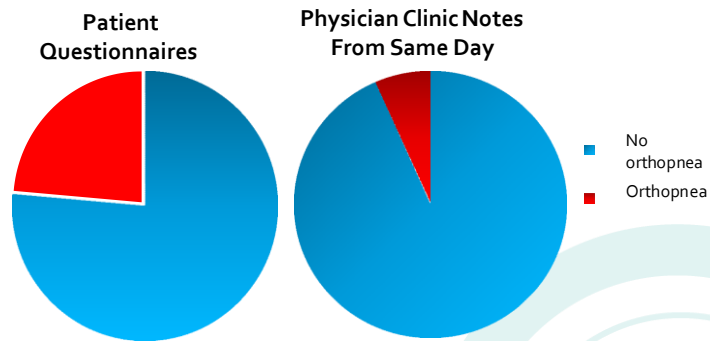
Reduction of unplanned hospital admissions




Reduction of ER visits



Example of Variation in PRO Versus Physician Reporting of Orthopnea



N=932

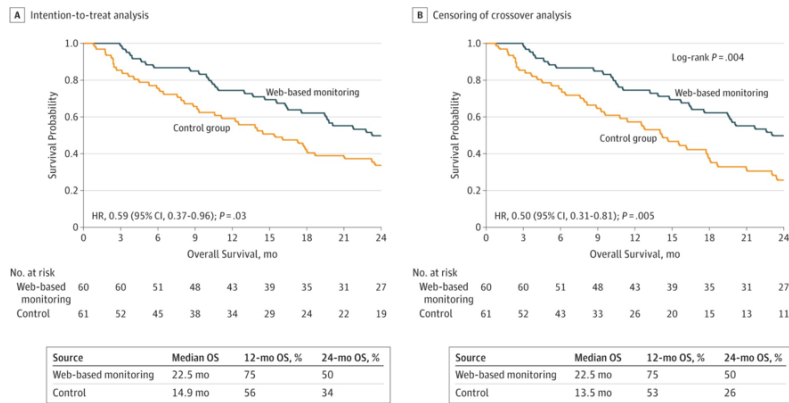
 Motiwala, Castro, Lewis et al, HFSA 2017



Why do we need to measure PROMs in clinical care?

1. To help us in better detecting disease and therapy related symptoms and so improve QoL Basch et al JCO 2016
2. To counsel patients better in regard to the long term consequences of cancer treatment
3. To facilitate communication and decision making during and after cancer treatment Velikova et al EJC 2010
4. To identify "unmet needs" for the individual patient and for subgroups of patients
5. **Improve mortality and morbidity** Denis et al JNCI 2017, Basch et al JAMA 2017

Overall survival after lung cancer in the PRO cohort is 8 months longer compared to the standard group $p = .005$



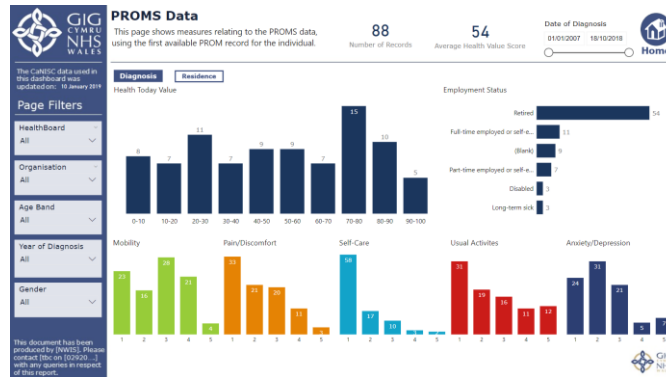
JAMA. 2019;321(3):306-307. doi:10.1001/jama.2018.18085

CHARITÉ UNIVERSITÄTSMEDIZIN BERLIN

So how can we then use this routinely collected PROMs data in clinical trials?

- Routine collection of PROMs for e.g. for registry purposes could
 - Facilitate RCTs that are embedded in routine practice
 - Act as observational data to complement to RCT data - norms
 - Extrapolate RCT results to specific populations
 - Extrapolate RCT outcomes over longer periods of time
 - Allow consideration of broader outcomes and comparators

Lung Cancer Dashboard: Patient Reported Outcomes



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What would be a good way to routinely measure PROMs?

ICHOM International Consortium Of Health Outcome Measures

Standard sets

Colorectal Cancer



Breast Cancer



Lung Cancer



Advanced Prostate Cancer



Localised Prostate Cancer

Source: ICHOM

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Example ICHOM data fields

ICHOM Standard Set for Breast Cancer

Case-Mix Variables

Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
Demographic Factors				
All patients	Gender	N/A		Patient-reported
	Date of birth			Clinical
	Body mass index	Height and weight		
	Ethnicity	Determined by country	Baseline	
	Educational level	Level of schooling completed		Patient-reported
	Relationship status	Relationship status		
Baseline Clinical Factors				
All patients	Comorbidities	Modified Self-administered Comorbidity Questionnaire (SCQ)	Baseline, update at least after 5 years	Patient-reported
	Laterality	Laterality of breast cancer		
	First or new primary tumor	First primary or new primary on contralateral or ipsilateral breast	Baseline	Clinical
Baseline Tumor Factors				
All patients	Date of diagnosis	Initial date of histological diagnosis	Baseline	
	Histological type	Histological type of tumor		
	Mutation status	Genetic mutation predisposing breast cancer	Baseline and 1 year	
	Tumor grade (invasive)	Grade of invasive component of tumor		
	Tumor grade (DCIS)	Grade of DCIS component of tumor		



Source: ICHOM

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Outcomes				
Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
Disutility of care				
Patients with surgery/radiotherapy	Reoperation due to positive margins	Reoperation due to positive margins after final surgery	Update at least 6 months after treatment	Clinical and patient-reported
All patients with treatment	Impact of acute complication	Acute complications will be recorded based on the type of therapy needed or action required to correct the complication as described in the Clavien-Dindo Classification and CTCAE v4.0	Updated at least 6 months, 1 year after treatment when a patient received hormonal therapy	Clinical
	Type of acute complication	Name of acute complication		
Degree of Health				
All patients	Overall well-being			
	Physical functioning			
	Emotional functioning			
	Cognitive functioning			
	Social functioning			
	Ability to work			
	Anxiety			
	Depression			
	Financial impact			
	Pain			
	Fatigue			
	Sexual functioning			
	Body image			
Patients with surgery/radiotherapy	Satisfaction with breast(s)	Tracked via BREAST-Q - Satisfaction with Breasts	Baseline, 1 and 2 year post treatment	Patient-reported
Patients with systemic therapy	Arm symptoms			
	Breast symptoms			
	Vasomotor symptoms			
	Peripheral neuropathy			
	Vaginal symptoms			
	Arthralgia			



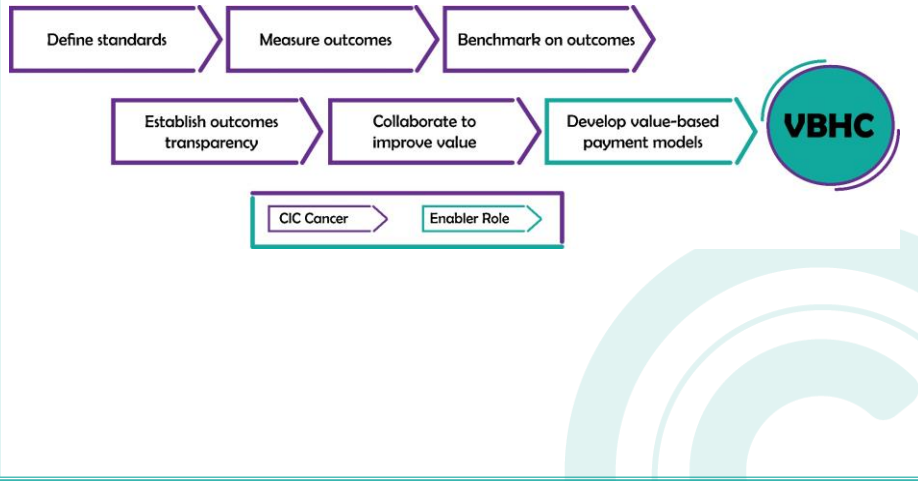
Value-based health care

The core purpose of health care is **value for patients** and delivering high value for patients must be the **central goal** of every health care organisation.

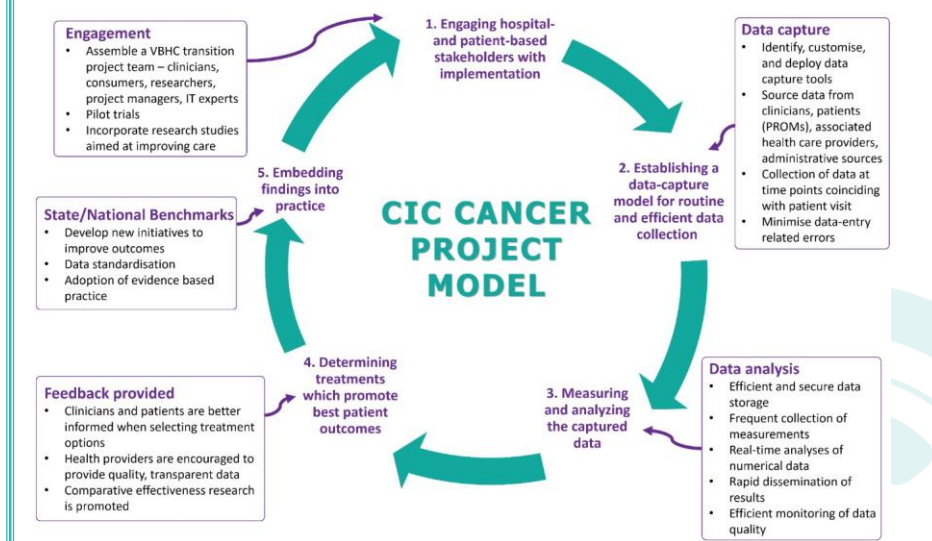
$$\text{Value} = \frac{\Delta \text{Health outcomes that matter to patients}}{\text{Costs of delivering those outcomes}}$$

Financial success is the result of delivering value, not the end in itself

CIC Cancer project - Implement VBHC in WA



WA – CIC Cancer project



Measuring PROMS routinely in Australia

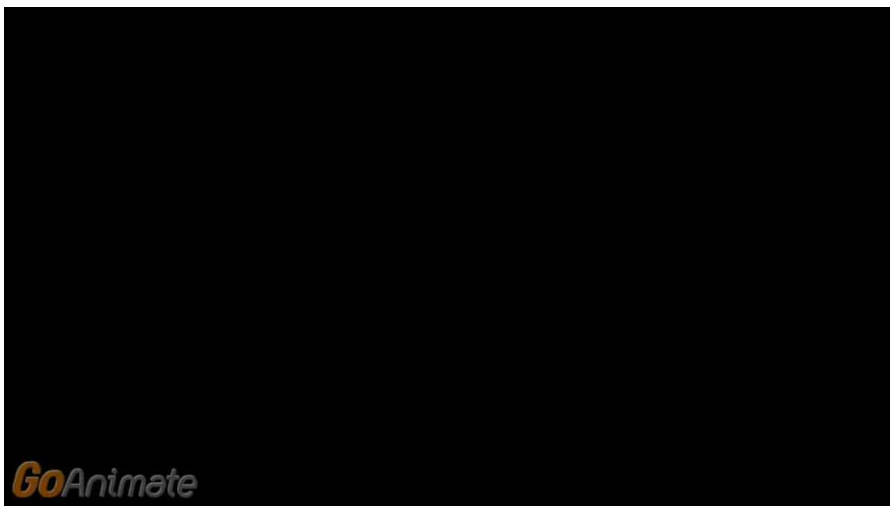


✓ Early evidence - NSW

- **Care planning changed** following use of PROMs and discussion of report between patient and clinician
- **Aggregated PRM data** has been used to monitor quality and refine service delivery
- Care **more patient-centred, more responsive** to patient's needs, **clinical practices improved**, service delivery **more effective and efficient**, **patient management improved**

Source: Raj Verma, NSW Agency for Clinical innovation, NSW (as presented to ICHOM Conference 2019)

- © In 2018 the Queensland health minister, Steven Miles announced that “the Queensland government had undertaken a data project that would underpin a new website – a TripAdvisor for hospitals – that would allow patients to compare public and private hospital outcomes in a range of specialty areas.”



Conclusions

- PREMs and PROMs are becoming part of routine health care
- Many registries are extending data collection to include at least PROMs
- Hopefully these will be standardised and electronic
- This will facilitate research and quality improvement

Save the date...

**VBHC
Conference
23RD - 26TH
March 2021**

www.ciccancer.com/vbhconf

Perth, WA

A graphic for the VBHC Conference. It features a teal circle with a purple dot and a purple line segment. To the right is a colorful abstract design with diagonal lines in teal, purple, and white. The text 'Save the date...' is underlined in purple. The conference details are in bold black text. The website URL is underlined in purple. An arrow points from the URL to the text 'Perth, WA'.