What are PROs?

What is the evidence that individual-level data can inform routine clinical care?

COSA Think Tank: Incorporating patient reported outcomes (PROs) into cancer survivor follow-up and care

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Terminology: PROs v PROMs (PROs v PREs)

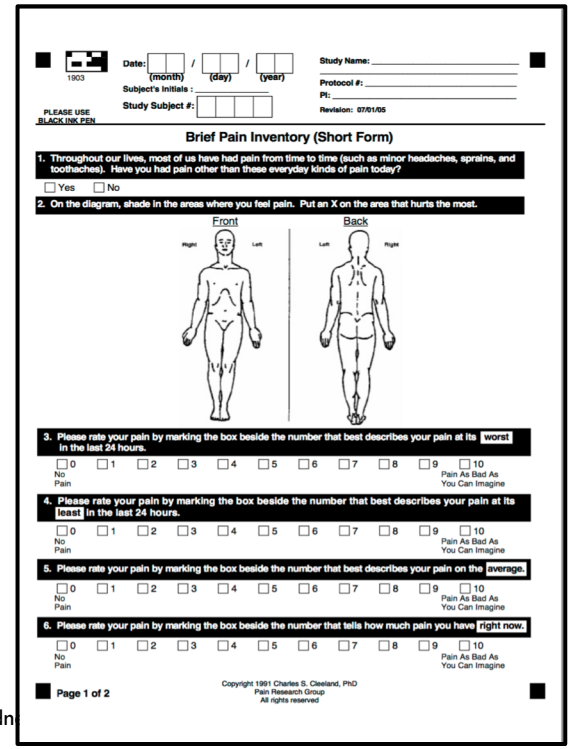
- PRO (E) = the patient-reported outcome (experience) , e.g. pain
  (timeliness of provision of information about pain medications)

The CONCEPT

- PROM = the measurement tool used to assess the PRO,
  e.g. BPI (Brief Pain Inventory)

How the concept is operationalized and quantified

- Aka PRO instrument = a questionnaire plus the information and documentation that support its use (FDA PRO guidance doc, 2009)



1903

Date: (month) / (day) / (year)

Study Name:

Subject's Initials :

Study Subject #:

Protocol #:

PI:

Revision: 07/01/05

PLEASE USE BLACK INK PEN

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?
   ☐ Yes ☐ No
2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

Front Back

3. Please rate your pain by marking the box beside the number that best describes your pain at its worst in the last 24 hours.
   ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
   No Pain — Pain As Bad As You Can Imagine
4. Please rate your pain by marking the box beside the number that best describes your pain at its least in the last 24 hours.
   ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
   No Pain — Pain As Bad As You Can Imagine
5. Please rate your pain by marking the box beside the number that best describes your pain on the average.
   ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
   No Pain — Pain As Bad As You Can Imagine
6. Please rate your pain by marking the box beside the number that tells how much pain you have right now.
   ☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
   No Pain — Pain As Bad As You Can Imagine

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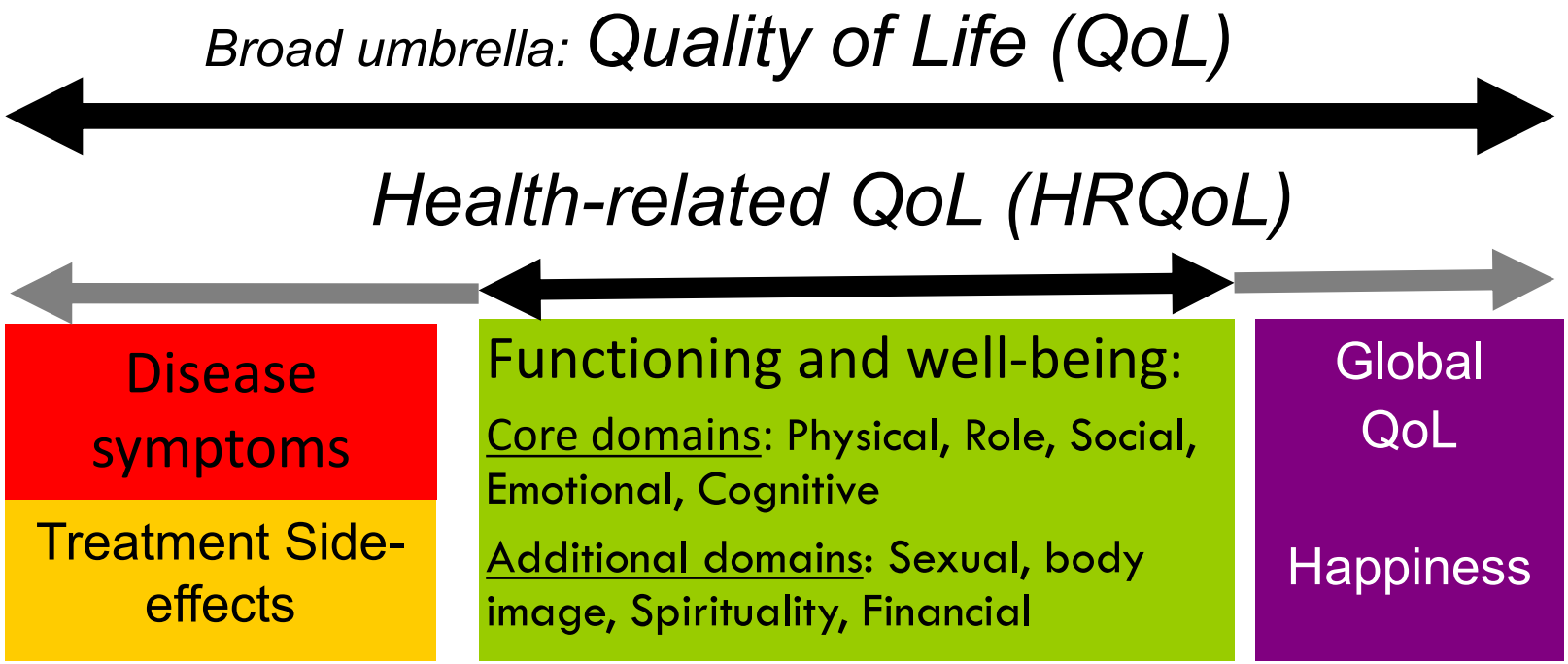
- clearly defined methods and instructions for administration and responding
- standard format(s) for data collection
  - Hard-copy, weblink, e-PRO apps for small-screen devices
- well-documented methods for scoring, analysis, and interpretation of results in the target patient population.

More terminology: QoL v HRQoL v PRO



Patient-reported outcomes PRO

'A measurement based on a report that comes directly from the patient about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else.'

FDA Guidance (2009)

HRQOL is a multi-dimensional PRO

- Several conceptually distinct definitions of HRQOL

- The dominant one in PROMs used in cancer research:

  "HRQOL is a multidimensional construct encompassing perceptions of both positive and negative aspects of dimensions, such as physical, emotional, social, and cognitive functions, as well as the negative aspects of somatic discomfort and other symptoms produced by a disease or its treatment."

  Osoba, D. Lessons learned from measuring HRQOL in oncology. JCO 1994; 12(3): 608-616.

- How that (any) definition is operationalized differs between PROMs
  - Need to look at items & how they are combined into domain scales

Why the momentum for PROMs in routine care?

- Central to patient-centred care
- The patient is the best informant of sensations, feelings and role/social function
- PROMs complement clinical measures

How might PROMs be used in clinical practice?

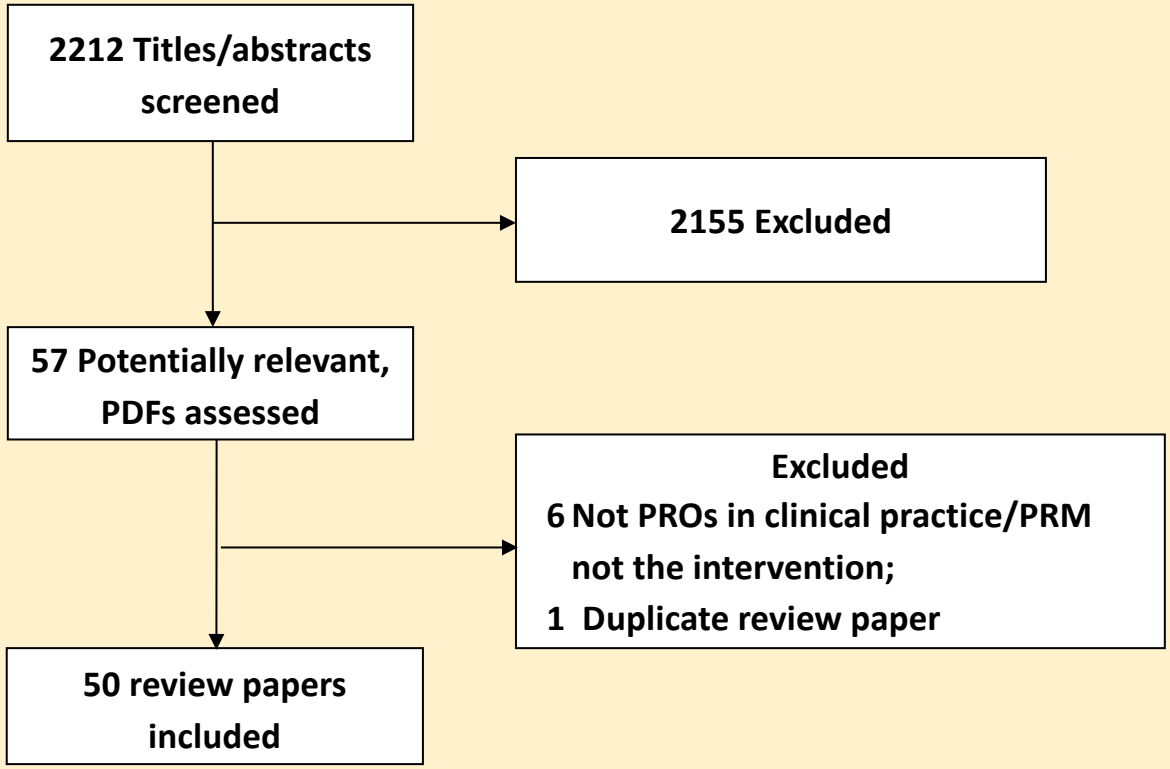
In the clinical consultation, systematic PRO assessment may help

- monitor response to therapy
- focus goals of care
- facilitate communication and shared decision making
- improve symptom control
- increase patient satisfaction
- allow for earlier integration of support services
- enhance continuity of care
- improve quality of care
- improve survival?

What is the evidence?

Lots of evidence!

Review of reviews – work in progress



Earliest review: Greenhalgh et al 1999 (included 13 RCTs 1987-1997)

Review aims:

- 21 PRM effectiveness in practice
  - Some characterise where PRMs work/don't work
- 11 How PRMs used in practice
- 8 Barriers/enablers to PRM implementation PRMs
- 11 PRM selection for use in practice

Populations/Patient Groups:

- 11 General/non-specific
- 10 Cancer
- 9 Mental Health
- 3 Rheumatoid Arthritis
- 4 Other chronic conditions

Broad brush: What the evidence says

Many RCTs across a number of settings, about 35 RCTs in cancer

Improves:
- Communication between patient & HCP
- Awareness of symptoms/problems/impact on the patient's life

Equivocal:
- patient management
- satisfaction with care
- outcomes - PROs / HRQoL, survival

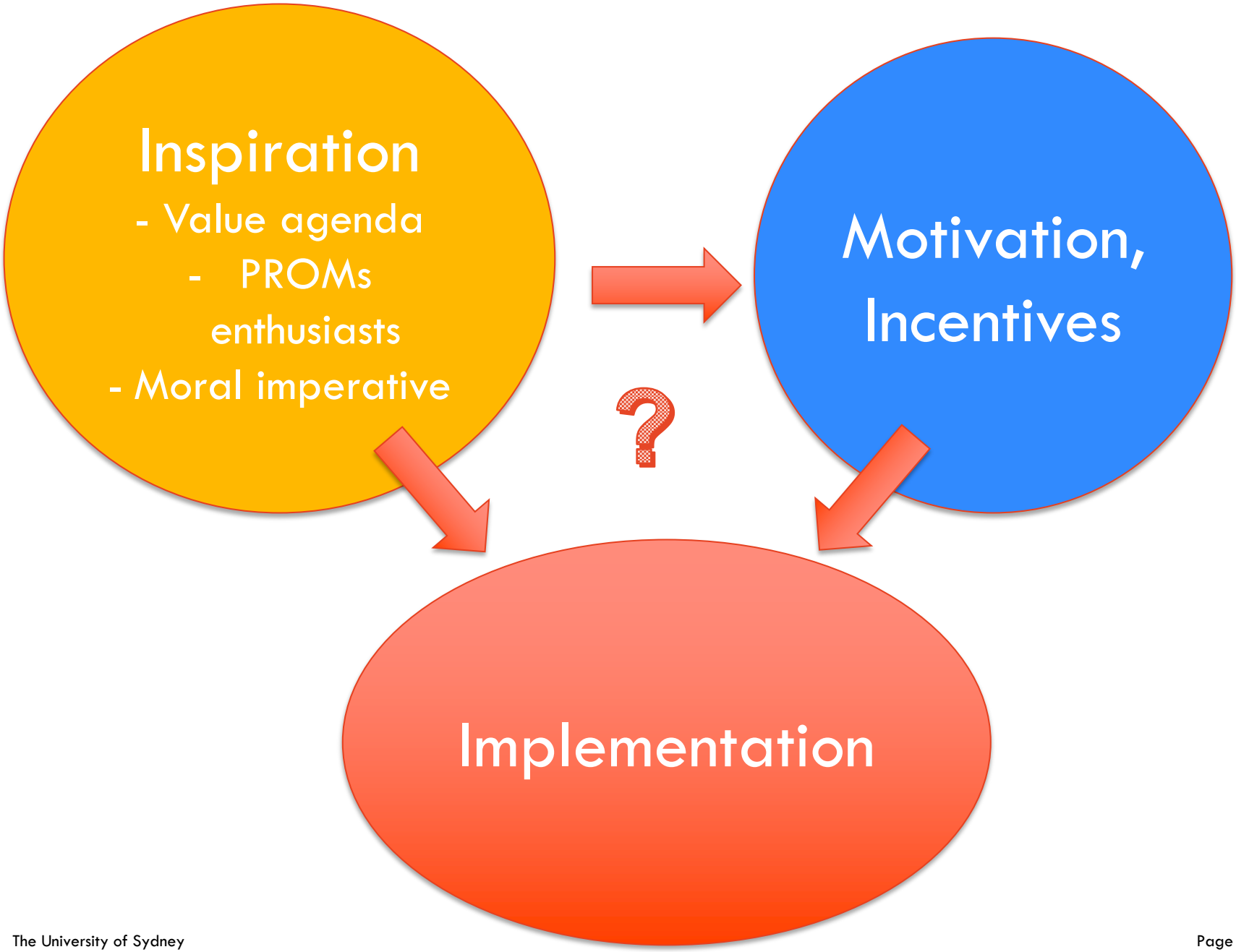
? consultation time

Limitations
- Methodological (quality, even though many RCTs)
- Success factors are not clear

Caveat

- Most/all of these studies included in these reviews were single site studies, designed and conducted by PRO enthusiasts.
- Results are best case scenario

- Greenhalgh 2017 'Realist Synthesis' conclusions:
  - *"PROMs are useful to enable patients with long-term conditions to raise or share their concerns with doctors, but do not always change what doctors ask patients about during consultations."*
  - *"Doctors have some concerns that PROMs may raise issues that they do not feel trained to address or do not know how to treat."*
  - *"Future work should examine whether or not it is possible to collect PROMs data to support the care of individual patients and to improve the quality of services at the same time."*


Inspiration
- Value agenda
- PROMs enthusiasts
- Moral imperative
Motivation, Incentives
?
Implementation

Challenges & Barriers

2 quotes from ICHOM conference Sydney May 2017

Elizabeth Coff (Sec, NSW Health) ….

"Implementation is the hardest part"

… reinforced by Thomas Keeley

"Everyone has their reasons why they can't do it"

What could possibly go wrong?

- Top down enthusiasm driving action
  - "Just do it!"
- Lack of enthusiasm at the coal face
  - "Why? I'm flat out as it is"
- Lack of involvement of stakeholders in planning: what, why, how
- Bad choice of questionnaire – measures the wrong thing
  - "This stuff is useless to me as a clinician!"
- No one can interpret the results
  - "I cant make head or tail of this!"
- Lack infrastructure/funds to collect data
- IT challenges
  - How to integrate with EHR
  - data security / patient confidentiality
- Lack of plan of how you are going to use the data
- Poor communication among stakeholders
  - No one know why the data are being collected or what to use it for

Do you remember when all we had to do was look after people?

Challenges and Barriers

- Changing attitudes and behaviour of health care providers

Greenhalgh et al, 2017

> *"… an important reason that PROMs feedback did not substantially change clinicians' communication practices … was that this would require a* ***shift in clinicians' perceptions of their remit.***
>
> *"****Professional boundaries and remit are developed through the socialisation*** *that different professional groups experience during training, and they are* ***mutually reinforced by the division of labour*** *among professional groups and the organisational structures that exist to support these ways of working.*
>
> *"****PROMs feedback alone is not going to change this.***"

Education, Engagement, Leadership

Challenges and Barriers

- Changing attitudes and behaviour of health care providers
- Time constraints on all stakeholders to implement and monitor data
- Lack of training on the use and interpretation of PROM data
- Liability issues regarding what to do in cases of patient electronically reporting of issues between visits.
- Lack of 'value' add of using PROMs
- High IT and infrastructure requirements
- Lack of standardization of PROMs
- Huge array of PROMs to choose from, few designed for use in clinic or quality assurance in health care provision

Success Factors

Collated from various guidance docs (written by PROM enthusiasts)

- Engaging stakeholders in each stage of development, delivery and evaluation (bottom up)
- Integration of PROMs in clinical practice guidelines (top down)
  - Adherence?
- Electronic PRO capture and integration with electronic health records
- Automatic flagging of clinically important scores
- Limit data collection / completion to < 30 minutes
- Collect PRO data at baseline and selected follow up times, whilst minimizing follow up
- Employ methods to minimize missing data including education of patients, providers and real time monitoring of adherence

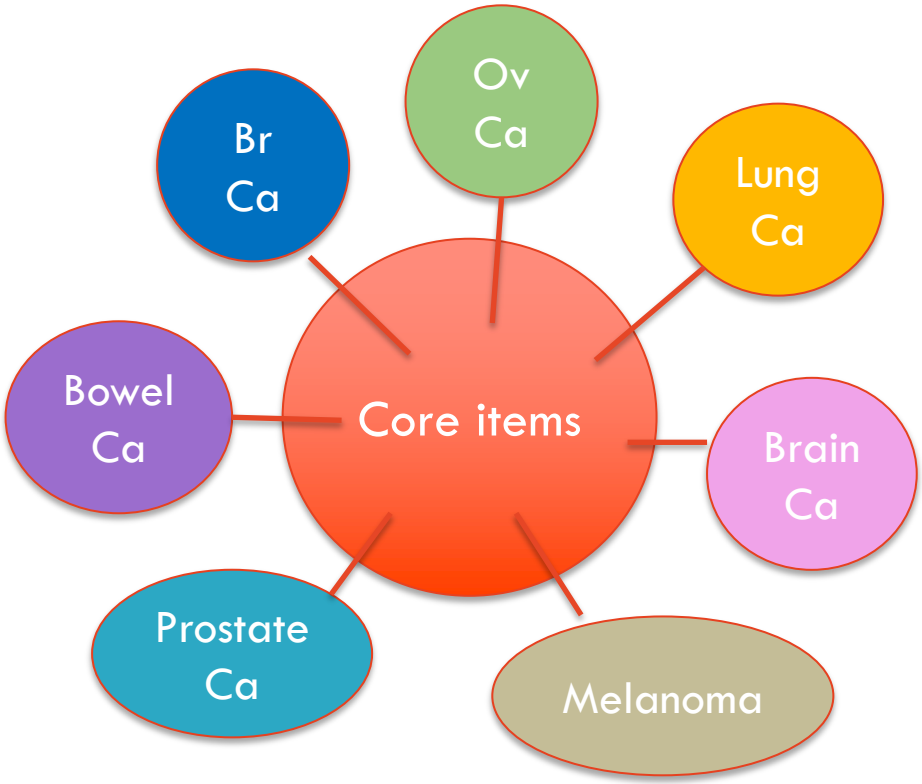
Talk ended here – som additional slide follow FYI

PROMs – what's in the toolkit?

Choose the right tool for the job

But before you choose a PROM, you need to work out which PROs you need to measure

- How narrow?
- How broad?
- How many?
- What's feasible?
- What's clinically useful?
- How will they be used?
- By whom?
- When?
- To improve what?
- If problems in care or outcomes are identified, how will they be improved?



- PROs/PREs, PROMs/PREMs core data set items vs condition-specific items (modular approach?)

Choosing the right PROM for the job

- There is no "best" PROM in an absolute sense
- Huge pool to choose from
  - most developed for research, not clinic
- Guiding criteria: purpose of measurement, target outcomes
- Thorough search & review to identify suitable candidates
  - Clinically meaningful
  - Psychometrically sound for intended purpose
  - Feasible
  - Available in languages required
    - Translation must follow rigorous forward-backward method by accredited translators – see EORTC guidance
  - Cost
    - Licensing
    - infrastructure

ICHOM Standard Sets

Julien Wiggins this morning …

ICHOM Std Set PROs (note: not PROMs, yet) **for Bowel Cancer**

- Pain
- Fatigue
- Depression
- Sexual dysfunction
- Neuropathy
- GI Symptoms
- Stoma functioning
- "HR-QOL" (Argh! Everything above = HR-QOL, multidimensional, best to assess each dimension discretely)

Individual data can be aggregated for other purposes

Clinical consultation:

Clinical Quality Registries:

- monitor outcomes
- report on quality of care

State/National

- QI, Benchmarking, Variation

Greenhalgh et al (2017) caution: *" Research is needed as to how PROMs can best be used both to assist individual clinical management and to compare the performance of providers."*