Patient-Reported Outcomes for Better Care, Better Research

23rd November 2020

10:00-11:30am

Maximising the impact of PRO assessment for patients and society

Professor Melanie Calvert

Director Birmingham Health Partners Centre for Regulatory Science & Innovation, Director Centre for Patient Reported Outcomes Research

@drmelcalvert @CPROR_UoB

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Disclaimer/Funding Statement

Prof Melanie Calvert is Director of the Birmingham Health Partners Centre for Regulatory Science and Innovation and Director Centre for Patient Reported Outcomes Research and is a National Institute for Health Research (NIHR) Senior Investigator. She receives funding from the NIHR Birmingham Biomedical Research Centre; the NIHR Surgical Reconstruction and Microbiology Research Centre and NIHR ARC West Midlands at the University of Birmingham and University Hospitals Birmingham NHS Foundation Trust; Health Data Research UK; Innovate UK (part of UK Research and Innovation); the Health Foundation; Macmillan Cancer Support; and UCB Pharma. M.J.C. has received personal fees from Astellas, Takeda, Merck, Daiichi Sankyo, Glaukos, GlaxoSmithKline and the Patient-Centered Outcomes Research Institute (PCORI) outside the submitted work.

The views expressed in this presentation are those of the author and not necessarily those of the NIHR, or the Department of Health and Social Care.

About me….

- Professor of Outcomes Methodology, University of Birmingham
- NIHR Senior Investigator and member National Research Ethics Advisory Panel.
- Director of Centre for Patient Reported Outcomes Research
- Director Birmingham Health Partners Centre for Regulatory Science and Innovation

- **Passionate about capturing outcomes that matter to patients to inform their care.**

Calvert Melanie, Kyte Derek, Price Gary, Valderas Jose M, Hjollund Niels Henrik. Maximising the impact of patient reported outcome assessment for patients and society *BMJ* 2019; 364 :k5267

Overview

PROs of value to multiple stakeholders

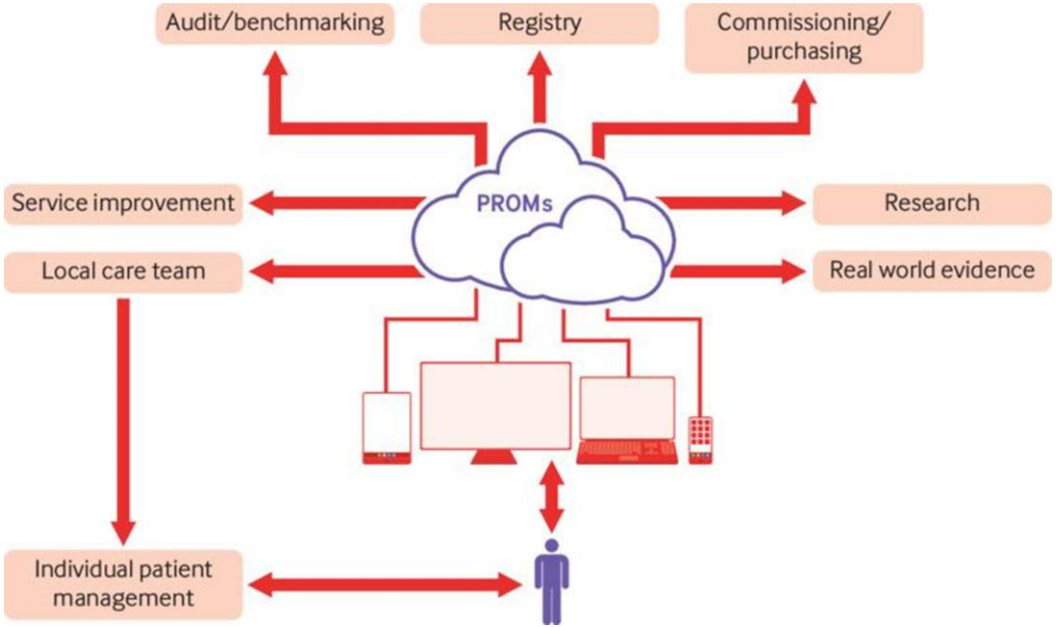
Current challenges- system fragmented and suboptimal

Examples of good practice

Proposal: Integrated evidence based approach to data collection to meet multiple stakeholder needs

The value of PROs to multiple stakeholders

The value of PROs to multiple stakeholders



Melanie Calvert et al. BMJ 2019;364:bmj.k5267

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The value of PRO to patients

- Inform shared decision making "How will it make me feel?" "What's the alternative?"
- Tailor care to individual needs
- Real-time monitoring of symptoms
- Can facilitate early detection of problems/triage/prompt clinical intervention
- Flexible scheduling of hospital outpatient/GP appointments in response to PRO data

Current challenges

Current challenges with PRO data collection

- Selecting/standardising use of appropriate measures
- Ethical issues
  - Who is accessing data? For what purpose? How is data used? PRO-Alerts
  - Patient burden
- Suboptimal data collection, analysis, reporting, and interpretation
- Data logistic issues - integration with the EHR
- Lack of coordination within and across clinical specialties/healthcare systems to meet multiple stakeholder needs.
- Fragmented suboptimal approach

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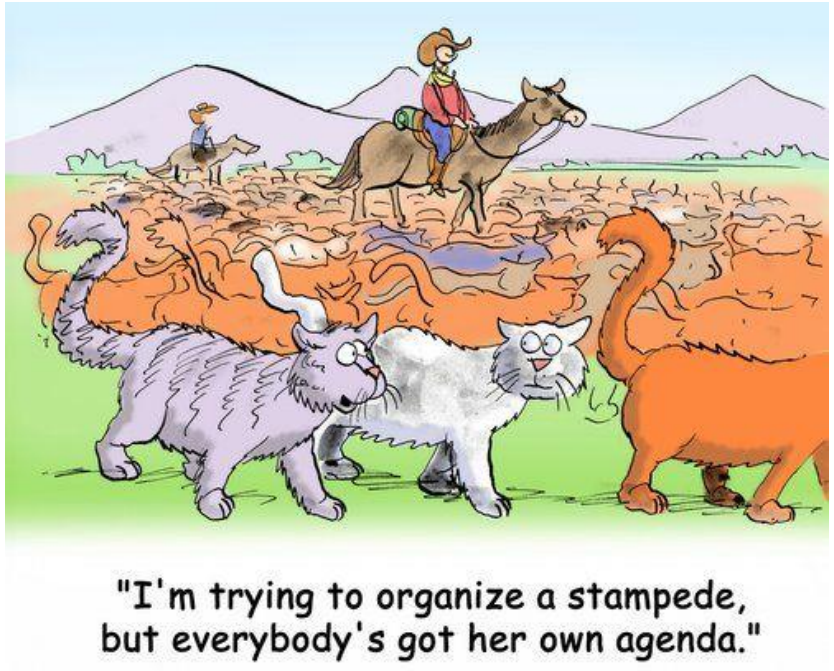
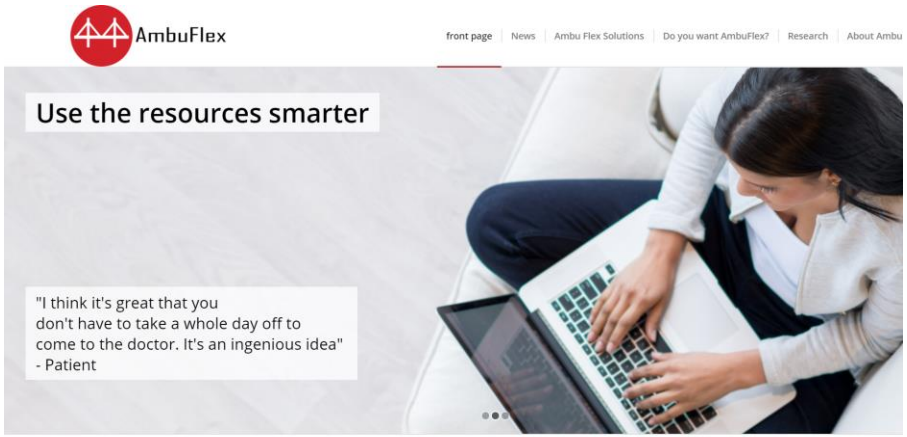


"I'm trying to organize a stampede,
but everybody's got her own agenda."

Examples of good practice



Value Based Health Care

in Aneurin Bevan University Health Board

Achieving the outcomes that matter to people, being good stewards of the finite resources available and working together to do the right thing across the whole system.

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Aneurin Bevan University Health Board

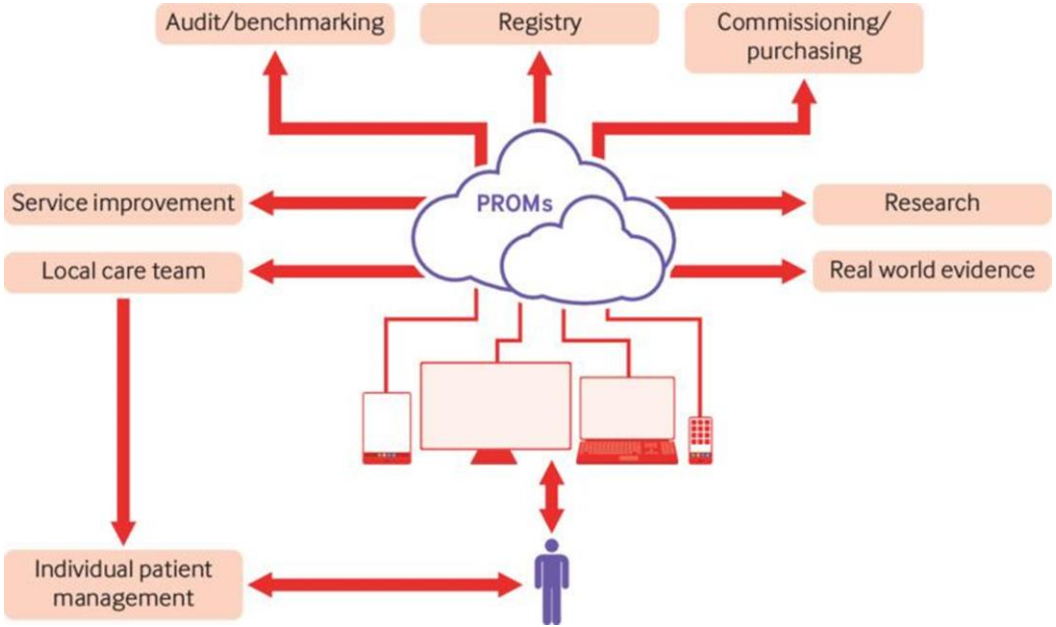
Welcome to the login page of the eRAPID research project

eRAPID stands for "**E**lectronic patient self-**R**eporting of **A**dverse-events: **P**atient **I**nformation and a**D**vice".

Renal
Trauma
Advanced therapies
++

Proposal: Integrated evidence based approach to data collection to meet multiple stakeholder needs

What we need: Integrated assessment of PROMs to meet multiple stakeholder needs.



Melanie Calvert et al. BMJ 2019;364:bmj.k5267

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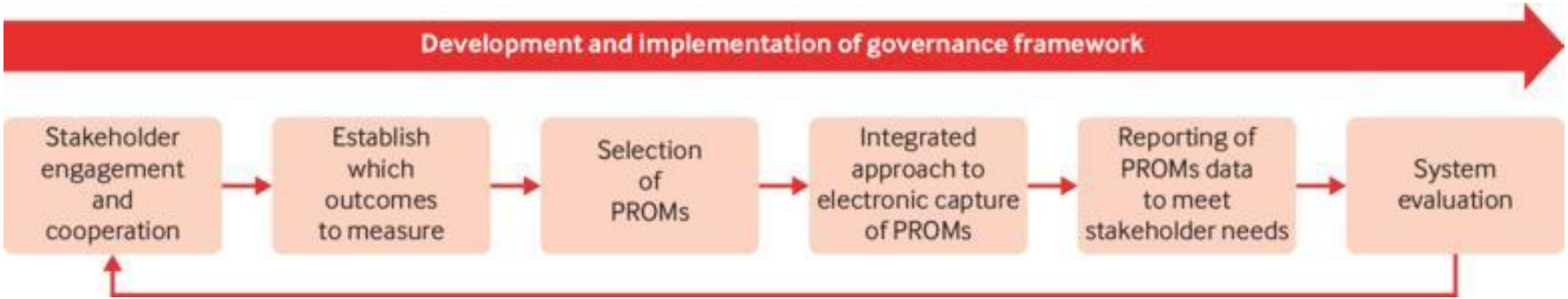
Steps to realising a fully integrated PROM system.



Melanie Calvert et al. BMJ 2019;364:bmj.k5267

Key messages

Patient reported outcome data are increasingly being used by a range of stakeholders in healthcare

These data may offer major benefits to patients and society, but current use is fragmented and suboptimal

We propose an integrated evidence based approach to data collection to meet multiple stakeholder needs

Melanie Calvert et al. BMJ 2019;364:bmj.k5267

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Many thanks – look forward to discussions!

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Supplementing registry data with PROM data collected through apps

HDR UK & MRC-NIHR TMRP Workshop, 23rd November 2020

Patient-Reported Outcomes for Better Care, Better Research

Keith Bodger

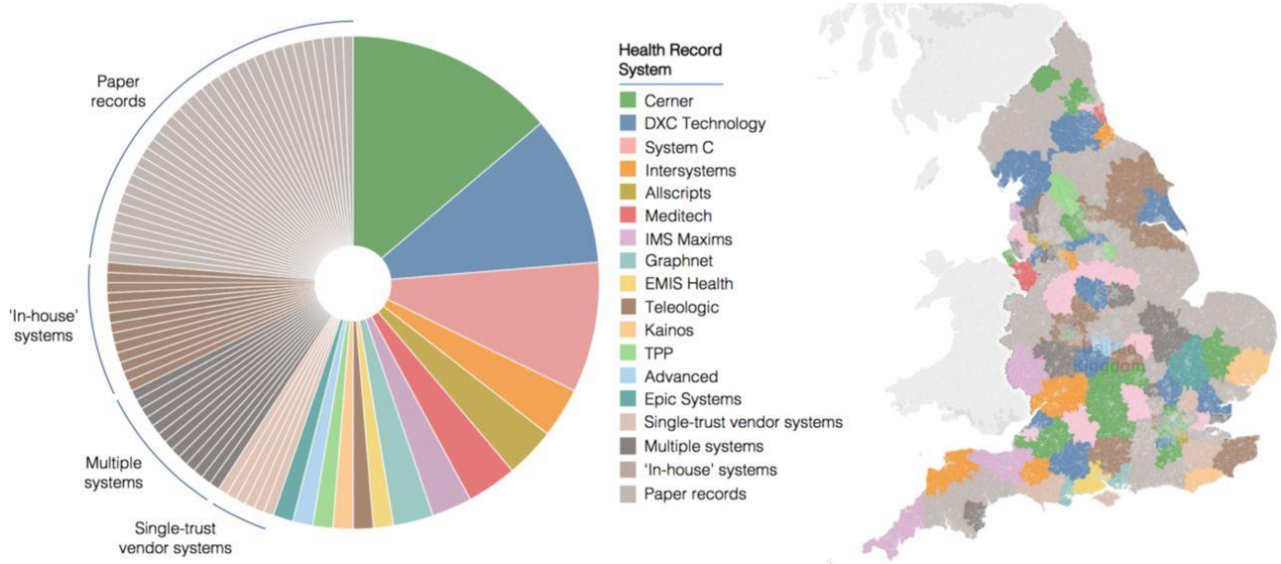
Reader & Consultant Gastroenterologist

Department of Health Data Science, University of Liverpool, UK

Academic Lead, UK IBD Registry

Fragmented IT infrastructure

Frequency of use of health record systems by trusts and distribution of health record systems in NHS England



Leigh R Warren et al. *BMJ Open* 2019;9:e031637

The IBD Registry

1. System agnostic data capture at point-of-care

Clinician-generated data

Registry Software Tools
Patient Management System
Registry Web Tool
Electronic Health Records
e.g. EMIS, EPIC, Cerner.

NHS Digital

2. Standardised Data Submission
NHS-D Audit Platform
Anonymized Data

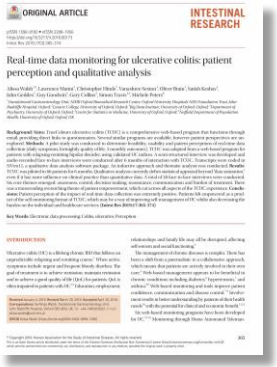
IBD Registry

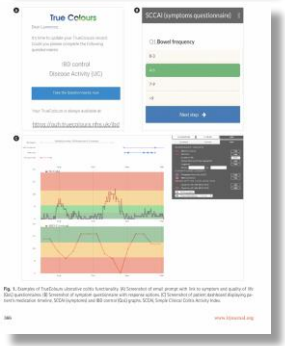
3. Quarterly Reporting
e.g. National Audit of Biological Therapies

How can we integrate *flexible* capture of patient-reported data?

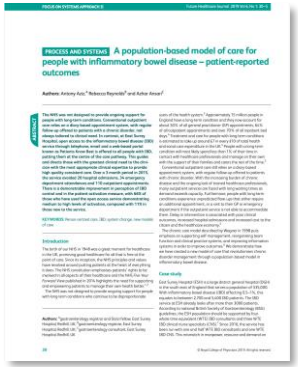
Expanding range of apps for IBD

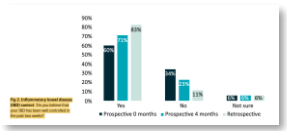
TrueColoursUC
Oxford


ORIGINAL ARTICLE
INTESTINAL RESEARCH
Real-time data monitoring for ulcerative colitis: patient perception and qualitative analysis

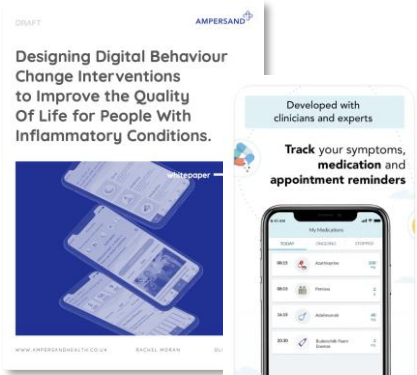

True Colours
SCCAI (symptoms questionnaire)

PatientKnowsBest
East Surrey


PROCESS AND SYSTEMS
A population-based model of care for people with inflammatory bowel disease – patient-reported outcomes


Prospective 0 months
Prospective 4 months
Retrospective

MyIBDCare
King's College Hospital


AMPERSAND
Designing Digital Behaviour Change Interventions to Improve the Quality Of Life for People With Inflammatory Conditions.
Whitepaper

Developed with clinicians and experts
Track your symptoms, medication and appointment reminders
ADD NEW MEDICATION

- **Functions and content vary**
- **Not formally evaluated as interventions**
- **Range of ePROMs** (but some standardisation*)

* These examples include the IBD-Control Questionnaire (Bodger *et al*, *Gut*, 2014).

The IBD Registry

Why integrate patient-reported data?

- Capture the patient perspective
- Engage patients in quality improvement (and research)
- Compensate for gaps in clinician-generated data (especially outcomes)
- Supporting partnership with HDR UK IBD Hub (BioResource)

What types of data?

- PROMs (exemplar, IBD-Control Questionnaire)
- PREMs (e.g. biannual benchmarking survey, currently separate)
- Selected data items (e.g. interventions, side effects)

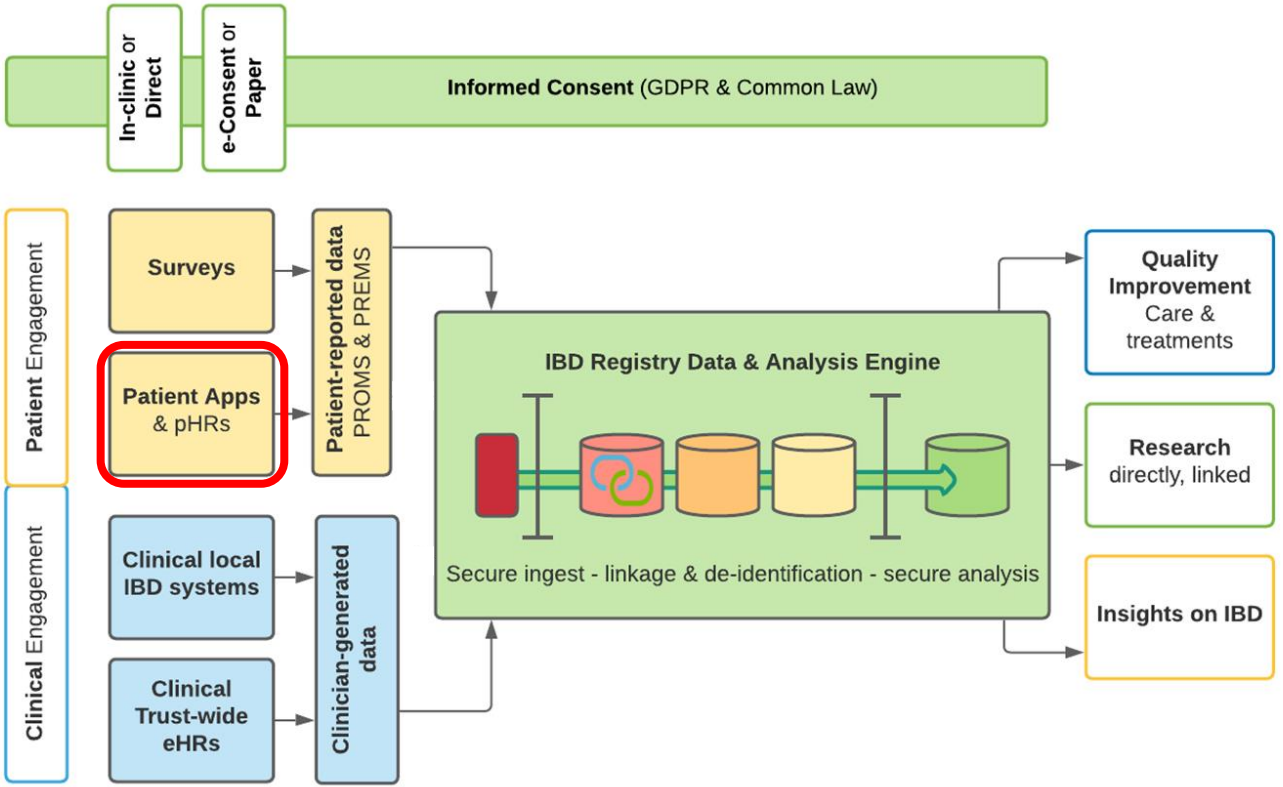
Is the information governance right?

- Requires a revised consent model and e-Consent (not s251) !
- Transition to collect *patient-identifiable* data to allow linkage

How to allow for equitable access and scalability?

- System and vendor agnostic
- Open standards and inclusive ('bring your own system')
- Flexible modes of capture (apps, portals, web surveys, tablets, paper)
- Direct from patients (central), submitted by Trusts, or via 3rd party apps (vendors)
- Provision of a 'Registry' survey option for sites with no alternative (COVID Tool)

Re-design of the IBD Registry



NIHR | Bristol Biomedical Research Centre

Randomised trials of PROM monitoring as a healthcare intervention

Angus McNair, Kerry Avery

Centre for Surgical Research, University of Bristol

TMRP Outcomes Working Group

Aim

1. Brief example of an RCT of an (electronic) PROM monitoring intervention

2. Possible methodological challenges we may encounter in trials of PROM monitoring

ROSE study

Aim:

To evaluate the effectiveness of **tailored feedback** from **real-time, electronic symptom monitoring** on post-discharge **recovery** from oesophago-gastric cancer surgery

eRAPID

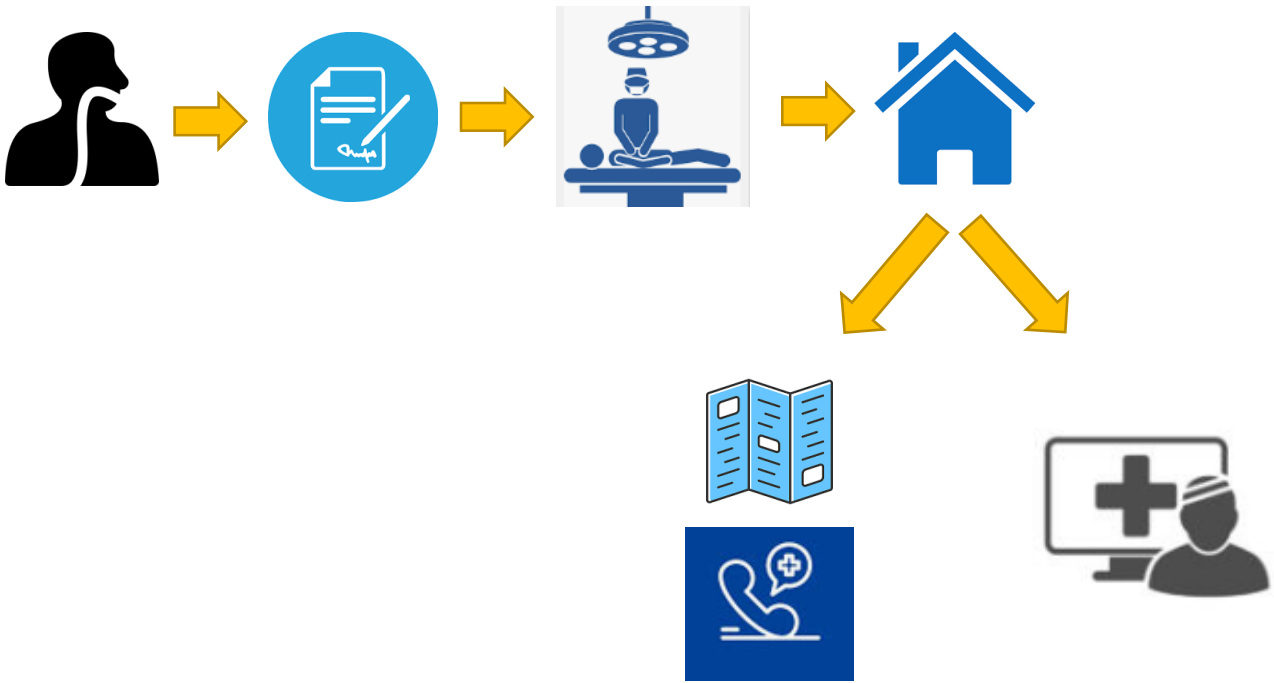
BMC Cancer

RESEARCH ARTICLE Open Access

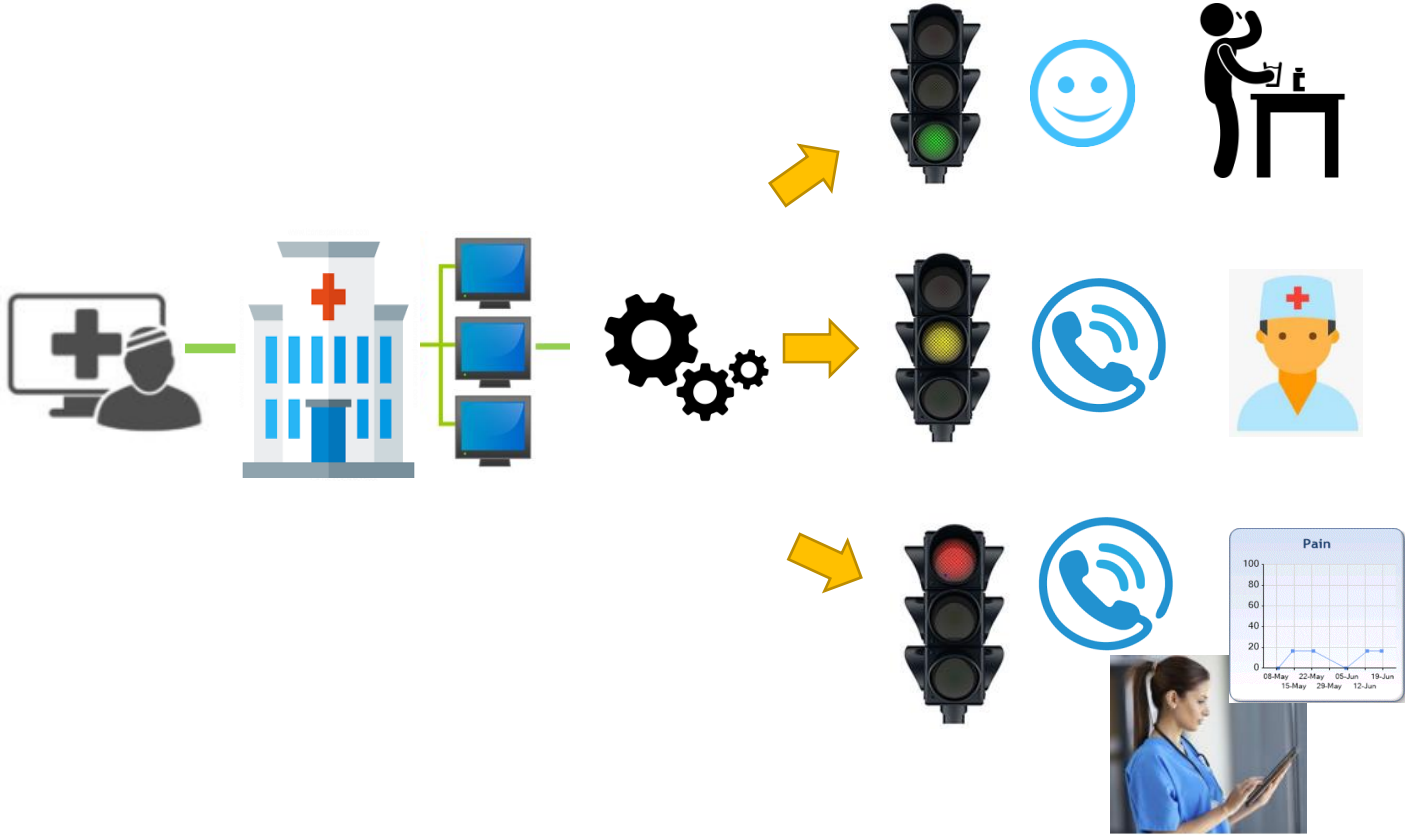
A real-time electronic symptom monitoring system for patients after discharge following surgery: a pilot study in cancer-related surgery

H. S. Richards[1*], J. M. Blazeby[1,2], A. Portal[3], R. Harding[2], T. Reed[2], T. Lander[2], K. A. Chalmers[1], R. Carter[4], R. Singhal[5], K. Absolom[4], G. Velikova[4] and K. N. L. Avery[1]

Design



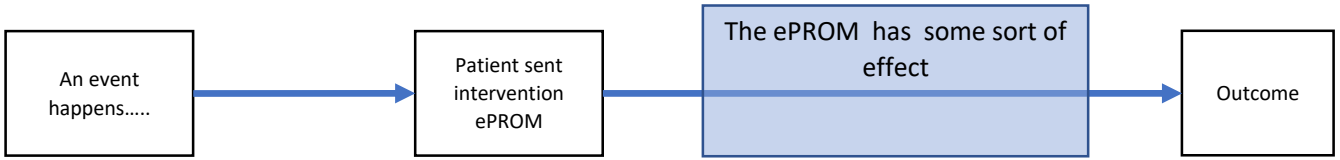
How the intervention works



(Some) methodology challenges

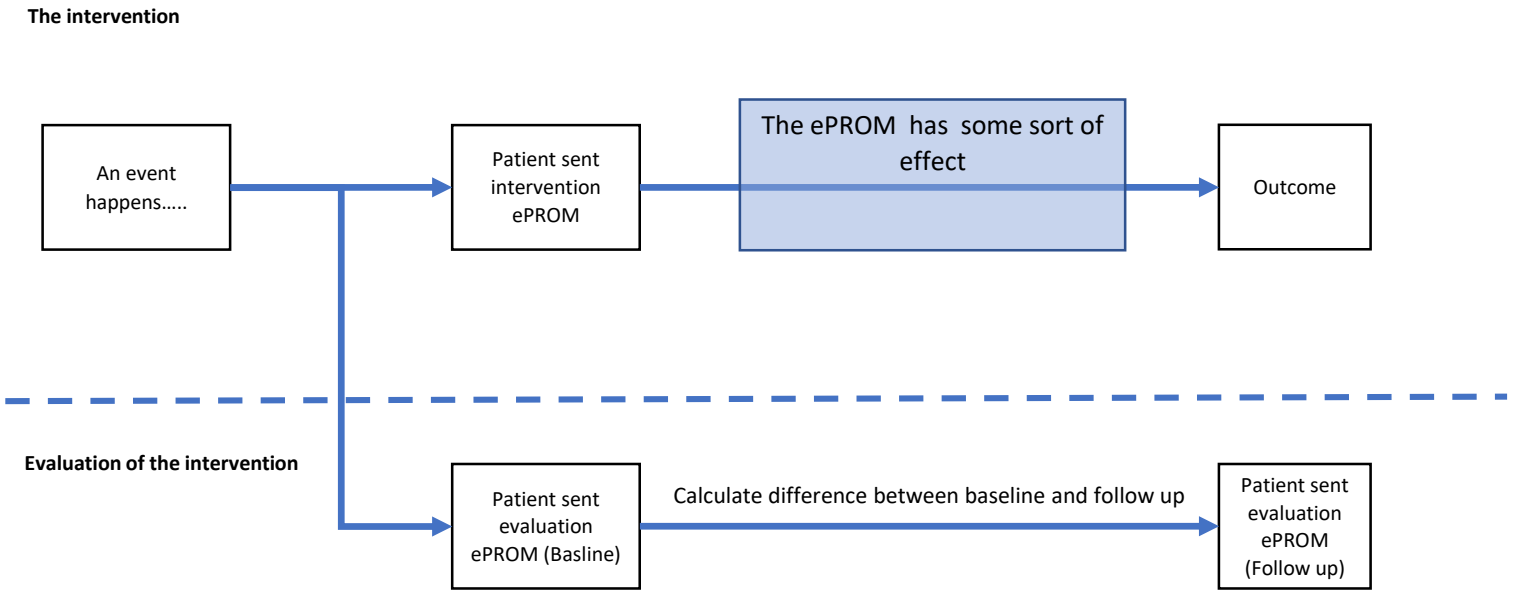
Generic ePROMs interventional design

The intervention



Challenge 1

Generic ePROMs interventional design

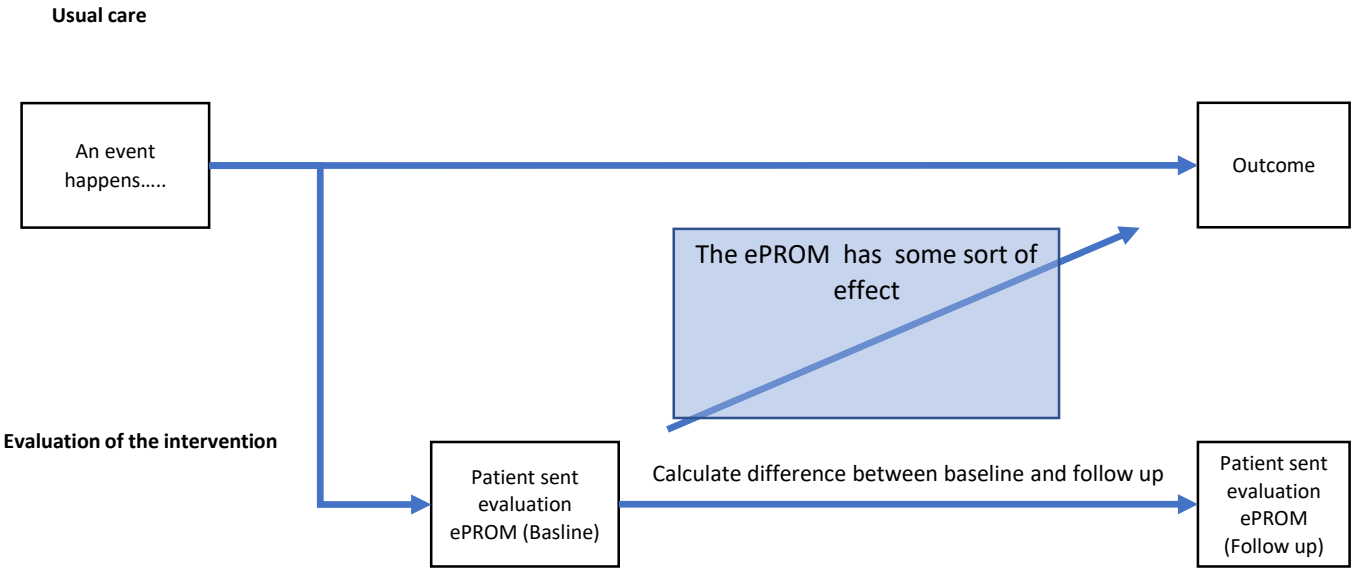


Challenge 2

Generic ePROMs interventional design

Usual care

Generic ePROMs interventional design



Thank you

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angus.mcnair@bristol.ac.uk

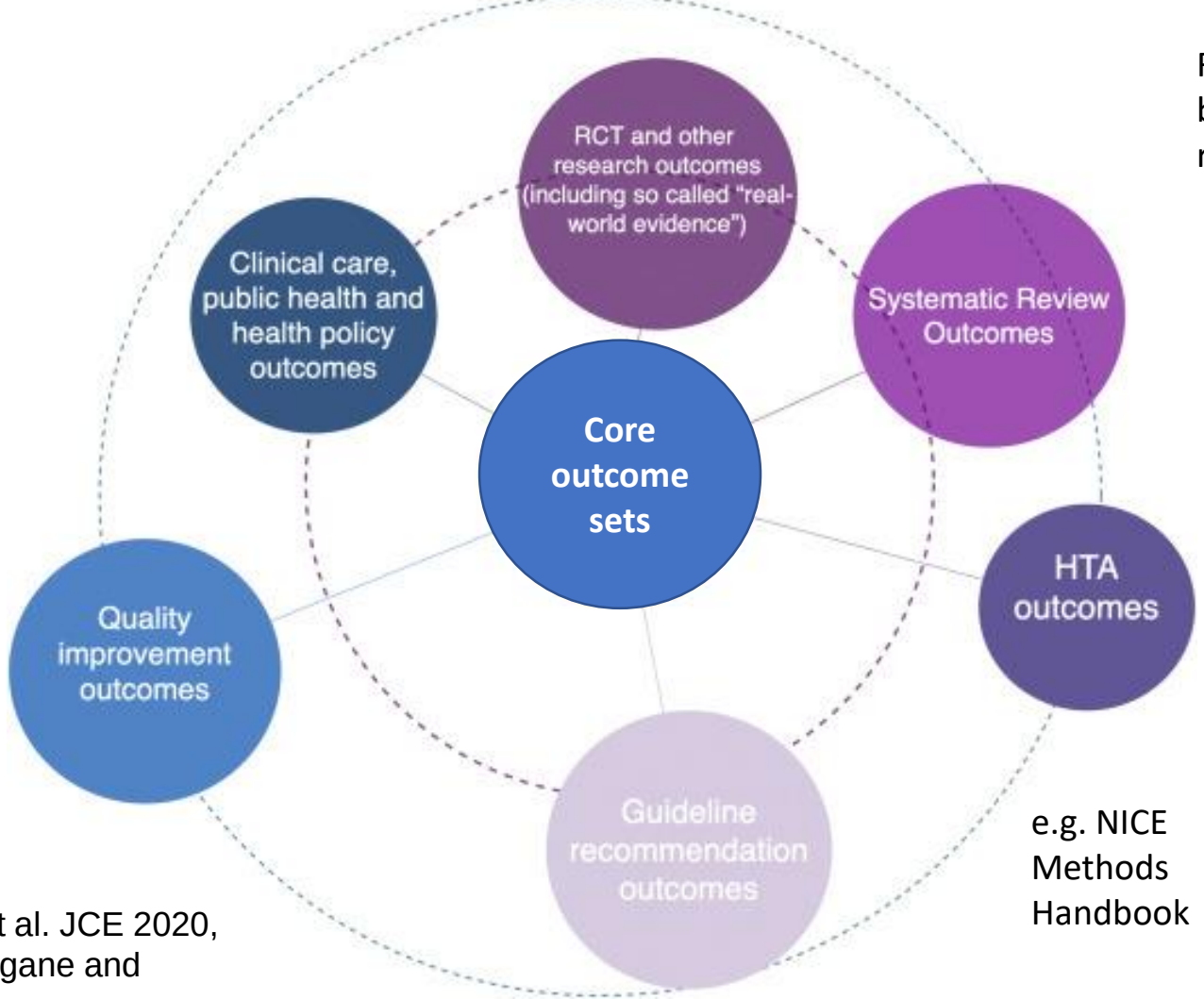
Mind the Gap: PROMs into the EHR

Paula Williamson and Susanna Dodd
Department of Health Data Science and Liverpool Clinical Trials Centre

COS for research and practice

-2019: 12%

Ongoing: 56%



Recommended by funders and regulators

Cochrane Handbook

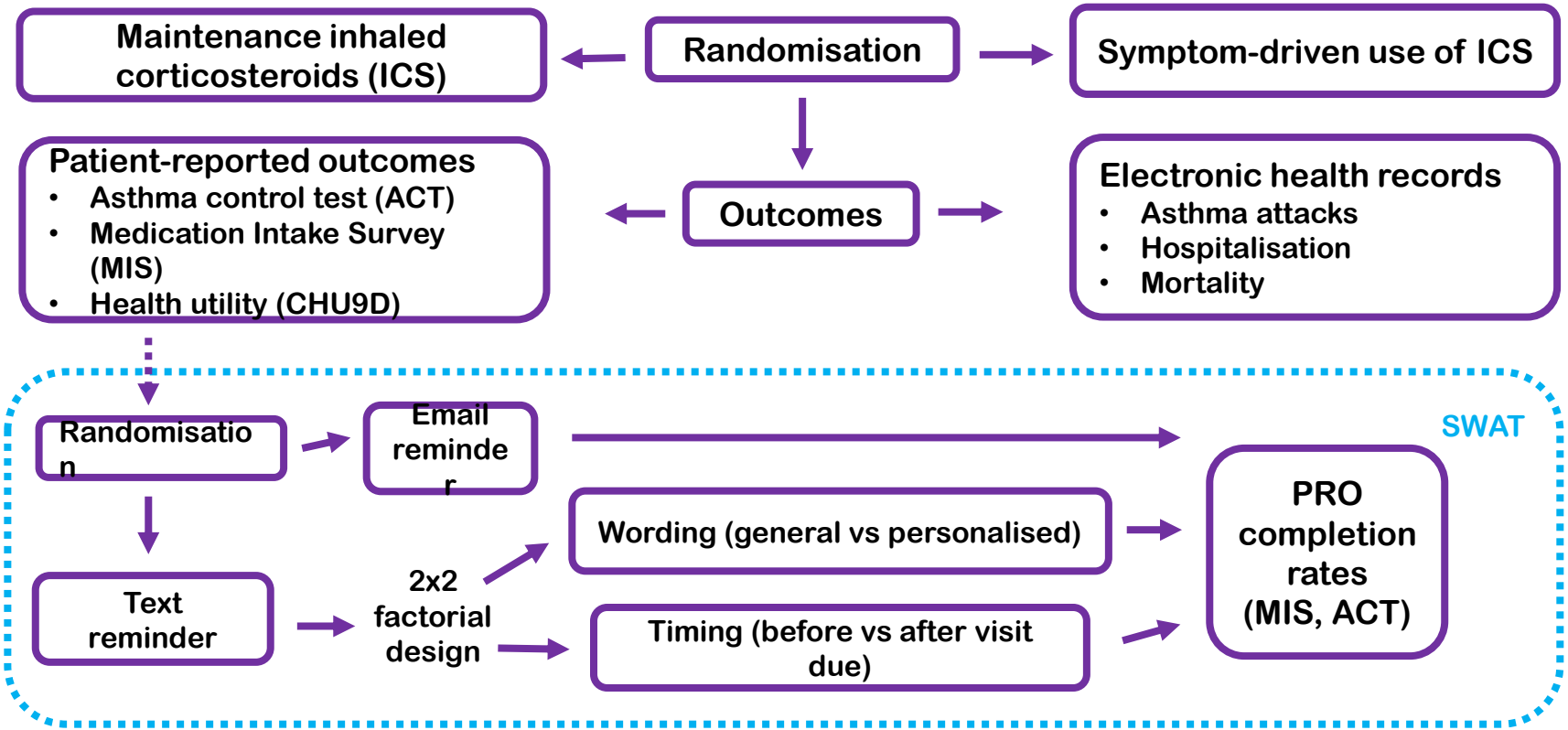
Alert system in place for INAHTA via COMET

e.g. HQIP methods guidance

e.g. NICE Methods Handbook

Schünemann et al. JCE 2020, modified by Biggane and Williamson

ASYMPTOMATIC



‘Balancing different stakeholder needs for clinical and research purposes: An Industry Perspective

Tom Willgoss, Head of COA Development, Roche

Disclaimer

Any opinions or information given by me are based on general industry standards and not the opinions of Roche. Any information given at this presentation should be used and disseminated by attendees at their discretion and Roche shall not be liable for any information relied upon by you or the attendees as a result of the presentation.

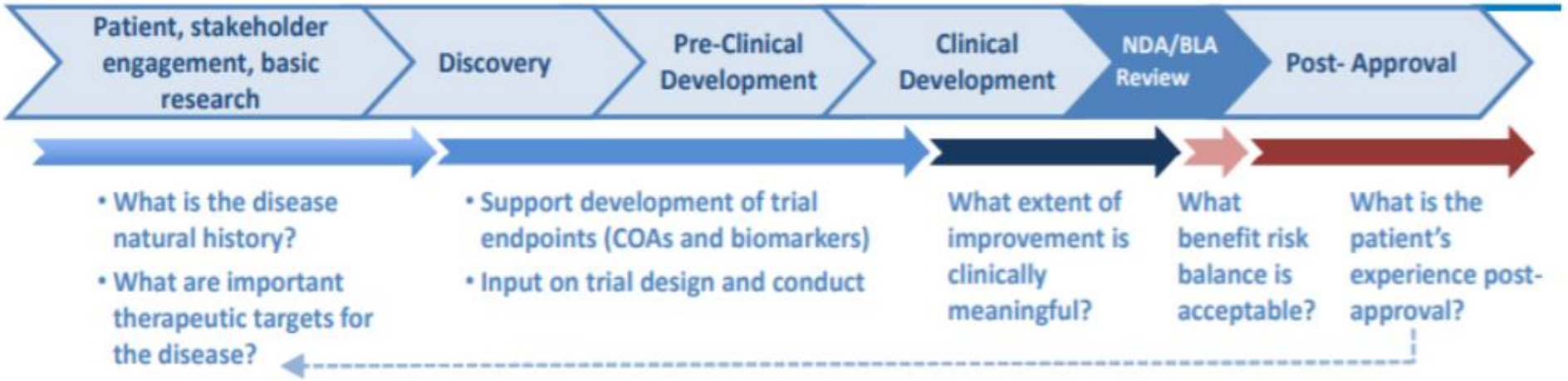
A bit about my role...

Our goal is to **measure what matters to patients**

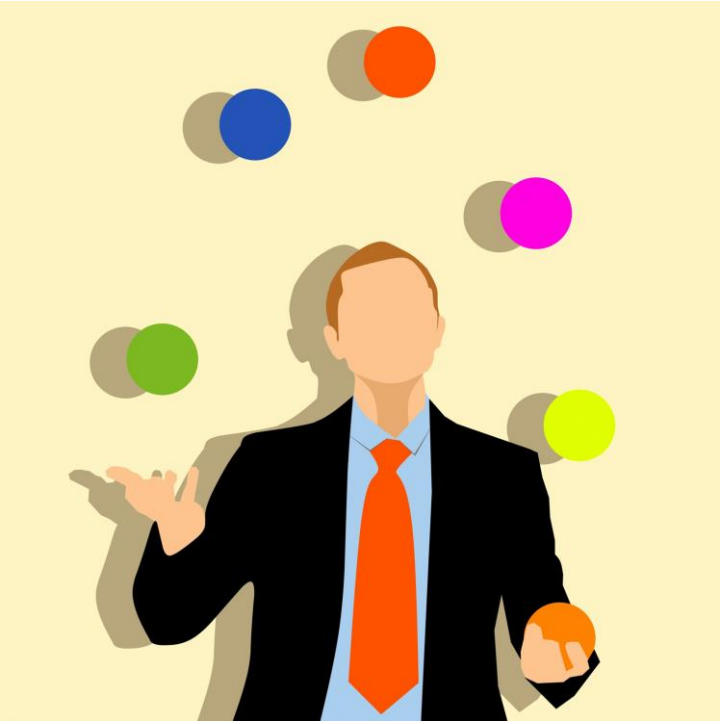
We work closely with patient communities to **develop measurement strategies** across the development lifecycle

In addition to PROs, we work with other COA types with an **increasing focus on digital measurement**

Strategy and evidence requirements vary considerably across the product life cycle:



Juggling multiple (evolving) needs of multiple stakeholders



Regulators	We want comprehensive, disease-specific measures
HTAs	We want measures to inform benefit and economic appraisal, they must be ‘validated’
Prescribers	We want clinically relevant and interpretable measures that are easy to collect
Patients	We want measures that capture what matters to us

Some potential solutions to meeting the needs of multiple stakeholders

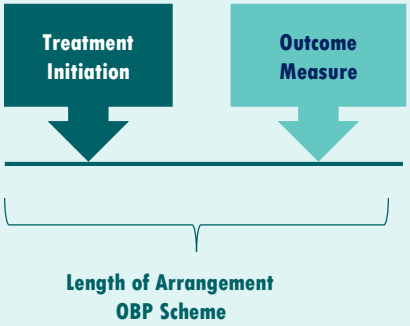
- Short-form measures
- Item banks, computer adaptive testing (CAT)
- Core outcome sets
- Multi-indication assessments e.g. physical function

A future where all stakeholders:

- recognize the value of PROs (and COAs)
- co-create with patient communities
- have a common understanding of evidence needs
- Support widespread implementation and interoperability

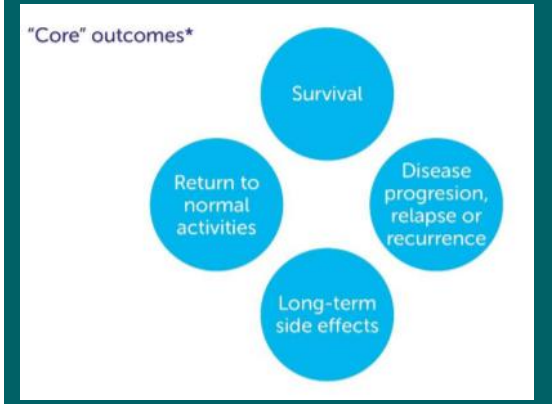
Doing now what patients need next

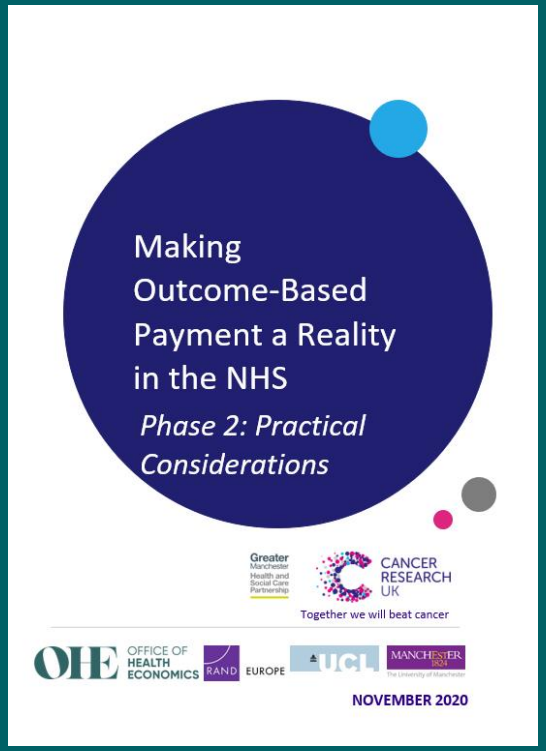
Outcomes-based payment (OBP) schemes: arrived and here to stay



- OBP is where the price paid for the medicine is linked to the **real-world outcome**(s) it actually achieves for patients
- Main advantage: it balances ('risk sharing') two main forces:
  - Innovative treatments (e.g. immunotherapies, cell therapies) → more **uncertainty** faced by regulators and Health Technology Assessment bodies (especially in the long-term) → need to assess more mature clinical data
  - However, delaying **patient access** while waiting for the evidence base to mature and uncertainty to reduce means patients miss out on the opportunity to benefit from them
- There are many examples (+86) internationally of schemes linking the amount paid for a medicine (for a wide range of diseases) to the outcomes achieved
- Nearly all such schemes rely on measuring **clinical outcomes** (like survival), rather than patient-reported outcomes
  - Usually a **single** clinical outcome

Some thoughts from a research project that explores the feasibility of introducing OBP scheme for cancer medicines into the NHS in England





OHE

Learnings (from literature search and interviews)

- **The quality-of-life data needed to measure long-term treatment side-effects and a patient's ability to return to normal daily activities are collected as well (e.g. in nurses or clinician notes), though rarely in a formal, systematic way as would be required for usage in an OBP**
    - **Data that are collected in a format most appropriate for use in an OBP scheme are in electronic health records (EHRs) and e-prescribing systems**
- **Long-term side effects and return to normal activities could be measured through self-reported patient questionnaires.**
    - **Experts suggested that to improve completion rates, efficiency and ease for patients to provide the information, that these data could be completed online, such as via a patient portal**
    - **For example, at The Christie NHS Trust, PROMs are collected directly from patients through the 'DrDoctor' data platform**
    - **PHE + NHSE Cancer QoL metric (EQ-5D-5L + EORCT-QLQ-C30)**

Learnings (from literature search and interviews)

- **Our findings suggest that it is not currently possible to undertake the routine, at scale data collected required for an OBP scheme incorporating all four outcomes**
- **However, ongoing developments and further data collection initiatives would likely create the conditions that are necessary for such an OBP scheme in the future**
  - **The lack of a national dataset providing structured data on return to normal activities outcomes is a critical barrier to an OBP scheme incorporating these outcomes**
  - **PHE and NHS England and Improvement's (NHSE&I) Cancer Quality-of-Life Metric Project may offer such an option in the near future, although the follow-up time of 18 months may limit its utility for an OBP scheme**
  - **Similarly, bespoke data collection arrangements would be needed as part of any national OBP scheme incorporating long-term side effects**

To enquire about additional information and analyses, please contact:

Dr. Patricia Cubi-Molla, PhD
Senior Principal Economist
Pcubi-molla@ohe.org

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