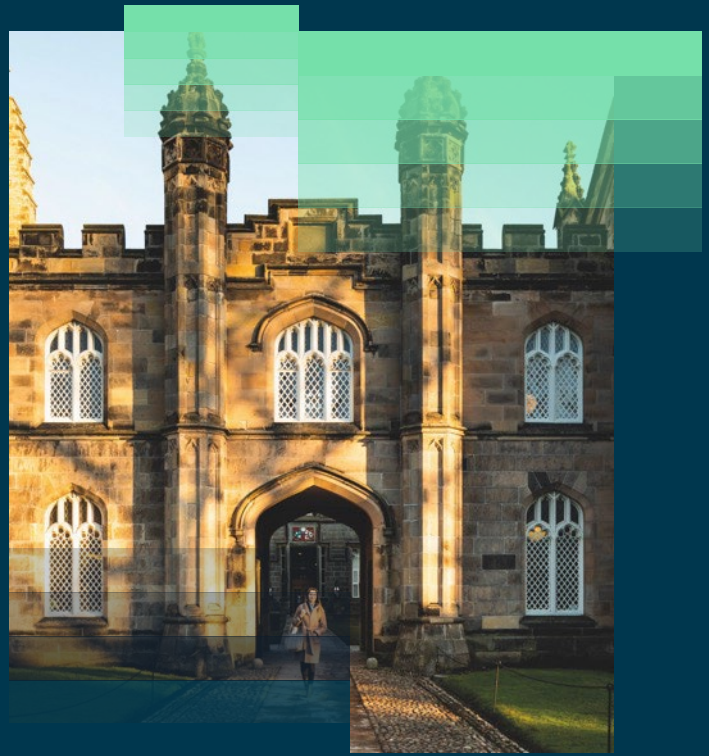
GO BEYOND BOUNDARIES



Invited session 8:

Designing and delivering robust system-level evaluations:

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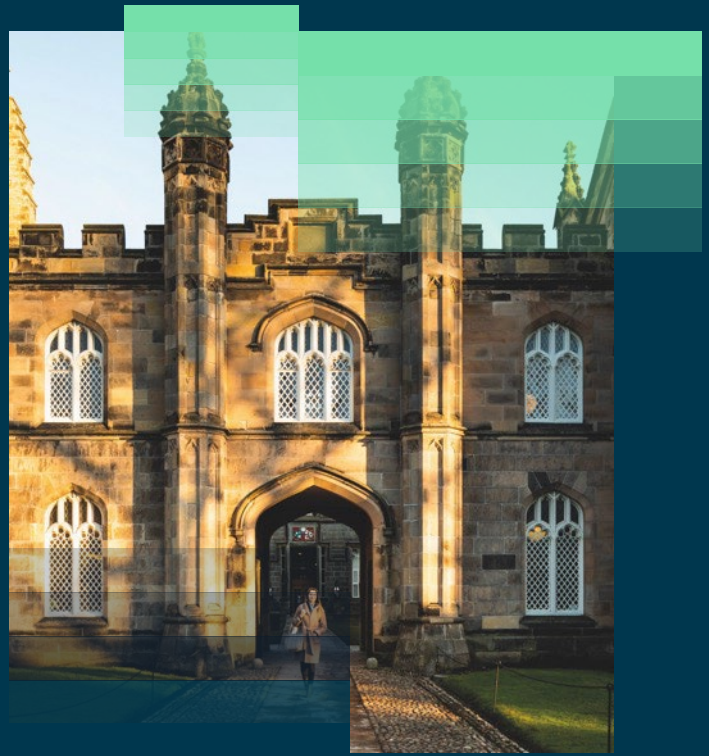

Designing and delivering robust system-level evaluations:

Introduction and key concepts

Marion Campbell
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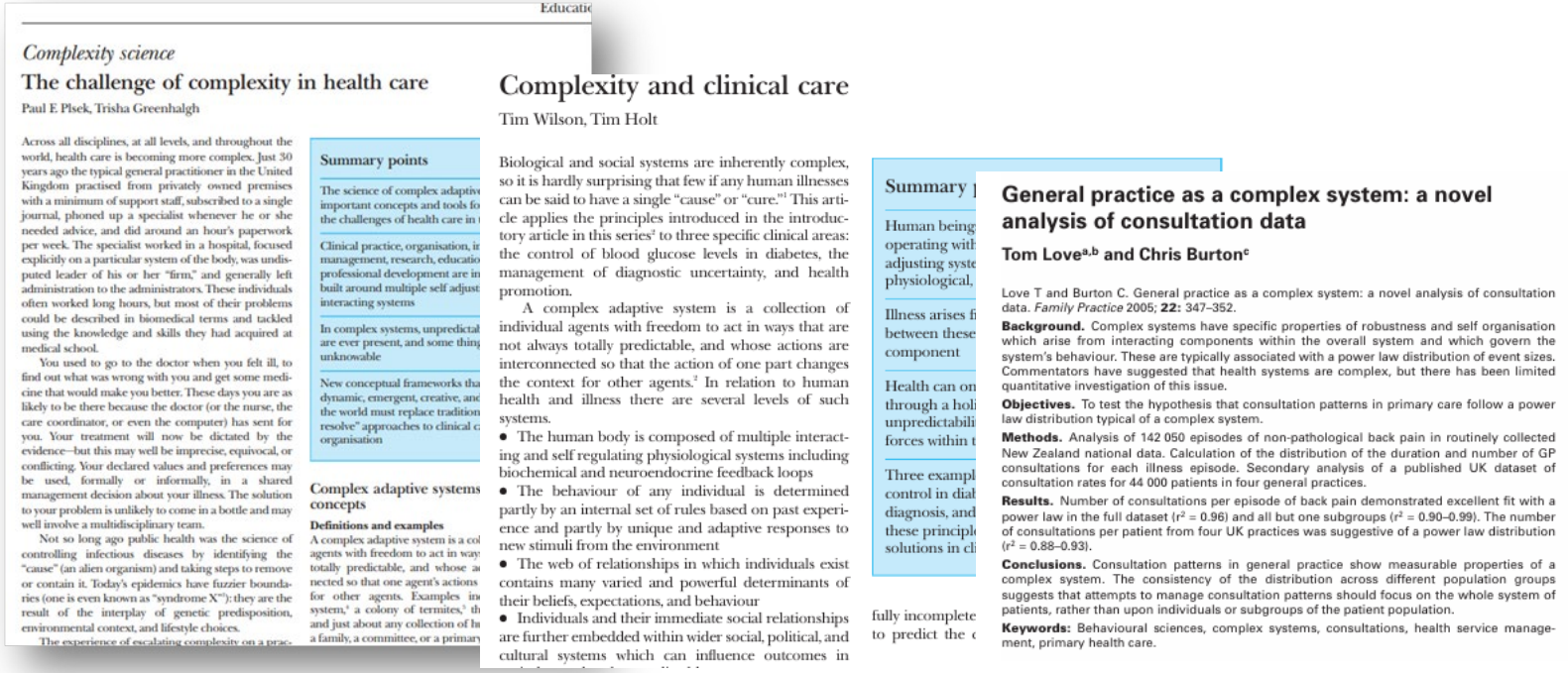
Disclosures

- Funding – including from NIHR, MRC, CIHR, Wellcome Trust & Intuitive Surgical European Research Board
- Co-Director, Royal College of Surgeons (RCS England) Aberdeen Surgical Trials Centre
- Chair, NIHR/MRC Better Methods Better Research Funding Committee

Plan for session

- **System-level evaluations – key concepts**
  - Marion Campbell
- **System evaluation in action – learnings from the REINFORCE study:**
  - David Beard, University of Oxford – REINFORCE study
  - Graeme MacLennan, University of Aberdeen – importance of contingency planning
  - Katie Gillies, University of Aberdeen – the role of process evaluation
- **Summary of learning**
  - Marion Campbell
- **Open discussion with Q & A**

Health care systems are complex systems



Complexity science

The challenge of complexity in health care

Paul E Plsek, Trisha Greenhalgh

Across all disciplines, at all levels, and throughout the world, health care is becoming more complex. Just 30 years ago the typical general practitioner in the United Kingdom practised from privately owned premises with a minimum of support staff, subscribed to a single journal, phoned up a specialist whenever he or she needed advice, and did around an hour's paperwork per week. The specialist worked in a hospital, focused explicitly on a particular system of the body, was undisputed leader of his or her "firm," and generally left administration to the administrators. These individuals often worked long hours, but most of their problems could be described in biomedical terms and tackled using the knowledge and skills they had acquired at medical school.

You used to go to the doctor when you felt ill, to find out what was wrong with you and get some medicine that would make you better. These days you are as likely to be there because the doctor (or the nurse, the care coordinator, or even the computer) has sent for you. Your treatment will now be dictated by the evidence—but this may well be imprecise, equivocal, or conflicting. Your declared values and preferences may be used, formally or informally, in a shared management decision about your illness. The solution to your problem is unlikely to come in a bottle and may well involve a multidisciplinary team.

Not so long ago public health was the science of controlling infectious diseases by identifying the "cause" (an alien organism) and taking steps to remove or contain it. Today's epidemics have fuzzier boundaries (one is even known as "syndrome X"): they are the result of the interplay of genetic predisposition, environmental context, and lifestyle choices.

The experience of escalating complexity on a prac-

Summary points

The science of complex adaptiv
important concepts and tools fo
the challenges of health care in

Clinical practice, organisation, it
management, research, educatio
professional development are in
built around multiple self adjust
interacting systems

In complex systems, unpredictal
are ever present, and some thing
unknowable

New conceptual frameworks tha
dynamic, emergent, creative, and
the world must replace tradition
resolve" approaches to clinical c
organisation

Complex adaptive systems concepts

Definitions and examples

A complex adaptive system is a col
agents with freedom to act in way
totally predictable, and whose ac
nected so that one agent's actions
for other agents. Examples in
system,[3] a colony of termites,[3] th
and just about any collection of hu
a family, a committee, or a primary

Educatio

Complexity and clinical care

Tim Wilson, Tim Holt

Biological and social systems are inherently complex, so it is hardly surprising that few if any human illnesses can be said to have a single "cause" or "cure."[1] This article applies the principles introduced in the introductory article in this series[2] to three specific clinical areas: the control of blood glucose levels in diabetes, the management of diagnostic uncertainty, and health promotion.

A complex adaptive system is a collection of individual agents with freedom to act in ways that are not always totally predictable, and whose actions are interconnected so that the action of one part changes the context for other agents.[2] In relation to human health and illness there are several levels of such systems.

- The human body is composed of multiple interacting and self regulating physiological systems including biochemical and neuroendocrine feedback loops
- The behaviour of any individual is determined partly by an internal set of rules based on past experience and partly by unique and adaptive responses to new stimuli from the environment
- The web of relationships in which individuals exist contains many varied and powerful determinants of their beliefs, expectations, and behaviour
- Individuals and their immediate social relationships are further embedded within wider social, political, and cultural systems which can influence outcomes in

Summary

Human being
operating with
adjusting syste
physiological,

Illness arises fi
between these
component

Health can on
through a holi
unpredictabili
forces within t

Three exampl
control in diab
diagnosis, and
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solutions in cl

fully incomplete
to predict the

General practice as a complex system: a novel analysis of consultation data

Tom Love[a,b] and Chris Burton[c]

Love T and Burton C. General practice as a complex system: a novel analysis of consultation data. *Family Practice* 2005; **22:** 347–352.

Background. Complex systems have specific properties of robustness and self organisation which arise from interacting components within the overall system and which govern the system's behaviour. These are typically associated with a power law distribution of event sizes. Commentators have suggested that health systems are complex, but there has been limited quantitative investigation of this issue.

Objectives. To test the hypothesis that consultation patterns in primary care follow a power law distribution typical of a complex system.

Methods. Analysis of 142 050 episodes of non-pathological back pain in routinely collected New Zealand national data. Calculation of the distribution of the duration and number of GP consultations for each illness episode. Secondary analysis of a published UK dataset of consultation rates for 44 000 patients in four general practices.

Results. Number of consultations per episode of back pain demonstrated excellent fit with a power law in the full dataset ($r^2 = 0.96$) and all but one subgroups ($r^2 = 0.90–0.99$). The number of consultations per patient from four UK practices was suggestive of a power law distribution ($r^2 = 0.88–0.93$).

Conclusions. Consultation patterns in general practice show measurable properties of a complex system. The consistency of the distribution across different population groups suggests that attempts to manage consultation patterns should focus on the whole system of patients, rather than upon individuals or subgroups of the patient population.

Keywords: Behavioural sciences, complex systems, consultations, health service management, primary health care.

Complex systems

Complex systems:

- Have dynamic properties
- Have multiple levels
- Aggregate behaviour of the system arises from interactions at lower levels
- Non-linear relationships between elements common
- System behaviour may be more/less than the sum of its parts
- Can be unpredictable

Example

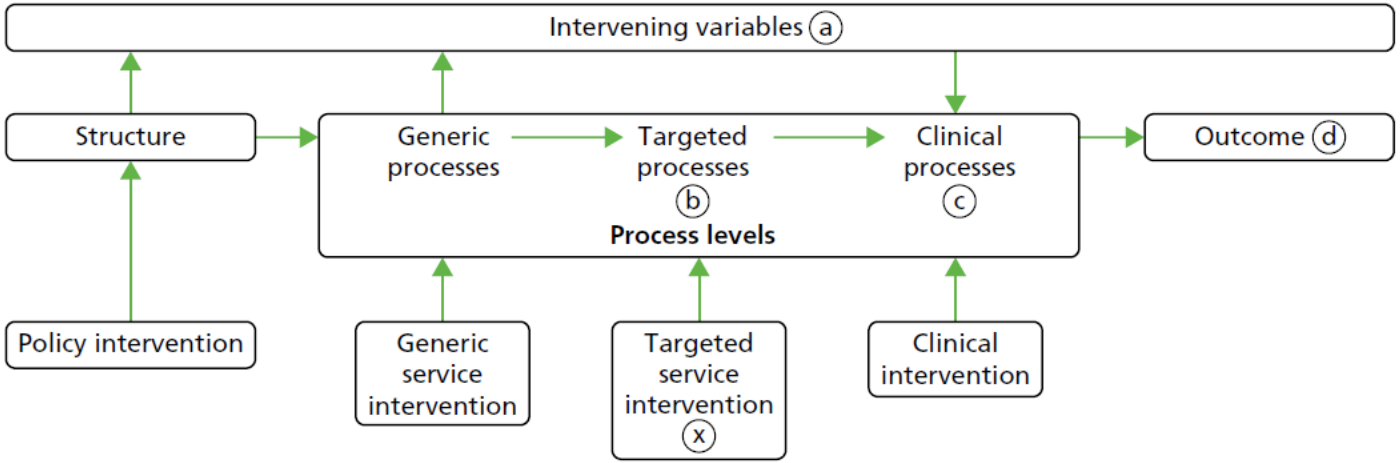
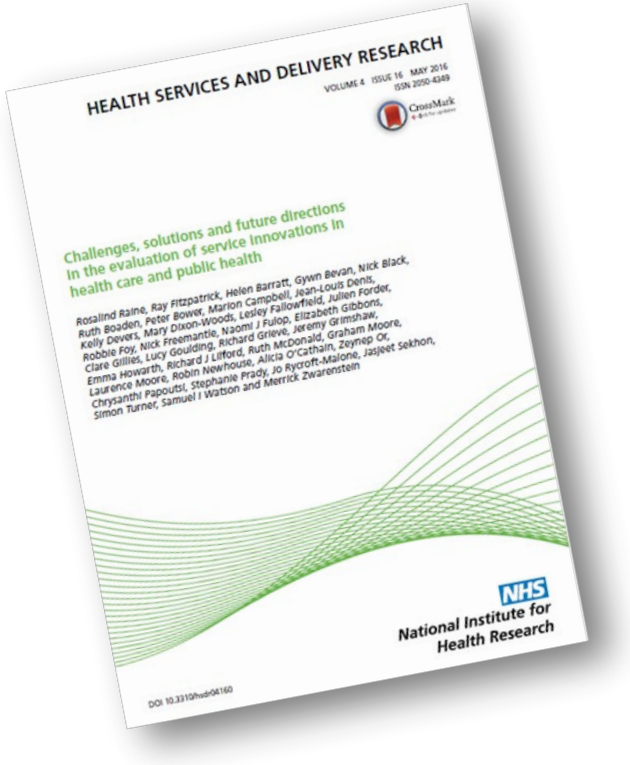


FIGURE 1.1 Causal chain showing how interventions at different levels may impact on downstream processes and outcomes. Reproduced from Evaluating policy and service interventions: framework to guide selection and interpretation of study end points, Lilford RJ, Chilton PJ, Hemming K, Girling AJ, Taylor CA, Barach P, vol. 341, p. c4413, 2016,[4] with permission from BMJ Publishing Group Ltd.

From: Raine R et al Challenges, solutions and future directions in the evaluation of service innovations in health care and public health. NIHR Journals Library; 2016 May.

Evaluation in health systems

- More difficult to evaluate
- Need to measure the effect on the whole system but also:
  - consider the impact of individuals levels
  - consider interactions between levels
  - be cognisant of the effect of context
  - be prepared for unanticipated changes



Raine R et al Challenges, solutions and future directions in the evaluation of service innovations in health care and public health. NIHR Journals Library; 2016 May.

Frameworks/methodologies that can help

Intervention level complexity:

- MRC complex interventions framework

System level influences:

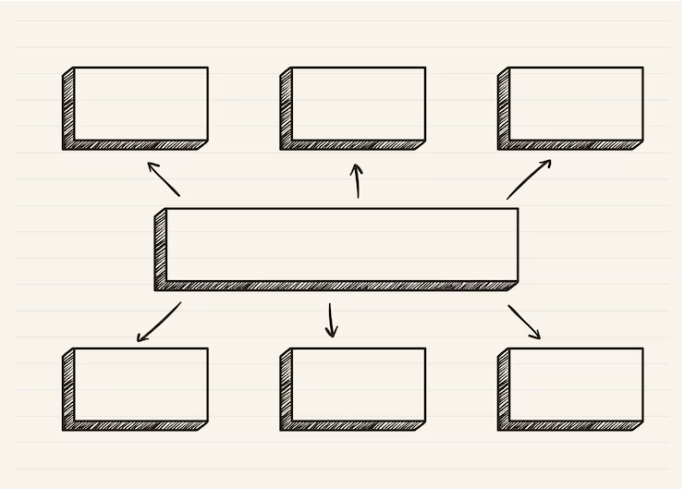
- CFIR – comprehensive framework of implementation research
- NPT – normalisation process theory
- etc

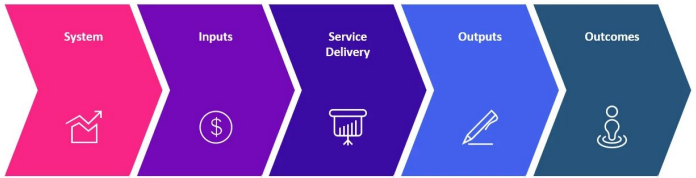
Context:

- Process evaluation methodology

Unpredictability:

- Contingency planning



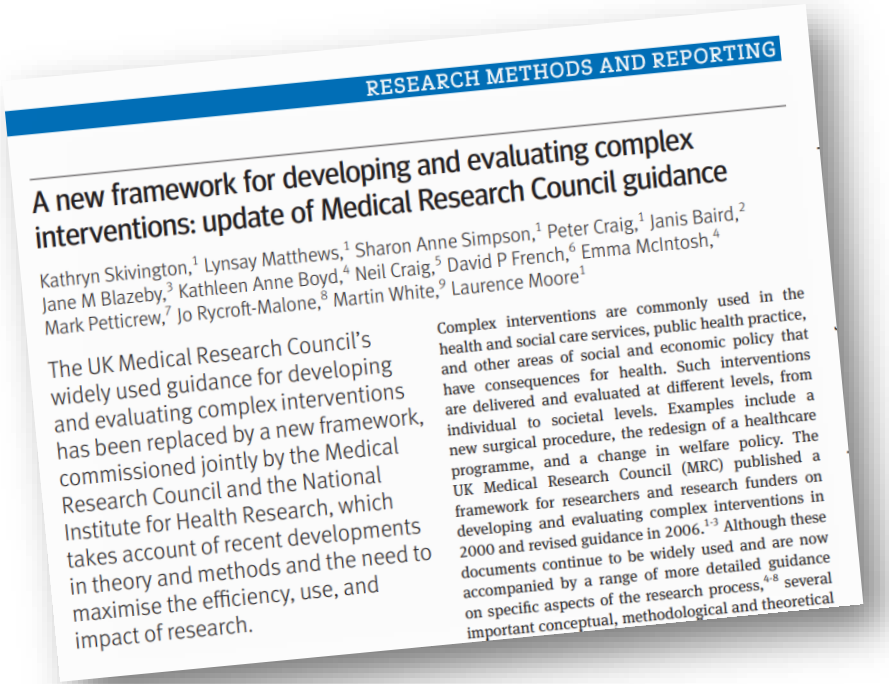


MRC complex intervention framework

- Framework to support complex intervention evaluation

Recognises:

- Complexity
- Need to take account of context
- Need to accommodate for inter-dependencies with the wider system
- Understanding the intervention delivery key



RESEARCH METHODS AND REPORTING

A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance

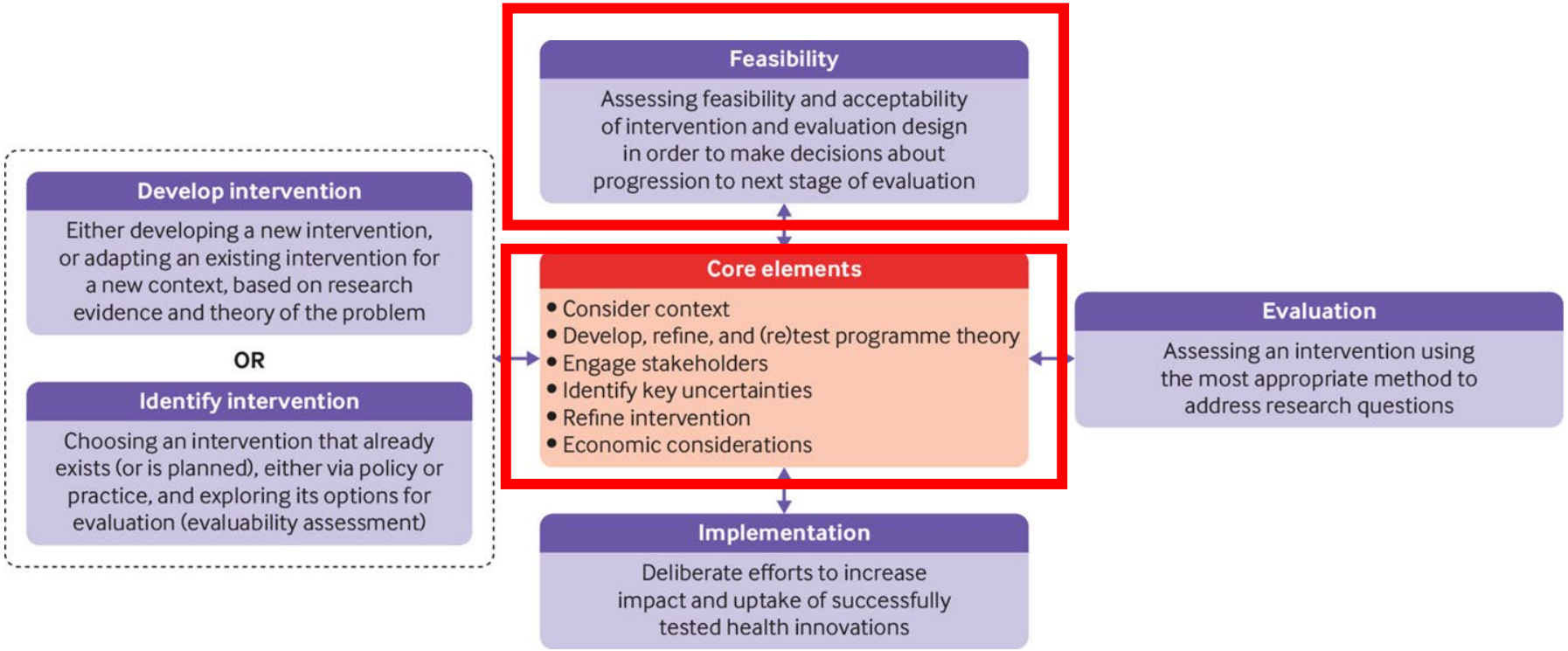
Kathryn Skivington,[1] Lynsay Matthews,[1] Sharon Anne Simpson,[1] Peter Craig,[1] Janis Baird,[2] Jane M Blazeby,[3] Kathleen Anne Boyd,[4] Neil Craig,[5] David P French,[6] Emma McIntosh,[4] Mark Petticrew,[7] Jo Rycroft-Malone,[8] Martin White,[9] Laurence Moore[1]

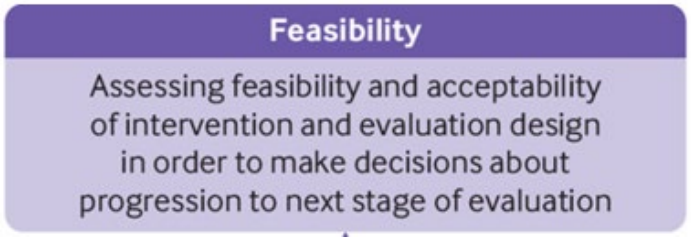
The UK Medical Research Council's widely used guidance for developing and evaluating complex interventions has been replaced by a new framework, commissioned jointly by the Medical Research Council and the National Institute for Health Research, which takes account of recent developments in theory and methods and the need to maximise the efficiency, use, and impact of research.

Complex interventions are commonly used in the health and social care services, public health practice, and other areas of social and economic policy that have consequences for health. Such interventions are delivered and evaluated at different levels, from individual to societal levels. Examples include a new surgical procedure, the redesign of a healthcare programme, and a change in welfare policy. The UK Medical Research Council (MRC) published a framework for researchers and research funders on developing and evaluating complex interventions in 2000 and revised guidance in 2006.[1-3] Although these documents continue to be widely used and are now accompanied by a range of more detailed guidance on specific aspects of the research process,[4-8] several important conceptual, methodological and theoretical

Skivington K, et al. BMJ 2021; 374 :n2061 doi:10.1136/bmj.n2061

MRC complex intervention framework

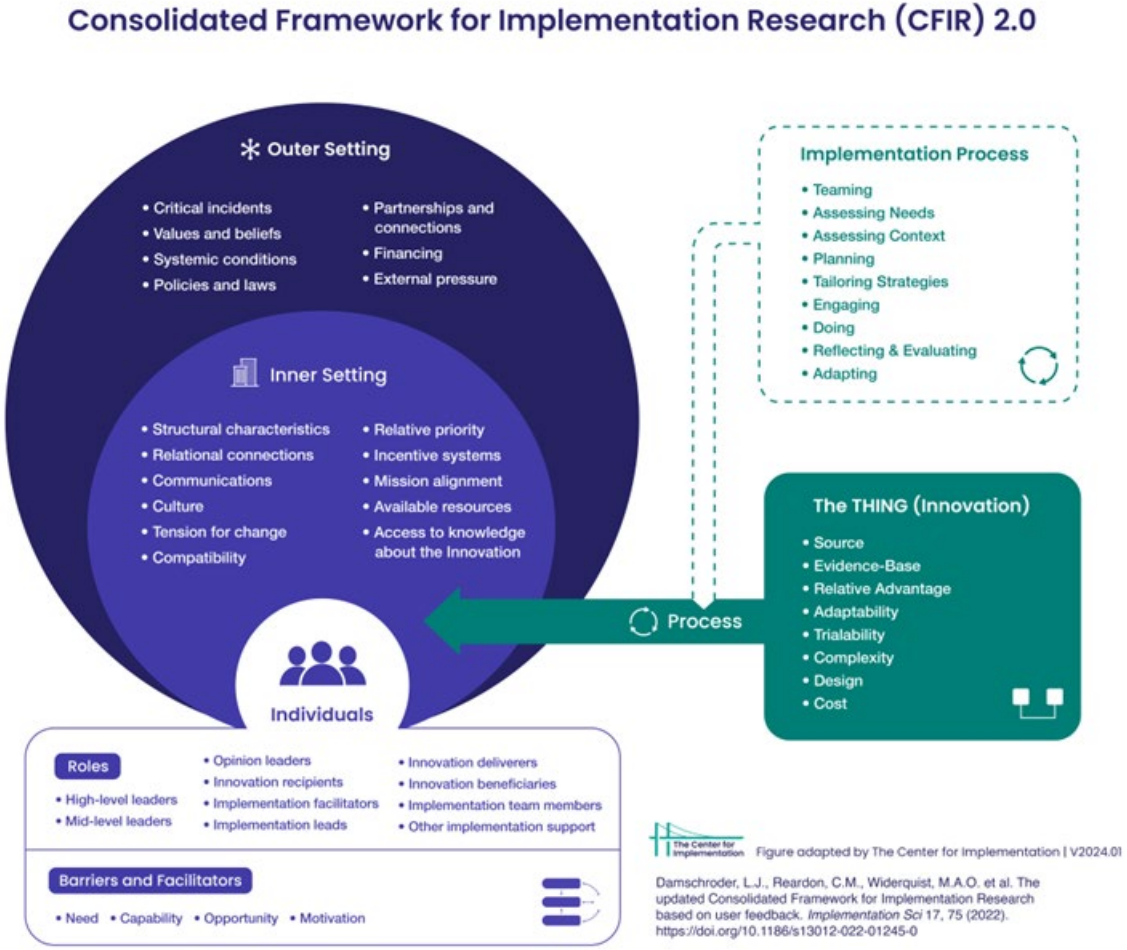




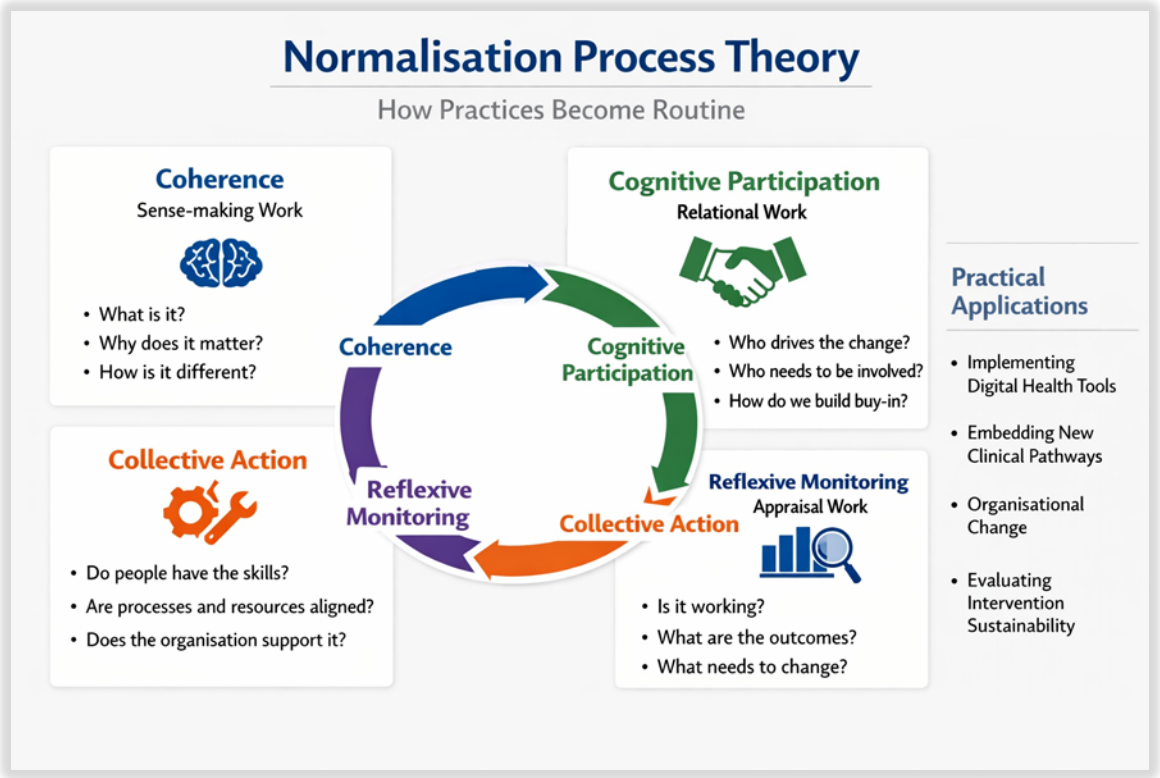
Importance of feasibility work:

- Crucial to undertake ahead of evaluation
- Identify barriers and facilitators early
- Use to shape the evaluation

System level influences: Examples



System level influences: Examples



Accommodating for context – process evaluation

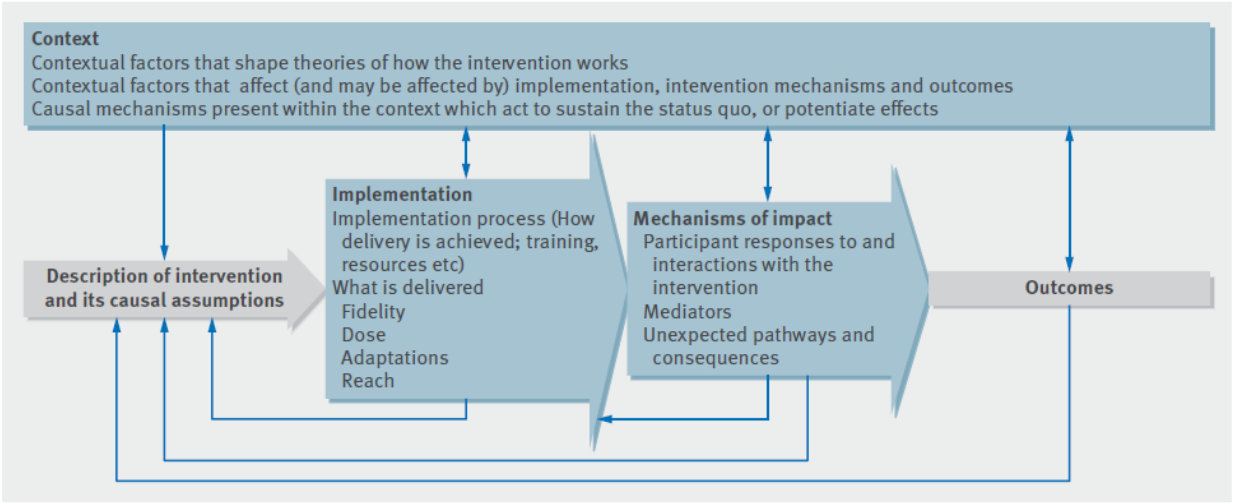


Fig 1 | Key functions of process evaluation and relations among them (blue boxes are the key components of a process evaluation. Investigation of these components is shaped by a clear intervention description and informs interpretation of outcomes)

Moore GF et al. BMJ 2015;350:h1258. doi:10.1136/bmj.h1258

Contingency planning essential

- Complex systems are unpredictable
- Contingency planning required
- Plan for plausible scenarios

MOTIVATING EXAMPLE

REINFORCE STUDY

introduction and scale-up of robot-assisted surgical services in the NHS:

FUNDED BY NIHR | National Institute for Health Research
UNIVERSITY OF OXFORD
1495 UNIVERSITY OF ABERDEEN
CHaRT Centre for Healthcare Randomised Trials
SITU SURGICAL INTERVENTION TRIALS UNIT
REINFORCE Real-World Evaluation of Robot-Assisted Surgical Services

THE UNIVERSITY OF SYDNEY

NHMRC Clinical Trials Centre

REINFORCE
Real-World Evaluation of Robot-Assisted Surgical Services

UNIVERSITY OF OXFORD

SITU

NDORMS
NUFFIELD DEPARTMENT OF ORTHOPAEDICS, RHEUMATOLOGY AND MUSCULOSKELETAL SCIENCES
Medical Sciences Division

DESIGNING AND DELIVERING ROBUST SYSTEM-LEVEL EVALUATIONS:

Design Principles and Considerations for the REINFORCE Study

DAVID BEARD

PROFESSOR OF MUSCULOSKELETAL AND SURGICAL SCIENCE, UNIVERSITY OF OXFORD

RCS ROSETREES DIRECTOR/CHAIR OF SURGICAL TRIALS, SITU, OXFORD

SURGICAL & COMPLEX INTERVENTION TRIALS PROGRAM LEAD, CTC UNIVERSITY OF SYDNEY

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david.beard@sydney.edu.au

RCS SURGICAL TRIALS CENTRE

Royal College of Surgeons (Eng)
RADAR ROBOTIC And DIGITAL SURGERY INITIATIVE

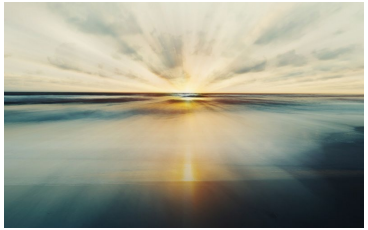
NIHR | National Institute for Health Research

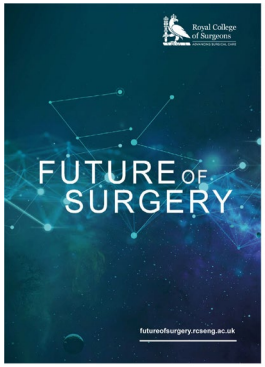
DISCLOSURES

- Institutional grants from;
  - NIHR HTA
  - NIHR RfPB
  - NIHR HS&DR
  - Versus Arthritis
  - Action Research
  - Royal College of Surgeons
  - Rosetrees Trust

- Director of Royal College of Surgeons Surgical Trials Unit
- NIHR Senior Investigator
- Chair & Director of Research Partnerships University of Sydney (Australia)

BACKGROUND & CONTEXT





- **RAS systems in use for several years** (urology)
- **Royal College Of Surgeons (England)**
  - Surgical Trials Initiative
  - Evaluation remit for new surgical tech
  - Future of Surgery Report 2018
- **But …**
  - Driven by proponents, enthusiasts and industry
  - Minimal good science

PAN-SURGICAL SYSTEMATIC REVIEW OF ROBOTIC ASSISTED SURGERY ACROSS ALL SPECIALITIES (2020)

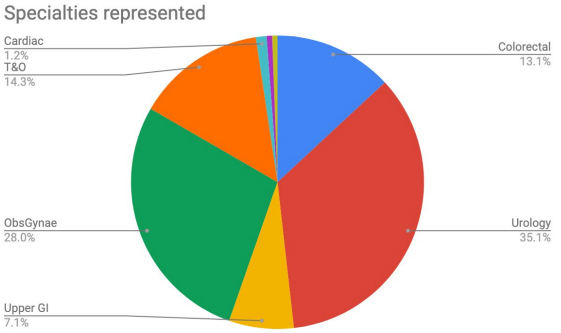
- Understand current evidence for robotically-assisted surgery;
  - safety, efficacy, cost effectiveness & outcomes

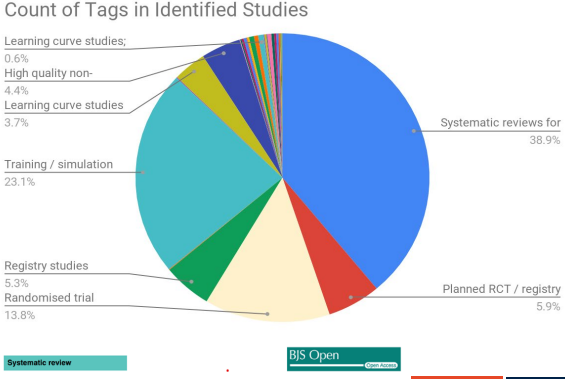
7142 studies

Systematic review of **183** randomised studies

(76 unique populations)

FEEL FOR MATURITY





Systematic review

BJS Open

Research quality and transparency, outcome measurement and evidence for safety and effectiveness in robot-assisted surgery: systematic review

P. Garfield Roberts[1], J. C. Glasbey[1], S. Abrant[1], D. Osei-Bordom[1], S. P. Bach[1,4,5] and D. J. Beard[1,2,3]

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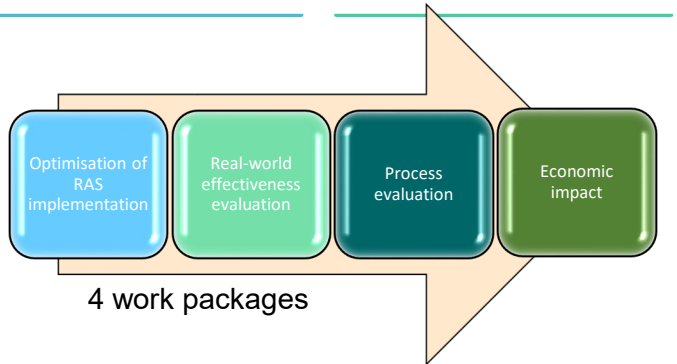
Study Aims

To undertake **a real-world**, large-scale, multidisciplinary evaluation of the **introduction and scale-up** of RAS **services evaluating its impact on NHS service** delivery, clinical effectiveness, budget and cost-effectiveness.
Objectives:

1. Knowledge gain about current RAS
2. Potential benefits and harms of RAS across and within specialty areas
3. Impact of RAS on clinical & service delivery including mechanisms underpinning change
4. Budget impact and cost-effectiveness to the NHS of the introduction of RAS at scale



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SYSTEMS APPROACH TO EVALUATION!

Integrated Programme of Research Aberdeen/Oxford/Birmingham/Newcastle)

RADAR INITIATIVE ROBOTIC And DIGITAL SURGERY

NIHR | National Institute for Health Research

INTUITIVE SURGICAL

NHS SCOTLAND

NHS

REINFORCE
Real-World Evaluation of Robot-Assisted Surgical Services

Systematic review what do we know?

Garfjeld Roberts/ Beard et al

RoboCOS what should we measure?

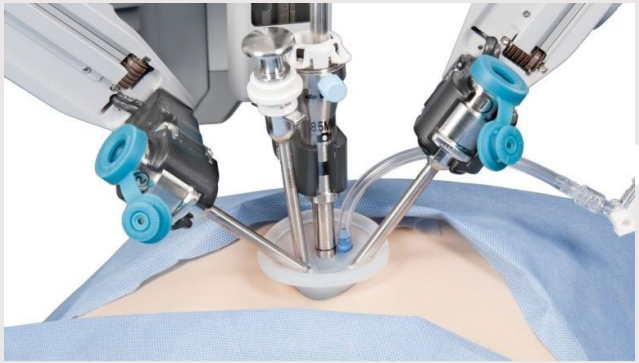
Shaikh/Campbell/ Beard/Gillies et al

REINFORCE WP1 optimise implementation

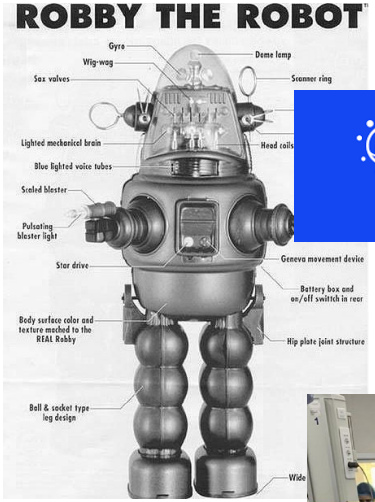
Campbell/Gillies/ Beard/Lawrie

REINFORCE Full scale evaluation

Beard/Campbell /Vale/Davies



PRE-WORK



PLOS ONE
A peer-reviewed, open access journal

BJS
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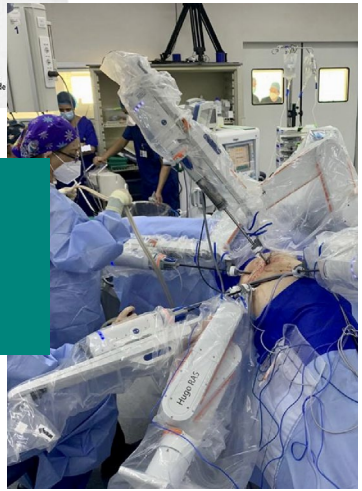

- **PPI – Perceptions of patients**
- **Knowledge accumulation**
- **WORK PACKAGE 1 (“State of the Game”)**
  - First pass – qualitative
  - Stakeholder Interviews
  - Barriers, facilitators, “the Landscape”
- **Especially important for PE studies …**

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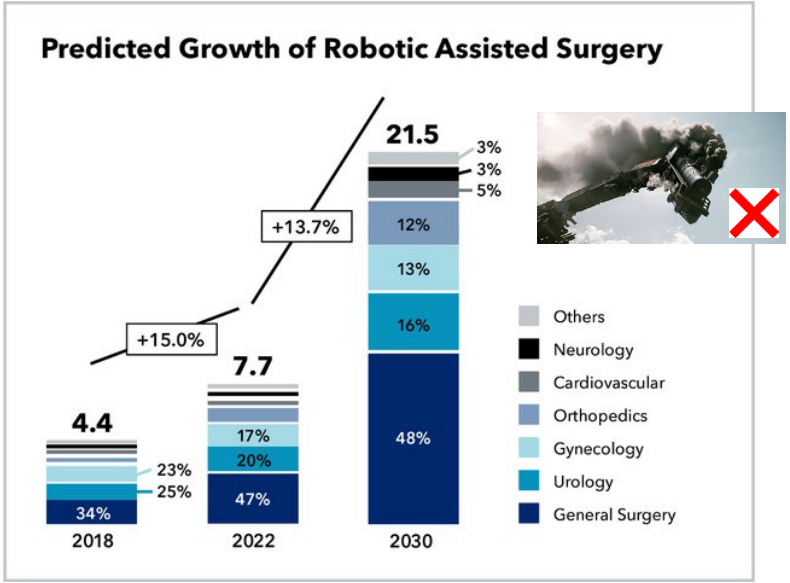
STUDY DESIGN PRINCIPLES

INDUSTRY

REINFORCE
Real-World Evaluation of Robot-Assisted Surgical Services



- Work with industry
- Stop the runaway train
- Not stifle innovation
- Stay "agnostic"

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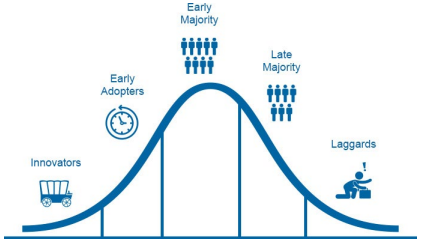
DESIGN DECISIONS (FOR REINFORCE)

- "Roll out" evaluation
  - Work with current practice
  - Step wedge (randomised)
  - Interrupted Time Series (ITS) – procurement



- Pan-specialty – wide lens – external validity

- Take account of current differing levels of uptake

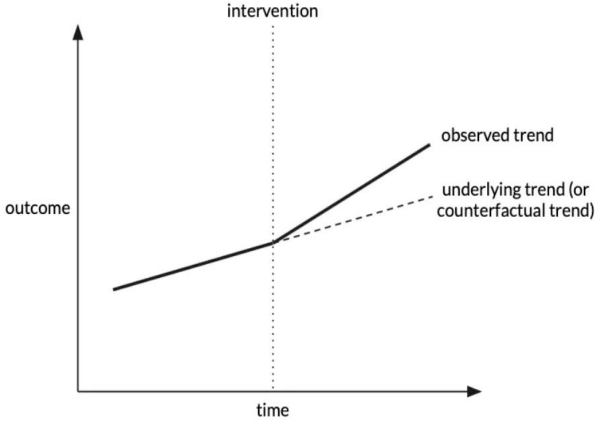
INTENDED DESIGN: STEPPED WEDGE

REINFORCE: Stepped wedge design and patient flow

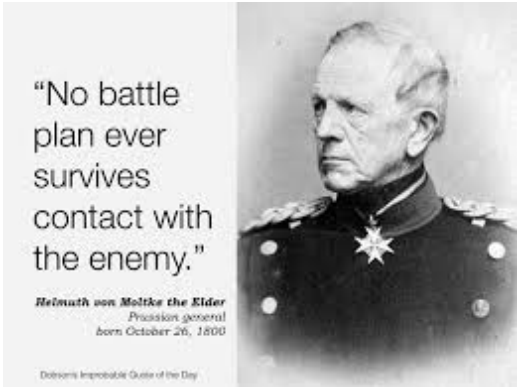
	Set up phase (6m)	Evaluation phase (24m; each period is 4 months)						Final follow-up (3m)	Final analysis (6m)
		Period 1 (4m)	Period 2 (4m)	Period 3 (4m)	Period 4 (4m)	Period 5 (4m)	Period 6 (4m)		
Sites 1-4									
Sites 5-8									
Sites 9-12									
Sites 13-16									

- set up
- before RAS-augmented service
- transition period
- after RAS-augmented service
- completion of follow-up
- final analysis

Interrupted time series evaluation



"A time series (i.e. data collected over time) is divided into segments by a policy or program change"

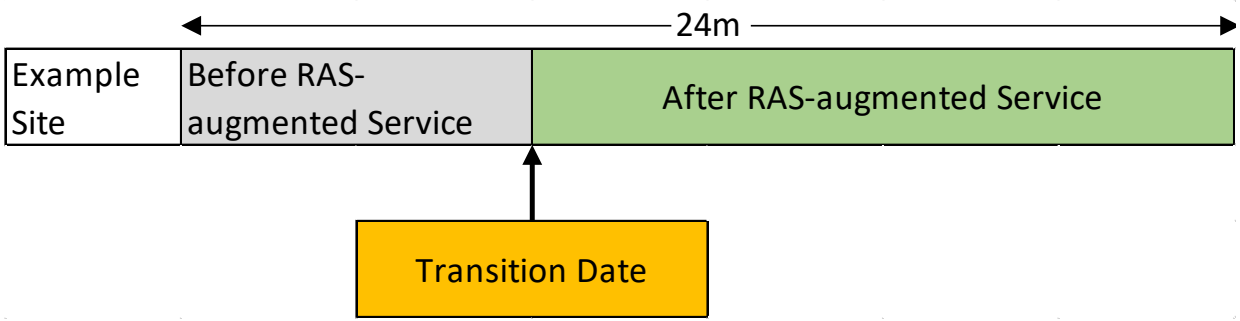


2,560 procedures

1. Urology
2. Colorectal
3. Thoracic
4. Gynaecology
5. Orthopaedics
6. Upper GI
7. Hep Bil
8. ENT (Head & Neck)

STUDY DESIGN

- Interrupted time series evaluation – multi specialty; 16+ sites; ~2560 procedures
- Index procedure chosen by site

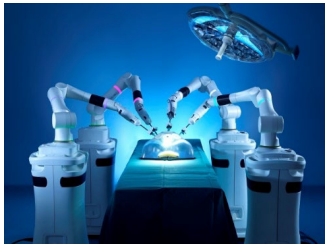


Examples of site types

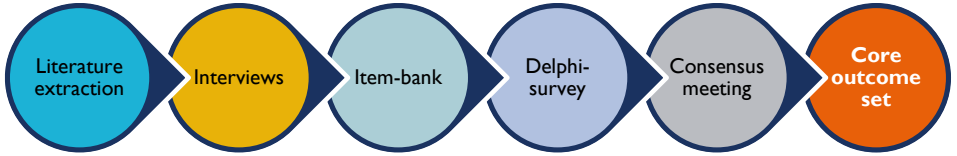
Site Type	Description	Example Index Procedure
1. Change in **Delivery** ***(RAS naïve)***	No previous provision in any specialty	Hysterectomy (as first RAS procedure performed at site)
2. Change in **Specialty**	RAS established in one specialty, commencing service for new specialty	Anterior resection (new specialty, having previously only performed RAS prostatectomy)
3. Change in **Procedure**	RAS established, commencing new procedure within specialty	Partial nephrectomy (same specialty, having previously only performed RAS prostatectomy)

NO OUTCOME SET – CORE OUTCOME SET

- **11 interviews:**
  - Surgeons, Nursing team, Service managers, International health technology assessment experts, LMIC perspectives



- **Patient & public focus group:**
  - 8 participants



- **Item Bank:**

412	Patient outcomes (PROMS)
98	Surgeon outcomes (precision)
180	Organisation outcomes (economic)
17	Population outcomes (equity of access)

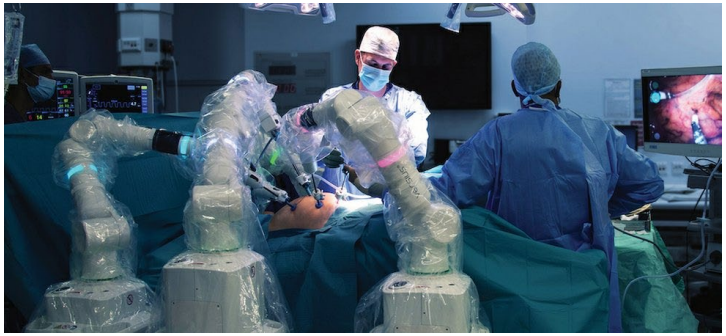
Delphi, n=150 respondents

OUTCOMES

LEVEL	OUTCOME NAME	Assessment	Timepoint
Patient level	Disease-specific quality of life	Procedure specific PROM	Baseline, 3-months
	Overall quality of life	EQ-5D	Baseline, 3-months
	Overall measure of treatment effectiveness/benefit	Patient Questionnaire	Baseline, 3-months
	Overall-measure of complications inc. mortality	Clavien-Dindo score	3-months
Surgeon/Team level	Precision/accuracy	Surgeon TLX	Day of surgery
	Visualisation	Surgeon TLX	Day of surgery
Organisation level	Equipment failure	Surgery Form	Day of surgery
	Standardisation of operative quality	Process Evaluation Interviews	Pre/Post RAS implementation
	Overall economic/cost-effectiveness	Health Economics review	Throughout study
Population level	Equity of access	Health Economics review	Throughout study

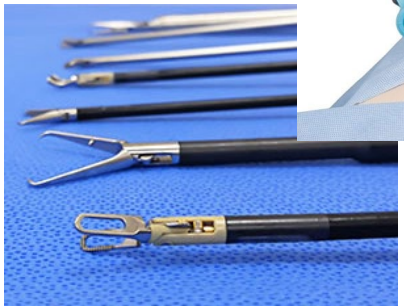
FUNDED BY NIHR | National Institute for Health Research

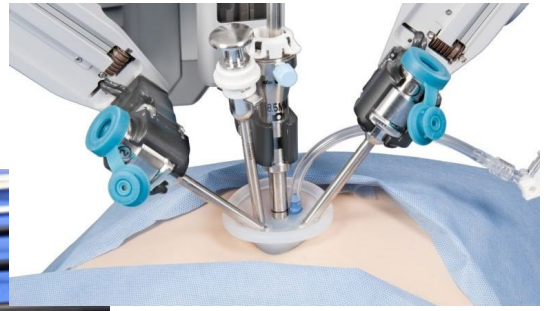
EXAMPLE OF "TRICKY" DECISIONS

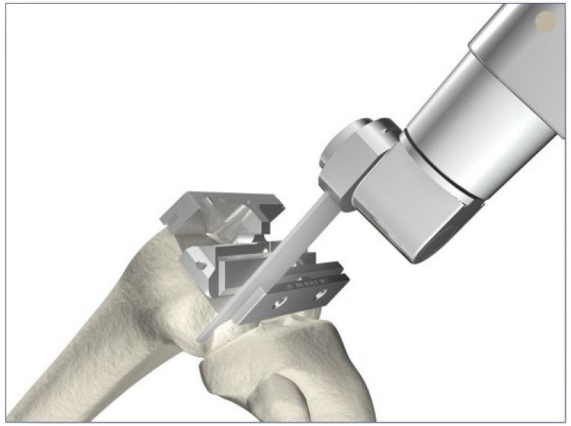


Cavity Based V Orthopaedics

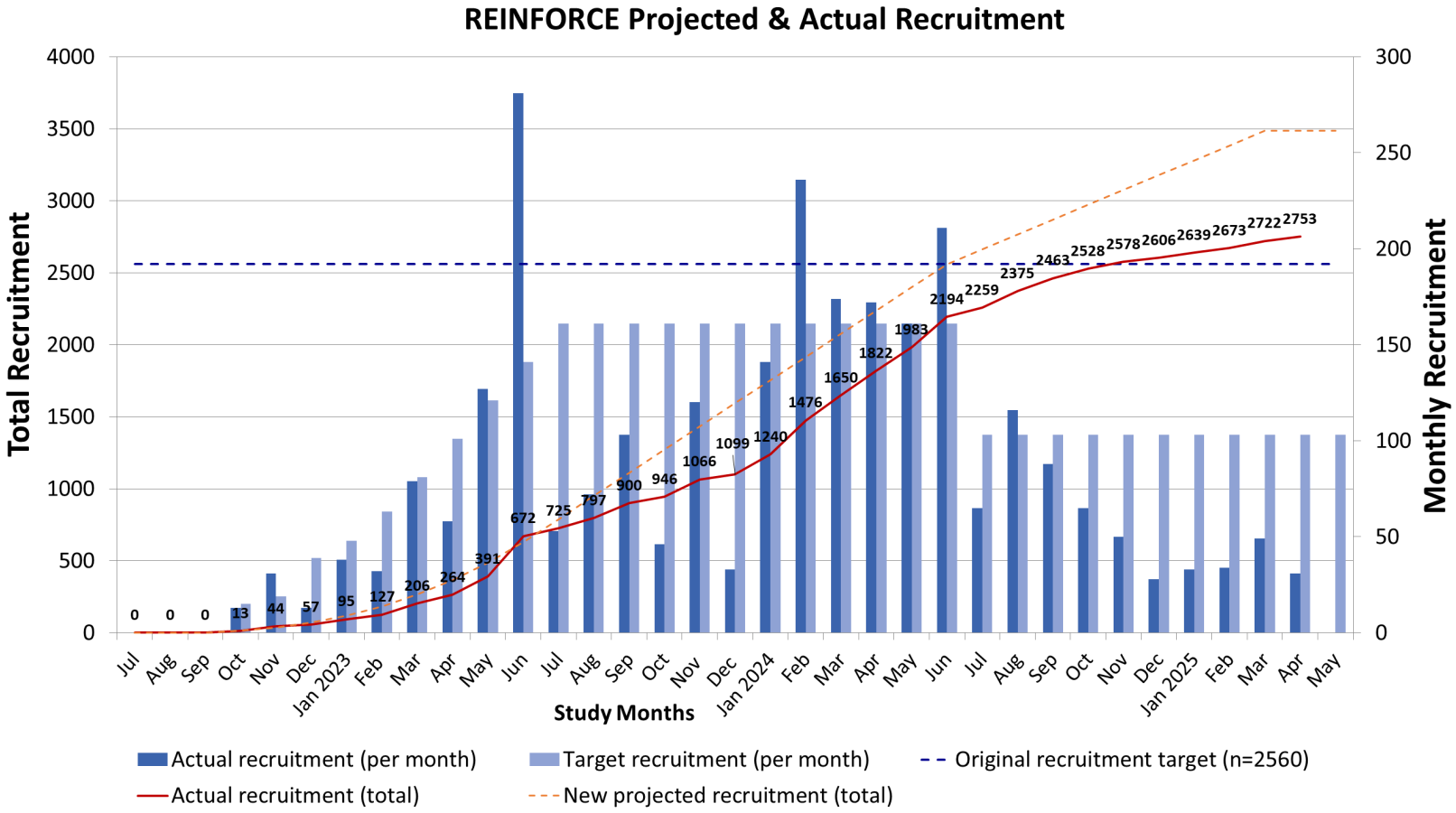
Orthopaedics in or out?





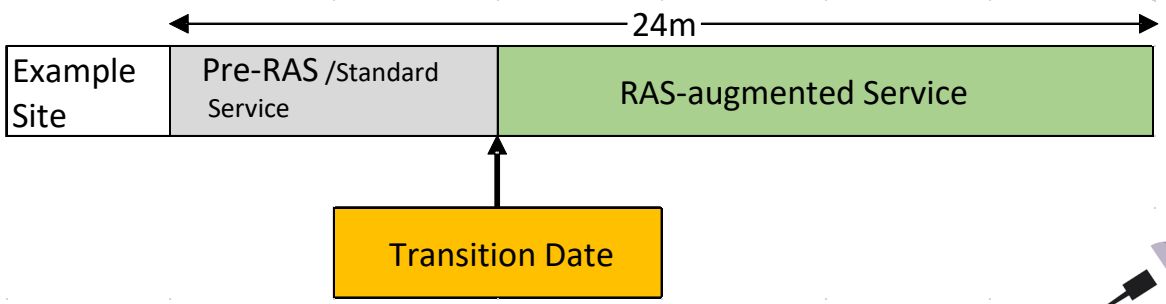


Patient Recruitment



TRANSITION TO RAS

THEORY



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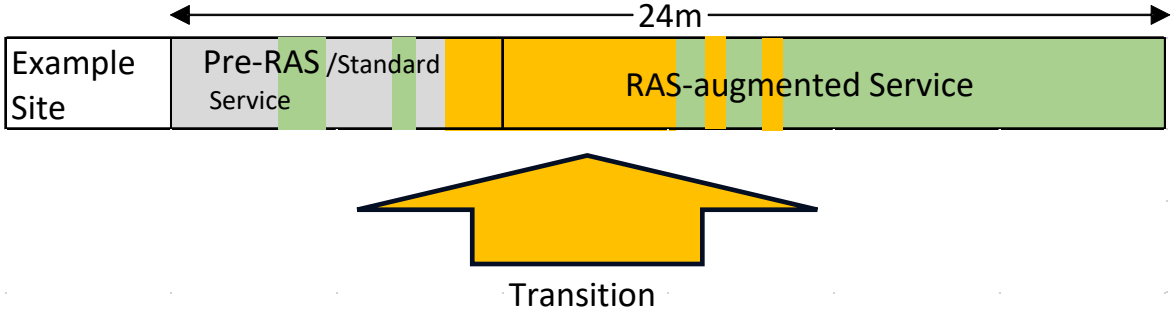
REALTY



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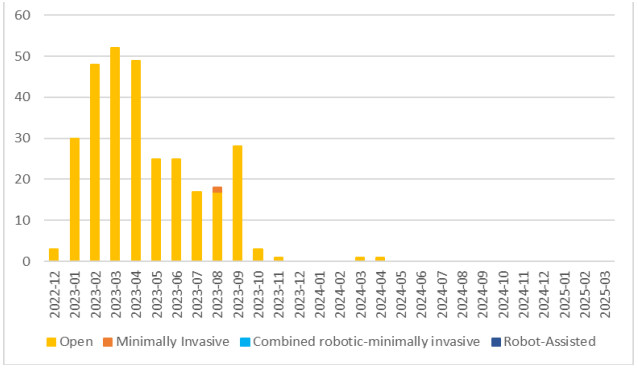
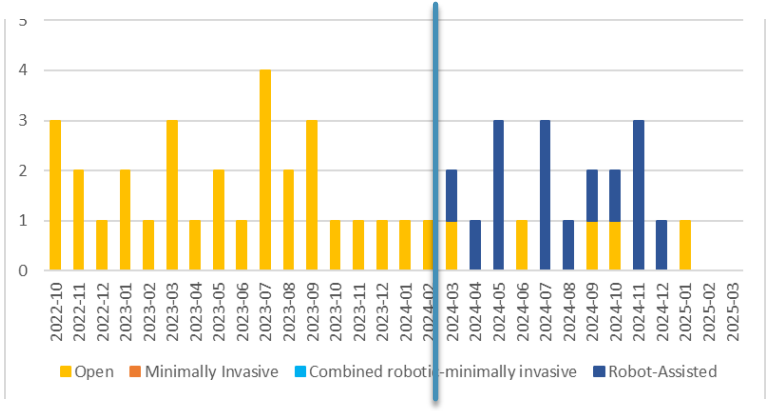
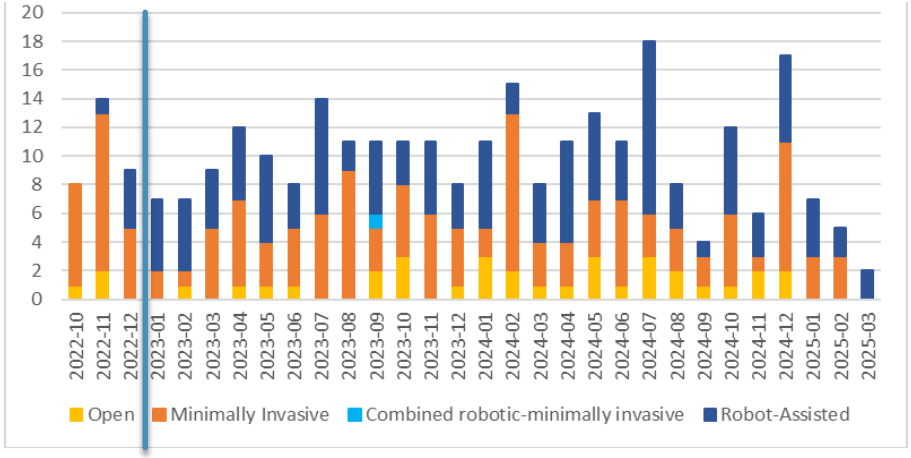
TRANSITION TO RAS (THE SYSTEM!)





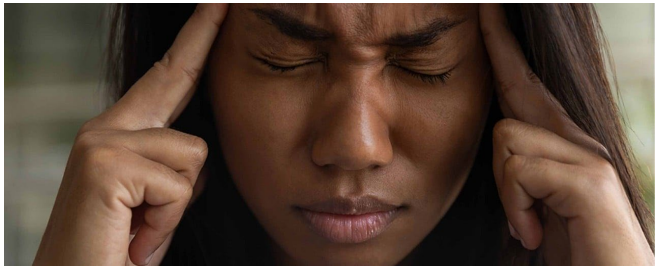
- RAS never arrived

- Perfect!

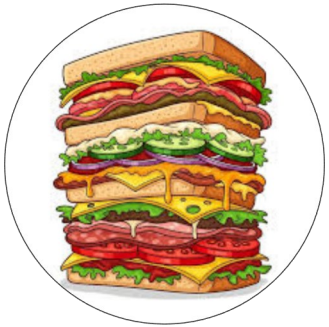


- The rest!

ANALYSIS & QUANTITY OF DATA



- Different analysis options
- Not just the quantitative data…



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ACCESS TO HEALTH ECONOMICS DATA

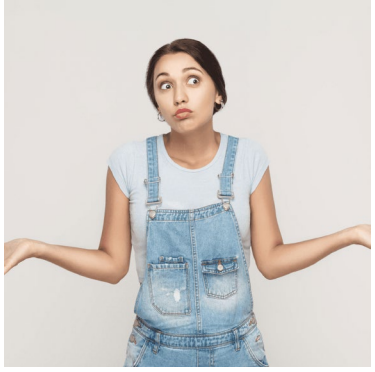
- Difficult to access
- No public disclosures
- No "price lists" – bespoke
- Broad stroke approach

The Guardian UK

Millions more to have robotic surgery in NHS plan to cut waiting lists

Head of NHS England to say robot-assisted surgery will become 'the default' for 90% of keyhole operations by 2035

Surgeons use a robot in an operation at University College London hospital. Photograph: Jeff Gilbert/Alamy



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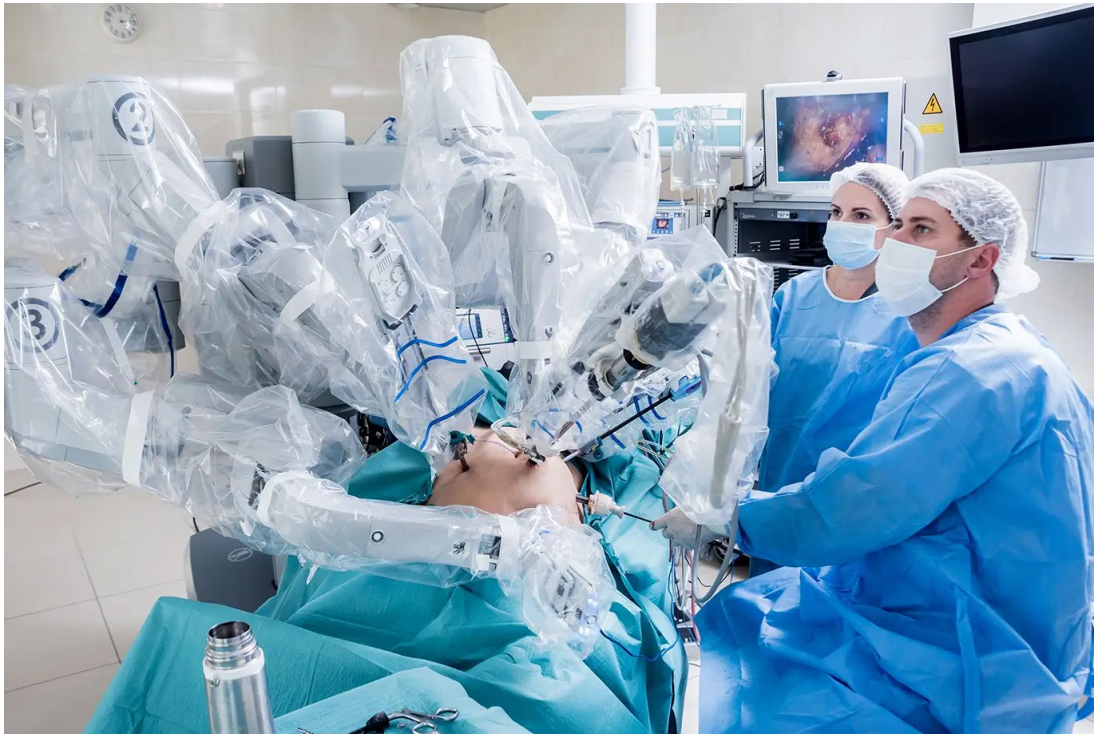
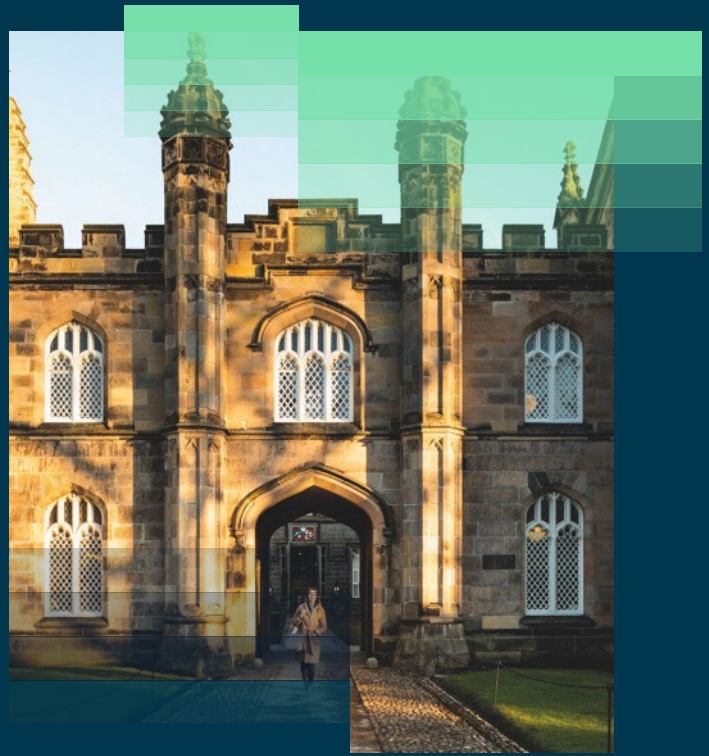
- THANK YOU



GO BEYOND BOUNDARIES



Designing and delivering robust system-level evaluations:

Importance of contingency planning

Graeme MacLennan
Aberdeen Centre for Evaluation

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Royal College of Surgeons of England
SURGICAL TRIALS CENTRE

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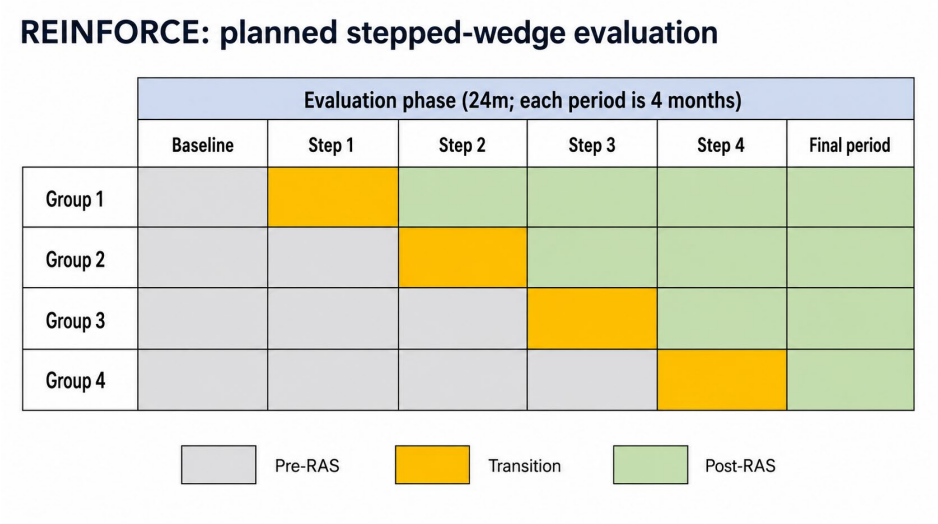
Original plan

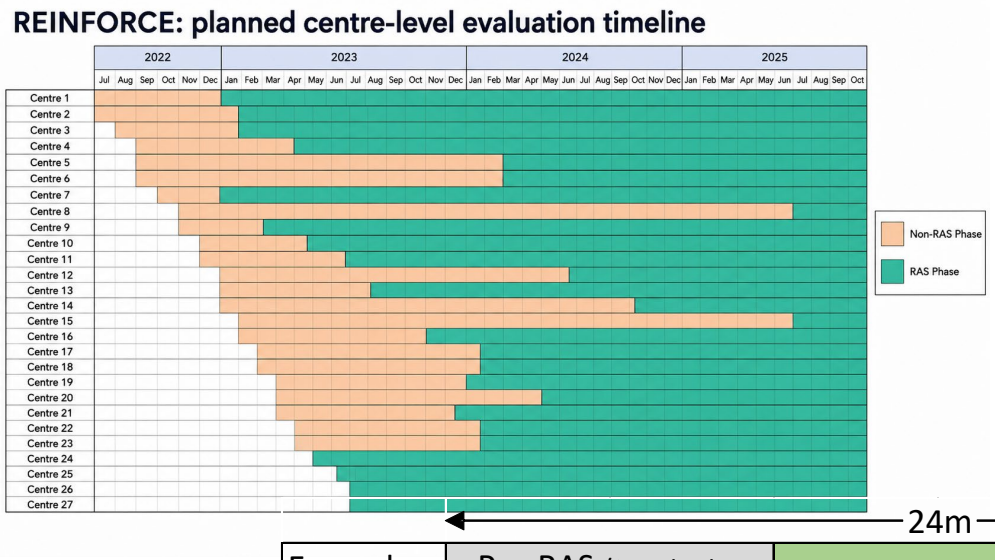
- 16 sites over 24 months
- 8 procedures per site per month
- 2,560 procedures
- 90% power 0.3 SD
- 80% power 0.25 SD

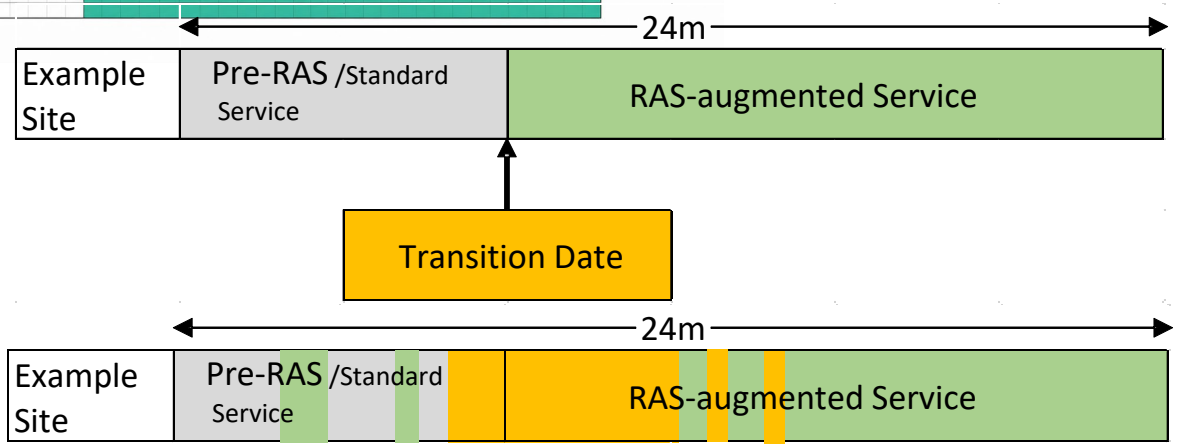


Why stepped wedge?

- Rollout over time
- All sites eventually post-RAS
- Accounts for time trends
- Service-level question, not just RAS vs non-RAS

Design meets system



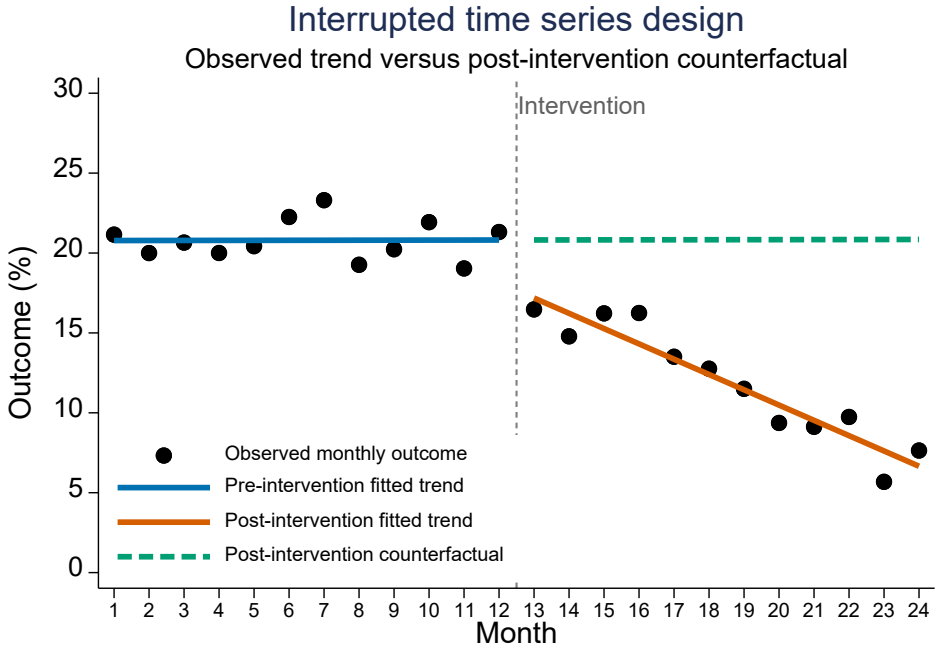


Contingency by design

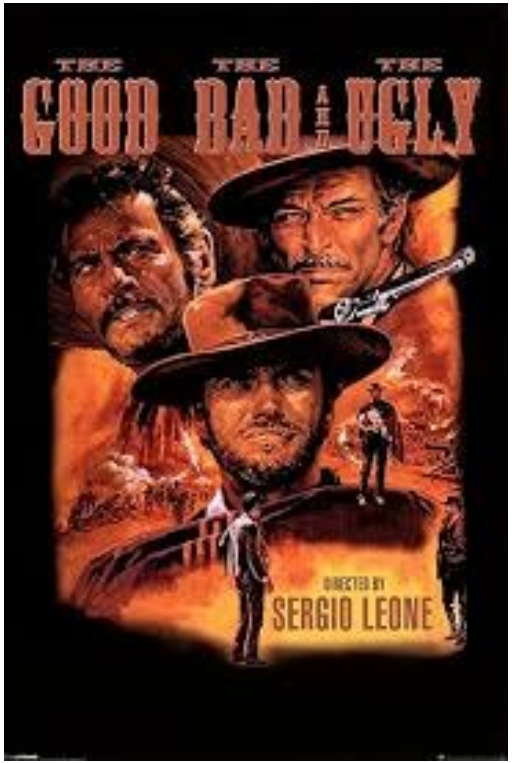
- Uncertainty anticipated
- Alternatives pre-planned
- ITS identified in advance
- Transition rules defined
- SAP before analysis
- Flexibility built in

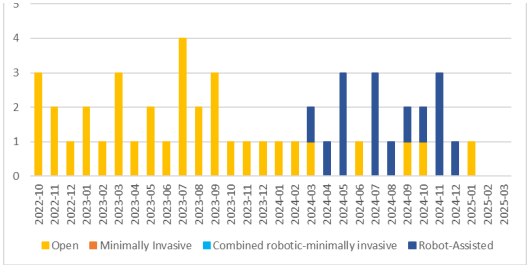
How we planned ITS

- Repeated outcome summaries over time
- Estimate the pre-RAS trend
- Compare observed post-RAS trend with counterfactual
- Estimate change in level and change in slope
- Repeat across centres, then combine estimates



$$Y_t = \beta_0 + \beta_1 Time_t + \beta_2 PostRAS_t + \beta_3 TimeAfterRAS_t + \varepsilon_t$$


THE GOOD
THE BAD
AND
THE UGLY
DIRECTED BY
SERGIO LEONE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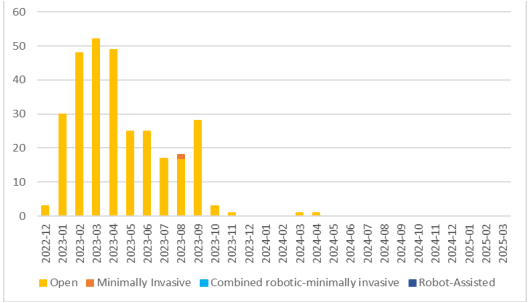
Open
Minimally Invasive
Combined robotic-minimally invasive
Robot-Assisted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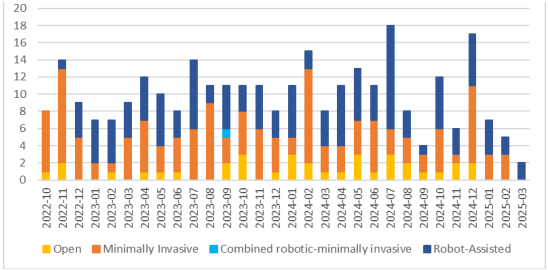
Open
Minimally Invasive
Combined robotic-minimally invasive
Robot-Assisted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2025-02
2025-03
Open
Minimally Invasive
Combined robotic-minimally invasive
Robot-Assisted

ITS meets reality…

- Planned approach: monthly centre-level ITS
- Problem: No pre-RAS or no post-RAS data
  - Sparse data, low and empty centre-months
  - Aggregate monthly models unstable
- Solution:
  - Individual-level segmented regression with ITS terms
  - Centre-level estimates pooled

$$Y_{it} = \beta_0 + \beta_1 Time_t + \beta_2 PostRAS_t + \beta_3 TimeAfterRAS_t + \gamma X_i + \varepsilon_{it}$$

Post-RAS intro comparison

- Post-RAS period only
- RAS vs non-RAS cases
- Same broad service context
- Propensity score adjustment
- Selection into RAS very likely

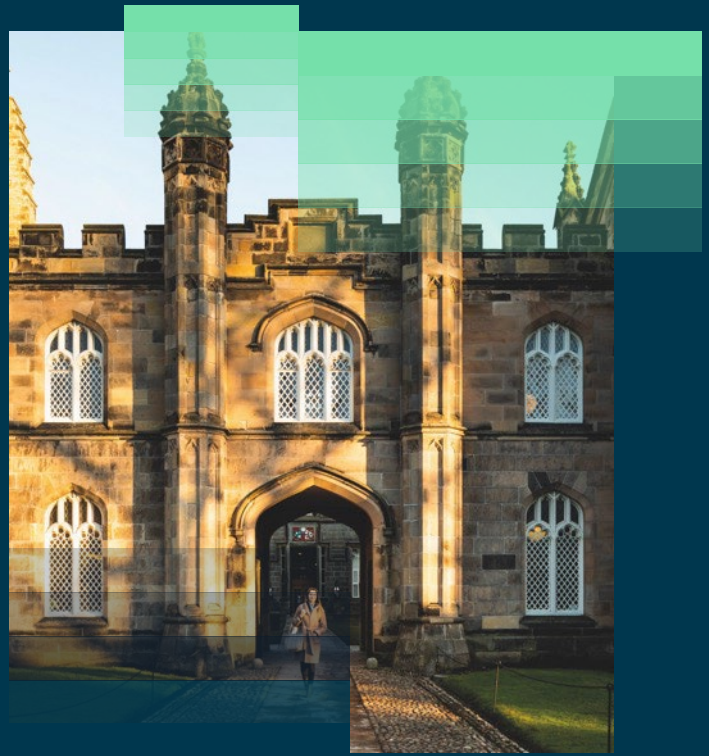
All-data comparison

- All available cases
- RAS vs non-RAS cases
- Pre-RAS and post-RAS periods
- Regression analysis
- Adjusted for age, sex, ASA grade, specialty and site where possible
- Larger dataset, but stronger assumptions
- More vulnerable to time and service-context confounding

What have I learned?

- Plan for the design you want
- Anticipate the design you may get
- Monitor implementation and data quality
- Adapt transparently, not opportunistically
- Be clear about what can and cannot be estimated
- Triangulate statistical analysis with process evaluation, health economics, and service data

GO BEYOND BOUNDARIES



Designing and delivering robust system-level evaluations:

REINFORCE Process Evaluation

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Aberdeen Centre for Evaluation

Email: k.gillies@abdn.ac.uk
Katie Gillies
@katiegillies.bsky.social

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Disclosures

- Funding paid to the University of Aberdeen – including from NIHR, MRC, CIHR, Wellcome Trust & Intuitive Surgical European Research Board, Boehringer & Ingelheim

What we knew

PLOS ONE

RESEARCH ARTICLE

Barriers and enablers to the effective implementation of robotic assisted surgery

Louisa Lawrie[1]*, **Katie Gillies**[1], **Eilidh Duncan**[1], **Loretta Davies**[2], **David Beard**[2], **Marion K. Campbell**[1]

1 Health Services Research Unit, Institute of Applied Health Sciences, School of Medicine, Medical Sciences and Nutrition, University of Aberdeen, Aberdeen, Scotland, United Kingdom, **2** RCS Surgical Interventional Trials Unit (SITU), Nuffield Dept Orthopaedics, Rheumatology and Musculo-skeletal Sciences, University of Oxford, Oxford, United Kingdom

* louisa.lawrie1@abdn.ac.uk

Citation: Lawrie L, Gillies K, Duncan E, Davies L, Beard D, Campbell MK (2022) Barriers and enablers to the effective implementation of robotic assisted surgery. PLoS ONE 17(8): e0273696. https://doi.org/10.1371/journal.pone.0273696

Editor: Rajagopalan Srinivasan, Indian Institute of

Abstract

Background

Implementation of Robotic Assisted Surgery (RAS) is complex as it requires adjustments to associated physical infrastructure, but also changes to processes and behaviours. With the global objective of optimising and improving RAS implementation, this study aimed to: 1) Explore the barriers and enablers to RAS service adoption, incorporating an assessment of behavioural influences; 2) Provide an optimised plan for effective RAS implementation, with the incorporation of theory-informed implementation strategies that have been adapted to address the barriers/enablers that affect RAS service adoption.

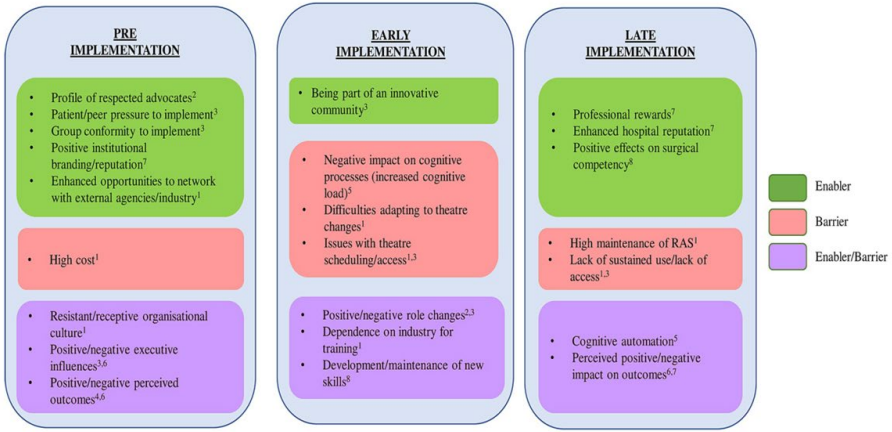
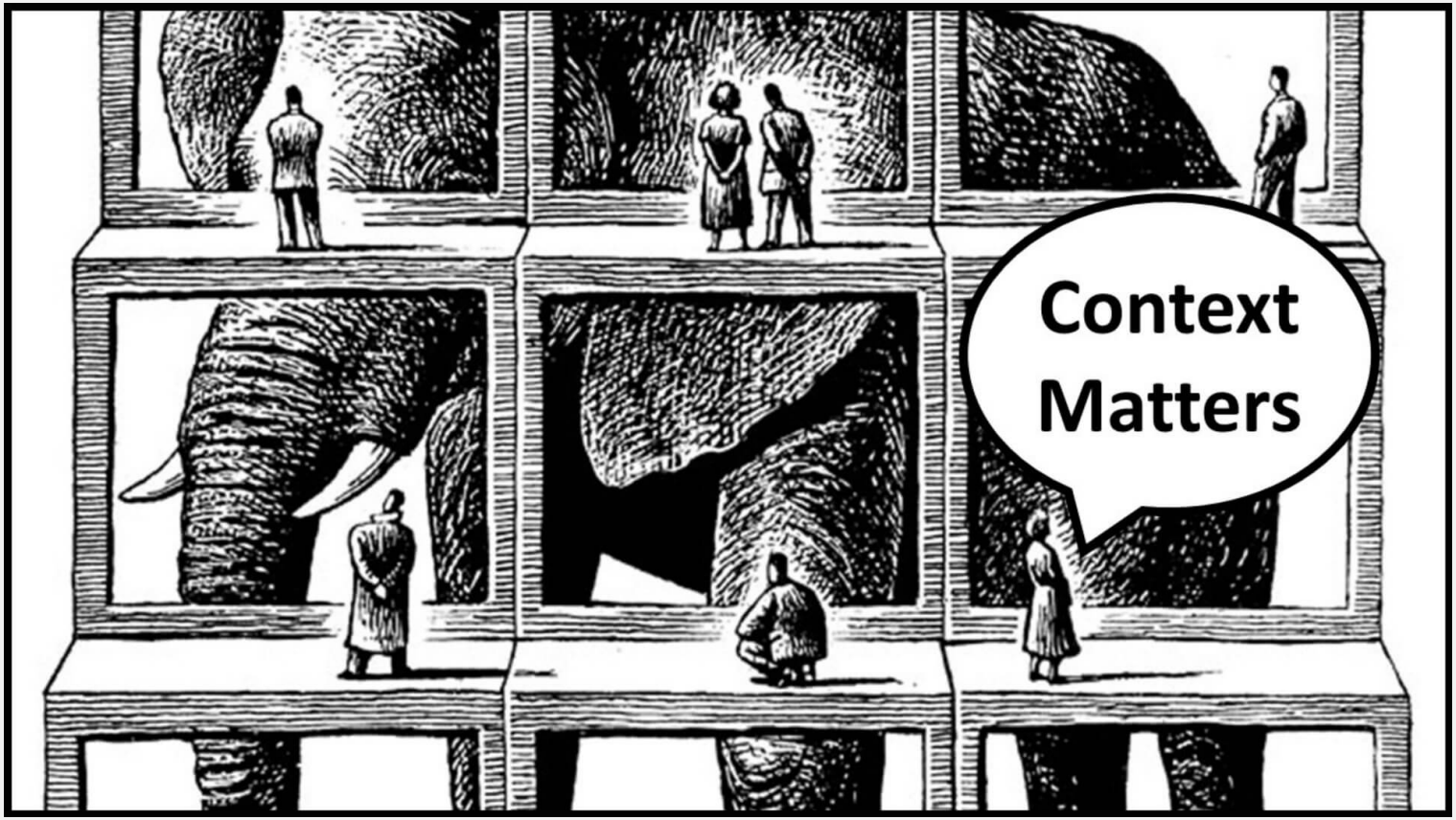


Fig 1. The barriers and enablers of implementation at each phase of adoption. TDF domains: [1]Environmental Context & Resources, [2]Social Professional Role & Identity, [3]Social Influences, [4]Beliefs about Consequences, [5]Memory Attention & Decision Processes, [6]Knowledge, [7]Reinforcement, [8]Skills.

https://doi.org/10.1371/journal.pone.0273696.g001


Context
Matters

Accommodating for context

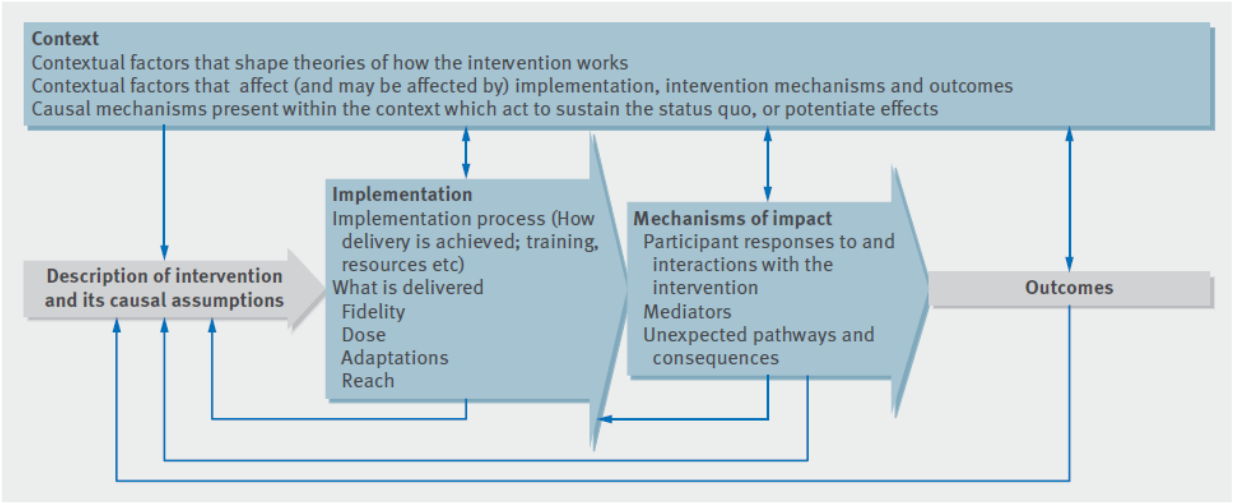


Fig 1 | Key functions of process evaluation and relations among them (blue boxes are the key components of a process evaluation. Investigation of these components is shaped by a clear intervention description and informs interpretation of outcomes)

Moore GF et al. BMJ 2015;350:h1258. doi:10.1136/bmj.h1258

What is the context?

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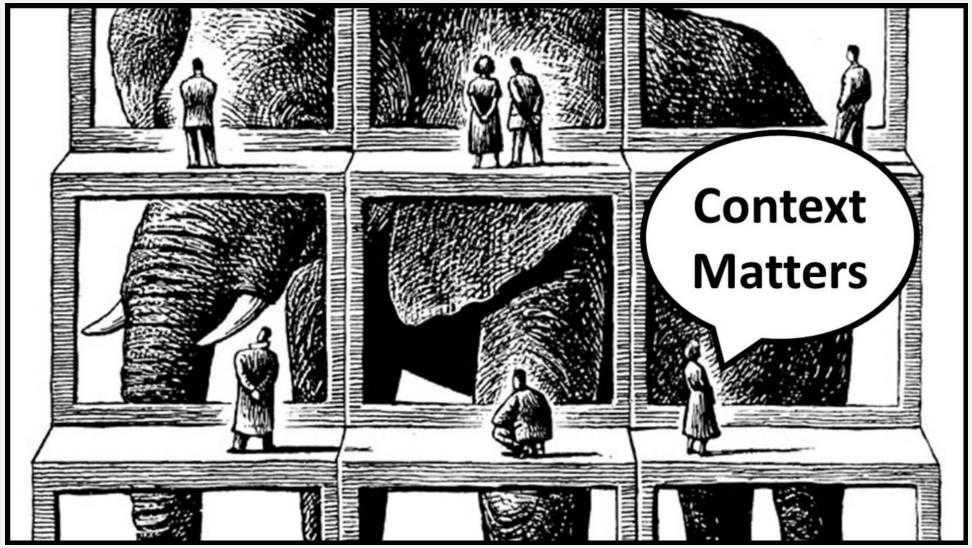
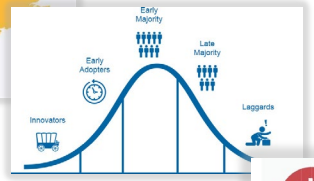
Real-World Evaluation of Robot-Assisted Surgical Services



NHS



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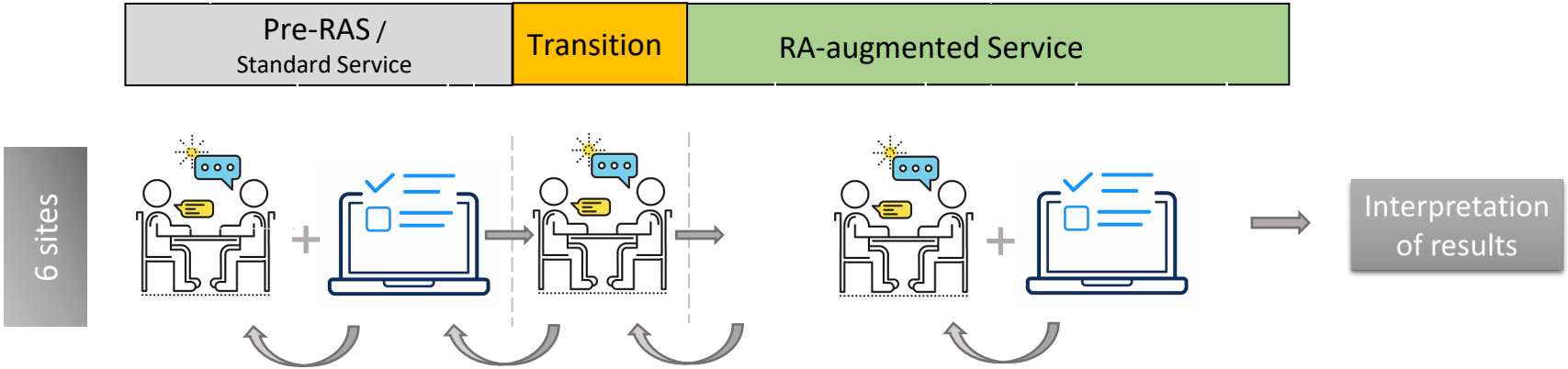
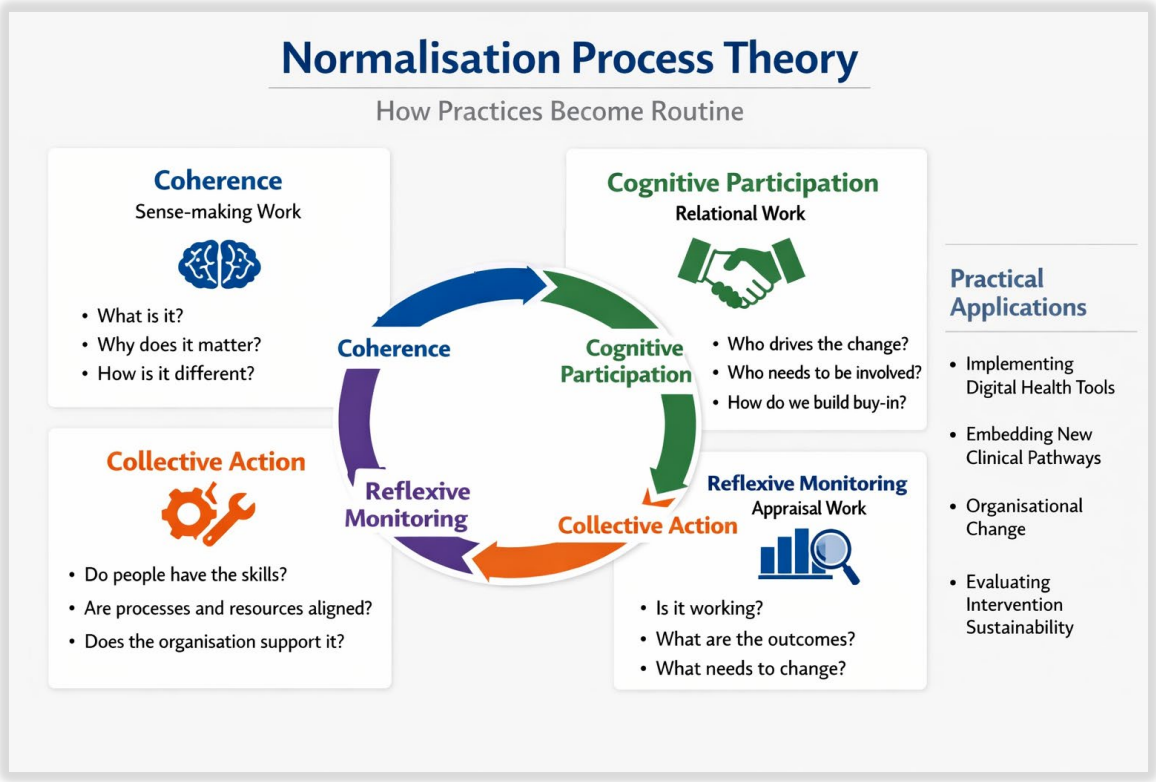
Process Evaluation – aims and design

REINFORCE
Real-World Evaluation of Robot-Assisted Surgical Services

- identify perceived challenges and solutions to RAS implementation
- explore the immediate impact of the introduction of RAS by assessing any change to process
- assess the impact of factors on speed of roll out and adoption
- explore how individual site characteristics influence uptake and effectiveness and outcome



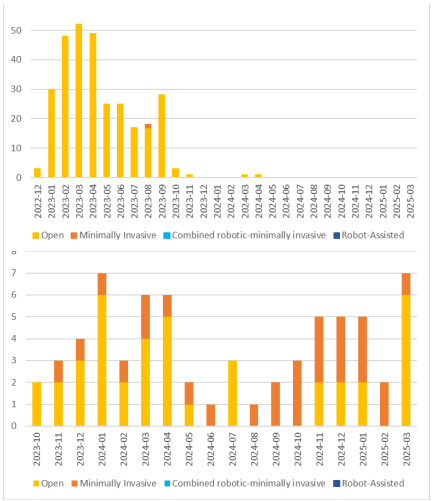
Guiding theoretical framework



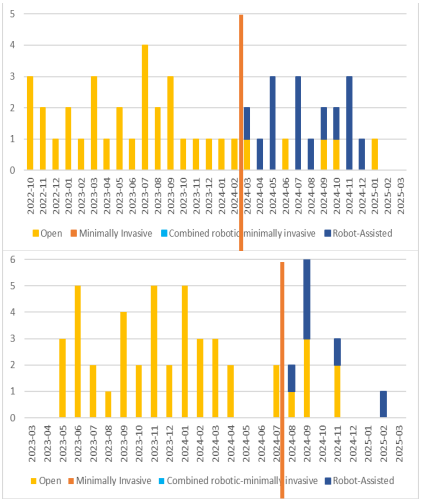
Uncertainty in the system

Types of adoption

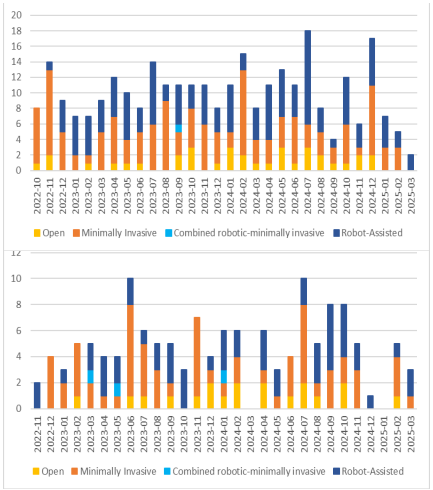
none



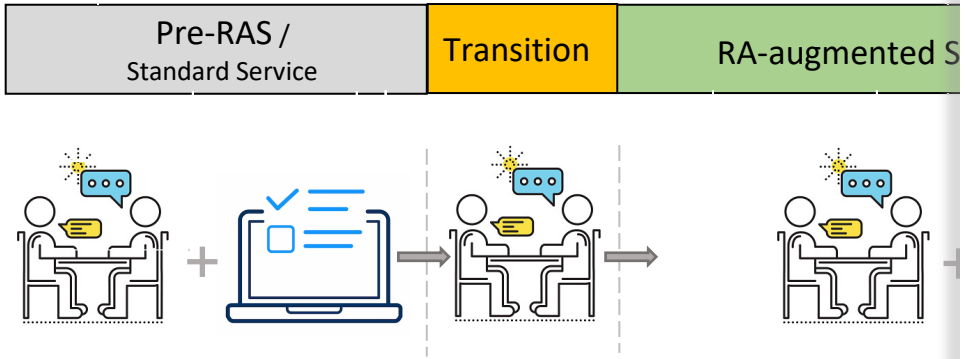
good



messy



Complex systems = complex data



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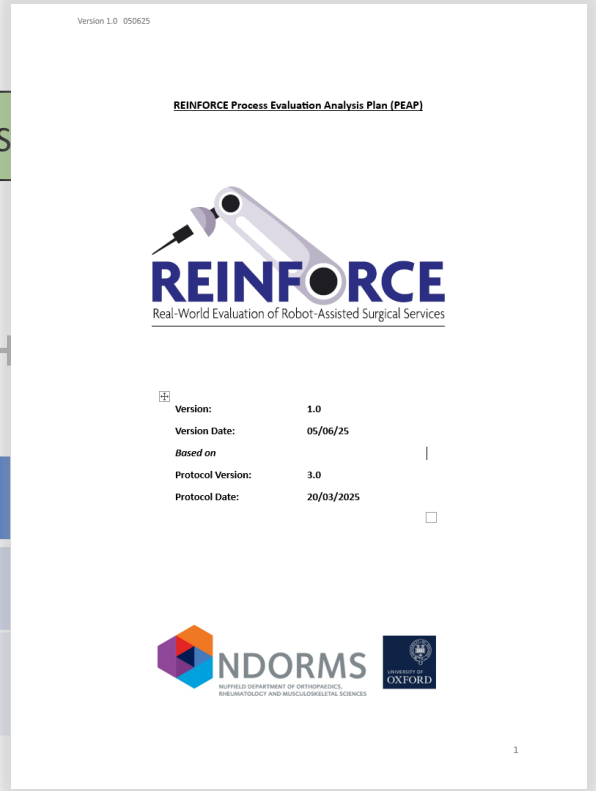

Version 1.0 050625

REINFORCE Process Evaluation Analysis Plan (PEAP)

REINFORCE
Real-World Evaluation of Robot-Assisted Surgical Services

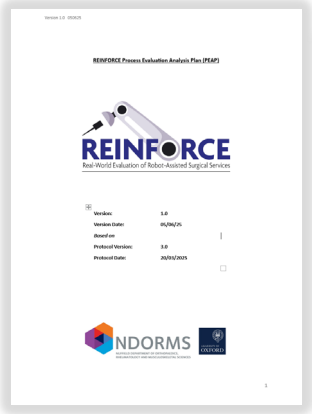
Version:	1.0
Version Date:	05/06/25
Based on	
Protocol Version:	3.0
Protocol Date:	20/03/2025

NDORMS
NUFFIELD DEPARTMENT OF ORTHOPAEDICS, RHEUMATOLOGY AND MUSCULOSKELETAL SCIENCES
UNIVERSITY OF OXFORD

1

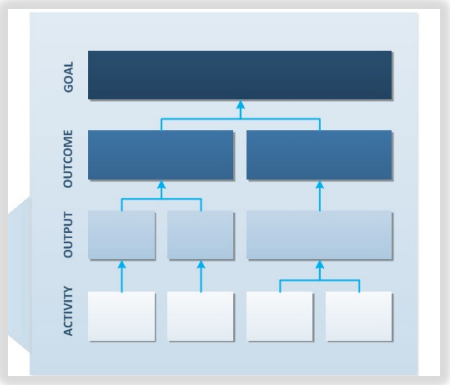
PE summary

- Pre-specify your plan for analysis - PEAP
- Inquiry driven – ability to pivot and be responsive
- Analyse as you go – mixed methods
- Use theory/model/framework
  - Design/analysis/interpretation (logic model)
- Triangulate data to interpret findings


REINFORCE Process Evaluation Analysis Plan (PEAP)

REINFORCE
Real-World Evaluation of Robot-Assisted Surgical Services

NDORMS



	Clinical effectiveness	Cost effectiveness	Implementation effectiveness	OVERALL
Objective 1				+
Objective 2				++
Objective 3				-

Summary and key messages

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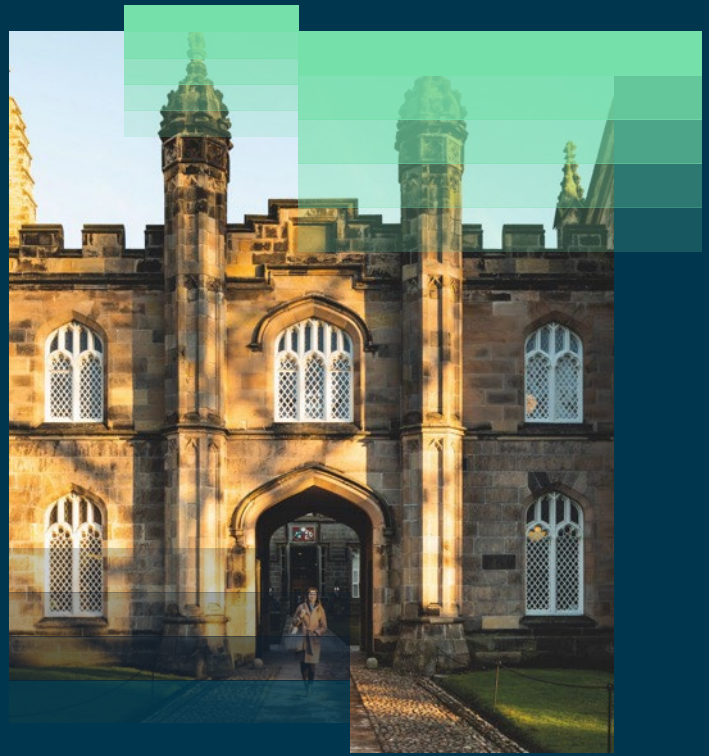
GO BEYOND BOUNDARIES



Designing and delivering robust system-level evaluations:

Summary & key messages

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ACE Promoting Excellence in Health and Social Care Research

Royal College of Surgeons of England
SURGICAL TRIALS CENTRE

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Summary

- **Systems evaluations are complex**
  - Have dynamic properties which need to be planned for
  - Context matters to interpret system inter-relationships
  - Can be unpredictable
  - Pre-planning is key
  - Be prepared to adapt

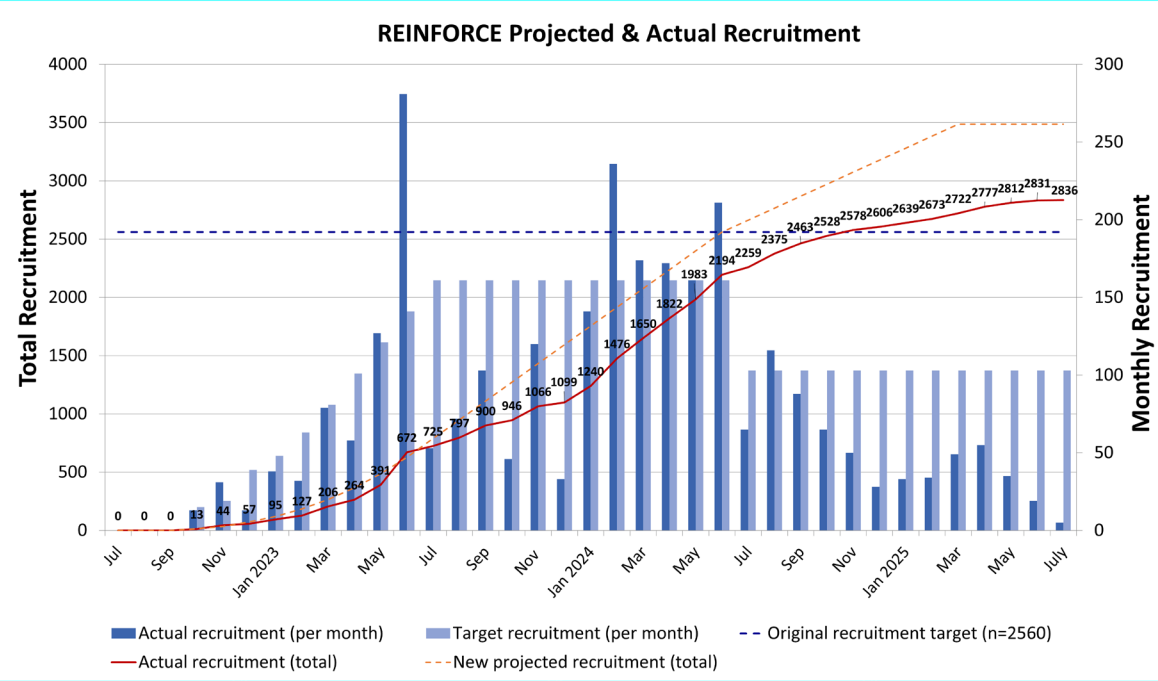
- **But … system level evaluations are important**
  - Drive high-level policy and practice
  - Are important to understand delivery in practice

What about REINFORCE?

- Displayed some classic system level evaluation issues
- Pre-planning helped us optimise the study
- Planning for contingency was crucial
- Context was important to interpret our findings
- Despite issues delivered large scale study with robust findings

REINFORCE
Real-World Evaluation of Robot-Assisted Surgical Services

- 2836 procedures recruited involving 18 sites;
- 7 specialties, 10 different operative procedures; 3 site types

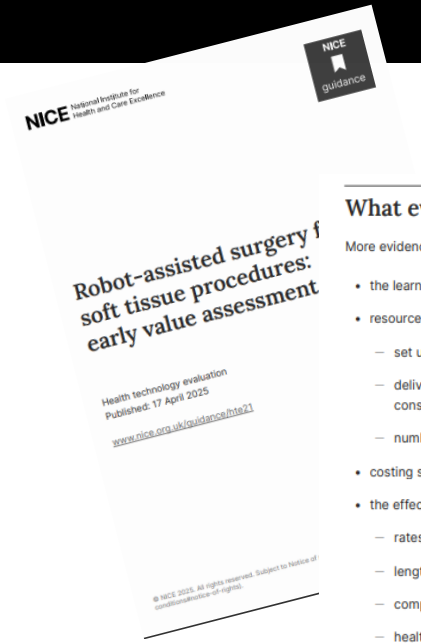


Data to inform national policy making

- Data generated:
  - clinical
  - system
  - surgeon
  - patient
  - process &
  - health economic
- All active robotic surgery systems covered

Large scale information to inform national policy making

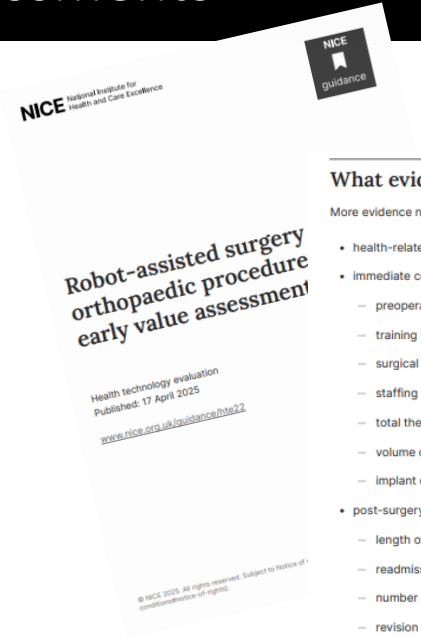
NICE early value assessments



What evidence generation is needed

More evidence needs to be generated on:

- the learning curve for the surgeon and centre
- resource use for robot-assisted surgery services:
  - set up, including staff training
  - delivery, including staffing, technology maintenance, additional training and consumables
  - number of procedures and robot use
- costing structures to procure and implement a robotic system
- the effect on outcomes including:
  - rates of conversion to open surgery
  - length of hospital stay
  - complications
  - health-related quality of life
  - procedure-related discomfort and ergonomics for the surgeon
  - rates of minimally invasive surgery compared with open surgery after introduction of robot-assisted surgery into a centre
  - hospital capacity and surgical waiting lists
  - readmissions
  - long-term outcomes for people having robot-assisted surgery.



What evidence generation is needed

More evidence needs to be generated on:

- health-related quality of life, including patient-reported outcome measures
- immediate consumables and resourcing associated with surgery, including:
  - preoperative CT imaging requirements
  - training time and costs
  - surgical and theatre accessories
  - staffing (number and NHS band)
  - total theatre time and total surgical time
  - volume of procedures per day and
  - implant costs
- post-surgery treatment and service use including:
  - length of hospital stay
  - readmission rates
  - number of physiotherapy sessions and
  - revision rates (stratified by implant type)
- characteristics of people having the procedure, such as age, body mass index and American Society of Anesthesiologists risk score
- population subgroups, such as people from Southeast Asian backgrounds
- where in the country the procedures are done.

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GIRFT implementation report

Research needs

- Inform research plans using the Evidence Generation recommendations from NICE.
- Data on safety, cost-effectiveness and clinical effectiveness will be required.
- Research studies should consider other areas pertinent to expansion of RAS programmes such as:
  - Implementation evaluation
  - Efficient pathway designs
  - Novel pathways in RAS
  - PREMs and PROMs
  - Workforce benefits

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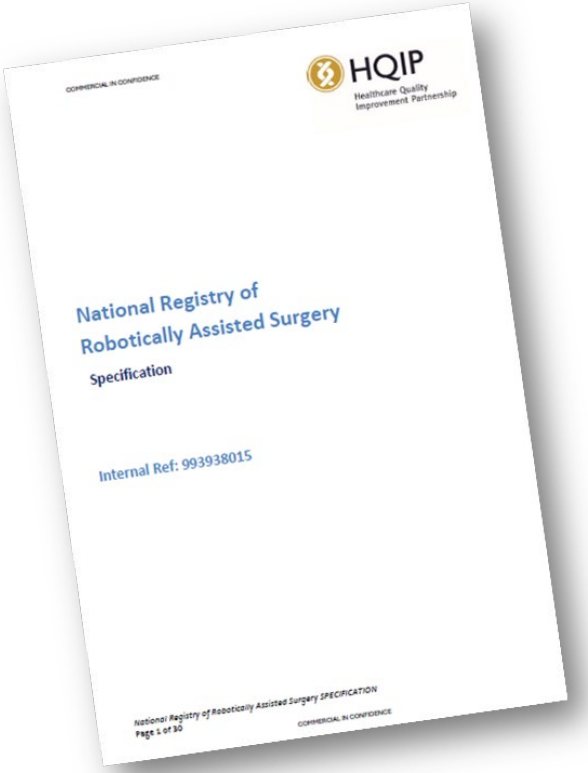
National Robotic Registry



- National registry being commissioned
- Informed by learnings from REINFORCE
- Aims to provide long-term data

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Finally …

Multi-disciplinary and stakeholder involvement essential in system level evaluation

- Clinical
- Statistics
- Health economics
- Qualitative
- Mixed methods
- Health psychology
- Implementation science
- Evidence synthesis
- Health care managers
- National policy makers
- Patients
- Public
- … and more

The RoboCOS Team








- Clare Robertson
- Katie Gillies
- Marion Campbell
- David Beard

- Shafaque Shaikh
- Cameron Matthew
- Terry Mackie
- Craig Ramsay

The REINFORCE WP1 team





- Louisa Lawrie
- Eilidh Duncan
- Katie Gillies
- David Beard
- Marion Campbell

The REINFORCE trial team

plus many, many more co-apps and site staff

REINFORCE PMG

- *Aberdeen* – Rumana Newlands, Sharon McCann, Katie Gillies, Jemma Hudson, Graeme MacLennan, Mark Forrest, Suzanne Breeman, Marion Campbell
- *Oxford* – Lottie Davies, Ivy Raymundo-Wood, Emma Blackmore-Bowes, Sian Saul, Heidi Fletcher, Davy Byrne, David Beard
- *Newcastle* – Luke Vale, Tomos Robinson, Giovany Orozco-Leal, Nawaraj Bhattarai

Questions and discussion