Qualitative studies of innovations in treatment, organization, and delivery of healthcare:

How Normalization Process Theory can help

Carl May

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

A few words about me and what I do…

Fundamental research question: **what mechanisms motivate and shape sociotechnical transformations in care?**

Applied Research Question: **How are new ways of thinking, enacting and organising care implemented and integrated in practice?**

Theory building from qualitative studies and evidence syntheses

(Normalization Process Theory)

Empirical Research & Systematic Reviews on innovation and intervention trajectories: Informatics, telemedicine, shared-decision-making tools, medical devices & diagnostics.

Empirical Research & Systematic Reviews on the production of reliable generalisable knowledge to inform practice: Randomized trials, process evaluations, algorithms, guideline development,

Applied Research Question: **How do professionals and service users interact, how are these interactions shaped by innovations in practice**

Theory building from qualitative studies and evidence syntheses

(Burden of Treatment Theory)

Empirical Research & Systematic Reviews on complex conditions and their trajectories: Chronic Pain, Long term Conditions, End of Life Care, Depression, Addiction, Construction of Patients & Caregivers

Empirical Research & Systematic Reviews on professional patient interaction and the construction of individualized clinical knowledge: Interaction processes, relational restructuring, social construction of professional practice

What I'm like in real life

What my cv says about me

Professor Tracy Finch
co-developer of NPT

(Respect due…)

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1. Methods

- Why does qualitative research matter?

How do we build explanations in practice?

How does NPT help us?

What is Normalization Process Theory?

- What is a coding manual and what does it do?

Can we grow interpretive power?

When we do qualitative research, we're most often trying to make sense of what is going on, from the perspectives of the people involved.

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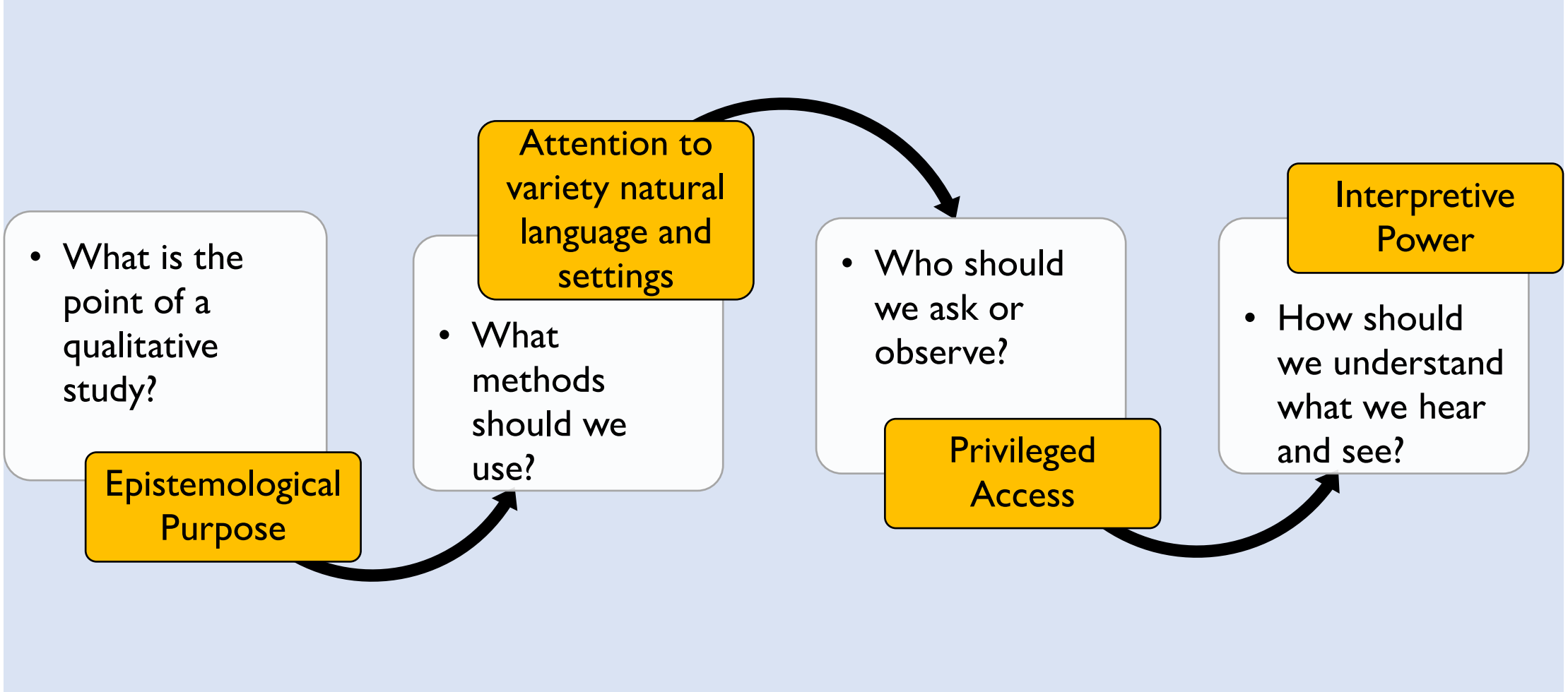
The value of qualitative research



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Qualitative work leads to discovery

Research Question – framing work

- ***Framing***: Defining a topic area of interest and clarifying aims and objectives informed by: theories (or theory-building strategies); clear research objectives questions; and methodological approaches that will shape investigation.
- (Can lead to a **plan of investigation)**

Identification – *classification work*

- ***Coding***: creates a comprehensive description of the different elements making up the data-set.
- (Can lead to a **taxonomy** of categories, themes, concepts, or constructs).

Characterization – *analytic work*

- ***Connections***: asks questions about what different elements in data **mean**, explores **relationships** between them, and considers their relative **significance**.
- (Can lead to a **map** or **model**.)

Explanation – *interpretive work*

- ***Implications***: plausible claims about what the data tells us, and that **explain the implications of the analysis**.
- (Can lead to hypotheses, propositions, or **theories**.)

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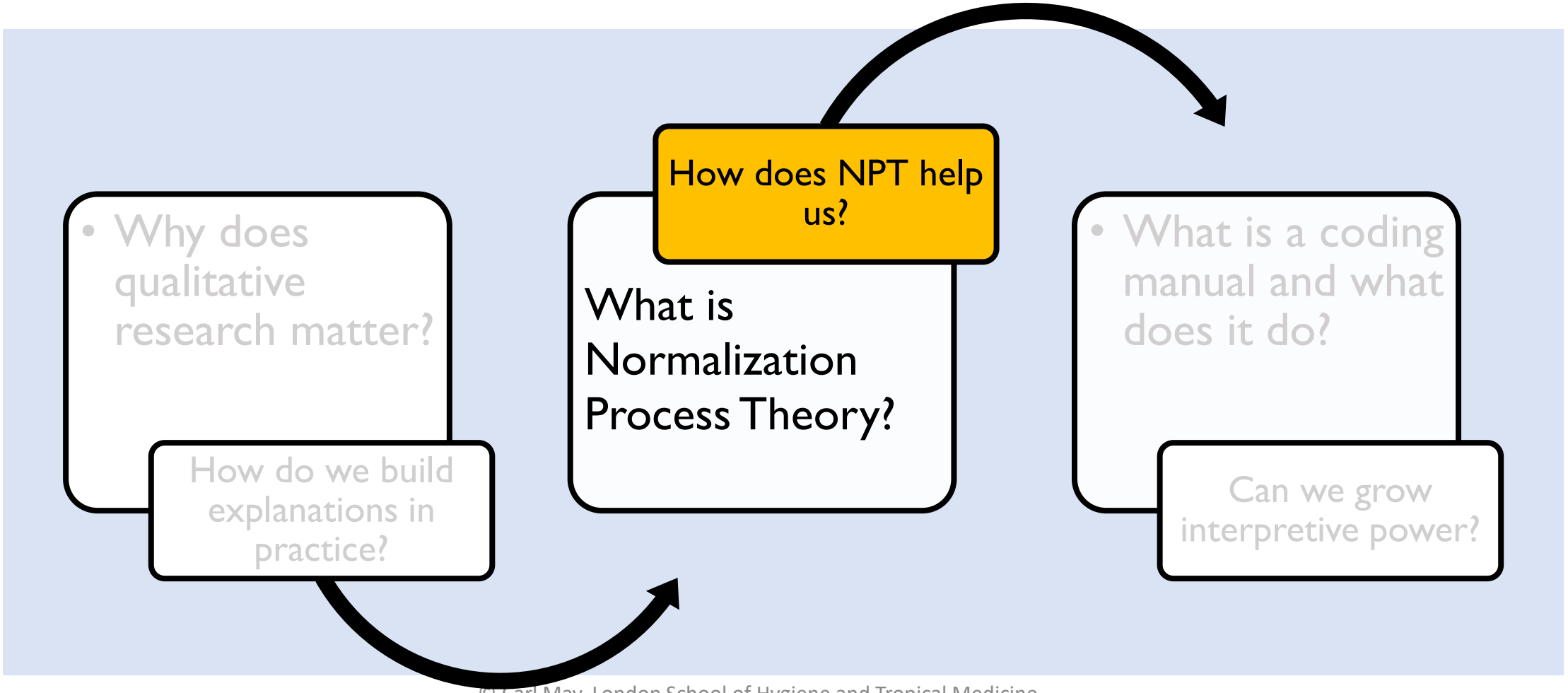
2. Theory



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When we're using theory, we're most often trying to make sense of what is going on, in a way that enables rational and reproducible *explanation*.

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Implementation processes and implementation science are not the same

- **Implementation science** is about methods of translation. It involves structured and disciplined activities through which evidence-based interventions are implemented, often in controlled studies.
- **Implementation processes** are non-linear, dynamic, and emergent. They involve complex interactions between intervention components, many different actors, and the contexts. They are often very messy.

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In 1998, we needed to understand why it was so difficult for healthcare providers to adopt and operationalize telemedicine systems – existing explanations did not help us

Practical problem: to develop a generalizable framework for understanding the implementation of new treatments and organisational innovations.

Fundamental problem: To better understand the dynamics of human agency under conditions of constraint.

Theory-Building Process: Much more difficult than it seems (twenty years later, still theory-building)

Outcome: Normalization Process Theory – a middle range theory strongly oriented to practice. Now around 800 protocols, empirical reports, theory discussions, and reviews.

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What does Normalization mean?

NPT is a theory that identifies, characterizes, and explains mechanisms that motivate and shape implementation processes

‘The trouble with telemedicine is that it doesn’t work. The name tells you that. If it worked, it would just be called medicine.’

May, C., T. Rapley, and T. Finch, (2020) Normalization Process Theory, in International Handbook of Implementation Science, P. Nilsen and S. Birken, Editors. Edward Elgar: London.

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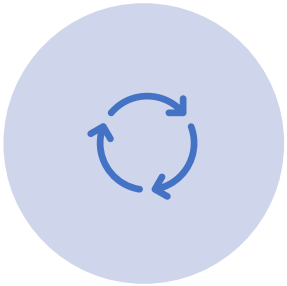
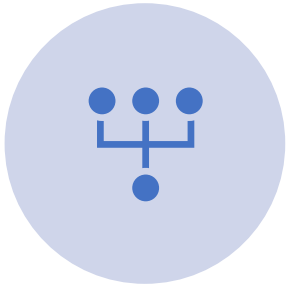
What is NPT a theory *of*…?



Implementation is ***the translation of the strategic intentions of one group of actors into the everyday practices of others***



The essence of implementation is ***collective action* and *collaborative work*.**

An implementation process is shaped by the collaborative work of participants, as they invest in ***continuing translational action***

NPT identifies, characterizes, and explains **mechanisms that motivate and shape implementation processes**

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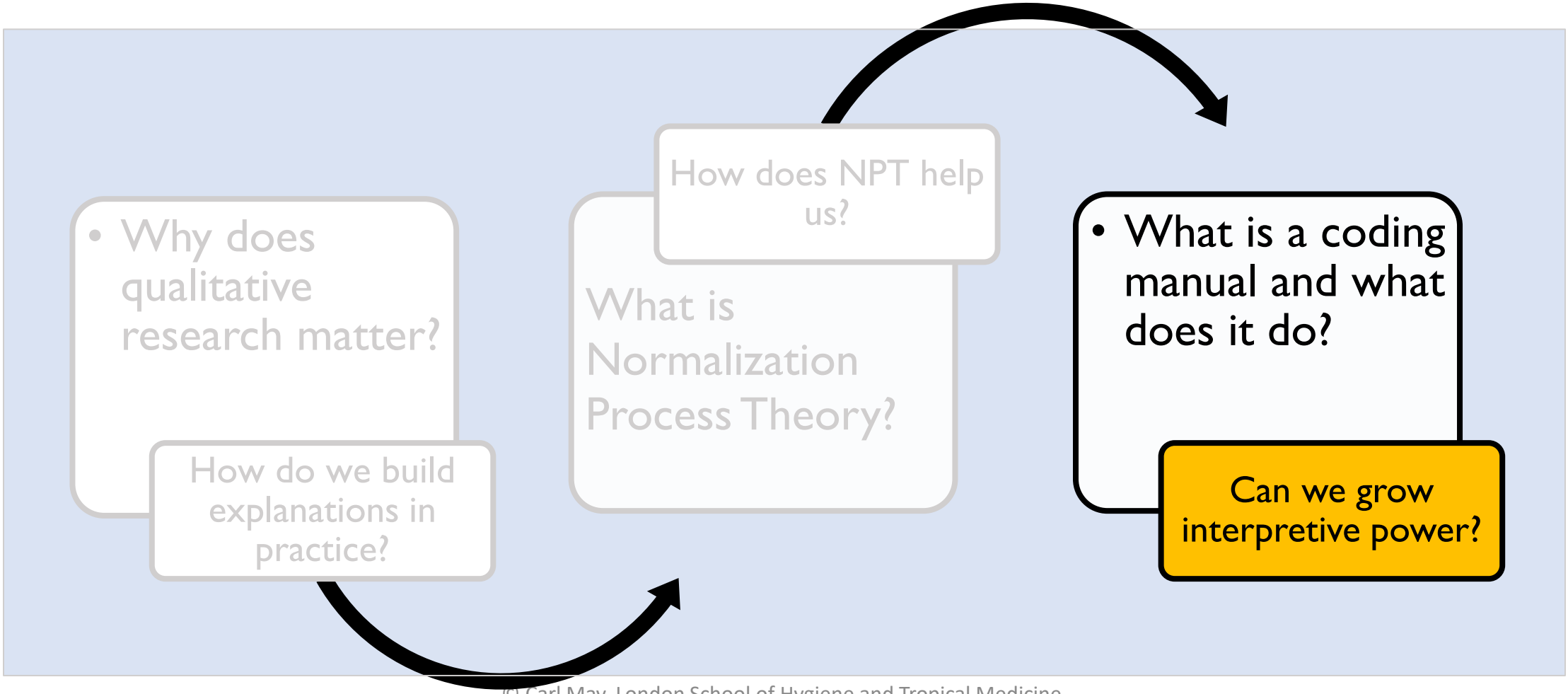
3. Application



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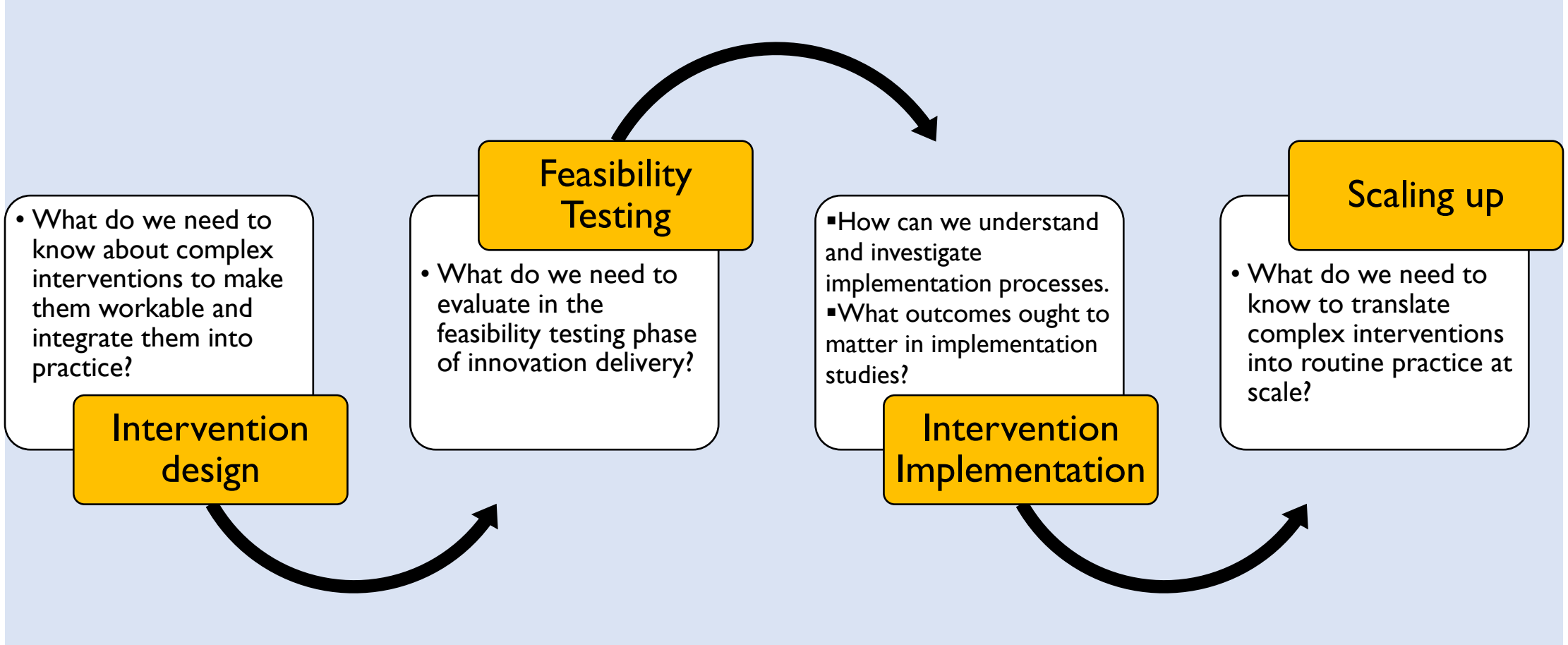
NPT offers a useful set of conceptual tools to underpin evaluation and research in the organisation and delivery of care: supporting complex intervention research



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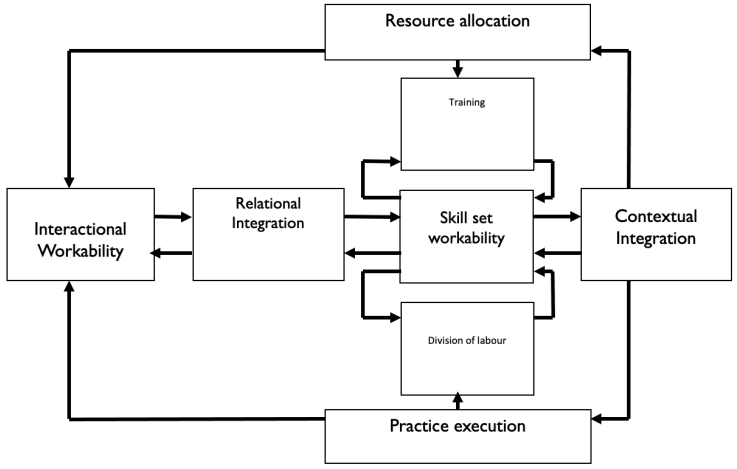
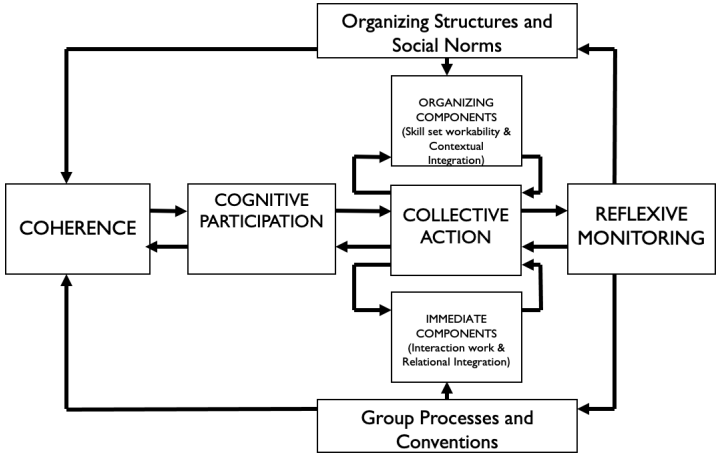
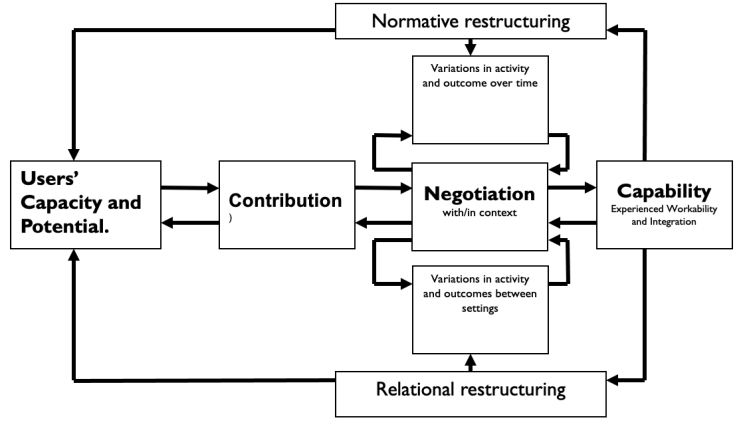
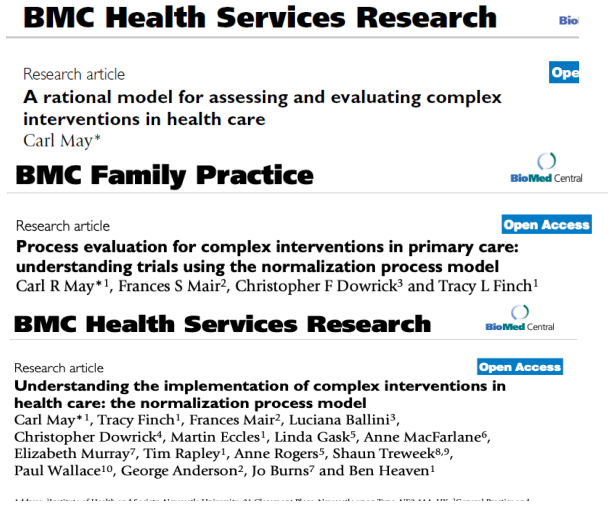
NPT focuses on action, but considers this at different levels of analysis – enables us to think through interventions, implementation, and negotiations with contexts








BMC Health Services Research

Research article

A rational model for assessing and evaluating complex interventions in health care

Carl May*

BMC Family Practice

Research article

Open Access

Process evaluation for complex interventions in primary care: understanding trials using the normalization process model

Carl R May*[1], Frances S Mair[2], Christopher F Dowrick[3] and Tracy L Finch[1]

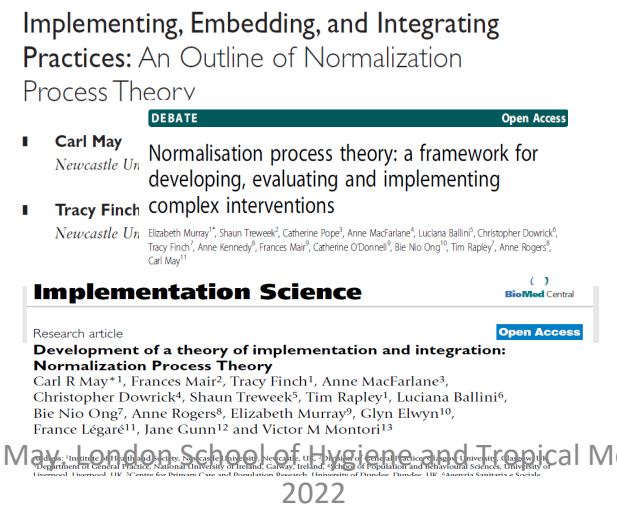
BMC Health Services Research

Research article

Open Access

Understanding the implementation of complex interventions in health care: the normalization process model

Carl May*[1], Tracy Finch[1], Frances Mair[2], Luciana Ballini[3], Christopher Dowrick[4], Martin Eccles[1], Linda Gask[5], Anne MacFarlane[6], Elizabeth Murray[7], Tim Rapley[1], Anne Rogers[5], Shaun Treweek[8,9], Paul Wallace[10], George Anderson[2], Jo Burns[7] and Ben Heaven[1]


Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory

DEBATE Open Access

Carl May
Newcastle Un

Tracy Finch
Newcastle Un

Normalisation process theory: a framework for developing, evaluating and implementing complex interventions

Elizabeth Murray[1*], Shaun Treweek[2], Catherine Pope[3], Anne MacFarlane[4], Luciana Ballini[5], Christopher Dowrick[6], Tracy Finch[7], Anne Kennedy[8], Frances Mair[9], Catherine O'Donnell[10], Bie Nio Ong[10], Tim Rapley[7], Anne Rogers[8], Carl May[11]

Implementation Science

Research article

Open Access

Development of a theory of implementation and integration: Normalization Process Theory

Carl R May*[1], Frances Mair[2], Tracy Finch[1], Anne MacFarlane[3], Christopher Dowrick[4], Shaun Treweek[5], Tim Rapley[1], Luciana Ballini[6], Bie Nio Ong[7], Anne Rogers[8], Elizabeth Murray[9], Glyn Elwyn[10], France Légaré[11], Jane Gunn[12] and Victor M Montori[13]

May *Implementation Science* 2013, **8**:18
http://www.implementationscience.com/content/8/1/18

IMPLEMENTATION SCIENCE

DEBATE Open Access

Towards a general theory of implementation

Carl May

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Implementation, context and complexity

Carl R. May[1,2,3*], Mark Johnson[2,4] and Tracy Finch[5]

Abstract

Background: Context is a problem in research on health behaviour change, knowledge translation, practice implementation and health improvement. This is because many intervention and evaluation designs seek to eliminate contextual confounders, when these represent the normal conditions into which interventions must be integrated if they are to be workable in practice.

Discussion: We present an ecological model of the ways that participants in implementation and health improvement processes interact with contexts. The paper addresses the problem of context as it affects processes of implementation, scaling up and diffusion of interventions. We extend our earlier work to develop Normalisation Process Theory and show how these processes involve interactions between mechanisms of resource mobilisation, collective action and negotiations with context. These mechanisms are adaptive. They contribute to self-organisation in complex adaptive systems.

Conclusion: Implementation includes the translational efforts that take healthcare interventions beyond the closed systems of evaluation studies into the open systems of 'real world' contexts. The outcome of these processes depends

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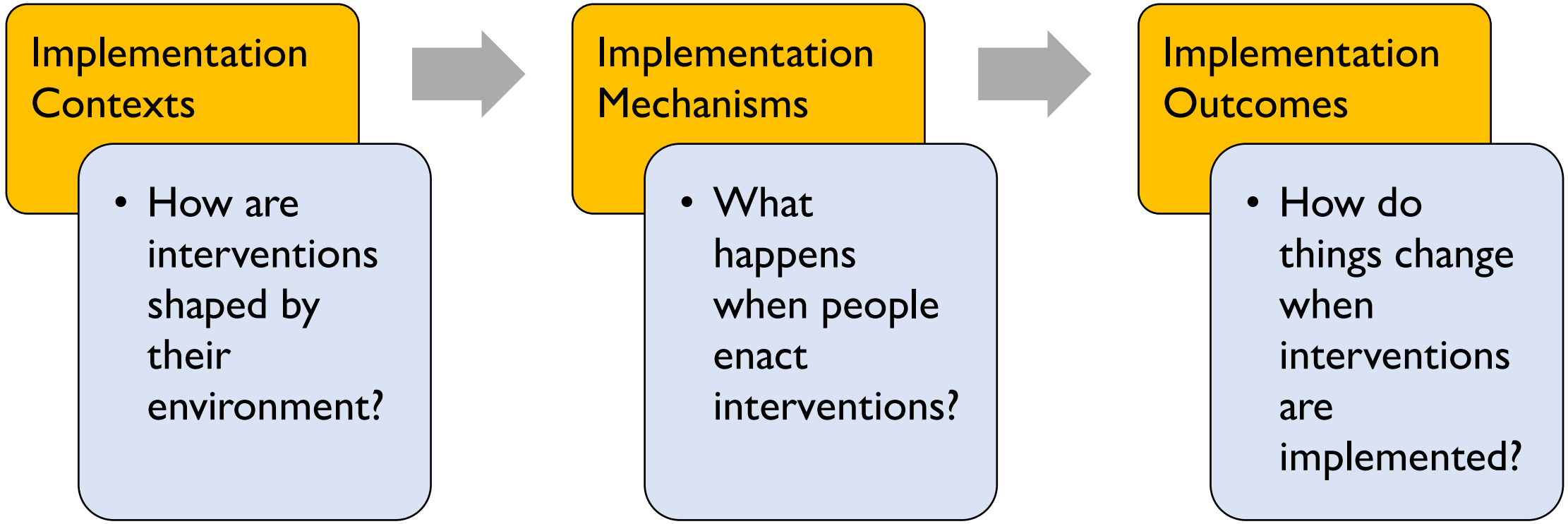
Iterations of NPT since 2006 developed 149 identifiable theoretical concepts – we rationalized and simplified these into a workable process model in 2021.



NPT Coding Manual

Not just a coding manual, though. It consolidates & simplifies NPT around a contexts → mechanisms → outcomes way of analyzing implementation processes.

May *et al. Implementation Science* (2022) 17:19
https://doi.org/10.1186/s13012-022-01191-x

Implementation Science

METHODOLOGY Open Access

Translational framework for implementation evaluation and research: a normalisation process theory coding manual for qualitative research and instrument development

Carl R. May[1*], Bianca Albers[2], Mike Bracher[3], Tracy L. Finch[4], Anthony Gilbert[5], Melissa Girling[4], Kathryn Greenwood[6], Anne MacFarlane[7], Frances S. Mair[8], Christine M. May[9], Elizabeth Murray[10], Sebastian Potthoff[11] and Tim Rapley[11]

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When we're using a coding manual we're most often trying to make sense of our data in the light of a theory or framework.

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May et al. Implementation Science (2022) 17:19
https://doi.org/10.1186/s13012-022-01191-x

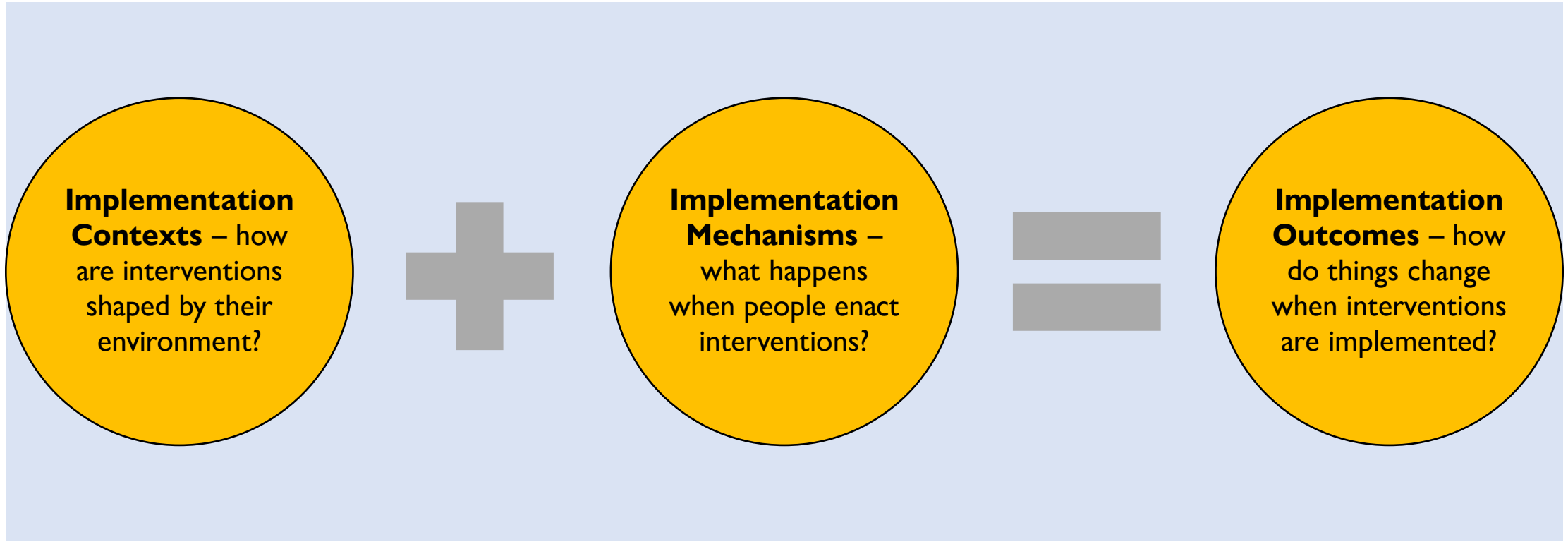
Implementation Science

METHODOLOGY Open Access

Translational framework for implementation evaluation and research: a normalisation process theory coding manual for qualitative research and instrument development

Carl R. May[1*], Bianca Albers[2], Mike Bracher[3], Tracy L. Finch[4], Anthony Gilbert[5], Melissa Girling[4], Kathryn Greenwood[6], Anne MacFarlane[7], Frances S. Mair[8], Christine M. May[9], Elizabeth Murray[10], Sebastian Potthoff[11] and Tim Rapley[11]

Simplification and recalibration of conceptual structure of the theory: reduced from 149 theoretical concepts to12 primary constructs & 16 subconstructs.



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Context is troublesome: it goes on forever in every direction.

When we use NPT, we always start by asking *what the work is? So, what's the work of making contexts, and how do they form process ecologies for action?*

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Implementation **Contexts**:

are patterns of social relations and structures that unfold over time and across settings. They make up the implementation environment.

Strategic Intentions: How contexts shape the formulation and planning of an intervention and its components.	**Adaptive Execution:** How contexts affect the ways in which an intervention and its components are made workable in practice.
Negotiated Capacity: How contexts affect the ways that an intervention and its components are integrated into practice.	**Organizational Framing:** How contexts change through enacting an intervention and its components.

The work that people need to do to enact new practices

What is the work that people need to do to enact new practices?

When we use NPT, we always start by asking *what the work is? So, what do people need to do to bring a treatment intervention or an organizational innovation into play?*

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Implementation mechanisms

Implementation Mechanisms motivate and shape implementation processes and are revealed through purposive social action—**collaborative work**—that involves the investment of personal and group resources to achieve goals

Coherence-building (people work together to understand and plan the activities that need to be accomplished to put intervention components into practice)	**Cognitive Participation** (people work together to **create networks of participation and communities of practice** around intervention components)
Collective action (people work collaboratively to enact intervention components)	**Reflexive monitoring** (people work together to appraise interventions and their components)

What changes as a result of all that implementation work?

Implementation outcomes are always greater than the sum of their metrics.

When we use NPT, we always start by asking *what the work is? So, what is the new work that an intervention or innovation calls for, how does it change the ways that people work with each other?*

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Implementation outcomes:

Outcomes are the practical effects of implementation mechanisms at work

Intervention Performance: How material practices change as the result of interventions and their components being operationalized, enacted, reproduced, over time and across settings.	**Relational Restructuring**: How working with interventions and their components changes the ways people are organized and relate to each other.
Normative Restructuring: How working with interventions and their components changes the norms, rules and resources that govern action.	**Sustainment/ Normalization**: How interventions and their components become incorporated/embedded in practice.

How do we keep an intervention going long after the implementation phase has ended?

Implementation contexts, mechanisms, and outcomes are generative of *continuous translational action.*

When we use NPT, we always start by asking *what the work is? So, what's the work that people need to keep doing to keep an intervention or innovation in play, long after it has been embedded in everyday practice?*

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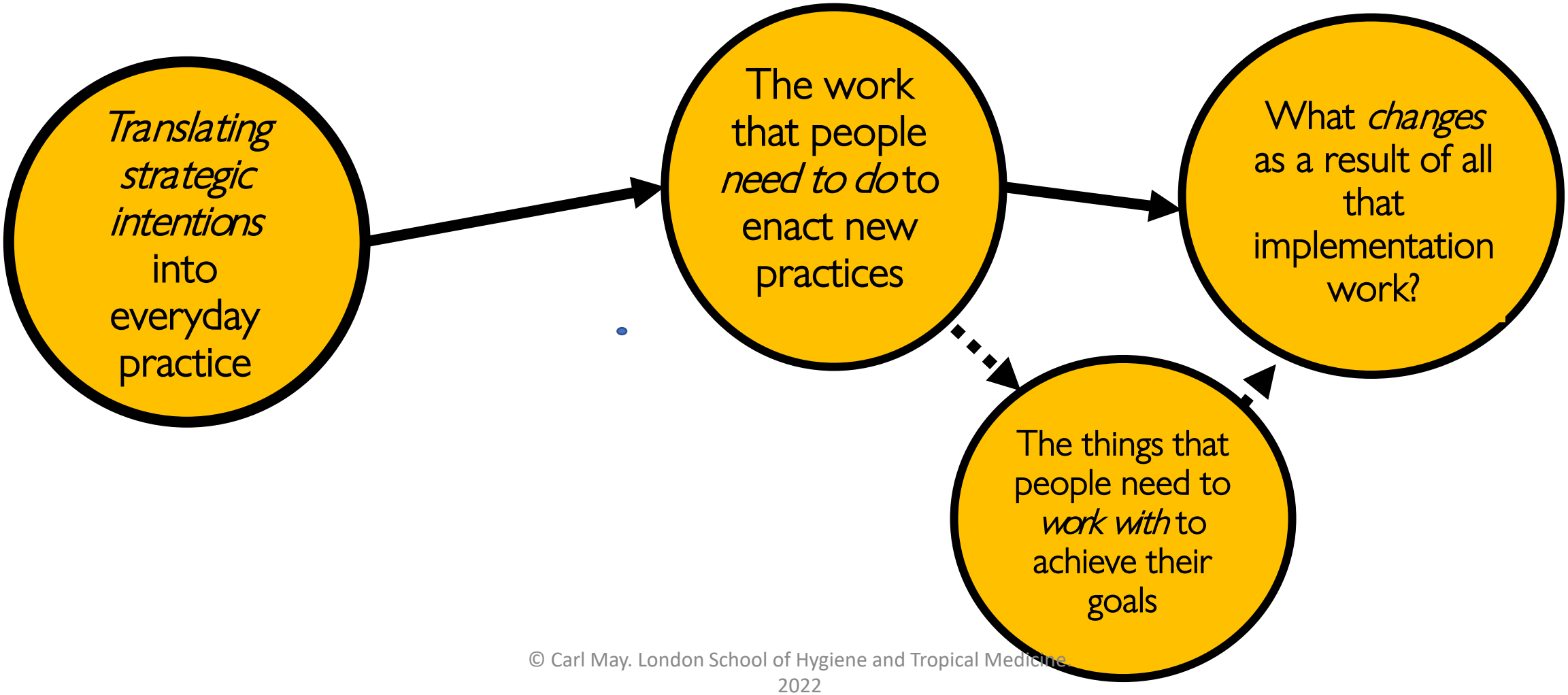
NPT focuses on what is happening *in practice*



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The NPT coding manual is a tool to *assist thinking*

- Not all data will 'fit' any particular theory.
- 'Surprises' or 'deviant cases' are often the most important discovery.
- It is *not* the purpose of a coding framework to verify the underpinning theory.

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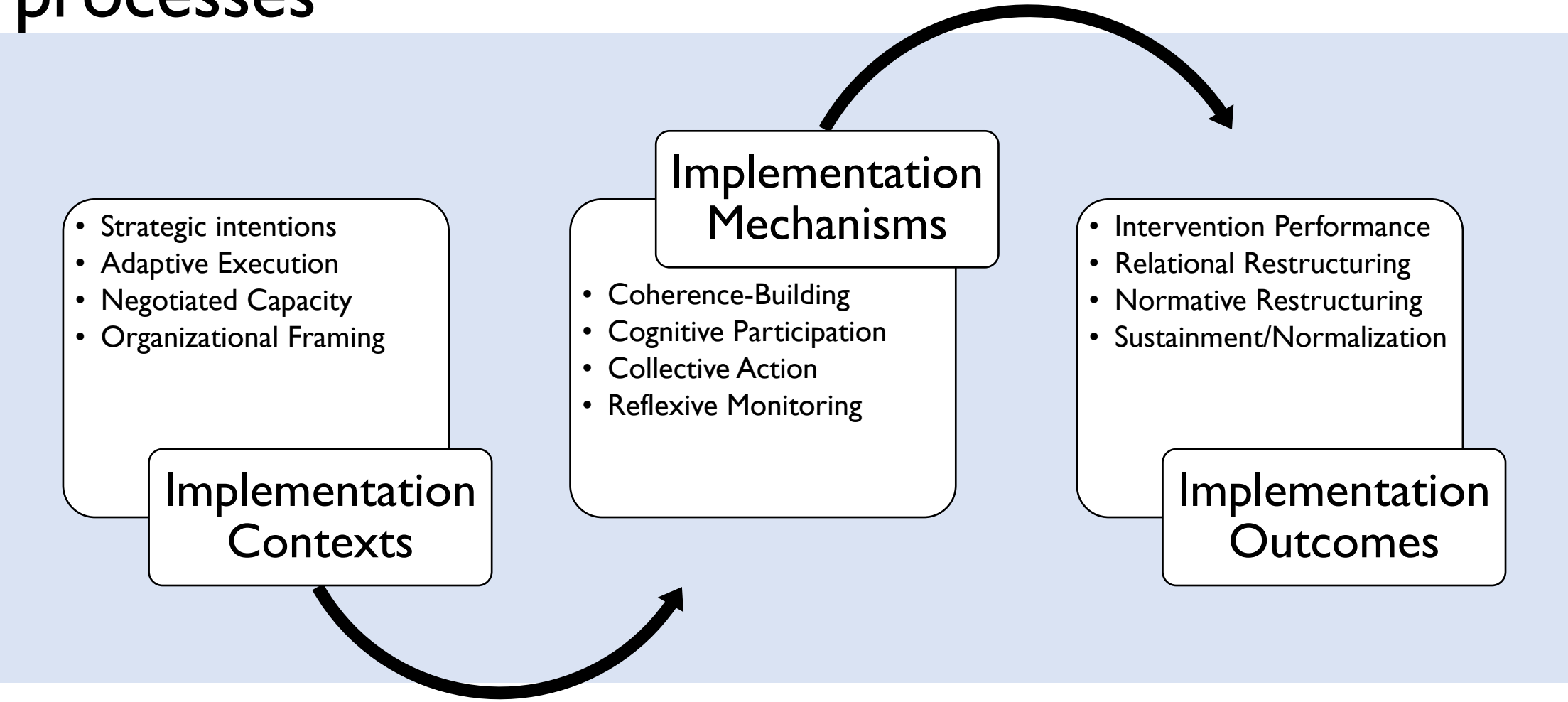
NPT coding manual clearly describes mechanisms that motivate and shape implementation processes



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Theory informed qualitative investigation is useful when it…

Provides a rational (and empirically supported) framework for both evaluation and implementation.

Supports transferability and generalization of interventions in practice.

Explains why, how, and for whom, complex interventions work

Offers robust and rigorously developed strategies for successful implementation

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FUNDED BY
NIHR | National Institute for Health Research

This independent research was funded by the National Institute for Health and Social Care Research (NIHR ARC North Thames). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Grateful acknowledgements to *many* co-authors and collaborators

Thank you for your kind attention

Questions?

Email me at carl.may@lshtm.ac.uk

Follow me on Twitter @CarlRMay

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Coming soon…

Complex Interventions and service innovations: the COMPLETE framework for patient-centered and justice-oriented design

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