

Introductory comments

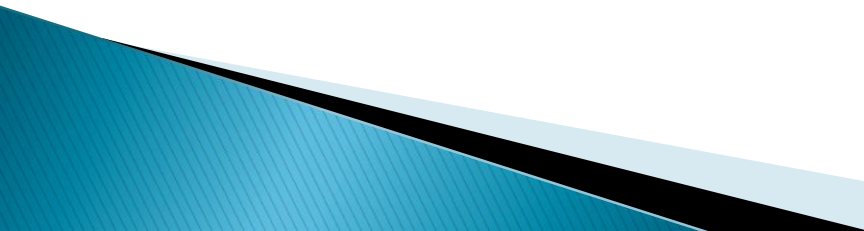
Kate Gerrish

Implementation: approaches

▶ Traditional models

- Translation of research findings into practice linear and technical process
- Responsibility on individual practitioners to use evidence in practice

▶ Contemporary models

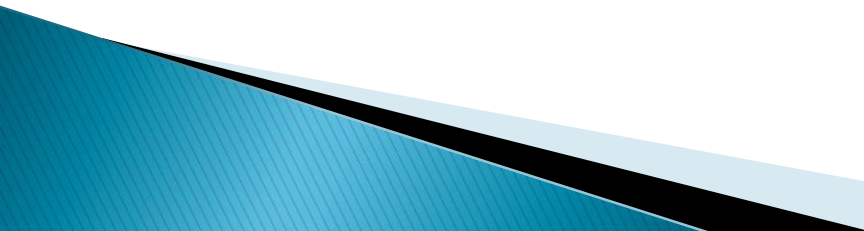
- Recognise that knowledge use is complex and mediated through multiple factors
 - Often adopt a multilevel approach to change that includes the individual, group/team, organization, and larger environment/system level
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Implementation – a complex process

- ▶ Different players use different approaches to changing clinical practice
 - most of these approaches are based on beliefs rather than on scientific evidence
- ▶ Implementing such change seldom entails a single action; it usually demands a combination of different interventions
- ▶ Inconclusive evidence of the effectiveness of implementation strategies
- ▶ Evidence-based practice should be complemented by evidence-based implementation

Eccles 2007

Implementation: the challenge

- ▶ Need for more robust evidence of effectiveness of interventions
 - Kate Seers
 - ▶ Harnessing the capacities of academia
 - Kate Farley & colleagues
 - ▶ Ensuring clinical engagement
 - Brendan McCormack
 - ▶ Pulling some issues together
 - Jo Rycroft-Malone
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Implementing evidence into
practice using different
approaches: methodological and
practical strengths & challenges

Evaluating the effectiveness of implementation strategies using randomised controlled trials

Kate Seers

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School of Health & Social Studies
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Why Randomised Controlled Trials?

- “Randomised controlled trials, when appropriately designed, conducted and reported, represent the gold standard in evaluating healthcare interventions.”

Schulz et al (2010)

- “RCTs are the most rigorous way to evaluate the effectiveness of interventions regardless of their complexity”

Oakley et al (2006)

Types of RCTs

- Pragmatic
 - Effects of an intervention under real world conditions
- Explanatory
 - Effects of an intervention under ideal conditions

From Schwartz & Lellouch (1967)

Advantages of RCTs

- Can determine probability of cause and effect via:
 - Random allocation that is concealed
 - Blinding
 - Treated equally except for intervention
 - Intention to treat analysis
 - Estimate size of difference in predefined outcomes between groups

Sibbald & Roland (1998)

RCTs for all questions of effectiveness?

- Drug trials – clear that appropriate
- Complex interventions – more issues
 - What are the active ingredients?
 - What is the “dose”?
 - How standardised can it be?
 - Key other factors affecting – complex intervention into a complex system

Can you standardise?

- “There are specific difficulties in defining, developing, documenting, and reproducing complex interventions that are subject to more variation than a drug.”

What are you standardising?

- Must “consistently provide as close to the same intervention as possible”

(Campbell et al 2000)

– BUT could define by function rather than form

(Hawes et al 2004)

Need to consider

- Intervention content – fully describe
- Intervention delivery
- Contexts
- Intervention fidelity
 - So know if failed as poorly implemented or not effective

Three RCTs implementing evidence

- Postoperative Pain
 - Implementing an analgesic league table
- Perioperative fasting
 - Implementing a fasting guideline before surgery
- Continence
 - Implementing continence guideline in nursing homes

RCT Challenges – pain

- Impossible to standardise intervention
- Blinding is difficult to maintain - divulged
- Factors emerging as important but not assessed:
 - Motivation of staff, confidence with research evidence, competing demands, level of organisational support, role of link nurses, culture of the ward, amount of help and support required

RCT Challenges – fasting

- Perioperative fasting evidence (19 sites)
 - Standardisation - variation between sites in amount of support needed
 - Clinical work takes priority, so interventions not always fully implemented – fidelity an issue

RCT challenges - continence

- Blinding
- Random allocation
- Standardisation – creates tensions
 - Using designs coming from different world views
 - What are the limits of being pragmatic?!

Can complex changes be evaluated within an RCT?

- What about including process data – including qualitative data
 - Looking at implementation and setting helps interpret outcomes

Oakley (2006)

Qualitative studies alongside RCTs uncommon and often poorly integrated

Lewin et al (2009)

MRC Guidance on Complex Interventions (2008)

- “ensuring strict standardisation may be inappropriate; the intervention may work better if a specified degree of adaptation to local settings is allowed for in the protocol.”

Craig et al BMJ **337**:979-983

RCTs for Policy Interventions

- Use RCTs when ever possible
- At individual study level, non randomised studies may lead to different effect sizes, but this is unpredictable

Oliver et al (2010) Health Technology Assessment 14(16)

MRC suggestions

- Experimental designs to use:
 - RCTs
 - Cluster RCTs
 - Stepped wedge designs
 - Preference trials
 - N of 1 designs

MRC suggestions

- If experimental not possible:
 - Quasi experimental
 - Observational
- Researcher's responsibility to explain pros and cons of experimental and non experimental approaches and the trade-offs in settling for weaker methods

A different way?

- Should we stay with RCTs or consider other approaches?



- Oliver et al (2010)

So why am I still using RCTs?

- Perception that only way to demonstrate effectiveness
- Difficult to get funding for looking at effectiveness without using an RCT
- If use something else, will policy makers, other health care professionals and patients accept it as evidence of effectiveness?

Gold Standard?



Lessons Learnt

- If you are going to do an RCT, seriously consider embedding process data collection, including qualitative.
- Be very clear what sort of RCT you are doing (continuum, not either/or)
- Consider other designs
 - Interrupted time series, action research, RE
- Work with policy makers, health care professionals and patients about how to best explain design issues



TRiP-LaB

PUTTING RESEARCH TO WORK FOR LEEDS AND BRADFORD



*National Institute for
Health Research*

Translating **R**esearch into **P**ractice in **L**eeds and **B**radford

TRiP-LaB: The University of York

Kate Farley, Andria Hanbury and Carl
Thompson



Translating Research into Practice in Leeds and Bradford

- One of nine CLAHRCs nationally
- Academic and NHS partnership working
- Five themes: stroke, **child and maternal health**, mental health, addiction, and TRiP-LaB
- Increase adoption of evidence-based healthcare technologies in the local context
- Increase research impact by translating it into evidence based improvements



TRiP-LaB: the process

Theory: Diffusion of Innovation (Rogers, 2005): How can we understand variation in innovation uptake?

Context: Mapping context at the level of the individual practitioner, their team, the organisation and the innovation itself

Multi-faceted approach: implementation strategies to the context



Theory

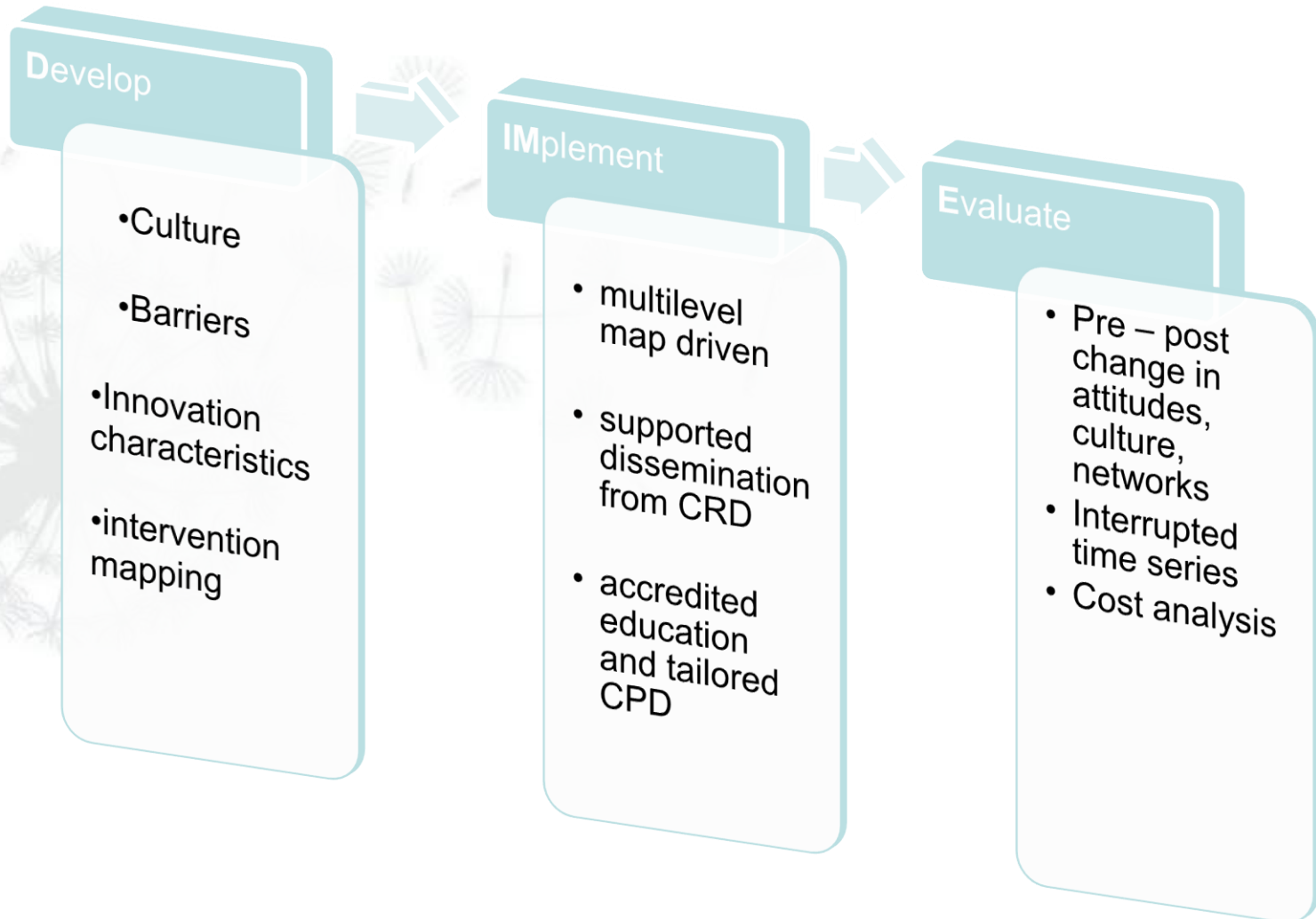
Diffusion of Innovation (Rogers, 2005)

Mapping processes of innovation adoption
(Greenhalgh et al, 2003)

Promoting Action on Research Implementation in
Health Services (PARIHS framework)



The **DIME** Approach





Context

Barriers to Implementation

TRiP-LaB Process

Innovation
characteristics



Mapping

Availability of data



Audit and self-report

Clinician values



Conjoint analysis

Local culture



Team Climate Inventory

Informal networks



Social Network Analysis



Implementation Strategies

How will we know if TRiP-LaB works?



Pre and post measures. Time series analysis

How do we manage contextual variation?



Multifaceted tailored interventions

Is it worth it?



Cost effectiveness and clinical outcomes



Where are we?

Maternal Mental Health in Bradford and Airedale

- Practitioner innovation preferences
- Mapping characteristics of innovations in the postnatal depression pathway
- Selection of innovation
- Development of survey tool to map contextual factors



TRiP-LaB

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*National Institute for
Health Research*

For further information please take a look at our website:

www.trip-lab.com



An Action Research Approach to Evidence Implementation and Evaluation

Brendan McCormack,

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Honorary Professor, University of Aberdeen

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Action research is a strategy that brings about social change through action, developing and improving practice and, at the same time, generating and testing theory.

Purposes of action research

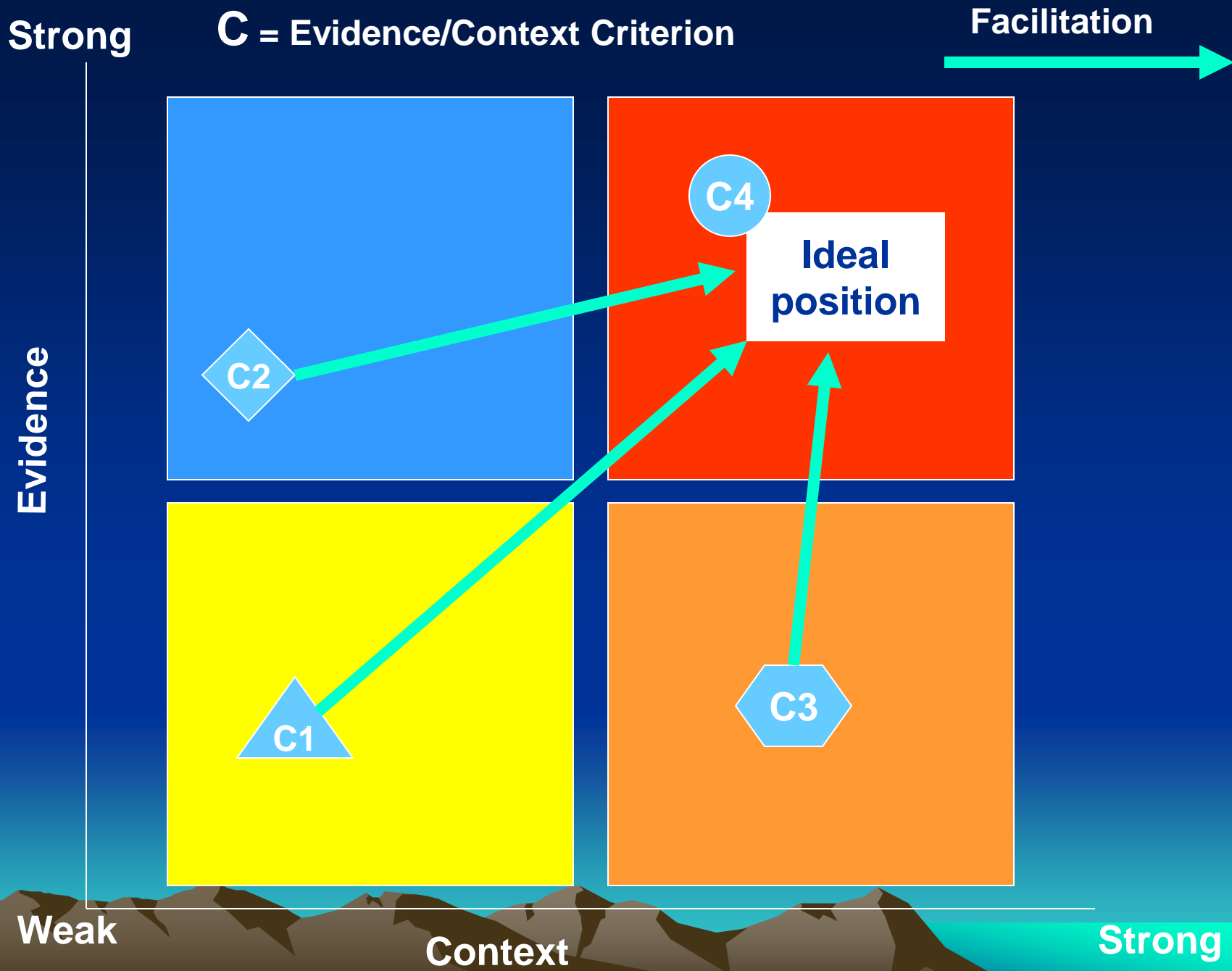
- Improving and developing better understanding of practice
- Introducing innovation and facilitating change
- Realising values in practice
- Facilitating professional learning and reflective practice
- Helping practitioners to research their own practice
- Democratising/reforming/politicising professional practice

.... And simultaneously generating and testing theory

.

Common characteristics

- Collaborative
- Inclusive
- Participative
- Future oriented
- Reflective/reflexive
- Evaluative
- Situational
- Value committed
- Brings about change and
- Generates theory grounded in practice



Facilitating changes in the practice context: using action research to uncover the significance of psychological safety – an example from pain management with older people

Dr Donna Brown, BHSCCT

This research was funded through the Northern Ireland Department of Health, Social Services & Public Safety (DHSSPS) Doctoral Fellowship Scheme

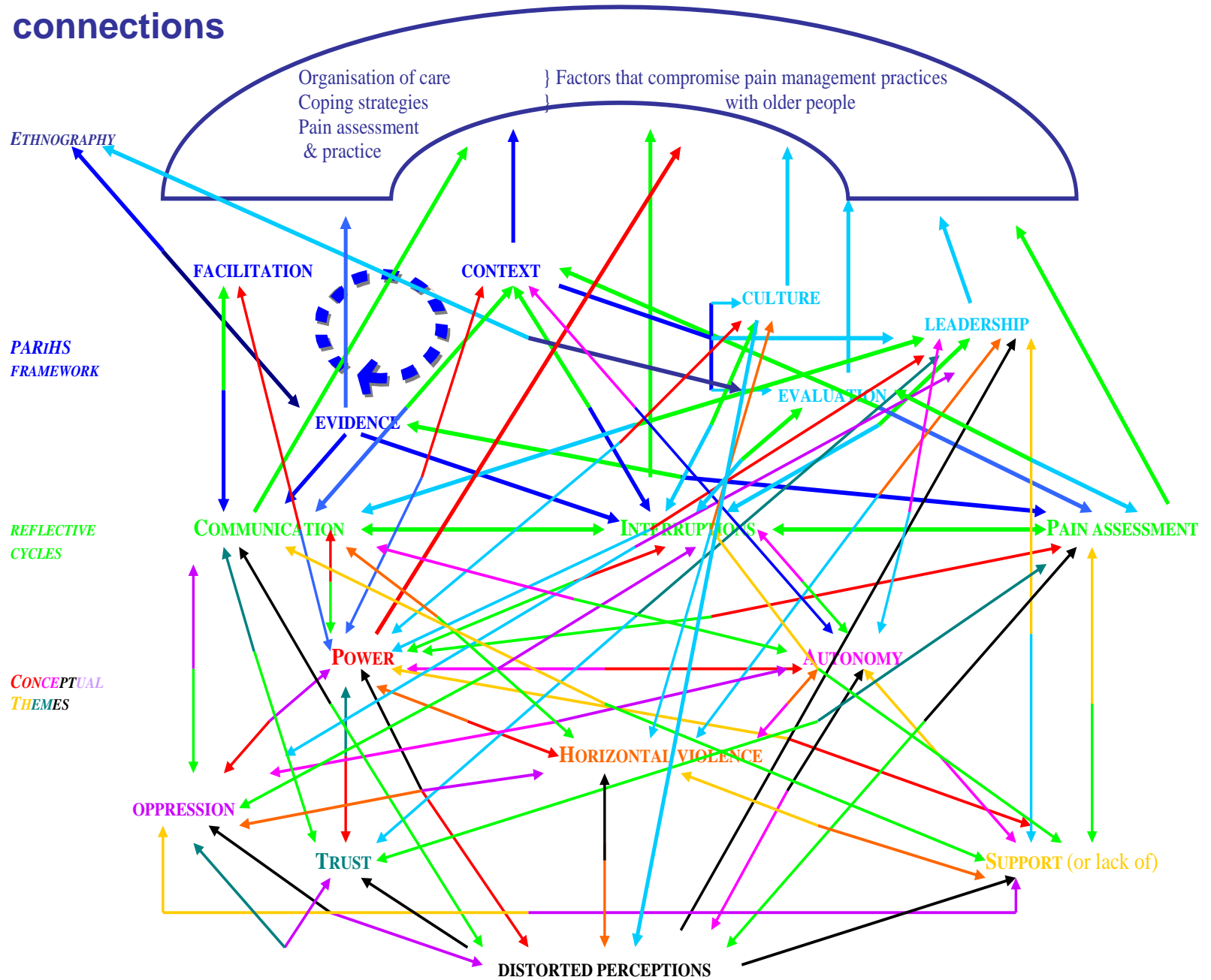
Psychological safety

People assisted to see possibility of solving a problem & learning something from it, without the loss of integrity or too much anxiety (Schein 2004).

What is the effect of a programme of action research on the practice of evidence-based pain management with older people following surgery?

- Implement and evaluate a programme of development that enables the team to critically analyse practice and put existing research into practice (**Evidence**).
- Develop effective team-working to enhance pain management practices with older people (**Facilitation**).
- Develop an understanding of the factors that inhibit or enhance pain management (**Context**).

All connections



- **Evidence:**

 - Development of pain algorithm

 - Psychological safety in the context of KU

- **Context:**

 - Development of a 'psychologically safe' environment

- **Facilitation:**

 - Effectiveness of the creation of 'meaningful critical social spaces' through reflexivity

- **Contribution to Theory:**

 - Presencing

 - 'Theory-U'

 - Psychological Safety



Older Persons Services National Practice Development Programme

Principal Investigators/Lead Facilitators

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- To engage in transformational change to prepare staff for culture change
- To extend the attributes of person-centred cultures of care for older people
- Extend key practice development and management interventions needed to achieve a person-centred care culture
- Systematically measure or evaluate outcomes on practice and for older people
- Introduce a specific model of person-centred practice in long term care/rehabilitation settings
- Enable local facilitators to work with shared principles, models, methods and processes in practice development work across older people's services

Over the 2 years:

- Small groups of staff formed practice development groups in each site to co-ordinate the work
- Sites had a regional facilitator and an internal facilitator working with the practice development group
- The group met for 1 day every 6-8 weeks and 2 hours in between
- The group followed a structured programme of development and evaluation over the two years.
- All staff in each unit were gradually involved in the practice development work along with the older people in each site in a range of ways

Evaluation (National) – 4 Time Points

- Observation of practice (WCCAT) – McCormack et al 2009
- Person Centred Nursing Index and Person Centred Caring Index - Slater et al 2009; McCormack et al 2008; McCance et al 2009
- Context Assessment Index (CAI) – McCormack et al 2008
- Resident Stories – Hsu & McCormack 2006

Action Evaluation (Local) - Continuous

- Resident Stories
- Environmental walkabouts
- Reflective groups
- Use of Local and National data to inform action planning / development cycles
- Action plan review and approval with management

- Knowing the person
- Knowing self as person/care worker
- Knowing own and others limitations
- Knowing the environment

(McCormack & McCance 2006; McCormack & McCance in press; McCormack 2004)

- Preparation for the role
- Staff support
- Knowledge of treatment decisions
- Communication and support
- Career development
- Role satisfaction
- Staffing and resources
- Commitment to the setting
- Workload
- Intention to stay in role

There was significant change in nurses perceptions of caring' as assessed using the Caring Dimensions Inventory (CDI). The data analysis shows that staff had shifted their views from one of seeing technical' aspects of nursing as caring, to a view that the 'non-technical' aspects of caring were more important. This was at a statistically significant level.

- **Hope and Hopelessness**
- **Choice**
- **Belonging and connectedness**
- **Meaningful relationships**

- **Evidence:**

- Use of multiple sources of evidence from empirical research, local audit/ information, reflections on practice, 'resident's voice'

- **Context:**

- Movement towards more person-centred cultures
 - Role of the Director of Nursing

- **Facilitation:**

- Internal/ external models
 - Structured context specific programming

- **Contribution to Theory:**

- Person-centredness
 - Practice development processes and outcomes

- ***Balancing the aspirations of AR with the reality of practice contexts:*** issues of ownership of evidence, co-construction of knowledge, and dealing with competing realities.
- ***Balancing and prioritising different forms of evidence:*** whilst all the studies had the intention of implementing empirical evidence, in all three, local information and audit findings were given greater priority by research participants.
- ***Balancing micro, meso and macro context issues:*** The degree of attention paid to these contexts played a significant role in how success was judged by different stakeholders.
- ***Balancing competing conceptions of success:*** In these projects, increased uptake of evidence was not a primary outcome, but evidence of a changing practice context that was more receptive to evidence was a key focus/outcome.

Pulling together some issues

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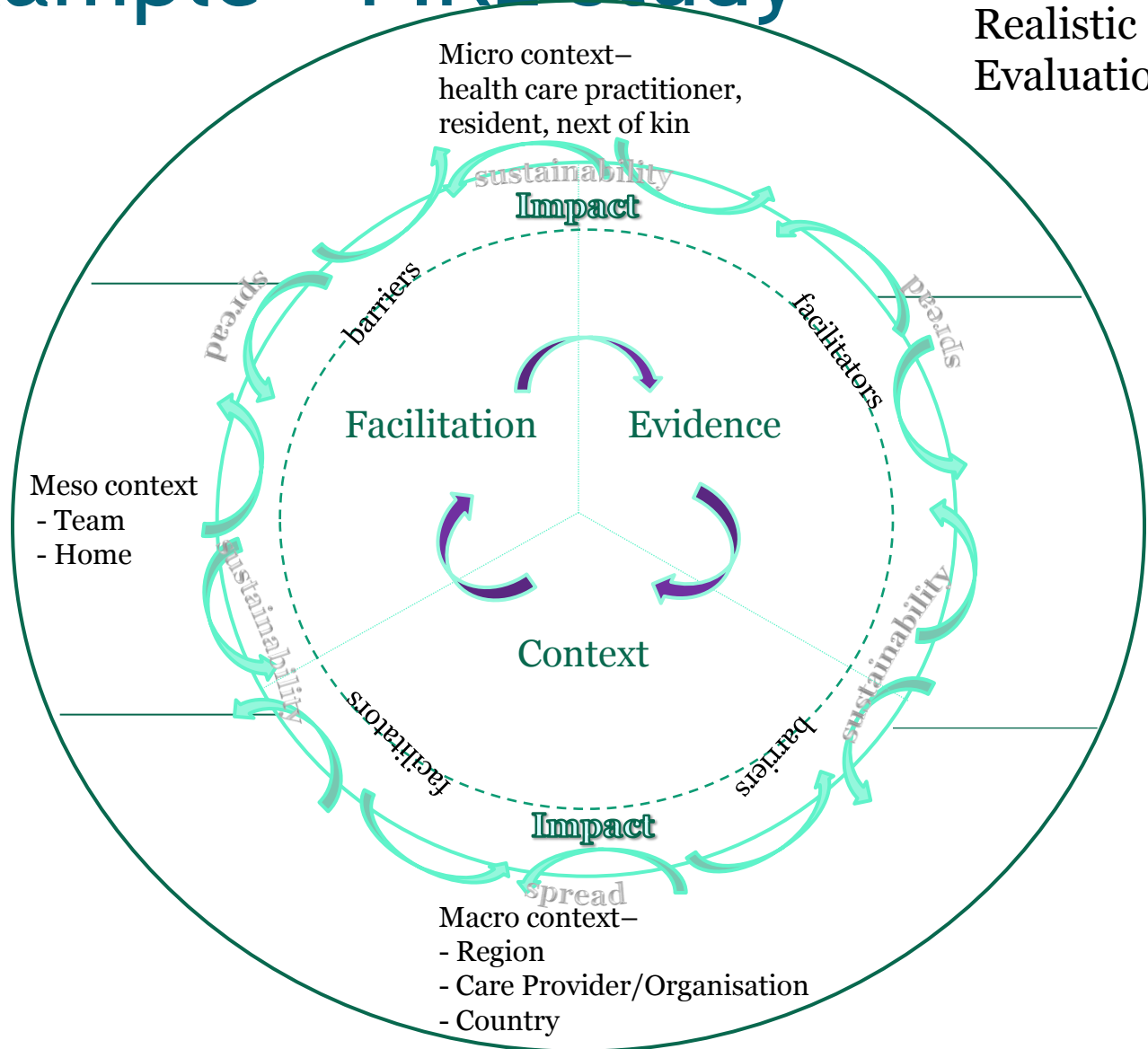


Methodological issues

- Approaches for capturing multiple factors, processes and interactions
- Should we not bother to ‘control’
- Study integrity
- Need for mixed methodologies and methods
 - Role of theory, frameworks
 - Creative approaches for capturing, integrating and synthesising findings

For example - FIRE study

RCT with embedded
Realistic (process)
Evaluation



Standardisation (vs) Tailoring

- Some evidence* to suggest better to tailor...
- However,
 - Methods to identify barriers & how to tailor interventions needs developing
 - Effectiveness of tailored compared to other interventions
- Implementation fidelity
 - Methods for tracing how interventions are played out

What are we implementing?

- Different starting points:
 - A piece of evidence, practice context.....
- Guideline, recommendations, research, audit....
 - Partial and complete implementation
- Evidence gets particularised – transformed – into local contexts
- How would we recognise use
 - Different types of use
 - Different types of impact
 - Mapping use

Engagement/involvement

- Implementation is a process, and therefore (usually) involves participant engagement
- What are the boundaries?
 - Support vs changing the nature of the intervention
 - ?compromise design
 - Participant approaches start with this as a key feature
- Competing agendas, ?and ownership

What works?

- Active ingredients of interventions
 - Need to build in approaches to being able to identify
- How much is enough? ('dose')
 - And how do we capture that?
- Underlying mechanisms of action?
 - What is the intervention designed to do?

Some ingredients

- Robust, theory led designs that facilitate a focus on processes and outcomes
 - At different levels
 - Fully integrated
- Scope for local particularisation – adaptation
 - Complete standardisation may be impossible
 - Process mapping therefore essential
- Flexibility
 - People will start from different places
 - Things won't go to plan(!)
- Appropriate level of resource