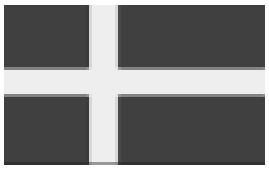
Research methods for understanding local improvements & helping spread

This PPT and other resources from:
http://homepage.mac.com/johnovr/FileSharing2.html



John Øvretveit,

Director of Research, Professor of Health Innovation and Evaluation, Karolinska Institutet, Stockholm, Sweden

What this is about

- Experimental evaluation good for
  - high certainty about effects of change on patient outcomes.
- Don’t answer decision makers questions about
  - Would it work here?
    - What was their situation – helping (or hindering)
  - How did they implement the change?
- VA research can help make more progress in improving safety and quality
- Non-experimental methods to help answer questions and assist spread.

This seminar overview

1 Subject
- Methods for studying improvements in the VHA system not involving researchers or QUERI – local unit and system-wide.
- Methods for studying spread

2 Problems and questions
- Some improvements catch-on or are implemented better
- Intentional spread slow and patchy
- Need to improve our “spread technology” – can research help?

3 Solutions
- Understand which improvements are “successful” and why
- Mixed method naturalistic research methods
- Researcher involvement in spread programmes different to QUERI

4 Your views and questions

Setting the scene - My experience and evidence

1) Effective QI =

1. Clinical change: single subject, single site, single project
   - Eg Improve beta blocker or diabetes care guideline adherance
2. Short-process improvement
   - eg within-laboratory process
3. Micro-system improvement
   - eg multiple changes within bounded clinical area

2) The real innovation is in implementation – local adaption and invention

How resourceful management and teams make improvements in resource constrained settings

With little outside assistance, little time divertable from clinical care, and few change skills

The Medical Management Centre
Karolinska Institutet

3) Challenges spreading (and sustaining)

<u>To get organisations to do changes</u> 1,2,3 – large scale spread programmes or administrative directive

- Limited evidence (Mittman 2004, Shojania & Grimshaw 2005, Schouten et al 2008)
- Variable implementation and outcomes (Øvrevteit 2005, 2009)

  (eg collboratives 10/20/30/40 rule; large scale QUERI?)
- What about others not in the programme?

If we know a change is effective

- Either QUERI-formed, or locally made-up (how to find these?)

How get better and wider implementation?

4) Need a "step change" in "spread technology"

- Better VSwit: Va System wide implementation technology
- "Throw over the wall" efficacy research of limited help

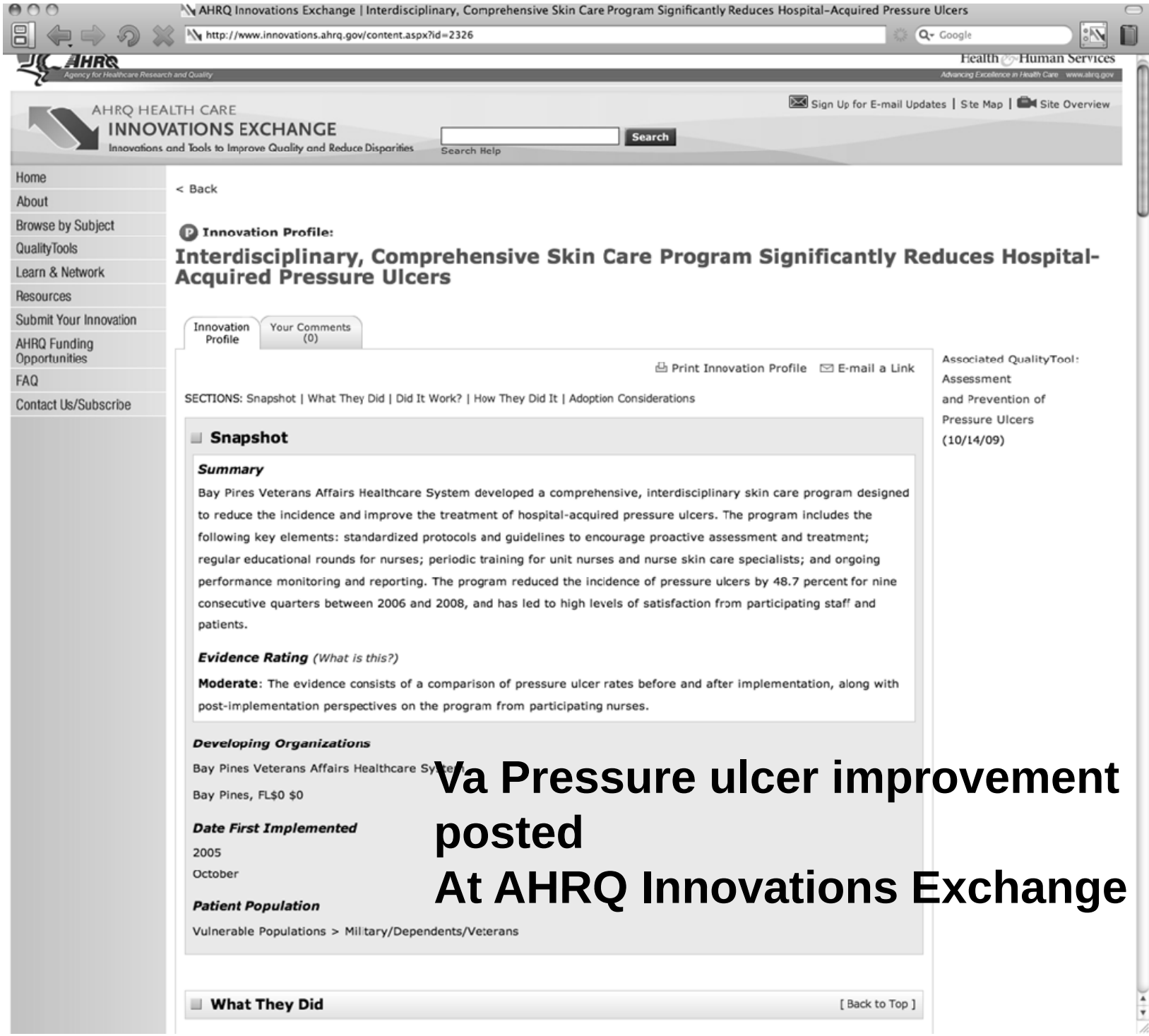
- Can research and researchers help find and spread effective changes?
- How best?
- What needs to change?

The Medical Management Centre
Karolinska Institutet

VHA NODs – where were the researchers?

- Practice/leader-led improvements not researcher-led
- Limited research description, evaluation or assistance
  - EHR development and implementation – where were the researchers and the publications?
  - Primary care programs system-wide
  - Increased preventive care & evidence-based guidelines adherence
  - VA performance measurement and incentives
  - New clinical programs: integrated care for returning soldiers, integration into primary care of mental health services
- *National program assists, but VISNs and facilities decide how to carry out the new ways of delivering care.*

The Medical Management Centre
Karolinska Institutet



Va Pressure ulcer improvement posted
At AHRQ Innovations Exchange

Observations

1 Difficult to evaluate large scale collaborative or other programmes

2 Can study intermediate results and describe causal chain

but uncertainty about effects on patient outcomes.

3 These programmes target social systems not patients – micro systems, facilities, larger organisations or regional systems (VISNs)

- Change mechanism works through how people perceive things
- Not biophysical natural causal processes Perceptions are causal mediators
- Can find out perceptions to help understand change

Observations

4 Quality and safety are systemic properties: depend on how the parts of each system works together

- One aim is to develop improvement capacity

5 The programmes themselves are complex social systems of actors and actions changing over time in a changing context.

Part 2: Problems and questions

Practical

- Need to speed spread of changes which improve quality
- Can use experimental to evaluate many improvements, to check if they do.
- But decision-makers want to know other things –

Decision-makers questions

- *Would it work here locally?*
- *How did they implement this change? (description)*
- *Which context factors helped and hindered implementation (attribution)*
- *In which range of settings and conditions did it work? (generalisation certainty)*
- *How do I adapt it, or the context, to implement it? (adaption)*

The Medical Management Centre
Karolinska Institutet

Can researchers help?

- Find and describe successful "locally-made up" improvements or administratively directed ones (diffusion)
- Describe intentional-spread programmes (ISPs)
- Evidence of what helps and hinders successful spread
- Give "spreaders" feedback for real time improvement in doing spread.

Need spread research assistance programme (SRAP) to help develop VHA System-wide implementation technology

The Medical Management Centre
Karolinska Institutet

Research-oriented questions

- What helps and hinders successful spread (eg some “barrier”-research)?
- What explains successful natural or administrative diffusion of some improvements?
- How do we conceptualise and describe large scale spread programmes?
  - Describing what happens between the plan and results
- How do we detect variation in sites,
  - adaptation of the intervention (e.g., guideline adaption)?
  - implementation methods (e.g., shorter training, EMR reminders)?
  - implementation fidelity and extent?
  - intermediate and end results?
- How do we synthesise the data to create valid and useful findings?

Research challenges

For studying system-wide intentional- or natural spread of different improvements

e.g., national collaborative, or administrative directive to implement X chronic care guideline

The Medical Management Centre
Karolinska Institutet

Can you grow pineapples in Sweden?

Seed

Gardener/planting & nurture

Climate / soil

Your change?

Change idea + Implementation actions + Context 0-5?
Evidence 0-5? - Local
0-5? - Wider

Distinguish

INTERVENTION	IMPLEMENTATION STRATEGIES	CONTEXT
Seed	*Planting*	*Soil and climate*
Effective treatment	Education Guidelines Audit and feedback Academic detailing	Organisational structure Culture Systems Financial system?
Effective organisation *Eg team organisation* *Care manager* *Or A* change idea	Breakthrough collaborative Implementation network	Organisational change support Culture Financial incentives
	Which effective for which intervention? *Classification of strategies?*	*Which features help and hinder which strategies/support which interventions?*

The Medical Management Centre
Karolinska Institutet

Emerging evaluation paradigm for CSIs

- Qualitative data on outcomes (participants valuations)
  - Multiple stakeholder perspectives of “effectiveness”, “success”
- Observational description of programme implementation in real setting (multiple data methods, & who, did what, when)
- Assessment of influence of context – which factors H&H
- Understanding of outcomes influenced by many factors, one of which is the CSI
- Description of CSI/programme-context interactions and dependencies
- Bias towards objective of improvement rather than causality attribution and generalisation

Observations: the intervention / context debate

- Experimental separates intervention from context
- Focus on the intervention – effect if present or absent?

- But disconnect with Systems thinking
  - Safety a result of combination of conditions, not just one intervention
  - Improvements through changes at multiple levels (higher levels create the context for lower levels)
- Need methods to study multiple changes at different levels over time and relate to safety performance

Ways forward

1 Match method to question

2 Combined design

- Experimental and
- Parallel process evaluation

3 Naturalistic mixed method with programme theory (case study evaluation)

4 Changes in understanding, respect, skills and funding

FOCUS on 3) and examples

Question matched to design

Q1 In which range of settings and conditions did it work? (generalisation certainty)

Experimental testing & add descriptions

- selection of settings and conditions:
- selection is theory-informed eg pre-assessment for do “change ready” settings implement better and get better results?)

Question matched to design

Q2 How did they implement this change? (description)

Which context factors helped and hindered implementation (attribution)

- ***Multi method case study - examples***
- EMR implementation Kaiser and Karolinska
- 12 innovations in Swedish healthcare
- UK PSI study
- Context which helps and hinder patient safety improvements - Reviews of research

EMR implementation Kaiser and Karolinska

- Kaiser first try: 2 years, stopped, cost 1.2m$
- Karolinska: 1 year, under budget, generally welcomed
- Discovered explained by different implementation and contexts
- Modified Rogers diffusion of innovation theory was predictive
- Some value to implementers and science: empirical descriptions and theory.

Øvretveit,J Scott, T Rundall, T Shortell, S Brommels, M Implementation of electronic medical records in hospitals: two case studies, Health Policy 84(2007)181–190

Table 3: Presence of factors identified in previous research as important for successful EMR implementation

Factor important for implementation	Kaiser	Karolinska
The EMR System		
Ease of navigation, efficiency in use and accessibility	No	Yes
Physician acceptance and implementer's responsiveness to concerns	No	Yes
Absence of system failures		
No conflicting suitability (managerial/clinical)	No	Yes
	No	Yes
Implementation process		
User involvement in selection and development	Low	Yes
Education provided at the right times, amount and quality	Yes	Yes
Previous computer or EMR experience		
	Little	Yes
Leadership		
Strong management support	Yes	Yes
Physician champion	No	Yes
Resources		
Adequate people and financial resources	Yes	Yes
Organisation culture and climate		
Academic medical centre more change ready	No	Yes

One, of 12 innovations in Swedish healthcare

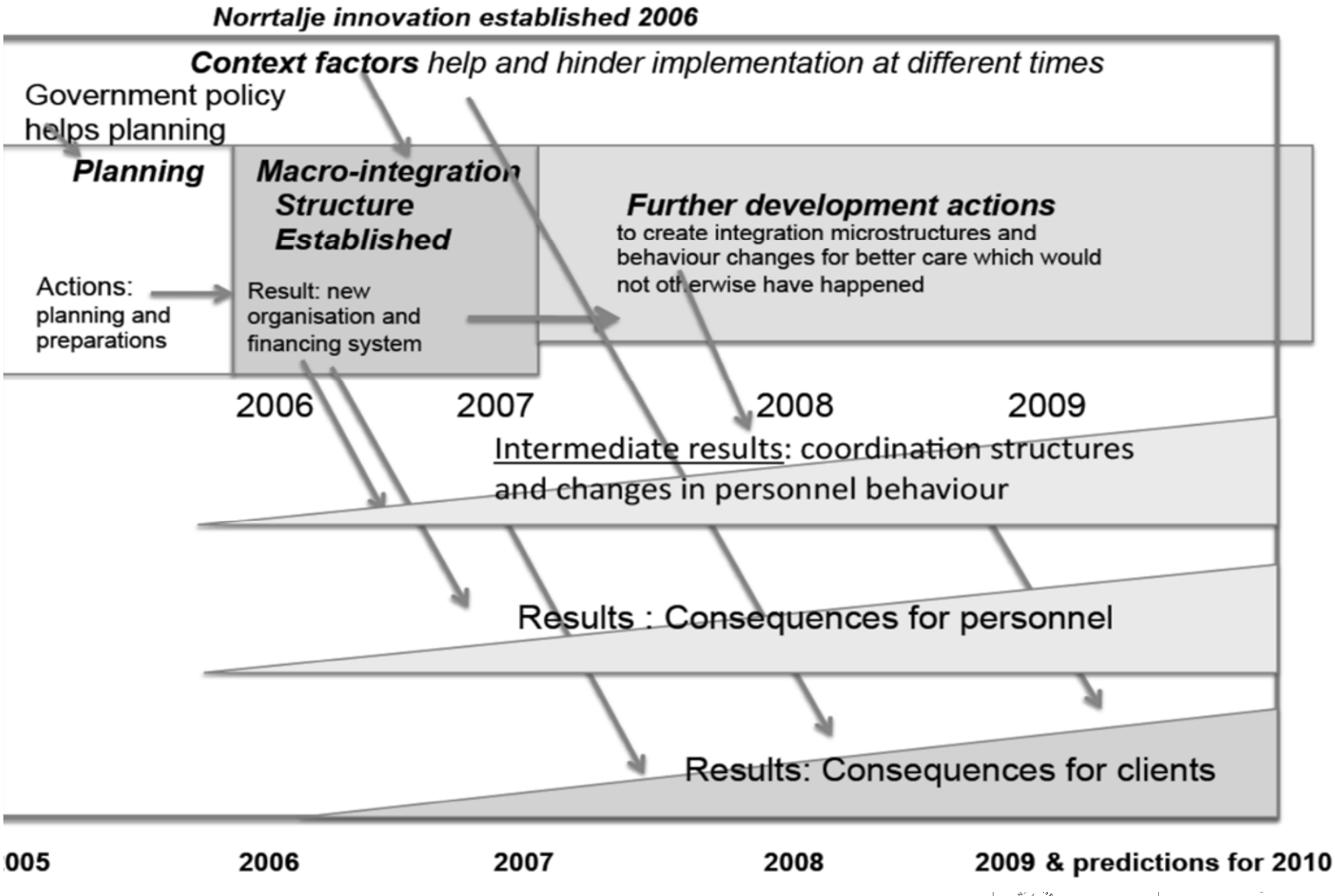
Integrated system: All services for 300k population merged:
Hospital, PHC and social care in one public company

- Corresponding merged Health and social care purchasing organisation
- Combined county and local political governing board.
- Case study described:
  - steps in change, conditions helping and hindering
  - before and after structures and clinical processes
  - effects on personnel work satisfaction

Cannot attribute changes in patient outcomes to the change

This case evaluation used in decisions of future changes

The Medical Management Centre
Karolinska Institutet



Karolinska Institutet

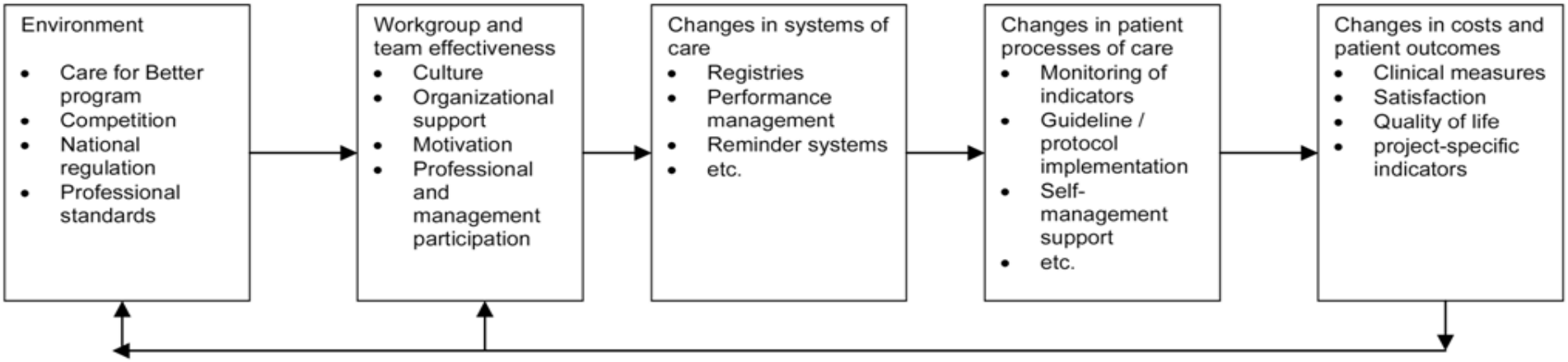
Case studies

Programme theory and concepts for describing change

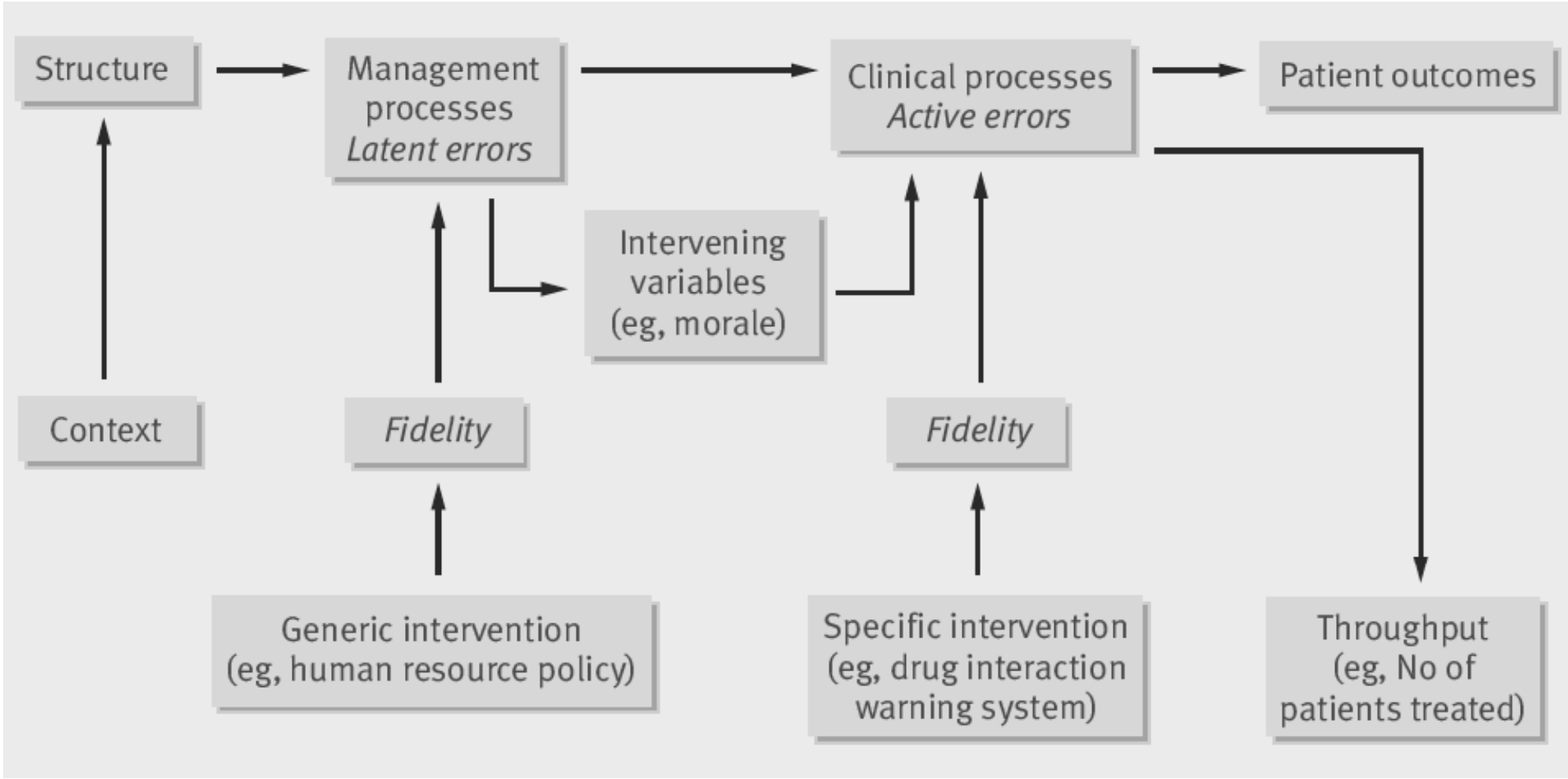
Programme theory

ideas about sequence of actions and situation factors leading to intermediate changes and output and outcome changes (their theory, our theory)

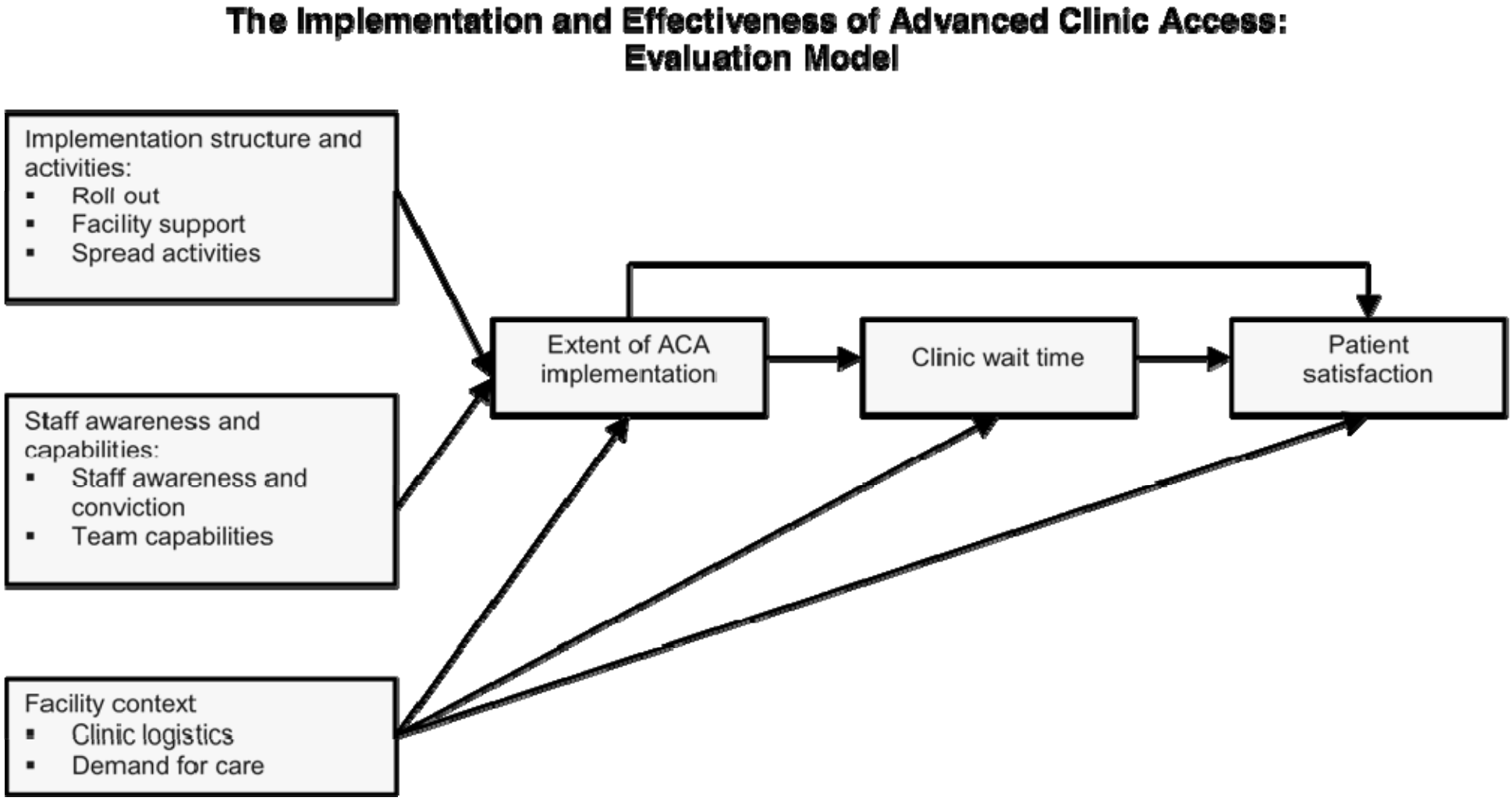
Cretin et al 2004 model



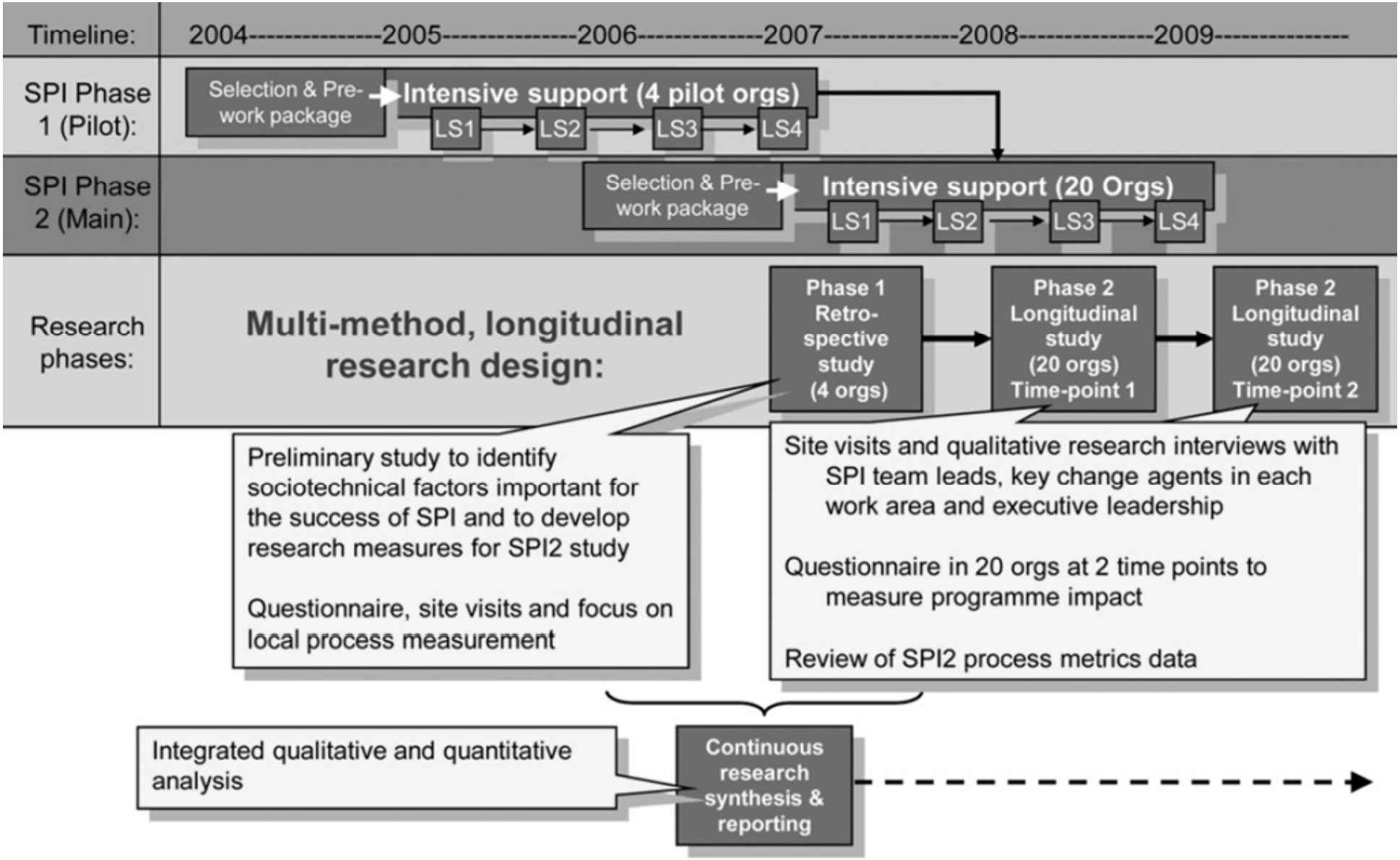
MRC CSI safety research model (Brown 2008)



VHA advanced access – evaluation model by COLMR

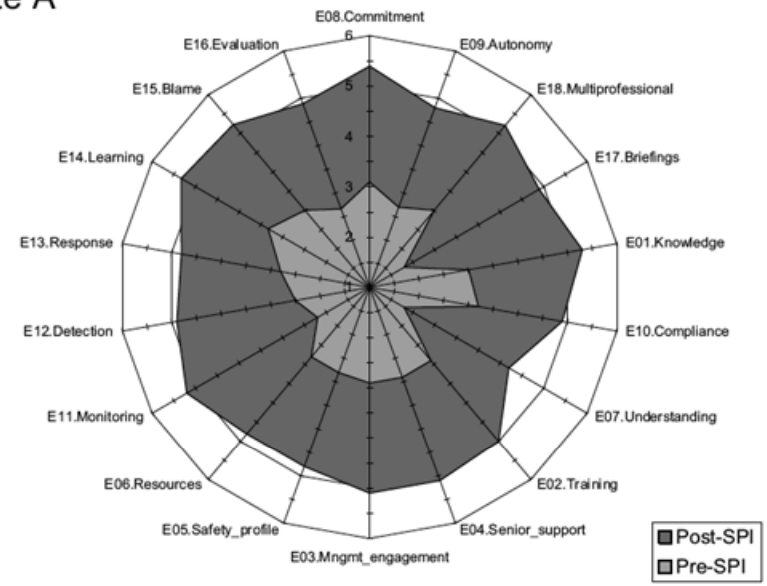


Naturalistic methods PSI study (UK 100k collaborative)

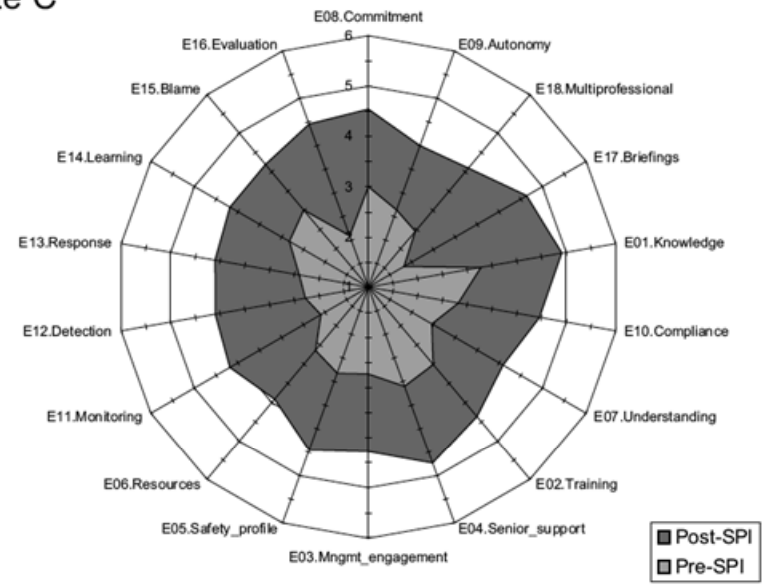


Naturalistic methods PSI study (UK 100k collaborative)

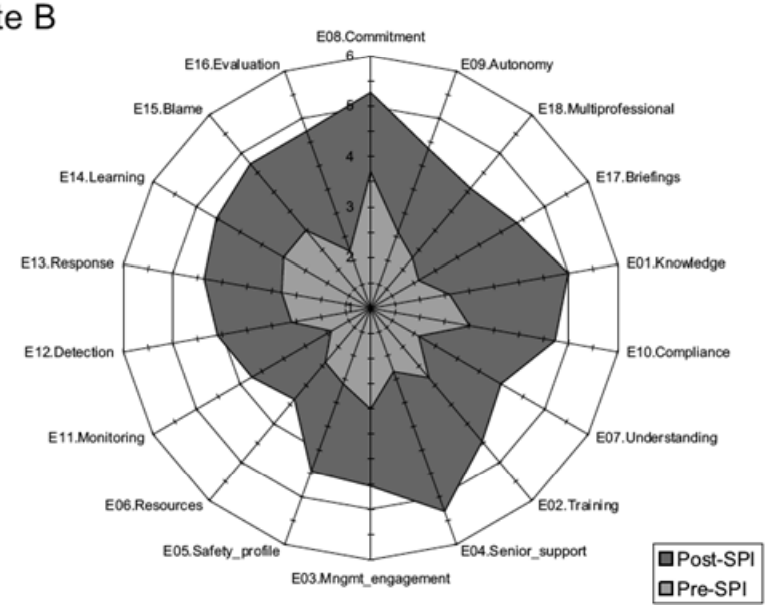
Site A



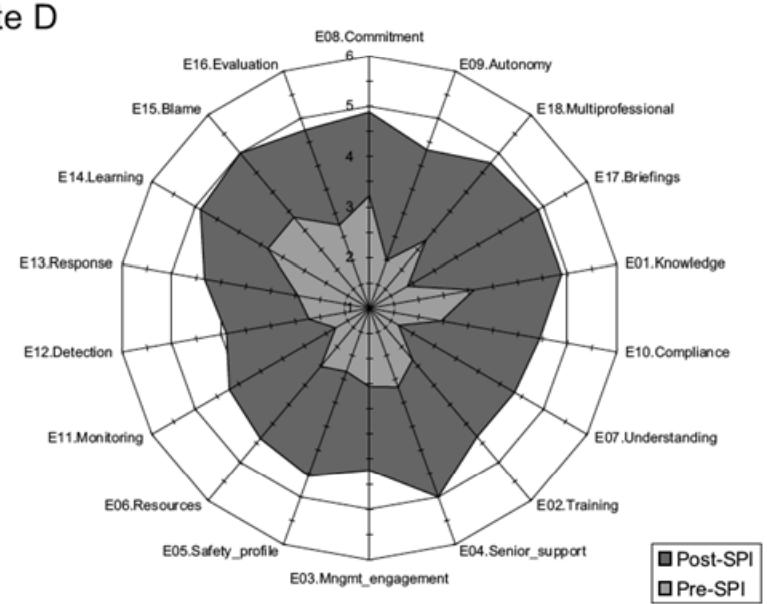
Site C



Site B



Site D



Karolinska Institutet

Tool are available for research describing and assessing context

Organisational readiness for change

- shared subjective sense of change commitment and change efficacy (Weiner 2009)

FOR Diabetes registry in community health centers

ORC high,

- staff skillfully and persistently take action to put a diabetes registry in practice and demonstrate more consistent, high-quality use of the registry.

ORC low

staff resist initiating change, put less effort into implementation, persevere less, and exhibit compliant registry use, at best. Registry likely to be intermittent, scattered, and uneven

Tool box for research - describing and assessing context

Organisational readiness for change

- Different from

Context receptiveness for change

– objective factors which influence change, often external

(Pettigrew et al 1992, Dopson et al 2002)

But does the best context for one intervention differ from best context for another intervention

E.g., context for hand hygiene intervention success

vs context for computer decision support intervention?

- Initial findings yes – from AHRQ PSP study

Contexts which helps and hinder patient safety improvements - Reviews of research

AHRQ funded Karolinska/RAND/Stanford/Johns Hopkins

- Five PSPs
- Evidence of context influences on implementation
- Designs and measures for researching this.

The Medical Management Centre
Karolinska Institutet

Summary so far

- Most research looks only at effectiveness of change
- Uses methods exclude context as confounders
- At best give description of context (eg reporting guidance SQUIRE)
- No theory of intervention influence pathway
- No theory of context
- Both help decision makers and implementer
- Some general frameworks of possible context influences on change implementation
- But likely different contexts for different change interventions

The Medical Management Centre
Karolinska Institutet

Common features of this research

- Intervention or change not a treatment
  - but a new service delivery model, system or type of organisation
- Intervention or change not fixed and standardised
  - but evolving intentionally and unintentionally
- Sometimes no control group or comparitor
- Context influences studied, not excluded by design
  - Some influences can be operationalised and measured
  - Some need qualitative exploration and understanding of how change participants interpret the influence
- Theory of "how it works" – models
- Weak on patient outcomes but shows pathway of changes
- Multiple data and perspectives about effects

The Medical Management Centre
Karolinska Institutet

Summary points

We have traded certainty about efficacy

for less knowledge about adaption, generalisation, implementation

and explanation of causal pathways

Other research needed

- Not experimental testing of practice change
- But observational documentation of successful developments

The Medical Management Centre
Karolinska Institutet

Other disciplines

- Developed evaluation methods to answer these questions
  - Public health and health promotion: causal pathways and theory of change
  - Programme evaluation, education and criminology: case study, realist evaluation
  - Social sciences and Business studies: case study evaluation and action research
- How would these methods be applied to answer improvers questions and build theory about improvement implementation in ordinary settings?

Ways forward?

1)Parallel implementation study to the experimental QUERI evaluation.

(QUERI – high certainty effective but widespread implementation less good)

2) Non experimental research of “naturally occurring developments” (NODs)

- The 3F approach: Find, Follow and Forward what works
- Observational “detective” research

Less objective certainty of effectiveness but good implementation lessons

Next – research methods for 2) and their uses

Summary

- Local developments – find evaluate and help spread
- Large scale programmes – spread technology
- Match method to question
- Some improvements can be evaluated using experimental. And parallel process evaluations.
- Others, and large scale changes need other methods – causal models and mixed methods

Summary

- ***Need Better VaSwit: Va System wide implementation technology***
- ***Research to study and explain spread and non-spread***
- ***Match methods to users question and the type of programme***
- ***Cutting edge developments in implementation research***
- ***Mixed paradigm, mixed methods***

Ways forward

1) Expand QUERI with Implementation studies parrallel to experimental.

2) Spread research assistance programme (SRAP)

Start a Find, Follow, Forward programme

Find successful improvements (and failures)

Follow: describe steps in development, context which helped and hindered, and different results

Forward to spread and study fate in other settings

tools to assess if others have the right conditions, tools for implementation, case study examples, experiential reports, implementation network

– Use Case study mixed methods, using context assessment frameworks

- Virtual QUERI centre for identifying evaluating and spreading service innovations VQSIs

The Medical Management Centre
Karolinska Institutet

Implications

- More flexible and tolerance. But know good from bad research for the question.
- Develop researchers to understand range
- More to specialise in mixed methods and implementation research.
- Methods to find local improvements and fund research

QUERI limitations

- Strong evidence of effectiveness – at research sites
- Spread requires destination services get assistance to design and carry out their own implementation
- QUERI evaluations give limited info on effectives in different situations or explanations for this
- Experimental methods not designed to

Reality check

Valid Assumptions?

- Little research into practice lead transformations of VHA?
- Research not useful to decision-makers implementers in other areas?
- QUERI research gives little info about implementation and conditions needed? Controls to assess effectiveness
- QUERI changes – limited spread?

Evidence for or against any of the above?

The Medical Management Centre
Karolinska Institutet

Comments on this view:

As researchers we too often try (and too often fail) to improve care through rigorous research,

while at the same time VA's clinical and administrative leaders are conducting numerous QI programs that succeed, or at least appear to succeed.

We (as researchers) need to help the policy/practice leaders understand if, and how, their programs succeed, but we (researchers) also need to learn from their strategies and successes.

This requires observational research that QUERI researchers (and too many grant reviewers) do not respect nor conduct.

Your reactions and questions

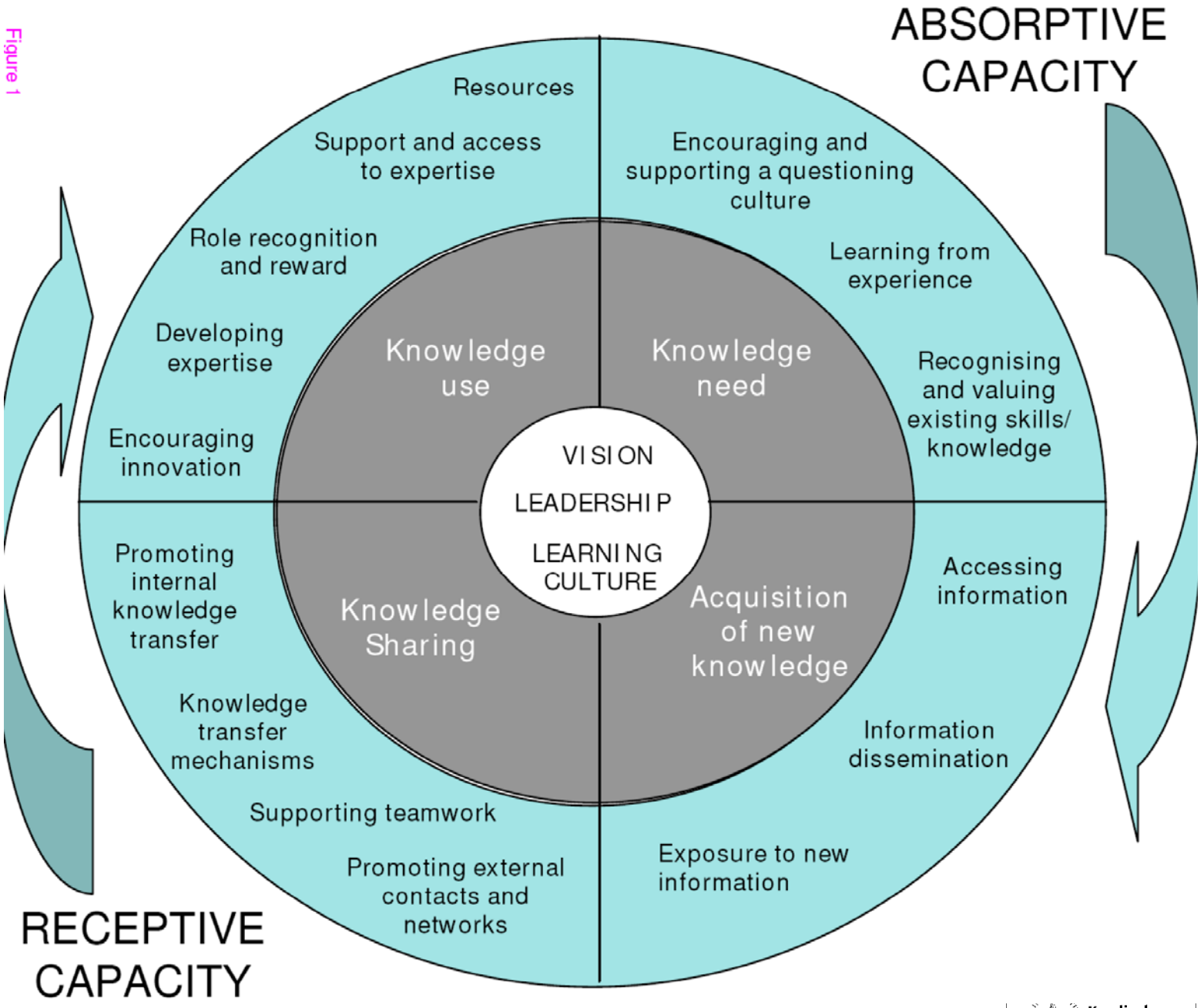
1. Any surprises…
2. Not certain about…
3. This could be useful…

DETAILS

Background: Note the French 2009 review

- Subject: implementing evidence based practice
- Approach: not individual clinician behaviour change, but social context and networks they are part of.
- Intervention highly dependent on social context
  - both context and intervention adjust
- Model they suggest for studying how context influences whether clinicians adopt EBPcs >>>

Figure 1


ABSORPTIVE CAPACITY
RECEPTIVE CAPACITY
Resources
Support and access to expertise
Encouraging and supporting a questioning culture
Role recognition and reward
Learning from experience
Developing expertise
Recognising and valuing existing skills/ knowledge
Encouraging innovation
Knowledge use
Knowledge need
VISION
LEADERSHIP
LEARNING CULTURE
Promoting internal knowledge transfer
Accessing information
Knowledge Sharing
Acquisition of new knowledge
Knowledge transfer mechanisms
Information dissemination
Supporting teamwork
Promoting external contacts and networks
Exposure to new information

French 2009 review

Categories and measures

- Climate:, *e.g.*, openness, respect, trust
- OL culture
- Vision
- Leadership
- Knowledge need
- Acquisition of new knowledge
- Knowledge sharing
- Knowledge use

Questions	Explanation	Research details
What is it?	Precise description of the change (intervention) and how the change was made (implementation).	Descriptive research of change as made in practice (not as planned) to document and describe what the intervention was (see different research reporting guidelines (eg SQUIRE). Use implementation assessment frameworks (eg REAIM)
Does it work, anywhere?	Efficacy: before/after difference on outcome measures which can be attributed to the change, at the study site for a (possibly) selected group. Efficacy for intermediate effects: does the change affect intermediate indicators (eg perceptions) in a causal pathway towards outcome measures.	Different experimental designs give different degrees of certainty that outcomes are due to the intervention and not something else (Internal validity) How many outcome measures and how to capture –ve outcomes to assess harm/benefit ratios/risks.
Will it work in my service?	Effectiveness in many different settings	(External validity or generalisability of research findings from study setting to others) Choose typical setting Do multiple studies in different settings Develop programme theory of how the change works through different influences and pathways, to help implementers think through if or how to get these changes. Develop theory of preconditions and context which most helps and hinders implementation Report "qualified generalisation": which range of settings could expect similar results for similar change under which circumstances, and which would not?
Can we afford it?	How much does it cost? Are there preparatory changes we need to make and how much do these cost?	Simple or full costing study.
How do we implement it successfully?	Selling: How do we sell it to the people who decide or need to cooperate? Starting: how do we introduce it? Spreading: how do we move it beyond a pilot or selective group? Sustaining: how do we maintain the change,	Descriptive studies of strategies and methods. Epi-intervention research designs studying intervention and implementation evolution in interaction with context.

Levels **Driver of change** (change originates from or is the responsibility of this level)	Intervention type (what is done to get the change)	Implementation method or strategy	Target entity and type of change (who or what is changed in which way)
National or regional		Financial: eg Changes to reimbursement Regulatory: mandates an intervention or an objective	
Health system		Same as above	
Institution		Policy change, training, CEO visits / spends time on it, new system support, new responsibilities, disciplinary procedures.	Change to who does what, relations, information flows (structure), how work is done, methods used, rules and procedures, (process), attitudes and unwritten norms (culture)
Unit	Multi level: multiple changes aimed at patients, providers, team culture, financing and regulation (eg collaborative assisted by higher levels)		Change to who does what relations, information flows, (structure), how work is done, methods used, rules and procedures, (process), attitudes and unwritten norms (culture)
Team	Iterative: change adjusted in different phases using feedback (eg medication adjustment; QI PDSA)	Training; leaders actions and supervision, checklists,	Change to who does what relations, information flows, (structure), how work is done, methods used, rules and procedures, (process), attitudes and unwritten norms (culture)
Clinician	Multiple simple: two or more actions action (for healthcare: VAP bundle, CLABSI bundle; for patient: surgery and chemotherapy)	Training, checklist, performance feedback, peer influence	Change to behaviour; attitudes; values
Patient	Simple: one action (for healthcare: hand hygiene, use SBAR; for patient treatment: one medication; amputation)	Training, checklist, performance feedback, peer influence	Change to bio-physiology; behaviour; attitudes; values

Pain medication	Does it work?	Standardise the treatment to each patient Compare to no treatment/placebo Exclude other factors Measure outcomes – are changes to these measures associated with presence/absence of the treatment?	
Pain medication improvement	Does it work	Are systems and supports changed? Do providers change their behaviour? Are patient outcomes better	Describe the intervention Measure stages in the causal pathway
Implementing a change	What did they do? Was this strategy effective to get the change?	Details of actions taken at different times (method/strategy for the change)	
Conditions which help and hinder	Could we do this?	Which influences help and hinder ordinary services to make the change (patients similar, organisations different)	

Questions and criteria

Efficacy Does it work (anywhere)? Better than….	Certainty about effects (internal validity) Key issue = Attribution
Effectiveness What are the effects in typical settings?	Certainty about effects on intermediate and ultimate outcomes (external validity) Key issue = Generalisation
Implementation Sell Start Sustain Spread externally	What were the actions taken to make the changes? Which conditions helped and hindered? Key issue = Description and explanation

re 2: Evaluation Questions for PSP Effectiveness, Impact, or Success

EFFECTIVENESS Questions

- Is the study PSP more effective in reducing patient harm than an alternative?
- Is the study PSP more effective than usual care?
- Is the study PSP safe, economical, acceptable for patients experiencing it?
- Which types of settings are the PSP findings applicable to?
- How well does the PSP's logic model or theory explain study results?

If Yes, EFFECTIVENESS Study

IMPLEMENTATION IMPACT Questions

- What changes occur in the study organization/organizational unit during/after implementation of the study PSP? E.g.
  - ❑ Org's clinical performance, economy of care delivery, culture/attitudes
  - ❑ Unintended consequences, positive effects on the org and its providers
- ❑ To what extent were the organizational changes affected or predicted by contextual factors?
- ❑ How well did the study logic model or theories predict observed organizational changes?

If Yes, IMPACT Study

SUCCESS OF ADOPTION, SPREAD, OR SUSTAINABILITY Questions

- How fully was the study PSP implemented? E.g.
  - ❑ Model adherence
  - ❑ Penetration/reach within sites
- How easily did the study PSP spread? E.g.
  - ❑ Economy/costs
  - ❑ Speed/timeline for implementation
  - ❑ Number/proportion of organizations/units adopting
- How well/easily was the study PSP sustained? E.g.,
  - ❑ Maintenance costs/resources,
  - ❑ Duration of implementation
- ❑ Were implementation, spread, or sustainability influenced by contextual factors?
- ❑ How well did the study logic model/theory predict implementation, spread or sustainability?

If Yes, SUCCESS Study

The MMC-USA patient safety intervention study

Summary points

- QUERI focus - Does it work?
  - but not good answers to local questions.
- Tendency to require exact replication
- But know adaption needed, and likely not to work without some conditions
- Few changes context insensitive and exactly replicable
- Information lacking for implementers
  - If use “evidence” – mostly practitioner reports (AHRQ, IHI) or JC Journal,
  - But limitations in items reported and validity

Summary points

We have traded certainty about efficacy

for less knowledge about adaption, generalisation, implementation

and explanation of causal pathways

Other research needed

- Not experimental testing of practice change
- But observational documentation of successful developments

The Medical Management Centre
Karolinska Institutet

But does the best context for one intervention differ from another intervention

- E.g., context for hand hygiene intervention success

  vs context for computer decision support intervention?
- Initial findings yes:
- Four types of interventions – each requires different context

Four types of interventions – each requires different context

with possibly different implementation approaches and different assisting contexts

- Complexity and dynamism
  - Single simple intervention (to patient, to provider: eg written guide)
  - Multiple simple interventions (eg surgery and meds; QI bundles)
  - Multi-level interventions (eg NDL team, manager, region collabs)
  - Evolving adaptive interventions (eg QI programmes in health systems)

Other grouping for interventions:

- Focus of intervention:
  - individual (patient or provider); team; unit; organisation; health system.