

Researching the context of programmes to improve health and health care

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Purpose: methods for discovering how context affects implementation and outcomes of QI

After 1 hour – be able to explain

1 Three designs for evaluating interventions and implementation

2 Frameworks to guide data gathering

3 When and why to collect data about context

4 How to present data to customers for their use

Three designs for complex programmes

1 Experimental- & Process- Evaluations in parallel

2 Theory informed context sensitive observational evaluation (TI-CSOE)

3 Action evaluation

(for developing interventions iteratively)

Experimental Outcome Evaluation - Findings

- Guideline implementation 1 sore throat and 2 women with urinary tract infection (Norway 142 PHC Centres) Flottorp 2002
- Little change overall in these measured outcomes
 - use of antibiotics (sore throat only)
 - use of laboratory tests
 - use of telephone consultations
- Great variation between practices in amount of change:
- Next slide shows: % patients receiving antibiotics before and after intervention for controls and Exp PHCs

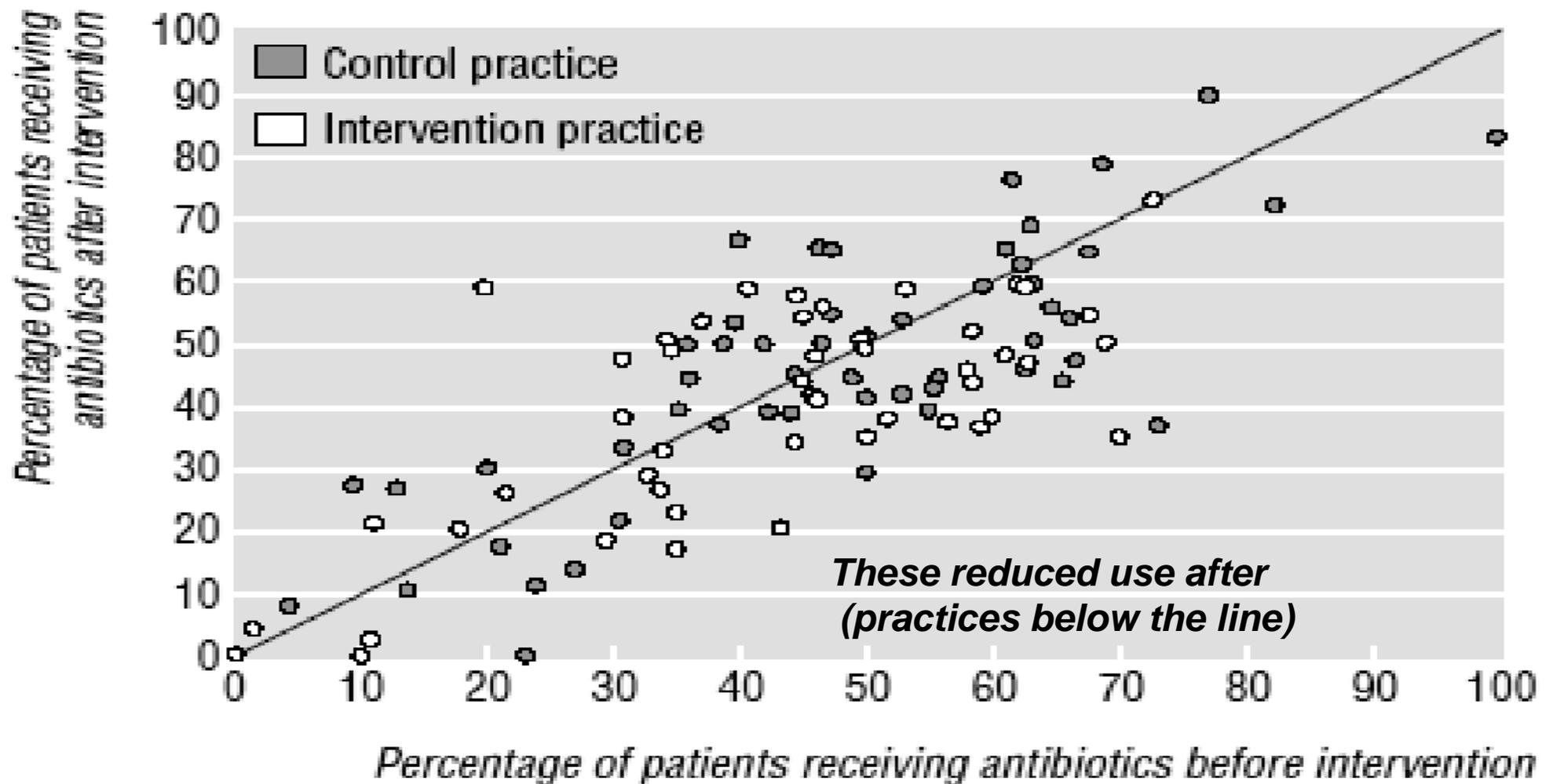


Fig 2 Rates of antibiotic use in consultations for sore throat before and after the tailored interventions from all practices with more than 10 consultations in each period

Why? – The parallel process evaluation

At same time as trial:

Investigated factors that might explain lack of change and variation:

- Data from 120 practices:
 - observations, semi-structured telephone interviews, a postal survey and data from electronic medical records.
- Found
 - agreement with guidelines; degree of participation in the project;
 - taking time to discuss the guidelines and their implementation;
 - use of the components of the interventions;
 - procedures for telephone consultations;
 - communication within each practice.

What do differently?

- Use more active interventions (eg outreach visit).
- Use a longer time period for intervention and follow-up.
- Focus more on organizational arrangements to change routines that involve not only physicians.
- On-line access to communicate with the practices, install software and collect data online.

(last two are conditions)

(“these make it easier and potentially more cost-effective to participate in and run quality improvement and guideline implementation projects in primary care”)

i.e. add to the intervention, other interventions to change the context
– context enfolded into the intervention (CLABSI)

Approach 2 Theory-informed context sensitive case evaluation

Example: Zapka et al 2004

Intervention to promote Smoking Cessation in Community Health Centers

“demonstrates the importance of process-monitoring methods to examine context factors of collaborative research,

outlines lessons learned and the challenges of research carried out in CHCs,

and summarizes implications for researchers and for practitioners”.

4 Formulate programme theory

- Assumptions about which actions lead to which intermediate and later results
- and which context factors critical to allow/enable actions
- EXAMPLE programme theory model coming...

Intervention to promote Smoking Cessation in
Community Health Centers

Smoking Cessation in Community Health Centers

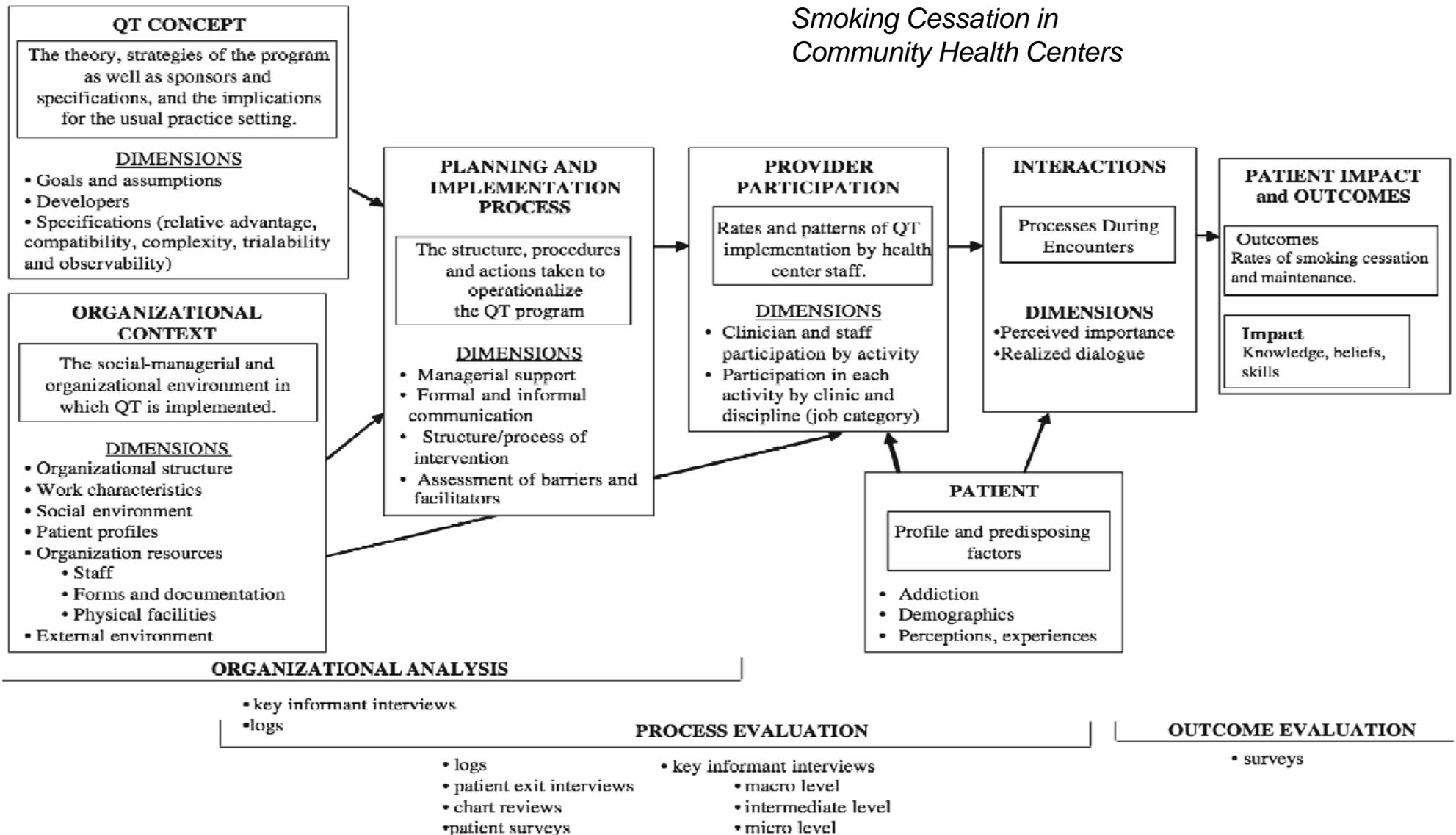


FIGURE 1 Conceptual Model of Relationships Among Constructs Assessed and Integrated Into the Quit Together (QT) Program

*Smoking Cessation in
Community Health Centers*

QT CONCEPT

The theory, strategies of the program as well as sponsors and specifications, and the implications for the usual practice setting.

DIMENSIONS

- Goals and assumptions
- Developers
- Specifications (relative advantage, compatibility, complexity, trialability and observability)

**ORGANIZATIONAL
CONTEXT**

The social-managerial and organizational environment in which QT is implemented.

DIMENSIONS

- Organizational structure
- Work characteristics
- Social environment
- Patient profiles
- Organization resources
 - Staff
 - Forms and documentation
 - Physical facilities
- External environment

**PLANNING AND
IMPLEMENTATION
PROCESS**

The structure, procedures and actions taken to operationalize the QT program

DIMENSIONS

- Managerial support
- Formal and informal communication
- Structure/process of intervention
- Assessment of barriers and facilitators

**PATIENT IMPACT
and OUTCOMES**

Outcomes
Rates of smoking cessation and maintenance.

Impact
Knowledge, beliefs, skills

IS

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OUTCOME EVALUATION

- surveys

ORGANIZATIONAL ANALYSIS

Zapka et al 2004

Summary report of context

Summary of Observations (Data Source in Parentheses)

The QT Concept

Goals and Assumptions

The concept of the intervention was met with enthusiasm at all levels of the organization. Commitment to tobacco treatment as an important issue facilitated moving forward with the trial.

The assumption of three key components (provider intervention, office management, and clinic linkages) was embraced.

Developers

Impetus came from the academic partners. A highly skilled intervention director was initially able to engage administrators and clinicians in refining the intervention to best fit their needs.

Specifications

The continuum of care for pregnant and postpartum women envisioned by academic and service partners proved inaccurate (NA, CL, M). The reality of relative autonomy of clinic operations meant changes resulting in real continuity could not be implemented.

Cooperation across clinics within community health centers (CHCs) was more difficult than anticipated. This was exacerbated at some sites by the complexity of medical records systems (NA, CL, M). Anticipated linkages were either not implemented or not sustained.

Nature of Change

Supplemental Food Program for Women, Infants, and Children (WIC) was not well enough integrated into the health care mission and culture of CHCs (CI). Cross-clinic communication and documentation were initially expected and viewed as beneficial.

Individual clinicians perceive smoking as important, however, special passion is needed over time. The three-component approach would hopefully build commitment.

The Organizational Context

Organizational Structure

Five of the six participating health centers underwent either a merger or financial restructuring during the grant period, resulting in a high degree of turmoil and chaos for each institution (NA, KII, M). Leadership and staff were distracted. Meetings were hard to schedule. Relationship building was difficult. Constant change meant difficulty not only implementing but institutionalizing change.

Several clinics experienced changes to their physical space, either moves or renovations (KII, M). The intervention became lower priority when execution of regular duties was made more difficult because of physical space issues.

Individuals key to project implementation and/or facilitation of research tasks were difficult to identify (NA, CL). Lack of sufficient buy-in from key players led to passive neglect or, less uncommonly, active resistance. The merger at one site brought new key individuals, identification of whom was a low priority for providers involved with the intervention.

Few perinatal work groups or committees existed prior to intervention implementation, resulting in little formal communication among clinics (NA, KII). The program board concept was implemented with mixed results. The approach for each clinic of each site had to be highly tailored to organizational structure.

Some clinics lacked strong leadership for the intervention (CI, M). Intervention implementation was often delayed, and full integration of the intervention into the organization was not always achieved.

Decision-making authority regarding the intervention was often unclear (CL, M). Critical decisions were delayed as the intervention coordinator sought to determine who had authority for a given aspect.

Difficulties resulting from a merger cut across an entire institution and distracted staff attention from the study. Occasional struggles between different types of clinicians or management within some clinics also contributed (M).

High staff turnover (16% to 41%) occurred throughout the study (T). The intervention director continually engaged in new relationship building and training.

The high level of patient scheduling and rescheduling was not anticipated in planning the research.

Social Environment

Staff morale was affected by organizational chaos (M). The intervention director found it difficult to build enthusiasm for the intervention or establish it as a priority for the staff individually.

Cooperation within and across clinics crucial for such a complex intervention was not established (CI, M).

External Environment

The Massachusetts Tobacco Control Program (MTCP) was viewed as a positive force (M). MTCP initially presented a historical threat to internal validity, as its programs prompted activity in usual care (UC) sites.

The Planning and Implementation Process

Buy-in from advisory boards varied across sites. Low buy-in resulted in the impression that the intervention director, rather than the CHC staff, was ultimately accountable (M). Approach needs to be highly flexible and tailored for each unit (site) and subunit (clinic). Strong leadership is needed for cross-clinic communication.

Every step took much longer than anticipated. The research timeline did not allow sufficient time for all phases (M, KII).



Approach 3 Action evaluation for interventions requiring iteration. *One version: Integrated research-implementation evaluation*

Purpose not to control,
...but to describe and improve the intervention and its results.

Researchers work with practitioners to assist implementation,
get and feedback data on progress and intermediate results.

Eg Rubenstien et al study of PCMH demos in Ca.
VHA & TIDES

•

Rubenstein et al 2010

- TIDES collaborative action research project
 - (using evidence-based quality improvement (EBQI) methods).

Intervention (s)

- Researchers helped regional leaders to select, adapt-
implement proven depression care models

Research role

- Provide evidence of EB practices/models. Discourage proven ineffective ones.
- Initiate use of QI methods (setting targets, data collection, PDSA, iteration)
- Evaluated results (Trained nurse depression care-managers collected data on patient adherence and outcomes)

Rubenstein et al 2010

- No randomisation, standardisation (fidelity assessment), or comparison group

Research products

- Examples of models and how implemented by local project teams
- Description of implementation structure steps and systems
- Outcome data (mean PHQ-9 scores from 15.1 to 4.7 (n=128)).

Result

- “TIDES achieved excellent overall patient outcomes, and the program is undergoing national spread”
(without researcher or other support?)

Summary: 3 approaches to study context

- Parallel process evaluation
 - to explain results of trial if little average change but wide variation – context factors discovered inductively from interviews and researcher observations
- Theory informed case evaluation
 - Initial theory frames data collection about intervention and context (theory modified in some)
- Action evaluation
 - Later versions more explicit theory – enfold context in later versions

Which aspects of context do I gather data about?

- Previous evaluations of similar type of interventions
 - Which context factors at different levels do they suggest were critical to success?
 - Leadership – which level, type of leadership, in what way – measures?
 - Culture – which aspect and how measure?
- Failing this, use a generic frameworks suited to the intervention
 - Eg for implementing evidence based practices in nursing - the PARHIS framework.

Context for EBP (PARiHS) Rycroft-Malone 2002

Context	Receptive context	Conclusions drawn	
		Physical Social Cultural Structural System Professional/social networks	} boundaries clearly defined and acknowledged
		Appropriate & transparent decision making processes Power and authority processes Resources – human, financial, equipment – allocated and Information and feedback Initiative fits with strategic goals and is a key practice/patient issue Receptiveness to change	
	Culture	Able to define culture(s) in terms of prevailing values/beliefs Values individual staff and clients Promotes learning organization Consistency of individuals role/experience to values: – relationship with others – teamwork – power and authority – rewards/recognition	
	Leadership	Transformational leadership Role clarity Effective teamwork Effective organizational structures Democratic inclusive decision making processes Enabling/empowering approach to teaching/learning/managing	

Understanding context for quality improvements MUSIQ (Kaplan et al 2011)

Context influences from 4 levels

- External environment
- Organisation
- Microsystem
- QI team

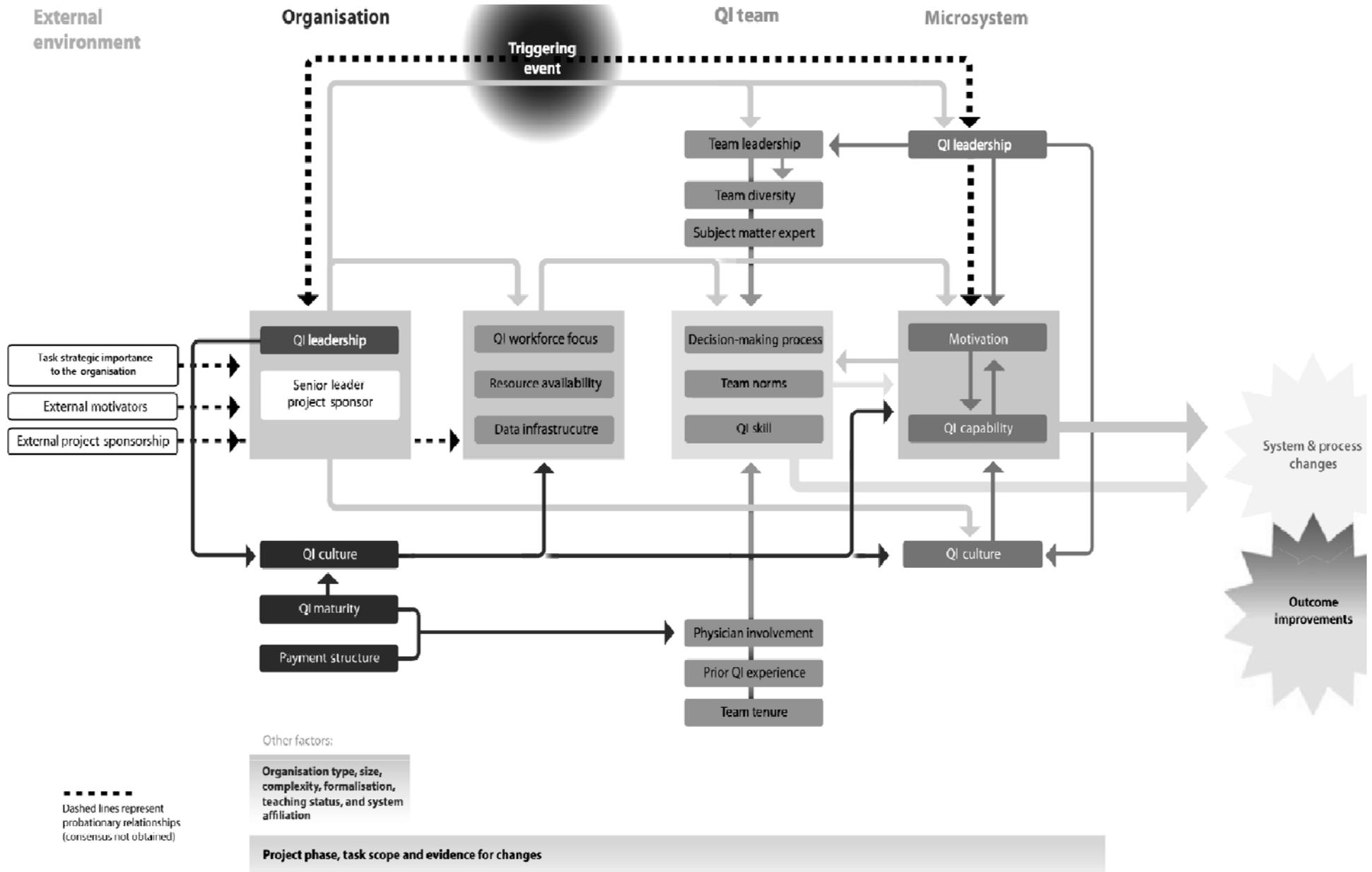
Kaplan et al 2010

- Reviewed research for evidence of context influences over QI success
 - Notes limitations in the research reviewed

Appeared to important to success:

- leadership from top management, organizational culture, data infrastructure and information systems, and years involved in QI.
- Other potentially important factors were: physician involvement in QI, microsystem motivation to change, resources for QI, and QI team leadership.

MUSIQ (Kaplan et al 2010)



French et al 2009 synthesis of 30 instruments measuring context

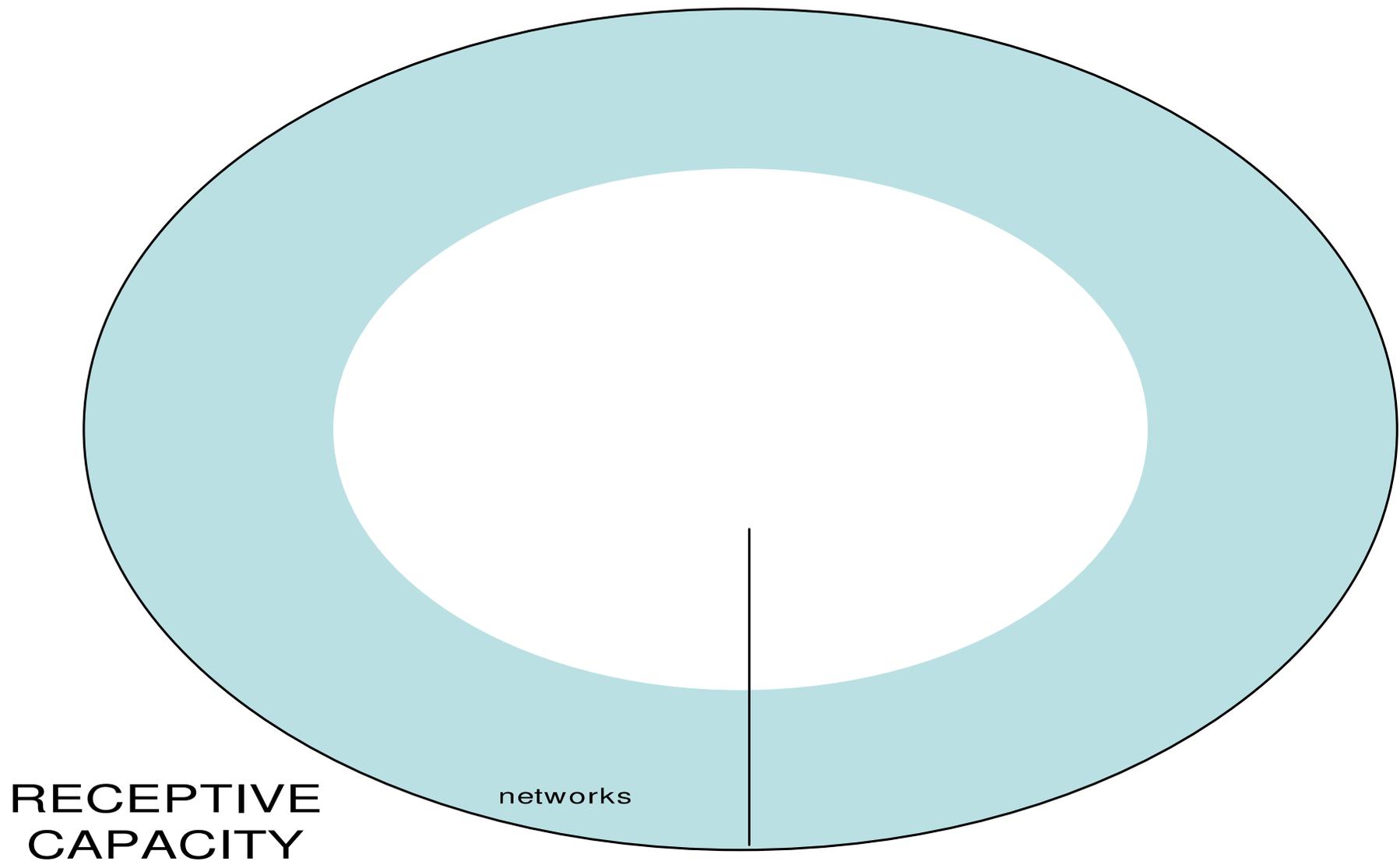


Figure 1
Model of categories and organisational attributes.

Measures of aspects of context – safety, Shekelle et al 2011

- Patient safety culture,
 - AHRQ surveys;
 - Patient Safety Climate (Pronovost et al 2003, Kho, et al 2005);
 - Safety Climate Survey (Kho et al 2005)
- Teamwork,
 - ICU Nurse-Physician Questionnaire (Shortell et al 1991).
- Leadership,
 - ICU Nurse- Physician Questionnaire (Shortell et al 1991)
 - Leadership Practice Inventory (Tourangeau & McGilton 2004)
 - Practice Environment Scale (Lake 2002).

Garden analogy framework (GAF, Øvretveit 2008)

Spreading plants to different settings?

Seed



Gardener/planting & nurture



Climate / soil



Modify seed for setting?
Can an ordinary gardener do this?
(*Change content*)

Modify gardening techniques for the situation?
(to those where the seed grew before?)
(*Change process*)

Can the gardener or others change parts of the context?
Sustainable?

3 Why study context?

1 Any evidence context affects outcomes of an intervention?

Why spend \$m doing RCTs?

Drugs affect patients differently (body is the context)

Training affects providers differently (receptiveness and ability to act depends on context)

QI interventions to organisation changes some, not others

But not much evidence of how and which context factors are influential (safety review (Øvretveit et al 2011))

Vote: which of these context influences affects QI success?

- leadership from top management,
- organizational culture,
- data infrastructure and information systems,
- years involved in QI
- whether CMO supports Dallas Cowboys
(Kaplan et al 2010 review)
- But how do you operationalise? (LATER)
 - define presence/absence or measure or assess or amount of these?

Review of evidence of context influences in 5 patient safety practices (Øvretveit et al 2011)

- Falls in institutions:
 - No strong evidence for or against context factors
 - either helping or hindering implementation of falls interventions
- Medication reconciliation tool and process redesign
 - “Blocking functions” in electronic systems to increase compliance with medication reconciliation steps.

(context or part of intervention? (Vote?))

More in Details section later in PPT

3 Why study context?

- Why not use a design which controls for context?
 - Comparison group of patients, or providers, or organisations
 - Randomise or match characteristics which make subjects more likely to be affected by the intervention
- Expensive
- Time consuming
- Difficult to arrange good comparison groups with organisational units
- (also controlling intervention may be difficult or inappropriate)

3 Why study context?

If it works – who cares about context?

Research customers have other questions

– especially if we say it works sometimes

Was it failure of implementation?

Partially implemented, or should be iterative adaptive implementation?

Or was it implemented the same, but a different contexts?

What was needed to allow implementation?

Should this be part of future interventions?

How much did it cost etc

3 Why study context?

1 Knowing which context influences help and hinder implementation

Enables our customers to decide whether they can implement

Or what they need to change to implement

2 Having a theory or model of the intervention

Enables our customers to replicate the principles locally rather than digitally copy but miss the active parts

4 Final points – then resources for studying context

- More implementation research is showing success of QI depends on facilitative organisational and external context
- Soft features: leadership, culture, project management, “interdisciplinarity”.
- Hard: IT support for data gathering and feedback, incentives.
- Success more likely if “the intervention” includes action to influence context favourably.
- Theorising and data collection about change steps allows evaluation of “fidelity” of implementation according to plan or documentation of adaptations

Summary Poll – agree or disagree or ”maybe”

- 1 Only implementation actions are sensitive to context..
- 2 Some interventions are more sensitive to context than others.
3. There are different context influences for different interventions
4. Different context influences are more and less important at different stages in selling, starting, progressing, sustaining and spreading an improvement.

Summary

5. Some context influences may need to occur together to have maximum effect in enabling implementation. Coordinated multi-level strategies may be needed.

6. We need to categorise quality interventions into groupings, according to which groups of context influences are most important for their implementation.

Resources

Resources on Johns web site folder

1) References in *OvretContext21Janfor14Feb2012 in

1 <http://public.me.com/johnovr> till summer 2012,

2) After summer 2012- Download files from idrive by going to web site: [http://www.idrive.com/;](http://www.idrive.com/)

- Log in user = jovr pass= anna. THEN use the search field on the right to enter in a word realated to the subject. You will see files on this subject – click on the file you want to download, after entering anna and it will download to your computer.

Ovretveit 2012 Guide for research into context covers...

1. When do I need to collect data about context?
- 2 Why do I need to decide the research user, questions and purpose?
- 3 How do I match the research design to the question?
- 4 Which data to collect?
- 5 How to collect the data?
- 6 How do I analyse data to find how much the context influenced implementation?
- 7 How do I report context data?
- 8 Checklist
- 9 Terms used in this guidance
- 10 Appendices: frameworks for deciding which data to gather about intervention implementation and context
- 11 References and resources

Ovretveit 2012 Guide for research into context covers...

Checklist

1. Who is the primary research user and their questions, and by when should the research deliver answers?
2. Which are the potential research designs and why the chosen one?
- 3 Which data are needed for a) others to replicate the intervention, b) others to assess how similar and different their context is, c) to be later able to explain the degree of implementation observed and what accounts for this and the outcome.
- 4 Which data sources and types might provide these data?
- 5 What is the data gathering plan and methods and the times for gathering the data
- 6 How will you analyse data to find how much the context influenced implementation?
- 7 How will you present the context data?

3/8/2012

References.

- See list in PPT in “presenters notes” view below,
- Also see in Implementation folder on web site:
- Ovretveit 2012
 - Guidance for research into the context of quality improvement, implementation or innovation in health services
 - Guidance for case study research and publications
 - Practical Tips for Context-Sensitive Implementation Research

Conclusions

1. These were the main points...
2. This was new or surprising, for me...
3. The most useful idea for my work was...
4. What I would like to find out more about...

DETAILS

7 Steps-guide for context-sensitive evaluation of QI intervention

- How would you carry out a context sensitive evaluation of one of these interventions
 - Medication reconciliation
 - SMAs for disadvantaged groups - diabetes
 - Remote monitoring of chronic diseases using biological sensors

Steps-guide for context-sensitive research

- 1 Define primary customer for the research, their questions, timescale and budget
 - Does it work? (for whom & what outcomes/measures?)
 - Costs? (for whom and savings)
 - How best to implement?
 - Can we do it here?
 - What results to expect?
- Evaluation and certainty? Generalisation maximization?

All of above, 6 months

Estimate time and cost to answer each and negotiate!

Steps-guide for context-sensitive research

2 Define the type of intervention

- simple/complex, replicate or configurable (adaption latitude)

and target subject of the intervention

- human body, behaviour, group, multi-group, health system, region

Eg Medication reconciliation

- Complex; replicate development process, but adapt contents
- Intervention directed at: behaviour, group, multi-group,

Step 3 Find previous research into this “type” of intervention

- Type: Complex, some adaptability, directed at behaviour, group and multi-group
- Did it report or suggest context influences affecting implementation? (reviews).
- If not, use one from EBM
 - eg PARHIS or other (eg innovation model, Greenhalgh 2004) – these shown later in DETAILS

4 Formulate programme theory

- Assumptions about which actions lead to which intermediate and later results
- and which context factors critical to allow/enable actions
- EXAMPLE programme theory model coming...

Intervention to promote Smoking Cessation in
Community Health Centers

Smoking Cessation in Community Health Centers

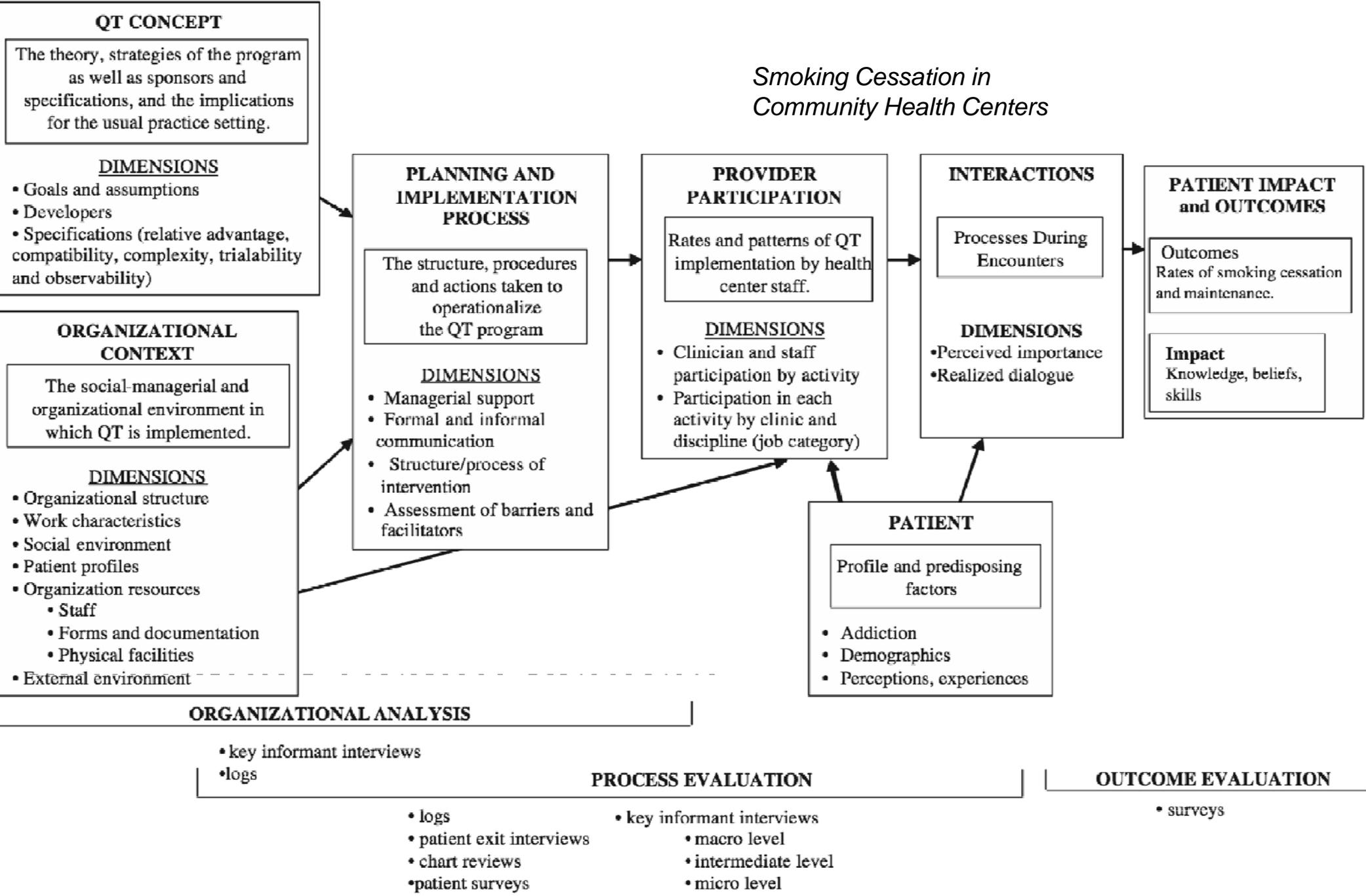


FIGURE 1 Conceptual Model of Relationships Among Constructs Assessed and Integrated Into the Quit Together (QT) Program

*Smoking Cessation in
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**PLANNING AND
IMPLEMENTATION
PROCESS**

The structure, procedures and actions taken to operationalize the QT program

DIMENSIONS

- Managerial support
- Formal and informal communication
- Structure/process of intervention
- Assessment of barriers and facilitators

**PATIENT IMPACT
and OUTCOMES**

Outcomes
Rates of smoking cessation and maintenance.

Impact
Knowledge, beliefs, skills

OUTCOME EVALUATION

- surveys

Together (QT) Program

Formulate programme theory using previous research and or implementers assumptions of links

– (use framework to help them articulate the steps and why),

- define intermediate stage outcomes and indicators.
- Include context factors.

5 List other explanations for any changes in indicators you may find

6 Decide measures or interview questions for gathering data about context and how to analyse.

7 Collect, analyse, report: examine and report data on likely influence of both the intervention and context factors on outcomes.

Why should we follow these steps?

- Presentation later shows evidence for context influences
- Customers need to know if it will work in their setting

& what they need to modify to increase chances of success

First – what do we mean by “context” of an intervention?

Vote: which are definitions of context:

- 1 the environment or setting in which the proposed change is to be implemented
- 2...physical environment in which practice takes place...
[with] boundaries and structures that together shape the [setting] for practice
- 3 willingness, preparedness and capacity for implementation of a specific, discrete practice change
- 4 everything which is not the intervention.

Next: Initial points about context of intervention

Example of one aspect of context

Part of “leadership support” context assessment (Damschroder 2009)

To what extent do leaders show active and visible support for this change or this type of EBP and implementation?

- *Is the leader willing to engage with the study team for planning?*
- *Is the leader willing to provide connections/entrees for the study team?*
- *Does the leader have experience/comfort in this role? o Does the leader hold service directors accountable for collaboration and coordination in such change efforts/this change effort?*

To what extent are appropriate stakeholders or teams held accountable and incentivized or rewarded to carry out the implementation?

- *What about past experiences with this type of change?*

1 Research finds some interventions less effective in some contexts.

- Statins may be less effective in women than men (possibly different “body context” of intervention)
- Guideline implementation interventions less effective in some primary health care clinics
- Re-engineering and process improvements less effective in some hospitals

2 Levels or layers of context

- The body is the context for drug,
 - but wider context for “implementation” is the patients lifestyle, wealth, social group.
- Context for many QI’s is
 - group, facility, and system or regional/national contexts
- Each level of context is the source of influences affecting implementation

3 Multiple level interventions

- Some chronic care interventions are multiple and multi-level:
- target the body and social group
 - (eg medications, & lifestyle changes, social support group to encourage adherence, and financial incentives)
- Prediction: the more context influences which are aligned with the intervention,
..... then the more effective it will be.

Context only affects outcomes through influencing implementation

Hospital CEO provides resources for QI project
after little progress

Helps and hinders the intervention actions and
intermediate stages in pathway to outcomes

More on Øvretveit et al 2011 review

Prevention of central line -associated bloodstream infections (CLABSI)

- Leadership involvement, teamwork, nursing staff empowerment and interdisciplinary rounds, and training resources (11)
- Barriers: insufficient time or resources, organizational and regulatory barriers, and lack of a quality improvement infrastructure within the organization (12).
- Involvement of hospital leadership, project leadership, quality improvement experience, education, and motivation (13).
- Hand washing campaigns (14).
- Safety culture (15)
- Previous education, teamwork and culture interventions, and leadership, feedback and support of outside quality improvement expertise (16).

Wrong site surgery universal protocol

- Participation of the surgeon in preoperative verification, participation of all surgical team members in the “time out”, and the surgeon explicitly empowering team members to speak up if concerned and acknowledging concerns when expressed (17). Strong correlation between technical error and teamwork failures (18).

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- Computer physician order entry (CPOE) and computer decision support system (CDSS)
 - Regulation (100% of the 23 papers reviewed), external incentives (100%), organizational size and type (100%), teamwork (74%), leadership (30%), culture (9%), training (61%), internal incentives (52%), audit and feedback (35%), and quality improvement consultants (13%).

Summary - Review found

- Little empirical evidence
- Weak strength of evidence (eg survey of implementers)
- But some evidence that context factors influence implementation
- These factors vary between organisations, intervention, and stage of implementation
- This for these 5 PSPs – probably so for many other CSIs

Research challenges (Øvretveit 2011)

- *Patient safety could be speeded and costs saved with a recognition that many “interventions” are not single time changes but evolve over time in interaction with their context – perhaps better described as “innovations”.*
- *Studies would be more useful to implementers if they defined more clearly what is the intervention and what is not (“context”), and which aspects of context were or may be important to implementation and outcome effectiveness.*

Guidance for research into the context of quality improvement, implementation or innovation in health services

V2, 15mar2012

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With thanks to Brian Mittman, CIPRS, Veterans Health Administration, USA.

Introduction

- Context is everything which is not the intervention
- Only some elements of the context affect implementation
- The purpose of context-sensitive research is to discover which elements most influence implementation of the intervention, and hence the outcomes.

Purpose of the guide:

- To help decide which context data to collect, for different types of research, and how to analyse and report it to answer the research user's questions.

Who for:

- Primarily quality and safety improvement researchers, but also researchers studying any change or intervention to patients, providers or services.
- Improvers and decision makers, to understand more about conditions necessary for successful implementation, and what research can and cannot provide to help.

What the guidance covers:

1. When do I need to collect data about context?
2. Why do I need to decide the research user, questions and purpose?
3. How do I match the research design to the question?
4. Which data to collect?
5. How to collect the data?
6. How do I analyse data to find how much the context influenced implementation?
7. How do I report context data?
8. Checklist
9. Terms used in this guidance
10. Appendices: frameworks for deciding which data to gather about intervention implementation and context
11. References and resources

1. When do I need to collect data about context?

In all evaluation research. To help users assess generalisability.

- **For controlled experimental trials:** context includes characteristics of patients selected for the trial. Most aspects of context are controlled for their influence on outcomes by having a comparison group, who are the same apart from the intervention, and ensuring full implementation of the standardised intervention.
- **For observational studies** (eg case studies, process evaluations): more details about certain context elements needs to be collected and about how these may change, depending on who the user of the research is, and as described below.
- **For action research or quality improvement reports:** the same level of detail and rigor will not be possible, but some description is needed if others are to assess how similar and

different their context is, and their likely success in implementing the intervention, as described below.

2. Why do I need to decide the research user, questions and purpose?

- Why - To save collecting data you do not need, and to decide the best design and the data needed.
- Does it work? If the purpose is to achieve high certainty that the intervention is associated with certain changes in measurable outcome variables, then a randomised or controlled experimental design is best, if this is feasible.
- If the research users are primarily decision-makers or implementers, and if a controlled trial is not feasible, then their main question is: what should decide the design – the next item.

3. How do I match the research design to question?

- Know the range of designs you could use, and their costs and timescales, and the one or two answers they are most well designed to answer. Best reference: Grol et al 2003, Craig et al 2008, Fan et al 2010.

4. Which data to collect?

Depends on the research user's questions.

Generally – Collect data to describe:

- the contents of the intervention evaluated (the before/after change-difference which was or is to be implemented),
- the implementation actions (and structure or systems for implementation),
- the surrounding elements which may affect implementation at different levels (eg group, facility, organisation, area, national).

About context:

- **For controlled experimental trials:** guidance for which aspects of context to collect data about and report is given in Consort 2012 reference below).
- **For observational studies** (eg case studies, process evaluations) formulate your theory of which 5-10 context elements are most critical to effective implementation and will help and hinder implementation. Formulate this by finding previous research into a similar type of intervention or programmes, and look for which aspects of context this research suggests may be influential on implementation. If there is no such research, then use one of the generic context frameworks or assessment models listed below in the appendix.
- Which context features help and hinder implementation will be different for, eg a patient fall prevention programme to those for implementing a computer decision support system for physicians, to those for implementing a clinical bundle in an ICU to reduce central line infections. Some may be similar (higher level leadership support).
- Generally the relevant context elements are features of the local facility, health system, funding and regulation that will affect implementation, and availability of investment resources, and payments for operations (eg reimbursement).
- Data will be needed about whether or how these context influences changed over time, if the data is to be used to explain outcomes and implementation success that was observed.
- **For action research or quality improvement reports:** If others are to use the study or reports, then some description of context will be necessary, following some of the general principles above.

5. How to collect the data

- Depending on your type of study and questions to be answered, the data can be collected by

using

- measures of aspects of context (eg see Shekelle et al 2011 for measuring instruments),
- interviews or surveys of informed observers,
- both of the above.
- If money and time is short, then select a reasonable cross section of informed observers and ask them,
 - which aspects of context helped and hindered implementation?
 - from this list which was the most influential? (try to get them to rank order the list). Why do you say this (more evidence please)?
 - over the period of implementation, did any of these influences change in strength, in a way in which their influence on implementation was significantly more, or less?

6. How do I analyse data to find how much the context influenced implementation?

- **For quantitative measurement data:** when comparing different implementation cases, relate context variables to variables summarising success in implementation, or to outcome variables.
- **For qualitative data** (eg from the informants, as suggested above):
 - See if a pattern of similar views begins to show,
 - or whether there are strongly divergent views,
 - and if these are associated with the interviewee's role position or not.

7. How do I report context data?

- In a scientific publication: RCT and controlled trials: see Consort 2012 references below.
- Observational: see SQUIRE reporting guidance (not much on context), or other papers (appendix) to see how they presented context data.
- In an evaluation report: probably the best way is a model diagram summary with the details of what is in the boxes of the diagram in a separate table.

8. Checklist

- Who is the primary research user and their questions, and by when should the research deliver answers?
- Which are the potential research designs and why the chosen one?
- Which data are needed for a) others to replicate the intervention, b) others to assess how similar and different their context is, c) to be later able to explain the degree of implementation observed and what accounts for this and the outcome.
- Which data sources and types of data might provide these data?
- What is the data gathering plan, and methods and the times for gathering the data?
- How will you analyse data to find how much the context influenced implementation?
- How will you present the context data?

9. Terms used in this guidance

- **Intervention:** what "comes between" what would otherwise have happened to the subject intervened-in, be it patient, provider, group or organisation.
- **Implementation:** sometimes it is useful to separate the actions, steps and structures established to deliver or carry out the intervention.
- **Context:** everything which is not the intervention.
- **Intervention/context boundary:** a dividing line between actions taken to change a person, group or organisation (subject), and the surrounding influences which may also affect the subject but which are not considered part of the intervention.
- **Simple intervention or implementation:** one item or action, constant or one time.

- **Complex intervention or implementation:** multiple actions, possibly at different or overlapping times, possibly with mutually reinforcing.
- **Multiple level intervention or implementation:** different and coordinated actions taken to change subjects at more than one level, such as actions to change individuals, and one or more groups, and organisations and to change influences emanating from higher-levels such as regulations or financing.
- **Cost of intervention and implementation:** the resources used and quantified in money terms to a) operate the new way of working after the intervention (ie sustaining the intervention) , and b) used to implement the intervention (this may be short term implementation actions).

Three types of intervention and three types of research

Depending on which type, you will need to need to collect and report slightly different data about intervention and context.

Three types of intervention

- **Prescribed:** the intervention is carefully specified and the implementation ensures fidelity to the specification (eg drug trial tries to ensure the correct patients take the medication in correct doses at correct times)
- **Part-prescribed:** a prescribed "core", but adaption is allowed or encouraged of other aspects of the intervention (eg the training materials and process of the sessions are prescribed, but some latitude allowed about frequency (within the prescribed frequency of once every two to four weeks).
- **Principle intervention:** the intervention is a "change concept" such as " Minimize hand offs" or "Reduce multiple brands of same item" (see Langley et al 1996, pp 295-359). These require considerable interpretation by implementers, although examples may be given to implementers.

Three types of research

- **Experimental and quasi-experimental:** eg RCT or other controlled trial.
- **Observational ("hands-off"):** eg descriptive or evaluative study of an intervention programme or one without controls, possibly retrospective.
- **Action research** or quality improvement project: where the research is intended to contribute to a change to the intervention to improve it in some way.

10. Appendix: frameworks for deciding which data to gather about intervention implementation and context

- **Clinicians implementing clinical research:**
 - PARHIS Guidance (Stetler et al 2011) and related:
 - Context Assessment Index (CAI) (McCormack et al 2008) – the best validated
 - Alberta Context Tool (ACT) (Estabrooks et al 2008).
 - CFIR Damschroder et al 2009, and French et al 2009
- **Quality Improvement Projects:**
 - MUSIQ (Kaplan et al 2012) or French et al 2009)
 - See also ORCA readiness for change assessment (Helfrich et al 2009).
 - EMR implementation (Øvretveit et al 2007)
 - Generic change/innovation French 2009 Greenhalgh 2004
- See also **measures of aspects of context** – for safety practice implementation in Shekelle et al 2011 which include:
 - Patient safety culture,
 - AHRQ surveys;

- Patient Safety Climate (Pronovost et al 2003, Kho, et al 2005);
 - Safety Climate Survey (Kho et al 2005)
- Teamwork,
 - ICU Nurse-Physician Questionnaire (Shortell et al 1991).
- Leadership,
 - ICU Nurse- Physician Questionnaire (Shortell et al 1991)
 - Leadership Practice Inventory (Tourangeau & McGilton 2004)
 - Practice Environment Scale (Lake 2002).

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CONSORT 2012 www.consort-statement.org

For RCTs: statement for reporting (and later revisions) www.consort-statement.org

http://www.consort-statement.org/consort-statement/3-12---methods/item5_interventions/

For "intervention", the above states: *The description should allow a clinician wanting to use the intervention to know exactly how to administer the intervention that was evaluated in the trial.* (102) *For a drug intervention, information would include the drug name, dose, method of administration (such as oral, intravenous), timing and duration of administration, conditions under which interventions are withheld, and titration regimen if applicable. If the control group is to receive "usual care" it is important to describe thoroughly what that constitutes. If the control group or intervention group is to receive a combination of interventions the authors should provide a thorough description of each intervention, an explanation of the order in which the combination of interventions are introduced or withdrawn, and the triggers for their introduction if applicable.*

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SQUIRE standards for reporting quality improvement projects

http://squire-statement.org/guidelines/explanation_and_elaboration/9_planning_the_intervention/

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