Shared Medical Appointments for Chronic Medical Conditions: A (Traditional) Systematic Review

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Shared Medical Appointments (SMAs)

- Subset of Group Visits
- Groups of patients with a defining chronic condition or other health care state meet over time for comprehensive care
- Involve both self-management training and medication management

SMAs-- Structure

- 60-120 minutes, usually 1-3 months apart
- Usually both a prescribing provider and a trained educator/facilitator
- Interactive education, often with techniques such as motivational interviewing; goal is patient activation
- Prescribing provider does med changes, often in one-on-one breakouts

Studies of SMAs

- Some studies in frail elderly
- Most in a single disease, most commonly diabetes
- Wide variability in:
  - Setting and patients
  - Intervention approaches, including staffing
  - Chosen outcomes to measure (ie, behavioral, clinical, cost/utiliization)

Objectives

- Summarize the effects of SMA on:
  - Patient outcomes
  - Staff outcomes
  - Economic outcomes
- Evaluate whether these effects vary by clinical condition or specific intervention components.

Outline of Methods

- Topic development
  - Key questions
  - Protocol
- Systematic searches of the literature
- Study selection via eligibility criteria
  - Screening
  - Full text review
- Data abstraction and quality assessment
- Data synthesis and report generation
- Peer review

Key Question 1

- For adults with chronic medical conditions, do shared medical appointments (SMAs), compared with usual care, improve the following:
  - Patient and staff experience?
  - Treatment adherence?
  - Quality process measures?
  - Biophysical markers (laboratory or physiological markers of health status such as HbA1c and blood pressure)?
  - Symptom severity and functional status?
  - Utilization of medical resources or health care costs?

Key Questions 2-3

- **Key Question 2.** For adults with chronic medical conditions, do the effects of SMAs vary by patient characteristics such as specific chronic medical conditions and severity of disease?

- **Key Question 3.** Is the intensity of the intervention or the components used by SMAs associated with intervention effects?

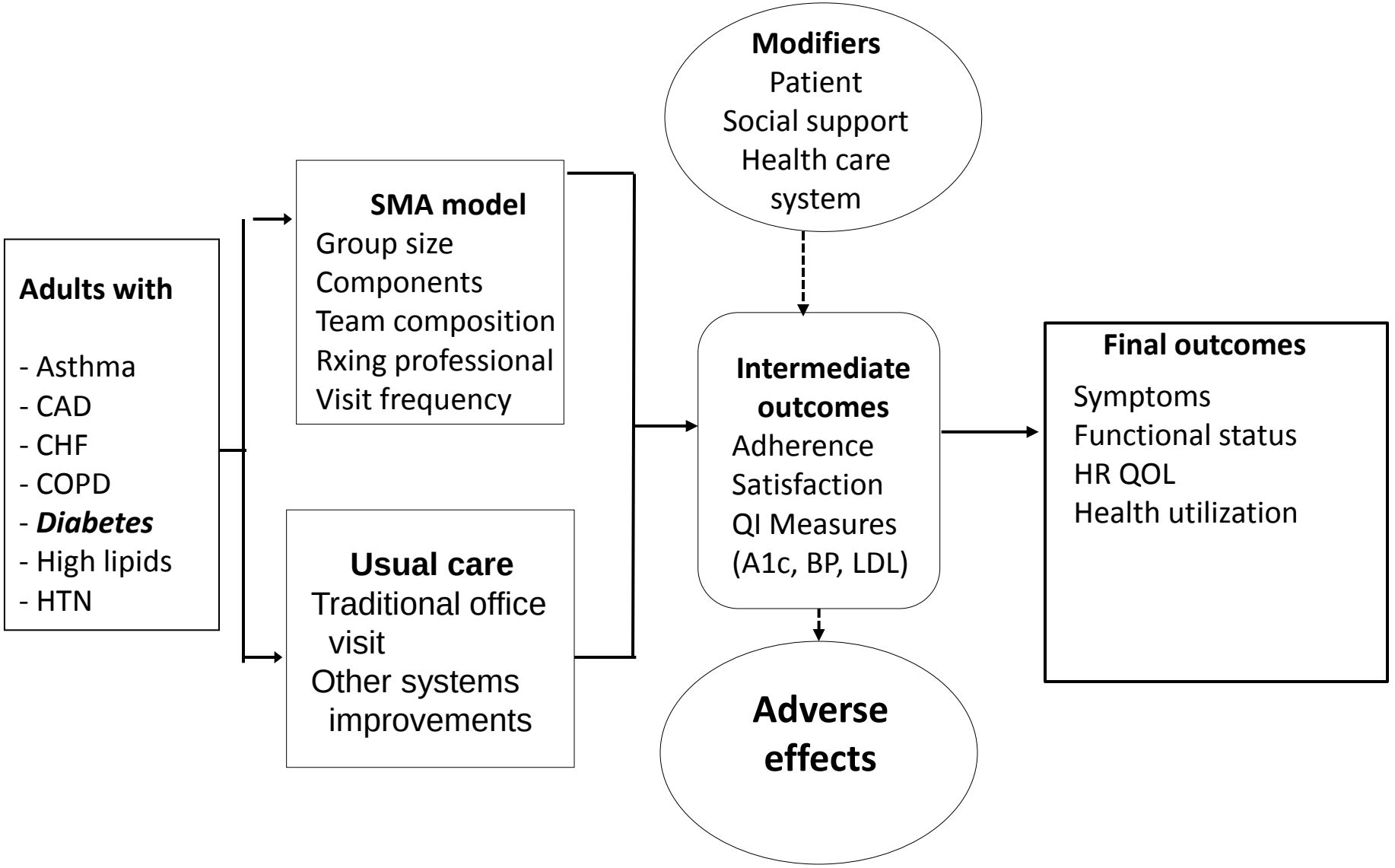
Protocol

- The protocol provides the analytic framework for the report and outlines a priori how each remaining step of the procedure is to be conducted

- The protocol is reviewed and vetted by both internal and external experts as well as the major stakeholders for the report

Literature Search Strategy

- Databases
  - MEDLINE® (via PubMed®), Embase®, CINAHL®, PsychINFO® and Web of Science®
- Search terms
  - Consult master librarian
  - Key words and MeSH Analyzer
- Supplemental searches
  - Bibliographies of exemplary articles
  - ClinicalTrials.gov


Modifiers
Patient
Social support
Health care system
Adults with
- Asthma
- CAD
- CHF
- COPD
- Diabetes
- High lipids
- HTN
SMA model
Group size
Components
Team composition
Rxing professional
Visit frequency
Usual care
Traditional office visit
Other systems improvements
Intermediate outcomes
Adherence
Satisfaction
QI Measures
(A1c, BP, LDL)
Adverse effects
Final outcomes
Symptoms
Functional status
HR QOL
Health utilization

Study Selection Criteria

- Exclusion
  - Publication is NOT English language or not peer-reviewed
  - Population selected for substance abuse or is from inpatient setting
- Inclusion:
  - Based on model in previous slide

Inclusion (1)– Study Quality

- Quality of study
  - Study designs recommended by Cochrane EPOC Group
  - Trials, or observational studies with contemporaneous comparator

Inclusion (2)– Patients

- Adult with one or more of 7 chronic medical conditions of *a priori* interest
  - Asthma
  - CAD
  - CHF
  - COPD
  - ***Diabetes***
  - High lipids
  - HTN
- Also reviewed– extant literature on older adults without a single unifying disease

Inclusion (3)– Intervention and its context

- Setting
  - Outpatient primary care or specialty clinic/practice
- SMA Model
  - Intervention defined as ≥2 medical visits where ≥1 healthcare professional (includes prescribing clinician) cares for a patient group
- Comparator
  - Defined as usual care or other quality improvement strategy

Inclusion (4)– Outcomes

- One of following outcomes reported at ≥ 3 months:
  - Patient or staff experience
  - Adherence (treatment, medication or self-management)
  - Biophysical marker, (e.g., HbA1c, LDL, BP)
  - Symptom severity or functional status
  - Utilization of medical resources

Data Abstraction

- Extraction of pertinent information from each eligible article into a customized, uniform database in DistillerSR®
- Performed by 1st reviewer and independently over-read by a 2nd reviewer
- Disagreements are resolved by discussion and consensus or referral to a 3rd reviewer

Robustness Score

- Devised to attempt to describe the more potent elements of an SMA intervention
- Seven variables
  - Education session
    - Qualifications of leader
    - Based on theoretical framework?
  - Group composition
    - Closed membership?
    - Stable healthcare team?
  - Intervention Process
    - Individual breakout sessions?
    - Medication changes within visit?
    - Number and length of visits
- Potential score range = 0-9

Quality Assessment

- Elements rated for RCTs
  - Adequacy of randomization
  - Adequacy of allocation concealment
  - Comparability of groups at baseline
  - Blinding of subjects and/or investigators
  - Completeness of and differential loss to followup
  - Management of incomplete data
  - Validity of outcome measures
  - Potential conflicts of interest
- Elements rated for observational studies
  - Selection bias
  - Performance bias
  - Detection bias
  - Reporting bias

- Reference: Agency for Healthcare Research and Quality's (AHRQ) *Methods Guide for Effectiveness and Comparatie Effectiveness Reviews*

Data Synthesis

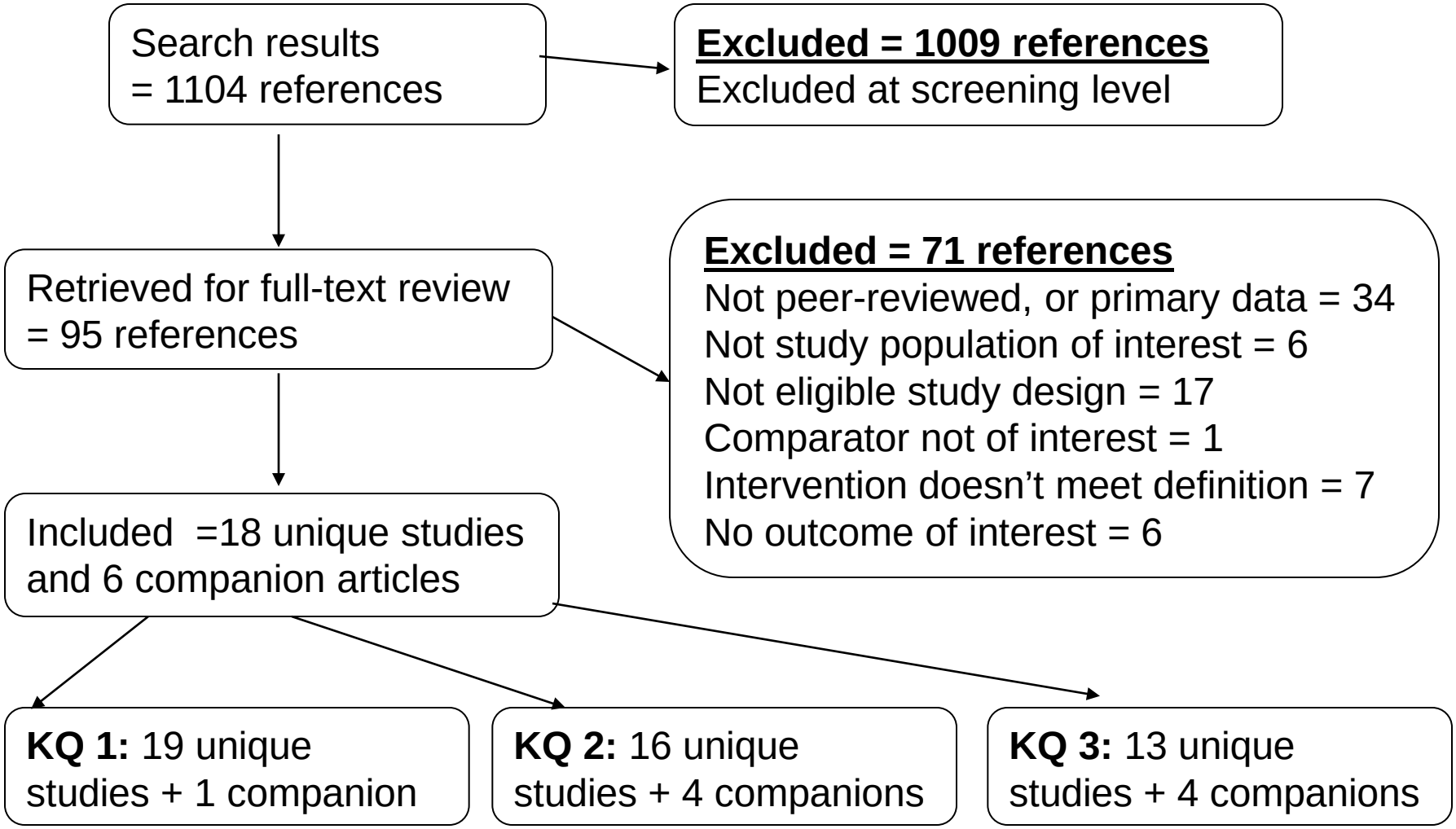
- Summary table of key outcomes
- Quantitative meta-analysis, if feasible
  - Dichotomous outcomes combined using RR; OR
  - Continuous outcomes combined using standardized mean difference and a random effects model
  - Tests for statistical heterogeneity (Q and i^2)
- Qualitative synthesis otherwise (e.g., too few studies or subgroup and sensitivity analyses)
- Assessment of publication bias

Strength of Evidence

- Assessment of four domains
  - Risk of bias
  - Consistency
  - Directness
  - Precision
- The strength of the evidence for the proposed answer to each key question is graded – high, moderate, low or insufficient

- Reference: AHRQ's *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*

Literature Flow

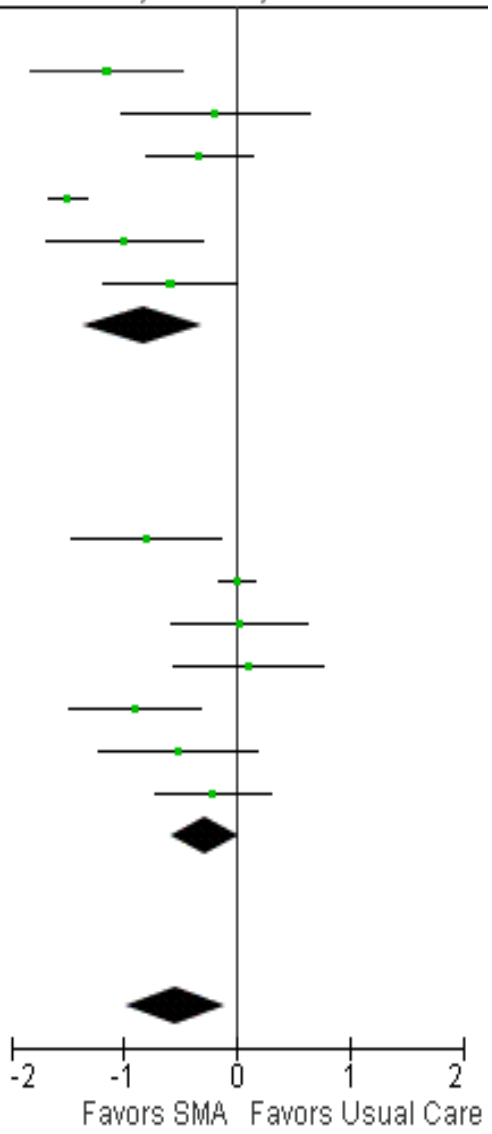


Study and subject characteristics

Study Characteristic	Adults With Diabetes	Older Adults
N studies (participants)	16 (3221)	3 (1851)
Mean age of sample: median (range)	60.8 (27 to 69.8)	74.1 (73.5 to 78.2)
Randomized controlled trial	13 (2921)	2 (615)
Observational	3 (300)	1 (1236)
Study quality: N (%) Good Fair Poor	 6 (46%) 6 (46%) 1 (8%)	 0 2 (67%) 1 (33%)
Single-site	14 (2106)	1 (321)
Multisite	2 (1115)	2 (1530)
Duration 6 to 12 months	4 (410)	0
Duration >12 months	12 (2811)	3 (1851)

Effect on A1c: mean = - 0.55%

Study or Subgroup	SMA Mean	SMA SD	SMA Total	Usual Care Mean	Usual Care SD	Usual Care Total	Weight	Mean Difference IV, Random, 95% CI	Year
1.1.1 A1c Good Quality									
Sadur 1999	8.18	2.1392	82	9.33	2.1392	74	7.4%	-1.15 [-1.82, -0.48]	1999
Clancy 2003	9.5	2.33	59	9.7	2.33	61	6.8%	-0.20 [-1.03, 0.63]	2003
Edelman 2010	8.3	1.8417	133	8.63	1.8417	106	8.1%	-0.33 [-0.80, 0.14]	2010
Trento 2010	7.3	0.9	315	8.8	1.2	266	8.8%	-1.50 [-1.68, -1.32]	2010
Taveira 2011	7.4	1.2	44	8.4	2	44	7.3%	-1.00 [-1.69, -0.31]	2011
Naik 2011	8.05	1.4	44	8.64	1.39	41	7.7%	-0.59 [-1.18, 0.00]	2011
Subtotal (95% CI)			**677**			**592**	**45.9%**	**-0.83 [-1.36, -0.30]**	
Heterogeneity: Tau² = 0.35; Chi² = 33.98, df = 5 (P < 0.00001); I² = 85%									
Test for overall effect: Z = 3.06 (P = 0.002)									
1.1.2 A1c Fair/Poor Quality									
Trento 2001	7.5	1.4	43	8.3	1.8	47	7.4%	-0.80 [-1.46, -0.14]	2001
Wagner 2001	7.9	1.0001	278	7.9	1.0001	429	8.8%	0.00 [-0.15, 0.15]	2001
Trento 2005	-0.38	1.2051	30	-0.4	1.1605	28	7.6%	0.02 [-0.59, 0.63]	2005
Clancy 2007	9.1	2.1947	96	9	2.4666	90	7.4%	0.10 [-0.57, 0.77]	2007
Taveira 2010	-0.9	1.6	58	0	1.5	51	7.7%	-0.90 [-1.48, -0.32]	2010
Gutierrez 2011	-1.19	1.66	50	-0.67	2	53	7.2%	-0.52 [-1.23, 0.19]	2011
Cohen 2011	-0.41	1.1612	50	-0.2	1.4274	49	7.9%	-0.21 [-0.72, 0.30]	2011
Subtotal (95% CI)			**605**			**747**	**54.1%**	**-0.29 [-0.59, 0.01]**	
Heterogeneity: Tau² = 0.09; Chi² = 15.23, df = 6 (P = 0.02); I² = 61%									
Test for overall effect: Z = 1.86 (P = 0.06)									
Total (95% CI)			**1282**			**1339**	**100.0%**	**-0.55 [-0.99, -0.11]**	
Heterogeneity: Tau² = 0.57; Chi² = 179.95, df = 12 (P < 0.00001); I² = 93%									
Test for overall effect: Z = 2.43 (P = 0.01)									
Test for subgroup differences: Chi² = 3.01, df = 1 (P = 0.08), I² = 66.7%									



Effect on SBP: mean = - 5.2 mmHg

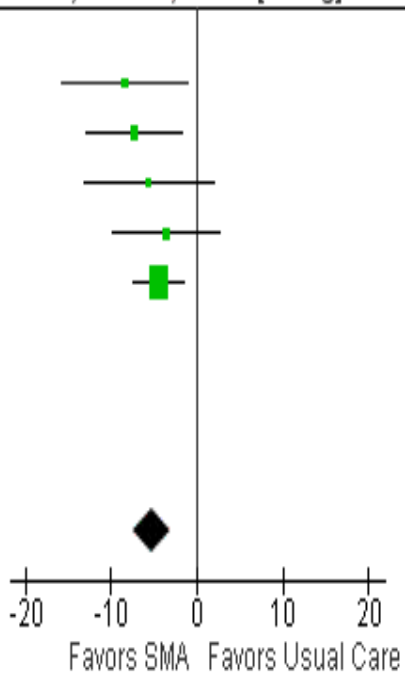
Study or Subgroup	SMA Mean [mmHg]	SMA SD [mmHg]	SMA Total	Usual Care Mean [mmHg]	Usual Care SD [mmHg]	Usual Care Total	Weight	Mean Difference IV, Random, 95% CI [mmHg]
1.4.1 Systolic Blood Pressure								
Cohen 2011 (1)	-9.19	20.2676	50	-0.8	16.746	49	8.8%	-8.39 [-15.71, -1.07]
Edelman 2010	139.2	21.5523	133	146.5	21.5523	106	15.6%	-7.30 [-12.80, -1.80]
Taveira 2010	-7.3	20.3	58	-1.7	19.6	51	8.4%	-5.60 [-13.10, 1.90]
Taveira 2011	123.4	12.3	44	127	17.3	44	12.0%	-3.60 [-9.87, 2.67]
Trento 2010	138.01	16.1	295	142.43	18.9929	266	55.1%	-4.42 [-7.35, -1.49]
Total (95% CI)			**580**			**516**	**100.0%**	**-5.22 [-7.40, -3.05]**

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 1.82$, df = 4 (P = 0.77); $I^2 = 0\%$

Test for overall effect: Z = 4.71 (P < 0.00001)

Test for subgroup differences: Not applicable

(1) Cohen 2011 and Traveira 2010 is mean change



Effect on LDL-C: mean = - 6.6 mg%

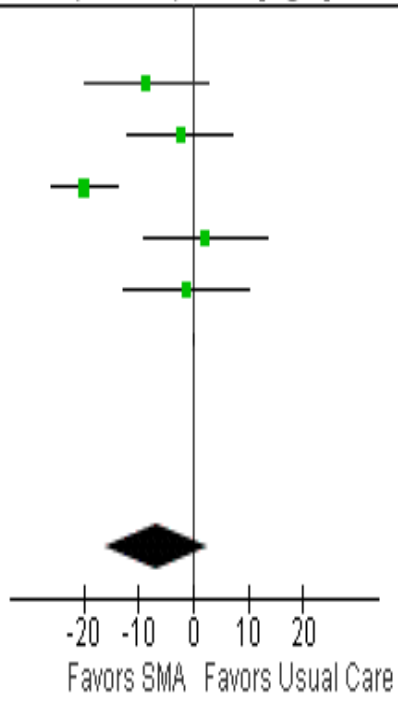
Study or Subgroup	SMA Mean [mg/dl]	SMA SD [mg/dl]	SMA Total	Usual Care Mean [mg/dl]	Usual Care SD [mg/dl]	Usual Care Total	Weight	Mean Difference IV, Random, 95% CI [mg/dl]	Year
1.3.1 LDL Cholesterol									
Clancy 2003	107.6	31.2	59	116.2	31.2	61	19.0%	-8.60 [-19.77, 2.57]	2003
Taveira 2010	82.8	24.1	58	85.2	26.7	51	20.4%	-2.40 [-12.00, 7.20]	2010
Trento 2010	107.9	36.4	315	127.9	37.5	266	23.3%	-20.00 [-26.04, -13.96]	2010
Cohen 2011 (1)	-9.4	23.716	50	-11.53	33.2134	49	18.8%	2.13 [-9.26, 13.52]	2011
Taveira 2011	92.5	24.3	44	93.9	30.6	44	18.6%	-1.40 [-12.95, 10.15]	2011
Total (95% CI)			**526**			**471**	**100.0%**	**-6.64 [-16.11, 2.82]**	

Heterogeneity: $Tau^2 = 90.57$; $Chi^2 = 19.46$, df = 4 (P = 0.0006); $I^2 = 79\%$

Test for overall effect: Z = 1.38 (P = 0.17)

Test for subgroup differences: Not applicable

(1) Mean change



Other outcomes—patient-level

- Patient experience?
  - No effect– but only 2 studies measured
- Staff experience?
  - Completely unmeasured
- Treatment Adherence?
  - No effect– but only 3 studies measured, and no single behavior was assessed in more than 2 studies
- HRQoL?
  - 3 studies used a disease-specific measure, found a positive effect, not highest quality trials
  - 2 used a general measure, no effect

Other Outcomes– costs and utilization

- Utilization?
  - 5 studies, 4 of 5 with reduced admissions
  - Same 5 studies, variable results on ER visits
- Costs
  - 4 studies, mixed results on overall costs

Older Adults?

- 3 studies, 2 trials, one observational
- Lower study quality than diabetes studies
- All studies measured patient satisfaction but with different, non-validated measures
  - All showed satisfaction improvement
- No change in global health or function
- Both trials showed lower ER use and admissions, ER statistically significant in both
- Costs lower, but not significantly so, in both trials

Key Questions 2 & 3

- No study reported specific patient characteristics that led to better response to SMAs (Key Question 2)
  - We evaluated whether baseline A1c was associated with response; it was not
- No study reports specific intervention components, or intensity, associated with effects of SMAs (Key Question 3)
  - We evaluated whether robustness was associated with effect size; it was not

Evidence Synthesis found no data to assess:

- Cost-effectiveness
- Non-patient benefits, such as improved access or staff satisfaction
- Key elements to successful implementation, especially outside academic or vertically integrated systems

Lessons learned

- Precise, highly scientifically valid estimates of SMA efficacy
  - SMAs are pretty efficacious; effects on A1c and SBP close to those seen in drug trials
  - Effect sizes 0.5, 0.33, and 0.25 for SBP, A1c, and LDL-c respectively
  - Taken together, a marked improvement in risk of complication; would still be important risk reduction if half the efficacy were lost in translation

Are these findings generalizable?

- Use **PICOTS** framework
- **P**opulation— likely generalizable, populations were well demographically balanced
- **I**ntervention—components VERY heterogeneous, remains quite possible that not all group strategies are effective.
- **C**omparator– Also heterogeneous, “usual care” poorly described in most studies
- **O**utcome—likely generalizable, biophysical outcomes are the generally agreed upon set
- **T**iming—likely generalizable, general agreement that 6 months improvement is important
  - But no studies of maintenance of improvement
- **S**etting—All studies in highly academic settings, not any “real-world” studies.

Where do we go from here?

- Other chronic illnesses
- Study designs that allow evaluation of particular components
- Multi-site implementation studies with good measurement of patient and staff impacts
  - Strongly consider mixed-methods studies
  - Carefully measure unintended consequences on the system
- Cost and cost-effectiveness analyses

Theory Driven, Context Dependent Studies of Shared Medical Appointments: A Realist Work in Progress

Susan Kirsh, MD, MPH and David Aron, MD, MS

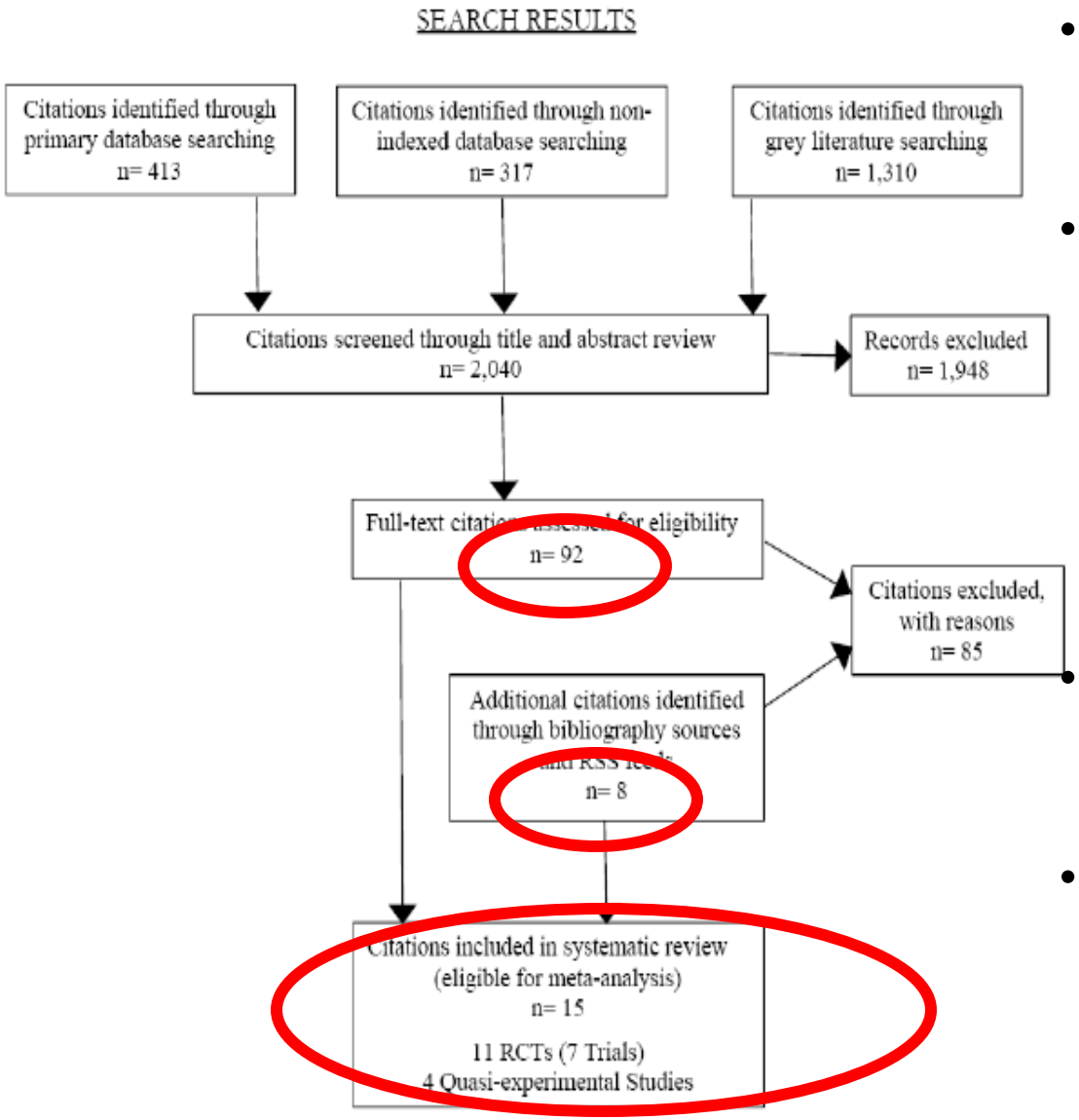
with Kim Johnson, RN PhD, Katherine Jones, PhD, Brian Mittman, PhD, John Øvretveit, PhD, Laura Santurri, PhD, MPH, CPH, Lauren Stevenson, PhD

Louis Stokes Cleveland DVAMC and Case Western Reserve University
Cleveland, OH 44106

The views are those of the presenters and do not reflect those of VHA or any other agency/institution.

Objectives

- Discuss theory-driven context-dependent review (realist) and why needed
- Describe our experience
- Q&A



Burke RE et al. The effectiveness of group medical visits on diabetes mellitus type 2 (dm2) specific outcomes in adults: a systematic review. JBI Library of Systematic Reviews JBL000433 2011;**9(23):833-885**

- **Main results:** benefits HbA1c; some evidence for SBP; none for LDL
- **Conclusions:** should be considered by clinicians as an effective, non-pharmacologic intervention that can have a positive impact on biologic markers such as HbA1c and SBP.
- **Implications for Practice:** most powerful model includes clinician prescriber
- **Implications for Research:** RCTs needed

What managers want to know is what works when and for whom.

In other words, context matters.

45 CFR 46 .102(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Nancy Cartwright

Scientists, including social scientists, are often dismissive of philosophy. Philosophy, it is said, is too abstract, too fussy and too taken up with its own problems to matter to real practice. With the issues discussed here (*efficacy, evidence, RCTs and policy*) I think just the opposite is the case. Bad practice, I maintain, is being recommended without intention and without sufficient notice in part because prissy issues that philosophy fusses about are being ignored, issues like what counts as a proper definition and whether an argument has been laid out with all the necessary premises.

What is This Thing Called 'Efficacy'?
http://personal.lse.ac.uk/cartwrig/PapersOnEvidence/What%20is%20that%20thing%20called%20efficacy.%2018%20June%20edited%20for%20web%20page.pdf

Philosophical differences: Positivism, Realism and Constructivism

	Positivism	Realism	Constructivism
Ontology	There is an objective reality, which exists independent of us.	Material & social reality – we interact with reality.	Subjective reality – we 'create' reality
Epistemology	Truth and final knowledge exists.	No final truth or knowledge, but improvement in knowledge is possible.	No way to choose between interpretations. What we jointly believe is true.
Causation	Constant conjunction, linear causation. Programs cause outcomes.	Mechanisms operating differently in different contexts generate patterns of outcomes.	Co-constructed interpretations lead to actions and outcomes.
Implications for evaluation	Evaluators 'tell facts'. Context factors should be eliminated: Randomised Control Trials/ Quasi-experimental methods.	Evaluators explain how and where programs generate outcomes. Mixed methods (qualitative and/or quantitative).	Evaluators describe stakeholder interpretations. Qualitative methods

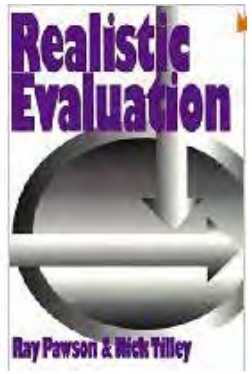
Realist Evaluation: an overview Report from an Expert Seminar with Dr. Gill Westhorp. Edited by Dr. G. Westhorp, Prins, E., Kusters, C.S.L., Hultink, M., Guijt, I., Brouwers, J.H.A.M. Centre for Development Innovation, Wageningen University & Research centre, May 2011

RCT	Theory Driven/Context Dependent
High Internal validity-independent from other external changes.	External validity-external changes part of interventions and must be reported together with the results.
Intervention group is compared with similar control or an internal control is used.	Based on identification of relevant context and mechanisms, the intervention group can be compared with similar external or internal control. Differences between controls and intervention are reported.
Isolation of confounding factors	Isolation of confounding factors is not possible, outcome cannot be seen isolated from context and mechanisms

Nielsena & Kinesb. Realistic evaluation as a new way to design and evaluate occupational safety interventions. Safety Science. 2012;50:48-54

Realist Evaluation and Realist Synthesis

- *Real* – deals with the real world
- *Realist* – grounded in 'scientific realism'
- *Realistic* – "The whole point is that it is a form of applied research, … pursued to inform the thinking of policy makers, practitioners, program participants and public."



1997

2006

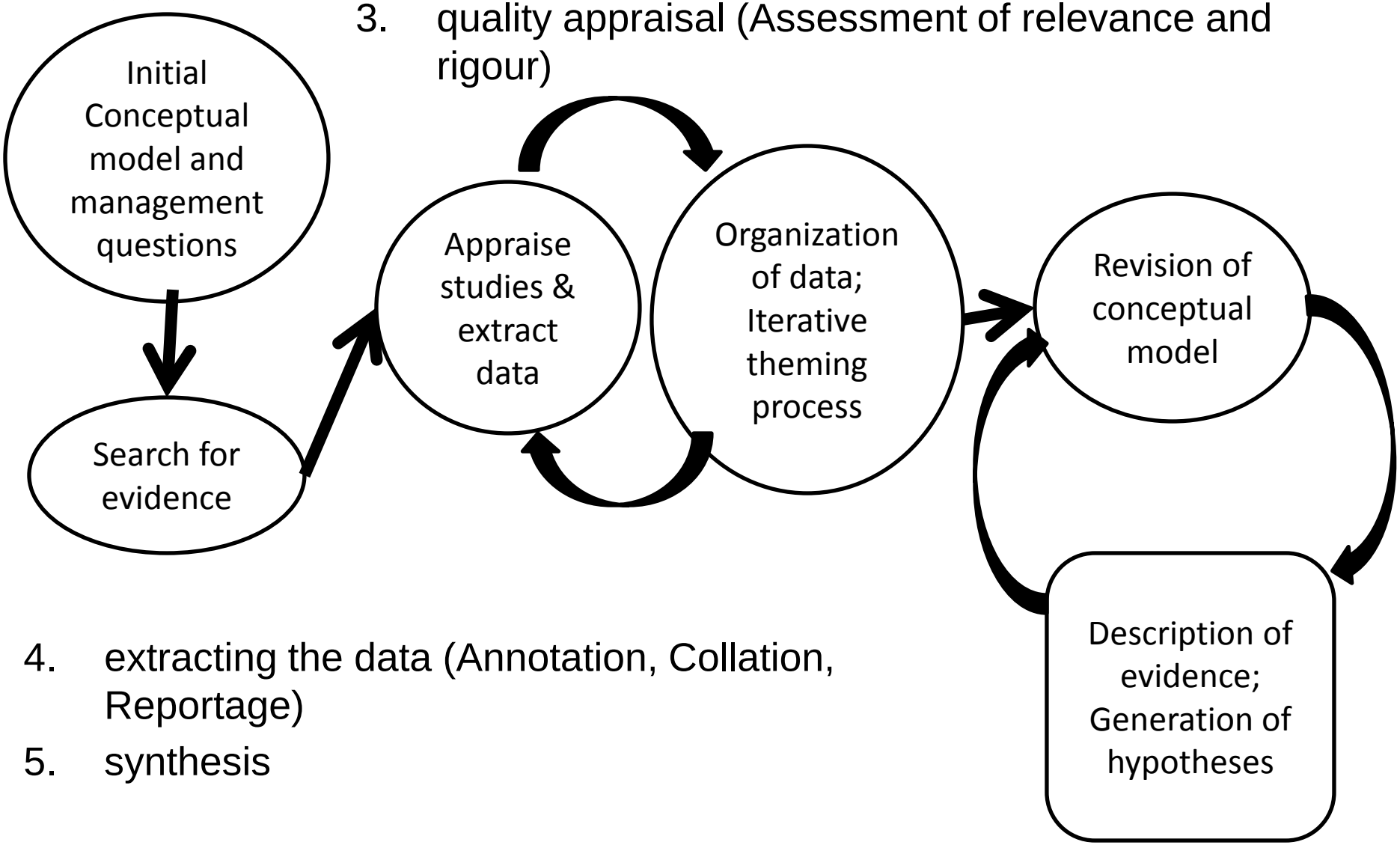
"What causes something to happen has nothing to do with the number of times we observe it happening" (Sayer, 2000 p. 14).

Not: "does it work or not?"

But rather, "what works, for whom, and in what circumstances?"

Methods, but…

1. identifying the review question
2. searching for primary studies (A search to track program theories and a search for primary studies)
3. quality appraisal (Assessment of relevance and rigour)



4. extracting the data (Annotation, Collation, Reportage)
5. synthesis

There is more than one way to conduct a “realist synthesis.”

Thus, on the continent the disease was pulled to pieces, bit by bit without the benefit of chemical determinations: in America it was put together by a group of men, almost no one of whom had ever looked a parathyroid cell face to face in a microscope.
All of which proves that there are two ways of killing a cat (see Fig. 8).

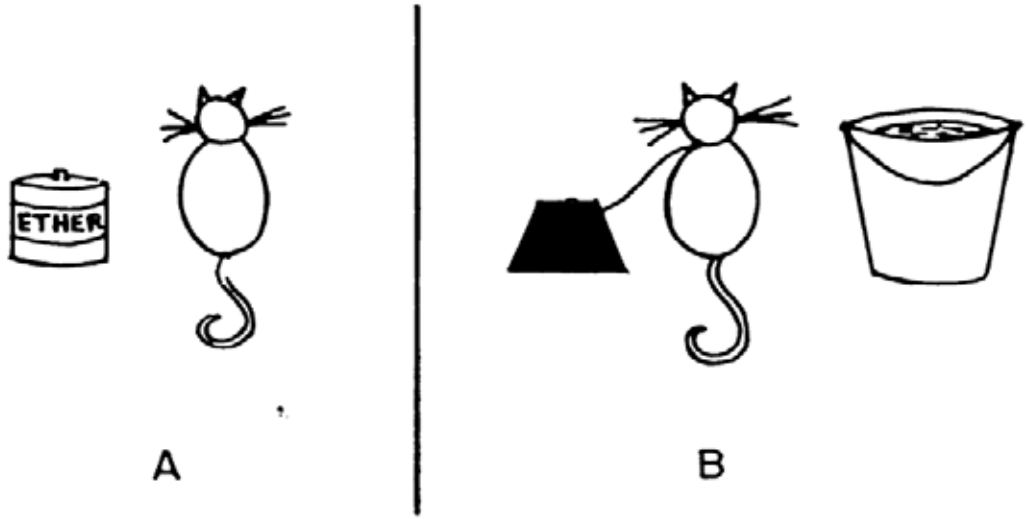


FIG. 8. Two ways of killing a cat.
At the Massachusetts General Hospital we prefer “A.”

•Albright F: A page out of the history of hyperparathyroidism. J Clin Endocrinol 8: 637–657, 1948
•Biographical Memoirs V.48 (1976) National Academy of Sciences (NAS)

What Realist Review Does

- Identifying mechanisms, the contexts in which they are (or are not) activated, and the outcomes to which they lead

- Categorizing and building these Context-Mechanism-Outcome clusters into Demi-Regularities
  - Not *laws*, but *things that tend to happen*

- Bringing to bear mid-range theories to help understand the patterns of these demi-regularities

- Ultimately building or testing a theoretical model of how a program works

AC Macaulay, J Jagosh, R Seller, J Henderson, M Cargo, T Greenhalgh, G Wong, J Salsberg, LW Green, C Herbert, P Pluye. Benefits of Participatory Research: A Rationale For a Realist Review (*in press*). Global Health Promotion. 18(2) June. 2011

Justin Jagosh, Ph.D , Participatory Research at McGill (PRAM)
Department of Family Medicine, McGill University, Montréal, Canada.

Understanding Mechanisms:

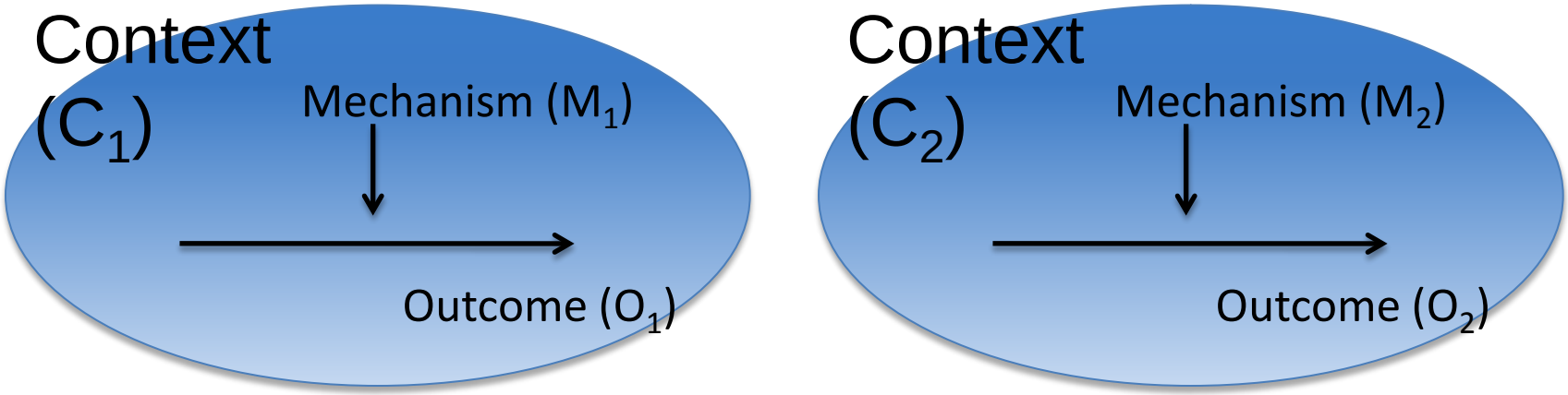
- Mechanism may be defined as:
  - "…underlying entities, processes, or structures which operate in particular contexts to generate outcomes of interest."*
- Mechanism:
  - Are usually hidden
  - Sensitive to variations in context
  - Generate outcomes
- For social interventions, mechanism typically refer to a cognitive process or what 'turns on' in the mind of program participants to make them want to participate in the program

*Astbury B, Leeuw F. Unpacking Black Boxes: Mechanisms and Theory Building in Evaluation *American Journal of Evaluation* 2010 31(3):363-381

- Justin Jagosh, Ph.D , Participatory Research at McGill (PRAM)
- Department of Family Medicine, McGill University, Montréal, Canada.

How do you do that?

- By identifying the basic logic (theory) behind programs under review;
- By configuring the contextual features and mechanisms which determine outcomes (C-M-O configuring) and comparing cases;
- By refining the theory that was originally identified, based on the CMO synthesis.



Basic components of realist causal explanation

Pawson R, & Tilley N. 1997 [2003]. *Realistic Evaluation*. Thousand Oaks, CA: Sage Publications.

Modified from Justin Jagosh, Ph.D , Participatory Research at McGill (PRAM), Department of Family Medicine, McGill University, Montréal, Canada.

Identifying the theory:

For a realist synthesis of a single case, the underlying logic is understood as 'program theory.' Every program has a theory, whether it is obvious or not

- For a realist review synthesizing many cases, the underlying theory is considered "Middle-range"
- *Middle-Range Theory:* not abstract to the point of being disconnected from the actual on-the-ground realities of program planning and implementation, yet, not specific to the point of being relevant to only one type of program.
- Middle-Range Theory According to Merton*:

  "theory involves abstraction, of course, but it is close enough to observed data to be incorporated in propositions that permit empirical testing."

*Merton R. On Theoretical Sociology. Five Essays, Old and New. New York: The Free Press, 1967.

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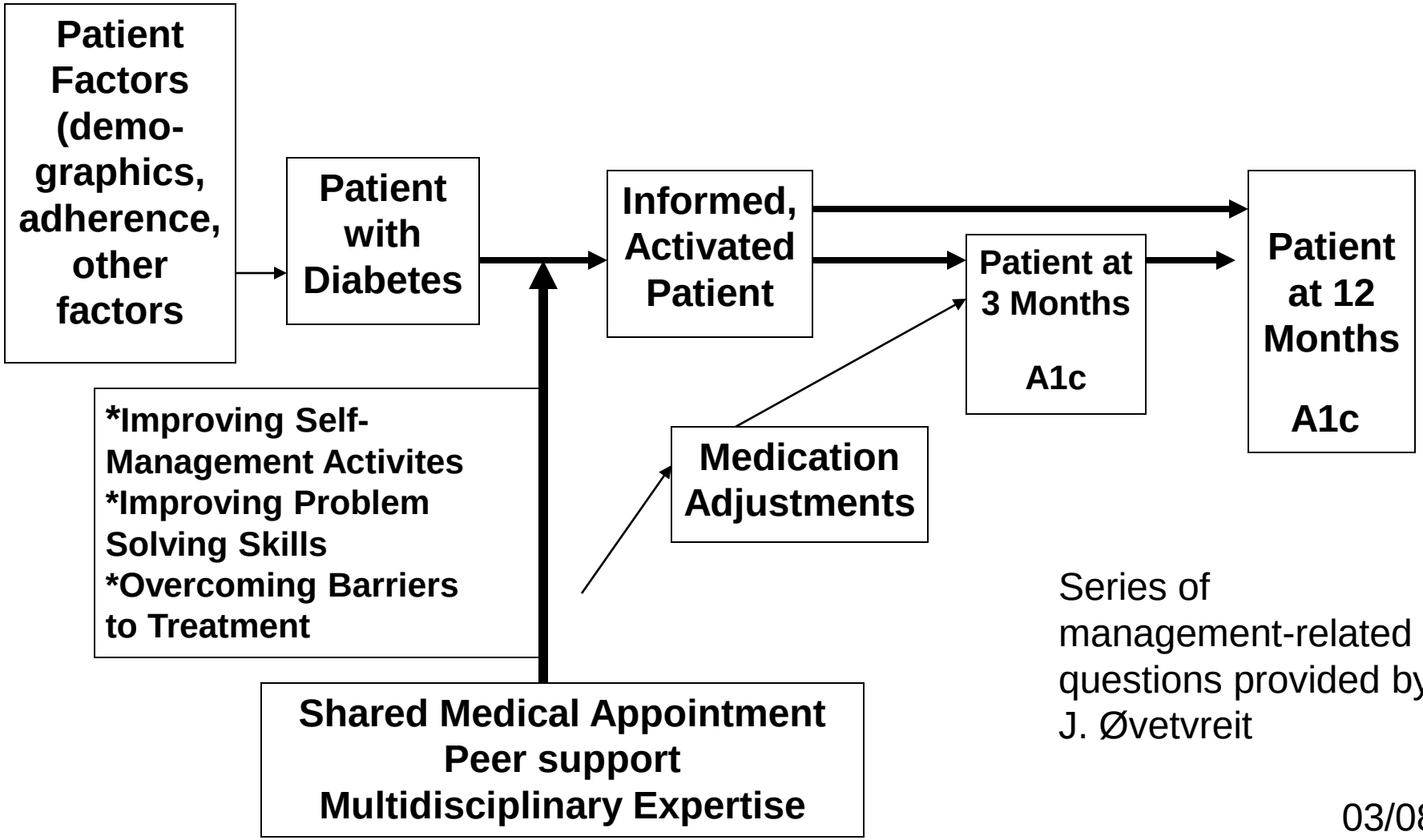
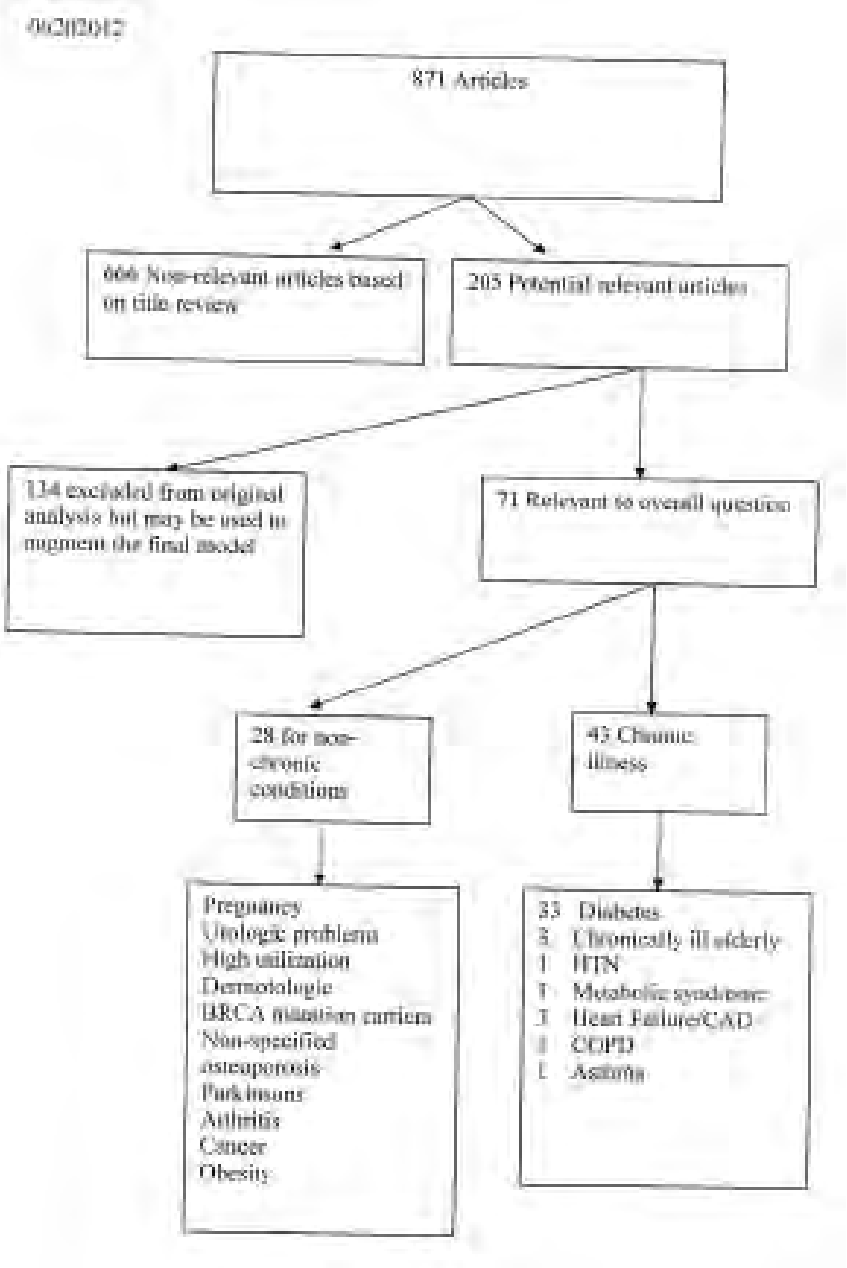
Initial Conceptual Model

(from prior work on SMAs)



Series of management-related questions provided by J. Øvetvreit

03/08



- Number of articles by year
  - 2008 or earlier: 38
  - 2009: 10
  - 2010: 9
  - 2011: 14
- Number of articles by U.S. or international
  - U.S.: 56 (78.9%)
  - International: 15 (21.1%)

Characteristics of SMAs

- Educational component – 88.7%
- Multidisciplinary members – 64.8%
- Included a behavioral intervention – 50%
- Included medication adjustment – 55.7%
- Included peer-to-peer support – 87.3%
- Included clinician training – 42.9%

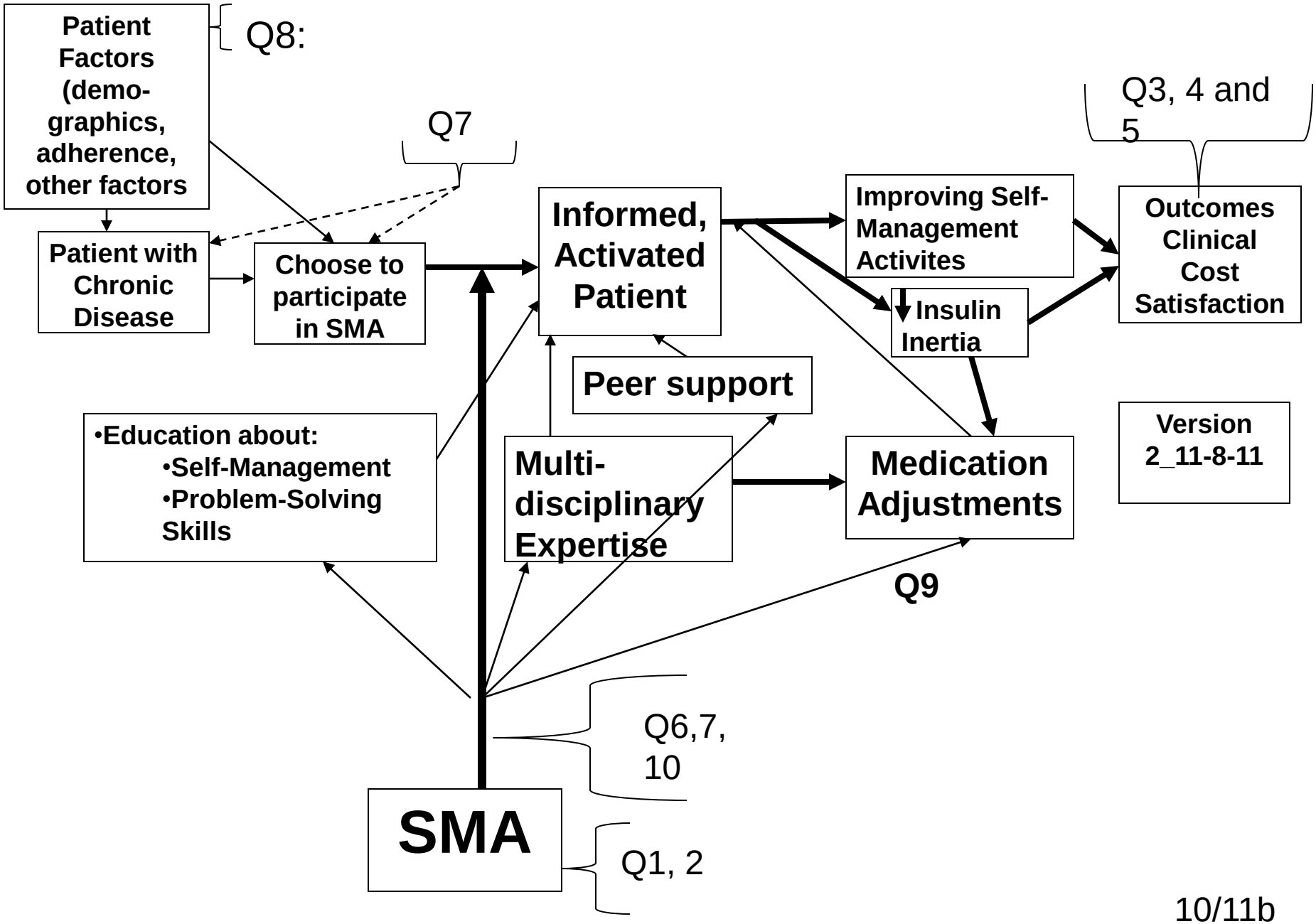
Characteristics of SMAs

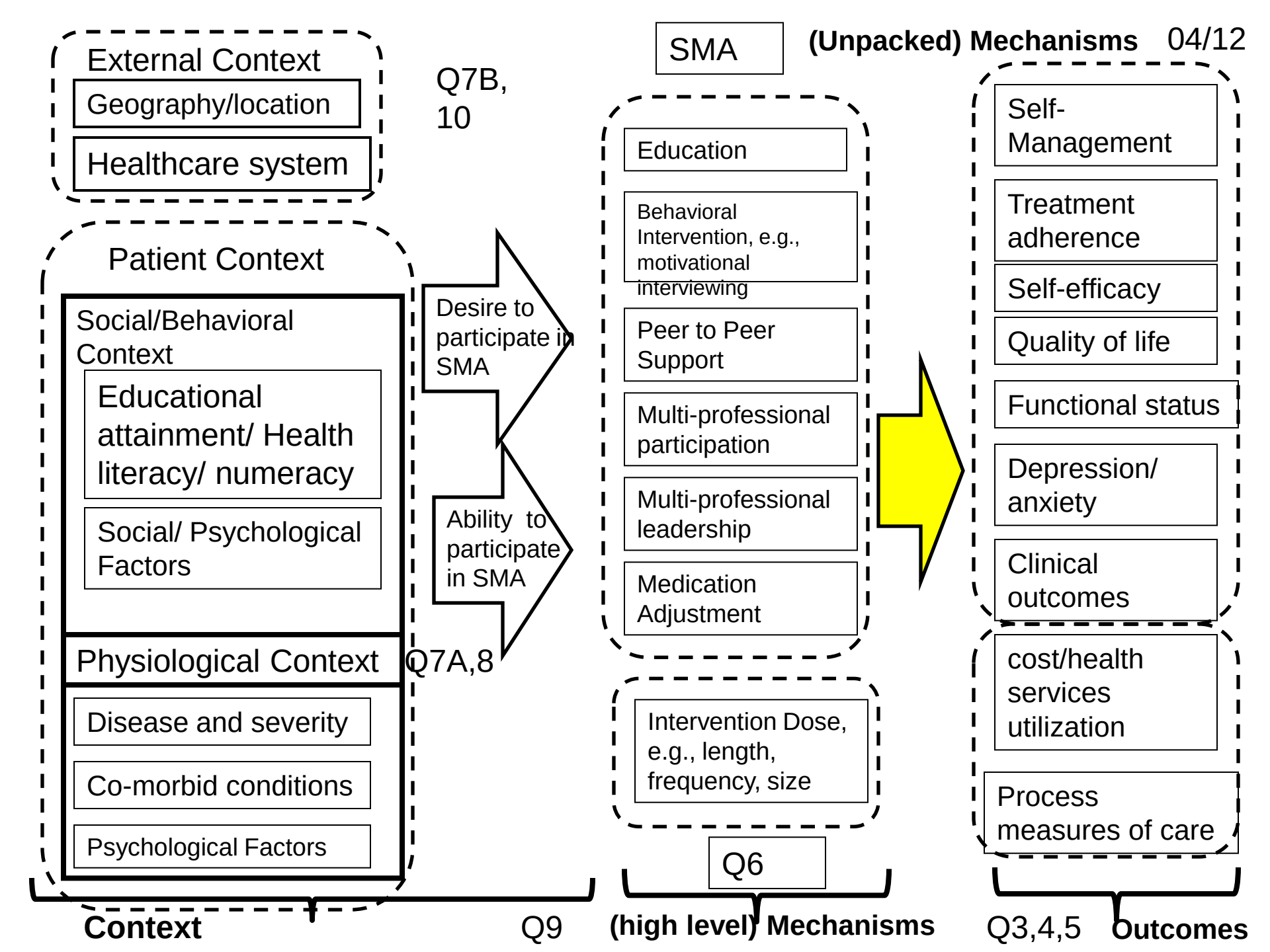
Visit duration

- <60 minutes: 1.7%
- 60-89 minutes: 9.9%
- 90-120 minutes: 59.2%
- >120 minutes: 12.7%
- Missing: 16.9%
- Missing: 23.9%

Visit frequency

- Once: 8.5%
- Weekly: 16.9%
- Every 2 weeks: 2.8%
- Monthly: 29.6%
- Every 2 months or more: 18.3%


Patient Factors (demo-graphics, adherence, other factors
Q8:
Q7
Q3, 4 and 5
Patient with Chronic Disease
Choose to participate in SMA
Informed, Activated Patient
Improving Self-Management Activites
Outcomes Clinical Cost Satisfaction
Insulin Inertia
Peer support
•Education about:
•Self-Management
•Problem-Solving Skills
Multi-disciplinary Expertise
Medication Adjustments
Version 2_11-8-11
Q9
Q6,7, 10
SMA
Q1, 2


External Context
Geography/location
Healthcare system
Q7B, 10
SMA
(Unpacked) Mechanisms
04/12
Patient Context
Social/Behavioral Context
Educational attainment/ Health literacy/ numeracy
Social/ Psychological Factors
Physiological Context
Disease and severity
Co-morbid conditions
Psychological Factors
Desire to participate in SMA
Ability to participate in SMA
Q7A,8
Education
Behavioral Intervention, e.g., motivational interviewing
Peer to Peer Support
Multi-professional participation
Multi-professional leadership
Medication Adjustment
Intervention Dose, e.g., length, frequency, size
Q6
Self-Management
Treatment adherence
Self-efficacy
Quality of life
Functional status
Depression/ anxiety
Clinical outcomes
cost/health services utilization
Process measures of care
Context
Q9
(high level) Mechanisms
Q3,4,5
Outcomes

Some preliminary (hypothetical) demi-regularities

C_1 Across geographies (urban vs suburban vs rural)	M_1 Travel distances affect participation rate	O_1 Effects similar
C_2 Across patient factors (Socioeconomic status)	M_2 SES associated with educational attainment	O_2 Effects similar
C_3 Across chronic diseases	M_3 Self management principles similar across disease	O_3 Effects similar

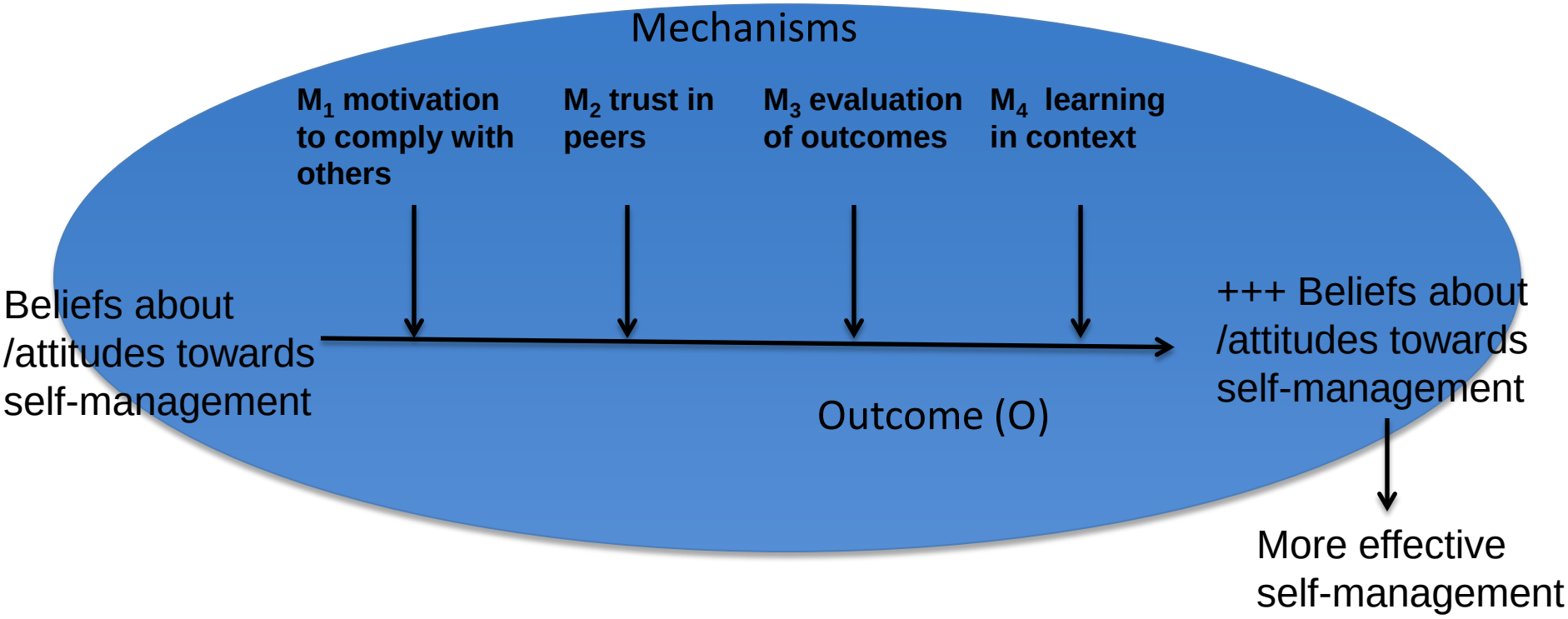
Some preliminary hypothetical demi-regularities

Context	Mechanism	Outcome
C_1	M_1 Behavioral component	O_1 better outcomes if present
C_1	M_2 Multiprofessional	O_1 better outcomes if present
C_1	M_3 Medication Adjustment	O_1 better outcomes if present
C_1	M_4 Duration of SMA	O_1 better outcomes if longer duration (90-120 minutes)
C_1	M_5 Peer support	O_1 better outcomes if present

Also found that SMAs that used more of these had better outcomes.

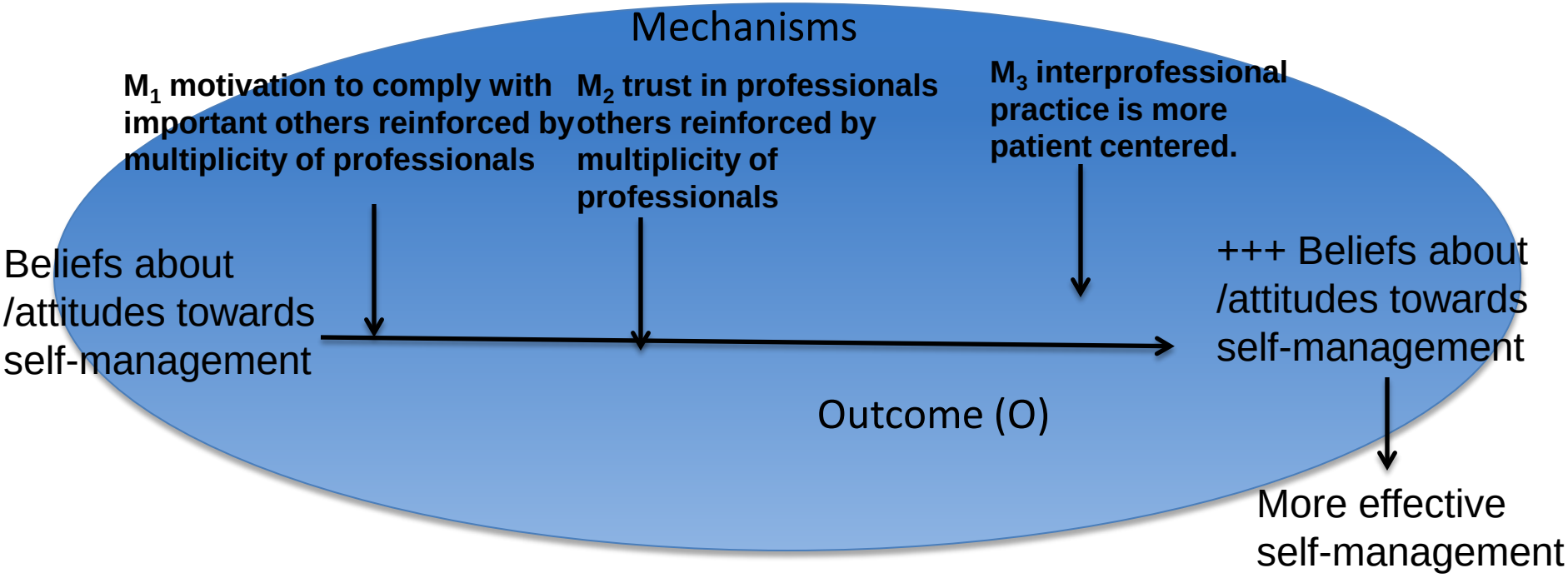
Further unpacking a mechanism seeking further support from established theory

- Peer Support is a strategy – a high level mechanism that becomes the context for the next level.

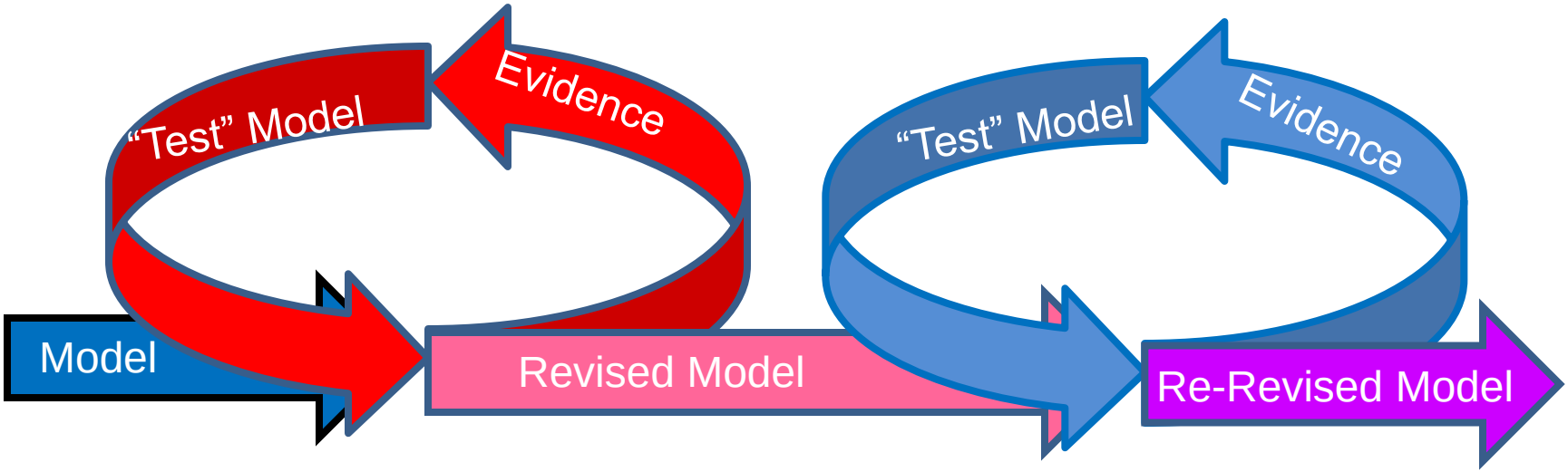


Further unpacking a mechanism seeking further support from established theory

- Multiprofessional/interprofessional team is a strategy – a high level mechanism that becomes the context for the next level.



How is this theory driven, context dependent evaluation different?



- Iterative development of conceptual model for contexts, mechanisms, outcomes
- Based on principles and not a series of sequential steps
- No particular preference for quantitative or qualitative methods
- Multidisciplinary stakeholders and participants
- Stakeholders are regarded as key sources for eliciting program theory and providing data on how the program works

Lessons Learned

- Generalizability is not “just” a philosophical question. It is core to practice in the real world. Not necessarily a need for further “research” but a need for researchers to report on different information.
- Cannot manufacture new data - can only look at existing data in a different way.
- Current literature has very little information on patient perspective. Need for qualitative data.

Pawson et al. ESRC Research Methods Programme, Working Paper Series, August '04

Traditional 'Cochrane' Review	Realist Review
1. Identify the review question	1. Clarify scope of review (identify review ; question; refine purpose of review; Articulate key theories to be explored
2. Search for primary studies, using clear predefined inclusion and exclusion criteria	2. Search for relevant evidence, refining inclusion criteria in the light of emerging data
3. Appraise quality of studies using a predefined and validated critical appraisal checklist, considering relevance to research question and methodological rigour	3. Appraise quality of studies using judgement to supplement formal checklists, and considering relevance and rigour from a 'fitness for purpose' perspective
4. Extract standard items of data from all primary studies using template or matrix	4. Extract different data from different studies using an eclectic and iterative approach
5. Synthesise data to obtain effect size and confidence interval and/or transferable themes from qualitative studies	5. Synthesise data to achieve refinement of programme theory – that is, to determine what works for whom, how and under what circumstances
6. Make recommendations, especially with reference to whether findings are definitive or whether further research is needed	6. Make recommendations, especially with reference to contextual issues for particular policymakers at particular times
7. Disseminate findings and evaluate extent to which practitioners' behaviour changes in a particular direction	7. Disseminate findings and evaluate extent to which existing programmes are adjusted to take account of elements of programme theory revealed by the review