



Issues and Challenges around Scoping, Focusing the Question & Use of Models and Theory

Janet Harris
ESQUIRE 4th September 2014



New review types are being developed...

- Focusing on
 - Complex interventions
 - Implementation
 - Realist synthesis
- How do we scope and focus questions for these types of reviews?
- Unlike intervention reviews, guidance on question formulation does not exist yet



Complex intervention reviews

- Definition
- Need for review
- Aims of the review
- Approaches to question formulation



What is a complex intervention?

- Complex interventions in health care, whether therapeutic or preventative, comprise a number of separate elements which seem essential to the proper functioning of the interventions although the 'active ingredient' of the intervention that is effective is difficult to specify... Complex interventions are built up from a number of components, which may act both independently and interdependently. The components usually include behaviors, parameters of behaviors (e.g. frequency, timing), and methods of organizing and delivering those behaviors (e.g. type(s) of practitioner, setting and location).'
- Medical Research Council: *A framework for development and evaluation of complex interventions to improve health*. London: Medical Research Council; 2000.



Why should we do complex intervention reviews?

- To map the range of components in an intervention
- To assess how well the components are defined
- To aggregate and clarify concepts in order to inform future primary studies as well as reviews
- To ascertain which components are core and which are discretionary
- To explore when, where, how and with whom tailoring of components is effective



A complex intervention review question

- How effective is community management of acute malnutrition (CMAM) in increasing food intake, improving nutritional status and reducing death in children aged 1-5 years of age in Ghana?
- Comparison: hospital management of acute malnutrition
- *What is already known about effective programmes?*



Using models and programmes theories to formulate review questions for complex interventions

- Programme theories articulate the relationship between the problem being addressed, the activities or strategies used to resolve the problem, and the desired outcomes
- These assumptions can be illustrated visually via a logic model to depict complex interventions

Complex intervention Logic model for Community Management of Acute Malnutrition (CMAM) (Akparibo, 2014)

Intervention components	Expected change/outcome
Train health workers and community members	→ Increased knowledge and awareness about malnutrition and the CMA protocol
Mobilise and sensitise community members to malnutrition causes, treatment and prevention	→ Increased participation and utilisation of services
Screening for malnutrition at the community level	→ Early identification of cases for prompt treatment
Distribution of therapeutic food to carers to treat children at home	→ Readily available supply of food
Frequent monitoring of children receiving treatment at home, and counselling to caregivers	→ Reduced barriers to utilisation will results in less than 15% dropout rates
	→ Early identification of issues with compliance; Increased nutrition intake
	→ Improved nutritional status; decreased risk of death.



Aims of a complex intervention review

- The review can focus on a particular area of interest:
- Elucidate mechanisms of action of complex interventions
- Explore effect modifiers
- Identify critical factors for implementation, scaling up, and implementability
- Determine the resources required to deliver the intervention in different settings
- Estimate the cost-effectiveness of intervention

(Squires et al, 2013)



Sources of complexity

- (1) the number of interacting components within the experimental and control interventions
- (2) the number and difficulty of behaviors required by those delivering or receiving the intervention
- (3) the number of groups or organizational levels targeted by the intervention
- (4) the number and variability of outcomes
- (5) the degree of flexibility or tailoring of the intervention permitted

(Craig et al, 2008)



Other possible sources of complexity

- nonlinear pathways between intervention and outcome
- feedback loops
- emergent properties
- the presence of interactions between the intervention and its context

(Meadows, 2008)



Issues with scoping complex intervention questions

- Lumping or splitting: including diverse studies on focusing on similar studies? Diversity will need to be mapped in order to justify the decision
- Getting at the definition of the intervention
 - Is there an underlying theory to why it will work?
 - Is the theory operationalised in the same way across studies, or is there a diverse range of variables for each concept?
- *More discussion and tips can be found in Squires et al, 2013*



Implementation reviews

- What is implementation and implementation research?
- Approaches to question formulation



What is implementation?

- Implementation is defined as a specified set of activities designed to put into practice an activity or program of known dimensions.
- It incorporates two levels of activity and outcomes:
 - Intervention level: treatment or prevention efforts at the consumer level
 - Implementation level: efforts to incorporate a program or practice at the community, agency, or practitioner levels.

(Fiksen et al. 2005)



What is implementation research?

- Implementation research has been defined as 'the scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health care. It includes the study of influences on health care professional and organisational behaviour.' (Eccles et al. 2009)



Comparing review types

- How is an implementation review different from a complex intervention review?
 - Broader focus on the process of implementation that surrounds the intervention e.g. how do you replicate an intervention across community, across practitioners, across health organisations, across health systems
 - Broader focus leads to scoping different types of literature, for example
 - Organisational studies, management, systems thinking, practitioner's behaviour change



An implementation review question

- Can community management of acute malnutrition (CMAM) be consistently delivered in rural areas of Ghana and achieve the same results in terms of improving nutritional status and reducing death in children aged 1-5 years as hospital management of acute malnutrition?
- Focus of interest: the process of incorporating a program or practice at the community level; the role of agencies in delivering the programme

Implementation Logic model for Community Management of Acute Malnutrition (CMAM 'pipeline' model)

Inputs and processes (agency level)	Implementation Outputs (short term)	Outcomes
Recruit community health workers and community volunteers	Adequate workforce with <ul style="list-style-type: none"> • Increased knowledge and awareness about malnutrition and the CMA protocol 	Increased participation and utilisation of services
Train CHWs and CVs	Confidence and motivation to implement CMAM;	Early identification of cases
Mobilise and sensitise community members to malnutrition	Local credibility and acceptability	
Screening for malnutrition at the community level	Skills to screen for malnutrition	
Distribution of therapeutic food to carers to treat children at home	Gaps in supply chain; Capacity to monitor supplies, delivery	Increased nutrition intake
Frequent monitoring of children at home, and counselling to caregivers	Readily available supply of food	Improved nutritional status; decreased risk of death.
	Capacity to monitor use of food	
	Early identification of compliance issues	



Issues with scoping implementation questions

- If the area is not well researched, the degree of uncertainty about the processes will be greater
- The processes might be listed but not described in enough detail to identify potential issues
 - *For example, what is counselling for caregivers and is it the same across different settings?*
- The core components of implementation may vary depending on the context
 - *For example, food may be delivered to the home in some areas, while in other areas mothers obtain it from the hospital clinic*
- The nature of the context may not be reported
 - *For example, one area may already have access to trained community health workers who are able to add nutrition to their current skills base while another area may have no experience of using CHWs*



What is a realist review?

- Traditional methods of review focus on measuring and reporting on programme effectiveness, often find that the evidence is mixed or conflicting, and provide little or no clue as to why the intervention worked or did not work when applied in different contexts or circumstances, deployed by different stakeholders, or used for different purposes.
- Realist review aims to discern what works for whom, in what circumstances, in what respects and how. (Pawson et al, 2005)



Realist reviews require a lot of scoping

- Realist reviews require scoping for three different processes in the review
 - To map the amount and nature of qualitative and quantitative literature
 - To map the theories that have been used by the intervention or programme
 - To identify potentially relevant theories in other disciplines (typically in the social, behavioural or psychological fields)



Issues with scoping realist review questions

- When the amount of literature is large, a decision about how to sample the literature needs to be explicitly made
 - Comprehensive?
 - Purposive?
 - Theoretical?
 - A combination of approaches?



Issues with scoping realist review questions

- Studies may not explicitly describe the underlying theory for the programme or intervention
 - *How do we 'extract' theory when it is not reported?*
- There is some guidance for this (Leeuw, 2003) but it is widely acknowledged that this needs further development



A realist review question

- How and why does community management of acute malnutrition (CMAM) work for families with children aged 1-5 years, in what circumstances and at what point in time?
- Focus of interest:
 - Identifying how context influences attitudes, beliefs and practices when delivering and participating in a CMAM programme
 - Determining how the interaction between local contexts and mechanisms affects potential impact of the intervention
 - Identifying patterns that appear across different contexts
 - Making associations between those patterns and known theories

Realist CMOs for Community Management of Acute Malnutrition (CMAM)

Context	Mechanisms	Outcome
Regional policies for CMAM Screening for malnutrition promoted at the community level	<ul style="list-style-type: none"> CHWs and CVs initially motivated to attend training; mobilise community; screen and implement CMAM CHWs and CVs have local credibility and acceptability 	Increased knowledge and awareness about malnutrition Consistent implementation of the CMA protocol
Distribution of therapeutic food to carers to treat children at home	<ul style="list-style-type: none"> Cultural beliefs about malnutrition; customs for feeding contradict programme Access to food constrained by husband's attitudes 	Less early identification of cases; some delayed treatment Inconsistent supply of food
Inadequate workforce with CHWs performing more than one job; Lack of incentives to retain CVs	<ul style="list-style-type: none"> Decreased motivation for monitoring children at home, and counselling caregivers 	Delayed identification of issues with compliance Improved nutritional status; decreased risk of death diluted by low compliance and dropout.



Moving from CMOs to propositions: The final theory

- In settings where Community Management of Acute malnutrition is supported via routine distribution of food and an adequate workforce
- Mothers will be motivated to keep their children in the programme and comply with advice
- If locally credible CHWs are able to partner with community elders in obtaining acceptance and support from fathers and families
- Resulting in the eradication of malnutrition in children aged 1-5 years



Where are we now? Developments in the field

- The process of question formulation for different types of reviews is rarely described
- Guidance for developing protocols for complex intervention reviews, implementation reviews and realist reviews is under development
- Funding for implementation studies is increasing as a result of global interest in health systems strengthening
- As the methods for complex intervention and implementation research evolve, reporting should improve making it easier to access information for reviews
- The number of worked examples of theory development is increasing, but more still needs to be done to make the process of arriving at the final theory more explicit



References

- Akpanbo R. (2014) Realist Evaluation of Community-based Model to Treat Children with Severe Acute Malnutrition in Non-emergency Context in Ghana. University of Sheffield PhD Thesis.
- Craig P, Dieppe PA, Macintyre S, Michie S, Nazareth I, Petticrew M. (2008) Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 337:979e83.
- Eccles M, et al (2009) An implementation research agenda. *Implementation Science* 4:18 doi: 10.1186/1748-5908-4-18
- Fixsen DL, Naoom SF, Blasé KA, Friedman RM, Wallace F. (2005) *Implementation Research: A Review of the Literature*. Tampa: University of South Florida.
- Leeuw FL. (2003). *Reconstructing Program Theories: Methods Available and Problems to be Solved*. *American Journal of Evaluation*, 24(1), 5-20.
- Meadows D. (2008) *Thinking in systems*. White River Junction, VT: Chelsea Green Publishing.
- Medical Research Council: *A framework for development and evaluation of complex interventions to improve health*. (2000) London: Medical Research Council.
- Pawson R, Greenhalgh T, Harvey G, Walshe K. (2005) Realist review--a new method of systematic review designed for complex policy interventions. *J Health Serv Res Policy* 10 Suppl 1:21-34.
- Squires JE, Valentine JC, & Grimshaw JM. (2013). Systematic reviews of complex interventions: framing the review question. *Journal of clinical epidemiology*. doi:10.1016/j.jclinepi.2013.05.013
- Winter SG & Szulanski G. (2001). Replication as Strategy. *Organization Science*, 12(6), 730-743.