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Realist Synthesis for Public Health: Building an Ontologically Deep Understanding of How Programs Work, For Whom, and In Which Contexts

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Abstract

Realist synthesis is a literature review methodology for understanding how, for whom, and under what circumstances complex interventions function in complex environments. Using a heuristic called the contextmechanism-outcome (CMO) configuration, realist synthesis produces evidence-informed theories about the interactions between intervention mechanisms and their implementation contexts. Public health interventions and their effects unfold over time and develop differently in different contexts. Much of what causes programs to function remains in a realm beyond empirical measurement. By scrutinizing the theories relevant to the interventions of interest, and by enhancing the conceptualization of complex outcomes, the realist approach deprioritizes evidence hierarchies and harnesses insights from diverse data sources to generate causal understanding. The dynamic learning process that can arise in conducting a realist synthesis may generate new ideas for program development and innovation apart from what can be achieved in reviews providing a summation and aggregation of quantified evidence.

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INTRODUCTION

Realist synthesis (39, 50) is a theory-driven approach to assessing programs, interventions, services, and policies. Rather than asking, Does the intervention work? or What works on average?, the realist inquirer asks, What works, for whom, under what circumstances, and how? Investigators of experimental design studies and systematic reviews involving meta-analysis of quantified results from primary studies (e.g., Cochrane Collaboration, the Community Guide) are often limited in their interpretation of results and in the use of research findings for directing policy development and implementation (17). Indeed, a scan through the author conclusions of Cochrane Public Health reviews published between January 2016 and February 2018 revealed that out of 15 reviews published and active during that period, 12 were inconclusive, citing either a lack of clarity in the evidence base (36, 48, 52), uninterpretability of results (4, 30, 33), or the need for better quality research to determine conclusions (7-9, 48, 55, 59). A realist critique of the Cochrane approach to reviewing complex social programs in public health is that data aggregation based on counterfactual logic from experimental trials does not typically account for the complexity inherent in socially contingent public health programming. Pawson & Tilley (46) have explained that experimental and quasi-experimental designs to address complex evaluation questions miss some of the most important aspects that help explain why programs work or do not work. The most significant of these issues is the fact that experimental design involving randomization to control and experiment groups is based on the idea that "random allocation, or efforts to mimic it as closely as possible, represents an endeavor to cancel out differences, to find out whether a program will work without the added advantage of special conditions liable to enable it to do so" (46, p. 52). They suggest that "[m]aking no attempt to identify especially conducive conditions, and in effect ensuring that the general and therefore the unconducive are fully written into the program, almost guarantee[s] the mixed results we characteristically find" (p. 52). Realist methodology reorients the inquirer to ask questions regarding the interplay between contextual elements and mechanisms of action. This approach moves away from generalizable claims and universal regularities and toward exploratory questions about how programs are shaped by particular contexts (10) and how program mechanisms are triggered when contexts are conducive.

THE PARADOX AND FALLIBILITY OF EVIDENCE-BASED POLICY

A fundamental tenet of realist synthesis is that programs are underpinned by hidden causal forces (mechanisms) responsible for the manifestation of empirically measurable outcomes (60). Paradoxically, the most important aspects of public health programming are those aspects for which it is most difficult to generate evidence. For this reason, realist synthesis uses not only results sections of primary studies but all parts of a primary study article, as well as background documents, grey literature, and interpretations of results by study authors. Gaps in the evidence regarding mechanisms are treated with theoretical claims. Diverse sources of evidence integrated with theory are used to model realist understanding through context-mechanism-outcome (CMO) configurations (39) (see Figure 1). Treating a variety of data sources on relatively equitable grounds (e.g., study results, unpublished reports, author interpretations, commentaries, theoretical papers) requires thoughtful consideration and transparency in the analytical process. The realist perspective asserts that all data sources are potentially fallible, limited, and subjective (socially constructed) by their very nature (51). For example, results from case study and qualitative data sources may be limited by idiosyncrasy (i.e., not representative of the broader picture), and, on the other hand, results of large quantified data sets may be limited by decontextualization (i.e., data not situated in context). By applying the concept of ontological depth (see Figure 2 and the sidebar titled Definition of Terms for Realist Philosophy and Methodology), realist methodology dismantles

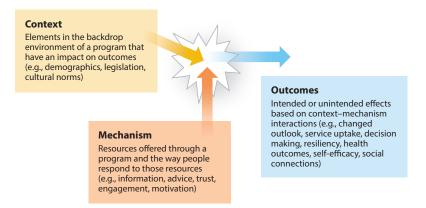


Figure 1

Framework for realist causal explanation: the context-mechanism-outcome (CMO) configuration. The CMO configuration is used in realist analysis to identify elements of context that support (i.e., trigger) or hinder (i.e., deactivate or keep latent) mechanisms.

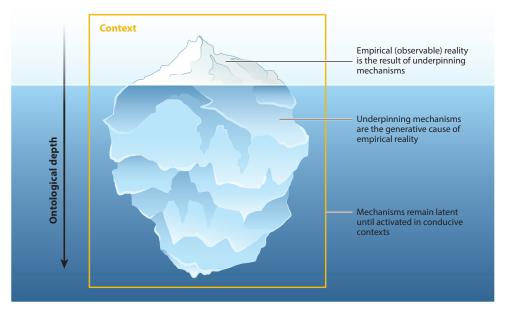


Figure 2

The iceberg metaphor depicting the realist concept of ontological depth. Reality is stratified in layers. The ice below the surface of the water represents activated mechanisms that produce reality at the empirical (i.e., observable) level. The water around the iceberg represents latent mechanisms that form the substrate upon which mechanisms activate in conducive context. Mechanisms exist in the deeper layers of reality.

the hierarchy of evidence. Qualitative case study research offers the opportunity to think deeply about the generative causal pathway to outcomes, and this approach has equitable value in relation to quantitative data sets. Rival theories and multiple causal pathways for different populations and contexts may arise. For these reasons, realists argue for a cumulative approach to knowledge generation, which is always going to reflect partial but still potentially critically important understanding for directing program implementation and innovation.

DEFINITION OF TERMS FOR REALIST PHILOSOPHY AND METHODOLOGY

Realist philosophy: an intellectual tradition involving a number of core ideas, including (*a*) mind-independent reality, (*b*) ontological depth, (*c*) generative causation, and (*d*) retroduction.

Mind-independent reality: the idea that the world exists independent of our knowledge of it. Our knowledge of reality is always partial and prone to fallibility.

Ontological depth: the idea that reality is stratified in layers. For example, a layered perspective may suggest that to understand why something has manifested in the way that it has involves mechanisms at the societal, community, family, individual, and intraindividual layers.

Generative causation: the idea that underpinning hidden mechanisms generate outcomes. This notion contrasts with successionist causation, which is based on the idea of observing correlations between empirical events to infer causation (i.e., constant conjunction of events).

Retroduction: the activity of unearthing causal mechanisms.

Middle-range theory: theory that is not abstract to the point of being disconnected from the on-the-ground workings of programs, yet not so specific to pertain to one program.

Realist program theory: theory that hypothesizes how a program is expected to work, given contextual influences and underlying mechanisms of action. A realist program theory takes into account all the factors involved in determining program success or failure and relies on middle-range theories to provide a level of abstraction that facilitates the analysis of complex data.

Although evidence-based practice (EBP) in public health is defined as "the conscientious, explicit, and judicious use of current best evidence in making decisions" (22, p. 188), what constitutes best evidence has been a focus of realist critique (37, 38, 47). Methodology that lacks a granulated contextual analysis can obfuscate explanatory claims about how programs work and for whom (39). At best, evidence-informed practice combines scientific evidence along with value judgments, resource assessments, and other contextual considerations for public health decision making to make research relevant to practice needs (2, 6, 15). Realist methodology has value in improving EBP as it can be used to study details of public health program design and to develop causal claims in relation to these details.

With few exceptions, the burden of chronic morbidity is growing on an international scale, and the field of implementation science contains examples demonstrating that practice and policy-making processes either underutilize research evidence (12) or fail to integrate evidence well into practice settings (13). This inadequacy of evidence-informed implementation can be attributed to a host of reasons, including review evidence that misses an analysis of preexisting power relations affecting stakeholder motivations, the impact of infrastructure enablers and limitations, or political or economic pressures and agendas (34). Effectiveness trials may deem an intervention to work; however, without taking into account the role of the background context in determining outcomes, such programs may show differential results when implemented in different contexts during scale-up. EBP critics and proponents alike have identified these problems in terms of a wider research–practice gap, flagging the need for "more practice-based evidence" (12) to contextualize the results of scientific studies and spurring an array of knowledge-transfer improvement strategies (53, 58). These include partnership models to generate context-sensitive evidence, such as integrated knowledge translation (11, 25), coproduction, and community-based participatory

Table 1 Paradigm differences between realist synthesis and systematic review

Realist synthesis	Systematic review (meta-analysis)
Theory driven	Method driven
Deprioritizes methodology hierarchies and	Appraises papers on the basis of a hierarchy of
emphasizes fallibility of all knowledge sources	study design. Prioritizes experimental design
Uses all parts of primary research papers as evidence	(i.e., randomized controlled trial) as gold standard
Uses a variety of data sources, including grey	Uses the results of primary studies in
literature, commentaries, etc.	meta-analysis
Moves away from generalizable claims and	Often uses primary research results only
advocates for cumulation of evidence-informed	Seeks research results that can be generalized
theory over the course of time	across contexts

research (19, 31, 49, 57). Realist methodology and its characteristic focus on context-mechanism interaction hold the potential to address these research–practice gaps.

HOW IS REALIST SYNTHESIS DIFFERENT FROM SYSTEMATIC REVIEW AND META-ANALYSIS?

Several differences distinguish realist synthesis (also known as realist review) from systematic reviews and meta-analysis, and these differences are summarized in Table 1. One difference is that the former is theory driven, whereas the latter is method driven (46, p. 51). Method-driven reviews frame the quality and trustworthiness of primary evidence in terms of a methodological hierarchy. Priority is given to experimental and quasi-experimental design, whereas qualitative and case study designs are ranked lower. Even the UK-based Medical Research Council guidelines for evaluating complex interventions suggest that randomized controlled trials are the gold standard and should be implemented when feasible (32). On the contrary, realist synthesis, on the whole, operates by rejecting this hierarchy and instead searches diverse data sources for insight into the nature of programs. This realist principle is summed up by Pawson's provocative notion that "even bad research can yield good evidence" (38). In systematic reviews, insightful explanatory claims risk being eliminated in the process of appraising study methodology. In contrast, theory-driven realist inquiry prioritizes an understanding of the social architecture of interventions, the assumptions implicit in intervention activity, and how such assumptions play out in diverse contexts (social, cultural, etc.) (for examples, see References 16, 23). Gaining understanding along these lines is accomplished by a variety of data sources. Prioritizing theory development and testing in realist synthesis leads inquirers to the possibility for deep understanding of complex social interaction within interventions, forming the basis of realist causal explanation. Pawson & Tilley (46) emphasize the need to cumulate such deep learning over the course of time in contrast with assuming a review will reach definitive, generalizable conclusions within a single, albeit robust, study. The emphasis on stepwise accumulation of evidence-informed theories of complex programs is increasingly convincing, given the reality of contexts in which there is rapid social, cultural, and technological change. As Pawson & Sridharan (45) note,

One of the more interesting aspects of the external validity/generalizability literature is how little this literature has dealt with the challenges of generalizing from evaluations of complex interventions. Often the business of learning from evaluations is almost entirely focused on the results of the impact evaluation—usually obtained at the end of the study that may take up to five years. The reality given the complexity of interventions is a need for a richer body of learning that can highlight the complexities of planning, implementation, and pathways by which the interventions work. (p. 60)

REALIST SYNTHESIS OF COMMUNITY-BASED PARTICIPATORY RESEARCH: TAKE-HOME POINTS

- 1. Long-standing community-based participatory research partnerships in which academic and community stakeholders had equitable roles in research cogovernance generated extensive benefits to communities and research processes. This finding was supported by the middle-range theory of partnership synergy.
- 2. Partnership synergy theory was incorporated into the analysis and refined further using data from the literature as well as from qualitative interviews with academic and community stakeholders. A key finding was that productive forms of dispute and negotiation became milestones in establishing trust and longevity in partnering. Partnerships in which there was no conflict and therefore no opportunity to resolve conflict remained vulnerable to exploitation. Partnerships that successfully resolved conflict through respectful negotiation were able to achieve significant benefits to communities and the research process beyond what could be achieved by these stakeholder groups working alone. In the context of academic members collaborating with historically oppressed communities, the demonstration of cultural humility on the part of academic collaborators was an example of a mechanism of participation.
- 3. CBPR partnerships that had a life cycle of 10 years or more demonstrated a host of outcomes, including (a) ensuring that research was culturally appropriate and logistically sound, (b) enhancing buy-in through the mechanism of vicarious endorsement in which respected community leaders endorsed outsider academics, (c) increasing skills and capacity in all stakeholder groups, (d) resulting in productive conflicts followed by useful negotiation, (e) increasing the quality of outputs and outcomes over time, (f) increasing the sustainability of project goals beyond funded time frames and during gaps in external funding, and (g) creating systemic changes in communities and new unanticipated projects and activities.

EXEMPLIFYING THE VALUE AND ACHIEVABILITY OF RESULTS IN A REALIST SYNTHESIS

A case that exemplifies the value of realist synthesis is the author's prior work with a team conducting a realist review of community-based participatory research (CBPR) (19, 20, 21, 28). In that review, coinvestigators conducted a realist synthesis in response to a prior systematic review of CBPR (56). That prior review exemplified the challenges and inconclusive findings that arose when attempting to fairly assess the scope and life cycle of complex outcomes using a method-driven approach (28). The realist review of CBPR focused on how theory could be used to assess the impacts of CBPR and open the black box of collaborative participation in research (20, 21, 27). The result of that realist synthesis was a detailed conceptualization of extensive collaborative outcomes using the theory of partnership synergy (26) and the ripple effect metaphor (18, 19). A summary of points from that review is presented in the sidebar titled Realist Synthesis of Community-Based Participatory Research: Take-Home Points.

UNDERSTANDING THE PHILOSOPHY, PRINCIPLES, AND PROCESS FOR CONDUCTING A REALIST SYNTHESIS

A number of important realist philosophical concepts can facilitate an understanding of how to conduct realist inquiry in public health. These concepts include generative causation (40), ontological depth (5), and retroductive theorizing (14, 35). Generative causation means that the manifested world is generated (i.e., caused) via underpinning mechanisms. Ontological depth is the idea that reality is stratified in layers, a notion that is depicted in the iceberg metaphor of realist

causation (see **Figure 2**). Retroductive theorizing is the activity of uncovering hidden mechanisms of action in those deeper layers (for more detail on these definitions, see the sidebar titled Definition of Terms for Realist Philosophy and Methodology). Realist synthesis uses the CMO heuristic in which context is the backdrop or background environment of programs. Mechanisms are defined as the resources generated from program strategies and how people respond to resources offered through those strategies. See **Figure 1** for a visual depiction of the CMO configuration.

Upon establishing initial research questions, the realist reviewers search for and establish candidate (i.e., potential) program and middle-range theories to explain how or why programs have worked, for whom, and under what circumstances. According to Pawson and colleagues, programs are "theories incarnate" (46, 62), meaning that all programs have corresponding theory, regardless of whether that theory is made explicit. The preoccupation of any realist synthesis then is to make explicit the implicit program theories and subsequently use the available literature to support, refute, or refine these theories. The CMO configuration (see **Figure 1**) is a basic framework for realist causal explanation (46) that can guide all stages of the review process, from theory construction to the development of data collection protocols and data analysis. Theories are cross-examined against available evidence and confirmed, refuted, or refined (21).

The explanatory focus in realist synthesis begins by framing questions along the lines of, What is it about a program that explains how it works and for whom? (41). Addressing this question leads to initial theories about the generative mechanisms at play, which are then tested across study cases reported in the peer-reviewed published literature as well as in grey (unpublished) literature and other sources. Realist synthesis is not about producing definitive facts about program effectiveness on the basis of average or aggregated data. Averages may obscure key explanations about causative factors of the context-mechanism interaction, which is fundamental to understanding realist causation (39). The advantage of the theory-driven approach is in addressing aspects of causation, providing explanatory power about why a program worked or failed given the resources offered through an intervention and the response to those resources. Unearthing the program theories means explicating the basic characteristics of interventions (e.g., autonomous versus planned, structured versus unstructured, reactive versus proactive, short term versus long term, localized versus widespread) and explaining how the nature of resources offered (e.g., information, incentives, restrictions, trust, safety) and the responses/reactions of stakeholders (e.g., feeling motivated, engaged, safe, trusting, encouraged or else defeated, demotivated, untrusting) can effect change. The process involved in developing candidate theories can be varied, depending on the nature of the research question. For example, formalized theories in the published literature that provide adequate explanatory power can be used and adapted, along with if-then statements or hypothetical CMO configurations. Middle-range theories that explain causation at a more abstract level can also hypothesize the trajectory of anticipated programmatic success over time (19).

USING REALIST SYNTHESIS TO ADVANCE EVIDENCE-INFORMED THEORY IN PUBLIC HEALTH POLICY

A key benefit of realist synthesis for public health is the ability to synthesize evidence from difficult-to-research areas, such as public health policy and legislation as well as areas with a lack of available evidence. While legislative policies can have wide-reaching social and societal effects, experimental design methodology to evaluate the impact of such legislation is challenging owing to the diffuse nature of legislative resources and how they are adopted across contexts (24, 44, 61). Mechanisms are understood as underpinning forces (3) that explain the people's agency and decision making in relation to resources offered (48, 59). As such, an important aspect of theorizing

programs is to ask, What are the resources produced by the intervention in question, and how do people respond to such resources, given their contexts? For public health, realist theorizing may uncover that a program may provide education, information, safety, and trust to which stakeholders may respond in various ways, including feeling trusting and feeling newly motivated, leading to outcomes that include health efficacy, service improvement, uptake, and sustainability of effects. A realist inquiry might theorize that public health programming works by numerous intervention mechanisms and contextual determinants interacting together. Outcomes can include formal and informal outcomes, or outcomes can inform the context of future stages of program implementation. Realist theorizing can also capture how interventions designed to solve problems may result in such problems being displaced to other areas rather than being truly solved (54). Pawson et al. (42) insightfully note that "in 'solving' a problem an intervention can create new conditions that eventually render the solution inoperable" (p. 41). Alternatively, an intervention can also interject resources into a context and show limited or no results in initial stages but, through a series of stages, produce results over time (18). These trajectories of impact, which reflect real-life circumstances, can be captured in realist program theories and then tested through available literature. Finally, the accumulation of program theories over time may lead to what Pawson terms 'reusable conceptual platforms' (40, p. 92). These platforms are like architectural blueprints of programs that can be transferred to address problems in other areas or used as starting points to begin theorizing the specifics of a given area.

CHALLENGES AND LIMITATION

Despite the promise and opportunity of realist synthesis, there are also a number of challenges in using the approach (29, 43). First, there is no specific instruction for conducting a realist inquiry nor is there an a priori protocol development framework, although reporting standards for realist synthesis have been developed (60). This challenge is both an advantage and a limitation because in the process of reflecting and making decisions on how to adapt realist constructs, realist reviewers may produce methodological innovations but also risk suboptimal analyses from a lack of prescriptive guidance (29). Conducting a realist synthesis is also time consuming for this reason. Second, realist syntheses require substantial resources to locate, develop, and validate program theories. Adequate evidence to support the theorized causal pathways is not guaranteed, and the possibility of exploring alternative data sources brings methodological questions to the table. Multidisciplinary teams conducting realist syntheses typically spend much time discussing and debating how to develop the methodology to suit their research requirements. The iterative process requires ongoing reflection, which also takes time. Third, the realist approach requires the reviewer to open the black box of program implementation, to theorize programs, and to uncover underlying mechanisms of action. Most primary study literature retained in a realist synthesis will not be written with the idea that a realist synthesis will be seeking clarity on underlying mechanisms. Thus, many papers will report on outcomes but not the process that would explain how outcomes accrue. Requiring this procedural and program design information, realist reviewers may be led to search for alternative theoretical literature or contact primary study authors to capture more information on mechanisms and context-mechanism associations.

Fourth, the product of a realist synthesis should be evidence-informed program theory and middle-range theory about how a set of programs work. However, it is common for reviewers to find overwhelming the complexity involved in unearthing all the possible causal mechanisms and pathways. A fifth challenge is in conveying the paradigm shift that realist methodology demands of the readership of a realist analysis. Commissioners and funders uninitiated in the realist paradigm

who fund realist reviews may expect results similar to those found in systematic reviews. Such contrasting pressures may further delay the progress in a realist review as reviewers determine how to conduct a realist inquiry in line with the principles while also satisfying the expectations of stakeholders who are not familiar with a realist approach.

Despite these limitations, the output of a realist review done well can be used to provide a platform for innovating future program development. Pawson & Tilley (46) note that "part of the remit of evaluation must be to take on the task of continual program refinement, which requires going back and back again to puzzle over present findings about the effectiveness of current practices, and then forward to attend to new puzzles which emerge from these deliberations" (p. 118). Realist reviews can help in this endeavor by explicating the complex array of factors involved in the production of interventions, but researchers must accept that any given piece of research reflects partial knowledge and that it is reasonable to limit the scope to study certain aspects of the program or few specific outcome(s). It is often necessary to find some degree of homogeneity in the collection of primary studies amid inevitable heterogeneity.

When doing a realist analysis, reviewers also often find it challenging to engage with CMO configuring and to determine which data fit into the context, mechanism, and outcome categories. Despite these challenges, the CMO configuration is a useful heuristic, not only for unpacking generative causation but also for coming to a clearer delineation of intervention resources and contexts. Realist reviews can help in the realization that through the implementation process, programs intentionally or haphazardly pick up existing resources in the context for their functioning. For example, a coordinated response to an epidemic outbreak may involve placing emergency response resources in existing contexts. However, preexisting skills, human resources, expertise, and networks of those contexts may become activated in the process of implementation, even if such involvement is not theorized by the policy architects and even though these contextual elements were not explicitly written into the program's design. It can be confusing to understand whether certain elements of context are, in fact, intervention resources (i.e., aspects of mechanism). This potential ambiguity is also an opportunity to gain clarity on the boundary line between interventions and their implementation contexts. Recommendations from realist inquiry may conclude that certain key elements of context should be built into the program theory in future iterations, cumulating the context-sensitive knowledge about how the intervention works and facilitating better prediction of the functioning of the intervention as it is scaled up and implemented in increasingly diverse contexts.

CONCLUSION

While the rationale underpinning evidence-based public health policy is sound, it is now widely understood within the field of implementation science that a linear model of knowledge translation from experimental studies to meta-analyses to policy development does not provide the conceptual grounding to facilitate understanding of the functioning of complex interventions in complex environments (1). To complement existing approaches, realist synthesis can support the evidence-informed practice movement. As such, the approach is highly suited to public health decision making, and, along with participatory approaches to policy and practice, the approach can address what works, for whom, under what circumstances, and how. Through creatively applying realist constructs and carefully considering design issues, investigators can utilize this approach to create a dynamic learning process about what works, for whom, and under what circumstances to build an evidence-informed theory base for innovating interventions in the public health sector and beyond.

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