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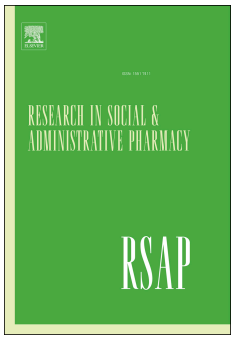

In search for gold - The relevance of realist reviews and evaluations to pharmacy research and policy development

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In search for Gold - the relevance of realist reviews and evaluations to pharmacy research and policy development

Abstract

Pharmacy services and programs can be regarded as complex interventions which are developed and implemented within the open, complex system of overall healthcare. Realist research considers matters of complexity and provides insights into what programs and interventions work, why and in which contexts. Based on the philosophy of science of critical realism, realist evaluations and realist reviews generate causative explanations which inform pharmacy practitioners, educators and policy makers in which context programs and services achieve particular outcomes. This more nuanced understanding of how pharmacy services contribute to overall healthcare provides guidance for the refinement and targeting of programs, interventions and practice models. This article outlines key aspects of realist research approaches and provides insight into how realism can contribute to research in and the practice of pharmacy.

Keywords

Pharmacy, critical realism, realist research, realist evaluation, realist review

1. Introduction

This article outlines how realist evaluations and realist reviews can add to the body of knowledge in many aspects of pharmacy research and support the development of programs, interventions, best practice models and policy at the micro-, meso- and macro-level. Research in pharmacy practice and education has mostly followed examples from other science-orientated disciplines, in that evaluations tend to favour experimental methods, such as randomised controlled trials (and various approaches similar to these). Randomised

controlled trials (RCTs) compare 'intervention on' with 'intervention off', may produce statistically accurate 'evidence' of efficacy or effectiveness, but often leave us none the wiser about where to target resources, how to adapt programs to different settings or maximise impact.[1] Whilst useful when evaluating the efficacy of a medicine, these approaches are less successful when multiple human actors, sociological and technological factors are involved in what is the archetypical, complex adaptive system - healthcare. Even in well conducted RCTs, systematic reviews and meta-analyses it is difficult to capture what it is about an intervention leading to its success or failure. Such research usually acknowledges the heterogeneity of policies/services/programs under investigation but often attempts to homogenise results when reporting findings as an effect size that has some causal attribution to observed outcomes. Realist research, on the other hand, contributes to our understanding of what is essential to the success or failure of health policies, practices, programs or educational strategies. Most pharmacy services or programs, whether evaluated at the individual patient/health professional, team/organisational or policy/regulatory levels, can be regarded as complex interventions which are trialled or implemented into the open, complex system of overall healthcare.[2, 3] Consideration and acceptance of this complexity in program and service evaluation increases the chances of recognising and figuring out which parts of a program and the implementation process are fundamental to its success, which external factors influence the way it works, who will benefit most from it and under which circumstances.[4] The evaluation of a program, intervention or the study of any phenomenon benefits from the considerations of matters of complexity and how research can provide insights into why things work the way they do. This includes an appreciation that outcomes will be valued differently by different stakeholders. A realist approach to research intends to answer what has become the catch phrase question of "what works for whom, why, under which circumstances and to what extent".[5] This calls for flexible approaches to research

which allow and account for (inevitable) changes to a program by those who implement or participate in it, departing from a narrow experimental and judgemental focus, exemplified by randomised, controlled trials.

2. Realism – a brief overview

Critical realism is a philosophy of science which bridges positivism (phenomena can only be observed empirically) and constructivism (knowledge about phenomena is mentally constructed). Realists distinguish between the world that exists outside of us, independent of our minds and our experiences of the world, hypothesizing a reality that exists beyond our perceptions of it. At the same time, they argue that all knowledge about the world can only ever be partial because we are limited by our human abilities and senses in how we come to know about it. As a result, knowledge of the real world remains uncertain, incomplete and will accrue over time.[6] Three domains constitute this 'stratified' understanding of the world; the empirical, the actual and the real. The empirical comprises of what can be observed or experienced; the actual contains all events or phenomena and exists regardless of whether these can be observed or experienced. Finally, the real, which all-encompassing contains both the empirical and actual, but also whatever causes things to be the way they are, the underlying causal mechanisms that generate (actual) events.[7] Most realists include attributes and mental states in their understanding of the real world, which links to both the character of context and mechanisms, which may be intentions, beliefs and behaviours. The understanding of mechanisms is central to realism. Mechanisms are often hidden and not directly observable on an empirical level, nonetheless they are real because they cause events to happen. The aim of realist research is to develop an understanding of how mechanisms are activated or behave in different contexts to cause certain outcomes.

Much realist research of health services follows a form of realism developed and described by Pawson and Tilley.[5, 8-10] Their work is one of many 'schools' of realism that draws and builds on the work of Roy Bhaskar and the critical realist philosophy of science.[7]

Realist research can employ a wide range of approaches, methodologies and methods to assemble the data needed in an evaluation of complex healthcare services or social phenomena.[11] Rather than regarding realist approaches to research as simply another tool in the toolbox of methods useful to health service or pharmacy researchers an understanding of realism as a philosophy of science is a prerequisite to their successful application.[12] The following discussions of the relevance of realist evaluation and review for research in pharmacy practice, education and policy development is framed by the realist approach developed by Pawson and Tilley and includes a brief overview of the realist jargon.[5, 10]

3. A realist logic of analysis

The central process of realist research is the realist logic of analysis which centres on explaining the causal links between the context in which a program, intervention or policy is implemented in and its related outcomes. It unpacks the 'black box', the inner workings of a program, moving from measuring effects without consideration of how these have been produced to understanding and explaining the components or inner logic which cause a program's success or failure.[13] A realist logic of analysis deliberately seeks to establish or propose mechanisms which provide the explanatory conceptual link between context and outcomes. Doing so explicitly, brings the relationships between context and outcome to the surface, something that is 'missing' in many approaches or methods that seek to make sense of complex interventions. This pushes the findings of an evaluation or review past showing that a program or policy achieves certain outcomes and transforms it into an explanation and understanding of program related causal processes.

In brief, under a realist logic of analysis, mechanisms are triggered in a particular context to cause specific outcomes and their identification provide a causal understanding of the relationship between context and outcome. This causal process has been succinctly summarised as Context + Mechanism = Outcome, which is not an equation but more an 'aide memoire' to remind researchers of the form causal explanations take in realist evaluations and realist reviews.

Mechanisms are not intervention strategies or components of an intervention - that is they are not the things that pharmacists might do, for example undertake a medication use review. Within pharmacy research, they are better conceptualised as the responses individuals have to the world around them. They are usually hidden and arrived at indirectly by theorising rather than empirical observation. Linking or configuring context (C), mechanisms (M) and outcomes (O) into CMO configurations (CMOCs) is one of the cornerstones of building a realist explanatory causal account of what makes a program work and why, iteratively supporting the generation of a program theory.

4. The role of program and middle range theory in realist research

Program theory is specific to an individual program, like a small working model, including the bits and pieces unique to the program, describing the ins and outs, framed by a narrative of underlying assumptions. Middle-range theories, a term and concept developed by Merton in response to general theorising in the development of sociological systems, assist in establishing program theory as they are describing an intermediary level between empirical research and theory.[14, 15] This positions middle-range theory, particularly as developed or applied in realist review or realist evaluation close enough to observable phenomena or data to be empirically testable. Realist middle-range theories have the added benefit of potentially being transferable to other settings, based on the assumption (which does need to be

confirmed or refuted) that a similar mechanism may also influence outcomes in a different setting. This provides an explicit reason for why findings from different studies may be useful for various settings. Within realist research these middle-range theories are usually expressed as CMOCs, of which there may be many for any given program theory.[16]

5. Realist evaluation and realist review

Realist evaluation and realist review are useful approaches when the goal of any research is the endeavour to account for complexity in the healthcare and pharmacy environment, the context of and natural variations in program design, implementation and normalisation by all participating agents. Realist evaluations and reviews of an intervention or program ideally start with an initial program theory. This program theory may be developed using a range of methods, for example, it may be based on what a subject expert suspects to be at play, an exploratory search of the literature and/or feedback and advice from relevant stakeholders. During the realist evaluation or realist review, data are used to iteratively develop and then confirm, refute or refine parts of this initial program theory.[10]

Realist evaluation is a type of theory driven primary research , meaning original data needs to be collected to inform the development of CMOCs. Like any evaluation it will include various outcome measures, e.g. of efficacy, effectiveness or qualitative indicators of satisfaction or acceptability, but also pays close attention to the environment and context in which a program or service implementation takes place and what exactly influences effectiveness or acceptability. The aim is to elicit which mechanisms are activated in a particular context, to cause specific and related outcomes of interest. This causal explanation for the outcome is expressed in the form of various CMOCs which provide the fine grained explanation for the outcomes found within a program and its theory. In other words, a *realist*

program theory should be underpinned by a number of CMOCs that explain, for example, how, why, for whom and in what contexts outcomes occur for a program or intervention. Realist reviews are the use of realist philosophy in the theory-driven synthesis of research findings from primary studies, i.e. they are a form of literature review. Realist reviews of pharmacy practice and education ideally provide us with a nuanced understanding of how the profession, its training and the practice of pharmacy contributes to the delivery of healthcare, e.g. which practice models, pharmacist initiated services and educational strategies may be effective in a particular context and why.[10] The insight generated by a review of what works, for whom, when and why, the development of program theory and associated CMOCs supports decision making in a more comprehensive way than the 'yes, no, maybe' answers generated by conclusions of causation under successionist assumptions.

In gathering data for a realist review a much wider net is cast compared to more 'traditional' systematic reviews. While the search and data gathering process follows a systematic approach it draws from multiple sources, including not only empirical research but also data from a broader range of study types (e.g. mixed method, qualitative), grey literature (e.g. policy documents, training manuals) and stakeholder or expert opinion which may provide insights into aspects of program theory. Such data are then analysed and synthesised (using a realist logic of analysis) to support or refute and iteratively add to program theory refinement. This process more or less precludes conventional quality appraisal of identified material. Instead, realist reviewers have to take a more pragmatic approach to judging quality of data and its sources by evaluating trustworthiness, plausibility and coherence.[17] Applying the principles of a realist logic of analysis to the synthesis of existing data and evidence again aims at developing a theory about the programs or interventions under review based on CMOCs. A realist review will not provide definite judgement of the effectiveness of interventions but an evidence-based understanding of the complexity and interplay of

intervention, context, and mechanisms causing outcomes. Given the multitude of often small studies into pharmacy related programs, pharmacist led interventions or health services, realist reviews may get past the 'not enough evidence' or 'not enough studies' statements pharmacy researchers and policy makers will be familiar with when trying to synthesise findings from multiple, heterogenous studies.

6. Getting started

A number of resources have been developed by the RAMESES group (Realist And Meta-narrative Evidence Syntheses: Evolving Standards - www.ramesesproject.org) for those who consider engagement with realist research. Methodological guidance, training materials, reporting and publication standards provide helpful synopses of how to conduct and evaluate realist research.[1, 18-21]

As discussed above, realist research starts and ends with theory, starting with what may be a rough, initial theory of why a program works (or not), ending with a more refined theory after a review of evidence or evaluation of data. As theory development and refinement via CMOCs is fundamental to realist research, one criterion for quality syntheses and evaluations is that these CMO configurations are developed in such a way that they provide a realist causal explanation for outcomes. This is based on a realist understanding of mechanisms, which should not to be confused with the actual activities or components within an intervention, program or policy being researched.

Underpinning the discussions on the merits of realist research in healthcare and pharmacy practice the following examples illustrate the contributions of realist evaluations and realist reviews to the generation of knowledge of what works for whom and why.

In 2017, Gordon et al. published their realist evaluation which examined what supports effective working in UK care homes with the aim of improving outcomes. The authors started

with a review, which deliberately did not centre on one 'intervention' but studied the policy levels and various ways in which these are implemented within the UK care home sector. The team were interested in how various models of service provision, activities and opportunities lead to different outcomes and the mechanism(s) that cause these in order to inform policy decisions going forward. The paper provides a clear programme theory at the outset as the basis of the evaluation, which aimed to 'test, refine and possibly refute' the starting theory. The study used both quantitative and qualitative data collection and analytical methods in a number of different care home sites which were chosen purposively to provide varying examples of practice and enable comparison where appropriate. The refined program theory is supported by multiple CMOCs which were configured in an accessible manner and maintain a clear link to the original data. The evaluation showed how NHS (National Health Service) services delivered to care homes can address the needs of staff and residents through building relationships and accessible networks, as well as expertise in dementia care.[22] Transferring these findings to pharmacy services in aged care homes, which are often provided externally on a referral or consultant basis, suggests that building long-term working relationships with facility staff and residents, creating mutal learning opportunities and referral networks may optimise service outcomes.

With their realist review, Ford et. al. aimed to "understand the contexts that effect access to primary care for socioeconomically disadvantaged older people".[23] Their starting point for an initial programme theory was the patient journey from the moment a problem is identified by the person seeking care to the outcome of a consultation with a healthcare professional. Using existing literature and practice experience supported the identification of component parts of the patient pathway and the definition of seven keys steps along the way. Each step formed a sub-outcome that lead to the overall outcome, each one having to be achieved or completed before progression to the next step. Ford and colleagues then examined the literature to

support the establishment of multiple CMOCs linked to each stage of the journey and each sub-outcome and expressed these in diagrammatic form, providing an example of how an overall programme theory is composed of multiple, more defined, middle-range theories in the form of CMOCs. These middle range CMOCs provide insight into what facilitates access and people's motivations to access health services which can be transferred and tested in other rural and healthcare settings.

Papoutsi et. al. examined how doctors-in-training engage with antimicrobial prescribing, adding to the knowledge around antimicrobial stewardship. Following the realist logic of analysis the investigation focused on the "resources offered to doctors (mechanisms) which were triggered in particular circumstances (contexts) to generate certain behaviours or outcomes".[24] The involvement of various stakeholders and consideration of substantive theory framing influences on prescribing behaviours informed a broad outlook. The formulation of multiple CMOCs underpinned the development of a program theory of how and why doctors-in-training engage with antimicrobial prescribing differently under different circumstances. The program theory points to individual and sociological factors and mechanisms which will be relevant in other settings where a change in prescribing behaviour is the desired outcome of a program or intervention.

To our knowledge two realist reviews of pharmacy services and practices have been published to date.[25,26] The reviews were limited by a lack of explicit theory framing the primary research design and data and insufficient contextual detail included in most study reports. One of the reviews shows how despite the lack of contextual data and theoretical detail the collection of a wide range of evidence and rigorous establishment of hypothesises can guide future researchers in designing and evaluating pharmacy based smoking cessation programs.[25] Their findings may also serve as a wake-up call to pay more attention to contextual, e.g. organisational or systems, factors when designing and implementing complex

programs in pharmacy practice. This may be more conducive to the development of program and middle range theories, which then can and should be empirically tested in future studies.

7. Conclusion

The explanatory power of realist approaches to research builds a nuanced understanding of programs and interventions to inform program development, implementation and related policy decisions. The understanding is generated by the development of middle-range theory, which links specific contexts to particular outcomes through connecting mechanisms, or in other words by building CMO configurations. Realist research employs various methodologies and considers a broad range of sources of data and information and is most suited to where there is a need to understand the influence of context on outcomes in complex systems. Attention to context and mechanisms and establishment of generative causation will allow pharmacy education and practice researchers, funders and policy makers to identify for whom, why and under which circumstances training programs, pharmacy initiated programs and services achieve outcomes for participants and stakeholders. This deeper understanding will assist in targeting limited healthcare resources and advanced services to those settings where they achieve the best outcomes for patients and inform the further and deeper integration of pharmacy as a profession into the complex system of healthcare.

Conflict of Interest

… declare no conflict of interest.

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