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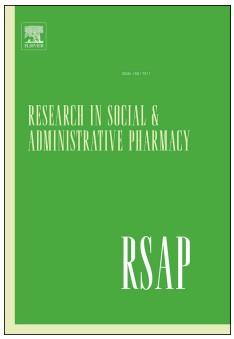

Realist research to inform pharmacy practice and policy

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Title:

Realist research to inform pharmacy practice and policy

Abstract: Theory-driven implementation and evaluation of pharmacy services can enhance their contribution to overall healthcare. As complex interventions most pharmacy practice programmes and services will be adopted and modified during their implementation into various healthcare contexts and systems. Realist approaches to theory-driven evaluation consider these variations in programmes, interventions and the contexts of their implementation and establish theories on how they work best, for whom and why. This paper illustrates the practical application of the realist philosophy of science to pharmacy practice relevant areas of healthcare using two case studies, a realist synthesis of existing literature on medication reviews and a realist review and evaluation related to medicines management. Applying realist logic establishes causative explanations of what could be essential factors in the success of programmes, enabling policy makers in their decision-making and pharmacy practice researchers as well as practitioners in optimising service design.

Key words: realist, research, pharmacy, healthcare, methods

Introduction

The design and introduction of pharmacy services and programmes is increasingly framed by implementation science and its theory-based approaches.[1, 2] Theories, models and frameworks informing the development of health care services are also utilised by pharmacy researchers and practitioners to facilitate the translation of best evidence into practice.[3, 4] Even when theory-driven design and implementation processes lead to initial success, the long-term sustainability of programmes is not guaranteed and may rely on balancing fidelity

with adaptability.[5-7] The majority of programmes aimed at improving pharmacy practice, health care and health outcomes are complex interventions, considering the quantity and interlinkage of components within the experimental interventions, the difficulty and range of behaviours required by those delivering or participating in the intervention, the organisational levels they target and the range and variability of outcomes. Once programmes are adopted more widely into practice the context of their implementation starts to vary and a significant degree of flexibility or tailoring to context is inevitable.[8] The triple threat of complex pharmacy programmes, their reliance on participants with varying motivations and capacities, playing out in the complex, adaptive system of overall healthcare confounds our understanding of how and why their effectiveness in routine day-to-day practice can be achieved. This may be related to the evidence which is selected in informing the design and implementation of programmes. Experimental or quasi-experimental designs of pharmacy programmes evaluations are necessary to establish effectiveness of interventions,[9] but will inevitably have to put aside the complexity of most pharmacy practice programmes and consequent service models. Effect size can tell us whether a programme achieved its intended or desired benefits, or caused inadvertent harm, in the context and at the time it was delivered, but still leaves policy makers and health care funders guessing how similar programmes will affect different people in different contexts.[10]

Closing the loop between evidence informed, theory-based implementation and evaluation calls for evidence syntheses and evaluation research which develops theory by analysing and incorporating complexity rather than ignoring it, informing future programme and implementation design. Implementation design and evaluations which pay attention to the multiple interacting influences which contribute to a particular outcome increase the chances of recognising and eliciting which parts of a programme and its implementation process are pivotal to its success, which external factors influence the way it works, who will benefit

most from it and under which circumstances.[11] A focus on emergent causality will potentially answer many questions which experimental studies designed with a linear, cause-and-effect model in mind leave unanswered.[12]

Realist research offers particularly useful approaches to inform theory-driven evaluation and implementation. Realist syntheses of existing evidence and literature can guide the design and implementation of a programme by developing models of causality and theories which explain why it may show effect, particularly when effect relies on social contingency as in the case of healthcare programmes.[13] Realist evaluations of programmes as primary research then assist in testing or refining these programme theories, establishing new ones and creating further causal links to observed outcomes.

The aim of this article is to provide a very short introduction to realism in health services research, demonstrate some of the methodological approaches, introduce and illustrate realist terminology. Two case studies, one of a realist synthesis and one of a realist evaluation, will provide the basis and practical examples on how its principles can be applied, integrating theory with practice.

Methods

The role of realism

Many authors have discussed the provenance of realism which contemporarily is applied in health care and social policy evaluation, and we are pointing readers to a number of readings, for a teaser, [14, 15] overview,[16-18] or in depth discussion.[13, 19, 20]

Realist research can employ a wide range of approaches, methodologies and methods to collect and analyse 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. This introduction on how to conduct realist research and how it can contribute to pharmacy practice evaluations and policy design focuses on scientific realism in evaluation research as described and applied by Pawson and Tilley.[13, 21, 22] Like other 'schools' of realism their approach draws on the work of Roy Bhaskar and the critical realist philosophy of science, but its grounding in scientific realism allows pragmatic testing of constructed programme theories against best available evidence. Pawson outlines the philosophical foundations of their approach to evaluation research, which also shows the various influences of other realists.[19, 22]

The most commonly engaged realist research approaches in evaluation science will be demonstrated by the discussion of two case studies. They are outlining the practical process of applied realist research. The case studies illustrate a realist synthesis of existing literature and a realist evaluation of qualitative data related to medicines management.

Results

The following case studies will now introduce strategies and common terms used in realist research and illustrate how to integrate different data and methods for the development of theory about when, why and how programmes work.

Case study 1

The first case study introduces a realist review and synthesis, applying realist logic to the synthesis of secondary data.

Overview

A realist synthesis of pharmacist-conducted medication reviews in primary care after leaving hospital: what works for whom and why?

We conducted a realist synthesis to establish for whom, under which circumstances, how and why a pharmacist-conducted medication review (MR) may be of benefit for people who return to primary care after a hospital admission.[23] Systematic reviews regularly attest to the heterogeneity between studied MR programmes, interventions and the outcomes they achieve and a realist synthesis potentially explains some of the ambiguity. The aim was to add to the significant body of work in this area by examining what leads to observed outcomes (whether desired or undesired by programme designers and implementers). Making sense of how an MR functions as a healthcare intervention in a given context, which mechanisms it activates in order to produce context-sensitive outcomes facilitates the identification of components or aspects which may be essential in achieving benefits for patients, healthcare professionals and the system in which it is implemented. Identification of underlying, generative mechanisms which are triggered by particular aspects of an intervention or programme, in this case an MR, in specific contexts, lies at the centre of realist enquiry.[24] Explanations of common units of analysis within realist research, for example, the programme theory, which is often expressed as context-mechanism-outcome-configurations (CMOC), are provided in table 1, with pointers to readings which will provide more in depth insights.

Table 1. Definitions of realist terms and how they are understood in the case studies

Programme theory From the 'Realist Synthesis: RAMESES Training Materials'[25]	The programme theory specifies what is supposed to be done in a policy or programme (theory of action) and how and why that is expected to work (theory of change).
CMOC From a realist review discussing definitions of realist terms.[26]	CMO configuring is a heuristic used to generate causative explanations pertaining to the data. The process draws out and reflects on the relationship of context, mechanism, and outcome of interest in a particular programme. A CMO configuration may

	pertain to either the whole programme or only certain aspects. One CMO may be embedded in another or configured in a series (in which the outcome of one CMO becomes the context for the next in the chain of implementation steps). Configuring CMOs is a basis for generating and/or refining the theory that becomes the final product of the review.
Context (C) From the RAMESES II project 'Why nothing works everywhere or for everyone' http://www.ramesesproject.org/media/RAMESES_II_Context.pdf	For policies and programmes, context describes those features of the situations into which programmes are introduced that affect the operation of programme mechanisms. The settings into which programmes are introduced do not, in and of themselves, constitute context in the realist sense. However, things about the way those settings operate can.
Mechanism (M): The cited articles provide in depth explorations of mechanisms in realism.[24, 27]	'…mechanisms are underlying entities, processes or structures which operate in particular contexts to generate outcomes of interest'.[27] and '…mechanisms are usually hidden, sensitive to variations in context and generate outcomes.'[24]
Outcome (O): From Pawson and Tilley's 'Realistic evaluation'[13]	Outcomes are a result of a programme firing multiple mechanisms which have different effects on different subjects in different situations, and so produce multiple outcomes. Realist evaluators examine outcome patterns in a theory testing role. Outcomes are analysed to discover if conjectured mechanism/context theories are confirmed.

The realist research process - realist review of the literature

We adapted a stepwise approach to the realist review which was iteratively expanded during theory development as conceptualised by Rycroft et al..[28] An initial programme theory was developed, supported by a Pubmed search, experience and discussions by the authors, and framed by the steps patients and healthcare professionals take in completing an MR. Mapping

their journeys and points of contact and interaction, eliciting how and why they chose to engage with invitations to participate in an MR, using guidance from realist training materials and literature then provided the structure for the extraction of comprehensive data supporting the refinement into a final programme theory.[25]

One of the main differences to other reviews conducted in this area was the systematic retrieval of a broad range of documents.[19] These included trial protocols, which often make underlying assumptions of why an MR should have a positive effect explicit, conference abstracts of mainly qualitative studies, which provided stakeholder experiences and opinions, programme evaluation reports, which yielded fine-grained detail supporting the inference of mechanisms, and PhD theses, granting insight into why interventions were not as successful as anticipated. This was in addition to studies customarily included in systematic reviews, which usually investigated existing service models or adaptations in the post-hospital-discharge setting. These, however, often provided little detail regarding the exact nature of the intervention or programme, how patients and healthcare professionals engaged with the MR and each other. The inclusion of other types of literature and policy documents allowed the research team to fill gaps and compare intention with actual implementation in the process of generating programme theory.

Instead of appraising the quality of documents under consideration through application of standard criteria, their inclusion into the realist synthesis was predicated on their relevance to the development of theory, with relevance shifting during different developmental phases. Although even poorly designed studies can yield information which adds to or supports theory,[29] rigour in intervention or study design and implementation was assessed by examining whether methods used to generate data were appropriate to answer the research questions, were employed with reliability and consistency and could credibly generate reported findings. In addition, the trustworthiness of selected data was considered by

ascertaining whether they had been obtained empirically and through a cross-examination of outcomes of similar studies conducted on MR in general.[19] When documents seemed highly relevant but lacked depth of information, authors were contacted to obtain additional or missing detail to enable judgements of trustworthiness and rigour.

Programme theory development – literature synthesis

Once data relating to contexts (C), intervention (I), outcomes (O) and potential mechanisms (M) were extracted they were iteratively linked into CMO configurations (CMOCs). This process is central to realist logic as it is not only the identification of relevant CMOs but their linkage and configuration which establishes generative causation and underpins programme theory development as to what works for whom, under which circumstances and why. At this stage everyone involved in the synthesis had to be prepared and familiar with the literature under investigation and realist philosophy of science to engage in the stimulating academic endeavour of discussing and arguing over how interventions influence context, contexts, mechanisms and outcomes link together, when and how a mechanism becomes context in a different CMOC, and which of the many CMOCs to finally abstract into programme theory. This high level of engagement may differ from approaching research meetings where one person reports and others agree or tweak. The composition and size of a research group undertaking a realist synthesis will be determined by the research questions, the methods employed and the expertise necessary to develop theory. At times realist expertise external to the discipline of pharmacy could have been of benefit, to arbitrate when it was difficult to come to an agreement or challenge potential bias when the small research group created an echo chamber of similar voices.

The final programme theory based on the synthesis of sixty-six documents points to components which seem essential for the success of an MR performed by pharmacists for patients in the community after they have been discharged from hospital. The realist synthesis

allowed the identification of contextual and programme mechanisms as causal factors which make an MR work. Based on the available documentation and literature, it describes the structures which ideally are put in place to maximise review benefits for people who left hospital but also their agency and choices within the MR process. Many outcome differences were accounted for through consideration of nuances in medication review programme activities and implementation, but also differences in the contexts of their implementation.

Implications

The programme theory, described here as a diagram of interlinked CMOCs (figure 1) could be applicable to most health systems in which pharmacists, patients and doctors navigate the transition from hospital to community.

[Insert figure 1 here]

A number of key messages based on the programme theory are of relevance to future MR programme design, implementation and policy development.

Box 1. Key messages for medication reviews after hospital discharge:

- Ensure stakeholders have awareness of and perceive a benefit from the medication review.
- Accommodate patients' preferences, needs and capabilities in terms of timing and location.
- Coordinate the medication review process.
- Ensure pharmacists performing the medication review have access to relevant patient information.
- Encourage or enable pharmacists to establish collaboration with other healthcare

professionals involved in the medication review and to take responsibility for outcomes.

Case study 2

The second case study illustrates how adding a realist evaluation to a synthesis drives theory development further by exploring how older people manage complex medication regimens, their health behaviours and the resources offered to them by health services.

Overview

MEMORABLE (MEdication Management in Older people: Realist Approaches Based on Literature and Evaluation) took a realist approach to synthesising literature and the personal accounts by older people living in the community, their families (informal carers) and practitioners of their behaviours managing medicines, relationships with and support by others at multiple layers of health and social care.[30, 31] An understanding of how older people and their carers manage complex medication regimens then provided the basis for a framework outlining medication management as a complex process and recommendations for interventions and improvements.

MEMORABLE was supported by many stakeholders, though working groups providing governance and management support, of which two were instrumental in taking a realist approach:

1. A multi-disciplinary research team providing oversight and expertise, including older people, practitioners, academics with expertise in realist and information management methodologies and experience in patient and public involvement and engagement (PPIE).
2. A stakeholder group of practitioners, older people and their family (informal) carers. They provided advice and feedback to the research group on the veracity of emerging evidence,

programme theories and proposed interventions, ensuring recommendations were appropriate, practicable and potentially making a difference for everyone involved.

Both groups advised on the dissemination strategy, which was proactive from the start of the project and added to its credibility. It included a web-site, registering the study protocol on PROSPERO and its publication in a peer reviewed journal,[32] which enabled the principal investigator to utilise publicly available documents and establish credibility when discussing MEMORABLE with stakeholders and potential participants.

The realist research process

Developing the research protocol and early informal theorising by stakeholders assisted in establishing an initial programme theory about how medication management might work for older people. This guided an initial systematic search and review of literature. Potential explanatory factors were extracted and used to develop context, mechanism and outcome configurations (CMOCs) related to the research questions. Searches were then extended iteratively, informed by initial findings and consequently established contexts and mechanisms, which, for example, included burden and shared decision making, and a subset of articles from the initial search containing causal accounts related to medication management was later included. Review of the literature led to refinement of CMOCs and mapping a tentative medication management process, supporting the development of a number of candidate programme theories. Although several substantive theories of interest were considered at this stage none could be sufficiently evidenced from the literature to support the complex process model which had been developed.

Realist evaluation

A realist evaluation exploring mechanisms and driving programme theory development further was then added by conducting and analysing fifty realist informed interviews with older people, family carers and practitioners. This added key strengths and innovation to MEMORABLE and encouraged stakeholders to directly articulate their "real world" challenges and capture the burden associated with medication management from their perspective. Realist interviews facilitate gleaning programme theories in the early stages of development and later invite interviewees to comment on developing programme theories, allowing researchers to refine and consolidate them.[33, 34] These interviews substantially offset the limitations of the literature on the subject and allowed particular lines of enquiry to be followed up in more detail. However, they did increase the duration (and therefore cost of the project), due to the ethical approval processes and additional researcher time needed. Both data sources (literature synthesis and interviews) were then combined to establish theoretical understandings of medication management by older people.

Programme theory development

Medication management, as an implementation process, was abstracted into a five stage model (table 2), breaking down the complexity of medication management processes, highlighting decision-making, behaviours and process loops.

Table 2: Five stages of medication management

Stage	**Stage 1** Identifying problem	**Stage 2** Getting diagnosis and/or medications	**Stage 3** Starting, changing or stopping medications	**Stage 4** Continuing to take medications	**Stage 5** Reviewing / reconciling medications

Who / Doing what	Older person identifies that something is wrong.	Older person and practitioner agree on the problem and how to treat it. A prescription is issued and dispensed.	Older person adjusts daily medication routine to include new medication and/or adjusts or omits current medication.	Older person fits new routine into day-to-day life.	Practitioner confirms safety and efficacy of medication. Older person and practitioner agree appropriateness, adherence and fit with day-to-day life.
	Family (informal) carers can be involved at any stages				

These five stages were then categorised into overarching stages of medication management:

a. Individual stages (numbers 1, 3 and 4), where older people (sometimes with support from a family carer) balance routines, coping and risks.

b. Interpersonal stages (numbers 2 and 5), where older people have contact with a practitioner, again sometimes with support from a family carer.

Having established the stages of medication management as complex interventions, Normalisation Process Theory (NPT) was identified as an existing substantive theory to frame and explain processes and behaviours. NPT articulates how new activities are introduced and made both routine and are sustained through work by those involved.[35] Substantive theories can progress understanding when making sense of CMOCs and in this case NPT provided a lens and structure to understand the work required when managing medications at an individual, interpersonal and system level and was applied to each of the five stages.

The synthesis of a realist review of the literature and interview findings established that older people/family carers and practitioners may have different priorities in relation to medication management. Practitioners focussed on process goals such as optimisation, adherence or de-

prescribing. Whereas quality of life, fitting medications into their day-to-day lives and reducing the burden of medication management were important for older people.

Implications

A key finding of MEMORABLE was the relationship between workload associated with medication management and capacity (table 3), how they fluctuated and the impact in terms of burden on the older person. For example, workload increased with polypharmacy and capacity decreased with cognitive impairment; both were likely to increase overall burden, whereas workload decreased if the medication regimen was simplified.

Table 3: Relationship between workload, capacity and burden

What capacity does the older person have? **What is the workload?**	**Increasing / high capacity**	**Decreasing / low capacity**
Increasing / high workload: May be high workload in general or may spike at times of change and uncertainty.	**Burden:** coping	**High burden:** not coping – high workload and low capacity risk
Decreasing / low workload:	**No burden:** coping	**Burden:** not coping –low capacity risk

Burden was often hidden from practitioners. Older people developed and established routines in dealing with medications, when medications changed burden potentially increased, at least temporarily.

Two potential interventions were identified and proposed from MEMORABLE. Firstly, because medication management burden is often hidden, it needs to be identified. Secondly, the provision of 'individualised information' for older people and family carers, to enable them making sense of complex diagnoses and medications; and find ways to fit medication into their day-to-day lives, thus mitigating the substantial burden.

These findings informed key messages for practitioners to assess burden (box 2).

Box 2. Key messages for practice from MEMORABLE

When prescribers start a new medication or change a dose they should routinely address burden: 'How are people coping with managing their medications? Will a change increase their medication management burden and how can we address it together so they can cope?'

Discussion

As illustrated by the case studies realist research exhibits a degree of agnosticism in regards to methodology and methods used to establish relevant contexts, mechanisms and outcomes. Realism provides the underlying philosophy of science, with realist research questions informing the choice of methodological approach. This allows realist researchers to draw on a wide range of evidence and methods.[36]. Many contributions to this special edition are outlining methods with relevance to realist research, by supporting the generation of trustworthy findings or ensuring rigour of intervention and study design.

The aim of most realist research, whether synthesis of existing evidence or evaluation of programmes or behaviours, is to increase knowledge and certainty as to how and why interventions or programmes work, while accepting that knowledge can only ever be partial and incomplete. As it is grounded in the acceptance and analysis of complexity the

application of standardised formulae would pose the inherent danger of a technical or reductionist approach, dealing with complexity is complex in itself. Heterogeneity of programmes, which is unavoidable even when they are implemented with exceptional consistency and fidelity, their desired and undesired outcomes and the observations and varied findings of studies describing them reflect what actually happens in the real world. Attempts to standardise complex interventions, reducing their natural variation and controlling the context of their implementation may be necessary to establish initial effectiveness but will reach a limit, and at the same time limit the applicability of any findings derived from their observation and analysis. At the same time, realist logic can assist in the identification of essential ingredients in contexts and programmes which facilitate the activation of mechanisms which cause desired (or undesired) outcomes. For example, the realist synthesis of post-discharge MR identified mechanisms which are ideally in place in various contexts and activated by the intervention, describing some of the essential ingredients of the MR process which are likely to lead to a beneficial outcome, e.g. a reduction in healthcare utilisation. It also made clear that these have to be combined with sensitivity to context and responsiveness to emergence and rivalry. Valuing complexity, acknowledging uncertainty and variations of context mean recommendations for a standardised approach to MR are likely to be futile, though the same ingredients may well be essential in many contexts the recipe will vary and needs local spice.

In its approach to data collection and analysis realist research integrates other theories that help to explain findings and underpin programme theories. As MEMORABLE demonstrated, often substantive theories can help build the theory development in the specific real world clinical environment under investigation, helping to explain what happens and why. The addition of a realist evaluation involving stakeholders aided the process of identifying the appropriate theory which supported the generation of final programme theory. Opening the

treasure trove of existing social and scientific theories will allow pharmacy practice researchers to leave the confines of deterministic cause and effect models and empiricism behind and gain new insights into how and why their programmes work through a combination of theory-integrating and -driven evaluations and evidence syntheses.

Ultimately pharmacy and healthcare programmes are funded and implemented to improve the status quo of healthcare and create benefit for people in need of care. Realist research is now recognised as a strategy to inform the decision-making of funders and policy makers as to where to allocate resources, which services and programmes to fund.[8, 37] Pharmacy practice researchers have ample scope to support this process by first developing, then iteratively refining pharmacy practice programme theories and generating new evidence through realist evaluations and syntheses. Making programme theories applicable and translatable into practice includes providing clear messages about what seems the best way forward based on the most relevant evidence currently available and theory-driven knowledge development to increase their relevance to policy makers, funders, stakeholders and programme participants. This closes the loop to implementation science, with programme theories identified through realist research informing the implementation of a new or modified pharmacy service or practice programme and forming the basis for the next round of theory driven analysis or evaluation.

A downside to realist research in the traditional sense is the requirement for considerable content and methodological expertise, and the length of time it can take to develop programme theory, particularly when it includes real world, lived experience. When decisions around programme implementation have to be made within short timeframes, the scope of analysis and review may have to be narrowed. Instead of aiming at the development of theory that is transferable across many domains reviews of evidence may have to focus on the 'theory-driven identification of contextually relevant interventions that are likely to be

associated with specific outcomes within a particular set of parameters'.[38] Rapid realist reviews often work backwards from the desired outcome in the quest of identifying interventions and programmes which will activate the mechanisms needed to achieve the outcome in a specific context of interest. While still applying the realist logic and constructs they may be able to provide answers to highly focused research questions in a time responsive manner, addressing more immediate needs in informing policy.

Panning for gold – getting started

Based on the practical applications and experiences of employing realist logic to pharmacy relevant practice programmes and patient behaviours a number of key recommendations were developed for those who may consider starting with realist research in pharmacy practice:

1. Explore the realist philosophy of science and embrace available realist research guidance, expertise, training materials and courses.
2. Involve a wide range of expertise, experience and programme stakeholders at all stages of theory development.
3. Publish the research protocol in a peer-reviewed journal.
4. Use an iterative literature search strategy, with later searches informed by initial results and theories, keep an open mind as to what can contribute to programme theory development.
5. Focus on generative causation and develop a programme theory to advance the conceptualisation of outcomes.
6. Draw on existing theories to help make sense of data and CMOCs.
7. Formulate clear messages based on programme theory for policy makers and programme participants.

Generating a more nuanced understanding through realist research of how pharmacy services contribute to overall healthcare supports all stakeholders in the refinement and targeting of programmes, successful adaptations to local contexts and resources, which may lead to greater effectiveness.

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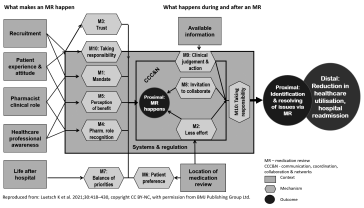

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