16 Realist Synthesis

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Key points

- Reviews using realist approaches represent one way of using qualitative studies to explore complexity alongside effectiveness studies and other evidence sources.
- Realist reviews draw upon their own terminology and assumptions but, put simply, they explore how an intervention or programme is believed to work in specific contexts to achieve intended or unintended outcomes.
- Realist reviews typically involve iterative searches and use relevance, richness and rigour to prioritise the evidence sources that they include.
- Realist reviews aim to suggest why interventions work in some contexts but not others, what needs to be changed to produce effective interventions, or where decision-making needs to recognise factors beyond effectiveness.
- Realist reviews share similarities with theory generating, theory exploring and theory testing functions of some QES methods

16.1 Introduction

Realist synthesis focuses on how and why interventions work through systematic exploration of how contextual factors interact with interventions and outcomes (Pawson, 2006) and has often been contrasted with the 'conventional Cochrane review' (R. Pawson, Greenhalgh, Harvey, & Walshe, 2005). Unlike a Cochrane review, a realist review has no standardised format but is a product of numerous realist synthesis procedures that adhere, in different ways and to differing extents, to methodological standards for conducting a realist synthesis (Wong et al., 2014). Realist synthesis is 'theory driven' in that the review team will develop a preliminary theory for how an intervention works which is then refined during the review process (Kent et al., 2022).

Realist synthesis and qualitative synthesis share a common intent in extending explanations beyond "what works" to factor in considerations of meaning, context and implementation. Both draw upon the explanatory power offered by qualitative evidence

but realist synthesis seeks to bring this together with quantitative evidence *within* the realist review. In contrast, qualitative synthesis can either offer such explanations via a complementary review or within a planned mixed methods review.

Early in the development of QES, Estabrooks and colleagues (1994) identified how synthesis of findings from qualitative studies "increases the level of abstraction, leads to greater generalizability, and…. can lead to the development of mid-range theory" (Estabrooks, Field, & Morse, 1994). Development of, or identification of pre-existing, mid-range theory in order to establish transferability, is an activity shared by realist synthesis and some types of QES (See also Chapter 3). The role of mid-range theory is explained below but, at this point, the take home message is that both QES and realist reviews seek to extend their explanatory power beyond the specifics of "how this phenomenon works" towards "how phenomena of this type work".

Researchers in the Campbell Crime and Justice Group were among the first to recognise the potential to fuse Campbell Collaboration review "standards" with realist synthesis (Van der Knaap, Leeuw, Bogaerts, & Nijssen, 2008). At about the same time, Greenhalgh and colleagues published a separate realist review that sought to explain the differential results of school feeding programmes that had been implemented in different contexts (Greenhalgh, Kristjansson, & Robinson, 2007). However, it was over a decade later before the first "exemplar" realist review was published within the Cochrane Library (Rivas, Vigurs, Cameron, & Yeo, 2019) and, to date, this remains the only example.

Notwithstanding increasing numbers of high quality published examples in the wider journal literature (e.g. Burton et al., 2021; Chadborn et al., 2021; Price et al., 2021), considerable variation persists in the conduct, quality and reporting of realist reviews (Berg and Nanavati. 2016; Booth et al. 2020). This chapter is important as it aims to clarify realist review methods for use in a Cochrane and Campbell context and to encourage review authors to consider where undertaking a realist synthesis could potentially best meet the needs of decision-makers. More examples of Cochrane and Campbell realist syntheses are needed to demonstrate the application and value of realist approaches in this specific context.

This chapter outlines the characteristics of realist synthesis before detailing the main stages of undertaking a synthesis. Realist synthesis is not considered a method specifically for the synthesis of qualitative data but, within the context of Cochrane and Campbell, it offers an analytical lens for juxtaposing observed effects from intervention studies with insights from qualitative research.

16.2 Formulation of review

16.2.1 Key concepts and terminology

Realist synthesis recognises that interactions, for example between clinician and patient or resident and policy, occur within a complex, continually-shifting context (Booth, Moore, et al., 2019), and seeks to understand what is taking place by focusing on explanations of how

interventions “work” and what happens when they are implemented. Through a review of the literature and by involving stakeholders, the review team develops an initial explanation for ‘what works’ with a particular interest in understanding “for whom, in what circumstances, in what respects and how?” (Pawson et al., 2005, p 25). They then seek to gradually refine this explanation using data from documents, identified as the review progresses, and patient and public perspectives (Ford, Wong, Jones, & Steel, 2016). This initial phase is *theory generation*. In the next phase, researchers ‘*test’* theories against existing empirical evidence. Testing a theory in a realist context often involves comparing the predictions of the theory to empirical observations, and evaluating whether the theory can account for these observations in a coherent and semi-regular way. The final phase is *theory refinement* where theories are revised in the light of ‘testing’. Some realist syntheses then relate the refined explanations for how programmes or interventions work to ‘formal theory’ or ‘substantive theory’ which operates beyond the level of the individual programme or intervention at a ‘middle-range’ level of abstraction (Wong et al., 2017) (See below for definition of terms).

Proponents of realist synthesis typically invoke “what works, for whom, in what circumstances and why” to communicate their approach. Realist reviews seek to uncover the underlying *mechanisms* that produce particular outcomes of interest, together with the specific aspects of context or participant characteristics that enable or activate these mechanisms. Mechanisms are assumed to be invisible and not directly observable. Likewise, the exact interactions of an intervention with a given context that are responsible for activating a mechanism in one situation and not another cannot always be directly observed.

Because an intervention could be introduced in multiple settings which embody varying potential contexts, any of which could activate single mechanisms, or combinations of mechanisms, resulting in the desired outcome, the central conceptual structures in a realist synthesis are Context-Mechanism-Outcome configurations (or ‘CMO’ configurations). Causation of outcomes is conceptualised as ‘generative’; i.e. generated by mechanisms activated by specific contexts some of which may have been deliberately manipulated by the intervention in question. For example, the mechanism underpinning reduction in observable crime following introduction of CCTV cameras (the example used by Pawson & Tilley’s seminal work on realist evaluation) is not activated by the intervention itself (the cameras), but possibly by increasing the expectation of potential perpetrators of being caught (Dalkin, Greenhalgh, Jones, Cunningham, & Lhussier, 2015). Hence, a “placebo camera” may activate the same mechanism.

This emphasis on phenomena that cannot be observed or measured gives rise to key differences between a realist synthesis and the types of systematic review described in the Cochrane Intervention Handbook (Higgins et al., 2019). Theory and explanation occupy a prominent place in realist synthesis compared with methods that focus on synthesising the findings of empirical studies testing intervention effects. Methodologically, realist synthesis

places more emphasis on achieving insight through theory than securing reliable effect estimates. Given that mechanisms are invisible, the realist reviewer theorises their characteristics from evidence identified in prior work, developing new theories about specific combinations of Contexts and Mechanisms that give rise to Outcomes. The reviewer follows "leads" or "hunches" to build up a theory that explains observed outcomes from an uneven patchwork of diverse research. They produce a list of 'CMO configurations' that explain the results in included studies. Critically, a CMO configuration describes how interventions offer or reconfigure resources which people then respond to (mechanism) if circumstances are conducive (context) leading to particular outcomes. It is an inductive and interpretative way of explaining the evidence, in contrast with causal claims evidenced from randomized trials. Moreover, although the steps in a realist synthesis are depicted as sequential, ongoing question refinement and iterative searching mean that the reality is less linear, and it can be challenging to conduct and present realist reviews.

A brief explanation of some of the key concepts introduced so far is given below and further concepts related to theory ('programme theory' and 'mid-range theory') are introduced.

(i) Programme theory

The ultimate and desired output of a realist synthesis is a refined and tested realist programme theory. Most Cochrane intervention effect reviews include an explanation of "How the intervention is thought to work" This explanation, which identifies activating "mechanisms", is known as a programme theory (Flynn, Schick-Makaroff, Levay, & Greenhalgh, 2020). Realist syntheses start with an *initial* programme theory. The review team then assembles data to confirm, refute and refine aspects of the programme theory.

(ii) Context

In a realist review, the key concept of context is conceptualised as being either:

> 1) observable features (space, place, people, things) that activate or block the intervention and operate at a single moment in time to then set in motion a chain reaction of events to achieve outcomes, or
>
> 2) the relational and dynamic features that shape the mechanisms through which the intervention works. (Greenhalgh & Manzano, 2022)

As these definitions exemplify, context in realist terms is inextricably bound together with the associated concepts of outcomes and mechanisms. These are the three essential building blocks of realist logic. In brief, mechanisms cause outcomes to occur, but the relevant mechanisms are only activated within the right contexts. By examining the "mechanisms", exploring the "contexts" where the intervention occurred, and then linking these contexts and mechanisms to the "outcome" of the intervention a review team is able to examine the relationships between these three components (Rycroft-Malone et al., 2012).

(iii) Outcomes

Within trials, and other experimental study designs, outcomes are presented as the main (primary) or associated (secondary) effects either intended or expected from an intervention. Typically, outcomes are proximal (close to the event) so that they can be captured within a feasible study period. As well as being interested in these types of outcomes, realist approaches cast their net further afield to extend inquiry to distal (longer term) outcomes resulting from programmes. In taking this broader perspective, realist inquiry may be equally focused on intended and unanticipated or unintended outcomes. For example, the co-existence of COVID pandemic vaccinations alongside influenza epidemic vaccinations disrupts the intended context in a positive way by allowing both vaccines to be administered at the same time (Singer, 2020). In contrast, co-occurrence of Ebola in endemic malaria regions works antagonistically to disrupt otherwise well-managed malaria prevention measures by restricting the travel and interaction of health workers and the public (Dunbar et al., 2017).

(iv)Mechanisms

Mechanisms are the means by which responses, either individual or organisational are activated to generate or cause either a desired or undesirable response. Typically, a mechanism is "fuelled" by a resource which may either be a tangible, physical resource or, equally an intangible emotional or cognitive resource (such as a belief). Mechanisms have been fully conceptualised by Dalkin and ccolleagues in a key methodology paper (Dalkin et al., 2015).

(v) Context-Mechanism-Outcome

Each combination of context (C), mechanism (M), and outcome (O) is labelled a "C-M-O configuration" (Linsley, Howard, & Owen, 2015). Where C-M-O configurations recur they offer semi-predictable patterns (known as demi-regularities) - broad "rules" for how and when certain outcomes typically occur (Minian et al., 2020). A review team constructs multiple C-M-O configurations in order to explore outcome patterns.

(vi) Mid-Range Theory

Commentators hold different interpretations of what is meant by mid-range theory. It is largely agreed that mid-range is an adjective for theories that operate at a level of abstraction and yet remain close enough to the data to permit empirical testing. At a literal level, some argue that a CMO configuration is a mid-range theory because it is specified in a way that permits empirical testing. However, others prefer to differentiate mid-range theories from programme theories and point to formal or substantive theories that operate at a higher level of abstraction (Davidoff, Dixon-Woods, Leviton, & Michie, 2015). For example, Diffusion of Innovations Theory and Normalisation Process Theory are mid-range theories to facilitate implementation of interventions which have been used in realist

reviews by Harris et al., 2015 andLewis, Harvey, Hogan, & Kitson, 2019. Mid-range theories lie mid-way, although not necessarily equidistant between the empirical data that are collected to support or negate a programme theory and all-encompassing grand-theoretical schemes that inform a wider world view (e.g. feminism, capitalism). The role of theory in general within Cochrane reviews has been well-summarised in a methodological review (Noyes et al, 2016) (See also Chapter 3 on Use of Theory).

(vii) Realist philosophy of science

Although the above section necessarily focuses on the unique terminology of realist approaches it should be recognised that this cannot be separated from an overarching realist philosophy of science which makes assumptions about how the world must be constituted for science to be possible. The epistemological and methodological implications of this realist philosophy of science extend beyond the scope of this chapter and can be accessed via Pawson's seminal text on *Evidence-Based Policy (Ray Pawson, 2006b)*.

16.2.2 Overview of stages and processes

Rather than being a defined method, realist synthesis is an overarching approach for which different authors have proposed slightly different stages. Those outlined by Rycroft-Malone et al (2012) are used as an illustration of the main processes involved here because they offer more detail into the component activities of each stage (Table 16.1). Our choice of this framework, however, should not imply that this framework is better than others. Readers are also encouraged to seek out guidance on the conduct of realist synthesis developed as part of the RAMESES (Realist And Meta-narrative Evidence Syntheses: Evolving Standards) project (Wong et al., 2014).

Table 16.1 - Four stages of realist synthesis as described by Rycroft-Malone and colleagues (Adapted from (Rycroft-Malone et al., 2012))

Stage	Action	Activity
Stage 1 - Define the scope of the review	Identify the question	What is the nature and content of the intervention? What are the circumstances or context of its use? What are the policy intentions or objectives? What are the nature and form of its outcomes or impacts? Undertake exploratory searches to inform discussion with review stakeholders.
	Clarify the purpose(s) of the review	From: (a) Theory integrity – does the intervention work as predicted? and/or (b) Theory adjudication – which theories around the intervention seem to fit best? and/or (c) Comparison – how does the intervention work in different settings, for different groups? and/or (d) Reality testing – how

Stage	Action	Activity
		does the policy intent of the intervention translate into practice?. Determine the perspective for the review (e.g. health system or individual interaction) Identify any particular lenses e.g. equity, complexity etc.
	Find and articulate the programme theories	Search for relevant 'theories' in the literature. Draw up list of programme theories. Group, categorise or synthesise theories. Design a theoretical framework to be 'populated' with evidence. Develop tailored data extraction forms.
Stage 2 - Search for and assess the limitations of the evidence	Search for the evidence	Decide and define purposive sampling strategy **(See Chapter 5).** Define search sources, terms and methods to be used (including cited reference searching). Conduct CLUSTER searches, if required, to complete citation networks Set thresholds for stopping searching.
	Assessing richness, relevance and rigour	Assess the interaction of **R**ichness – does the research provide sufficient conceptual richness and contextual detail to understand the focus of interest? **R**elevance – does the research address the theory under test?; and **R**igour – does the research support the conclusions drawn by the researchers/reviewers?
Stage 3 - Extract and synthesise findings	Extract results	Extract data against a framework of programme theory components.
	Synthesise findings	Decide whether to sample comprehensively or purposively (e.g. according to clusters) Compare and contrast findings from different studies. Use findings from studies to address purposes(s) of review. Seek both confirmatory and contradictory findings. Refine programme theories in the light of evidence including findings from analysis of study data.
Stage 4 - Develop narrative	Communicate take home messages	Conduct supplementary searches for mid-range theories Involve commissioners/decision makers in review of findings. Disseminate review with findings, conclusions and recommendations.

16.2.3 Defining the scope of the review

A realist review team needs to provide a rationale for their review and identify both the need for the review and how it contributes to current knowledge of the topic. While it is not essential to articulate the rationale using "what works for whom under what circumstances and why" it should be clear how the review will identify and link the impact (outcomes) of the intervention with the circumstances (context) under which this is achieved. The review team should also identify the initial programme theory - a tentative explanation of how the intervention is expected to work and in what contexts. The programme theory can be informed by theories from various disciplines, empirical evidence, and expert opinion. In addition, the review team should consider the depth and breadth of the literature for inclusion, the geographical and temporal range of the literature, and the type of evidence to be included. Realist synthesis typically utilises diverse types of empirical study including process evaluations, qualitative research, RCTs, before-and-after studies and existing systematic reviews. This contrasts with comparable intervention effects review which can have a narrow focus on particular types of evidence. Realist syntheses often also require a broadening of outcomes and engagement with data on other aspects of the programme or policy under review such as context, setting, staffing models, funding (Table 16.2) . Studies not previously eligible for an intervention effects review now may be considered relevant to a realist synthesis.

Table 16. 2- Evidence types and potential uses within realist synthesis (see Claire Duddy & Roberts, 2021))

Evidence type	**Use**	**Example of use in a realist synthesis**
Commentaries and opinion pieces	Identification of theories	Networked information systems & patient safety (Keen et al., 2019)
Policy documents	How programmes are intended to work	Interprofessional teamwork in health and social care (Hewitt, Sims, & Harris, 2014)
Primary research reports and programme evaluations	Whether interventions work; how people experience the intervention; how the intervention worked/was implemented.	Transition to parenthood (Gilmer et al., 2016)
Social media	Lay explanations of programme consequences	First contact physiotherapy in primary care (Stott et al., 2020)
Systematic reviews	Whether interventions work; strands of programme theory	Networked information systems & patient safety (Keen et al., 2019)

The scope of the review can be refined and revised iteratively as the review progresses, based on new data and insights gained from the analysis. Although Table 16.1 places

"Identify the question", "Clarify the purpose(s) of the review" and "Find and articulate(the programme theories" in sequence, in reality these processes are iterative and overlapping.

(i) Identify the question

Evidence syntheses are typically characterised by a clearly formulated review question (Booth, Noyes, et al., 2019) (See Chapter 2). A realist review team will usually begin by identifying the population, intervention, context, and outcomes (PICO) of interest.

Other realist reviews have used a free-form review question; given that an intervention may or may not be pre-specified, with a question focused on mechanisms. In Table 16.3 the team build up from identified mechanisms (empowerment, participation and responsibility) to specify desirable attributes of candidate interventions (See Table 16.3).

Table 16.3- Sample CIMO questions for intervention and mechanism focused questions (Rivas et al., 2019)

Context	**Intervention**	**Mechanism(s)**	**Outcome**
Intervention-focused question(s)			
• How do advocacy interventions for abused women achieve specified positive outcomes? • How does the success of advocacy interventions differ according to the circumstances of abused women?			
(i) Physical dependencies, (ii) Being pregnant or (iii) Having children.	Advocacy Interventions for Abused Women		e.g (i) Increasing successful court orders (ii) Decreasing depression
Mechanism-focused question			
• How do mechanisms associated with the therapeutic alliance contribute in achieving positive outcomes for abused women? • In what way do particular mechanisms associated with the therapeutic alliance achieve positive outcomes for abused women in different circumstances?			
(i) Physical dependencies, (ii) Being pregnant or (iii) Having children.	*[Therapeutic Alliance]*	Closeness to advocate Feeling able to share problems Security of a safe, neutral place Feeling supported Feeling able to trust advocate	Any Positive or Negative Outcomes

(ii) Clarify the purpose(s) of the review

As well as being stand alone reviews which integrate a diverse range of evidence sources (e.g. Rivas et al. 2019), realist reviews offer multiple potential applications alongside existing Cochrane and Cambell intervention effect reviews (Table 16.4).

Table 16.4 – Four purposes of realist synthesis alongside existing Cochrane and Campbell intervention effect reviews

Using realist synthesis to:	Example
Explore intervention effects	A Cochrane review of school feeding programmes in disadvantaged children included trials from five continents and spanned eight decades. Programmes demonstrated positive effects on growth and cognitive performance. However, programmes were successful in some contexts but not others(Kristjansson et al. 2007). In a subsequent realist inquiry, reviewers examined the trials to identify which aspects determine success and failure in various situations (T. Greenhalgh et al., 2007).
Inform intervention design	Reviewers used 22 papers to uncover mechanisms that affect women's experiences of maternity care and explore how women with diverse social risk factors experience maternity care in the United Kingdom (UK). Access to services, appropriate education, interpreters, practical support, and continuity of care were particularly relevant for women unfamiliar with the UK system and those living in chaotic circumstances. Findings provide practical guidance to inform development of safe services to reduce inequalities in women's experiences and birth outcomes (Rayment-Jones, Harris, Harden, Khan, & Sandall, 2019).
When an intervention review is inconclusive	An effectiveness review for medically unexplained symptoms found no single intervention to be effective across all symptoms. A realist synthesis based on a QES showed that the relationship between patient and primary care provider is key to a successful intervention. Future research should test the therapeutic effects of the doctor-patient relationship and explore between-study differences for the same intervention (e.g. with detailed reporting of mechanisms) (Leaviss et al., 2020).
Informing implementation	A realist synthesis on evidence based interventions focused on how to achieve successful change in individuals and organizations). Fifty-two papers provided insights into how change agents' function, how individual change agent characteristics effect evidence-informed care, the interaction between the change agent and the setting and the overall effect of change agency on knowledge utilization. Issues surround how accessibility of the change agent, their cultural compatibility and

	their attitude impacted on effectiveness. Findings revealed the importance of reflective practice and role modelling (McCormack et al., 2013).

Realist syntheses should include an explicit statement of the review question together with a rationale for any specific focus of the review. This prevents readers from assuming that the review includes more comprehensive coverage of directly applicable evidence than intended. Under other cirumstances the team may have gathered evidence beyond the original review question (cp. indirect relevance (Noyes et al, 2018)), seeking explanations through analogy and similarity. If this is the case the team should flag up that they have sought evidence for topics not initially identified in the formulated question. The iterative nature of realist inquiry means that it is not always possible to anticipate all aspects of the methods or subsequent lines of enquiry. In these cases a *changes from protocol table* is useful to report these alterations.

(iii) Find and articulate the programme theories

A realist synthesis sometimes begins with a draft (often also called candidate or initial) programme theory, first described within the protocol, then "tested" and refined against the studies included in the review. Otherwise, a team might identify or generate programme theory within the review itself. As with framework synthesis (Chapter 9); a team may identify programme theory from programme documents, from the academic literature, from stakeholders, patient and public contributors, from their own resources or from any combination of the four (Booth & Carroll, 2015) (see section 16.3 below). Programme documents, particularly project initiation documents, may elicit intended mechanisms and outcomes, before the official version is revised or modified. Conversely, evaluation reports may reveal that the intervention now "works" in a way that is different from that originally planned.

16.3 Identification of evidence for theory generation, testing and refinement

16.3.1 Overview

Different elements of Context-Intervention-Mechanisim-Outcome can be used at different points in the search. For example an information specialist may combine 'Context' and 'Intervention' to generate a list of 'Outcomes' to populate a preliminary logic model. Subsequently, they might combine 'Context' and 'Intervention' with study type filters to identify effectiveness or qualitative evidence. Once a team has identified mechanisms they may run searches for combinations of 'Context-Mechanisms', 'Intervention-Mechanisms', or 'Mechanisms-Outcomes'. Finally, they could choose to combine 'Mechanisms' with terms used for theory (i.e. theor* or concept* or framework* or model*) to link to formal theory (Booth & Carroll, 2015). Any permutation may be tried if it leads to a set of relevant documents.

To identify relevant programme theory a realist review team may choose to search the academic literature systematically, looking for either full-text accounts of how interventions work or for descriptions and/or diagrams of logic models (Booth, Wright, & Briscoe, 2018) (See below and also Chapter 5). Others will seek to generate programme theory from their own experience and resources. The titles and abstracts of bibliographic references do not commonly articulate programme theories. Diverse search approaches are required, beyond conventional database searching (See Box 16.1).

Box 16.1 - Finding Logic models or programme theories using Google search engines

1. Combine a string of the following terms: 'logic model', 'theory of change', 'theory of action', 'outcomes chain', 'program(me) theory', 'program(me) logic', or "logical framework(s)' AND the intervention/phenomenon of interest [on full-text publisher websites or Google Scholar]
2. Combine the intervention/phenomenon of interest (e.g. "postnatal depression") AND ('logic model' OR 'theory of change' OR 'programme theory') on the Images search function of the Google search engine.

A team may also search for models and theories to elucidate candidate programme theories and a structured question formulation, BeHeMoTH, has been proposed as a systematic approach to structuring the search ((Booth & Carroll, 2015).).

Theory may be identified by using citation chaining for papers identified during theory generation, by using "Search similar citations" in PubMed or "Related articles" on Google Scholar and by pursuing links to alternative reports of the same study (Booth et al, 2013). Such searches are recursive until the review team judge they have a sufficient understanding of the intervention of interest. At the same time the team generates additional ideas about theory and uses these ideas to guide further sampling (Emmel, 2013) until they no longer generate further insights.

16.3.2 Further considerations for identifying evidence for theory generation, testing and refinement

As the relationship between identifying evidence and using that evidence in relation to theory is integral we have chosen to present the two side by side. In reality, searching for evidence and the generation, testing and refining of theory are iterative, continually responding to each other. Furthermore, we present theory generation, theory testing and theory refinement as if they are discrete activities, to reflect differences in their respective processes more clearly. In reality, these may act either separately or in conjunction depending upon the contribution of the evidence and the priorities at each time point of the review.

(i) Theory generation

Theory generation takes place throughout the entire realist synthesis. During scoping the team identifies theories or mechanisms suggested by study authors or stakeholders. A theory may offer a structure for data extraction (**See Chapter 3 on Theory**). In other instances, a theory may become an analytical lens throughout analysis, interpretation and write up. Again, the theory may be unearthed at the beginning or during the analysis phase. In yet other instances a pool of candidate theories is put to one side during the synthesis phase and then revisited during the final refinement stage.

In contrast to the precise searches of conventional systematic reviews, realist searches are exploratory (Booth et al., 2018). Searches could start from a rich exemplar and explore related terms as "stepping stones" to a wider literature. Realist syntheses are distinctive by using diverse evidence types for theory generation, beyond empirical studies. These include official documents, Web pages, bulletin boards, meeting minutes, media reports etcetera (Booth et al., 2018). Not all realist reviewers use all these evidence types. Qualitative studies exploring a condition may describe what an intervention is expected to achieve, papers supplying extra detail of a context, a condition or a theory may help to understand how a programme works. In a Cochrane/Campbell context it is not feasible to accommodate representative evidence in all languages, health systems or contexts. Neither is it easy to make consistent judgements about the quality and rigour of diverse sources of non-empirical evidence (see section 14.2.2.1). At the same time, searches may serendipitously unearth empirical studies to support or refute the programme theories. By carefully documenting studies as they discover them a review team can adopt, adjudicate between or discard different versions of the programme theories as the review progresses.

(ii) Theory testing

Typically, a team tests (i.e. supports, negates or refines) theory against empirical studies (quantitative and qualitative research) once a provisional set of programme theories has been developed and agreed. In actuality two types of theory need to be tested:

(1) theories that explain causation within a programme theory (i.e. the CMO configurations) and;

(2) the programme theory itself (as it explains the relationships between the CMO configurations contained within it).As mentioned above, specific search strategies may be used to identify theoretical papers (Booth & Carroll, 2015). Alternatively, theoretical papers may be linked from citations in the Background or Discussion sections of included empirical studies or, ideally, in a subsection on how an intervention is thought to work.

The review team may construct a sampling frame or map of the included studies. Subsequently, they may sample from these, either comprehensively or purposively, looking for evidence to support, negate or refine the CMO configurations contained within the programme theories or parts of a programme theory itself. Some review teams conduct parallel reviews of effectiveness and qualitative evidence as key inputs to the testing stage

of a realist synthesis. Combining reviews in this way may work well when effectiveness and qualitative studies in the two reviews are largely unrelated (C. Rivas et al., 2019). Alternatively, where related quantitative and qualitative studies cluster in groups (either sibling studies that share context or kinship studies that are conceptually-linked), richer citation networks can be selected as case studies (See CLUSTER searching detailed in Chapter 5).

Searching at this stage is no longer exploratory, resembling the searches of a conventional systematic review (Booth et al., 2018). Searching for empirical studies to test theory may be combined with searches or updates for an effectiveness review (C. Rivas et al., 2019). Sources include trials registers, health, nursing and psychology databases, social science databases, databases of reviews, grey literature and dissertations and theses together with relevant websites.

(iii) *Theory refinement*

Theory refinement can involve revisiting a different set of literature from that used to generate or test the theory. For example, the team could return to a complementary Cochrane review of effects to identify whether further variation, not explained by their theories, is present in included trials. Refinement may involve re-engaging with stakeholders whether "policymakers, researchers, experts by lived experience or service providers" (C. Rivas et al., 2019). Consultation may be face to face, by email or via videoconferencing. Stakeholders can be asked, specifically, to comment on the credibility and validity of the explanatory theory and its coherence along with any omissions (C. Rivas et al., 2019). Identification of gaps is important, particularly when engaging with the lived experience of stakeholders, as potential end users.

16.4 Appraisal of evidence

16.4.1 Assessment of richness

In realist reviews, richness encompasses both conceptual richness and contextual thickness. Conceptual richness is important for the development of theory and contextual thickness is important for understanding study contexts (e.g. descriptions of setting, participants and/or procedures). A review team needs to acquire a sufficient understanding of the *study context* (how, why and for whom and in what contexts an intervention worked) if they are to be able to assess how findings are transferable to the *target context*. Intervention detail is also useful (Charles et al., 2016) to link intervention features to associated mechanisms; for example what is achieved through repeated sessions, providing feedback or meeting in a group.

Some evidence sources contribute to the development of theory, others describe study contexts (Roen, Arai, Roberts, & Popay, 2006), yet others contribute to both. In practice, richness may extend beyond contextual detail and conceptual richness. Study reports must also supply sufficient details to support the generation of explanations and, subsequently,

to test those explanations; requiring details of interventions. So richness can be thought of as requiring, first, a potentially useful level of detail in order for evidence sources to be prioritised for attention and, second, detail of particular features, ideally in empirical studies, that help in understanding and testing subsequent programme theories.

To assess richness, review teams may borrow from useful concepts and tools within the wider synthesis literature; for example, the GRADE-CERQual component of 'adequacy' may prove helpful (Glenton et al., 2018) (Chapter 13). The Cochrane realist review on advocacy (Rivas et al., 2019) assessed both conceptual richness and contextual thickness. The team also asked: "How valuable is the research (richness of the data for the review research questions)?" (C. Rivas et al., 2019). Examples of approaches to assessing richness and other data quality issues are shown in Table 16.8.

Table 16.8 - Assessing data quality in realist synthesis

Approach	**Application**	**Criteria**
CART criteria (Aslam et al., 2017)	Assessing overall data quality	**C**ompleteness; **A**ccuracy; **R**elevance; **T**imeliness
Richness scale (Ames, Glenton, & Lewin, 2019)	Assessing adequacy of data supporting specific findings	1 - Very few qualitative data presented. Findings fairly descriptive; 2 - Some qualitative data presented; 3 - Reasonable amount of qualitative data; 4 - Good amount and depth of qualitative data; 5 - Large amount and depth of qualitative data
GRADE-CERQual (Chapter 13)	Assessing confidence in review findings	Methodological limitations, Adequacy, Coherence; Relevance
TiDiER (Hoffman et al., 2014) or TiDiER-Lite (Chambers et al., 2020)	Assessing completeness of intervention description	12 (or 5) items describing an intervention

16.4.2 Assessment of rigour

Superficially, rigour for realist synthesis shares concerns of risk of bias or risk to rigour encountered in systematic reviews. However, more than their counterparts, realist syntheses draw upon diverse types of study and non-empirical publications such as policy documents and descriptions of existing programmes. Not all sources suit formal checklist- or criterion-based quality assessment. Other frameworks for quality may be required to handle non-research types of evidence, for example governmental or non-governmental organisation reports or Web pages. For example, the Completeness-Accuracy-Relevance-Timeliness (CART) framework may be used across diverse literature (Houghton et al., 2020) (Table 16.7) and the ACE tool has been developed to assess strengths and limitations of documents describing programme implementation and policies and systems (Lewin et al. 2024). Formal quality assessment, using checklists, tends to be used when testing theories

with findings from empirical studies rather than during the exploratory theory generating stages. Within Cochrane and Campbell, the emphasis on formal quality assessment typically requires diverse tools and instruments. The Cochrane realist synthesis on advocacy for example used the CASP checklist for qualitative research studies, the Cochrane 'Risk of bias' criteria for “different trial designs” (and criteria to inform 'Risk of bias' in cross-sectional surveys (C. Rivas et al., 2019).

16.4.3 Assessment of relevance

In realist synthesis relevance is not simply bounded by a PICO-like question. The focus on mechanisms, rather than interventions, opens up inclusion of evidence by analogy, rather than direct similarity. For example, is it conceivable that the mechanisms that cause a person’s response to mandatory mask wearing are similar to a person’s response to mandatory safety belt legislation? Realist synthesis positions relevance on a continuum, alongside rigour and richness. A team may therefore relinquish a tight concern with relevance as per PICO criteria for a “foray” into conceptually related, but less-directly relevant, evidence to yield illuminative insights. For example, when a review seeks to understand the impacts of mandatory *vaccination* it may prove illuminative to include and analyse data about mandatory *testing* because the data may inform mechanisms behind an individual’s response to mandates within a health context.

16.4.4 Bringing it all together

Tests of richness, and of rigour and relevance help to limit and prioritise numbers of included sources. Where evidence is limited, a review team may process all sources of evidence anyway so it can prioritise the most rich, relevant and rigorous items to “fast-track” their progress. Where evidence is plentiful a team may sample to ensure that rich, relevant and/or rigorous items are included in the synthesis (**Chapter 6).**

Ultimately, the team uses decisions on rigour, richness and relevance to feed into their assessment of confidence in the programme theory as an explanation for what is happening and why. Given the similarity here with the assessment of confidence in the review findings within GRADE-CERQual, use of an equivalent approach within a realist synthesis may offer a potential route to further strengthen realist inquiry (Li et al., 2021; Rivas et al., 2019). However, to date, assessments focus on the quality of supporting data and no tool currently exists for arbitrating on the quality of interpretation or inferences.

16.5 Synthesis and interpretation of evidence

16.5.1 Data extraction

With no specific software designed for realist synthesis, teams can choose systematic review software (such as EPPI-Reviewer used, for example, in the review by Rivas et al., 2019) or generic software such as Microsoft Word, Access (e.g. Charles et al., 2016), Excel or Google Sheets and Google Forms**.** Several teams have used NVivo software for coding study

characteristics and handling text extracts (Bergeron & Gaboury, 2020; Milsom, Smith, Baker, & Walls, 2021) (S. Dalkin, Forster, Hodgson, Lhussier, & Carr, 2021).

After importing bibliographic records into relevant software teams may construct an initial 'map' or sampling frame (MacDonald et al., 2016). Broad categories include publication type/study design, academic discipline, country and setting. The resultant map helps to sensitise the review team to the available evidence and to inform decisions about sampling. Detailed data extraction within a coding framework follows as decisions on sampling become apparent. Codes may relate to study characteristics, PICO characteristics or be specific to realist methods (See **Table 16.9** for suggested data elements). As with other interpretative synthesis, data extraction and coding often include data from beyond the 'Methods' and 'Results' sections to include the 'Discussion' sections as well as reviewer annotations.

Table 16.9 - Data Extraction elements and their contribution

Study elements	PICO elements	Realist elements
Study aims and rationale Discipline/Profession Country Study design/publication type Sampling strategy/ Recruitment Consent Data Collection Data Analysis Length of time to follow up Risk of bias/ methodological limitations Weight of Evidence	Recipient demographics Length and intensity of the interventions Programme or intervention description Programme Fidelity Expertise of person delivering intervention Quality of relationship between provider and recipient Stage of change of recipient Availability and quality of programme Ethical and safety considerations Comparator Outcomes – primary and secondary Effectiveness of interventions or qualitative themes where relevant Economic costs and benefits	Context Underlying programme theory Programme strategies or underpinning theories Mechanisms Implementation issues **Reviewer annotations:** How successful study was Why success/failure

The review team extracts relevant data into their chosen software, and add inductive labels for concepts not previously identified. One Cochrane team (Rivas et al., 2019) used the EMMIE realist evaluation framework deductively to provide fields for data extraction (Johnson, Tilley, & Bowers, 2015). EMMIE codes the **E**ffectiveness of the intervention, the **M**echanism theorised to be at work, **M**oderators that could affect the response to the

intervention, **I**mplementation issues in practice, and **E**conomic costs and benefits for each study.

Several options are available for presenting outputs from the coding and classification procedures. The credibility of a realist synthesis is closely tied to explicit and transparent presentation of the analytic process. One such output is a 'CMO matrix'; a series of rows depicting multiple configurations of Context-Mechanism-Outcome. Some reviewers seek to make these intuitive using an IF-THEN-LEADING TO notation (**See Table 16.10**) (Chambers, A. Cantrell, & A. Booth, 2020). CMO configurations are not necessarily provided in the form of a matrix – some may be presented within the 'Results' section of a review report as tables.

Table 16.11 - Context Mechanism Outcome (CMO configurations)

Context (IF)	**Mechanism (THEN)**	**Outcome (LEADING TO)**
IF service recipients are matched to a service provider of their own ethnic group	**THEN service recipient and service provider share socio-cultural values and language**	**LEADING TO high trust and effective communication**
"Data from 2nd cohort of the National Survey of Child and Adolescent Well-Being, found that when non-Caucasian caseworkers share the same racial/ethnic background as caregivers, caseworkers use more active strategies to connect caregivers to needed housing services". [Empirical](McBeath, Chuang, Bunger, & Blakeslee, 2014)	Representative bureaucracy theory suggests that cultural similarity in the caseworker-caregiver relationship activates minority caseworkers as stewards of minority client interests [Mid-range Theory]. (McBeath et al., 2014)	Patients and clinicians in ethnically-matched dyads may be responding to culturally-accepted expectations of communication in which shared understandings about communication content and context, rather than just ethnicity, improve treatment participation. [Alternative interpretation](Aggarwal et al., 2016)

Table 16.11 shows three different contributions of data extracted to the IF-THEN-LEADING TO (C-M-O Configuration). First, empirical data suggests that caseworkers matched by ethnicity/race may be more active advocates for caregivers than Caucasian caseworkers (McBeath et al., 2014). Second, representative bureaucracy theory, from the same paper (McBeath et al., 2014) suggests a mechanism by which caseworkers become activated "as "stewards" for their clients. Finally, evidence from another study suggests an alternative interpretation, that it is the shared socio-cultural values of communication content and context, that achieve this outcome (Aggarwal et al., 2016).

Without tabular or graphical representation of C-M-O configurations it is challenging for a reader or decision-maker to judge for themselves the plausibility of the knowledge claims made. The CMO configurations which are developed and then confirmed, refuted or

refined, based on interpretations of the data from included sources, supply the required fine-grained workings for these knowledge claims. Providing such tables enable the readers to sense check the CMO configurations as causal statements and to verify that the review team is able to interpret mechanisms in realist terms. The central role of the transparency of these presentations (of the "workings out" for the plausibility and coherence of the programme theory) is analogous to the focus on the detail of reporting of methods required to establish the credibility of a systematic review. A researcher conducting their first realist review will therefore find it helpful to collect a variety of alternative formats for presentation. Examples include "Detailed CMO configurations" (Supplementary Tables S6 to S8 in (C. Duddy & Wong, 2021)). While the actual format by which a team chooses to present their CMO configurations remains a matter for personal choice the above alternatives meet the requirement for transparent presentation.

16.5.2 Synthesise findings

Synthesis involves looking for patterns in the data and therefore starts with the processes described above for extracting and coding data and developing CMO matrices (Booth, Sutton, Clowes, & Martyn-St James, 2021). A review team examines extracted data looking for data that confirm, refute or modify the original CMO configurations and then refines the initial theory.

The analytic process may draw upon such techniques as compare and contrast, mapping and charting or comparing down columns or across rows**.** Realist synthesis does not prescribe a specific way to undertake analysis but whatever processes are used should be coherent and applied consistently. One team, for example, devised a series of questions to guide analysis thereby providing a way to structure this stage of a realist synthesis (Step 5: synthesising the evidence and drawing conclusions in Papoutsi et al., 2018). Once coding and hypothesis formation is complete, based on individual subsets of evidence, the team revisit the entire corpus of evidence identified in the review to check consistency of interpretation. The team seeks to explain unanticipated outcomes by, for example, exploring differences between populations or settings and revising or modifying the programme theory to fit nuances within the evidence.

Where gaps in evidence exist, for example, where an author does not make a mechanism clear, the missing connection may be revealed from further evidence sources. Sources may reveal a complete chain or a team may splice together sub-chains of context to mechanism and of mechanism to outcome from across evidence sources. Where verification is not possible a team draws a probable conclusion from what is known and then seeks the simplest explanation that fits the available information (i.e. abductive reasoning which involves inventive thinking required to imagine the existence of hidden mechanisms (Jagosh, 2020)). Such abductive reasoning (what now? what next?) is informed by empirical examples, theoretical commentary or discussions within the literature or combinations of these.

16.5.3 Develop narrative to explain intervention

Summary tables, logic models or other conceptual diagrams (e.g. pathways or trajectories) can be used to develop the narrative and emerging theory, and, subsequently, to describe the final realist programme theory. This narrative should be grounded in data, illustrated from published papers and views from stakeholders.

Linking back to theory can support the development of the narrative. Researchers either identify formal or substantive theory *a priori,* and then seek to substantiate this alongside the candidate programme theories throughout the review, or they make links to theories that operate at a mid-range level towards the end of their review. The former requires a multi-disciplinary group with a good grounding in different theories. It carries a risk of confirmation bias –making the data fit the identified theory. The latter requires creative information seeking skills, particularly in seeking ideas not yet labelled by their creators (e,g, "a theory of what happens when….") or ideas that are not yet attributed to an identifiable theory. Supplementary searches may target papers that link an intervention to formal or substantive theory (e.g. "family planning" and "Diffusion of Innovations") (Booth, Briscoe, & Wright, 2020).

16.5.4 Reporting the review

Guidance for reporting realist synthesis has been developed illustrating how a realist synthesis should be written up and includes a set of 19 'publication standards' and useful exemplars and explanations to encourage good practice in the reporting of realist syntheses (Wong et al., 2013)

Like reporting guidance for other review types, the publication standards cover what should be reported in the title, abstract, background, methods, results and discussion sections. The iterative nature of realist inquiry makes documentation challenging but iteration makes capturing detail of review methods even more important.

For example, it is important to clearly report what searching was undertaken to develop the candidate programme theory, and like other types of review, a flow diagram detailing numbers of eligible and included documents together with reasons for exclusion. Despite increasing recognition of the importance of richness in realist synthesis, some reviews have been criticized for providing minimal detail regarding how they have conducted some methodological steps, including the assessment of richness (Dada et al., 2023).. Reviews should specify their methods for prioritisation of particular sources of evidence and justify their approach.

Given the diffuse nature of sources included in a realist review, it is important to focus main findings on theory building and testing Realist reviewers may be tempted to make claims about effectiveness that are best sustained by a formal systematic review of interventions. The strengths and limitations of the available evidence and of the realist methods should be discussed including how programme theories were prioritised, especially if promising

leads remain unexplored. Even if the realist review does not use GRADE or GRADE-CERQual type assessments authors should "comment on the overall strength of evidence supporting the explanatory insights which emerged" (Wong et al., 2013).

16.6 Strengths, limitations and future developments of realist synthesis

Realist synthesis complements QES methods that seek to understand how interventions "work". As discussed above, realist inquiry possesses its own logic which may function as an internal structure for data extraction. However, realist synthesis is equally versatile in being adapted to use external frameworks (Rycroft-Malone et al., 2012). Realist syntheses offer nuanced interpretations that extend beyond an average 'effect size' to consider what interventions work well (and less well) for whom in what circumstances. They offer the prospect of *targeting* finite resources where they can achieve most effect and of *tailoring* interventions to optimise them for local delivery. Realist syntheses include diverse study designs and create value from different publication types, including non-research sources. The focus on theoretical mechanisms, and the context in which they are likely to operate, assists in producing policy and practice recommendations that are transferable to other settings or contexts.

Causal claims made in a realist synthesis are generated from theory and reviewer interpretation, although subsequently grounded in empirical evidence from theory testing. Some dismiss conclusions from realist synthesis as 'hypothesis generation' and deny their role in decision-making (Roberts, 2014). To some extent this is an inevitable consequence of the fact that many realist reviews focus primarily on qualitative evidence and do not go on to integrate outcome data within the review. Others criticise the data-driven mode of enquiry, questioning its apparent 'data dredging'(Pawson & Manzano-Santaella, 2012) and its lack of protection from bias by failing to follow analyses as pre-specified in a protocol (Wong, Greenhalgh, Westhorp, & Pawson, 2012) . Finally, they have been criticized for being more philosophically inclined and less methodologically robust, with findings that have little implication for practice (Mukumbang et al, 2024). In response, the publication and conduct standards (Wong et al., 2013) have helped to systematise presentation of realist reviews and drive up the quality of their conduct and reporting (Berg & Nanavati, 2016; Booth et al., 2020) .

Although realist syntheses seek to explain what works under what contexts, many find it challenging to link theoretical explanations of a range of outcomes to effects particularly when evidence on intervention effects is limited. Theorisation may be limited by the type of available evidence; it is challenging to generate complete causal chains of contexts-mechanisms and outcomes when evidence sources are largely atheoretical and descriptive and detail of the intervention and the organisational and implementation setting is lacking (Greenhalgh, Macfarlane, Steed, & Walton, 2016). As a result, some context–mechanism–outcome links are tentative and preliminary requiring further empirical testing through collection of primary data.

Realist synthesis shares many ambitions of QES, and indeed frequently draws upon qualitative evidence and qualitative methods. For example, realist reviewers were among the first advocates of purposive searching and of searching explicitly for theory. In attempting to address the "what works, for whom, under what circumstances and why" issues that are key to real-world implementation, realist synthesis offers a genuine mixed methods alternative to combining an effectiveness review with a QES. The label "realist review" has been used for reviews with varying degrees of systematicity. To date, Campbell and Cochrane, review teams have either followed a systematic variant of realist synthesis (C. Rivas et al., 2019), undertaken a mixed methods systematic review (Charles et al., 2016), or integrated a parallel QES and systematic review of effects within a realist framework (Leaviss et al., 2020). While a realist approach clearly has value, less systematic approaches to realist synthesis probably do not meet the methodological expectations of Cochrane or Campbell reviews which require that review teams use a systematic approach to reviewing the literature.

16.7 Stakeholder engagement and involvement

Stakeholder engagement and involvement has always figured prominently within realist synthesis (Pawson et al, 2004). Early documents interpret "stakeholders" as those who shape how the programme is intended to be delivered. Opportunities for stakeholder involvement occur at each stage of the realist synthesis process (Abrams et al., 2021), for example, in formulating initial theories through to developing policy recommendations. Public and patient participants may work with members of the research team to co-generate theory. They may occupy established roles as individual research informants, supplying experience to confirm or refute the programme theories. They may constitute a formal patient and public involvement group to discuss, challenge and contextualise the research that is being conducted. Some argue that the role of the patient/public is sometimes lost alongside that of academics, clinicians and professionals (Abrams et al., 2021).

Typically, a realist review harnesses input from stakeholders alongside data from the literature to develop an initial explanation for what works. Stakeholder perspectives may help to refine this initial explanation, adding personal insights from circumstances that confirm or negate the initial explanation. Stakeholders (including patients and the public) may offer alternative explanations to the "official" version of how the intervention was expected to work. They may question emerging explanations. At an early stage, key stakeholders, including patient and public representatives, may be invited to help prioritise programme theories for further investigation. For example, the Cochrane realist synthesis on advocacy (Rivas et al, 2019) sought to determine which candidate theories were most useful for identifying priorities and gaps, thus reducing a "long list" to a short list of priorities.

Patients, relatives and professionals may offer insights on the intervention itself. Managers and professionals may volunteer experiences from successful or unsuccessful instances of implementation. Throughout the review process the review team discuss tentative findings with, and invite comments from, stakeholder groups, leading to final adjustments to theory.

16.8 Equity, diversity and inclusion

Realist synthesis is fundamentally participative, foregrounding the explanations of stakeholders for why an intervention does or does not work (Power et al, 2024). Potentially, it offers a route by which Cochrane and the Campbell Collaboration can enhance "the social relevance of reviews through involvement of stakeholders" (Abrams et al., 2021) and thus to address equity concerns. By their fundamental logic of "for whom, under what circumstances and why" realist approaches seek to go beyond the average effect to understand areas of difference and to distinguish between these. In addition, several realist syntheses have sought to address the equity agenda by targeting community engagement as the topic for their synthesis (De Weger, Van Vooren, Luijkx, Baan, & Drewes, 2018). Exploration of "under what circumstances" specifically engages with implied social considerations such as equity and offers opportunities to explore why such differences exist. Some realist reviews focus specifically on equity related topics (e.g. the review on maternity care by Rayment-Jones et al. which focused on those most likely to experience the worst outcomes). Like for any other review, the review team should strive for diversity in its membership (e.g. disciplines, backgrounds) and consider issues of equity, diversity and inclusion in the methods used to conduct the review.

16.9 Reflexivity

Immersion, meticulous data collection, systematic analysis and reflexive thinking are fundamental to the realist approach (Wong et al., 2012). Reflexive thinking is important within realism because it acknowledges that a researcher's perceptions of the world are always mediated by their own subjective experiences and perspectives. This means that within an objective reality that exists independently of the researcher, their understanding and interpretation of that reality are always filtered through their own personal lens.

Reflexivity within realism encourages a review team to acknowledge the role that their own subjectivity plays in their understanding of the world. In not denying the existence of an objective reality, it recognizes that understanding of that reality is always partial and incomplete. Reflexivity constitutes an important element of realism because it encourages the review team to surface their own subjective biases and limitations, while also recognizing the existence of an objective reality that exists independently of them. However, realist reviews are not as advanced as recent QESs in formally acknowledging the importance of a reflexive element. Clearly realist teams could benefit from adopting approaches to reflexivity already in use within QES, not only in relation to prior allegiance

to the review topic, but also in relation to selection of data and, most significantly, in generation of interpretations and inferences. Guidance on how to arbitrate on the quality of interpretation is needed to structure such reflexive practice.

16.10 Chapter information

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