Methodological reflections on using qualitative research to explore the causal mechanisms of complex health interventions

Abstract

We reflect on how qualitative research can be used to develop or refine theories about how the mechanisms triggered by intervention enactment might generate outcomes, referring to examples from a 'realist trial' of a whole-school health intervention. Qualitative research can explore mechanisms directly, by asking participants how they think interventions work, or indirectly, by exploring participant experiences of intervention-related actions to understand the conditions and consequences of these actions. Both of these approaches can inform theorisation of how mechanisms are triggered and generate outcomes, and how this is contingent on context. We discuss methods for sampling, data collection and data analysis, and recommend dimensional analysis as a means to analyse qualitative data on mechanisms. We then consider how to draw on qualitative research to inform hypotheses to be tested statistically.

130 words

Key words

Evaluation; qualitative; realist; mechanisms; complex interventions

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Introduction

In this paper, we consider how qualitative research can be used to inform theorising of the mechanisms which enactment of complex interventions trigger and which generate outcomes. Our reflections are illustrated with examples from our 'realist trial' of a whole-school health intervention. Our ideas about what mechanisms are, and how they should be examined, are informed by realist concepts. Nonetheless, our aim is to provide useful suggestions for those evaluating complex interventions, regardless of the model of evaluation to which they subscribe.

Complex interventions are commonly described as social interventions with components that interact with each other and with the context in which they are enacted (Moore et al., 2014). There is increased interest in evaluating complex interventions not only by quantifying their effects or describing their implementation, but also by understanding the underlying mechanisms by which they generate outcomes (Bonell et al., 2012; Moore et al., 2014; Burchett et al., 2020). Understanding such mechanisms can help us understand how interventions work. When linked with an understanding of how these mechanisms are contingent on context, as realist approaches to evaluation aim to do, this can also help us understand for whom and where interventions work (Pawson & Tilley, 1997). This can help inform assessments of potential transferability (Burchett et al., 2020), intervention refinement (Bonell et al., 2021), and broader scientific understanding and future interventions (Davey et al 2019). Such approaches can be broadly described as theory-driven evaluation because they aim to develop and refine theory as to how interventions work (Marchal et al, 2012).

A substantial literature considers what mechanisms are (Lemire et al, 2020) in terms of their ontological features and the epistemological status of knowledge we have about them. Informed by this literature, we see mechanisms as new human responses, actions and interactions triggered by the provision of new economic, informational or other resources, and by the resultant enactment of intervention activities (Pawson & Tilley, 1997; May 2013; Lemire et al., 2020). Mechanisms consist of "underlying entities, processes, or structures which operate in particular contexts to generate outcomes of interest" (Astbury & Leeuw, 2010) (p.368). Mechanisms might operate at the individual, group, institutional or societal level (Marchal et al., 2012). Mechanisms can involve intra-individual changes in cognitions or emotions generating changes in behaviour (Carey et al., 2019) or changes to inter-individual interactions (Giddens, 1984). Mechanisms have been categorised as involving: macrosocial influences on microsocial outcomes (e.g. media influencing attitudes); microsocial influences on microsocial outcomes (e.g. peers educating peers); or microsocial influences on macrosocial outcomes (e.g. communities lobbying politicians) (Hedstrom & Swedborg, 1998).

Realist evaluation literature suggests that mechanisms are not directly observable, are contingent on local context and generate outcomes. They are triggered by, but are distinct from, intervention activities. They are not reducible to the variables used to assess them or the lines used to suggest them in logic model diagrams (Astbury & Leeuw, 2010). Interventions may trigger one or more different mechanisms. Whereas intervention activities are the 'form' of intervention (events), mechanisms are the 'function' of these interventions (the generative processes triggered by them) and outcomes are the events thus generated (Hawe et al., 2004; Lacouture et al., 2015). Realists define context in terms of the individual actor capacities and relationships, institutional setting and wider social structures which precede intervention, and which interact with the mechanisms triggered to generate outcomes (Lemire et al., 2020).

Some authors have noted confusion in the literature surrounding the distinctions between, on the one hand, intervention activities and mechanisms, and, on the other, between mechanisms and context (Barnes et al., 2003; Lemire et al., 2020). Our own view is that, while intervention activities and mechanisms are ontologically distinct (as indicated above), mechanisms and context are not ontologically distinct phenomena (contexts will include pre-existing mechanisms which may then interact with mechanisms triggered by intervention activities) but that nonetheless using these distinct terms is useful in framing propositions about how interventions work and collecting data to examine these propositions.

In traditional trials and other quantitative evaluations of complex health interventions, mechanisms are indirectly assessed via moderation (e.g. assessing if intervention effects differ for different populations) and mediation (e.g. assessing if intervention effects on outcomes are explained by their effects on intermediate measures) analyses (Gardner et al., 2006). In such studies, interventions are increasingly informed by theories of change but these are of variable sophistication and plausibility, often consisting of little more than strings of variables with no consideration of actual mechanisms or how these might interact with context to generate outcomes (Breuer et al., 2016; Moore & Evans, 2017).

In contrast, realist evaluators use context-mechanism-outcome (CMO) configurations which postulate what mechanisms might be triggered by use of intervention resources and how these mechanisms might interact with context to generate outcomes. These CMO configurations are tested and refined through iterative analyses drawing on qualitative and/or quantitative data. This approach has a number of advantages: it provides a theorisation of mechanisms which goes beyond strings of variables to explore deeper processes; it distinguishes between the reality of how mechanisms operate and the data used to examine these; and it considers how mechanisms might operate variously to generate different outcomes in different contexts. Some realist or critical realist evaluators have modified the

configurations so that these incorporate agency, or focus on how interventions and contexts interact to trigger mechanisms which generate outcomes (Porter, 2015; Lemire et al., 2020). As suggested above, we prefer to use CMO configurations to frame propositions about how mechanisms operate while recognising the importance of agency and that there is no sharp ontological distinction between context and mechanism.

A key argument of this paper is that it is important to use qualitative research to refine CMO configurations or other forms of theories of change before subjecting them to quantitative analysis. Initial theories informed by existing academic theory may be sharply at odds with how those delivering or receiving the intervention perceive interventions as working. Qualitative evidence may propose important refinements or augmentations to our theories about how mechanisms might generate outcomes. Therefore, initial CMO configurations or other theories may need to be revised in the light of analysis of data on the lived experiences of those involved in implementation and receipt (van Urk et al., 2016). There is therefore an important role for qualitative research in refining our theories about mechanisms before these are quantitatively tested (Unrau, 2001). There is also an important role for qualitative research in examining mechanisms that are too complex to be amenable to typical measurement approaches in quantitative evaluation, such as those including complex chains of causation or feedback loops (Cohn et al., 2013).

While the above arguments for qualitative research on mechanisms are widely recognised in the literature, there is little detailed guidance on conducting qualitative research on mechanisms. The Medical Research Council (MRC) frameworks for complex interventions and for process evaluation have suggested some general principles about the importance of process evaluation examining mechanisms (Moore et al., 2014; Skivingyon et al., 2021). The process evaluation framework suggests, for example, that process evaluations use mixed methods to examine mechanisms, using qualitative research to explore mechanisms that are unanticipated and/or too complex to be captured

quantitatively. However, the framework does not offer specific guidance on how qualitative data might be sampled, collected or analysed in order to do this.

A recent paper by Thirsk and Clark has argued for the importance of hermeneutics-oriented qualitative research on mechanisms (Thirsk & Clark, 2017). Thirsk and Clarke argue that a hermeneutic approach can focus on the reality of mechanisms, and not merely the subjective meanings attributed to these by participants. They also suggest that analysis of qualitative data on mechanisms can be informed by researchers' pre-understandings of a phenomenon while still leaving the research open to new findings:

> Previous experience and understanding of a topic does not prevent a researcher from being open to new understanding of the topic but is an asset that enables the researcher to be better prepared for understanding." (Thirsk & Clark, 2017) (p.5)

There have also been some useful suggestions from realist evaluators on using qualitative research to examine the mechanisms which interventions trigger (Pawson, 1996; Manzano, 2016). Pawson, for example, has offered a number of suggestions about how to structure interviews so that these can be drawn on to assess the validity of CMO configurations (Pawson, 1996). But while useful, this existing literature does not aim to offer comprehensive guidance on the different ways in which qualitative research might examine mechanisms, on how to conduct qualitative research to explore mechanisms, or on how qualitative research might inform testable hypotheses.

Drawing on examples of qualitative research conducted within a 'realist trial' to examine the mechanisms of a whole-school intervention to prevent bullying and improve student mental and physical wellbeing, we aim to reflect methodologically on: how qualitative research can contribute to

understanding mechanisms; how we should decide which participants can provide authoritative data on mechanisms and construct samples of these; how we should analyse transcripts to develop ideas about mechanisms; and how we should draw on these analyses to develop testable hypotheses. As suggested above, our aim is to make useful suggestions for conducting qualitative research on mechanisms which are informed by our own realist evaluation but which are also useful to those who subscribe to different models of evaluation.

Case study

Learning Together is a whole-school intervention that aims to enable prevention of bullying and improve student mental and physical health. It provides various intervention resources (such as manuals, curriculum materials, training) to facilitate students and staff in secondary schools enacting 'action groups' which review local survey data on student views and needs, and then decide locally appropriate actions, supported by an external facilitator. Actions can involve reviews to policies as well as changes to school management and environment. Additionally, staff are trained in using restorative practice to build strong relationships between and among staff and students, and to resolve conflicts by exploring different perspectives, identifying harms and repairing relationships. Student are also taught a social and emotional skills curriculum.

Learning Together was informed by an a priori theory of change built on the theory of human functioning and school organisation (Markham & Aveyard, 2003), as well as some initial CMO configurations which proposed how mechanisms which the interventions triggered might interact with context to generate outcomes. The theory of change proposed that student involvement in risk behaviours may be reduced by promoting student commitment to their school's 'instructional' (teaching and learning) and 'regulatory' (discipline and community) orders. This in turn requires that schools 'reframe' provision to focus on student needs and erode 'boundaries' between: staff and

students; academic and broader personal development; and the culture of the school and its local community (Markham & Aveyard, 2003). Initial CMO configurations proposed, for example, that these mechanisms would be more likely to generate beneficial outcomes for socio-economically disadvantaged students, for whom commitment to school is less likely to be the socialised norm and whom schools are more likely to engage by the above reframing and boundary-eroding mechanisms.

Learning Together was evaluated using an explicitly realist cluster-randomised controlled trial with 3-year follow across 40 English secondary schools. The overall trial analyses reported that the intervention was associated with reduced bullying victimisation, smoking, alcohol use, smoking tobacco and police involvement, and improved mental wellbeing, psychological functioning and quality of life (Bonell et al., 2018). A process evaluation quantified fidelity, reach and acceptability using observations of training, action groups and other activities, checklists completed by staff delivering the curriculum action groups and restorative practice, and staff and student questionnaires. The process evaluation also used semi-structured observations, interviews and focus groups to collect qualitative data on observed and reported processes of implementation and receipt of intervention activities, and the consequences of these for staff and students (Warren et al., 2019). The realist trial used this qualitative research to inform refinement and augmentation of the initial CMO configurations (Warren et all., 2020). These were then examined using qualitative comparative analysis (QCA) as well as moderation, mediation and moderated-mediation regression analyses (Melendez-Torres et al., 2021). Since this paper is a methodological reflection rather than an empirical report, interested readers should seek further methodological details in the above cited papers.

How qualitative research can explore mechanisms

Qualitative research can inform development, refinement or augmentation of theory relating to mechanisms. This can occur via two approaches, which are not mutually exclusive. Firstly, qualitative research can directly explore the accounts of providers, recipients and other participants about how they think interventions work. This approach in effect develops 'second-order' constructs describing causal mechanisms by interpreting and critically weighing participants' 'first-order' constructs of these (Schütz, 1962). Realist evaluators have pioneered this useful approach, usually exploring participants' views on a priori CMO configurations, to validate, refine or falsify these (Pawson, 1996; Manzano, 2016). As Pawson has argued:

[T]he researcher's theory is the subject matter of the interview, and the subject is there to confirm or falsify and, above all, to refine that theory. (Pawson, 1996) (p.299)

Pawson suggested that the interview should first 'teach' the participant about the possible theories before 'learning' from the participant which of these theories align with their experiences and how they might be refined:

The subject's task is to agree, disagree and to categorize themselves in relation to the attitudinal patterns as constructed in [the researcher's] questions but also to refine their conceptual basis. It is at this point that mutual knowledge is really achieved. The subject is saying in effect 'this is how you have depicted the potential structure of my thinking, but in my experience it happened like this… (p. 306)

In evaluating Learning Together, we used such techniques to ask participants to consider our a priori CMO configurations and articulate their own theories. For example, one student responded to such enquiries by describing how he theorised restorative practice could resolve conflicts:

I just thought [restorative practice] was a brilliant idea because it's showing the younger kids how to be mature about difficult situations and teaching them how to deal with it. And rather than just getting angry, sitting down and talking through things is a better solution. And it's just showing them that. (Focus group with year 9 students, Meadowood School)

We did not conclude that such participants' theories were straightforwardly true representations of mechanisms. Instead, we iteratively compared and contrasted such accounts with other qualitative data to help refine our CMO configurations.

In engaging in such comparisons, we often drew on qualitative data in a second, less direct way. We examined participants' accounts of their experiences of enacting intervention-related activities, the conditions within which this occurred, and what actions or other consequences flowed from these. We used this to refine our theories as to how mechanisms were triggered and how these interacted with context to generate outcomes. Any single participant might only be able to discuss the actions involve in one sub-section of a causal mechanism (Giddens, 1984; Pawson, 1996). However, as researchers, we could draw on multiple accounts, as well as our own observations, to develop a more authoritative and comprehensive understanding of mechanisms. This drawing from multiple sources to iteratively develop, augment or refine theorised mechanisms has been described in previous empirical studies (Unrau, 2001).

There may be a quasi-quantitative aspect to such work, looking for regularities in what conditions seem to be associated with accounts of certain actions or what reported consequences seem to be associated with particular actions. But the exploration should go beyond this 'black box' assessment of such regularities. Sayer, for example, has described how qualitative research should explore *exactly*

what it is about certain conditions that appear to enable particular actions to occur or what is it about certain actions that allow certain consequences to follow (Sayer, 2000).

In the case of Learning Together, multiple participant accounts were drawn on to theorise how the conditions present within action groups in some school contexts enabled staff and students to develop mutual understanding and hence better relationships. For example, one student participant described coming to understand teachers' perspectives on the group:

> I think mainly just having other people's, seeing other people's views and seeing how... if we had the same views or... hearing someone else's point of view and thinking, "Oh yeah."
> (Focus group with year 9 students, Meadowood School)

Interviews with other students highlighted how such insights encouraged students to develop stronger and more affective relationships with teachers. As one student commented:

> If you have a bond with your teacher... you want to do well for the teacher because you feel like she's paid attention to you and gave her respect [in action group meetings]. And the way you can respect her back is by working hard. (Focus group with year 8 students, St. Anselm's School)

But it was also apparent that such processes only occurred, and indeed *could only occur*, in schools in which action groups were led by senior staff. This was because only senior staff possessed the authority to ensure that action groups were well attended and well facilitated enough that empathy might develop among staff and students through their interactions on such groups. This allowed us to

begin to theorise that action groups could trigger mechanisms by which staff and students developed better relationships and mutual empathy, which in turn might engender increased student commitment to school. Reference to other accounts helped us to theorise that such mechanisms were contingent on schools' ability to ensure senior staff committed to attend action groups and that these were well facilitated so that participative and productive conversations ensued. It is important to note that no single participant proposed such an entire theory but this theory was developed indirectly from iterative in-depth exploration of multiple accounts of intervention-related actions.

In another example, interviews explored students' experiences of restorative practice sessions. One interview was with a boy who had been involved in taking a photo of another boy on the toilet. This boy described his emerging sense of responsibility in the restorative session and how the conditions present in the session enabled him to take responsibility for his actions:

> I normally would have been moaning [about being punished], saying "No"… But this time I actually felt what I had done was really wrong. It just made me realise... I mean it's... just when I saw him sitting there in that state [crying during the meeting]. (Interview with year 8 student, Harper's School)

Along with other qualitative data, such data informed refinements to our a priori CMO configurations. We theorised that restorative practice actions could trigger mechanisms involving the development of a sense of accountability among participants. Other qualitative data suggested that this might only generate reductions in bullying when a critical mass of staff were committed to delivering restorative practice and a critical mass of incidents of bullying ensured that such practices were widely deployed. Thus, qualitative data could help us refine how we theorised mechanisms in terms of individual meaning and how this interacted with intervention processes (Sayer, 2000; May, 2013).

Both approaches might be used in the same study, or even in the same interview, to explore mechanisms from different perspectives. Manzano has suggested that, in realist evaluations, initial exploratory interviews help the evaluator to articulate tentative theories of how intervention activities might trigger generative mechanisms and the contextual contingencies that might affect this. Later interviews might then aim to consider and refine these tentative theories by exploring with participants the particularities of their experiences and what light these might shed on the researcher's emerging understandings of how local conditions are implicated in mechanisms as well as the way in which implementation of interventions modified practitioner's actions and interactions (Manzano, 2016). Our own experience is that, while useful, qualitative research need not always follow such phases in order. It can also be useful for qualitative research to begin from participants' account of their actions and how these might have been modified by intervention activities before moving on to explore participants' own theories of how interventions work and how context affects this.

Sampling

As described above, qualitative research aims to examine the mechanisms triggered by enactments of interventions, the contextual contingencies involved and their consequences. This is best fulfilled by in-depth research in a manageable number of varying case studies. There should be diversity in terms of sampling different contexts and different participants involved in different intervention activities. If possible to ascertain at the sampling stage, it is also good to sample settings or individuals who report different consequences of their involvement in intervention activities. In the case of Learning Together, for example, schools were selected as case studies based on rates of eligibility for free school meals (as a measure of different school cultures and student bodies) as well as facilitator reports of the success of implementation (as a rough measure of the apparent consequences of intervention activities). It is also useful for the research to have some flexibility in its design so that, if

initial analyses of qualitative data suggest different mechanisms or different interactions with context than initially theorised, there is scope to explore these by including new cases.

Within case studies, there should similarly be purposive sampling of individual participants involved in different aspects of intervention delivery and receipt. In the case of Learning Together, for example, interviews were undertaken with school leaders as well as classroom teachers, with intervention developers as well as facilitators, and with teachers and students involved in action groups, restorative practice and the curriculum.

A key issue for sampling as well as analysis is which accounts are most useful to examine which aspects of mechanisms. Manzano has suggested that: provider managers will have the broadest overview of patterns of local successes and failures and so provide particularly authoritative information on how mechanisms are continent on context; local practitioners will be able to add information about the specific conditions which might affect mechanisms; and clients will offer detailed accounts of their personal experiences of impacts but may have less to say about mechanisms or how these interact with context (Manzano, 2016).

However, in our own study, school leaders and external facilitators often merely offered accounts focused on implementation of intervention activities rather than the consequences of these, so their accounts were less useful in exploring mechanisms. These groups also sometimes presented the 'official' theory of change and offered fewer insights into lived experience of the enactment of the curriculum or restorative practice or the actual consequences of these for preventing bullying. We found that student accounts were often more useful in exploring the mechanisms triggered through intervention-related actions and how these interacted with context to generate reductions in bullying. For example, student accounts were much more useful in exploring the consequences of participation in restorative practice.

Data collection

Observations can allow researchers to witness the actions and interactions that constitute or spin off from the enactment of interventions, which may offer insights into how outcomes might be generated. However, it is likely that observations will only shed light on the sections of mechanisms most proximal to the intervention actions triggering them rather than to the generation of outcomes. In the case of Learning Together, for example, observations provided insights into the nature of interactions within restorative practice sessions but offered fewer insights into the consequences of these. Interviews and focus groups were therefore also essential. As suggested earlier, interviews and focus groups can take a direct approach, exploring participants' views on theories of change. The direct approach will involve the researcher tightly controlling the interview process and asking questions about mechanisms. Manzano gives the following examples (Manzano, 2016):

> For example: 'How was your work different before the programme was implemented?', 'Is this new programme going to work for everyone?', 'Could you explain to me the types of people and places where you think it may be more effective?' Stronger questions about context should encourage people to compare subgroups, location, times, before and after. The objective is to draw the interviewee into comparison to explore contextual effectiveness. (p.354-5)

As discussed, interviews and focus groups can also take a less direct approach, exploring participants' accounts of actions, the meanings and goals ascribed to these actions, their conditions and consequences This approach will involve a more participant-centred interview, exploring participants' accounts of their experiences. Prompts might explore how participants' actions were influenced by:

intervention resources and other intervention-related activities; local policies or norms; or the distribution of economic, informational or other resources within a setting (May, 2013). In the case of Learning Together, for example, interviews with those participating on action groups explored how the group's activities were enabled or constrained by the intervention manual and presence of the external facilitator, the training which staff underwent, as well as the broader culture, management structure, priorities and resourcing of the school. Interviews also explored the consequences that enactment of action groups had for how school processes operated and how staff and students acted and interacted, and how this was affected by the broader context of the school.

Analysing qualitative data on mechanisms

Existing literature offers some guidance on analysis. Realists have suggested, for example, that qualitative data be coded in terms of "'description of the actual intervention', 'observed outcomes', 'context conditions' and 'underlying mechanisms'" (p. 195) to inform refinement of theory (Marchal et al., 2012). But existing literature has not aimed to offer comprehensive guidance on analysis.

Participant accounts are themselves an interpretation of their experiences of reality so that analysis of such accounts is a 'double hermeneutic' exercise (Giddens, 1984; Thirsk & Clark, 2017). As Thirsk and Clark argue, this does not mean that qualitative research cannot examine phenomena external to the participants (Thirsk & Clark, 2017), but it does mean that this is unavoidably mediated by participants' own interpretations of these phenomena. This is not a weakness of qualitative research but a strength because how participants understand an intervention will often be central to its mechanism (Thirsk & Clark, 2017). With Learning Together, for example, interviews explored how staff and students talked about the intervention. The quote below illustrates one recurring theme, that staff and students tended to emphasise its participative nature, which appeared to be associated in multiple accounts with its ability to transform relationships within a school:

I think that the students will certainly enjoy the fact that we're doing something like this so they can be involved in it and that they can actually have their voice heard, that they can feel safe at school, that they can feel engaged with the teachers, that they can feel they're listened to. (Staff, Harper's School, staff interview)

Qualitative analysis can be used to develop completely new intervention theory, where little or none previously existed for an intervention, or inform refinement or augmentation of existing theorisation. Although our intervention was informed by a priori theory of change and initial CMO configurations, we put these aside when analysing our qualitative data to inductively generate analyses of how mechanisms worked. We chose not to focus analysis of qualitative data on validating and refining our existing theory so that we could make full use of all our qualitative data and so that our qualitative analysis was not overly influenced by our starting theories.

If qualitative research is to inform theorisation of mechanisms, analysis needs to do more than identify recurring themes. Depending on the intervention in question and the frameworks informing evaluation, analysis may need to consider interactions between microsocial and macrosocial levels (Hedstrom & Swedborg, 1998) or the multiple levels of individual, group, institution and/or society (Marchal et al., 2012). Within realist evaluation, analysis will also need to engage with how mechanisms interact with context or, alternatively, how mechanisms arise from the interaction of intervention activities and context (Lemire et al., 2020) or how agency, context and mechanisms interact to generate outcomes (Porter, 2015).

In our own evaluation, we found that analytical approaches based on grounded theory were useful since these methods explicitly aim to develop theory focused on the identification of social processes

(Charmaz, 2014). We used a variant of grounded theory called dimensional analysis because this offers a framework for thinking about how social mechanisms operate with regard to their broad *context* (the boundaries of a phenomenon), *conditions* (the specific factors facilitating, blocking or otherwise shaping social action associated with a phenomenon), *process* (the actions or interactions involved in a phenomenon), *consequences* (what occurs as a result of the actions involved in a phenomenon) and *outcomes* (changes in people or groups of people as a result of the phenomenon) (Schatzman, 1991). Although this terminology differs from that used in realist evaluation, we felt that use of this approach aligned well with realist evaluation. While grounded theory methods and dimensional analysis were developed within the symbolic interactionist approach to sociology, they may be, and indeed are widely, used within other approaches (Oliver, 2011; Charmaz, 2014; Hoddy, 2018). The analytical techniques they involve, such as constant comparison, theoretical sampling and abductive reasoning, can be undertaken within other approaches, such as realist evaluation. We used dimensional analysis to analyse staff and student accounts describing or implying *process* (for example, increasing commitment to school), linked within and across interviews to accounts of *conditions* (for example, having positive experiences of participating in the action group), *consequences* (for example, decreasing involvement in anti-school peer groups) and *outcomes* (for example, reduced involvement in behaviours such as aggression).

In terms of practical procedures, analysis will need to draw on different accounts in order to develop a hermeneutic, pluralistic theorisation of mechanisms from the point at which they are triggered by intervention enactment to how they generate outcomes. For example, through qualitative analysis we developed theory as to how enactment of action groups might trigger mechanisms generating student commitment and, through this, reducing student involvement in aggression. This was pieced together from insights gathered from many different interviews, focus groups and observations. Analyses will need to compare and contrast different accounts, deciding which accounts provide more or less authoritative insights into particular sections or aspects of the mechanism. This requires axial coding which draws on an initial wave of in-vivo coding to generate cross-cutting and higher-order concepts.

As argued above, as well as theorising or refining theorisation about mechanisms by analysing participants' own theories, qualitative analyses can also explore the conditions necessary for mechanisms to 'trigger'. This can take into account quasi-quantitative analysis of patterns of contingencies but it also requires an analysis of *exactly what it is* about certain conditions that enable certain actions, or what is it about the characteristics of certain actions that enable certain consequences. Such analysis will usefully employ techniques associated with grounded theory, such as deviant case analysis. For example, some of the insights into what conditions were necessary to ensure action group actions could trigger mechanisms generating increased student commitment came from observations and interviews in a school in which the action group did not attract broad staff participation and hence failed to encourage staff and students to better understand each other's perspectives.

Informing quantitative hypotheses

Through these different approaches, qualitative research can develop, augment or refine theory of how mechanisms appear to interact with context to generate outcomes. As discussed above, we oriented our analysis of qualitative data to theorising mechanisms without limiting this to the validation or refinement of our initial theories. However, once our analyses were complete, we used the completed qualitative analysis to refine and augment our CMO configurations.

Depending on the precise form of theorisation (or in the case of realist evaluation, the components that configurations include (Porter, 2015; Lemire et al., 2020), qualitative research might inform refinement of theories about how mechanisms interact with pre-existing context to generate outcomes

(as we and most other realist evaluators conceive it) or about how mechanisms triggered by intervention activities in interaction with context generate outcomes.

However, we have to accept that any such theories, even if refined through qualitative research, might be wrong for several reasons. Firstly, analysis of participants' accounts will be limited by the extent to which these accounts are themselves fallible (Sayer, 2000). Drawing on the accounts of multiple others to develop a hermeneutic, pluralistic account will to some extent compensate for this. However, even a research account based on multiple accounts will sometimes be wrong.

Secondly, qualitative analyses drawing on patterns of regularities to consider what contingent factors appear to be important for actions or consequences to occur will inevitably be based on a relatively small number of observations and accounts of events and may therefore be subject to chance coincidences. This is particularly likely to be a problem where intervention impacts are not large (which is commonly the case in most public health interventions for example) so that it is hard for case studies to determine what factors are influential.

Thirdly, analyses of what it is about certain conditions or actions that enable certain other actions and consequences will be limited by the available data, the theories used to inform analysis and the broader conceptual hinterland of the researcher. For example, in the Learning Together evaluation, broad staff participation was identified as a key enabler of action groups being able to trigger sharing of perspectives between staff and students. This was informed by powerful evidence from a small number of cases. Other factors might have also been apparent had processes in other schools been explored.

We are arguing therefore that there is a role for correlational quantitative research in checking whether broader patterns of regularities appear to align with the theories developed or refined through qualitative research. This is a controversial area. Some realist evaluators are open to the use of quantitative alongside qualitative data to examine mechanisms (Marchal et al., 2012). Others, including some from a critical realist perspective, are critical of quantitative research examining regularities, arguing that explanation of social mechanisms cannot be reduced to a search for regularities. Andrew Sayer, for example, argues that this approach fails to appreciate that, in 'open systems', simple regularities rarely occur (Sayer, 2000):

> … events arise from the workings of mechanisms which derived from the structures of objects, and they take place within geo-historical contexts. This contrasts with approaches which treat the world as if it were no more than patterns of events, to be registered by recording punctiform data regarding 'variables' and looking for regularities among them... Given the variety and changeability of the contexts of social life, this absence of regular associations between 'causes' and 'effects' should be expected. (Sayer, 2000) (p.15-16)

While we recognise this very real risk, we do not think it is always wrong to explore regularities quantitatively. Examples of regularities identified through statistics that are informative include that: people in nations with high levels of income inequality generally experience worse health outcomes across all social classes once other confounding differences, such as gross domestic product, are accounted for (Wilkinson & Pickett, 2009); within countries, those of lower socioeconomic status experience worse health (Marmot, 2004); and schools which engage all students in learning generally have lower rates of student violence and substance use (Bonell et al., 2013).

We also note that more advanced forms of statistical analysis can be used to examine more complex forms of regularities. Examining effect modification enables an assessment of how the association of

two factors is contingent on the presence of one or more other factors, allowing for an assessment of what works for whom and where. Examining mediation enables an assessment of whether the causal association between two factors can be explained by a pathway through a third intervening factor, allowing for an insight of how an intervention might work. To the extent that variables are ontologically different from mechanisms (Falleti & Lynch, 2009), mediation analyses themselves do not 'test' mechanisms. However, they provide analytic traction in developing and refining models of intervention functioning.

Statistical research can even examine moderated mediation, which assesses whether the mediation of the causal effect of one factor on another is contingent on the presence of another factor. For example, we used moderated-mediation analyses to examine whether our refined CMO configurations aligned with broader regularities. These statistical analyses suggested that intervention beneficial effects on bullying and mental health outcomes were mediated by a quantitative measure of student sense of belonging in school - but that such mediation only occurred in a subset of schools with good baseline measures of management capacity, student belonging and low levels of bullying. In other schools, the intervention was similarly effective in reducing measures of bullying and mental distress but these effects were not mediated by increased student belonging (Melendez-Torres et al., 2021).

Hence, we believe that there is a role for quantitative research in assessing whether CMO configurations or other hypotheses that emerge from, or are refined via, qualitative research appear to explain broader regularities. The use of qualitative research to inform these hypotheses is important in ensuring that quantitative research is limited to assessing plausible hypotheses and does not merely dredge statistical data looking for spurious associations.

The hypotheses that qualitative research offers up for testing should be orientated towards a view of causation which recognises the contingency of correlations in open social systems. As already

reported, we used CMO configurations as developed by realist evaluators (Pawdon & Tilley, 1997). Qualitative analyses usually generate 'thick' descriptions and theories but these can inform the specification of more abstracted CMO configurations. These can then be tested using the various statistical analysis methods described above. Where these hypotheses are not supported by quantitative evidence, this should encourage reflection. It may be that the quantitative measures fail to capture the phenomena identified in qualitative research or that quantitative samples are insufficiently powered to identify real patterns of regularities. But it may also indicate that qualitative research has provided misleading evidence as to the mechanisms triggered in a setting or how these interact with context to generate outcomes.

As suggested earlier, some mechanisms may be too complex to subject to quantitative analysis using data collected using measurement strategies standard in evaluations. In such cases, quantitative research may be able to focus on testing some but not all aspects of mechanisms and, for other aspects, qualitative research may be as far as the analysis can be taken. Some mechanisms might in principle be open to quantitative examination but be developed at a point in an evaluation when it is too late to identify suitable quantitative measures. In such cases, these hypotheses might form the focus of future studies.

Conclusion

Qualitative research can be useful in developing, augmenting or refining theories about the generative mechanisms which interventions trigger. This might occur directly, whereby interviews and focus groups explore participants' theories of how interventions work (Pawson, 1996. Manzano, 2016). Or it might be indirect, exploring intervention activities, the conditions which enable these and the consequences of these (Sayer, 2000) to build up a picture of a mechanisms. The direct approach requires interviews or focus groups to be tightly controlled by the researcher, who asks direct

questions about participants' ideas about mechanisms (Pawson, 1996; Manzano, 2016). The indirect approach requires a more participant-centred agenda exploring experiences of intervention activities, and the conditions and consequences of these.

Analysis of qualitative data needs to focus on building or refining theory rather than merely identifying themes. We found that dimensional analysis (Schatzman, 1991) provided a useful framework for theorisation. Qualitative research might then inform more abstracted CMO configurations or other hypotheses about how mechanisms generate outcomes. Qualitative and quantitative research can together build stronger though still indirect and fallible evidence of how mechanisms might generate different outcomes in different contexts. This mixed-method approach to analysing mechanisms should help ensure that evaluation contributes to assessments of potential transferability (Burchett et al., 2020), intervention refinement (Bonell et al., 2021) and broader scientific understanding and future interventions (Davey et al., 2019).

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