Chapter 18. Using qualitative comparative analysis (QCA) to understand intervention complexity

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Key points:

- Qualitative Comparative Analysis (QCA) is a method that is increasingly applied in systematic reviews because of its suitability for examining intervention complexity.
- QCA combines processes and principles of qualitative inquiry with quantitative analytical methods and follows a well-defined sequence of six stages within a broader iterative approach.
- Unlike synthesis approaches which assume that the interventions in a review are broadly similar, QCA assumes that no two interventions are the same and that outcomes result from an interplay of intervention with its implementation and context.
- Whilst advanced meta-analyses can examine one or more factors that moderate an outcome, QCA is able to examine more complex interplays of factors, for example situations where the same factor is associated with both positive and negative outcomes, depending on context. QCA also allows for situations where the same outcome may be generated by different combinations of factors.
- QCA does not provide the causal certainty associated with some statistical methods, however, it does provide a formal and systematic way of identifying important intervention, implementation, and contextual factors.
- QCA should be considered an advanced method of synthesis because its detailed procedures will be unfamiliar to most systematic review authors.

18.1 Introduction

This chapter introduces Qualitative Comparative Analysis (QCA), and its application to systematic reviews of interventions. Because a detailed account of each QCA stage is beyond the scope of this single chapter, readers are directed throughout to further guidance on how to undertake each stage and to examples of the application of QCA in reviews. Review authors should bear in mind the following issues when considering using QCA. QCA is an advanced form of synthesis. As such, it is recommended that review authors have at least intermediate knowledge of evidence synthesis methods before undertaking QCA. QCA remains a relatively new approach in the field of systematic reviews. Therefore, it is advised that QCA is undertaken in combination with more established review methods for examining intervention effectiveness, such as synthesis with and without meta-analysis. Researchers are still learning how best to apply this method (Haesebrouck and Thomann 2021). Review authors are therefore advised to keep updated with thinking on its application in reviews.

The chapter begins by outlining key features of QCA to illustrate its suitability for understanding intervention complexity (Thomas et al 2019). This is followed by an overview of methods for reviews using QCA, including an overview of the six key stages of synthesis. The chapter concludes with practical advice about using QCA within the context of a systematic review as well as guidance on the nature of the evidence produced by a QCA and how it should be interpreted. The chapter goes onto describe the importance of stakeholder engagement and involvement, equity, diversity and inclusion and reflexivity in relation to QCA.

18.2 What is QCA?

QCA is a research method that synthesises codified qualitative and quantitative data to identify critical intervention and / or contextual elements that combine in non-additive or non-linear ways to produce a successful outcome (Ragin 1987). Developed by Charles Ragin (Rihoux and Ragin 2009), QCA was originally applied in the field of political science to explore, for example, why some countries achieved stable democracies whilst other apparently similar countries did not (Berg-Schlosser and Cronqvist 2005). More recently employed in systematic reviews, QCA can explore the reasons for variation in outcomes amongst apparently similar interventions (and, vice versa, i.e. why similar outcomes results from seemingly quite different interventional configurations) (Sutcliffe et al 2020; Thomas et al 2014).

Qualitative Comparative Analysis (QCA) has potential application in Cochrane and Campbell reviews of multi-component interventions (Thomas et al 2014). There is growing acknowledgement that multi-component health and social interventions are complex in nature (Lewin et al 2017; Skivington et al 2021; Thomas et al 2019). For example, interventions such as the school-based self-management interventions for asthma in children and adolescents described in Box 1 below, have multiple interacting intervention

components (e.g. variation in curriculum content and pedagogical style), are affected by how they are implemented (e.g. variation in whether parents are involved, and whether sessions occur during or after school) and the context in which they are implemented (e.g. the age of children involved, the size of the school in which they are delivered) (Harris et al 2019). The complexity of such interventions and contexts means that replication of a specific combination of intervention, implementation and contextual factors is highly unlikely. Aggregative synthesis approaches that assume replication are therefore less suitable for synthesising evidence on this type of intervention (Thomas et al 2014).

As illustrated in Box 1, a Cochrane review revealed key intervention and contextual factors that distinguished between successful and unsuccessful implementation of school-based asthma interventions. As such, QCA can help to reveal the critical features of successful multi-component interventions, and their interaction with context and implementation factors, to support adaptive application of their findings in practice (Glasziou et al 2014).

Box 1: Example Cochrane Review using QCA

Review: Harris et al. (2019) School-based self-management interventions for asthma in children and adolescents: a mixed methods systematic review

Review objectives:

- 1. To identify the intervention features aligned with successful intervention implementation.
- 2. To assess the effectiveness of school-based interventions for improving asthma selfmanagement among children.

Methods:

- 1. To address objective 1, QCA was used to identify the combinations of intervention components and processes that are aligned with successful intervention implementation.
- 2. To address objective 2, meta-analysis was used to examine effectiveness and separate models and sub-groups were used to explore the link between intervention implementation and effectiveness. Sub-group analyses were guided by the findings from objective 1.
- **Key findings:** QCA of 33 process evaluations showed that the more successfully implemented interventions were those which were guided by a theoretical framework, engaged parents and run outside of children's free time. Meta-analysis of 33 RCTs showed that school-based self-management interventions improved rates of hospitalisation emergency department visits, and health-related quality of life. Sub-group analyses informed by the QCA findings were generally uninformative, but one showed that interventions that were theory-based achieved significantly better outcomes with respect to reducing school absences than interventions that were not. This corresponded with the results of the QCA where all the combinations of factors leading to successful implementation included an intervention being theory-based.

18.3 Key features of QCA and its suitability for understanding intervention complexity

Several key features of QCA lend it to examining intervention complexity within systematic reviews.

18.3.1 Integrates features of qualitative and quantitative research

On the one hand, QCA is a 'case-oriented' approach, which requires an in-depth and holistic knowledge of individual cases (or studies – see Box 2): a key strength of qualitative analysis. But on the other hand, it involves systematic comparison to identify generalisable cross-case patterns in the data which is a key strength of quantitative analysis. Thus, while QCA shares many perspectives and principles with qualitative research, it is not a purely qualitative method. Ragin describes the goal of QCA as to 'integrate the best features of the case-oriented approach with the best features of the variable-oriented approach', transcending the divide between qualitative and quantitative data and analysis (Ragin 1987).

18.3.2 Assumes outcomes result from a complex interplay of multiple intervention and contextual conditions

The 'variable oriented' approach used in statistical meta-analysis emphasises identification of the 'net effect' of each independent variable (referred to as conditions in QCA – see Box 2) on the dependent variable (Rihoux 2020). By contrast, the case-oriented approach of QCA assumes that multiple intervention and contextual conditions combine in nonlinear and potentially emergent ways to reach an outcome (this combination is described as a configuration in QCA – see Box 2) (Rihoux 2020). By focusing on configurations rather than individual conditions, QCA is able to accommodate and explore the dynamic interplay of conditions that characterises complex interventions. Box 2 below clarifies some of the terms used in QCA and throughout this chapter and Figure 1 illustrates the concepts of conditions and configurations.

Box 2: Key terminology used in QCA

Case: A case refers to 'A well-defined real subject with boundaries, description and characteristics defined for study purposes.' (Chandler 2020) In systematic reviews a 'case' typically refers to a single intervention study in a review (or distinct intervention arm that is synthesised separately), with the 'description and characteristics' of both the intervention and the context important for analysis.

Conditions: '*A* [single] factor implied to connect a cause to an effect (outcome).' (Chandler 2020) Within systematic reviews a 'condition' typically refers to a single intervention component or contextual feature.

Configuration: A combination of conditions or factors. In systematic reviews this is often seen as the *'intervention, participant, and contextual characteristics that together are responsible for the intervention resulting, or not resulting, in the outcome of interest'*. (Thomas et al 2014) See Figure 1.

Truth table: The principal analytical device in QCA that presents all possible logical configurations of the selected conditions, how many cases (if any) cover those condition combinations, and their association with successful or unsuccessful outcomes (see example in box 6).

Logical remainder: Logically possible configurations of conditions for which there are no cases in the data set.



Figure 1: Conditions and configurations

QCA is based on an assumption of causal complexity in real systems. The key tenets of causal complexity are outlined in Box 3. QCA therefore reflects recent interest by systematic review authors in understanding intervention complexity – the number of intervention

components, how these components interact and are interdependent on each other, and how these components interact with the wider system in which they are deployed (7).

Box 3: Key tenets of causal complexity

Causal complexity: Defined as comprising the states of:-

- **Conjunctural causation:** Multiple factors or conditions come together to bring about an effect; they are seen as interdependent and complementary.
- **Equifinal causation**: There is not necessarily a single set of conditions that obtain the outcome. The same outcome may result from several different configurations of conditions.
- **Asymmetric causation:** Causal conditions that obtain an outcome do not mirror those conditions not obtaining the outcome. '*That specific factors explain success does not imply that their absence leads to failure.*' (Hanckel et al 2021)

18.3.3 Analysis is based on set relationships

QCA employs a configurative approach which 'engages and exploits' the heterogeneity associated with intervention complexity in order to identify configurations of intervention and contextual conditions most aligned with successful interventions (Chandler 2020). Analyses are based on set relationships (see Box 4 for an overview) with studies belonging to condition sets and outcome sets (Ragin n.d.). The characteristics of sets of cases with distinct outcomes are examined. For example, based on the outcome, a set of effective interventions is compared with a set of ineffective interventions. QCA seeks to identify the degree of overlap between these outcome sets and sets of cases with similar intervention components and contextual features (condition sets). Core causal concepts underpinning set relationships are the arrangements of sufficient and necessary conditions (see Box 4) (Chandler 2020); that is some conditions are seen as necessary for an outcome to occur whilst others are sufficient.

Box 4: Overview of set relationships

Set relationships: A set is a collection of 'things' with something in common; essentially a category. In QCA set relationships are used to examine cases belonging to a particular condition set (i.e. cases with a particular condition or configuration of conditions in common) and to a particular outcome set (i.e. cases with a successful or unsuccessful outcome in common), see Figure 1. The Truth Table (see Box 2) analysis examines the intersection or overlap between condition and outcome sets to identify whether a condition or configuration of conditions is necessary and / or sufficient for the outcome.

- **Necessary condition**: A condition that is essential for generating an outcome. The outcome does not occur in the absence of that condition.
- **Sufficient condition**: A condition that is enough to generate an outcome, but the outcome might also be generated by alternative conditions. The outcome occurs whenever a sufficient condition is present, but the condition is not present in every instance of the outcome.

Using the example of virus transmission, Figure 2 illustrates the relationship between necessary and sufficient conditions; it depicts the conditions (in green) that lead to the outcome of infection with a virus (in blue). The left-hand diagram illustrates how exposure to the virus is a necessary condition for the outcome of infection. Although not everyone exposed to the virus will become infected, without being exposed an individual cannot be infected; those infected (outcome) are a subset of all those exposed (condition).

The right-hand diagram illustrates that being exposed to someone in the same household with the virus is a sufficient condition for acquiring an infection. Transmission within households is a common way that viruses spread; but transmission can occur in other contexts, such as at school or work. Not everyone in the population who becomes infected will acquire it from someone within their household; household transmission (condition) is a subset of all infections (outcome). Identification of the necessary and sufficient intervention and / or contextual conditions that lead to successful intervention outcomes generates useful information to support policy and practice decision-making. See Box 5 for an example of consideration of necessary and sufficient conditions within a review.



Figure 2: illustration of necessary and sufficient conditions

18.3.4. Provides systematic explanatory knowledge

Other chapters such as 10 (Thematic synthesis) and 11 (Meta ethnography) describe qualitative synthesis methods which use an inductive approach to generate theory based on observations. Systematic reviews of intervention effectiveness, particularly those employing meta-analysis, use a deductive approach to test and verify pre-specified theoretical assumptions. QCA is an abductive approach in that it starts by identifying outcomes and works backwards to identify the simplest most likely explanation. This abductive approach is much like a clinician observing a patient's symptoms to diagnose a disease. QCA provides this explanation by conducting systematic cross study comparisons, maintaining the study context and intervention complexity in this understanding. As such QCA offers explanatory knowledge, not prediction. It offers a plausible explanation of causation but is not able to provide confirmatory evidence as provided by experimental designs. Whilst abductive approaches are generally susceptible to data dredging and spurious findings, QCA protects against this by requiring that patterns of association are observed consistently (see section 18.7.3) and that the analysis is underpinned by existing theory (see section 18.5.4). Whilst QCA may not hold the certainty associated with deductive methods, it is a formal and systematic way of exploring study findings in relation to contexts, participants and intervention components that otherwise can be done informally and unsystematically by decision-makers.

18.3.5 Copes with a relatively small number of studies

Though not exclusively used with limited numbers of cases, one advantage of QCA for examining intervention complexity in systematic reviews is that it is well suited to complex analyses with a relatively small number of studies or cases (Rubinson et al 2019; Rutten 2020). Statistical methods such as meta-regression draw strength from having many studies and a relatively small number of variables. Guidance for undertaking simple meta-regression analyses typically specifies that at least ten studies should be available for each characteristic modelled (Deeks et al 2019). However, given that typical systematic reviews rarely contain tens of studies, and given the complexity of multi-component interventions, the number of characteristics that might plausibly be responsible for variation in outcomes often exceeds the number of studies in the review, greatly limiting the application of meta-regression.

As noted above, QCA was developed in the field of political science to compare outcomes at the country level, and so by definition, in situations with a restricted number of relevant cases. The key analytical tool used in QCA, Set Theory (see Box 4), was therefore specifically selected to analyse complex causality in situations with a restricted number of cases (Rihoux 2020). As such QCA is suited to the typical situation found in systematic reviews; a relatively small number of cases (studies). Kahwati and Kane (2020) note that whilst QCA is unlikely to be useful in reviews with fewer than ten studies, since a general rule is to have a ratio of three to four cases for every condition examined, reviews with ten or more cases permit an analysis of three conditions (Kahwati and Kane 2020). See also Marx and Dusa (2011) for simulations of acceptable case : condition ratios (Marx and Dusa 2011).

Moreover, the QCA approach is not only designed to cope with 'small n' scenarios, the caseoriented approach, which is dependent on a deep and holistic understanding of the cases under study, is seen as a cornerstone of QCA (Rutten 2020); a key threat to the analysis would be having 'too many cases for researchers to keep all the case knowledge "in their heads" (Ragin). It should be noted, that for 'large n' scenarios QCA can be applied using a condition-orientated approach (Thomann and Maggetti 2017).

18.4 Formulation of the review

The formulation of reviews using QCA differs from other types of systematic review. Below three key features of reviews using QCA that distinguish them from other types of review are outlined. Also considered is how stakeholder engagement may be particularly valuable for reviews using QCA and the particular contribution that QCA can make to considering equity, diversity and inclusion in reviews (see section 18.11 below).

18.4.1 Use of configural questions

The questions addressed by reviews using QCA differ from those asked in reviews of effectiveness. Whilst effectiveness review questions may vary in their breadth (e.g. asking questions about a broad range of interventions or a single intervention type) they typically take the format:

'What are the **effects** of *[intervention or comparison]* for *[health problem]* in [types of people, disease or problem and setting if specified]'? (Thomas et al 2019)

By contrast questions addressed in systematic reviews using QCA are configural, that is they seek to identify the combinations of conditions that produce an outcome (Kahwati et al 2016) and typically take the format

'What **combinations** of [intervention and/or contextual conditions] are found among [cases – i.e. studies] that demonstrate [outcome]? (Chandler et al 2017)

18.4.2 Use with other synthesis methods

In line with recommendations not to use QCA as the sole method of analysis, primarily because of its abductive nature, (Wagemann and Schneider 2010) QCA is typically used in systematic reviews in combination with other methods of synthesis for examining intervention effectiveness i.e. synthesis without metaanalysis or meta-analysis. The variation arises from the sequence in which QCA is used in combination with other synthesis methods, as illustrated in Figure 3 below (Sutcliffe et al 2020).

Figure 3: Variation in sequencing of QCA with other synthesis methods



One approach (illustrated in the left half of Figure 3) involves using QCA as the first analysis method in order to drive a subsequent meta-analytic or narrative investigation of intervention heterogeneity. Review teams using this approach seek to provide a sound basis for theoretically informed sub-group analysis.

In the other approach (illustrated in the right half of Figure 3) QCA is used as the second analysis method. In this approach QCA is employed after a synthesis without meta-analysis or meta-analysis to unpack and explain observed heterogeneity. The majority of reviews that have used QCA have employed this

second approach (Sutcliffe et al 2020); a synopsis of such a review is provided in Box 5 below.

Box 5: Example of a review using QCA to explain heterogeneity observed in a metaanalysis

Review: Melendez-Torres et al. (2018) Weight management programmes: Re-analysis of a systematic review to identify pathways to effectiveness

Objectives:

- 1. To understand which weight management programme features are perceived by service users and providers as key to successful weight loss.
- 2. To test whether features perceived to be important are associated with greater weight loss.

Methods:

- 1. To address objective 1, Qualitative Evidence Synthesis (QES) was used to synthesise evidence on the views of people in the UK who had used or delivered weight management programmes.
- 2. To address objective 2, the 10 most effective and 10 least effective interventions among 40 RCTs included in a previous meta-analysis were selected and compared. QCA was used to examine the presence or absence features identified as important in the QES in the selected interventions.
- **Key findings:** The ten most successful weight management programmes concurred with key QES findings which were characterised by: a) supportive relationships with programme providers combined with activities that foster self-regulation and b) a high level of direction from providers.

Supportive provider relationships were identified as a necessary condition for successful outcomes. Supportive provider relationships were present in all most effective interventions, and those interventions in which this condition was absent were all least effective. However, supportive relationships did not appear to be sufficient for generating the most successful outcomes. Interventions also need to include a mechanism for encouraging self-regulation, either via direct provision of exercise or via an intentionally graduated reduction in support after an initial more intensive period.

18.4.3 Analysis is underpinned by theoretical knowledge

A further key feature of the formulation of reviews using QCA is that, in line with all QCA studies, existing theoretical explanations are used to 'ground' or 'underpin' the analysis and findings (Kneale et al In Press) such that QCA is informed by "an ongoing dialogue between case-oriented knowledge and theoretical knowledge" p.16 (Rihoux and Ragin 2009). The abductive nature of the QCA, as described in 18.3.4, means a theory-driven approach is essential both to structure the analysis and to avoid data dredging (Melendez-Torres et al 2019). Theory may be drawn from a range of sources (see section 18.5.4) but is typically at the level of 'mid-range' or 'programme' theory (Berg-Schlosser et al 2009). As Berg-Schlosser et al. note, theory plays an important role at crucial stages throughout the QCA process. They describe how theory is useful, "upstream," for helping to identify conditions to be included in the model and for operationalising them, for example in terms

of specifying thresholds. They also note that during the analysis, theoretical knowledge, as well as a deep knowledge of the empirical field, is essential for helping researchers make decisions regarding several practical QCA operations. Lastly, they describe a "downstream," use of theory when interpreting the findings.' (Berg-Schlosser et al 2009)

18.4.4 Analysis is iterative

Although QCA follows a well-defined sequence of six stages (detailed in Figure 4 and section 18.7) a key characteristic of the work is its iterative nature. As with QES, an evolving understanding of the issues during the synthesis stage, may indicate to review authors that their initial specification of conditions needs amending, or that further cases with particular features may be important for the analysis. Figure 4 illustrates how earlier and later stages of the work can inform each other.

Figure 4: Iterative nature of the analysis



Figure 4 Reproduced and adapted with permission from Kahwati and Kane 2020

18.5 Identification of evidence

Like guidance for effectiveness reviews (McKenzie et al 2019), QCA guidance (Rihoux and Ragin 2009) recommends that cases are similar enough for a meaningful answer to be obtained when considered together. QCA guidance also recommends that explicit and detailed rationale for the selection (or non-selection) of cases is provided (Wagemann and Schneider 2010), which mirrors the use of explicit inclusion criteria in systematic reviews (Kahwati et al 2016).

To ensure 'maximum of heterogeneity over a minimum number of cases' (Kahwati and Kane 2020; Rihoux and Ragin 2009) QCA guidance is similar to guidance for study identification for QES (see chapters 5 and 6) in that it recommends 'purposive' selection of cases. In practice, systematic reviews using QCA tend to blend these approaches; combining an exhaustive systematic search for studies, followed, if necessary, by purposive selection within the comprehensive set of studies to obtain an optimum data set for QCA.

Below some distinctive features of study identification for reviews using QCA are outlined.

18.5.1 Seeking heterogeneity

In the case of meta-analysis, where very high levels of heterogeneity are encountered, and particularly where there is variation in the direction of the effect, this could lead to a decision that a meta-analysis may be unsuitable or misleading. In the case of QCA, such variation in outcomes, particularly in the direction of the effect, can be the very focus of the analysis. Statistical synthesis needs to assume homogeneity between interventions and participants for the purpose of comparison. Whereas QCA assumes heterogeneity is a key aspect of the real world and that outcomes can be achieved by a combination of multiple factors and QCA findings are beneficial in that respect [5].

18.5.2 Seeking a 'minimum' number of cases

Whilst effectiveness reviews draw strength from having a large of number studies, in QCA the inclusion of the 'minimum' number of cases possible for analysis is recommended to support deep case knowledge whilst allowing sufficient diversity. No clear guidance exists on how many cases will be adequate and how many would be 'too many' (Kneale et al In Press). Some suggest that QCA is most suited to an 'intermediate N analysis' which is described as between 10 and 40 cases (Berg-Schlosser and De Meur 2009). The findings of a recent systematic review of 26 QCA studies (including 9 systematic reviews) of public health interventions are consistent with this; the vast majority of included studies (n=22) analysed a 'medium' number of cases (defined in the review as being in the range 10–50)(Hanckel et al 2021). CARU-QCA (Critical Appraisal for Reviews Using QCA) encourages review authors to critically assess the number of cases in their analysis (Kneale et al In Press). Others suggest that the number of cases that can be managed in an analysis, depends upon whether sufficient familiarity (empirical "intimacy") can be gained with each case (Berg-Schlosser and De Meur 2009). The optimum number of cases, however, is also dependent on the number of conditions to be examined, see section 18.7.2 for further consideration of this.

18.5.3 Purposive selection of cases

The recommendation in QCA guidance to 'purposively' select cases contrasts with guidance that effectiveness reviews should employ a comprehensive or 'exhaustive' approach to searching to minimize bias (Lefebvre et al 2019). However, the aim of QCA is not to produce an unbiased pooled estimate of effect along with its precision, rather it is to understand what drives intervention effectiveness (or lack of). Nevertheless, because typical effectiveness reviews that use exhaustive searching tend to be characterised by the inclusion of an intermediate number of studies and by variation in outcomes (Schneider and Wagemann 2012), they often produce an ideal scenario for conducting a QCA.

However, within some systematic reviews an element of 'purposiveness' may be useful, especially for larger reviews, to drive a 'maximum of heterogeneity over a minimum number of cases' scenario, thereby 'preparing the ground for efficient analyses' p.3 (De Meur and Gottcheiner 2009). The MDSO–MSDO (most different cases, similar outcome/most similar cases, different outcome) is an approach to address the issue of how to find cases that will transmit the most information through their comparisons (De Meur and Gottcheiner 2009). The MSDO (most similar cases, different outcome) has been successfully employed in QCA reviews, such as the review described in Box 5, to include only the most and least effective cases in the analysis, and exclude the moderately effective ones (Melendez-Torres et al 2018). This approach may enhance the ability to detect critical intervention and contextual features both by reducing the number of included cases and so supporting deep case knowledge and by filtering out the 'noise' of moderately effective cases that could obscure differences between the most effective and least effective cases (Melendez-Torres et al 2018).

18.5.4 Seeking theory to inform, structure and ground the analysis

In addition to identifying cases to analyse, review authors also need to seek theory papers to support the analysis (see section 18.4.3). Identification of relevant theory papers is likely to be non-systematic, but may also draw on approaches such as realist and framework synthesis to identify and explore theoretical papers (see Chapters 3 Role of Theory, 9 Framework Synthesis and 16 Realist Synthesis)

An alternative to seeking papers reporting existing mid-range or programme theories, is to develop theoretical insights through a logic model (Chapter 4) or through a QES (See Box 5 for an example) in which evidence is synthesised from both sibling studies (qualitative studies directly associated with an RCT) and non-sibling studies (qualitative studies on the same topic but not directly associated with an RCT) or process evaluations (Candy et al 2013; Melendez-Torres et al 2019). This approach offers the potential for very specific insights about the interplay of intervention and contextual features within the intervention or phenomenon under study (Sutcliffe et al 2018). Similarly, Intervention Component Analysis (ICA) has been used by review teams to gather insights reported by the authors of intervention studies about important intervention and contextual conditions (Sutcliffe et al 2022) and as noted below engagement with stakeholders may also provide important theoretical insights.

18.6 Appraisal of evidence

Appraising the evidence for a QCA has both similarities and differences with evidence appraisal for effectiveness reviews.

18.6.1 Assessing and interpreting risk-of-bias

Since QCA seeks to identify the features of successful interventions, the conclusions depend on the results of the included cases (studies) being unbiased. Just as with a meta-analysis of effectiveness studies, if the results of individual studies included in a QCA are biased, then the analysis could produce a misleading conclusion. Review teams using QCA should use standard procedures and tools for assessing the risk of bias of randomized controlled trials (Sterne et al 2019) and non-randomized controlled trials (Sterne et al 2016) and systematically take into account risk-of-bias in results of included studies when interpreting the results of their QCA (Boutron et al 2019). For example, if the treatment effect estimate is biased, assignment to outcome sets may be inaccurate.

There are several strategies that may be appropriate for handling studies found to be at risk-of-bias at the analysis stage. These include restricting analyses to studies at low risk-of-bias, conducting a sensitivity analysis to assess whether studies at high risk-of-bias appear to affect QCA results, or be explicit that confidence is reduced in QCA findings largely or exclusively supported by studies at high risk-of-bias [26].

18.6.2 Assessing and interpreting intervention and contextual descriptions

In addition to assessing the methodological risk-of-bias, review authors should consider the contribution to theory development offered by each case. As Hanckel et al. note, QCA is only feasible when the investigators have sufficiently in-depth understanding of the cases in the analysis to make sense of connections between conditions (Hanckel et al 2021). An individual case may be considered to be at low risk-of-bias but in order for it to be of maximum utility in a QCA it must also provide a strong description of the intervention components as well as implementation and contextual features. Poor reporting of interventions has long been recognised as a challenge for reviews (Hoffmann et al 2013) but review authors using QCA have found poor intervention reporting to be a particular challenge (Candy et al 2013; Kahwati et al 2016; Parrott et al 2018; Thomas et al 2014). To aid their understanding of a case, review authors may seek out other published papers reporting on the same case such as process evaluations or sibling qualitative studies, or they may contact authors for further details. If this is unsuccessful or impractical, review authors may either exclude cases with insufficient descriptions or they may adapt the QCA approach to cope with poorly reported cases. For example, in a review using QCA to examine implementation factors associated with successful influenza vaccination drives among healthcare workers, several of the included cases were 'letters to the editor' rather than full journal manuscripts. The review authors found that although these cases showed successful outcomes, they did not report the presence of intervention features that had been identified in successful cases reported in longer journal manuscripts. The review authors assumed that in the shorter letter reports, because of word-length constraints, some intervention features may have gone unreported. Thus the analysis involved a

condition to allow those cases reported in letters some leeway in the analysis (Sutcliffe et al 2022).

18.7 Synthesis of evidence

QCA guidance outlines six key stages of analysis (Thomas et al 2014). Below the purpose, procedures and important considerations for each key stage are outlined. These are summarised in Table 1.

Table 1: Summary of six key stages of QCA

Stage	Name	Details
1	Building the data table	A data table or 'matrix' is constructed in which each case is represented in a row, and columns are used to represent the conditions.
2	Constructing the truth tables	The truth table is the key analytic device in QCA, it summarises how many cases with a particular configuration of conditions are instances of an outcome.
3	Resolving contradictory configurations	Where multiple cases have an identical configuration of conditions but differ with respect to their outcomes this is known as a contradictory configuration. Review authors use case knowledge and theory to identify an explanation for such a contradiction.
4	Boolean minimisation	Boolean minimisation, which is based on mathematical principles of set theory, is used to develop the solution.
5	Consideration of logical remainders	Consideration of logical remainders, potential configurations not observed in any cases, may be used to simplify the solution.
6	Interpretation of the solution	Review teams interpret the solution in terms of consistency and coverage, and in terms of its coherence with the theory and cases.

18.7.1 Stage 1: Building the Data Table

In the first stage of analysis, a matrix is constructed in which each case is represented in a row. Columns are used to represent the conditions (intervention components and / or contextual features) that are present or absent in each case and whether the outcome of interest is present or absent in each case.

Purpose

The purpose of this stage is to capture and code information about whether key conditions are present or absent in each case. In its creation, the Data Table also supports the development of familiarity with the cases, and enables review authors to identify emerging patterns of configurations.

Procedures

Calibrating condition and outcome sets

To produce the Data Table, key aspects of the work include a) setting rules around outcome sets – i.e. rules to assign cases to the 'most effective' or the 'least effective' sets (or partial membership values) and b) identifying potentially important conditions and setting rules around condition sets – i.e. determining how to code the presence or absence of each

condition. This work is referred to as set calibration, and once the rules for calibration have been determined a numeric value between 0 and 1 is assigned. This numeric value is known as a set membership value (SMV).

There are two principal approaches for assigning SMVs within QCA and review authors will need to decide fairly early on within the analysis whether to use a 'crisp-set' or a 'fuzzy-set' approach Crisp-set QCA examines conditions and outcomes as binaries – as present or absent. That is, cases can be categorised either as being a member of a set of cases which all share a particular feature or condition, or as a member of set of cases without that feature or condition. In relation to outcome sets, in crisp-set QCA cases would all be members of either a successful outcome set or an unsuccessful outcome set. Fuzzy-set QCA allows for a more nuanced analysis; cases can be categorised as being full or partial members of condition and / or outcome sets (see Section 18.7.4). Fuzzy-set QCA was developed to reflect the ambiguities of the social world better (Ragin 2008).

Neither approach is advocated over the other, and there are advantages and limitations to each. Whilst fuzzy-set QCA may better reflect the complexities of the social world, crisp-set QCA may provide a more interpretable and unambiguous solution. Review teams will need to consider which approach best reflects their needs and the cases under study.

Assigning set membership

With crisp-set QCA, 1's are used to represent the presence of a given condition and 0's are used to represent its absence. Similarly, this binary approach is used to indicate the outcome, for example a 1 would indicate a case in the set of most effective interventions, and a 0 would indicate a case not in the set of most effective interventions. Assignment to outcome sets should be based on defensible 'rules' for allocation, for example based on the direction of effect or a clinically significant or meaningful effect size threshold. A statistically significant result may be clinically insignificant and so statistical significance alone should not be assumed to indicate an 'effective' outcome (Thomas et al 2014). A portion of an example crisp-set Data Table (taken from the review on weight management programmes described in Box 5 (Melendez-Torres et al 2018)) is provided Figure 5 below. In Figure 5 the top 10 rows with a 1 in the column for 'most effective' denote the cases in the most effective set (SMV =1), those with a 0 are the cases in the least effective set (SMV =0). The column labelled 'practical info' denotes a condition in which practical information about dietary intake is provided as part of the intervention. The following columns indicate other intervention or contextual features identified as potentially important in a QES. The 1's and 0's are the condition set SMVs and indicate the presence or absence of each of these conditions in each of the cases.

As described in section 18.7.4, partial membership of a set is supported using 'fuzzy sets'. With fuzzy-set calibration, numerical descriptors between 1 and 0 are used, e.g. in addition to 1 indicating full set membership, and 0 indicating non-set membership, values such as 0.67 (indicating that a case is more in than out of the set) and 0.33 (indicating that a case is more out than in a set) can be applied. Where there is insufficient information to determine set membership, some recommend that a value of 0.5 is given to indicate the point of greatest ambiguity between whether the object is in or out of the set, and effectively represents missing data (Chandler 2020). However, because of poor reporting of intervention features and contexts, systematic reviews using QCA typically assume that where an intervention process or component is unreported, it is absent from the intervention and assign a membership score of '0', rather than assigning 0.5 to indicate missing data (Sutcliffe et al 2022). These options allow for four or five (or more) assignment options (e.g. 1, 0.67, 0.5, 0.33, 0) as opposed to the binary of crisp sets.

							Physical
		Diet advice		Diet monitoring		activity	
	Most		De-	Visual	Diet	Diet	Direct
	effectiv	Practic	emphasi	demo	monitorin	monitorin	provision
Cases	е	al info	s 'diet'	S	g 'easy'	gʻother'	exercise
Bertz 2012	1	1	0	1	0	1	1
DPP 2002	1	1	0	0	1	0	1
Foster-Schubert	1	0	0	0	0	1	1
2012	1	0					T
Kuller 2012	1	1	0	0	0	1	0
Rejeski 2011	1	1	0	1	0	1	1
Rock 2010 (CB)	1	1	0	0	0	0	0
Rock 2010 (TB)	1	1	0	0	0	0	0
Villareal 2011	1	0	0	0	0	1	1
Vissers 2010 (fitness)	1	0	0	0	0	0	1
Vissers 2010	1	0	0	0	0	0	1
(vibration)	÷	Ŭ	Ŭ	0	Ű	Ŭ	-
Eriksson 2009	0	1	0	0	0	0	1
Hersey 2012 (2)	0	0	0	0	0	1	0
Hersey 2012 (3)	0	0	0	0	0	1	0
Jolly 2011 (GP)	0	1	0	1	0	1	0
Jolly 2011	0	1	0	1	0	1	0
(pharmacist)	Ŭ	-	Ŭ	-	0	-	Ũ
Jolly 2011 (SW)	0	1	0	1	0	1	0
Munsch 2003 (clinic)	0	0	0	0	0	1	0
Nanchahal 2011	0	1	0	0	0	1	0
Patrick 2011	0	1	0	0	1	0	0
Vermunt 2011	0	1	0	0	0	1	0

Figure 5: Example of a crisp set Data Table

Considerations

The selection and definition of outcomes and conditions requires iteration but must be underpinned both by case knowledge and existing theory (Wagemann and Schneider 2010). Once the Data Table has been constructed review authors should check for gaps and errors in the table. Since successful analysis requires a good representation of individual conditions, review authors should check whether each condition is well represented. If a condition is present in only a very few cases then review authors should consider whether it requires re-definition or removal. Another check is for collinear conditions (conditions which always co-occur). Review authors should consider whether it is appropriate to collapse any co-occurring conditions into a single condition. Once checks are complete, review authors should develop an analytical plan informed by theory and case knowledge. If there are many relevant conditions that could be analysed, review authors should consider whether several separate analyses would be appropriate, and which conditions should be assessed in each analysis; for example using the two-step approach proposed by Schneider and Wagemann (Schneider and Wagemann 2006).

18.7.2 Stage 2: Constructing the truth table

Once relevant conditions have been selected, the second stage of QCA involves another type of matrix known as a Truth Table (See Box 2). The Truth Table differs from the Data Table in that rather than listing each individual case with their details, it lists each possible configuration of the selected conditions and the sets of cases associated with each configuration. The Data Table is considered a representation of the 'raw data' and the Truth Table as 'an aggregated form of the raw data' (Wagemann and Schneider 2010).

Purpose

By grouping cases with a particular configuration the Truth Table provides the framework for assessing consistency of association between configurations and outcomes (Ragin 2008).

Procedures

A Truth Table can be produced manually, but they are generally produced using a specialist QCA software package. See section 18.8.2 for guidance on available software.

Each Truth Table row denotes one possible configuration of conditions, how many cases were instances of that configuration and the consistency between that configuration and the outcome (Ragin 2008). For example, if two conditions are examined in the analysis, four configurations are possible and each would be represented in a separate row of a four row Truth Table. The greater the number of conditions in the analysis, the greater the number of rows in the table since the number of logically possible configurations is increased. An analysis with three conditions would have eight possible configurations (2³), with four conditions the number of configurations is 16 (2⁴) and so on.

The initial columns in the Truth Table indicate the conditions in a given configuration. As with the data table the absence of a condition is denoted by a 0 and its presence by a 1. The consistency score which indicates the proportion of cases with that specific configuration that are associated with the outcome of interest is also displayed. A score of 1 or close to 1 indicates high consistency and that the cases in the row are associated with successful outcomes. A score of 0 or close to 0 also indicates high consistency – in that that most or all of the cases do not display successful outcomes. In crisp-set QCA a score other than 1 indicates that some cases within that configuration are contradictory with regards to their association with outcomes – that some cases with that configuration are associated with successful outcomes whilst others are not (see section 18.7.3 for guidance on resolving

contradictory configurations). For further information on fuzzy set contradictions see Schneider and Wagemann (2012) and Rubinson (2013) (Rubinson 2013; Schneider and Wagemann 2012).

A portion of the Truth Table from the review on school-based self-management interventions for asthma in children and adolescents by Harris et al. [35] is depicted in Box 6 to show the columns in the output of Truth Table analysis. This partial table indicates just the first four of the 32 possible configurations. The full Truth Table would have a further 28 rows including both those with cases supporting them and 'empty' rows signifying the logical remainders where no cases were observed with that configuration (see Box 2).

Truth t	Truth table for QCA model 6 - consolidated model									
High school	Child satisfaction	Theory driven	Intervention takes place during students' own free time	Good relationships/ engagement with parents	Outcome code (based on consistency score)	Number of studies with membership in causal combination > 0.5	Consistency score with subset relationship (n = 27 in each assessment)	Proportional reduction in inconsistency	Cases	
1	1	1	0	0	1	2	1	1	<u>Al-Sheyab</u> <u>2012; Berg</u> <u>2004</u>	
1	0	1	1	1	1	1	1	1	<u>Joseph 2013</u>	
1	1	1	0	1	1	1	1	1	<u>Bruzzese</u> 2008	
1	0	1	0	0	1	2	0.924	0.841	<u>Bruzzese</u> <u>2011</u> ; <u>Joseph</u> <u>2010</u>	

Box 6: Example of a Truth Table

Box 6 – image reused with permission from Harris et al. 2019

Considerations

The selection of conditions to examine in a configuration should be guided by theory and case knowledge. Given the complexities of multi-component interventions the number of possibly important conditions may be very large. However, given that the number of possible configurations increases rapidly with each additional condition, it is important to balance the number of conditions assessed in the Truth Table with the number of available cases (Berg-Schlosser and De Meur 2009).

One consequence of having too many conditions for the number of cases is limited diversity, or the risk that the analysis will form an individual explanation for each individual case (Berg-Schlosser and De Meur 2009). If each configuration in a Truth Table is only supported by a single case, the analysis is unable to offer insight regarding the replication of patterns across cases or the relevance or importance of different configurations (Kneale et al In Press). Another problem of limited diversity is that if the number of possible configurations outnumbers the cases under study there will inevitably be configurations

which are unobserved (logical remainders – see Box 2). The proportion of unobserved configurations will increase if (as is hoped) multiple cases support individual configurations (Schneider and Wagemann 2012). Whilst logical remainders are expected, and can be incorporated into the analysis (see sections 18.7.4 on minimization and 18.7.5 on consideration of logical remainders), a large proportion of logical remainders indicates that insufficient evidence is available to support a meaningful interpretation of the results (Schneider and Wagemann 2012). In such a situation, review authors should return to their strategy to manage the number of conditions, and consider the removal or re-specification of conditions. The ratio of conditions to cases is somewhat contested (Marx and Dusa 2011) and there is little guidance regarding an acceptable level of logical remainders (Kneale et al In Press). Rihoux and Ragin (2009) suggest that between four and seven conditions is appropriate for an analysis based on between 10-40 cases (the typical number of cases found in a systematic review) (Rihoux and Ragin 2009).

18.7.3 Stage 3: Resolving contradictory configurations

Purpose

Where multiple cases have an identical configuration of conditions, but they differ with respect to their outcomes this is known as a contradictory configuration. Review authors should use their case knowledge and theory to identify an explanation for such a contradiction. It is expected that contradictory configurations will be present in an initial Truth Table and several iterations will likely be needed to obtain a contradiction-free Truth Table (Berg-Schlosser et al 2009). As Berg-Schlosser et al. note, the observation of contradictory configurations does not mean that the analysis has failed. Rather, they argue that through the process of seeking a resolution for contradictions, researchers gain a more thorough understanding of the cases and an opportunity to further test and refine the theory underpinning the analysis (Berg-Schlosser et al 2009).

Procedures

The first step is to identify any contradictions. In crisp-set QCA consistency scores other than 0 or 1 are a clear indication of contradictory configurations. Although it is widely accepted that for crisp-set QCA a consistency score above 0.75 can be used to claim a relationship of sufficiency, review authors should aim to resolve contradictions whenever the consistency score is below 1. In fuzzy-set QCA identifying contradictory configurations is somewhat harder (Haesebrouck 2015). Review teams are advised, in addition to examining the consistency score, to return to the cases to check for the presence of true logically contradictory cases (Schneider and Wagemann 2012).

There are several options for resolving contradictory configurations. The first logical step is to re-examine how cases are allocated to conditions and to check if the conditions are appropriately specified. Close examination of the contradictory cases in a given row might reveal that the definition or coding for a condition was too ambiguous or 'just plain wrong' (Schneider and Wagemann 2012). Other options are to add or remove or substitute conditions, but review authors should be mindful of the balance of conditions to cases as described above. An example of adding a condition is noted above in section 18.6.2, where

the reviewer authors added a condition to denote short reports or letters to resolve contradictory configurations (Sutcliffe et al 2022). Whichever approach is used, review authors should be transparent about these revisions and draw on case-based, theoretical or logical evidence to justify the revisions.

In some instances, if at this stage review authors are unable to identify a way to solve contradictory configurations, the contradiction can be left in place for the next stage in the analysis and a qualitative explanation of contradictory configurations may be reported.

Considerations

It is vitally important that review authors return to theory and cases to support any changes in adding, subtracting or redefining conditions. As Schneider and Wagemann (2012) note, without clear justification a change of the meaning and thus calibration of concepts can degenerate into a 'blunt data-fitting exercise' (Schneider and Wagemann 2012).

18.7.4 Stage 4: Boolean or fuzzy set minimisation

Purpose

When the data is organised satisfactorily in the Truth Table the next step is to analyse the Table using software (see Section 18.8.2) to identify 'solutions'. A solution is a simplified expression of the combinations of conditions that are found among cases with membership in the outcome set (e.g. studies with effective interventions). Different solutions are generated depending on the assumptions made about logical remainders. Boolean minimisation is used to develop the solution, which is based on mathematical principles of set theory. Sets (see Box 4) are a collection of objects that relate to each other under a specified set of rules and logical mathematical expressions can be used to describe the relationship between sets: "AND" means the intersection between two or more sets (e.g. a minimised solution identifies that both condition A and condition B must be present for the outcome to occur), whereas "OR" means the union between two sets (e.g. a minimised solution identifies that either condition A or condition B are sufficient for the outcome to occur). A third expression "NOT" is the negative, not in the set (e.g. a minimised solution specifies that condition A must be present but condition B must not be present for the outcome to occur).

This process of Boolean minimisation is applied to the Truth table rows of individual configurations to logically reduce those configurations that meet the threshold consistency score for claiming a relationship of sufficiency (typically >0.75) to a simpler "solution" that best fits the data. This process aims to identify the prime implicants (configurations that can be minimised no further) that best explain the data. Any condition or configuration that is necessary for the outcome to occur should be identified as an initial step (although most frequently, QCA applied within systematic reviews seeks to identify sufficient conditions).

A solution is therefore composed of prime implicants that generate the outcome. Prime implicants can be regarded as 'pathways' that have been identified as generating the outcome. Three different solutions may be produced. The most parsimonious (or simplest), the fullest (referred to as the conservative or complex solution) and an intermediate

solution between parsimonious and conservative. A detailed account of these set theory expressions is provided in Schneider and Wagemann, Chapter 2 (Schneider and Wagemann 2012).

Procedures

As with other statistical techniques, it is expected that review authors will use readily available software (see Section 18.8.2) to conduct minimisation. Necessity then sufficiency analysis are conducted sequentially (Schneider and Wagemann 2012). Analysis of necessary conditions or configurations (Truth Table rows) and those identified as sufficient to achieve the outcome is followed by consistency and coverage of the solution terms. The software output, Figure 6, similar to statistical software outputs provides the following output.

Figure 6: Example of software output of minmised solution

The table below represents the solution for a review that involved examining why some mandatory vaccination programmes for healthcare workers were more effective than others, and focusses on 'hard' mandates that involve sanctions for healthcare workers who refuse vaccination on non-medical or religious grounds. It shows that there is one pathway that explains why some interventions are highly effective which is composed of three intersecting conditions. This pathway shows that interventions are effective when there is two way engagement between healthcare workers and managers (represented in shorthand by 'TWOWAYENG'), visible leadership support (LEADSUP) and previous engagement with healthcare workers around vaccinations so that there was not a 'don't go in cold' approach (DONTGOCOLD). The asterisks '*' represent the boolean operator 'AND'; as such the configuration 'TWOWAYENG* LEADSUP* DONTGOCOLD' reflects that all three conditions need to be present. The solution shows high levels of consistency. There is also high Proportional Reduction in Inconsistency (PRI) such that there is little evidence that the same solution would trigger the absence of the outcome. The solution covers all cases (a coverage value of 1). As there is only one pathway below that accounts for all successful cases, the 'unique coverage' column is blank below. However, in solutions with multiple pathways where cases may feature in multiple pathways, it can indicate the share of the outcome that is explained by cases that exclusively appear in that pathway. Similarly, for solutions with multiple pathways, there would be consistency and coverage statistics presented for each pathway, as well as the overall model (represented in the row named M1 below). In this solution, the cases supporting each pathway are named, and the pathway is expressed at the bottom of the table. As the notation of QCA is unfamiliar to many, it is common to have to provide substantial explanation and a key for notation. Visual methods of displaying the results can also aid interpretation (see below).

		Consiste	PRI	Raw	Unique	cases	
		ncy		Coverag	Coverag		
				е	е		
1	TWOWAYENG*LEADSUP*DONTGO	1	1	1	-	Stuart; Babcock,	
	COLD					Rakita, Smith	
М		1	1	1			
1							
TWOWAYENG*LEADSUP*DONTGOCOLD=> SUCCESS							

Table 5: Minimised intermediate solution for crisp-set hard mandate QCA

Notes: See Table 3 for condition names; Upper case conditions indicate the condition is present and lower case indicate a

condition is absent; * = 'AND' relationship; + = 'OR' relationship; Raw coverage: share of outcome covered by a

configuration; Unique coverage: share of outcome uniquely coverage by a configuration

Software packages produce visual representations of the Truth table for binary or crisp sets, and Venn diagrams or XY plots for fuzzy set analyses. These are useful as with other exploratory visual representation of data in both quantitative and qualitative software and permit examination for contradictory Truth table rows (condition configurations).

Solution outputs

Software (see section 18.8.2) will produce three solution types as outputs, which differ according to how the logical remainders are accounted for in the solution as follows:

- **Complex or conservative solution:** Does not incorporate logical remainders in the solution. Provides the broadest solution that covers all data assigned set membership in the condition sets.
- **Parsimonious solution:** Incorporates all logical remainders to find the most parsimonious solution, regardless of its plausibility. The software identifies the solution that covers the majority of cases and produces the simplest solution.
- Intermediate solution: Review teams identify the most plausible logical remainders for inclusion in the solution term and make assumptions about their direction/outcome (this could be considered a form of imputation akin to statistical analysis, albeit based on theory and/or reviewer knowledge rather than generated from the data). This allows the solution term to include empty configurations whereby data from future primary studies is feasibly possible, or likely to occur. This solution is a midway step between the complex and parsimonious solutions.

Consistency and coverage measures provided in the output denote the strength of the relationships identified within the solution as well as how well the solution explains the outcome. To conclude that a solution is sufficient, a consistency level above 0.75 is acceptable (Chandler 2020). To conclude that a solution is necessary, all conditions evaluated must be necessary and the consistency measure should be above 0.9 (Schneider and Wagemann 2012). For solutions which have an acceptable level of consistency, their level of coverage is examined. Coverage quantifies how many of the cases in the outcome set are included in the configurations identified by the solution. Reference to raw coverage is the proportion of cases that are sufficient for a single configuration of conditions (prime implicant). Unique coverage refers to how much of the outcome can be uniquely attributed to that set of cases.

Considerations

Analytical decisions made during minimisation should be grounded in theory and substantive knowledge in the specialist field as to which configuration of conditions best explains the outcome.

18.7.5 Stage 5: Consideration of the 'logical remainders' cases

Purpose

As noted above logical remainders are not only expected, but can be used to simplify the solution. There are several different types of logical remainder, some of which it would be inappropriate to use in helping to simplify the solution, including those that are incoherent or implausible (Schneider and Wagemann 2013). And some for which assumptions about the expected outcome can be made drawing on theory or logic (see Dusa 2018 (Duşa 2018)).

As noted in section 18.7.4 the parsimonious solution will provide the greatest simplification of the Truth table. However, this means that the parsimonious solution may be based on assumptions about logical remainders that are implausible or untenable. The intermediate solution option provides the review author the option of using their knowledge to make assumptions about the likely outcome that might be observed for logical remainders, and to use this knowledge to simplify the solution.

Review authors need to make transparent and informed decisions about how to treat logical remainders when producing an intermediate solution (Schneider and Wagemann 2012). These decisions may involve, whether there is sufficient information from the included studies to make a judgement on whether each logically possible configurations is viable/plausible and whether new cases with that configuration are likely to emerge.

It is important to provide a justification for the selection of logical remainders to include in the intermediate solution. Intermediate solutions are considered the best presentation of the Truth table ((Rihoux and Ragin 2009) p 111). See section 18.8.3 on reporting solutions.

Procedures

Logical remainders to include in the intermediate solution are selected within the software package. Consistency and coverage parameters will change with the different solutions and

therefore will have an impact on the final presentation and interpretation of the solutions. Inclusion of plausible logical remainders may also present contradictions (combinations of conditions that are untenable or contradictory in reality), inevitably the analytic process in QCA requires iteration to identify the best representation of the data based on current knowledge or theory. In their chapter on Crisp Set QCA Rihoux and DeMeur offer a complete checklist for minimization procedures using software (Rihoux and Ragin 2009). Software developed by Dusa (2019) also helps to support researchers to generate solutions which includes the removal of untenable and contradictory logical remainders that could be otherwise be used to generate the solution.

Considerations

The treatment of logical remainders for the intermediate solution must be supported by case and theoretical knowledge. QCA guidance suggests that where an analysis includes the complete set of cases that cover all possible combinations of conditions, examination of logical remainders is not required. However, in practice, it is rare for this situation to occur in the case of a QCA within a systematic review, and it is recommended that the number of logical remainders should be reported, and that they should be incorporated in developing the intermediate solution.

18.7.6 Stage 6: Interpretation of the solution

Purpose

The final stage of QCA is to interpret the solution in terms of consistency and coverage, and in terms of its coherence with the theory and cases.

Procedures

Interpreting the solution:

Thresholds for identifying 'poor consistency' and solutions with poor consistency should be stated in earlier steps but further consideration of solutions with low consistency may nevertheless be useful at this point particularly to help identify contradictions. Solutions with low consistency suggest only weakly sufficient relationships so poor consistency scores should be investigated and the viability of the solution critically assessed. Review authors may first want to consider whether there were any issues in the execution of the analysis, e.g. Were the key conditions adequately specified? Were the measures of fit adequately evaluated? Could there have been a problem with the way logical remainders were handled? But it may also be useful to consider whether insufficient engagement with theory accounts for the problem. For example, a solution in which none of the conditions examined lead to a successful outcome could suggest that initial theory has not contributed to the development of the solution, in contravention to QCA guidance. Similarly, a solution that includes a particular pathway (e.g. the presence of an educational component and the absence of audit and feedback) and the converse of the same pathway (e.g. the absence of an educational component and the presence of audit and feedback) with no additional conditions as part of the configuration, could suggest the identification of a solution with little analytical value without further investigation (and also undermines the epistemological foundations of QCA, see below).

There are no strict thresholds as to what constitutes coverage that is deemed 'too low', and there may be some or perhaps several cases where an explanation for success has not been identified through the QCA. Where low coverage scores are generated, a first measure would be to develop further familiarity with those 'unexplained' cases.

Once a solution with adequate consistency and coverage has been identified, a further quality check is to make sure that the identified solution does not also generate the negation of the outcome. The causally asymmetric nature of QCA can mean that the same set of conditions used to identify successful interventions may also be used to identify unsuccessful interventions. Although a possibility, such a solution would have little analytic value and would need further iteration. Checking the Proportional Reduction in Inconsistency (PRI) statistic that is produced by software as part of the model fit statistics will indicate the extent to which this is a possibility in the solution. PRI scores should be close to consistency scores with scores under 0.5 being indicative of instances where the solution may be a subset of the negation of the outcome.

Finally, the nature of the studies included within a QCA may also require consideration when interpreting the solution. For example, review authors may wish to consider the extent to which their solution is dependent on evidence from studies with high risk of bias (as noted above if the effect estimate is biased assignment to outcome sets may be inaccurate) and may wish to examine whether the identified solution applies to particular subsets of cases (e.g. studies with low risk of bias).

Coherence with data: The review team should examine the cases that support different pathways (i.e. the different configurations within a solution), with some cases possibly supporting multiple pathways. Within case analysis needs to be conducted to check that cases have been allocated to the right configurations, and that the relationship between the configurations identified as being important in triggering a successful intervention is commensurate with the deep case knowledge developed by the review team. Within-case analysis also needs to be developed into cross-case analysis to examine if the groupings of studies identified through the QCA solution distinguishes studies in a meaningful way. Examination of deviant cases that are not included in the solution, or that decrease consistency can add depth to the understanding of the solution produced by the QCA.

Considerations

The relationship between the solution and the theoretically driven assumptions needs to be considered as part of the interpretation to avoid making spurious claims.

18.8 'Practicalities of carrying out QCA in a review

This section of the chapter provides guidance on how the methods outlined above can be practically applied within the context of a systematic review.

18.8.1 Carrying out QCA as part of a review team

By now, some of the core elements needed to carry out a QCA may be clear. These include (i) a set of studies showing variation in outcome; (ii) a rationale for allocating studies into sets based on the value of their outcome; (iii) a working theory upon which to base which conditions will be investigated; and (iv) the means to investigate how combinations of conditions are aligned with studies allocated into different outcome sets. The stages outlined above emphasise that conducting a QCA involves moving nimbly between engaging with complex theory, qualitative data and quantitative data, and into later stages of identifying solutions using computer-based software and through to interpretation and re-engaging with the original study data. Not only does this process require two reviewers to work together to enhance the transparency and replicability of the QCA process, but it also requires that review authors with a range of skills work together in conducting a QCA. This can involve review authors who are more comfortable with the other qualitative synthesis techniques outlined in this handbook working closely with review authors who are less familiar with qualitative approaches. Review authors with mixed-methods expertise may be particularly helpful in conducting a QCA. Compiling this mix of skills is one of the main practical recommendations for undertaking a QCA.

Unlike other synthesis processes or in the conduct of many mixed-methods systematic reviews, where a meta-analyst may work discretely from other parts of the review team, the abductive nature of QCA requires this mix of skills to be integrated from the outset. Specifically, review authors with different skills need to work together to: identify heterogeneity and determine how to calibrate studies into different sets; verify the interpretation of data that underlie the calibration of QCA conditions; theorise how conditions may work together; conduct the abductive process of adding and substituting conditions; challenge and verify the identified solution. This requires skills that range from engaging with and developing theory through to writing software code to run and check different models. Review authors who feel that they may lack sufficient experience within their own team are advised to consult with teams who have used QCA for systematic review synthesis in the past for advice and support.

18.8.2 Available software

QCA is a method that is rapidly gaining traction within the field of systematic reviews and more broadly within the social, health, and political sciences. Recommendations around specific support will be subject to change. At the time of writing, review authors could rely on different software options for conducting a QCA, including different software options for data management and creating a Data Table and for minimizing the Data Table.

Data management and creating a Data Table

Review teams will probably be familiar with software for managing the extraction of data within a review and will probably draw on their software of choice for this stage. While no specific software should be recommended, the software needs to allow review authors to extract and record the original data, to apply a calibration scheme to the data, and to produce a Data Table that facilitates visual checks of the data for coding issues and for initial inspection of the data to start to identify patterns. Specialist systematic review

software such as EPPI-Reviewer (Thomas et al 2022), or DistillerSR or other software such as Microsoft Excel can also be used as the basis for extraction and creating Data Table.

The analytical moment and minimisation

Although it is possible to conduct many of the steps of a (relatively rudimentary) QCA entirely by hand (see example in (Grofman and Schneider 2009)), it is recommended that software is used to produce a Truth Table and to undertake Boolean minimization. Statistical software that supports QCA includes a package written by Dusa for use within R which provides a comprehensive suite of options for QCA analysis (with users writing and running their own syntax), and is supported by a helpful textbook to guide users both on the methods and their execution (Duşa 2018).

In addition, standalone software packages for conducting QCA are available, the most wellknown being fs/QCA (Ragin and Davey 2016). Fs/QCA offers flexible menu driven software that allows Data Tables to be imported through a variety of formats, supports the conduct of crisp and fuzzy-set QCA and is supported by a detailed manual that walks users through the steps of conducting QCA(Ragin 2018). An alternative standalone software is TOSMANA (Cronqvist 2019), which supports crisp and fuzzy-set QCA, as well as multi-value QCA (not discussed in this chapter). Another package written within R by Oana and Schneider (2018) allows users to implement advanced QCA methods.

Finally, STATA (a statistical package used widely across the social sciences) also supports a user-written package for conducting QCA (fuzzy) that involves using writing and running their own syntax (Longest and Vaisey 2008), although at the time of writing this has less flexibility, for example in the treatment of logical remainders, than more recent software. An extensive list of available software for conducting QCA can be found at https://compasss.org/software/.

18.8.3 Good practice in conducting and reporting a QCA

QCA is an emerging synthesis method, particularly when applied to evidence syntheses, where standards of good practice are in development. Within the QCA literature more broadly , guidance developed by Wagemann and Schneider (Wagemann and Schneider 2010) stands out as offering a comprehensive overview of good practice in the field. Other resources that provide guidance on how to conduct QCA, for example the guide produced by Duşa (Duşa 2018) on conducting QCA through R, can also simultaneously serve as good practice guides. There are also specific sources suggesting good practice around some of the specific technical issues encountered when conducting QCA, for ensuring an appropriate balance of conditions to cases (Marx and Dusa 2011). Other sources recommend specific steps to improve the robustness of the QCA, such the need to undertake back and forth validation between the solution and individual cases, and the need to pre-specify data requirements, case and condition selection (without impeding iteration in model development) (Chandler 2020).

An emerging tool for supporting the conduct and reporting of QCA within systematic reviews is the CARU-QCA tool (Critical Appraisal of Reviews Using QCA tool) (Kneale et al In Press).

In the interests of transparency, all stages of the conduct of QCA should be reported and/or made available in supplementary materials. Review teams should report how they selected and revised the conditions and configuration(s) analysed in each Truth Table, and how this is consistent with the underlying theory. At minimum the truth table and the preferred solution (usually the intermediate solution) should be presented, with a full Data Table made available as an appendix or supplementary file. It is good practice to report all solution types, to allow the reader to determine how they may best apply that information in their setting. QCA uses specific notation to indicate the types of relationship between conditions/sets that form configurations based on Boolean algebra. Somewhat counterintuitively to those encountering QCA afresh, logical AND relationships are usually denoted with an asterisk, 'x' or '.'. Logical OR relationships are denoted with a '+'. It is also possible for QCA solutions to use notation from set theory (e.g. \cap to denote intersection (and) or ∪ to denote union (or)), although this presentation is not frequently encountered in the systematic review literature. The absence (negation) of a condition is denoted through the use of a tilde (~). In other schema the absence of a condition is denoted through the use of lower case letters and the presence of a condition denoted by upper case lettering. Each solution should also be expressed in plain language to ensure the differences between inclusion and exclusion of logical remainders is clearly understood in how it is applied to the QCA outcomes chosen. Solution coverage and consistency scores should also be presented and included in statements of solution interpretation. The withinand cross-case analyses should be discussed as part of the reporting of the interpretation. New knowledge developed as part of the QCA, that confirms or expounds upon (or perhaps contradicts) existing theory also needs to be identified and discussed within the interpretation. When discussing the solution, review authors should be cognisant of the types of causal claims that can be made from the QCA solution (see section 18.9).

18.8.4 Sources of help

Within the QCA literature the optimal ways of conducting and interpreting data are debated. For example, counter to recommendations in this chapter, whether the intermediate solution is the optimal solution is contested in some of the literature (Baumgartner and Thiem 2017). Similarly, updates to software including through user written packages, as well as new perspectives and innovations, offer new possibilities in terms of, for example, undertaking multi-value or temporal QCA (Mattke et al 2021). This is a rapidly changing field, and one source that (at the time of writing) is coordinating many of these developments is the COMPASSS network (COMPArative Methods for Systematic cross-caSe analySis) whose website includes sources of help, tutorials and guides, and links to community spaces (see www.compasss.org). Finally, for review authors new to the approach, given that recent estimates suggest that fewer than 100 reviews have used QCA as a synthesis model (Sutcliffe et al 2020), many reviews that draw on QCA tend to include

detailed methods descriptions of how the synthesis was conducted (Harris et al 2019; Melendez-Torres et al 2018; Thomas et al 2014).

18.9 The nature of evidence offered by QCA

QCA allows us to explore and illuminate the presence of different 'causal' pathways (equifinal causation) and the arrangement of configurations of conditions that generate an outcome (conjunctural causation). QCA also allows us to identify the presence of different types of causal relationship (necessary and sufficient) and to expand and identify highly complex relationships (INUS (insufficient, but necessary part of an unnecessary but sufficient condition) relationships) (Wagemann and Schneider 2010). Among the different synthesis methods available, not only is QCA best placed to identify these relationships, but it is also often the only method available to do so. However, the type of causal account developed in QCA is also distinct from other evidence synthesis approaches, given that QCA does not constitute a case series analysis (where there is little cross-case focus) or statistical analysis (in setting out to identify broad-brushed patterns to make inferences beyond the data). QCA employs a different form of causal narrative based on theoretically grounded regularities where successive observation of patterns within a (usually small) dataset are used to develop an account of causality (Cartwright 2007; Haesebrouck 2019; Reiss 2009). A regularity approach to identifying a causal relationship holds that (i) the same cause leads to the same effect; and that (ii) the effect is only triggered in the presence of a cause (Haesebrouck 2019). In many ways a regularity account is one of the most 'minimalistic' approaches to developing a causal narrative, and therefore the expectation that the conditions explored are grounded in theory or theoretical principles becomes all the more important. When conducting QCA, review authors should be aware that they are making assumptions about the causal nature of the conditions that feature in the solution; they are assuming that each condition that emerges as part of the solution is an indispensable part of the causal recipe of why the intervention is successful or the phenomenon emerges. The resulting casual recipe derived from QCA provides an explanation of the emergence of an outcome for those studies within the dataset. Inferences beyond the dataset are not advised, although given that systematic review evidence is assembled to represent a 'census' of activity, the causal recipe developed may nevertheless have wide-ranging salience.

18.10 Stakeholder engagement and involvement

Since the purpose of reviews using QCA is to understand how contextual conditions combine in nonlinear and often unpredictable ways to reach an outcome, experiencebased insights about which intervention features are important, which contextual moderators may influence outcomes, and how different factors may interact can provide additional insights. Engaging early in the review with stakeholders who deliver interventions and those with lived experience of receiving them can be an effective way of identifying potentially important conditions and for understanding how to set rules around the presence or absence of such conditions (see set calibration in section 18.1.1). Stakeholders may also support identification of appropriate theories to underpin the analysis. Engaging with and involving stakeholders and patient and public representatives who use systematic reviews may help later in the review to ensure that the complex findings are presented in an accessible format (Kahwati et al 2022). Patient and public contributors with lived experience will however potentially require a lot of support to understand and feel confident about the complex QCA methods and processes.

18.11 Equity, diversity and inclusion

Given the utility of QCA for exploring the influence of context on intervention outcomes, it can be a useful tool to examine equity, diversity and inclusion in reviews. For example, QCA allows examination of configurations of both intervention and contextual factors to determine whether they are associated with better outcomes among disadvantaged groups compared with more advantaged groups. Or it may be possible to study whether interventions with the same configuration have differential outcomes for disadvantaged and advantaged groups. Some methods work examining QCAs utility for this endeavour indicated its potential added value (Candy et al 2022). Equity, diversity and inclusion is also an important consideration when engaging and involving key stakeholders, including patients and the public. The people and organisations selected should best represent the target population and subgroups of interest in the QCA.

18.12 Reflexivity

Given the abductive nature of QCA, the number of critical decisions to be made as the QCA progresses and the high level of interpretation required, review author reflexivity is an essential part of reviews using QCA. Key stakeholders involved in engagement activities may also bring their own biases regarding the interpretation of evidence, choice of theory. However, increasing the range of viewpoints through stakeholder engagement can help to expose both conscious and unconscious biases that could affect the interpretation and therefore the outcomes of the QCA. As noted in section 18.5.4, existing theory should be used to structure and ground the QCA to ensure that reviewer or stakeholder biases do not overly influence the analysis.

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