Assessing Research Protocols: Case Study Research
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Case study research: "a research approach that is used to generate an in-depth, multi-faceted understanding of a complex issue in its real-life context" (Crowe et al, 2011, p.100)

Case study research is a "naturalistic" design which examines a phenomenon in its natural context as opposed to an "experimental" design (like an RCT) where a researcher aims to control/manipulate a particular variables or set of variables of interest. Case studies are appropriate when we want to explain, describe and/or explore a phenomenon in its everyday context. Lends itself to answering 'how', 'what', and 'why' types questions which can support the development and refinement of theory (*Ibid*).

Advantages of Case Study research:
- Can yield rich descriptive information about the phenomenon of interest
- Allows for the exploration of rare or unique cases
- Can include inquiry at micro, meso, and macro levels (i.e. patient, organization and system level)
- Shares many advantages associated with mixed methods research (i.e. using multiple forms of data to address limitations and fill knowledge gaps

Disadvantages of Case Study research:
- Can be extremely time and resource intensive given the amount of data to be gathered and analyze to allow for in-depth inquiry
- Often difficult to generalize findings to other populations or settings (however, generalizability may not be the purpose of the study)
- Difficult to replicate study
- Poses some potential ethical issues particularly with regard to participant or subject burden, and the ability to assert anonymity and confidentiality. As some cases may be rare it may be easy for the public to identify organizations or even individuals that participate in the study.

Types of case study research

Table X. Common case study typologies

Stake (1995)	Yin (2009)	Robson (2002)
Intrinsic Used when we want to learn about a particular case; the case itself is the area of interest (i.e. community-based healthy eating program)	**Descriptive** "What is happening or has happened?"	**Descriptive** Portraying a situation or phenomenon
		Exploratory Finding out what is happening, seeking new insights and generating ideas and hypotheses for new research
Instrumental Using a particular case to get a	**Explanatory** "How or why did	**Explanatory** Seeking an explanation of a

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broader understanding of a particular issue/phenomenon. The case(s) chosen exemplifies a particular phenomenon or issue of interest (e.g. integrated care)	something happen?"	situation or a problem, mostly but not necessary in the form of a causal relationship.
Collective Studying multiple cases simultaneously to generate an even broader understanding of the issue. Involves comparing possibly the same or different examples within the phenomenon of interest.	**Cross-case** Exploring a particular phenomenon across multiple cases. Should define if looking at most-similar or most-different design	
		Improving Trying to improve certain aspect of studied phenomenon

Stages in Case Study Research (Crowe et al, 2011; Stake, 1995; Yin, 2009)

1. Case study design

Case study design should include:

> Objective: What the researchers plan to achieve
> The cases: What is being studied
> Theory: The frame of reference
> Research questions: What the researchers intend to learn
> Methods: How data will be collected
> Selection strategy: How the cases will be selected
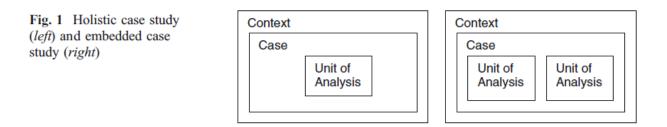
Defining the case(s)

Good case study proposals should have clearly identified definitions that set up boundaries around inclusion and exclusion. The definition should be informed by the theoretical groundwork (and literature) used to define the case (Crowe et al, 2011). Case definitions should be clear in terms of:

- Scope and time period (although beginning and end may be difficult to define)
- Relevant social group/organization/geographical area of interest
- Types of evidence to be collected, and
- Priorities for data collection and analysis.

It's important to note that theoretically driven case (using theory to identify a case of interest and justify its selection) may more easily become broadly applicable to other settings.

We need to distinguish between holistic (looking at the whole case) or embedded (looking at multiple unites of analysis within a single case) case study designs. In a holistic design the case is the unit of

analysis (e.g. single hospital), while in an embedded design there may be multiple units of analysis within a single case (e.g. units within a single hospital) (see Fig.1) .

Fig. 1 Holistic case study (*left*) and embedded case study (*right*)

Runeson and Host, 2009 referring to Yin's design approach

The distinction is in what level of context is important to the analysis. In an embedded design the case itself provides a number of different instances where the phenomenon of interest occurs (Cavaye, 1996 citing Yin). For example, we may be interested in looking at hospital units use of electronic medical records. If we looked at two units within a single hospital and were considering the hospital context as the same for both units then this would be an embedded design. However, if we were interested in comparing across contextual factors at the unit level like work-flow or team structure, in which case it would be considered a cross-case design.

Selecting the case(s)

Case selection should be driven by both the research questions and the purpose of the study (i.e. a cross-case vs. descriptive study) (Curtis et al, 2000; Seawright and Gerring, 2008). A clear justification of case selection should be provided. Case selection may be *intrinsic* (the case is pre-specified) or *instrumental/collective* (requiring selection of cases from possible alternatives) (Curtis et al, 2000 citing Stake, 1994). In general case study selection may fall into the following categories outlined by Seawright and Gerring (2008):

Table X. Case selection methods

Selection method	Definition	Use
Typical	One or more cases selected are typical or representative examples of phenomenon of interest	Confirmatory
Diverse	One or more cases cover diversity across variables of interest	Exploratory or confirmatory
Extreme	One or more cases are extreme examples of a particular variable or phenomenon	Exploratory
Deviant	One or more cases which are different from some normal variable or phenomenon	Exploratory or confirmatory
Influential	One or more cases that influence a particular outcome. Cases are influential with regard to a larger cross-case theory.	Confirmatory
Most similar	Two or more cases are similar across specific variables	Exploratory or

		confirmatory
Most different	Two or more cases are different across specific variables	Exploratory or confirmatory

2. Preparation for data collection

Case study research often requires several different data sources. Yin (1999) suggests six sources of evidence that can be used as part of case study research:

- Documentation
- Archival records
- Interviews
- Direct observations
- Participant-observation
- Physical artifacts

Proposals should outline all anticipated sources of data and how these sources will support the research questions being asked. Researchers should outline appropriate methods for collecting each form of data (see overviews from previous methods sections). There should also be adequate justification for the selection of data sources. Qualitative data is often most common in case study designs.

In order for case study research to be successful the researchers will need to have access to individuals, organization, processes or anything else identified as part of the data gathering. Drawing on existing relationships or a clear strategy for creating new relationships in order to allow access to the case will need to be demonstrated. This can be demonstrated through providing letters of support from cases in instances where the cases have been selected prior to the submission of the proposal. Here ethical considerations like resonant burden and potential threats to confidentiality/anonymity of participants should be addressed.

3. Collecting evidence

There should be a clear plan in place to determine how data will be collected, stored, and potentially shared across the research team. Some additional considerations for cross-case designs include:

- Data collection should allow for detailed description of individual cases prior to cross-case comparison
- Data gathering across cases should be similar enough to allow cross-case comparison.

Studies should adhere to standards associated with gathering each form of evidence. As is the case with mixed methods research, ensuring that collection of data is rigorous and methodologically sound will require appropriate expertise from team members, as well as time and resources required.

It is important to note that it may required that researchers return to a case several times in order to gather all data required. If this is the case then participating cases should be made aware of and agree to this plan.

4. Analyzing data

As with collective on data, analysis of case study research may follow approach similar to mixed methods design. In collective approaches it is often recommended that a single case be explored first before starting to make comparisons. In a proposal the researchers will need to clarify how data will be organized and coded to allow key issues to emerge (either deductively or inductively). As in other methods theory may be used to analyse, interpret and guide the reporting of results.

Given the likely large amounts of data to be analyzed, enough time and resources should be allocated to this stage of the study.

5. Reporting

The key aspect of reporting is the need for detail and transparency regarding how the method supports the research questions being asked. The report muse adequately reflect all the prior steps in the research process, and do so in an engaging way that demonstrates relevance and applicability of findings.

Potential Issues (Crowe et al, 2011)

Unclear definition/boundaries for the case and selecting the wrong cases: Without a clear definition the study may be difficult to operationalize in terms of identifying appropriate cases and analyzing data in a meaningful way. This may also lead to the selection of the wrong cases.

Large amounts of data: Often case study research will capture a large amount of data. There will need to be a clearly defined strategy to manage data and analysis as well as enough resources (personnel, time) to analyze all the data that will be captured

Generalizability: There are sometimes concerns regarding generalizability but these can be mitigated by the use of theoretical sampling, respondent validation (participants checking emerging findings), and transparency on the research process

Lack of rigour: The use of multiple methodologies and limited expertise and resources may result in a lack of rigour with regard to data gathering and analysis.

Ethical issues: Case studies often involve a lot of time on the part of the participants which can result in a high respondent burden. There may also be issues around anonymity for participants, particularly in instances where the cases being studied are highly unique. A clear strategy for seeking ethics approval (or demonstration of pre-approval) is important.

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Simple Case Study Protocol Checklist (Crowe et al, 2011; from Stake's model)

Communication	Clarity: Does the proposal read well?
	Integrity: Do its pieces fit together?
	Attractiveness: Does it pique the reader's interest?
Content	The case: Is the case adequately defined?
	The issues: Are major research questions identified?
	Data resource: Are sufficient data sources identified?
Method	Case selection: Is the selection plan reasonable?
	Data gathering: Are data-gathering activities outlined?
	Validation: Is the need and opportunity for triangulation indicated?
Practicality	Access: Are arrangements for start-up anticipated?
	Confidentiality: Is there sensitivity to the protection of people? (ethics approval process outlined)
	Cost: Are time and resources estimates reasonable?

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Full Case Study Checklist (Ruenson and Host, 2008 – derived from Yin's stages of case study research and drawing on broader literature)

Case study design
1. What is the case and its units of analysis?
2. Are clear objectives, preliminary research questions, hypotheses (if any) defined in advance?
3. Is the theoretical basis—relation to existing literature or other cases—defined?
4. Are the authors' intentions with the research made clear?
5. Is the case adequately defined (size, domain, process, subjects…)?
6. Is a cause–effect relation under study? If yes, is it possible to distinguish the cause from other factors using the proposed design?
7. Does the design involve data from multiple sources (data triangulation), using multiple methods (method triangulation)?
8. Is there a rationale behind the selection of subjects, roles, artifacts, viewpoints, etc.?
9. Is the specified case relevant to validly address the research questions (construct validity)?
10. Is the integrity of individuals/organizations taken into account?

Preparation for data collection
11. Is a case study protocol for data collection and analysis derived (what, why, how, when)? Are procedures for its update defined?
12. Are multiple data sources and collection methods planned (triangulation)?
13. Are measurement instruments and procedures well defined (measurement definitions, interview questions)?

14. Are the planned methods and measurements sufficient to fulfill the objective of the study?
15. Is the study design approved by a review board, and has informed consent obtained from individuals and organizations?

Collecting evidence
16. Is data collected according to the case study protocol?
17. Is the observed phenomenon correctly implemented (e.g. to what extent is a design method under study actually used)?
18. Is data recorded to enable further analysis?
19. Are sensitive results identified (for individuals, the organization or the project)?
20. Are the data collection procedures well traceable?
21. Does the collected data provide ability to address the research question?

Analysis of collected data
22. Is the analysis methodology defined, including roles and review procedures?
23. Is a chain of evidence shown with traceable inferences from data to research questions and existing theory?
24. Are alternative perspectives and explanations used in the analysis?
25. Is a cause–effect relation under study? If yes, is it possible to distinguish the cause from other factors in the analysis?
26. Are there clear conclusions from the analysis, including recommendations for practice/further research?
27. Are threats to the validity analyzed in a systematic way and countermeasures taken? (Construct, internal, external, reliability)

Reporting
28. Are the case and its units of analysis adequately presented?
29. Are the objective, the research questions and corresponding answers reported?
30. Are related theory and hypotheses clearly reported?
31. Are the data collection procedures presented, with relevant motivation?
32. Is sufficient raw data presented (e.g. real life examples, quotations)?
33. Are the analysis procedures clearly reported?
34. Are threats to validity analyses reported along with countermeasures taken to reduce threats?
35. Are ethical issues reported openly (personal intentions, integrity issues, confidentiality)
36. Does the report contain conclusions, implications for practice and future research?
37. Does the report give a realistic and credible impression?
38. Is the report suitable for its audience, easy to read and well structured?

Readers' checklist
39. Are the objective, research questions, and hypotheses (if applicable) clear and relevant? 1, 2, 5, 29, 30
40. Are the case and its units of analysis well defined? 1, 5, 28
41. Is the suitability of the case to address the research questions clearly motivated? 8, 9, 14
42. Is the case study based on theory or linked to existing literature? 3
43. Are the data collection procedures sufficient for the purpose of the case study (data sources, collection, validation)? 11, 13, 16, 18, 21, 31
44. Is sufficient raw data presented to provide understanding of the case and the analysis? 32

45. Are the analysis procedures sufficient for the purpose of the case study (repeatable, transparent)? 22, 33
46. Is a clear chain of evidence established from observations to conclusions? 6, 17, 20, 23, 25
47. Are threats to validity analyses conducted in a systematic way and are countermeasures taken to reduce threats? 27, 34, 37
48. Is triangulation applied (multiple collection and analysis methods, multiple authors, multiple theories)? 7,12, 22, 24
49. Are ethical issues properly addressed (personal intentions, integrity, confidentiality, consent, review board approval)? 4, 10, 15, 19, 35
50. Are conclusions, implications for practice and future research, suitably reported for its audience? 26, 29, 36, 37, 38

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