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A clinician's guide to performing a case series study

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ABSTRACT

Background: Whilst some guidance exists, the literature is relatively scarce on designing and reporting on case series studies for non-surgical techniques/interventions or interventions that may be considered outside the medical model. This commentary presents a set of thirteen design attributes and an adapted checklist for consideration by clinicians when considering a case series design focused on a non-surgical intervention.

Since the inception of the Evidence-based medicine (EBM) framework by Sackett et al. (1996), guidance on the best available clinical evidence typically directs clinicians to meta-analyses and systematic reviews (Burns et al., 2011; Mercuri et al., 2018). However, being guided by the 'best available clinical evidence' when there is limited or no high-level evidence for the desired intervention, poses a challenge for the clinician seeking an evidence-based approach to practice.

Research has shown clinicians are challenged when they perceive a conflict between an identified lack of high-level evidence and their person-centred model of practice (Harding et al. 2014; Cerritelli et al., 2021). This perceived or actual conflict is particularly relevant to disciplines where patients' individual needs impact clinical decision making, such as the allied health and complementary and alternative medicine professions which involve shared decision making. Further, clinicians may not base treatment solely on clinical practice guidelines or results from high level evidence. Rather they often base clinical decisions on intuition (Greenhalgh 2002) and complex processes involving observation, critical thinking, evaluation of evidence, application of pertinent clinical knowledge, reflection and clinical judgment (Smith et al, 2008; Holdar et al., 2013).

The randomised controlled trial (RCT) sits close to the top of the evidence hierarchy and is considered the 'gold standard' for determining causal relationships in clinical research (Hariton and Locascio 2018). Clinicians may see only limited value in RCT findings as it may be difficult to translate these findings to their day-to-day practice (Rothwell 2005). Randomised controlled trials may use a non-clinically relevant treatment approach as opposed to 'real-world' clinical practice where a combination of treatment techniques are used (Nichol et al., 2010) and may use patient populations (e.g. asymptomatic, University students) that may differ to those seen in clinical practice, thus decreasing external validity.

Use of observational research designs may assist in identifying and evaluating what clinicians do in 'real world' settings (Sayre et al., 2017). Observational research designs, such as a case series, may provide a bridge between RCTs and the evidence that is generated from, and directly relevant to, a clinician's practice (Carey and Boden 2003, Sayre et al., 2017).

Case series designs are a crucial component of healthcare research, often serving as the first line of evidence in identifying and understanding new diseases or conditions (Mohammad Hassan et al., 2018). A case series involves the detailed analysis of a group of patients/participants with a particular disease or condition, allowing researchers to identify common features that may provide hypotheses about disease causation. They are integral to learning by pattern recognition and advancing medical knowledge. For instance, the discovery of sickle cell disease was based on a case report (Mohammad Hassan et al., 2018).

Case series present an opportunity to generate further research questions about effectiveness of an intervention(s) that typically fall outside the medical model and can be explored in experimental studies - leading to a higher level of evidence (Dekkers et al., 2012). Case series have been used to explore various aspects of healthcare interventions, including treatment outcome trend analyses (Tate et al., 2010), health care planning and healthcare benchmarking (van Lent et al., 2010), initial reports of a new diagnosis or innovative treatment (Somerville et al., 2020), and health clinic setting report(s) of intervention outcomes

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(Remppis et al., 2021). Despite their uncontrolled nature and the associated risk of bias, case series and case reports have profoundly influenced the healthcare literature and continue to advance our knowledge.

Case series studies exploring surgical interventions are common, and clear guidance is provided to authors (Agha et al., 2020). However not all pathologies or conditions require surgical intervention, and minimal guidance exists for the publication of non-surgical case-series including care offered by allied health and complementary and alternative medicine practitioners. Some researchers have argued that the guidelines developed by the CARE (CAse REport) Group (http://www.care-statement.org/) (Gagnier et al., 2013; Riley et al., 2017) are limited for non-surgical interventions and emphasise the differences between surgical intervention and manual therapy (Munk and Boulanger 2014). Subsequently, authors have proposed modification of some sections of the CARE guidelines to make them compatible with case reports focusing on non-surgical interventions (Munk and Boulanger 2014). One modification, proposed by Munk and Boulanger (2014), is the inclusion of the patient perspective, providing an opportunity for the patient to 'voice' their experience. In 2017, the CARE guidelines were updated and included a recommendation to add in one or two paragraphs about the patient perspective (Riley et al., 2017). However, the guidelines do not provide clear guidance about how to seek this perspective for a case series study.

Unlike the CARE guidelines for case reports (Riley et al., 2017), no consistent set of guidelines exists for case series studies for allied health and complementary and alternative medicine practitioners. The key difference between a case study and a case series typically lies in the scope and scale of the reported cases. Case series provide a broader perspective and may contribute to the understanding of patterns, trends, or variations within a specific group of patients. Both case reports and case series contribute valuable information to healthcare literature, offering insights into rare conditions, treatment responses, or clinical observations that may guide future research and patient care (Carey and Boden 2003, Dekkers et al., 2012; Mohammad Hassan et al., 2018).

To illustrate an example of a case series, Simões et al. (2022), recruited seven older adults with chronic pain who were provided with six sessions of pain neuroscience education and dance (*exposure)*. Participants were assessed at baseline and at the end of the intervention regarding knowledge of pain neurophysiology, pain intensity, and other behaviours (*outcome)*. The researchers posited that pain neuroscience education may be a feasible intervention and, when combined with dance, may have a positive impact on pain intensity (Simões et al., 2022). –In this study, observations were made on a series of individuals with the same pathology/condition (i.e., chronic pain), receiving the same intervention (i.e., pain neuroscience education and dance), with no control group.

Due to the lack of clear guidance on designing and reporting on case series studies for non-surgical interventions, we present a set of thirteen design attributes and an adapted checklist from the Preferred Reporting Of CasE Series in Surgery (PROCESS) guidelines (Agha et al., 2020) for use by clinicians when considering a case series design focused on a non-surgical intervention. The thirteen attributes presented are an extension of the PROCESS guidelines adapted for non-surgical interventions, with a focus on clear reporting of exposure (*intervention)* and outcome variables, a clear description of the outcome measures used, and inclusion of the patient perspective, as described by the patient themselves.

The thirteen key attributes to consider when designing and reporting on a case series are.

1. A clear rationale for study.
2. A clearly defined question.
3. An explanation of whether the case series is observing the *exposure,* or the *outcome*, or both.
4. A clearly defined study population.
5. A detailed informed consent process.
6. A clearly defined intervention.
7. A rationale for sample size.
8. Detail about the use of validated and reliable outcome measures.
9. An exploration of the patient perspective
10. Use of appropriate statistical analyses.
11. A clear description of results.
12. A discussion/conclusion sections which are supported by data; and,
13. Detail about any conflicts of interest.

1. A clear rationale for study

Provide the rationale for undertaking the case series including rationale for why the case series is the best design for the research question. Describe the reason(s) the topic has been chosen, including the significance of the study and what gap(s) the research intends to fill. If the case series is building on previous research and does not aim to fill an identified gap, explain how the research will offer fresh perspectives on existing healthcare issues or complaints. In short, provide an explanation supported by relevant literature that rationalises the need for the case series.

2. A clearly defined question

The focus of the research question should be *observational* meaning the outcome(s) of interest - treatment/intervention outcomes, or course of a disease/pathology or both - is observed. The research question should not focus on determining whether one treatment is better than another, or whether a treatment is effective for a particular condition/pathology. That is, the question should not be framed to examine superiority (or inferiority) of a treatment for an outcome. Answerable questions can take several forms, but we encourage the use of the PICOC framework (Table 1) to generate a well-considered clinical question. Using the PICOC framework by Petticrew and Roberts (2008), provides specific detail of the Population of interest (P); the Intervention (I); the Outcomes of interest (O), and the context (C) of the intervention (see Table 1 below). As a case series does not compare effectiveness of interventions, no Comparison (C) is required.

3. An explanation of exposure and/or outcome

When considering the use of a case series design it is important to identify what is to be observed and reported on. A case series may report on the *exposure* - such as patients receiving a treatment over time - and/or an *outcome* - such as the report of patient outcomes during their period of care from a healthcare provider. A clear description of the exposure and/or outcome of interest and the associated observations must be presented.

For interventions that target health outcomes, the hypothesised physiological and/or psychological therapeutic mechanism of action should guide the development of the exposure definition (Lee and Pickard 2013). Details such as the timeframe, changes in exposure status or exposure to other therapies, and consistency and accuracy of exposure measurement should be addressed.

When considering which outcomes to measure, include a range of health outcomes that may be of interest to patients, health care providers, and other decision-makers. These should include health-related or general quality of life (QoL) measures (Velentgas et al., 2013). If the outcome is a disease, the nature of the disease state to be treated, and the intended effect of the treatment under study need to be described, as well as a description as to whether these are new disease presentations, or repeat presentations (Velentgas et al., 2013).

Table 1
Building a clinical question using PICOC framework.

	Population	Intervention	Outcome(s)	Context
Element of the Clinical Question	Describe the group of patients of interest as accurately as possible.	Describe the main intervention or therapy or technique.	Describe the clinical outcome, including a relevant time frame.	Describe the context of intervention delivery. Describe the clinical setting in a hospital care setting?
Example 1	In adult patients who have a total hip replacement	does pain medication (opioids)	reduce post operative pain in the first 4 weeks	
Example 2	Among family-members of patients undergoing diagnostic procedures	does standard care,	reduce self-reported anxiety	as delivered by psychologists in a private practice setting?

4. A clearly defined study population

The operational definition of the pathology or condition needs to be clearly defined, including where the operational definition came from. This could be sourced from previous research that used the same definition for comparison or definitions from classification systems such as the International Classification of Diseases from the World Health Organization.

The specific criteria used to diagnose the pathology or condition should be detailed so readers can compare their patients with those described in the case series. Include explicit inclusion and exclusion criteria for the defined pathology/condition, and the specific characteristics of the patients of interest. The background and experience of the practitioners involved in the diagnosis and/or intervention should also be included.

It is best to ask for informed consent and the patient's perspective before the writing of the case series is commenced. Preferably, descriptive information about all patients, including age, gender, and socioeconomic status (income, part of compensation schemes, etc.) should be included to provide the reader with an understanding of the patient population.

Further, it is recommended the authors provide clear clinical information of the patients such as (where relevant): identified comorbidities; stage of disease; previous interventions/treatment received; and results of pertinent diagnostic tests. This descriptive information allows clinicians to appreciate whether the patients in the case series are like the patients they see in their own practice, thus informing decisions around the clinical impact of the study.

Be sure to include detail about any patients lost to follow up. This should be detailed enough to allow the clinician to appreciate why a patient was lost to follow-up. Reasons for discontinuation may include the patient(s) being dissatisfied with care, their condition improved enough for them to feel as though they no longer required care, or they failed to return for follow-up care. It is important to note, a participant *may* provide the clinician with the reason(s) for leaving the case series study but *is not obliged* to provide their reason.

5. A detailed informed consent process

Consent for participation in a case series requires an informed consent process. This process involves an information exchange and ongoing communication that takes place between the clinician and the potential participant (patient). The requirement for formal ethics committee/institutional review board approval will vary from country-to-country but is often not required. Clinicians should seek advice as to whether this approval is required.

The consent process starts with the initial presentation of a research activity to a potential patient (including advertisements and notices), continues with a discussion and information exchange between clinician and patient, and requires documenting that consent was obtained. The process may also be ongoing through the case series until the patient decides to end their participation or until the study closes.

Obtaining consent involves explaining the research and assessing participant comprehension using aninformation sheet, as a guide for the verbal explanation of the study. Informed consent from the participant and/or their legally authorised representative must be obtained prior to initiating any research activities, including screening procedures.

An effective informed consent process typically involves these elements.

- Conducting the process in a manner and location that ensures participant privacy;
- Obtaining the prospective participant voluntary agreement to participate;
- Giving adequate information about the study in a language understandable to the potential participant;
- Documenting the consent appropriately;
- Providing adequate opportunity for the potential participant to consider all options;
- Providing copies of the information sheets and consent documents to the patients;
- Responding to the potential patient questions and/or concerns;
- Ensuring the potential patient comprehends the information provided;
- The patient should provide informed consent (including a patient perspective) and the author should provide this information if requested. Some journals have consent forms which must be used regardless of informed consents obtained. In some cases, additional approval (e.g., Institutional Review Board or ethics committee) may be needed; and,
- Continuing to provide information as the patient or research requires;
- An option for the patientsto withdraw consent at any point during the study without penalty, must also be added.

6. A wclearly defined intervention

When planning to observe an intervention targeting health, there should be a clear description of each technique(s). The description of the technique(s) should contain sufficient detail for clinicians to replicate in their practice, increasing its generalisability (Hagopian 2020) and clinical impact. If the procedure is not explicitly described in the case series, references to other research that detail the technique(s) should be added so other clinicians can replicate it. If more than one technique is planned in the case series, all treatment techniques should be clearly outlined so they can be replicated. Adding volume of treatment, dosage of treatment techniques, and patient education provided will enhance the case series' impact on clinical practice (Fleischmann and Vaughan 2019). Avoid using phrases such as "treatment was applied at practitioner discretion" without providing specific detail about the technique (s), as this does little to aid clinicians in identifying exactly which technique(s) were used.

7. A rationale for sample size

The size of a case series can range from two cases to hundreds or even thousands (Carey and Boden 2003). When considering how many patients are needed (sample size) in the case series, consider the prevalence of the pathology/condition and the sociodemographic characteristics of the most affected populations, and the context of the

clinical setting. For example, if the case series is observing patients with back pain – which has a high prevalence (Wu et al, 2020) - consider including more than two patients from one locale. For example, a clinician may aim to recruit 10 patients from various sociodemographic settings to provide an opportunity to observe patient outcomes in different settings. Given the higher prevalence of back pain, it is possible these patients may present to the clinician more often, thus providing an opportunity to study a population that is feasible. Consideration should also be given to whether patients who have the same characteristics will be included so other health professionals using the same techniques can compare their own clinical decision making.

8. Detail about the use of validated and reliable outcome measures

Given a case series is useful for detailing patient treatment outcomes, it is imperative that validated and commonly used patient-reported outcome measures (PROMs) are used (Fleischmann and Vaughan 2018). The choice of outcome measure should be guided by the outcome of interest. For example, if the Population (P in the PICO framework) of interest is patients with chronic neck pain, the Neck Disability Index would be a reasonable choice (MacDermid et al., 2009). In clinical practice, there are numerous PROMs and other functional measures available to the clinician that can be used in a case series. Examples of PROMs and other functional measures include: 'non-specific measures' such as the Patient Specific Functional Scale (Horn et al., 2012); 'screening measures' such as Orebro Musculoskeletal Pain Screening Questionnaire (Maher and Grotle 2009) and the Keele STarT Back Screening Tool (Robinson and Dagfinrud 2017); 'Functional tests' such as Timed Up and Go (TUG) (Herman et al., 2011) and the 10 Metre Walk Test (Kempen et al., 2011); 'Psychological measures' such as the Depression, Anxiety and Stress Scale 42 Item (DASS-42) (Imam 2008); and 'Quality of Life measures' such as the Short Form 36 (SF-36) (Ware Jr 2000).

Clearly documenting which outcome measures and patient reported outcome measures are planned is crucial for detailing study outcomes (Fleischmann and Vaughan 2018). It is suggested that at least one outcome measure should be used to evaluate each of quality of life (QoL), functional status, symptoms and symptom burden and patient experience. Any changes shown on outcome measures are important to demonstrate a difference large enough to have an impact on the patient's treatment (Wyrwich and Tardino 2006).

Justification about timing of measurement of outcomes should be provided and where possible, based on prior research. The length of observation and the intervals between clinical observations should be standardised between patients, and of sufficient duration to be clinically meaningful. For example, after an intervention, patients may feel better, but the duration of improvement is sometimes relatively short, for example in low back pain, pelvic girdle pain and neck pain (Franke et al, 2014; Franke et al, 2015; Franke et al., 2017), thus decreasing its clinical impact.

9. An exploration of the patient perspective

Seeking feedback from patients who participated in the case series may serve several purposes including: developing further research hypotheses; gathering complementary information to contribute to answering research questions; help to explain findings from observations made; and identify whether interventions can and should be implemented. Methods to gather feedback about patient experience may include, individual interviews, focus groups, open ended questions on surveys or providing patients with a standardised questionnaire, such as the Generic Short Patient Experiences Questionnaire (GS-PEQ) (Sjetne et al., 2011).

Further, gathering feedback about the patient's experience of the case series can assist clinicians with exploring what the results of the interventions were (outcome), how the interventions were experienced (process), how the process of intervention was seen as leading or not leading to outcomes (progress), and how patients and the clinician interacted (communication) (Chenail 2011).

10. Use of appropriate statistical analyses

Case series designs require reporting of descriptive statistics, which can be useful for two purposes: (1) to provide basic information about variables in a dataset; and (2) to highlight potential relationships between variables. Statistical tests yielding P values or confidence intervals are not needed and in most cases are inappropriate as case series do not aim to measure causality.

Measures of central tendency are descriptive and the most basic, and often, the most informative description of a population's characteristics. These statistics describe the 'average' of the population or variable of interest. There are three measures of central tendency: mean - the sum of a variable's values divided by the total number of values; median - the middle value (when data is ordered highest to lowest) of a variable; and mode - the value that occurs most often in a group of numbers.

When reporting mean values, it is standard practice to report the standard deviation. Standard deviation is a statistic that measures the dispersion of a dataset relative to its mean. Low standard deviation values indicate data are clustered around the mean, and high standard deviation indicates data are more spread out.

When presenting median values, it is standard practice to report medians and interquartile ranges (IQR), or the range of values that include the middle 50% of the data. The interquartile range is the difference between the upper quartile and the lower quartile. The IQR is a useful measurement because it is less influenced by extreme values as it limits the range to the middle 50% of the values.

Typically, the mode is reported when describing categorical, ordinal, and discrete data. It is the only measure of central tendency that can be used with categorical data—such as the most preferred physical examination procedure to administer for neck pain. However, with categorical data, there is no central value because groups cannot be ordered. With ordinal and discrete data, the mode can be a value that is not in the centre. Again, the mode represents the most common value.

11. A clear description of results

As noted above, the case series should utilise only validated outcome measures and the results from these should be reported. If the data set includes all information from several patient reported outcome measures, it would be unusual to report all the scores in the results sections – rather provide total and/or subscale scores as appropriate.

It is important to note, one of the reasons to provide descriptive statistics such as means and standard deviation and scores from outcome measure is to condense large amounts of information into a more manageable dataset for the reader. Presenting the entire data set defeats this purpose. When citing several statistics about the same topic, it may be best to include them all in the same paragraph or section. If there is high volume of analysis to report, strongly consider presenting this in tables or charts, then highlight statistics of interest within the text, but do not report all statistics. Consider providing a supplementary file with all statistics which draws attention to the key findings.

Mean and standard deviation are most clearly presented in parentheses. For example, suppose average age was calculated as 29 years of age, with a standard deviation of 3. This should be written as Mean 29 years (SD = 3). Medians and interquartile ranges are most clearly presented in parentheses. For example, using the same hypothetical average of 29 years of age, but this time the interquartile (IQR) range was provided and was 23–35. This would be written as Median 29 (IQR 23, 35) years old. Modes are not commonly reported; however, the mode might be used in examples when reporting the most used technique or outcome measure.

In addition, adequacy of follow-up should be described. This includes the number of patients who were lost to follow-up, number of patients who decided to consult another healthcare provider and patients who discontinued treatment. As an example, a case series of patients treated for 'XX headache' should indicate the number of patients evaluated with 'XX headache' in clinical practice, the proportion who received specific treatment as outlined by the researchers, the number of patients who were lost to follow-up, and the reasons for loss to follow-up.

12. A discussion/conclusion supported by the data

The conclusion should be supported by the data in the article. Conclusions about treatment effectiveness should not be made as case series do not examine causal relationships. Supporting information and links to literature should be made as frequently as possible. Limitations should be made explicit and discussion as to why the limitations existed, and what was done to mitigate them, should be included. Consideration should be given to the natural history of the pathology/condition, the potential that the exposure preceded the outcome, and whether the outcome may be a random finding and not a normal characteristic of the disease.

Given case series studies are often hypothesis generating (Dekkers et al., 2012), the final paragraph(s) should provide a hypothesis, or recommendation for future work. Clinicians should discuss how hypotheses could be tested in future studies. Stating "more research is needed" adds little to any evolving topic area. The more specific the recommendations for the next steps in the research area, the better. Recommendations for future work could include how the methodology and findings used may impact future research and clinical practice, and the alternative research designs are best suited to address the research question.

13. Detail about any conflicts of interest

There are a broad range of research-related activities that may be a conflict of interest and its possible clinicians will have one or more. A conflict of interest in research exists where an individual may preference, or be perceived to preference, their own interests over their responsibilities as a clinician-researcher. The existence of a conflict does not imply wrongdoing and in some cases is unavoidable (Romain 2015). Rather, declaring conflicts of interest may maintain the integrity and reliability of the conduct and outcomes of research by mitigating the risks associated with relationships between clinicians and organisations, and may increase public trust in individuals involved in research (Smith 1998).

Disclosure of conflicts of interest to clinicians, funding bodies, research participants, publishers, and journal editors may be required. Financial, personal, familial, professional, and organisational interests need to be considered and disclosed at the time of submission to a journal or dissemination of results from the case series – for example when presenting findings at a conference.

Financial interests requiring disclosure include the following examples: direct payments to the clinician; indirect payments to the clinician, for example funding of travel and accommodation; payments to support research, such as funding from an industry or interest group. For example, if shockwave therapy is proposed as the intervention for the case series, a potential conflict might arise with the manufacturer who provided the device for free or at a reduced cost.

The table below (Table 2) is a proposed checklist for clinicians to consider when developing a case series study.

Table 2
Checklist for a case series[a].

Checklist item	Yes	No	N/A	Page #	Comments
Design:					
A clear rationale for the study is provided	☐	☐			
The research question is clearly defined	☐	☐			
The inclusion and exclusion criteria for the population is clearly defined	☐	☐			
The clinical setting is described	☐	☐			
Valid methods are used for the identification of the pathology/condition for all participants	☐	☐			
Intervention:					
The technique provided to patients is clearly described	☐	☐			
All techniques of the treatment provided to patients are clearly described *(Case series involving more than one technique)*	☐	☐	☐		
Participants:					
The case series has consecutive inclusion of participants	☐	☐			
There is clear reporting of the demographics of the participants	☐	☐			
There is clear reporting of clinical information of the participants	☐	☐			
The patient perspective is included	☐	☐			
Outcomes:					
Validated outcome measures are used	☐	☐			
Values from outcome measures are clearly presented	☐	☐			
Discussion/Conclusion:					
Appropriate statistical data is reported	☐	☐			
The discussion and conclusion are supported by the results	☐	☐			
Conflicts of interest are described	☐	☐	☐		

[a] Adapted from Moola et al. (2017).

14. Conclusion

Clinical guideline developers and decision-makers often struggle when dealing with results from case series as they are considered lower-level evidence. Additionally, non-surgical clinicians may feel conflicted when there is no high-level evidence to substantiate or inform their decision making in their day-to-day practice. Case series present an opportunity to generate further research questions about effectiveness of an intervention(s) for clinical practice through a pragmatic lens and may assist with exploring what occurs in clinical practice. In this guide, we propose an approach to develop robust case series studies and provide a checklist to evaluate the methodological quality of case series studies. It is hoped this guide provides a clearer understanding of what a clinician should address when designing, undertaking, and writing a case series for non-surgical interventions. Further, we encourage debate about the characteristics of quality case series studies for non-surgical interventions, including refinement of the proposed checklist.

Ethics approval and consent to participate

No ethics approval was required for this manuscript.

Consent for publication

Consent has been given to publish this works.

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Availability of data and materials

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CRediT authorship contribution statement

Michael Fleischmann: Writing – review & editing, Writing – original draft, Methodology, Conceptualization. **Pat McLaughlin:** Writing – review & editing, Writing – original draft, Methodology. **Brett Vaughan:** Writing – review & editing, Writing – original draft, Methodology. **Alan Hayes:** Writing – review & editing, Writing – original draft, Methodology.

Declaration of competing interest

All authors declare there are no conflicts of interest.

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