

Guidelines for reporting evaluations based on observational methodology

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Abstract

Background: Observational methodology is one of the most suitable research designs for evaluating fidelity of implementation, especially in complex interventions. However, the conduct and reporting of observational studies is hampered by the absence of specific guidelines, such as those that exist for other evaluation designs. This lack of specific guidance poses a threat to the quality and transparency of these studies and also constitutes a considerable publication hurdle. The aim of this study thus was to draw up a set of proposed guidelines for reporting evaluations based on observational methodology. **Method:** The guidelines were developed by triangulating three sources of information: observational studies performed in different fields by experts in observational methodology, reporting guidelines for general studies and studies with similar designs to observational studies, and proposals from experts in observational methodology at scientific meetings. **Results:** We produced a list of guidelines grouped into three domains: intervention and expected outcomes, methods, and results. **Conclusions:** The result is a useful, carefully crafted set of simple guidelines for conducting and reporting observational studies in the field of program evaluation.

Keywords: Program evaluation, observational methodology, designs, low intervention, reporting guidelines.

Resumen

Directrices para publicar evaluaciones basadas en metodología observacional. Antecedentes: la metodología observacional es una de las más apropiadas para la evaluación de la fidelidad de la implementación, especialmente en el caso de intervenciones complejas. Sin embargo, a diferencia de lo que ocurre con otros diseños evaluativos, en este caso no existe una guía que delimite los componentes necesarios a incluir en el reporte de estudios observacionales, con lo que su divulgación, transparencia y calidad podrían quedar mermadas. El objetivo de este trabajo es proponer un protocolo específico para el reporte de estudios evaluativos basados en la metodología observacional. **Método:** la idoneidad del protocolo propuesto se basa en información procedente de estudios observacionales en distintos ámbitos realizados por expertos consolidados en metodología observacional; guías generales para cualquier tipo de diseño y específicas para diseños similares a los observacionales; y propuestas de expertos recibidas en reuniones científicas. **Resultados:** se obtuvieron elementos a considerar para realizar un informe de metodología observacional, encuadrados en tres dominios: intervención y resultados esperados, método y resultados. **Conclusiones:** se presenta un protocolo útil y parsimonioso para el desarrollo y elaboración de reportes de evaluación de programas con metodología observacional.

Palabras clave: evaluación de programas, metodología observacional, diseños, baja intervención, directrices para la comunicación.

Evaluating a program requires taking evidence-based decisions, and there is an increasing call for evidence that not only focuses on the questions “What works?” and “What is the effect size?” but also seeks to explain how or why a particular program works in a particular context (Wong, Greenhalgh, Westhorp, Buckingham, & Pawson, 2013).

When observational designs based on observational methodology are used as a basis for decision-making in program evaluation, priority is given to collecting information on the behavior(s) of interest in a context of minimum intervention (Anguera, 2008; Chacón-Moscoso, Sanduvete-Chaves, Portell, &

Anguera, 2013). Observational designs complement other program evaluation designs and offer several advantages:

(1) They build evidence through the close monitoring of behavior in context, providing descriptions of moment-by-moment changes and offering the possibility of drawing causal inferences based on regularities within causality models such as Mackie’s INUS model (cf. Tacq, 2011).

(2) They prioritize the contextual representativeness of the data set (Anguera, 2003).

(3) They relinquish control over the experimental (high-intervention) or quasi-experimental (moderate-intervention) setting and minimize intervention by stakeholders other than program users or those close to them (Chacón-Moscoso et al., 2013).

(4) They are ideal for evaluating implementation fidelity (Dusenbury, Brannigan, Falco, & Hansen, 2003), which is the extent to which a program is delivered as intended (Durlak & Dupre, 2008). Implementation fidelity assessment is essential for

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determining how and why a program works and for providing evidence on adherence to theoretically important components, such as completeness and dosage of implementation (e.g., number of sessions, duration, intensity); quality of program delivery (e.g., quality of interaction in the case of a teacher implementing a program); degree of participant engagement; aspects of program differentiation (Dusenbury et al., 2003); and fidelity of translation (adaptation of programs to the local context) (Lara et al., 2011).

(5) They are useful for evaluating complex interventions with various interacting components (Griffiths & Norman, 2013).

(6) They provide methodological solutions for obtaining quality data in the absence of standardized evaluation tools (Anguera, 2003).

Observational designs are well established in several fields, such as sport (Anguera & Hernández-Mendo, 2014), and their usefulness has been demonstrated in many others (e.g., Blanco, Sastre, & Escolano, 2010; Cerezo, Trenado, & Pons-Salvador, 2006; Gimeno, Anguera, Berzosa, & Ramírez, 2006; Herrero, 2000; Herrero & Pleguezuelos, 2008; Pérez-Tejera, Valera, & Anguera, 2011; Riberas & Losada, 2000; Roustan, Izquierdo, & Anguera, 2013). Nevertheless, there have been claims that little value is given to the extra effort expended in studies involving the direct observation of behavior (Patterson, 2008), and that it can be difficult to publish or procure funding for research on complex processes in natural settings, as this requires a shift from a standard of rigor based on experimental paradigms towards an approach favoring relevance (Rozin, 2009).

The application of reporting guidelines on observational studies would improve the completeness and transparency of reports and increase the chances of publication (Moher, Schulz, Simera, & Altman, 2010).

On reviewing the collection of reporting guidelines in the EQUATOR (Enhancing the Quality and Transparency of Health Research) Library for Health Research Reporting (Simera, Moher, Hoey, Schulz, & Altman, 2010; updated tables, 23 August 2013), we found numerous guidelines suited to moderate- and high-intervention evaluation designs, such as the CONSORT Statement for randomized clinical trials (Schulz, Altman, Moher, & CONSORT Group, 2010). We also found guidelines for methods with some similarities to observational designs because they deal with intensive repeated measurements in naturalistic settings (Stone & Shiffman, 2002), qualitative aspects (Blignault & Ritchie, 2009; Tong, Sainsbury, & Craig, 2007), or mixed methods research (Leech & Onwuegbuzie, 2010; Pluye, Gagnon, Griffiths, & Johnson-Lafleur, 2009). There were, however, no specific guidelines suited to the structural characteristics of observational methodology designs used for evaluation in low-intervention situations. The well-known STROBE (STrengthening the Reporting of Observational Studies in Epidemiology) guidelines (von Elm et al., 2007) are used for epidemiological studies such as cohort, case-control, and cross-sectional studies, and as such, are not suited to observational designs as we define them.

We believe that the lack of reporting guidelines specifically addressing evaluation studies based on observational methodology may constitute a publication hurdle, and that adherence to reporting guidelines created for other types of studies only serves to amplify the weaknesses and undermine the strengths of observational studies. The aim of this paper is to describe a set of guidelines we propose for specifically reporting evaluations based on observational methodology.

Method

To develop the proposed guidelines for reporting observational studies in the field of program evaluation, we drew on the experience of experts in the field of observational methodology and analyzed a wide range of studies that have used this methodology in different situations and contexts. We also reviewed the content and structure of (a) general reporting standards (i.e., standards that are not specific to any particular research design) (American Educational Research Association, 2006; American Psychological Association —APA—, 2010 —Journal Article Reporting Standards (JARS)—; Möhler, Bartoszek, Köpke, & Meyer, 2012; Zaza et al., 2000) and (b) reporting standards for research designs with some similarities to observational designs (Blignault & Ritchie, 2009; Leech & Onwuegbuzie, 2010; Pluye et al., 2009; Stone & Shiffman, 2002; Tong et al., 2007). Three drafts of the proposed guidelines were discussed (the first in 2011) by experts in methodological quality and observational designs at congresses of the Spanish Association of Methodology in Behavioral Sciences (AEMCCO) and the European Association of Methodology (EAM).

The main criteria underlying our guidelines are sufficiency of warrants and transparency of reporting (American Educational Research Association, 2006) to promote the presentation of sufficient, accurate, and transparent information that will enable other researchers to critically appraise and replicate the methodology used (Moher et al., 2010). The validity framework of our work was based on Chacón-Moscoso, Anguera, Sanduvete-Chaves, and Sánchez-Martín (2014).

Results

Table 1 summarizes the Guidelines for Reporting Evaluations based on Observational Methodology (GREOM), which contains 14 guidelines grouped into three domains. We deliberately omitted indications that are common to all types of evaluation designs (e.g., ethical considerations) and recommend referral to the JARS (APA, 2010) for guidance on these aspects. Below we provide a more detailed explanation of our proposed guidelines.

Domain A: Intervention and expected outcomes

(1) *Fitting intervention-observational method.* The aims related to this guideline are to describe the intensity of the intervention (low, moderate, or high) and justify the use of observational methodology (i.e., rationale and benefits) in the given study. Observational designs applied to program evaluation are usually associated with low-intensity programs (Anguera, 2008). They are used in situations in which a program, or part of it, is implemented (without the manipulation of specific orders or instructions) in an everyday context in which users continue with their daily activities or in which new (but non-disruptive) activities are generated. Manipulation of variables does not form part of observational methodology. Observational design elements, however, can be incorporated into moderate or high-intensity programs, but in all cases, access must be provided to a description of the intervention and its theoretical background and supporting evidence (Craig et al., 2013; Möhler et al., 2012).

(2) *Outcomes.* The structure of the expected outcomes has to be described and justified (Schünemann, Oxman, & Fretheim, 2006). This requires justification of the response levels chosen

Table 1
Guidelines for Reporting Evaluations based on Observational Methodology (GREOM)

Guideline number	Description
Domain A: Intervention and expected outcomes	
1. Fitting intervention-observational method	Justify choice of observational method in the context of the intervention (low-, moderate-, or high-intensity)
2. Outcomes	Describe structure of the expected outcomes in relation to program components and clarify link between outcomes and specific study measures. Justify choice of response level(s)
Domain B: Method	
3. Design	Describe study design using the extensive/intensive sub-criterion (Figure 1). Check consistency between study design and information related to guidelines 2 and 7
B1: Samples	
4. Study units	Indicate study units (participants, groups, response levels, etc.), eligibility and exclusion criteria, participant selection criteria, intended and actual sample size, and participant characteristics
5. Times	Indicate number of sessions. Specify criteria for starting/ending a session. Describe method used for within-session sampling and, in the case of follow-up designs, between-session sampling
6. Contexts	Describe attributes of research context in relation to its applicability to other contexts. Define context and setting selection criteria
B2: Instruments	
7. Observation instrument	Describe observation instrument and rationale behind its structure. Provide access to observation instrument
8. Primary recording parameters	Indicate recording units used for each code (occurrence, position within a sequence, duration). Specify type of behavioral indicator: static (e.g., frequency and duration) and, where applicable, dynamic (e.g., frequency of transition or indicators related to the sequential structure of behavior and/or the detection of T-patterns)
9. Recording instrument	Describe recording instruments and procedures
B3: Data quality control	
10. Session acceptance criteria	Specify factors taken into account to justify within- and between-session consistency and maximum allowable time-related disruptions for each session
11. Observer characteristics	Describe any observer characteristics that might have influenced observations (e.g., training/competence) and indicate relationship between the observer and the person being observed
12. Reliability	Demonstrate reliability of data set and give details of coefficient of agreement and, where applicable, generalizability theory used
Domain C: Results	
13. Flow of study units	Show flow of participants throughout the study and include information on response levels and, where appropriate, within and/or between-session monitoring
14. Analyses	Explain rationale for analyses of associations between overall measures and/or analyses aimed at identifying response patterns (e.g., lag sequential analysis, T-pattern detection and polar coordinate analysis). Specify the software used
Note. These guidelines are complementary to the Journal Articles Reporting Standards (JARS, American Psychological Association, 2010)	

(perceivable components of the target behavior), which should be guided by the literature or created *ex novo* based on experience accumulated in the relevant context (Anguera, 2008). This information will help the reader to identify the most meaningful outcome(s) for decision-makers (Green & Glasgow, 2006) and establish a link between these outcomes and the specific measures that will be obtained with the observational study.

Domain B: Method

(3) *Design*. The study design must be clearly described. In observational methodology, the term *design* refers not only to what units are going to be observed and when, but also to how the data are going to be collected, organized, and analyzed (Anguera, 2008). Figure 1 shows the three dichotomous criteria that give rise to eight possible observational designs (Anguera, Blanco, & Losada, 2001). The first criterion relates to level of response or dimensionality and differentiates between unidimensional and multidimensional designs (single vs multiple levels of response). The second criterion relates to number of units and differentiates between idiographic studies, which focus on a single user or a

natural group of users (e.g., a family) and nomothetic studies, which focus on groups of users. The third criterion relates to time and differentiates between single-session (point) studies and multiple-session (follow-up) studies. We recommend complementing the description of the design with a fourth criterion related to sequential data (Figure 1). This criterion distinguishes between extensive studies (focusing on static behavioral indicators, such as frequency or duration) and intensive studies (focusing on dynamic behavioral indicators or sequential data, such as frequency of transition, relative frequency of transition, or detection of T-patterns).

B1: Samples. In observational studies, it is essential to distinguish between three samples: units, times, and context.

(4) Information must be provided on the *study units* (participants, groups, response levels, or other units), the inclusion and exclusion criteria used, and the participants' characteristics (Lapresa, Álvarez, Anguera, Arana, & Garzón, 2015). Details should be given on the intended and actual sample size, including information on individuals who refuse to participate or withdraw from the study (APA, 2010; Pluye et al., 2009).

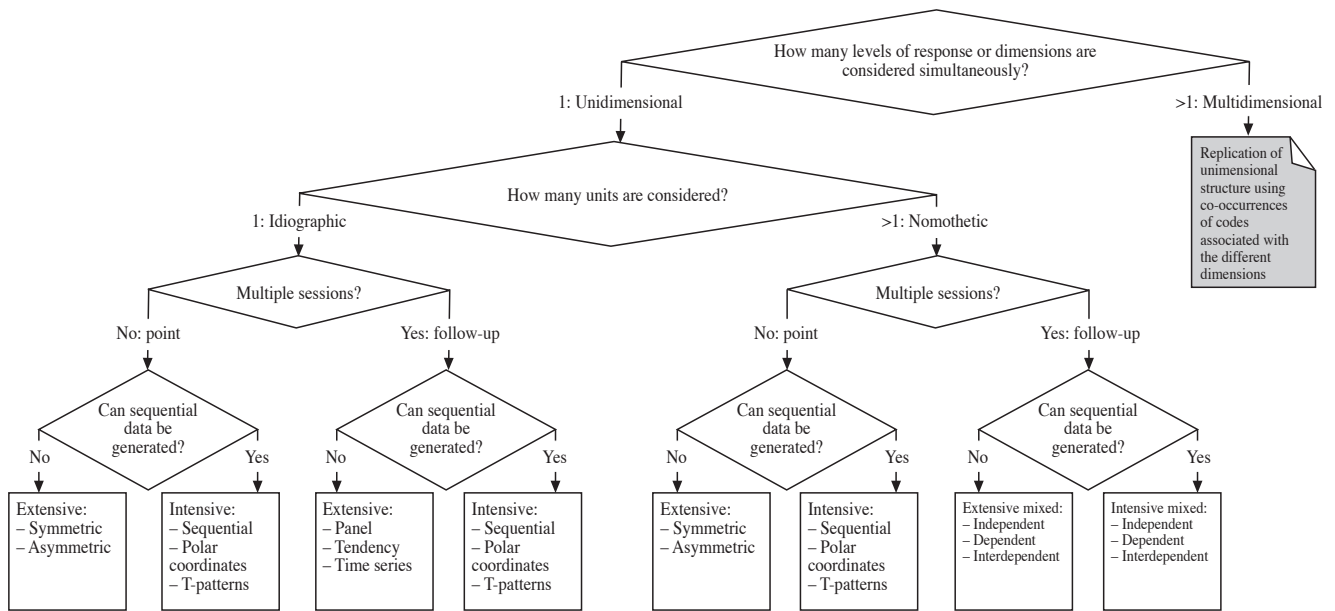


Figure 1. Identification of observational designs. The extensive / intensive sub-criterion complements the basic observational design taxonomy that distinguish between eight designs: (1) Point/Idiographic/Unidimensional; (2) Point/Nomothetic/Unidimensional; (3) Follow-up/Idiographic/Unidimensional; (4) Follow-up/Nomothetic/Unidimensional; (5) Point/Idiographic/Multidimensional; (6) Point/Nomothetic/Multidimensional; (7) Follow-up/Idiographic/Multidimensional; (8) Follow-up/Nomothetic/Multidimensional

(5) *Times*. The study report must include clear information on what moments of a session are observed and for how long (within-session sampling). Observational studies with a follow-up design can provide what Moskowitz, Russell, Sadikaj, and Sutton (2009) call *intensive repeated measures in naturalistic settings*. In this case, it is important to describe the between-session sampling method (number of sessions and criteria for starting/ending each session). The best way of obtaining representative between-session samples is through random sampling (Stone & Shiffman, 2002), and new technologies offer interesting resources for performing non-participative observational studies with randomized inter-session sampling (e.g., Mehl & Robbins, 2012).

(6) *Contexts*. It is essential to describe the context in which the data are recorded, with coverage of demographic, socioeconomic and cultural aspects, to justify the criteria used to choose this context and explain similarities between the study context and the context of interest. According to Pawson, Greenhalgh, Harvey, and Walshe (2005), evaluative research should answer the following questions “WHAT is it about this kind of intervention that works, for WHOM, in what CIRCUMSTANCES, in what RESPECTS, and WHY?” (p. S1:31). Such an approach places context in a central role and highlights the importance of the concept “mechanism”, which is defined as the underlying processes operating in a particular context to generate outcomes of interest (Wong et al., 2013). Observational methodology includes techniques and procedures designed to capture these mechanisms in daily interactions between stakeholders (Anguera, 1999).

B2: Instruments. A transparent report will include information on the observation and recording instruments used and on the primary recording parameters.

(7) *Observation instrument*. The aim here is to justify the use of the observation tool (explain why it is suited to the goals of the

study) and provide the reader with access to the full coding manual (e.g., in an appendix or as supplemental material). Observational methodology prioritizes the use of observation instruments that are fully adapted to the context of interest, and this generally requires the design of ad hoc tools (Anguera, 2003). The category system is the basic tool used in observational methodology, but the field format system is being increasingly used (Anguera, Magnusson, & Jonsson, 2007) to meet the needs of multidimensional designs.

(8) *Primary recording parameters*. When a report deals with observations made by humans (as opposed to automatic devices) using categorical codes, it is essential to clearly specify the recording units used (Anguera, 2008). For each code, the observer can record their occurrence, their position within a sequence, and/or their duration. The type of recording unit used will determine the type of behavioral indicator that the data set will produce. It is important to specify whether the study deals only with static behavioral indicators (frequency and duration) or also with dynamic indicators (e.g., frequency of transition, relative frequency of transition, or other indicators related to the sequential structure of behavior and/or the detection of T-patterns) (Bakeman & Quera, 2011; Casarrubea et al., 2015).

(9) *Recording instrument*. The study report must contain a description of the tools (software, etc.) and the procedures used to record the data. Several open-source software applications are now available that greatly simplify the recording of observational data. Two examples are LINCÉ (Gabin, Camerino, Anguera, & Castañer, 2012) and HOISAN (Hernández-Mendo, López-López, Castellano, Morales-Sánchez, & Pastrana, 2012).

B3: Data quality control. The data set can only be analyzed for the intended purpose once its quality has been established (Anguera, 2003). Researchers therefore need to report on how they controlled for factors that might affect the quality of the data set

by describing session acceptance criteria, observer characteristics, and reliability analyses.

(10) *Session acceptance criteria.* It is important to indicate the factors taken into account to justify within and between-session consistency and the maximum allowable time-related disruptions established for each session (Anguera, 1990).

(11) *Observer characteristics.* The relationship between the observer and the person being observed is one of the most important aspects that need to be described when characterizing the observer. It is essential to identify the observer within the hierarchy of stakeholders and describe the type of observation (participative, non-participative, participation-observation, or self-observation) (Anguera, 1979). Finally, information should be given on observer training and competence (Losada & Manolov, 2015).

(12) *Reliability.* An instrument is reliable if it produces few measurement errors and demonstrates stability, consistency, and dependency across individual scores (Blanco, 1989). Data set reliability can be analyzed qualitatively (e.g., the consensus agreement method; Anguera, 1990) or quantitatively. Interobserver agreement indices are the most widely used quantitative measures of reliability in observation studies. Additionally, the generalizability theory can be used to analyze multiple sources of variance (observers, occasions, tools, etc.) simultaneously (Blanco, 2001). These analyses can be performed using SAGT (Software for the Application of the Generalizability Theory) (Hernández-Mendo et al., 2014).

Domain C: Results

(13) *Flow of study units.* The study flow chart should depict the flow of participants throughout the study (including information on discontinuations and withdrawals), in addition to response levels and, where appropriate, the times at which these were studied within and between sessions.

(14) *Analyses.* The logic of observational methodology combines qualitative perspectives (more common in the early stages of a study) and quantitative perspectives (more common at later stages) (Portell, Anguera, Hernández-Mendo, & Jonsson, 2015; Sánchez-Algarra & Anguera, 2013). Accordingly, many JARS (APA, 2010) recommendations for the reporting of quantitative studies also apply here. The purpose in this guideline is to highlight aspects that are specific to evaluation studies based on observational designs. Thus, it is essential to differentiate between and justify analyses of relationships between overall measures and analyses designed to identify response patterns. The options available for analyzing observational data vary according to the study design and the nature of the data (Blanco, Losada, & Anguera, 2003). Sequential analysis is particularly relevant in observational methodology because it can uncover “hidden” response patterns and help to better understand the mechanisms involved in an intervention. Sequential techniques include lag sequential analysis (Bakeman & Quera, 2011), T-pattern detection (Magnusson, 2000), and polar coordinate analysis (Sackett, 1980). Both the rationale behind the

analyses chosen and the software used should be specified. Open-source programs include GSEQ (Bakeman & Quera, 2011) for lag sequential analysis, Theme (Magnusson, 2000) for T-pattern detection, and HOISAN (Hernández-Mendo et al., 2012) for polar coordinate analysis.

Discussion

From a perspective that advocates methodological complementarity (Chacón-Moscoco et al., 2013, 2014), we have proposed a set of simple guidelines for conducting and reporting evaluations based on observational methodology that we hope will become a standard tool for researchers and practitioners. We believe that this step was necessary to increase awareness of the contribution of observational methodology to program evaluation, to improve the completeness and transparency of reports, and to increase the chances of publication.

Our proposal requires the inclusion of information that is not traditionally reported (e.g., the full coding manual). Reporting transparency has been limited by space constraints in journals for many years, but this is no longer a problem in many journals thanks to online supplements.

Finally, we would like to stress that our proposed GREOM guidelines constitute an initial step in a process that we hope will be enriched by contributions from other experts and studies that provide empirical evidence on the usefulness of these guidelines.

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