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RMJ Research Series – Using a Reporting Guideline (Checklist)

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Case study

You have recently completed a research project. During this process, you may have already invested considerable amounts of time in undertaking adequate literature searching, writing a methodology for ethical approval, collecting data, conducting analysis and writing up your results in the form of a manuscript for submission to a peer-reviewed journal such as the RMJ [1]–[4]. After submitting your paper, you receive a rejection letter from the journal. The peer-reviewer describes "poor methodology."

As a researcher and author, this is disheartening but also requires some consideration. The question to reflect on is "did I perform a bad study" or rather, "did I describe my study badly"? You wonder if there was any way that you could have written your manuscript more completely?

My story - Dr Christian Nsanzabaganwa

When undertaking my research as a final year medical student, I had no idea how to start, what to start with and where to search for information. The research journey was a new one for me. At every step I had to go and learn how to develop it and come back and practice at the same time while writing the proposal.

Writing up my dissertation was challenging. Being a native Rwandan, I had to write in English (my second language) and the most difficult aspect was to read, understand and summarize the project in my own words. My university didn't require that we submit our projects for publication, but I wanted to learn this skill. Writing up research for publication was a challenge, especially for the first time in a second language. Having a checklist, along with good supervision and perseverance helped me to write a complete manuscript which was accepted for publication. I was new to research and so I didn't know what I should and shouldn't include in the manuscript. Having a checklist was a big help to ensure that I gave a full description of the project.

INTRODUCTION

Why are standards of reporting research important

Human research is entirely dependent on the co-operation of participants who expose themselves to the risks involved in the study [5,6]. These risks are ethically justified because of the understanding that society will eventually benefit from the knowledge gained from the study. Researchers, therefore, have an ethical responsibility to report the results of research involving human subjects [7-9]. This could include but is not exclusive to, publication in a peer-reviewed journal.

The Declaration of Helsinki (2014) states that "Researchers, au-

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thors, sponsors, editors, and publishers all have ethical obligations with regard to the publication and dissemination of the results of research" [10].

Inadequate reporting of the research is also a significant problem, for several reasons; namely, readers are unable to fully judge the validity and reliability of the results and/or interpret them [11]. Good reporting does not replace poor methodology. Rather, sound methods and good reporting should go hand-in-hand.

The EQUATOR network (Enhancing the QUAlity and Transparency Of health Research) is hosted by the Centre for Statistics in Medicine (CSM), at the University of Oxford [12]. The EQUATOR network asks a series of pertinent questions; before you submit your paper to a journal, has the article achieved its purpose, namely:

- Would another researcher be able to replicate your study?
- Would someone undertaking a systematic review be able to scrutinize your study's methods to assess the risk of bias, identify key data etc.?
- Can numerical results be easily extracted from your paper?
- Have you provided enough detail about your intervention to allow its use in clinical practice?

This has led to the production of checklists called "Reporting guidelines." Reporting guidelines help researchers write up their research to maximize the value to others. Adherence to a reporting guideline will increase the transparency and completeness of health research publications, and thereby provide peer-reviewers and readers with sufficient details to enable them to critically appraise the study [11,13].

What are reporting checklists, how were they created, and who created them

Reporting guidelines are tools developed, methodically, by a group of experts that serve to enhance and facilitate the presentation and reporting of research results. These guidelines can be in the form of checklists, diagrams, or descriptive text. As stated by EQUATOR "A reporting guideline lists the minimum set of items (usually as a checklist) that should be included in a research report to provide a clear and transparent account of what was done and what was found" [11].

Guidelines for reporting began to emerge in the mid-1990s as various leaders in academic medicine had realized the lack of rigor in reporting and joined forces to establish guidelines to improve quality. Generally, these steering committees performed a significant literature review and other pre-work, hosted a conference where experts met to create guidelines, conducted a trial of the guidelines, and subsequently published the fruits of their labor. Below, we inform you of the details regarding this process for the key guidelines.

Which checklist should I use

The EQUATOR Network website (http://www.equatornetwork.org) contains a search feature that allows for the retrieval of specific guidelines [12]. It is important to note that new guidelines, updates of current guidelines, and extensions of guidelines are continuously in development. The EQUATOR Network lists some of these on the EQUATOR Network website, and updates and extensions are also available from the reporting guideline's website.

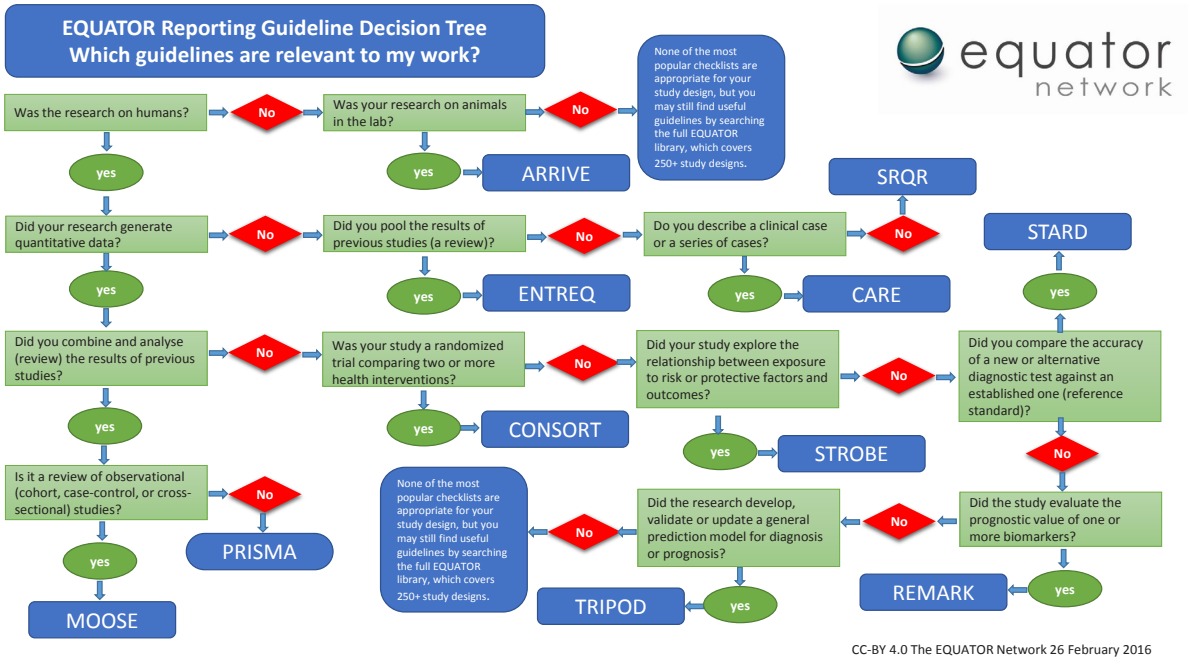

Figure: Decision tree for checklist [14,15]

Which checklists are most important to authors at the RMJ

Some of the most common study types reported in the Rwandan Medical Journal are case reports and cross-sectional studies.

- Case studies: For case reports and case series, the CARE (CAse REport) guideline is most applicable [16]. On the CARE website (www.CARE-statement.org), you can find a link to an online course through Scientific Writing in Health and Medicine (SWIHM) that will help you in writing a case report. Additionally, an Explanation and Elaboration article was published in 2017 that provides a detailed explanation and elaboration on the checklist items as well as helpful examples from published case reports [17].

- Cross-sectional studies: Guidelines for cross-sectional studies are covered within the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement [18,19]. A distinct checklist is available for cross-sectional studies and is available from the STROBE website (http://www.strobe-statement.org/). There are many extensions available on the EQUATOR Network website. An Explanation and Elaboration article also exists for the STROBE guidelines [18].

How to use a checklist

When you are writing a manuscript for submission to the RMJ, or other peer-reviewed journals, it is essential to refer to the appropriate checklist before submission (see the Which checklist should I use section above), and this may even be required by the journal to which you are submitting. If you are in the early stages of writing a research proposal you may find it helpful to refer to a checklist when developing the study as this may serve to ensure that all important aspects of a study are being considered before collecting data [11].

To access a guideline, you can visit the EQUATOR Network website (http://www.equatornetwork.org) where checklists for the major study types are available for download directly from the website. A link to the PubMed listing of the article (and guideline contained within) is available from the EQUATOR Network website as well as a reference to the article.

Potential pitfalls of reporting guidelines

While checklists have been shown to improve the quality of reporting, there are several factors that you should consider before employing a checklist or perhaps you have some of the following concerns already. First, you may find a checklist to be just another "box to check" and simply another time-consuming burden that has to be dealt with. It is important to remember that the guideline helps you in addition to the journal to which you are submitting. By improving the quality of your paper, peer-review will be more straightforward, you are likely to get greater respect and your paper may be cited more often and ultimately your findings will have more meaningful impact.

Also, it is important to note that completing a checklist does not mean that your manuscript is whole and complete. There may be other key items in your study that must be reported that are not in a checklist; thus, you must think critically about conveying all the necessary information. This brings us to another concern that has been voiced formally in the BMJ: checklists could result in the "tail wagging the dog" and thus your study could become more prescriptive, and the critical and creative component that you bring to your research may be lost [20]. It is important to keep these possibilities in mind while using a checklist.

Which checklists are currently available

The EQUATOR Network references 412 reporting guidelines at the time of this writing [12]. It is most likely, given the volume and scope of guidelines, that a reporting guideline exists for your mode of study. Indeed, reporting guidelines exist for the most common study types (randomized trials, observational studies, systematic reviews and meta-analyses, case reports, quality improvement studies) and for less-frequently used modes of study (such as reliability and agreement studies). Table 1 contains a description and the key items that pertain to guidelines for the most common study types.

STROBE: The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for observational studies was developed in Bristol, United Kingdom, in 2004 through the efforts of the STROBE Initiative group. Here, editors of such journals as BMJ, JAMA, Preventive Medicine, and The Lancet met with experts in epidemiology and statistics and draft checklists were created. The founders of the STROBE Initiative and additional researchers and numerous editors subsequently developed the final checklist and published this in 2007 [18,19].

CARE: The CARE (Case REport) guidelines were developed through a three-phase consensus process, consisting of a pre-meeting with the steering committee, followed by a consensus meeting in which 18 experts in case reports. The guidelines, and subsequently draft editing was performed by the steering committee followed by several rounds of feedback with the entire CARE group. These phases resulted in the CARE publication in 2013 [16].

CONSORT: The CONSORT (Consolidated Standards of Reporting Trials) Statement was born at a meeting in Chicago, IL, USA in 1995 from 9 members of both the SORT (Standard of Reporting Trials) group of researchers and the Asilomar Working Group [26]. A revision was performed in 2001, and as updates to this statement were required, 31 members of the CONSORT group met in Quebec in 2007 [21,27] . This group is comprised of "an international and eclectic group of clinical trialists, statisticians, epidemiologists, and biomedical editors" [21].

PRISMA: The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses), previously known as QUOROM (Quality of Reporting of Meta-analyses), guidelines were initially developed in 1996, also in Chicago, by the steering committee and a panel of thirty clinicians, epidemiologists, statisticians,

Reporting guideline name	Study type	Publication year(s)	Key elements	Additional comments
CONSORT [21]	Randomized trials	1996, 2001, 2010	25-item checklist, flow diagram	Focuses on the most common design type: individually randomized, two group, parallel trials. Extensions available for additional designs
STROBE [18], [19]	Observational studies	2007	22-item checklist	Cohort, case-control, and cross-sectional studies; extensions available for case-cohort studies, antimicrobial stewardship, others
PRISMA [22]	Systematic reviews and meta-analyses	1999, 2009	27-item checklist, flow diagram	PRISMA-P developed for systematic review protocols
CARE [16]	Case report	2013	13-item checklist	Online training in case report writing following CARE guidelines is available through Scientific Writing in Health and Medicine (SWIHM)
SRQR [23] and COREQ [24]	Qualitative research	2014	21-item checklist	COREQ (COnsolidated criteria for REporting Qualitative research) available for interviews and focus group reporting
SQUIRE [25]	Quality improvement	2008, 2015	18-item checklist	Additional Exploration and Elaboration document provides examples

and editors who were all intimately involved with metanalyses and their guidelines were initially published in 2000 [28]. Thereafter, a group of 29 medical editors, clinicians, review authors, and a consumer met in Ottawa, Canada in 2006 to update this work. The draft checklist that came as a result of this meeting was revised multiple times by those in attendance at the conference and those invited but unable to attend. The final version of the PRISMA guidelines was published in 2009 [22].

SQUIRE: The history of the development process of the Standards for Quality Improvement Reporting Excellence (SQUIRE) guidelines is complex. An initial draft of guidelines was created in 2005 by Frank Davidoff and Paul Batalden and was primarily based on the authors' personal experiences in quality improvement work [29].

The purpose of this work was to develop primary guidelines and to inspire public feedback. In 2007, 30 key stakeholders met to analyze and redraft the guidelines, and this work was followed by multiple cycles of improvement by 50 consultants. This work resulted in the first formal set of SQUIRE guidelines [29]. "SQUIRE 2.0" was developed after three years of work in multiple phases. These phases were characterized by focus groups and interviews with 29 researchers who had used the initial guidelines. The authors then discussed via conference calls with expert authors, reviewers, and improvement professionals. Finally, 44 authors of quality improvement studies used a draft version and provided feedback, the draft was also reviewed by 11 journal editors, and commentary was provided by 450 end users of a penultimate draft. This resulted in the publication of SQUIRE 2.0 in 2016 [25].

CONCLUSION

Reporting guidelines help increase the completeness, clarity, and transparency of research publications and increase the quality of the write-up. They help editors and readers judge the reliability of results and efficiently interpret, appraise and criticize them. While preparing your study and writing your manuscript, you should first define your study design and choose the relevant guidelines from the EQUATOR Network website. The guidelines should not be seen as limiting you as an author or as a prescription – they form the basis for preparing your manuscript, and your creativity and thought will combine with this to make for a rewarding publication.

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