

Replicating and publishing research in different countries and different settings: advice for authors

At *BMJ Quality and Safety*, we frequently receive manuscripts that in some way replicate prior research. For example, authors submit research seeking to validate previously published tools such as safety climate surveys, to measure the frequency of a known safety event or quality concern, or to test an existing intervention in new settings such as in different countries. This research is clearly important for stakeholders in the new setting concerned. However, a key question for us as editors is when such studies should be published in our journal, which has a broad and international remit, versus a national or more context-specific journal.

We seek to publish research from a wide variety of settings, and indeed would like to publish high quality work from a wider range of countries than we do at present. However, as for most international journals, we would not publish a study evaluating intervention 'X' or describing safety problem 'Y' in every country of the world or in every different setting. A key question is therefore the extent to which a replication study enhances our understanding of how an intervention works or the types of safety problems that occur, over and above earlier studies. This will determine the importance of such a paper for our international readership.

Replication of research findings is a critical step in most scientific endeavours. However, the role of replication in quality and safety research, and in implementation science, is perhaps less well explored. At this point, it may be helpful to consider the different types of replication and how these relate to our field. A recent concept analysis and meta-narrative review¹ identified three main types of replication studies: 1) repetition of a study as closely as possible to find out whether the findings of the index study hold true; 2) replication to 'extend' a prior study, such as to assess generalizability in a different population or using different data collection methods; and 3) replication to test a theory through the intentional use of different methods. According to this classification, testing the generalisability of a study's findings is therefore a type of replication, and perhaps the most common of the three in our field.

For example, this issue of *BMJ Quality and Safety* includes an example of this second type of replication study: a study that seeks to assess generalisability of previous research findings in a new context. In this paper, Rabelo da Silva and colleagues from the PICC-Brazil research group present a descriptive study of the patterns, appropriateness and outcomes associated with peripherally inserted central catheters (PICCs) in 16 Brazilian hospitals.² The study used the Michigan Appropriateness Guide for Intravenous Catheters (MAGIC) to assess appropriateness, an approach previously used in the USA³ and Canada.⁴ Complications such as deep vein thrombosis, central-line associated blood stream infection and line occlusion were prospectively recorded by trained staff at each hospital. The authors found that more than half (62.3%) of 12,725 PICCs were inappropriate according to the MAGIC criteria, most often due to multi-lumen lines being used inappropriately. Such inappropriate multi-lumen lines were also associated with greater odds of major complications (odds ratio 2.54). Despite being in the very different context of a developing nation with fewer resources, potentially different patient demographics, and likely different healthcare cultures and practices,⁵ the authors conclude that these findings were broadly similar to those previously reported in North America. For instance, 62.3% and 68.1% of PICCs were considered inappropriate in the Brazilian study and a comparable US study³ respectively. In both settings, the major drivers of inappropriate PICC use were also insertion of multi-lumen devices, and short-term use. Interestingly, the prevalence of complications such as thrombosis appears to be lower in the Brazilian study, a finding the authors do not discuss in detail but infer may be due to use of advanced tip location techniques in Brazil. The study also confirmed that MAGIC, previously applied only in high-income countries, could be operationalised and used in the same way in a lower resource setting. So while

demonstrating a similar frequency and major drivers of inappropriate PICC lines in this new context, the lower complication rates may point to potential for improvement elsewhere. The study also confirms that assessment criteria and data collection methods that were developed and used previously only in high income countries, can be applied in a lower income country with potential differences in resource and data availability.

Similarly, replication studies of interventions (as opposed to descriptive studies) may investigate whether a new context may change the impact of that intervention. Researchers in our field collect data and intervene in contexts that comprise complex sociotechnical systems. These can vary dramatically and cannot be controlled in the same way as laboratory and many psychology experiments. An intervention to improve patient safety, such as a checklist, is likely to have a different impact at different times in the same organisation, and perhaps even more so in different organizations. This is because of the different, idiosyncratic and largely unpredictable ways in which people, processes and the general contexts at different times and in different organizations interact with the intervention. Context will affect how each organisation implements the intervention and thereby how it affects processes and outcomes. These issues have led to important and ongoing efforts to determine the contextual factors that influence the quality and safety of care,⁶ and the outcomes of interventions in different organizations and settings,⁷ increasing our understanding how the implementation and impact of an intervention may be markedly different from organization to organization. Replication studies of this type may therefore contribute to our understanding of how the intervention works, precisely because of that different context. Drawing from this and moving forwards, what would we recommend to researchers seeking to replicate quality and safety studies in a different context?

First, it is important to be clear on what a study adds, over and above it being the first study on the subject in a given setting or country. This might include establishing findings or operationalising a method or approach in a very different setting, as in Rabelo da Silva and colleagues' paper, with the objective of adding to our understanding of the role of contextual factors. Specifically, papers need to outline exactly why the situation may be different in the new setting or country – and then how this may also apply to other similar settings, thus broadening the study's relevance beyond the one new setting studied. For example, differences might include: the approach to healthcare funding; the structure of the healthcare system; resource availability; and/or differences in patients' race, ethnicity, age, or comorbid illnesses. Published frameworks may be helpful when explicitly describing context, which should at least describe the key features of the new context as well as other characteristics that differ from those in earlier studies.⁸ Second, research in a new setting or country might add particular value if it clarifies how to successfully implement an intervention, perhaps by addressing a wide range of contextual factors, to help explain a possible difference in outcome.⁹ Applying these criteria to the study of Rabelo da Silva and colleagues, the context is defined by a lower income country with potentially fewer resources and data availability, which may change the pattern of inappropriate PICC use, its drivers and outcomes. However, more explicit information and data with regard to the local implementation would have been helpful to help explain the lower complication rate.

Third, as for any study, the research question or topic itself needs to be sufficiently important to merit publication. A number of factors may determine the importance of a topic or research question – we give some examples in the box. For example, in the case of Rabelo da Silva and colleagues' study, PICCs are both relatively common and associated with potentially serious yet preventable complications, representing an important patient safety issue.

In contrast, we often receive descriptive papers where the authors assume that simply replicating established methods in a different context is sufficient to warrant publication. For example, reporting local (or national) assessments of safety culture¹⁰ or safety attitudes¹¹ from different countries would not meet the criteria outlined above because it is not clear how such studies add to generalisable knowledge about, for example, the role of context. Such studies may certainly be of value for that country, and if so, are likely to be of interest to a national medical journal. Similarly, we have limited interest in publishing more large-scale chart review studies to assess adverse event rates in different countries.¹² Unless such studies otherwise advance the field by adding to our understanding of the measurement instruments, or elucidating the frequency of causes of understudied preventable events and their associated harms, we tend not to publish them in *BMJ Quality and Safety*. The results tend to have value primarily for readers from the country involved, rather than a broad international readership.

In conclusion, replicating research in different countries and different settings can play an important role in advancing knowledge about healthcare quality and safety. However, authors must be clear about the study's importance, how it adds to our understanding and knowledge, and be realistic about whether the study is of national or international interest and why. Doing this will aid authors in deciding where best to publish the work, aid readers in ascertaining the relevance of the work to their context, and most importantly, increase the likely impact of the work on patient care.

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Box: Examples of factors that help to make a research topic or question important.

The topic or question:

1. Is understudied:
 - Very few prior studies
 - Few studies in high volume clinical areas or common diseases
 - Conflicting studies so more research needed
 - Low quality research
 - Untested approach to measurement or improvement
2. Has not been studied from different perspectives:
 - Patients, families, and care partners
 - Healthcare professionals
 - Organizations
 - Payers/government
3. Has a large quantitative impact:
 - A relatively large number of patients
 - A common disease (coronary artery disease, colon cancer, breast cancer)
 - A clinical location with high patient volumes (operating room, primary care)
 - A frequent process of care (medication administration, handovers)
 - A common type of error (medication errors, surgical errors, diagnostic errors)
4. Addresses a concept that has wide impact (i.e., it may be relevant to the study of many diseases, error types or interventions):
 - Safety culture
 - Teamwork
 - Training and education
5. Is a rigorous, generalizable evaluation of efforts to improve quality and safety that:
 - explain why improvement efforts do or do not work
 - assess context for quality improvement
 - could evaluate a wide variety of interventions (computerized decision support, team training, bundles, culture interventions, etc)
6. Introduces a new concept, methodology, or new way of thinking that can lead to new ways to improve care:
 - This may be “new” to a healthcare audience, but not new to other disciplines such as human factors engineering, systems engineering, psychology, sociology, anthropology, etc

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