How to Write Up Your Quality Improvement Initiatives for Publication

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The *Journal of Graduate Medical Education* often receives submissions from trainees and educators highlighting work they do in quality improvement (QI). This is remarkably encouraging given the emphasis that the Accreditation Council for Graduate Medical Education (ACGME) Next Accreditation System has placed on integrating QI into the clinical learning environment.[1] A major challenge for editors reviewing these manuscripts is the inconsistency with which authors report QI initiatives. After reviewing a large number of these submissions, we have noted common problems that arise and have prepared the following guide to help prospective authors prepare QI reports for publication.

Consistent with the *Journal*'s common format for Original Research or Educational Innovation articles (ie, Introduction, Methods, Results, Discussion, and Conclusion), our suggestions will highlight what authors should explicitly emphasize within each of these manuscript sections as it pertains to their QI initiative. We realize that a number of other frameworks and guidelines exist, the most common being the SQUIRE guidelines, which were updated in the fall of 2015.[2] Our suggestions are synergistic with the updated SQUIRE 2.0 guidelines, yet they also provide a high-level view of the philosophies that underpin these guidelines to help authors not only at the time of writing, but also when planning and implementing their QI initiatives.

What Is the Quality Problem, Why Is It Important, and What Is Your Aim?

The Introduction section must be brief. This is not the time to provide an in-depth review of the literature on your quality problem of interest—which could be an important but separate paper. Instead, it is most important to articulate *why this quality problem is relevant beyond your local institution*. Is it a common safety problem ubiquitous to multiple care settings, such as the need to improve patient handoffs? Or perhaps there are legislative changes or financial incentives that promote interest in your issue, such as the linking of financial reimbursement to readmission rates. Whatever the reason, it is critical to make clear what the external impact of your QI initiative would be for other groups and the readers of the journal. If the QI problem can be framed only as a need specific to your own setting, then the results may be best published in a local newsletter rather than a national or international journal.

After succinctly outlining the importance and relevance of the QI problem, the Introduction must describe the *gap between current practice and preferred practice*. What prior QI strategies have or have not worked to address this quality problem? If there is no gap in our understanding on how to improve practice, then further study of the area would be of limited value. Authors must demonstrate understanding of the pertinent literature in order to briefly discuss prior strategies that have been attempted; this usually includes the strategy as well as the required resources and resulting outcomes. Replication of a successful intervention in a new setting can help to fill key gaps in understanding: here the evidence gap is whether a prior strategy can be replicated in a different setting, one that is dissimilar in important features to the initial study.

Finally, the Introduction must also make clear what you hoped to achieve by carrying out your QI initiative. In 1 or 2 sentences, the final paragraph should clearly state the primary aim of your QI project. There are numerous references providing guidance on how to write good "aim" statements, by making sure that they are "SMART" (specific, measurable, achievable, realistic, anytime bound).[3] A clear and concise statement of the primary aim, and any relevant sub-aims, will ground the readers in the main purpose of your QI project.

Describing the Proposed Intervention, Including a Theory for Change, and the Road Toward Improvement

For QI reports the Methods section is probably the most important section as it ensures that readers

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understand how they can translate your reported innovation into their own settings. To facilitate this, authors must attend to several important issues. These include the *context in which the QI work was carried out* (ie, setting and participants) and a *detailed description of the implementation strategy.* The strategy must also include a *theory for why a specific intervention* (or set of interventions) was chosen.

Let's start with the proposed intervention. In QI, too often authors simply reach for the first available solution off the shelf without first considering why that particular solution could address the problem at hand. Frequently, authors appear to believe that checklists and order sets will solve everything. The truth is that if authors do not articulate a theory or rationale for why their proposed intervention should fix the quality problem of interest, they run the risk of designing a suboptimal intervention or choosing the wrong approach altogether. For example, attempts to reduce physician prescribing of unnecessary antibiotics to children with upper respiratory tract infections (URTIs; eg, continuing medical education, postcard reminders summarizing treatment guidelines, etc) consistently fail because they primarily address provider awareness rather than the dominant driver, which is parental demand for antibiotics. Theorizing that the ideal intervention should address parental expectations, one would instead choose an approach such as implementing the use of delayed antibiotic prescriptions, which in a recent Cochrane review has been shown to significantly reduce antibiotic utilization for the treatment of URTIs in children.[4]

Similar to the general call for more theory-based interventions in medical education,[5] there has been a recent call for more theory-based QI interventions.[6] Therefore, the preferred approach is to clearly articulate the link between the proposed solution and the problem it will solve. For example, a hospitalist team seeking to reduce unnecessary urinary catheter use might theorize that a key driver is that residents do not know whether a patient has a urinary catheter *in situ*. A sensible solution therefore might bypass the physician altogether. For example, instituting automatic stop orders[7] and nursing advanced directives[8] to remove urinary catheters are 2 interventions that have previously been shown to be effective.

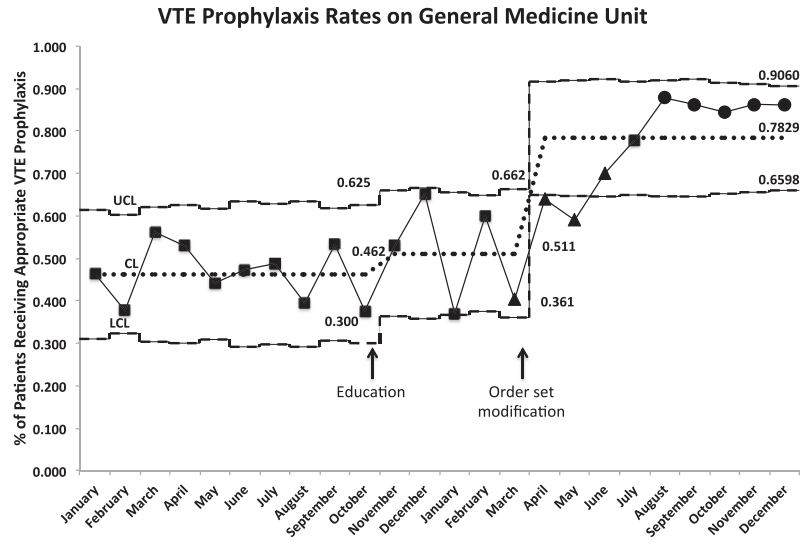
It is also crucial that authors state not only what the intervention was and its underlying rationale, but also how it was iteratively tested, refined, and eventually implemented. A common framework used in QI is rapid cycle change methodology or PDSA (plan-do-study-act) cycles.[9] Unfortunately, many published QI reports, despite claiming to use PDSA cycles, demonstrate little evidence that they refined their intervention prior to implementation.[10] This is a problem because for QI initiatives the devil really is in the details. It is simply not good enough to say that "we implemented a checklist" or "we created a new care pathway." Instead, authors need to report how changes were tested and refined; reflect on what worked, what did not, and why; and provide a description of the eventual intervention. Recognizing how challenging it can be to chronicle the evolution of the proposed intervention from start to finish in a concise manner, authors should consider the use of a figure or a table to summarize the key PDSA cycles, which will avoid excess word length while still providing a concise summary of what was actually done. Another option for providing more details is to include additional supplemental information for publication online. For QI projects it is imperative that at least 2 cycles, and usually more, are described in the Methods section.

The Local Context and Its Impact on the QI Initiative

In evaluative research, authors go to great lengths to describe how they have controlled for contextual factors to ensure that they have eliminated any bias that might unduly influence their outcomes of interest. QI is different in this regard: *context is critical to understand and characterize, not control.* Authors must include details about their context and how these might influence the implementation or outcomes of QI projects to sensitize readers to the contextual factors that require careful consideration when introducing the QI intervention to local institutions.

Batalden and Davidoff[11] described the importance of context in a brief commentary. They provided a framework for QI that links generalizable scientific evidence to a particular context in order to generate measured performance improvement. Importantly, they emphasized that the focus should be both on the context, as well as how the generalizable scientific evidence (or the proposed intervention) integrates within the particular local context. In QI, a detailed description of the context is just as important as a detailed description of the proposed intervention.

Consider the example of a QI project to reduce unnecessary lab ordering. The reader would want to know: Does the institution have computer-based or paper-based orders? If computer-based, is it easy to make changes to the order entry system to introduce clinical decision support? How engaged is the lab in



FIGURE

Example of Control Chart to Display Quality Data Over Time

Note: This is an example of a control chart (specifically a P-chart). A typical control chart has the quality measure of interest on the Y-axis. The X-axis is always a time scale (in this case, consecutive months). As the team carries out the quality improvement initiative, they collect data prospectively over time and plot the data on a control chart. Using statistical process control software, several lines are plotted. The dotted line is the center line (CL) and is equivalent to the mean. The dashed lines on either side of the mean are the upper and lower control limits (UCL and LCL; approximately 3 standard deviations, or sigmas, on either side of the mean). Using this information, the statistical process control software can identify segments of the chart where nonrandom variation is occurring (so-called special cause variation). On this graph, the 2 times where nonrandom variation are occurring are indicated by the triangle and circle markers, suggesting that modification to the order set, and not education, was likely responsible for the improvement seen in venothromboembolism (VTE) prophylaxis ordering.

clinical QI initiatives? What is the front line staff capacity and capability for QI? All of these contextual factors play heavily into the choice of the intervention, how the intervention gets implemented, and how it affects project outcomes.

This emphasis on context for QI reports parallels a similar need in reports of educational interventions. For example, educators implementing bedside procedure training must also account for and describe relevant contextual factors, such as whether a simulation lab is available, whether faculty have maintained competence in bedside procedures, whether a culture of direct observation and feedback exists, and whether there is a mechanism to track procedures and monitor for complications. Similar to medical education research, explicitly acknowledging the role of context is paramount in the reporting of any QI initiative.

What Is the Evaluation Plan?

Most QI initiatives rely on the Donabedian model of *outcome, process, and balancing measures* to evaluate the impact of their intervention.[12] While beyond the scope of this article to address the specifics of measurement in QI, we will offer several practical suggestions. First, most QI projects will focus on improving processes of care and may not be able to demonstrate downstream impact on clinical outcomes. This is acceptable, as long as the authors have selected process measures that are tightly coupled with the clinical outcome of interest. For example, an orthopedic surgery residency team aiming to improve venothromboembolism (VTE) prophylaxis rates could justifiably track VTE prophylaxis administration as a clinical process because hospitalized patients who receive VTE prophylaxis have a very low likelihood of developing VTEs.[13]

Another useful process measure to report is one that measures the fidelity of the intervention. In other words, include a process measure that tracks how consistently or reliably your intervention is applied. For example, if your main intervention to improve VTE prophylaxis is the creation and implementation of a standardized order set, a measure of implementation fidelity would be to track whether residents and faculty actually used the order set. This is particularly informative for unsuccessful QI projects—interventions with high fidelity suggest that other contributing factors require attention, whereas interventions with low fidelity suggest that the evaluation may have been premature and more work is needed to increase

TABLE
Quality Improvement (QI) Reports: Recommended Elements and Common Pitfalls

Manuscript Section	Elements	Common Pitfalls
Introduction	▪ Importance and relevance of QI problem beyond authors' site ▪ Gap between what we currently know and what we need to know to achieve desired QI outcomes ▪ Project aims	▪ Too long ▪ Too much on review of importance and too little on evidence gap ▪ Specific project aim not clearly articulated
Methods	▪ Context of the project ▪ Theory connecting QI problem, context, and proposed intervention strategy ▪ Multiple, iterative, intervention steps ▪ Use of a family of measures, ideally including outcome, process (fidelity), and balancing (unintended consequences) measures	▪ Superficial description of, or general lack of attention to, context ▪ No theory supporting intervention reported ▪ Many intervention steps reduced to single intervention ▪ Single measure used to track project impact
Results	▪ Data presented over time, with use of run or control charts ▪ May include contemporaneous control group or unit to account for secular trends and co-interventions	▪ Data aggregated as simple before-after design
Discussion	▪ One short paragraph summarizing most important findings ▪ Place study in context of others' work ▪ Reflect on implications of results ▪ Lessons learned, especially the influence of context on results ▪ Discussion of how limitations may have affected findings ▪ Future steps, in brief	▪ Discussion limited to implications for local institution or setting ▪ Results repeated without analysis or deeper reflection ▪ Reflections omitted ▪ Lessons and context effects omitted ▪ Listing of limitations, as if all of equal importance, without thoughtful consideration of potential effects
Conclusion	▪ Brief summary of key study findings	▪ Suggest "further research is needed" ▪ Overgeneralize from study site to all settings

uptake of the intervention before large-scale implementation and evaluation are undertaken.

Last but not least, balancing measures, which are intended to measure unintended consequences, often are missing from QI reports. A medical journal would not accept a clinical trial that reports only on the potential benefits and not the harms of a novel therapy, and we need to hold reports of QI interventions to a similar standard. Therefore, balancing measures of unintended consequence should be reported to ensure that the QI intervention improves care and does not create new problems. For example, if a QI initiative focuses on improving resident adherence to guidelines for a clinical area, such as diabetes care, does adherence to other guidelines, such as preventive screening, decline? If a new electronic handover tool is developed to support handoff communication, are there errors in the new document due to cut/paste activities? Selecting and reporting on sound balancing measures ensures a healthy respect for the law of unintended consequences in QI.

Providing Data With Greater Clarity

When it comes to displaying the data, it is best to avoid simple before-after comparisons. This evaluative approach is suboptimal because secular trends make it difficult to attribute observed differences to the intervention. Traditional approaches to research and evaluation would typically address this limitation through the inclusion of a contemporaneous control group or setting, which is also suitable for QI studies.

An alternative approach would be to display your outcome or process measures over time through the use of statistical process control. This methodology often utilizes *run charts* or *control charts* to display data over time (FIGURE). Following run chart or control chart "rules," one can interpret the data plotted sequentially over time to identify instances when variation is not due to random chance (so-called special cause variation). Such handling of data enhances the ability to determine whether changes that occurred were a result of the interventions introduced, and greatly strengthens the evaluative

approach as compared to aggregated before-after data. The *BMJ Quality & Safety* journal has published an overview on the use and interpretation of run charts.[14]

What Are the Implications of the Work? What Are the Next Steps?

For QI papers, the Discussion section will be similar to papers describing educational innovations or research. This section should concisely summarize the main findings of the QI project, relate the key findings to what is already known in the published literature, reflect on the broader implications of the findings, discuss how important limitations could have affected the findings, and briefly introduce next steps to further understand the field.

Perhaps most important are the reflections on lessons learned and future directions. In particular, reflections on the influence of the local context on project implementation and outcomes are highly relevant as readers will need to understand this if they want to replicate the intervention within their local context.

Well-conducted QI interventions that produced "negative" results (ie, did not achieve their intended outcomes) are still important and worthwhile for dissemination. Your reflections on why the intervention did not work can be helpful to others who might consider a similar initiative. In some cases, the problem may be the intervention itself, which signals the need to consider an alternative approach to addressing the QI problem of interest. More commonly, the implementation of the intervention lacked fidelity, or the integration of the intervention within the local context was suboptimal. In these instances, your QI report will still be helpful to others who can build on your work.

The Conclusion section of the report is also similar to Original Research and Educational Innovation articles. This short paragraph succinctly summarizes the most important findings from the study, without speculating beyond the results. Conclusions should be appropriately conservative in relation to the study findings. See the TABLE for a summary of elements essential for QI reports.

Conclusion

By providing this overview of the approach to writing up QI initiatives, we hope to clarify, up front, those aspects of your initiative that require the most emphasis. The considerations presented here can serve as a high-level guide to authors, with the goal of disseminating QI reports that are more useful for other programs. QI studies that involve residents, faculty, or the general graduate medical education environment as key elements of the context or intervention are appropriate for submission to the *Journal of Graduate Medical Education*. We look forward to publishing reports that inform programs and educators about effective faculty and learner engagement in QI activities within the graduate medical education learning environment.

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