

DEVELOPING RESEARCH AND PRACTICE

Toward stronger evidence on quality improvement. Draft publication guidelines: the beginning of a consensus project

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Qual Saf Health Care 2005;14:319–325. doi: 10.1136/qshc.2005.014787

In contrast with the primary goals of science, which are to discover and disseminate new knowledge, the primary goal of improvement is to change performance. Unfortunately, scholarly accounts of the methods, experiences, and results of most medical quality improvement work are not published, either in print or electronic form. In our view this failure to publish is a serious deficiency: it limits the available evidence on efficacy, prevents critical scrutiny, deprives staff of the opportunity and incentive to clarify thinking, slows dissemination of established improvements, inhibits discovery of innovations, and compromises the ethical obligation to return valuable information to the public. The reasons for this failure are many: competing service responsibilities of and lack of academic rewards for improvement staff; editors' and peer reviewers' unfamiliarity with improvement goals and methods; and lack of publication guidelines that are appropriate for rigorous, scholarly improvement work. We propose here a draft set of guidelines designed to help with writing, reviewing, editing, interpreting, and using such reports. We envisage this draft as the starting point for collaborative development of more definitive guidelines. We suggest that medical quality improvement will not reach its full potential unless accurate and transparent reports of improvement work are published frequently and widely.

We have suggested elsewhere that both scientific discovery and experiential learning are required for improvement in medical care to flourish (F Davidoff, P Batalden, submitted for publication). The principal goal of science is to discover and disseminate new knowledge, a process that can be briefly summarized as "Plan-Do-Study-Publish" (T Nolan, personal communication). In contrast, the principal goal of experiential learning is to enhance performance. As a consequence, neither the action cycle used to characterize informal experiential learning ("Experience-Question-Conceptualize-Retry"¹) nor the formal version of that cycle ("Plan-Do-Study-Act") that is now a central component of medical quality improvement² include a "Publish" step. As discussed below, however, we suggest that, just as the growth of scientific knowledge would be unthinkable without publication, the improvement process will not realize its full potential unless the experiential learning that makes up much of quality improvement is also widely shared through publication.

WHY IS PUBLICATION ESSENTIAL IN QUALITY IMPROVEMENT?

The canon of science absolutely requires that scientific work must be captured in written or graphic form. Indeed, the biologist E O Wilson has gone so far as to state that "One of the strictures of the scientific ethos is that a discovery does not exist until it is safely reviewed and in print".³ It is true that publication in science does have an unfortunate tendency to be overvalued (the "publish or perish" phenomenon), since the principal instrument of social control in the scientific community is the exchange of information for professional and social status, funding, and power.⁴ Nonetheless, publication remains essential in science for many reasons:

- Most importantly, publication is essential because of the central role it plays in both disproof and corroboration (lack of disproof), which lie at the heart of the logic of science. The philosopher Karl Popper puts it this way: "Those among us who are unwilling to expose their ideas to the hazard of refutation do not take part in the scientific game".⁵ Only full and open publication provides the kind of access and transparency needed for the exercise of that logic.
- Without the cumulative "collective memory" available in the published record, new findings cannot be interpreted in the context of prior work, which inevitably distorts their meaning.^{6,7}

A great deal of creative effort currently goes into making medical care safer and more reliable. The results of that improvement work are sometimes shared informally among those in the field and are occasionally published, primarily in the administrative and management literature and in a small number of journals devoted to the subject. Although much of that work is both useful and rigorous, most of it is unfortunately never made publicly available in either print or electronic form, and the reports that do appear vary considerably in accuracy, completeness, and transparency. The lack of such reports is particularly noticeable in the clinical literature, which is regrettable since, despite the crucial role they play, clinicians are notably reluctant to become involved in improvement efforts.

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Accepted for publication
10 August 2005

- The lack of a published record also permits scarce resources to be wasted on work that has already been done.
- It is arguably unethical to consume time, effort, and money in research (and, in the case of clinical research, expose participants to inconvenience, cost, and risk) and then not return some benefit to the public by sharing the knowledge gained from that research.⁸ Failure to publish clinically relevant data has recently even become a legal issue, as it is now being prosecuted in court as a form of fraud.⁹

Failure to publish new knowledge about improvement work also has a number of serious consequences:

- Perhaps most importantly, the lack of well organized complete reports of quality improvement work makes it difficult to establish repeatability, the *sine qua non* of evidence regarding the efficacy of experiential learning. This lack is particularly frustrating for those interested in aggregating multiple published reports of similar improvement efforts in various ways, including study data banks^{10–12} and qualitative systematic reviews,¹³ which can strengthen causal inferences about efficacy.^{14 15}
- The dearth of published reports means that much quality improvement work is not open to serious critical public scrutiny and hence accountability, since peer review, editorial input and comment, letters from readers, and general debate about the specifics of improvement projects are prevented from taking place.
- Without the expectation that they should publish their work, those involved in improvement lack the incentive and the opportunity to clarify their thinking, verify their observations, and justify their inferences that writing up their results provides.
- Failure to publish improvement experiences, including negative results, slows the dissemination of known effective innovations and wastes the time, effort, and money that others spend independently rediscovering those same innovations—and making the same mistakes.
- Failure to publish slows the development of improvement science, since dissemination of information about one innovation sparks others.^{16 17}
- As is true for scientific research, quality improvement uses public resources and exposes participants to inconvenience, cost, and risk. Failure to share publicly the results of improvement efforts, in return for those contributions, can therefore be challenged on ethical grounds.

THE IMPROVEMENT-PUBLICATION PARADOX

Unfortunately, the strengthening of quality improvement evidence through publication has recently become entangled in the following bureaucratic paradox, with potentially serious consequences. The Common Rule that governs the conduct of federally supported human subject research in the US defines research as a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge”.¹⁸ Since the most widely used and respected criterion for the generalizability of knowledge is whether it has been published, quality improvement projects that have been (or even *may* be) published are now being considered “research” under the Common Rule definition. To complicate matters, since quality improvement in medicine virtually always involves human participants, quality improvement work that is published is now frequently considered to be a form of human subject research.¹⁹ Framed in those terms, virtually all quality improvement immediately becomes subject to the

regulatory mechanisms that govern clinical research—most importantly, protection of human participants through ethics committee or Institutional Review Board (IRB) review.

Protection of participants in quality improvement is, of course, essential. But a conceptual shift of medical quality improvement from an intrinsic professional responsibility^{20 21} to a research activity seems both illogical and counterproductive on several grounds. First, the transitivity of the Common Rule’s logic is itself open to question. Although all research strives to be generalizable (hence publishable), it does not automatically follow that all investigations that are published (hence generalizable) are research—for example, case reports and case series, reviews, analytical studies, commentary and opinion pieces, many of which contain important, original, and generalizable knowledge, are not generally considered “research,” or at least not pre-planned “systematic investigations” in the usual sense. In fact, the Belmont Report itself, on which the Common Rule is based, recognizes that valuable generalizable knowledge can and does flow from the experience of health care delivery per se, not just from research; in its words:

*“Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is a practice and need not be reviewed as research”.*²²

Thus, since quality improvement is fundamentally “a procedure applied in practice”, designed to enhance the well being of particular individuals or groups rather than to produce generalizable knowledge, there is no reason for it to be considered a priori as “research”. Of course, such work can and should be seen as research if the initial improvement plan contains formal elements designed specifically to generate new generalizable knowledge, over and above its intended immediate benefit to its local participants.

Secondly, when protection of participants is at stake, it does not matter whether quality improvement is characterized as “research” or as some other kind of activity (such as experiential learning); protection is necessary in any case. Indeed, it can be argued, ironically, that patients need more protection in medical care systems that are *not* actively engaged in quality improvement than in systems that are. Finally, most IRBs are overburdened, understaffed, and underfunded;²³ formal IRB review is generally slow and cumbersome;²³ IRB judgments are often inconsistent;^{23 24} and most IRBs have little familiarity with the nature and methodologies of quality improvement. Requiring all quality improvement efforts to undergo such review could therefore have the paradoxical and damaging result of actually discouraging improvements in care.

For all of these reasons, we suggest that no one should be deterred from working to improve the care of individual patients and groups simply because of concerns that the results of that work may ultimately turn out to warrant publication. Similarly, no one who has already done improvement work should be reluctant to publish their results if they recognize, after the fact, that what they have learned is generalizable. The critical issue here is not whether they are doing research; it is whether staff engaged in improvement have taken the appropriate steps to protect those people who participate in their efforts to improve care.

WHY ISN'T QUALITY IMPROVEMENT WORK PUBLISHED MORE OFTEN?

If publication of quality improvement evidence is so crucial, what explains the “publication gap”? To some extent it has to do with the nature of the people who do the work. Most are busy “front line” healthcare professionals—managers, administrators, planners, clinicians—with heavy competing

Table 1 Draft proposed guidelines for stronger quality improvement evidence*

Item	Paper section	Descriptor and topic
1	Title and abstract	Indication that this is a quality improvement article
2	Introduction: Background	Current organizational and clinical knowledge about the problem area
3	Problem	Nature and severity of specific local dysfunction or failure
4	Purpose of change(s)	Specific aim(s) of proposed changes, i.e. questions to be answered
5	Methods: Setting	Relevant details of geographic location, local organization, staffing
6	Function	Purpose, processes, and activities of department, team, unit, program
7	Intervention(s)	Precise details of initial strategy for intended changes/improvements
8	Measures	Balance of methods used to assess dysfunction/failure and outcomes of changes, including measurement perspective (e.g. patients, staff, administration, cost, etc); methods used to validate measures
9	Analytical methods	Statistical and time series techniques used; specific software (if any)
10	Results: Situation analysis	Initial assessment of local context of the care system (e.g. specifics of the patient population, local experience with change, etc) and how that assessment helped understand the problem
11	Outcomes	How the initial improvement plan evolved over time (if it did), including alternative change strategies considered and rejected, with reasons; how and why this evolution occurred and who was responsible for it What effects the changes/improvements actually had on clinical and/or organizational and professional outcomes and processes including benefits, harms, unexpected results, problems, failures
12	Discussion: Summary	Key findings, lessons learned from evolution of changes, outcomes achieved
13	Context	Comparison and contrast of results with the findings of others; broad formal review of the literature is desirable
14	Interpretation	Inferences about mechanisms of changes/improvements, including prior changes, change making in this setting
15	Limitations	Sources of bias or imprecision; factors affecting generalizability, particularly unique features of local setting, and potential confounders; efforts made to minimize and correct for limitations; effect of limitations on interpretation and application of results
16	Conclusions	Implications for practice and further study; plans for maintenance of improvement and for follow up to assess maintenance; next steps

*Although each section of the text of a quality improvement report in the Introduction, Methods, Results, and Discussion (IMRaD) format (for example, the Introduction) generally needs to contain at least some information about all of the guidelines items listed for that section, individual items from one guideline section are often needed in various sections of the text.

service responsibilities. Many are neither oriented to, nor experienced in, academic work, including writing and publication; they also generally do not work in academic environments where they would “perish” if they failed to publish. And writing itself, particularly writing well, is hard.²⁵ (A widely quoted saying among writers is: “Writing is easy. Just sit down at your desk and open a vein.”)

But other powerful intellectual and cultural forces are also at work here. Editors, peer reviewers, and the academic medical community generally control both biomedical and clinical publication, and all of those stakeholders are deeply immersed in the culture of scientific discovery whose primary purpose is generation of new knowledge. As a consequence, they may be unfamiliar with the goals and methodologies of experiential learning, which is the principal approach used in solving the complex non-linear problems of quality improvement. The editors of, and reviewers for, biomedical journals may therefore have difficulty recognizing the nature, importance, or even the existence of many of those problems, which consequently can interfere with publication of reports of quality improvement work, even when that work is clinically important and methodologically sound. Moreover, until recently, little guidance has been available for authors, editors, and reviewers on how best to write, review, and edit complete and precise accounts of quality improvement.

PUBLICATION GUIDELINES FOR IMPROVING QUALITY IMPROVEMENT EVIDENCE: A DRAFT PROPOSAL

With these considerations in mind, we offer here a draft set of guidelines in the form of a checklist, designed to increase the completeness, accuracy, and transparency of original reports of quality improvement work (table 1). The guidelines proposed here are intended primarily to support publication of the strongest and most definitive evidence on quality improvement in the permanent peer reviewed journal literature. They may also be useful in preparing reports of quality improvement work, much of it still preliminary or in progress, that are presented in the many important but more transient venues used for disseminating that information such as meetings, white papers, and media reports.

These proposed guidelines build on an earlier and more limited set of publication standards.²⁶ In our view, those earlier guidelines are most appropriate for reporting on small, relatively informal improvement projects or “quality improvement reports”—the equivalent, perhaps, of clinical case reports. In such reports the primary focus is on the specific clinical or delivery system problem rather than on quality improvement methods. The guidelines proposed here may be somewhat more appropriate for publications whose primary purpose is to demonstrate the efficacy of quality

improvement methods. In our view, however, all original applied quality improvement work involves both real problems to be solved plus new and better ways of solving them; we therefore see the distinction between “quality improvement reports” and reports of quality improvement methods as a matter of emphasis rather than mutual exclusivity. We believe the guidelines proposed here should, in fact, be applicable to any well thought out improvement project, large or small, but particularly to complex, formal, planned interventions.

They have been developed with informal input from people with extensive experience in quality improvement, medical ethics, clinical research, and medical editing, and have been modified in response to feedback from people who have used them in writing and critiquing reports of quality improvement projects. They generally conform to the principles used in creating guidelines for reporting randomized clinical trials,²⁷ and for studies that use other designs^{28–33} and studies in specific content areas.^{34–35} Importantly, the consistency and completeness of reporting has been found to improve in journals that have endorsed and used such guidelines.³⁶

The guidelines in table 1 differ in a number of significant ways from the earlier set.²⁶ For example, the new draft guidelines are organized according to the IMRaD (**I**ntroduction, **M**ethods, **R**esults, and **D**iscussion) format. The earlier guidelines explicitly rejected the IMRaD format on the grounds that, unlike the invariant protocols of clinical research, the initial plans used in improvement projects are frequently (and intentionally) altered during the course of the projects, which was seen as making them intrinsically incompatible with that format.²⁶ In our view, the IMRaD structure is generic, reflecting the flow of thinking that underlies *all* learning and discovery, which is why it is widely used to report study designs of all types. More specifically, we would argue that, far from violating the logic of discovery, the shifts in improvement plans are, in fact, among the more important outcomes of the experiential learning (improvement) process, and therefore fit comfortably into the Results section of the IMRaD structure.

Secondly, the number of items in these draft guidelines has been expanded from eight in the earlier set²⁶ to 16, to accommodate several important additional topics including: prior information available on the problem area; failures, risks or harms encountered; assessment of the project’s limitations; evaluation of the project’s internal and external validity; and specific plans for assessing maintenance of the improvement. Although 16 items is a substantial number, it should be manageable. Authors, editors, and peer reviewers have not had difficulty using 20–25 items in other publication guidelines.

NEXT STEPS

We view the draft reporting guidelines offered here as a reflection of the rapidly developing science of quality improvement, and hence as a further step in the evolution of publication standards, not as a finished product. It would be helpful if readers would send the editors of this journal their comments and criticisms regarding this version of the guidelines. Feedback on their strengths and limitations from people who use them to write and critique reports of quality improvement would be particularly valuable.

We also propose that, at the earliest opportunity, a group representing the many stakeholders in quality improvement—clinicians, administrators, health services researchers, social scientists, editors, ethicists, statisticians, patients, and others—should be convened to assume stewardship of the guidelines. Diffusion of an innovation such as reporting guidelines is a complex and intensely social process.^{37–38} Drawing on the experience gained in creating other publication

guidelines^{27–28–30} and similar standards documents,³⁹ this group would undertake a systematic critique of the completeness, clarity, and appropriateness of specific guideline items. It should also consider a number of general questions including:

- How good is the evidence supporting the inclusion of items in the guidelines?
- Is more such evidence needed and, if so, what studies would be most likely to produce it?
- Would it be useful to develop other related guidelines, including possible variants or extensions of this set?
- How can the guidelines be distributed and endorsed for maximum effectiveness?

We recognize that the use of reporting guidelines is not justified unless they improve the quality of reporting. We therefore urge, that, once a more definitive version of the guidelines has been formulated, their impact on quality improvement reports be formally and carefully assessed. For example, editors and peer reviewers could be asked for subjective judgments of their value in making editorial judgments; authors could judge their value in organizing and writing reports; and readers could judge their value in understanding and applying published papers. The impact of the guidelines could be assessed objectively and quantitatively by comparing papers prepared with and without them with regard to completeness, accuracy, and precision of reporting,⁴⁰ and the suitability of such papers for inclusion in systematic reviews.

Finally, we recognize that, by itself, accurate and transparent reporting is of little value if the work being reported is fundamentally flawed. On the other hand, we would argue that reporting standards can actually play a role in improving improvement work. Thus, although the primary purpose of such guidelines is to improve the reporting rather than the planning and conduct of improvement work, they could very well have a positive secondary (or “backwash”) effect on the quality of the work itself by providing an explicit consistent framework for its design and execution. In that sense, the guidelines could serve an important educational purpose, particularly in conjunction with an “elaboration and explanation” document such as the one created to support the CONSORT guidelines.⁴¹ Systematic consideration of specific background elements and criteria related to each guideline item, such as those listed in table 2, is an example of such an educational function.

SUMMARY AND CONCLUSIONS

In contrast to the integral role that publication plays in scientific discovery, publication in medical quality improvement has unfortunately had only a limited role to date. This lack of published reports has arguably deprived the health-care system of rigorous scholarly evidence on improvement work and, hence, has slowed improvement of the improvement process.

The improvement-publication gap in part reflects the reality that most people who do the work of quality improvement are more interested in actually improving care than in writing about what they do. But widespread misunderstandings about the nature of experiential learning and experimental discovery—the perceptions, for example, that experiential learning deals with problems that are intractably “messy;” that the evidence for the efficacy of most experiential learning is intrinsically weak; and that “applied” disciplines are of less intellectual and social value than “pure” ones—also appear to play important roles in discouraging publication, particularly in the clinical literature. Moreover, because the current editors and peer

Table 2 Examples of elements and criteria to be considered in reporting guideline items**Title and abstract**

- What was improved?
- What was the name of the process that was changed?
- What outcome was affected?
- Have the key words been identified so that future search strategies will be able to identify the contributions of this paper?

Background

- What is generally known about this clinical area? About the limits of knowledge? About cause and effect in this condition?
- What is known about this area locally (and elsewhere) based on earlier efforts to change it?
- Who was in a position to know about this locally? Why?
- Was there an advantage to the local setting to address this problem now?

Problem

- What was the history of performance dysfunction, and its degree, over time?
- What made the current situation unacceptable? For whom and how was it unacceptable? What contributed to the local awareness of unacceptability?

Purpose of change(s)

- What was the specific aim of the proposed change/improvement?
- What question(s) was this test of change trying to answer?

Setting

- What were the structures, processes, and patterns of the setting?
- What were the relevant habits and traditions in the setting?
- Was the setting tightly or loosely coupled?
- Did people in this setting know their own work as a process? Were they included in the change?
- Did people in this setting have a history of working to change their own work processes? If so, what had contributed to successful change in the past?

Function

- What was the aim/role of the clinical unit being changed?
- Did the unit understand itself as a functioning, interdependent system? As a system, did it include the patient beneficiaries of care as an integral part of the system?
- What activities/processes do the staff and patients regularly engage in?
- How were the leadership needs of the unit met? What was most valued about the unit's leadership?
- How had this system changed in the past? How did that change contribute to the participants' understanding of themselves as a system?

Intervention

- What was the nature of the initial process change planned (who, what, when, where, how, how much)?
- Who were the people connected to the process that was to be changed? Was there a "natural" work group connected to the daily operations of the process and the intervention intended to change it? Did they have successful experiences changing in the past?
- What were the anticipated outcomes?
- Who was expected to lead the effort? What was their prior experience leading change? What made them curious about this situation? What had made them successful in their prior change leadership efforts?
- What about the local setting was conducive to addressing the problem?
- What resources were locally available to facilitate the learning and the testing of change?

Measures

- What balanced (biological, function, satisfaction, cost) measures of the existing situation—process and outcome—were available prior to the change? Which measures had to be developed de novo for the change effort?
- Were the conceptual and operational definitions of the measures and the measurement process available to all involved in conducting the measurement process?
- What processes were used to assure that the measures accurately represented the phenomenon under study?
- Were the different perspectives of patients, staff, and payers taken into account in the measures used?

Analytical methods

- Were the methods for longitudinal measurement appropriately standardized and validated?
- Was the software used (if any) well documented and tested?

Situation analysis

- What were the initial findings concerning the specific dysfunction, lack of effectiveness or efficiency of processes, patterns, outcomes? Were the problems assessed from the point of view of both patients and professional staff?
- What was the history of efforts to change the particular problems being addressed? Had change been successful in the past?
- Were there artifacts of the helpfulness of the organizational culture that enabled the change?

Outcomes

- How did the initial plans for improvement evolve during the course of the improvement effort and what contributed to that evolution? For example, as the initial change efforts took shape, how did the organization respond—signalling the way the system would process the change, and allow modifications to be made in the change designs?
- What did leaders do to encourage the improvements and modifications thereof?
- What alternative change strategies were considered, and why were they not selected?
- What were the major effects of the change(s) on the process and outcomes of clinical care for patients? The effects on staff?
- What harms or system/process failures were considered and looked for?
- Did the change process or the changes themselves introduce burdens or harms?
- Were there any unexpected changes, either beneficial or harmful? Why do you think they were unexpected?

Summary

- What were the most important lessons learned? From the sequence of changes that occurred? From the outcomes achieved?
- What contributed most importantly to the successful change(s)? On what basis do you think so?
- What might be necessary to sustain these gains and/or test a similar change elsewhere?
- What new possibilities emerged as these (successful, intended changes) were reflected upon?

Table 2 Continued

Context

- How does what you found in your setting compare with other experiences in dealing with the problem (published and unpublished), and efforts to change? Similarities and differences in other settings reporting success/failure?
- How did you search the literature? What limited your review?

Interpretation

- What are the implications of these findings for the leadership of change? The degree of agreement regarding the desirability of or need for change?
- Does this work help understand the predictability of cause and effect in improvements of this type?
- What did the improvement process reveal about perceptions of “competing commitments” that might have surfaced during the project, and the way those were best managed?
- Did the improvement effort provide insight into the roles of process owners/operators?
- What are the inferences from this work regarding the means necessary to sustain and spread the new levels of performance?
- What are the implications of this work for future professional and staff development?

Limitations

- Were there aspects of the process of change or the changes themselves that were dependent on locally distinctive/unique characteristics?
- Were there any “artifacts” (things you could see or directly observe/witness) that would illustrate the relevant culture-in-use of the setting? Did locally held assumptions about daily work and care affect the interpretation of results?
- Did changes other than the specific improvement intervention occur during the period of measurement that could have confounded the interpretation of its apparent efficacy? If so, what were they? What did you do to mitigate any such confounding? How do any such confounders influence your interpretation of the observed outcomes?
- Were there failures in, or harms from, the change process that occurred because of special local circumstances?
- Did the characteristics and application of the measurement process and analytical techniques create any problems?

Conclusions

- Why does this experience make sense? How does it fit into the context of prior experiences?
- How does this experience invite changes in the rationale underlying the patient care involved?
- What are the implications from this work for patient care, the improvement process, future research, and the development and formation of health professionals—either initially or in mid career?

reviewers of biomedical journals are relatively unfamiliar with the elements that are most worthwhile in making improvements, they have not encouraged authors to use an inclusive typology of those elements, thus possibly contributing to the lack of progress toward a “science” of improvement.

We therefore strongly encourage the widest possible reporting of quality improvement work in print and electronic form. In support of that goal, we urge the further development, adoption, and widespread use of publication standards such as those proposed here, that contain a systematic and comprehensive set of the elements of medical quality improvement.

ACKNOWLEDGEMENTS

Donald Berwick, Ann Davidoff, Joanne Lynn, Lloyd Provost, Jane Roessner, Mark Rzeszutarski, Mark Splaine, and David Stevens all contributed importantly to the development of ideas in this paper.

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Financial sponsors: None

Competing interests: None

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