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DESCRIPTION

Published monthly, The Joint Commission Journal on Quality and Patient Safety is a peer-reviewed publication dedicated to providing health professionals with the information they need to promote the quality and safety of health care.

The Joint Commission Journal on Quality and Patient Safety invites original manuscripts on the development, adaptation, and/or implementation of innovative thinking, strategies, and practices in improving quality and safety in health care. Case studies, program or project reports, reports of new methodologies or new applications of methodologies, research studies on the effectiveness of improvement interventions, and commentaries on issues and practices are all considered.

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GUIDE FOR AUTHORS

Your Paper Your Way
We now differentiate between the requirements for new and revised submissions. You may choose to submit your manuscript as a single Word or PDF file to be used in the refereeing process. Only when your paper is at the revision stage, will you be requested to put your paper in to a 'correct format' for acceptance and provide the items required for the publication of your article.
To find out more, please visit the Preparation section below.

INTRODUCTION
The Joint Commission Journal on Quality and Patient Safety is a peer-reviewed publication dedicated to providing health professionals with new ideas and information to improve the quality and safety of health care. The Journal invites manuscripts on the development, adaptation, and implementation of innovative concepts, strategies, methodologies, and practices in quality and patient safety.

The Journal's scope includes publications that are relevant for all types of health care organizations-health systems; hospitals; ambulatory care; behavioral health facilities; community health centers; nursing care centers; health plans and disease management programs; and home health care programs. We believe that publishing this breadth of articles will help disseminate ideas and improvement strategies across disciplines and sectors of our health care system. Our target audience is just as diverse: senior leaders in health care organizations, quality and patient safety managers, physicians, nurses, other health care professionals, information technology professionals, educators, and researchers, as well as health policy makers, health care researchers, business and government purchasers of care, and health insurers.

Why publish in The Joint Commission Journal on Quality and Patient Safety? First, the Journal provides tremendous visibility for your work. The Journal is widely read and respected because of its long history and record of publishing seminal articles. The articles we publish are frequently highlighted by The Agency for Healthcare Quality and Research’s Patient Safety Network. Our new publisher Elsevier is dedicated to further highlight authors’ articles through a new website for the Journal, social media, ScienceDirect, and an innovative method of semantic tagging to provide more accurate searches so people can more easily find your articles. Second, The Journal is now working more closely with The Joint Commission to make the Journal a key component of how The Joint Commission fulfills its mission to partner with organizations to improve quality and safety. The Joint Commission accredits and certifies more than 20,000 health care organizations, and we are working to ensure that the Journal is essential reading for professionals in these organizations who are looking for ways to improve care. Finally, we offer tremendous support to authors. With our new online system, it is easy to submit articles for publication, and the system will help ensure rapid reviews and decisions. Once accepted, articles will be published online as soon as proofs are available. We have adopted Elsevier’s "Your paper, your way" philosophy that allows authors to submit articles with references in whatever format they wish. Most importantly, we do not have strict word limits, so authors can provide the detail necessary for readers to be able to fully understand their work and put their research into practice to improve care.

We look forward to receiving your article!

Optimal Reporting of Improvement Studies
Incomplete or "suboptimal" reporting in the improvement literature is receiving increasing attention. Descriptions of implementation strategies need to be specified with sufficient detail that readers can work to reproduce those strategies and activities and improve care at their own institutions. The Journal is committed to a reporting standard that provides the needed detail regarding the methodology, implementation, and evaluation that was used. Such detailed reporting of the intervention should enable readers to determine (1) whether an intervention should be considered for implementation in their own organizations, and, if so, (2) how they might maximize the likelihood of success, given the reporting organizations’ barriers and limitations and their own organizations’ challenges and resources. Further guidance on this is provided in the section 1A. Improvement Articles.
**General Considerations**

Ensure that your paper fits the mission and scope of the Journal. If you are not sure, contact the Editorial Office. The Journal strongly suggests that authors use standard formats as described at http://www.equator-network.org. For example, use CONSORT for randomized trials, STROBE for observational studies, SRQR or COREQ for qualitative studies, CHEERS for economic evaluations, and SQUIRE for quality improvement studies. Authors are strongly encouraged to use the checklists included in these guidelines, and those checklists may be requested during manuscript review to ensure completeness. Make sure that your manuscript is accurate and readable. Authors who feel their English language manuscript may require editing to eliminate possible grammatical or spelling errors and to conform to correct scientific English may wish to use the English Language Editing service available from Elsevier. Consult the sample articles provided for each article type for guidance. To provide the chronological context and time frames of different steps in the study, please provide dates, as closely as possible, for important decisions and actions. Make clear which authors [position; indicate with author’s initials, as applicable] were involved in different study-related activities discussed in the methods (e.g., reviewing charts, assigning global rating of quality of care), where appropriate. Provide headers to break up major sections—Methods, Results (will often correspond to Measures in Methods), Discussion.

**Article Types**

Please ensure that your submissions to the Journal follow the guidelines provided for each article type. For instructions on how to format the text of your paper, including tables, figures, panels, and references, please see our Submission Directions below. In the event of uncertainty as to the appropriate article type, ask the editors to determine the Article Type in your cover letter.

1. **Original Articles**

Original Articles report work on any topic or issue relevant to the improvement of quality and patient safety. The manuscript text should be organized into Introduction, Methods, Results, and Discussion, with subheadings within those sections, as appropriate. Subheadings are usually most appropriate in the methods and results sections.

The Journal strongly suggests that authors use standard formats as described at http://www.equator-network.org (i.e., CONSORT for randomized trials, STROBE for observational studies, and SQUIRE for quality improvement studies). Authors are strongly encouraged to use the checklists included in these guidelines, and those checklists may be requested during manuscript review to ensure completeness.

Original Articles may consist of the following: Improvement Articles Research Articles Conceptual Articles

Suggested limit: 4,000 words (but see Introduction).

1A. **Improvement Articles**

Articles should describe the implementation and evaluation of an improvement intervention (which need not be successful).

**SQUIRE 2.0 Guidelines**

Authors are requested to use the SQUIRE 2.0 Publications Guidelines for reporting quality improvement studies (available at http://www.squire-statement.org/). Authors should consider every SQUIRE item, but it may be inappropriate or unnecessary to include every SQUIRE element in a particular manuscript. Please remember to use the full citation for SQUIRE in the manuscript references.

Articles should include the sections below and usually include the elements listed.

**Abstract**

Use the headings Background, Methods, Results, and Conclusions. The conclusions section should not simply repeat the study results. Word Limit: 250.

**Introduction**

Statement of the problem: Summary of key literature on the problem or previous studies of interventions to address the problem. The study’s objective(s) or key questions and how the study addresses previously unanswered questions.
Methods
This should include the information needed for the reader to assess both the validity and the generalizability of the study results. For example: Study Design/Evaluation Methods Ethical considerations (e.g., IRB approval or waiver) Setting Organizing for the Intervention: Who led the effort? Who was the champion and who were members of the intervention teams? Intervention: the various steps involved in the intervention, which itself is likely to consist of a series of sequential if overlapping, mutually reinforcing interventions Study population, including eligibility and exclusion criteria Data (measures) and data collection (sources) Statistical Analysis

Discussion
Brief summary of key findings Specify if the intervention is still in place (and with what modifications, and why), and if data are still being tracked—or explain why it is not and when it was discontinued Comparison of these findings to previous studies in the literature, including possible reasons for differences Discussion of unexpected findings Weaknesses of the study (Limitations), including failure to prove sustainability of the intervention (in terms of processes and data) Conclusions Implications for research, improvement practices, practice (health care, organizations), and, if applicable, policy makers Next steps (at the study site), including plans to achieve sustainability

Examples:
Pronovost P, et al. Sustaining Reliability on Accountability Measures at The Johns Hopkins Hospital. (Feb 2016)
Mermel, LA. Reducing Clostridium Difficile Incidence, Colectomies, and Mortality in the Hospital Setting: A Successful Multidisciplinary Approach. (Jul 2013)
Richardson MG, Domaradzki KA, McWeeney DT. Implementing an Obstetric Emergency Team Response System: Overcoming Barriers and Sustaining Response Dose. (Nov 2015)

1B. Research Articles
In contrast to Improvement Articles, which report an evaluation of an intervention, research articles are usually observational studies, e.g., studies of the accuracy of screening and diagnostic tests, quality measures, associations between quality measures and clinical outcomes, cost-effectiveness analyses and decision analyses, surveys, qualitative studies, etc. Include an abstract with no more than 250 words, and use the headings Background, Methods, Results, and Conclusions. The conclusion should not simply repeat the study results.

Examples:
Kozmic SE, et al. Factors Associated with Inpatient Thoracentesis Procedure Quality at University Hospitals. (Jan 2016)

1C. Conceptual Articles
These articles can provide frameworks, models, methodologies, or approaches to problems. Descriptions of how these have been used in actual practice to help address quality and safety problems or to design improvement strategies is strongly encouraged. Articles should include a structured abstract (up to 250 words) with up to 4 headings that conform to article sections. Authors can choose headings that they think are most appropriate and useful.

Examples:

2. Improvement Briefs
Improvement Briefs are shorter versions of Improvement Articles (See 1A above). They should follow the same basic structure for the abstract and headings. Suggested word limit: 2500. These should be submitted as an "Abbreviated Article" in the online system.

Generally, an article is more likely to be suitable when the improvement project Involves one simple intervention rather than a multifaceted or multi-phase intervention Involves one or a few clinical unit(s) rather than a systemwide intervention Has straightforward outcome measures

Examples:
Shieh, L. Assigning a Team-Based Pager for On-Call Physicians Reduces Paging Errors in a Large Academic Hospital. (Feb 2014).

3. Innovations Reports
Innovation is a critical feature of all work we seek to publish in the Journal, especially Original Articles. However, we want to create an opportunity for authors to publish innovations that have not yet been "scaled up" for full implementation and evaluation. Innovation Reports will therefore focus on the earlier phases of innovation-idea generation and early-stage testing, which typically requires understanding of the context, problem definition, and rapid-cycle testing and experimentation. We previously called articles like this "Field Notes."

Innovation Reports should generally have the same structure as Original Articles. However, manuscripts can have other headings if more appropriate. Authors should include a structured abstract (up to 250 words) with up to 4 headings that conform to article sections. Authors should consider addressing the following questions as part of the manuscript: Problem Definition. Who is this problem affecting? What is the magnitude of the problem? Context. In which clinical setting is this occurring? Who are the key participants and stakeholders? Initial Approach. What was the initial idea and hypothesis? Iteration and Pivots. What was actually tested? What changed about the solution? Outcomes. What outcomes were measured? (could include earlier-stage metrics, such as usage, experience, and perception) Key Insights and Surprises. What was interesting and unique about this process? Next Steps. What happens next to learn more about whether this innovation will work? (Can include documentation of failures and areas that should not be pursued)

Suggested word limit: 2500 words. These should be submitted as an "Abbreviated Article" in the online system.

Example:
Wyskiel RM, Weeks K, Marsteller JA. Inviting families to participate in care: a family involvement menu. (Jan 2015)

4. Research Letters
Research Letters are similar to Research Articles (1B), but they should not exceed 600 words of text (not including acknowledgment, table, figure, or references) and 6 references. They may include up to 3 tables and/or figures. Online supplementary material is not allowed. Research letters may have no more than 7 authors. In general, Research Letters should be divided into the following sections: To the Editor (which serves as an introduction), Methods, Results, and Discussion. There is no abstract. These should be submitted as a "Research Note" in the online system.

Example:

5. Tool Tutorial
This section of the Journal is designed to showcase new tools and preliminary experience using these tools. Articles should describe the development methods for the tool and present data on use and preliminary experience in a real-world test environment. The results should include a description of how often it was used when it was appropriate to do so, whether the tool was used as intended (i.e., fidelity), and an assessment of whether the tool had a positive effect on care. The tool should be available for use by readers in their own organizations and sufficiently described to enable implementation. Evaluations of proprietary tools that require licensing or other fees for use will not be considered.

Articles should include an unstructured abstract with no more than 100 words and the following sections:

**Background**
Quality or safety need, as represented in the literature

**Tool Development**
How, when, why, was it developed, with what resources and feedback, testing, and so on?

**Tool Description**
Narrative description, with illustrations, of components

"How To"
Step-by-step process for tool use - generic supported by example(s), walking the reader through its use.

**Results and Lessons**
Data on extent of use of the tool and an evaluation plan or evaluation, if data not readily available-and further development or refinement in use of tool on the basis of the evaluation.

What results have been achieved and what has been learned through use of the tool. Specifically address potential pitfalls if any (e.g., specific cautions to be noted, alerts based on experience with the tool, practical tips)

**Summary and Next Steps**
Summary of tool and impact, next steps in its evaluation, refinement, spread of use, and so on.

These should be submitted as a "Tools and Techniques" article in the online system. Suggested word limit: 4000.

Examples:


6. **Review Articles**
Reviews on clinical topics or improvement methodologies provide an update on current understanding of clinical (such as prevention or treatment of frequent and/or important adverse events, such as patient falls) and improvement topics (such as morbidity and mortality conferences).

Review articles should include an unstructured abstract of no more than 250 words. Headings should include the same headings as for Original Articles. The Methods section should include a subheading for "Search Strategy and Selection Criteria," which states the sources (including databases, MeSH and free-text search terms and filters, and reference lists from journals or books) of the material covered, and the criteria used to include or exclude studies. Authors should describe how their findings add value to the existing evidence and should state the implications for clinical or improvement practice and future research. Suggested word limit: 4000.

6A. **Narrative Reviews**
Narrative reviews should address a problem or issue by combining expert opinion with a thorough and balanced review of available evidence. Narrative reviews are appropriate when the question of interest is too broad, the body of evidence too sparse, or the topic too new or controversial for a systematic review. Otherwise, systematic reviews are preferred. The review should put the topic into the context of the literature and interpret the evidence to help solve the problem for the reader.

Example:


6B. Systematic Reviews

Systematic reviews (or meta-analyses) should follow the guidelines in the PRISMA statement which can be found at http://www.prisma-statement.org/. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) provides an evidence-based minimum set of items for reporting systematic reviews and meta-analyses, and is an update and expansion of the QUOROM Statement. The PRISMA Statement consists of a 27-item checklist and a four-phase flow diagram. Authors will be required to submit the PRISMA checklist and flow diagram along with their manuscript. Although PRISMA focuses on randomized trials, the PRISMA Statement can also be used as a basis for reporting systematic reviews of other types of research, particularly evaluations of interventions.

Examples:

Ong MS, Coiera E. A Systematic Review of Failures in Handoff Communication During Intrahospital Transfers. (Jun 2011)

7. Conference Reports

Conference reports summarizing proceedings at a conference on quality and patient safety issues. Authors interested in submitting a conference report should contact the editors prior to submission.

Examples:


8. Commentary

These papers may address virtually any important topic in quality and patient safety. They should be focused on a particular problem or issue. They can include personal vignettes (drawing on the author's or relative’s own health care experiences) but should still address a known issue, such as patient-centered care, patient engagement, or patient-physician communication. If the patient(s) described in the manuscript is identifiable, a Patient Permission Form must be completed and signed by the patient(s) and submitted with the manuscript. Omitting data or making data less specific to de-identify patients is acceptable but changing data is not. Suggested word limit: 2500 words. (See Authors' Ethical Responsibilities.)

Examples:

Kirby, TJ. In Search of Water: South Carolina Hospitals Apply High Reliability Thinking to Protect Patients in the Midst of Flooding. (Sep 2016)
Buist M. Patient-Centered Care: Just Ask a Thoughtful Question and Listen. (Jun 2016)

9. Editorial

Editorials are solicited by the Editors and provide commentary on articles published in the same issue. Word limit: 1,200.

10. Letters to the Editor

We welcome correspondence on content published in the Journal or on other topics of interest to our readers. Letters are not peer reviewed, but the Journal may invite the authors of the article of interest to respond in the same issue. Some Letters might be chosen for online-only publication.
Article Type Summary, Including Word Length Limit, Abstract Requirements, and Article Type in Online Submission

1. Article Type Word Length Limit Abstract Article Type in Online Submission

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<td>Abbreviated Article Innovation Reports</td>
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<td>Abbreviated Article</td>
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Use of inclusive language

Inclusive language acknowledges diversity, conveys respect to all people, is sensitive to differences, and promotes equal opportunities. Articles should make no assumptions about the beliefs or commitments of any reader, should contain nothing which might imply that one individual is superior to another on the grounds of race, sex, culture or any other characteristic, and should use inclusive language throughout. Authors should ensure that writing is free from bias, for instance by using 'he or she', 'his/her' instead of 'he' or 'his', and by making use of job titles that are free of stereotyping (e.g. ‘chairperson’ instead of ‘chairman' and ‘flight attendant' instead of 'stewardess').

PREPARATION

Submission Directions

To ensure timely processing of manuscripts, the Journal only accepts manuscripts online via the website https://www.editorialmanager.com/jcjqps. Our online submission system guides you stepwise through the process of entering your article details and uploading your files. The system converts your article files to a single PDF file used in the peer review process. Editable files (e.g., Word, LaTeX) are required to typeset your article for final publication. All correspondence, including notification of the Editor's decision and requests for revision, is sent by e-mail.

New Submissions

Submission to this journal proceeds totally online and you will be guided stepwise through the creation and uploading of your files. The system automatically converts your files to a single PDF file, which is used in the peer-review process.

As part of the Your Paper Your Way service, you may choose to submit your manuscript as a single file to be used in the refereeing process. This can be a PDF file or a Word document, in any format or layout that can be used by referees to evaluate your manuscript. It should contain high enough quality figures for refereeing. If you prefer to do so, you may still provide all or some of the source files at the initial submission. Please note that individual figure files larger than 10 MB must be uploaded separately.

Cover Letter

All manuscripts must be accompanied by a cover letter. This should include: A brief manuscript overview (manuscript title, type, design, contribution, and relevance of the manuscript for the journal). As necessary, include additional context to help the editors and reviewers assess this submission. A statement that all authors listed on the manuscript have contributed sufficiently for the project to be included as authors A statement that the work has not been published elsewhere and is not being considered for publication elsewhere Description of any related articles published from the same project Previous presentations or publication in abstract form Description of any commercial associations or other situations that might pose a conflict of interest in connection with the submitted article OR a declaration that none of the authors have a relevant conflict of interest The funding source and the role of the funding source in the work (if any)

Double-blind review

This journal uses double-blind review, which means the identities of the authors are concealed from the reviewers, and vice versa. More information is available on our website. To facilitate this, please include the following separately:

Title page (with author details): This should include the title, authors' names, affiliations, acknowledgements and any Declaration of Interest statement, and a complete address for the corresponding author including an e-mail address.

Blinded manuscript (no author details): The main body of the paper (including the references, figures, tables and any acknowledgements) should not include any identifying information, such as the authors' names or affiliations.
Use of word processing software

It is important that the file be saved in the native format of the word processor used. The text should be in single-column format. Keep the layout of the text as simple as possible. Most formatting codes will be removed and replaced on processing the article. In particular, do not use the word processor's options to justify text or to hyphenate words. However, do use bold face, italics, subscripts, superscripts etc. When preparing tables, if you are using a table grid, use only one grid for each individual table and not a grid for each row. If no grid is used, use tabs, not spaces, to align columns. The electronic text should be prepared in a way very similar to that of conventional manuscripts (see also the Guide to Publishing with Elsevier). Note that source files of figures, tables and text graphics will be required whether or not you embed your figures in the text. See also the section on Electronic artwork.

To avoid unnecessary errors you are strongly advised to use the 'spell-check' and 'grammar-check' functions of your word processor.

Article Structure

Manuscripts should be double-spaced, in Times New-Roman, with 1-inch margins at top, bottom, and sides, and in 12-point type. The order of items in the manuscript is the title page, acknowledgments, abstract, text, references, tables, figure legends, and figures. All pages should be numbered.

Title Page. Include the title of the article, lead author's address and contact information (e-mail address and direct phone number; authors' (no more than 10) names and titles, affiliations, and, if different, the affiliation when the article was written. Authors should list only a primary and secondary affiliation. Grant support that requires acknowledgement must be mentioned on the title page.

Acknowledgments. You must obtain permission to reprint or adapt any illustrations or tables published previously. A copy (PDF) of the original signed letter granting such approval must accompany the manuscript. All material reprinted or adapted from previously published literature must be accompanied by the name of the original author, title of the article, title of the journal or book in which it appears, date of publication, and publisher's city and name.

Abstract. Please see the description of the specific article type for instructions on abstract requirements. See also, Article Type Summary, Including Word Length Limit and Abstract, above.

Text. Use standard abbreviations and acronyms as much as possible. If a non-standardized abbreviation is used, spell out fully at first use and use the short version thereafter. Use generic names for drugs whenever possible. If using brand names, put in parenthesis after first citing generic names.

References. Number references consecutively as they are cited (in superscript following punctuation), as in the following examples:

Patient handovers (also termed handoffs) following surgery have often been characterized by poor teamwork, unclear procedures, unstructured processes, and distractions.¹

Such tools serve as building blocks for Robust Process Improvement capability and sometimes even overlap with Robust Process Improvement methods.²⁻⁹

Cite page sources for quoted text:

... "patient-centered care," which the IOM defined as "providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions,"¹(p. 6) we use the term personalized care.

Each reference should be assigned only one number. The examples of citations for periodicals show the International Committee of Medical Journal Editors (ICMJE) uniform requirements, also known as the Vancouver style, for periodicals. Vancouver should be used for periodical sources only. Please note that these examples show full page ranges and use of et al. when there are 4 authors with only first author listed, which are deviations from the Vancouver style. (See also http://www.nlm.nih.gov/bsd/uniform_requirements.html.)

Author Name(s). Title of article. Journ abbrev. Year abbreviated month day if known; volume:inclusive page numbers. Include issue number if page numbers are not continuous from issue to issue.
Data references. This journal encourages you to cite underlying or relevant datasets in your manuscript by citing them in your text and including a data reference in your Reference List. Data references should include the following elements: author name(s), dataset title, data repository, version (where available), year, and global persistent identifier. Add [dataset] immediately before the reference so we can properly identify it as a data reference. This identifier will not appear in your published article.

Examples:


Tables and Figures. Cite tables and figures (for example, Table 1, Figure 1) consecutively in the text. All tables and figures should have titles that can be easily understood. Figures should also have short legends that comment on the information in the figure.

Tables may be submitted as a separate file or may be included in the manuscript file.

Electronic artwork
General points
- Make sure you use uniform lettering and sizing of your original artwork.
- Embed the used fonts if the application provides that option.
- Aim to use the following fonts in your illustrations: Arial, Courier, Times New Roman, Symbol, or use fonts that look similar.
- Number the illustrations according to their sequence in the text.
- Use a logical naming convention for your artwork files.
- Provide captions to illustrations separately.
- Size the illustrations close to the desired dimensions of the published version.
- Submit each illustration as a separate file.
- Ensure that color images are accessible to all, including those with impaired color vision.
A detailed guide on electronic artwork is available.

You are urged to visit this site; some excerpts from the detailed information are given here.
Formats
If your electronic artwork is created in a Microsoft Office application (Word, PowerPoint, Excel) then please supply 'as is' in the native document format.
Regardless of the application used other than Microsoft Office, when your electronic artwork is finalized, please 'Save as' or convert the images to one of the following formats (note the resolution requirements for line drawings, halftones, and line/halftone combinations given below):
EPS (or PDF): Vector drawings, embed all used fonts.
TIFF (or JPEG): Color or grayscale photographs (halftones), keep to a minimum of 300 dpi.
TIFF (or JPEG): Bitmapped (pure black & white pixels) line drawings, keep to a minimum of 1000 dpi.
TIFF (or JPEG): Combinations bitmapped line/half-tone (color or grayscale), keep to a minimum of 500 dpi.

**Please do not:**
- Supply files that are optimized for screen use (e.g., GIF, BMP, PICT, WPG); these typically have a low number of pixels and limited set of colors;
- Supply files that are too low in resolution;
- Submit graphics that are disproportionately large for the content.

**Color Artwork**

Please make sure that artwork files are in an acceptable format (TIFF (or JPEG), EPS (or PDF), or MS Office files) and with the correct resolution. If, together with your accepted article, you submit usable color figures then Elsevier will ensure, at no additional charge, that these figures will appear in color online (e.g., ScienceDirect and other sites) regardless of whether or not these illustrations are reproduced in color in the printed version. **For color reproduction in print, you will receive information regarding the costs from Elsevier after receipt of your accepted article. These costs may be waived if color is deemed essential.** Please indicate your preference for color: in print and/or online only. Further information on the preparation of electronic artwork.

**Illustration services**

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the study should be collected as part of routine care, including patient demographics, comorbidities, and outcomes. If additional data are needed from patients, informed consent should be obtained for the part of the study that requires these data (e.g., a survey of patients knowledge, attitudes, and behaviors related to the study aim). Remember also that health care providers are often a subject of quality improvement research, and it may be appropriate to obtain informed consent from them even if a waiver of consent from patients is approved. Using these principles, we believe it is possible to conduct large, rigorous, generalizable quality-improvement research while maintaining stringent protection for human participants. Because of the subtleties in judging whether these criteria are met, we believe the decision regarding a waiver of informed consent is best left to an IRB.

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