

Introducing quality improvement to the *Emergency Medicine Journal*

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SUMMARY

The *Emergency Medicine Journal* (EMJ) is introducing a new article format: Quality Improvement (QI) reports. In this editorial, we offer answers to the two critical questions any new article type poses: 'why publish?' and 'why read?'. We also explain what is the difference between a QI report and a research paper and describe the requirements of these articles for potential authors.

WHAT IS QI?

The origins of QI as a discipline are often traced to post-World War 2 Japanese manufacturing, with W. Edwards Deming as a founding father of both QI, and the 'Japanese economic miracle' of this period. Building on the work of fellow mathematician and statistician Walter Shewhart, Deming recognised he could understand and reduce variability through regular measurement, and as an engineer, he was able to improve design of both product and process. While it could be argued that attempts to improve quality in medicine can be traced back to Florence Nightingale, the focus on quality of care was given significant impetus in the decades of 1960–1980 when several articles identified deficits in care delivered at national levels.^{1,2} However, before it is assumed these deficiencies are behind us, in 2003, published data suggested that under 55% patients received recommended care in the USA.³ There are also several recent papers suggesting that internationally and across medical specialities this pattern continues.^{4,5} During the 1990s, there was an increase in the application of QI techniques and processes to healthcare settings, which has accelerated over the past two decades.¹ Knowledge of QI is now an established part of many emergency medicine curricula and engagement in QI often a requirement of regulatory bodies.

Batalden and Davidoff⁶ define QI as: 'The combined and unceasing efforts of everyone to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning)'. Other definitions mention the critical components of improving patient outcomes and experience using *change* management methods to alter systems, behaviour and culture of providers of care. The importance of measurement to identify improvement is inherent in the founding work of QI; there should be data to demonstrate improvement.

The essential elements of QI are:

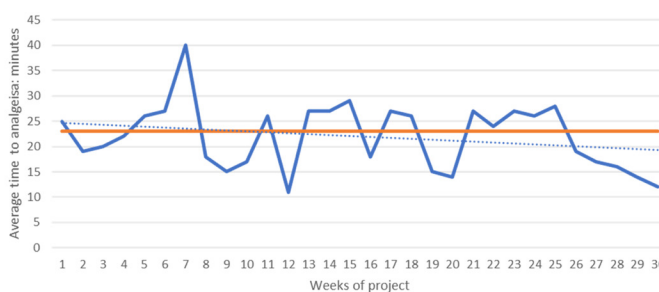
1. A focus on patient outcomes and experience.

2. Analysis of the issue to provide options for intervention and data monitoring (continuous measurement of outcome, process and balancing measures).
3. The use of data to feedback to ensure the process is iterative and good change management.^{7,8}

WHY IS THE EMJ PLANNING TO PUBLISH QI REPORTS?

Worldwide, EDs are struggling with several common challenges to their ability to deliver the highest quality care. These include rising numbers of patients, crowding, an ageing and more complex patient population, substance abuse and mental health. The nature of our specialty requires that we can quickly change our practice to translate new knowledge into standard of practice in areas of sepsis, stroke, cancer and infectious disease. Notably, the James Lind Alliance found that of the top 10 research priorities for adults, seven were related to the delivery of care.⁹

1a: Example Run Chart: Time to Analgesia



1b: Example SPC Chart: Time to Analgesia

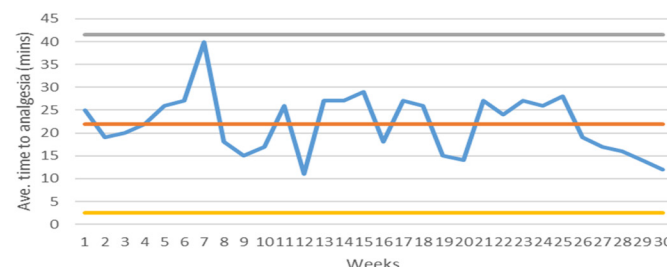


Figure 1 Control charts. (A) Example run chart. Run chart showing data points in blue, median in red and trend line (hashed). Run chart rules: a shift: 6 or more points above/below median: as unlikely this is due to chance, intervention likely to have been effective in producing change. A trend: 5 or more points consecutively increasing/decreasing. A run: indicates if sufficient data points exist; the data plot should cross median line often. A run is a series of points above or below the line. Run number is the number of times the median line is crossed, add one. For a given number of data points, there is an upper and lower acceptable number of runs to identify if enough data points collected. An astronomical point is one that is clearly abnormal, usually special case variation. (B) Example SPC Chart. SPC Chart showing data points (blue), upper control limit (grey), lower control limit (yellow) and mean (red). SPC rules include: 1 point is >3 SD from mean: one out of control point. Six points increasing/decreasing: a trend exists. Nine points same side of average: prolonged bias exists. Other rules exist regarding identification of non-random data and out of control data.

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QI is not the sole (or even the primary) province of those who consider themselves core researchers, meaning that more emergency physicians, nurses and support staff can contribute to the improvement of healthcare through these efforts and publications. The change ideas published in QI reports may, in many cases, be equally if not more practice changing to our readership than specific advances in diagnosis and treatment. QI provides an opportunity for emergency clinicians to share common issues and concerns with possible interventions and solutions.

WHY SHOULD I READ QIP REPORTS?

The benefits to the reader are many: principally these are insight, inspiration and ideas. It is often said that 'the fish does not notice the ocean'. As clinicians, we like to think we give exemplary care to our patients and cannot identify areas to improve, but reading a QI project may serve to make us question our practice, particularly the outcomes for our patients. While it is true that a QI project may not be fully generalisable to another ED, we are probably more similar than we are different. Reading a QI report may also serve to give us a few ideas for change (or bear traps to avoid) and enthuse us for making these changes. Lastly, there is comfort that 'nihil novum sub sole' (there is nothing new under the sun) in that we all face the same challenges in improving care for our patients.

HOW IS QI DIFFERENT FROM RESEARCH?

Research aims to test and disprove a hypothesis: for example, is drug A safer than drug B for sedating a patient? To be certain that the patient's outcome is solely a result of one drug or the other, researchers will attempt to control for things that are known to affect the outcome measure (eg, other medications and degree of monitoring) or randomise to reduce differences between groups (reducing effects from confounding variables such as age and comorbidities). The investigators and the subjects may be blinded to the intervention. The intention is that the groups (intervention and control) differ only in one aspect—the drug they receive—and only receive one of the treatments. In terms of measurement, the researchers attempt to measure the outcomes in all the patients within the study group. The data collection also involves Patient Identifiable Data. This leads to a widely generalisable result: drug A has less adverse events when performing sedation in a similar group of patients.

By contrast, QI does not have a fixed hypothesis and does not seek a concurrent control (there is no comparison group) or to control for known confounding variables. There is no blinding of patient, staff or project team, and bias is accepted (although variability should be reduced). Measurements in QI are very different in several aspects. During QI, there is only sufficient measurement to identify positive or negative effects of the interventions (of which there are usually multiple), and these measurements are continuously taken, hence the interventions are tested serially (unlike a research trial). With a control chart (developed by Shewhart, see [box 1](#) and [figure 1](#)), serial measurements are plotted against time to identify both variation and the impact of interventions, and the comparison is against statistical controls (usually running average and range) rather than a control group. The 'hypothesis' (which intervention or combination of interventions influences the outcome) is not fixed. Using the example of a QI process for sedation, the aim is to establish what, if any, interventions improve the sedation experience and safety in a specific department, rather than providing an externally generalisable, specific single 'solution' to the identified problem. There will frequently be a series of interventions including protocolling, checklist introduction, educational packages and initiatives, credentialing processes and the use of different sedating agents. These interventions often will be 'routine' accepted solutions, and previously tested processes, although used in a novel way. Hence, a new drug or indication is not being evaluated, but the choice of drug, the processes of sedation or the structures surrounding sedation are assessed. The outcomes may well include clinical outcome measures such as adverse events and recovery speed and patient reported outcomes (such as tolerability) and process measures (compliance with protocol).

ETHICAL CONSIDERATIONS FOR QI

Research involves experimentation. Ethical considerations and ethical approval are essential and legally required for publication. With QI, there are rarely completely 'novel' or untried interventions (although the setting or use may be novel) and no experimentation. Ethics is still paramount as interventions in a QI project may unintentionally adversely affect outcomes, including those of seemingly unrelated areas, hence the need for 'balancing measures'. One common example is projects that front load and accelerate sepsis bundles may affect triage time in patients with stroke or pain management in patients

Box 1 Emergency Medicine Journal (EMJ) instructions to authors for quality improvement manuscripts

From EMJ Instructions to authors¹⁴:

This should comply with the SQUIRE 2.0 reporting guideline (endorsed by the EQUATOR Network) and a completed checklist is to be included with the submission.

Abstract: 300 words maximum.

Word count: up to 3000 words.

Illustrations and tables: up to 6.

References: up to 25.

The paper should describe a quality improvement initiative, that is, describing the process whereby patients benefit from a change to (or within) a service. The function of Quality Improvement (QI) is to aim to improve patient experience and/or outcomes, hence to enhance the clinical care delivered to patients in a sustainable manner.

Recommended sections:

Introduction

This should include a description of the 'local problem' and the background to this, including the evidence available from previous studies, improvement projects, grey literature and so on. An analysis of the problem with description how this was conducted, and how it relates to the generated specific aims of the project should be included.

Methods

A description of the chosen interventions, QI methodology and metrics (including rationale for choosing) should be included. How the interventions and metrics are related and how inferences about the effect of interventions on metrics were made (eg, understanding variation in data) should be discussed.

Results

The data of outcome, process and balancing measures should be included, along with details of the interventions and the change in outcomes over time (eg, using a run chart, Statistical Process Control chart and timelines).

Discussion

This should include the association between the interventions and the measures, together with a discussion of the utility of the project (especially to other contexts) and including suggestions for further work. The limitations section should include barriers/difficulties encountered and elements of the project that may affect internal validity and generalisability.

Table 1 Suggested quality improvement tools

Stage of project	Tool	What is it?	How to use	Example
Identifying problems	Fishbone (cause and effect).	Cause and effect analysis helps you to think through the causes of a problem, including possible root causes, before you start to think of a solution – not just symptoms.	Create diagram to identify all possible causes of a problem.	Figure 2 . Antibiotics in sepsis.
	Process map.	Diagrammatic representation of all steps within a patient pathway.	To understand the 'flow' of patients and to identify replicated and redundant processes.	https://improvement.nhs.uk/documents/2143/conventional-process-mapping.pdf
	Root cause analysis ('5 whys' is a simpler tool).	To identify the ultimate cause (s) of failure within a process.	To understand key elements of process and where they have failed.	https://improvement.nhs.uk/documents/2156/root-cause-analysis-five-whys.pdf
	Healthcare failure modes and effect analysis.	To identify where a process could fail.	To understand key elements of process and where they could fail.	https://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp
	Driver diagram.	Similar to fishbone diagrams, driver diagrams can be used to illustrate your theories for cause and effect in your system.	It is helpful to create driver diagrams during the initial planning stages of a change programme.	Figure 3 . Example driver diagram.
Developing aims	SMART Aims	An aims statement should be included stating what you want to achieve from your project and timeframe for completing it.	You should include the following elements: Specific: don't just say 'we will improve time to triage'. Measurable: has a numerical target that can be measured (eg, reduction in time to triage by 30 min). Achievable: is the goal possible? Relevant: is it patient centred and/or linked to strategic aims of your institution? Time-bound: dates should be provided for when you want to achieve this aim by.	'We aimed to reduce average time to triage by 30 min (from 60 min) at North Bristol Hospital by December 2019'.
	Pareto diagram, dot voting, priority matrix.	These tools all evaluate possible interventions to establish which to use.	To select 'best' intervention in the context of the individual setting.	https://improvement.nhs.uk/documents/2137/pareto.pdf
	De Bono's Thinking Hats, 'Breaking the Rules', 'Fresh eyes', 'Stop before you start', TRIZ and so on.	These are variety of tools that give a systematic approach to creative thinking regarding problems and potential solutions.	For use in small groups when considering possible interventions.	https://improvement.nhs.uk/documents/2167/six-thinking-hats.pdf
Measurement for improvement	Plan, Do, Study, Act (PDSA) Cycles	This model for improvement provides a framework for testing small-scale interventions in a structured way prior to whole system change. A high-quality ID project will include a number of PDSA cycles testing small interventions over time.	The four stages of the PDSA cycle are: Plan: the change to be implemented. Do: carry out the change. Study: collect data before and after the change to see if an improvement in chosen outcome was achieved. Act: plan next change cycle or implementation.	Figure 4 . The PDSA cycle model for improvement.
	Control charts, such as: Statistical Process Control (SPC) chart (run charts are simpler).	A graph showing a measure (eg, time to triage) over time. We suggest a minimum of 25 data points, together with means and some upper and lower control limits as lines.	Control charts are used to understand the scale and variation of the problem. It is encouraged that specific interventions (PDSA cycles) are illustrated on SPC charts to allow the reader to determine whether the intervention leads to improved process measures.	Figure 1 . An example of run chart and SPC chart. Different 'rules' exist for SPC and run charts defining sufficiency of data, trends and shifts/changes (see explanation in figure legend).

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Box 2 Useful resources

Introduction to quality improvement
Batalden PB, Davidoff F. What is Quality Improvement and how can it transform healthcare? *BMJ Quality and Safety* 2007;16:2–3.

The Heath Foundation. Quality Improvement made simple. 2013, ISBN 978-1-906-47-8. Available at <https://www.health.org.uk/sites/default/files/QualityImprovementMadeSimple.pdf>.

Organisations that focus on QI in healthcare

The Institute for Healthcare Improvement (www.ihl.org).

The Health Foundation (www.health.org.uk).

Healthcare Quality Improvement Partnership (HQIP) (www.hqip.org).

Agency for Healthcare Research and Quality (www.ahrq.gov).

Basic Science

Methods

HQIP. Guide to Quality Improvement Methods. Available at:

https://www.hqip.org.uk/resource/guide-to-quality-improvement-methods/#.XGaAHrcV_IU.

Varkey P, Reller K, Resar RK. Basics of quality improvement in health care. *Mayo Clinic Proceedings* 2007;82:735–739: <https://doi.org/10.4065/82.6.735>.

Metrics

Raleigh VS, Foot C. Getting the measure of quality. The Kings Fund 2010. ISBN: 978 1 85717 590 5 Available at: <https://www.kingsfund.org.uk/sites/default/files/Getting-the-measure-of-quality-Veena-Raleigh-Catherine-Foot-The-Kings-Fund-January-2010.pdf>.

<https://improvement.nhs.uk/documents/2135/measuring-quality-care-model.pdf>.

Ethical debate

Lynn J, Baily MA, Bottrell M, et al. The ethics of using quality improvement methods in health care. *Ann Intern Med* 146:666–673. doi: 10.7326/0003-4819-146-9-200705010-00155.

Casarett D, Karlawish JH, Sugarman J. Determining when quality improvement initiatives should be considered research: proposed criteria and potential implications. *JAMA* 2000;283:2275–80.

with trauma (as these are also commonly front loaded).

Most organisations will have a process for approval of QI projects. Like audit, there is sometimes a rapid review process by the Institutional Review Body. While

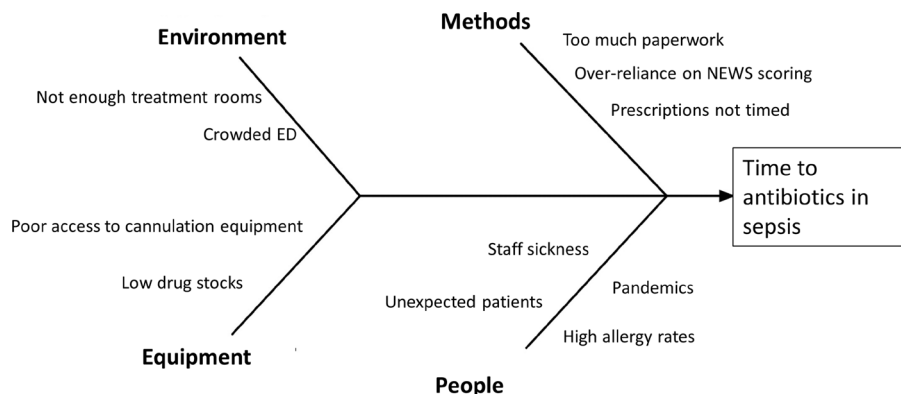


Figure 2 Example fishbone diagram: time to antibiotics in sepsis. NEWS, National Early Warning Score.

formal ethical board approval is not a requirement for publication of true QI projects, local institutional policies and processes must be followed, and evidence of this is needed for publication. However, authors should be mindful that the debate continues as to whether in some circumstances ethical approval is required.¹⁰ In the UK, the NHS Health Research Authority provides a decision tool to help decide whether a project is research or QI as defined by the UK Policy Framework for Health and Social Care Research (<http://www.hra-decisiontools.org.uk/research/>).

HOW IS QI DIFFERENT FROM SERVICE IMPROVEMENT/COST IMPROVEMENT?

There is some overlap between service improvement, cost improvement and QI. The main difference is the intended aim of the project and specifically how patient centred the project is, particularly in relation to patient experience or outcomes. The lines can become blurred, especially with larger scale projects. For example, it is known that adequate staffing levels, well trained staff and contented staff can improve patient

outcomes^{11 12} so projects aimed at improving such aspects of care delivery are often argued as having a QI aim. While this may be true, the key question is how will the patient 'feel' the benefit or more precisely what outcome metrics will demonstrate the effect of the project on patients. For example, a project aimed at improving rostering for staff well-being (or to match to service requirements) may help with staff retention (or reduce waiting times), but what metrics will be used to identify improved experience for patients? Another consideration is the number of interventions: in this case, a new rota (regardless of how many times it is revised and improved) is the sole intervention.

HOW TO WRITE UP A QIP REPORT FOR PUBLICATION: STANDARDS FOR QUALITY IMPROVEMENT REPORTING EXCELLENCE (SQUIRE)

The SQUIRE,¹³ revised in 2015, provide a useful checklist and glossary for authors to use when considering writing up a QI initiative for publication. Box 1 reproduces the instructions for authors available

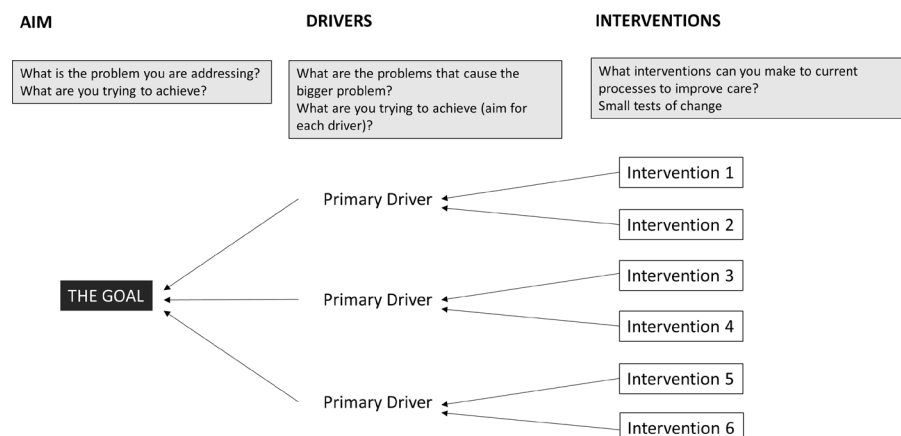


Figure 3 Example driver diagram template. Note: there may be secondary and tertiary drivers.

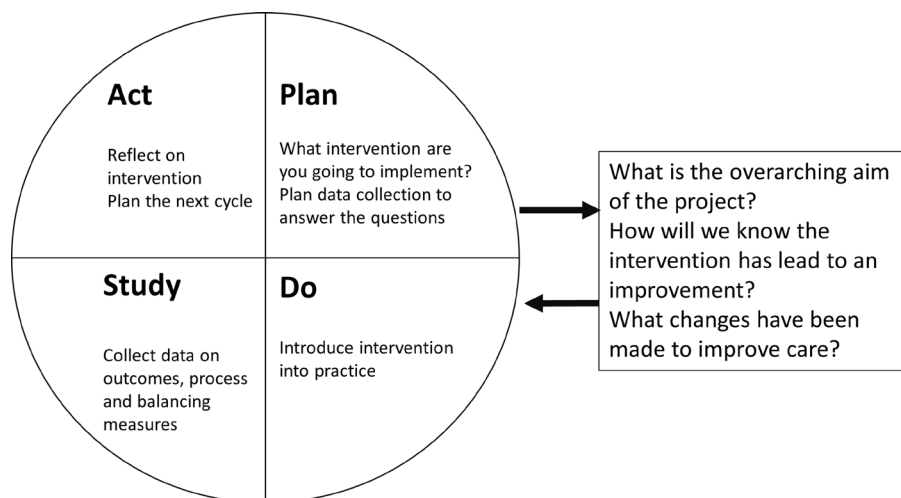


Figure 4 Model for improvement: plan, do, study and act (DSA).

on the *EMJ* website,¹⁴ which provides a summary for authors wishing to submit a QI report to the *EMJ*.

WHAT TO INCLUDE WHEN SUBMITTING A QIP

When describing a QI initiative, there are several key elements that should be included. The first step is to identify what the initial local 'problem' or issue was, including contextual aspects (eg, what internal analyses were performed). This may include pilot data collection, patient and staff interviews and surveys. There are several QI tools (table 1 lists commonly used QI tools, and box 2 lists useful resources) that when used may increase the likelihood of success: choosing a methodology appropriate to the issue is important.¹⁵ Next, further analysis of the issue with potential interventions, metrics and how these were identified and the rationale for choosing them is required. Various tools for analysis of the issue and generation of suite of interventions exist and could usefully be described: this could include, but is not limited to, pilot data, focus groups and observation/process mapping. Describing the links between the issue and the interventions, and the issue and the metrics will help with analysis of the data and enable the reader to draw inferences regarding associations between these. Ethical considerations should be addressed, including local institutional review and approval (including confirmation that this is not a research project).

In the results section, a run chart or and Statistical Process Control (SPC) chart (figure 1) is essential^{7,8} as this will particularly help with revealing how the interventions (and iterations of these) affected the metrics. When considering the conclusions of a QI report; limitations of the work

project should be discussed, and the benefits of the work (eg, potential for translation to other systems and the impact on the system and staff). Any novel aspects, whether in terms of choice of interventions, approach or measurement should be highlighted. Reports of projects that do not demonstrate improvement or succeed in their aims are eligible for publication, provided they explain why the project did not succeed, how this might be done differently and/or to highlight new ideas or innovations.

WHAT NOT TO INCLUDE WHEN SUBMITTING A QIP

The project should not be an uncontrolled study: the *EMJ* has specific requirements for before and after (pre-post) studies.¹⁶ One of the key differences between a before-and-after study and a QI project is the number and timing of the interventions and the monitoring of the effect of interventions. A QI project is iterative and not a 'one off'. Returning to the example of sedation safety, a pre-post project implements a change (single or multiple) and then at the end of the project compares outcomes (ie, two data points) to see whether the interventions have improved safety. In a QI project, the data are continually collected (multiple data points), and the effect of each iteration of the intervention is seen. For example, the project might start with introduction of a proforma and finesse this, then after reviewing effect on the metrics consider whether increased personnel has an effect, then assess personnel activity, then the effect of different monitoring systems, then the effect on safety of different medications, then automated monitoring and alarms and so on. With a QI project, there is continuous measurement of the

data, and interventions are implemented in a series, with the effect of the interventions monitored in 'real time'. The inclusion of a run chart or SPC chart will help demonstrate the effectiveness (or not) of interventions as they are added and assist with supporting and inferences regarding association between the actions and the outcomes.

GOING FORWARD

Quality improvement is an integral part of emergency medicine practice. Over the next year, the *EMJ* will begin to review and publish QI reports. We hope it will inspire readers to explore the discipline of QI further, perhaps conduct their own work and have a positive impact on patient outcomes in emergency care. We encourage you to review these recommendations for publication and submit your work to the *EMJ*.

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