e1 The Safety and Quality of Health Care

David W. Bates

The safety and quality of care are two of the central dimensions of health care. It is increasingly clear that both could be much better, and in recent years it has become easier to measure both safety and quality. In addition, the public is—with good justification—demanding measurement and accountability, and increasingly payment for services will be based on performance in these areas. Thus, physicians must learn about these two domains, how they can be improved, and the relative strengths and limitations of our current ability to measure them.

Safety and quality are closely related but do not completely overlap. The Institute of Medicine has suggested in a seminal series of reports that safety is the first part of quality, and that health care first must guarantee that it will deliver safe care, although quality is also pivotal. In the end, it is likely that more net clinical benefit may be derived from improving quality than safety, though both are important, and safety is in many ways more tangible to the public. Accordingly, the first section of this chapter will address issues relating to the safety of care, while the second will cover quality of care.

SAFETY IN HEALTH CARE

Safety Theory Safety theory clearly points out that individuals make errors all the time. Think of driving home from the hospital; you intend to stop and pick up a quart of milk on your way home, but you find yourself entering your driveway, without realizing how you got there. We all use low-level, semi-automatic behavior for many of our activities in daily life; this kind of error is called a "slip." Slips occur often during care delivery; e.g., when someone intends to write an order but forgets because they have to complete another action first. "Mistakes," by contrast, are errors of a higher level; they occur in new or non-stereotypic situations in which conscious decisions are being made. An example would be in dosing a medication with which the physician is not familiar. The strategies used to prevent slips and mistakes are often different.

Another theory relating to errors is human factors theory, which describes how activities are carried out and offers a variety of insights into how to make them safer and more reliable.

Systems theory suggests that most accidents occur as the result of a series of small failures, which happen to line up in an individual instance such that an accident can occur (Fig. e1-1). It also suggests that most individuals in an industry such as health care are trying to do the right thing (e.g., deliver safe care), and most accidents can be seen as the result of defects in the systems. Correspondingly, systems should be designed both to make errors less likely and to identify those that do occur, as some inevitably will.

Factors That Increase the Likelihood of Errors A number of factors ubiquitous in health care systems can increase the likelihood of errors, including fatigue, stress, interruptions, complexity, and transitions. The effects of fatigue in other industries are clear, but its effects in health care have until recently been more controversial. For example, the accident rate in truck drivers increases dramatically if they work over a certain number of hours in a week, and especially with prolonged shifts. A recent study of house officers in the intensive care unit demonstrated that they were about one-third more likely to make errors when they were on a 24-h shift than when they were on a schedule that allowed them to sleep 8 h the previous night. The American College of Graduate Medical Education (ACGME) has moved to address this issue by putting in place the 80-h work week. While this is a step forward, it does not address the most important cause of fatigue-related errors, i.e., extended-duty shifts. High levels of stress and workload can also increase error rates. Thus, in extremely high-pressure situations, such as cardiac arrests, errors are more likely to occur. Strategies

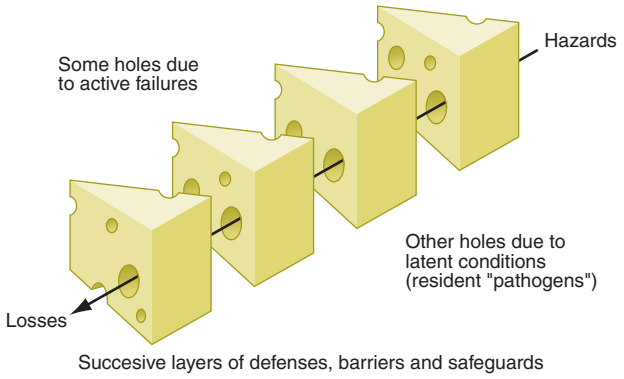

FIGURE e1-1 "Swiss cheese" diagram. Reason has argued that most accidents occur when a series of "latent failures" in a system are present, and that they happen to line up in a given instance, resulting in an accident. Examples of latent failures in the case of a fall might be that the unit was unusually busy that day, and that the floor happened to be wet. *(Adapted from J Reason: Human error: Models and management. BMJ 320:768–770, 2000; with permission.)*

such as using protocols in these settings can be helpful, as can simply recognizing that the situation is stressful.

Interruptions also increase the likelihood of error and are frequent in health care delivery. It is common to forget to complete an action when one is interrupted partway through it by a page, for example. Approaches that may be helpful in this area include minimizing the use of interruptions and setting up tools that help define the urgency of the interruption.

In addition, complexity represents a key issue that contributes to errors. Providers are confronted by streams of data, such as laboratory tests and vital signs, many of which provide little useful information, but some of which are important and require action or suggest a specific diagnosis. Tools that emphasize specific abnormalities or combinations of abnormalities may be helpful in this area.

Transitions between providers and settings are also frequent in health care, even more so with the advent of the 80-h work week, and generally represent vulnerabilities. Tools that provide structure in exchanging information, e.g., when transferring care between providers, may be helpful.

The Frequency of Adverse Events in Health Care Most of the large studies focusing on the frequency and consequences of adverse events have been performed in the inpatient setting; some data are available for nursing homes, and much less information is available in the outpatient setting. The Harvard Medical Practice Study was one of the largest studies to address this issue, and was performed with hospitalized patients in New York. The primary outcome was the adverse event, which is an injury caused by medical management, rather than the patient's underlying disease. In this study, an event either resulted in death or disability at discharge, or prolonged the length of stay by at least 2 days. Key findings were that the adverse event rate was 3.7%, and 58% of adverse events were considered preventable. Although there was some concern that New York is not representative of the rest of the country, the study was replicated later in Colorado and Utah, where the rates were essentially similar. Since then, other studies have been performed in a variety of developed nations using analogous methodologies, and the rates in most countries appear to be ~10%.

In the Medical Practice Study, adverse drug events (ADEs) were the most frequent type, accounting for 19% of adverse events, followed by wound infections (14%) and technical complications (13%). Almost half of the adverse events were associated with a surgical procedure. Among the nonoperative events, 37% were ADEs, 15% were diagnostic mishaps, 14% were therapeutic mishaps, 13% were procedure-related, and 5% were falls.

ADEs have been studied more than any other category. Studies focusing specifically on ADEs have found that they appear to be much

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more frequent than was suggested by the Medical Practice Study, although most other studies use more inclusive criteria. Detection approaches in the research setting include chart review and use of a computerized ADE monitor, which is a tool that explores the database and identifies signals that suggest an ADE may have occurred. Studies that use multiple approaches find more ADEs than any individual approach, suggesting that the true underlying rate in the population is higher than would be identified by any individual approach. About 6–10% of patients admitted in U.S. hospitals suffer an ADE.

Injuries caused by drugs are also frequent in the outpatient setting. One study found a rate of 21 ADEs per every 100 patients per year when patients were called to assess whether or not they had had a problem with one of their medications. The severity level was lower than in the inpatient setting, but approximately one-third of the ADEs were preventable.

Another area that appears to be very risky is the period immediately after the patient is discharged from the hospital. One recent study of patients hospitalized on a medical service found an adverse event rate of 19%; about a third of these were preventable, and another third were ameliorable in that they could have been made less severe. ADEs were the single leading category.

Prevention Strategies Most of the work on adverse event prevention strategies has targeted specific types of adverse events in the inpatient setting, with ADEs and nosocomial infections having received the most attention. For ADEs, several strategies have been found to reduce the medication error rate, although it has been harder to demonstrate that they reduce the ADE rate, and studies with adequate power to demonstrate a clinically meaningful reduction have not been published as yet.

Computerized physician order entry (CPOE) linked with clinical decision support has been found to reduce the serious medication error rate—serious medication errors are those that harm someone or have the potential to do so. In one study, CPOE, even with limited decision support, decreased the serious medication error rate by 55%. CPOE can prevent medication errors by suggesting a default dose, ensuring that all orders are complete (e.g., include a dose, route, and frequency), and checking orders for allergies, drug-drug interactions, and drug-laboratory issues. In addition, clinical decision support can suggest the right dose for the patient, tailoring it to the patient's level of renal function and age. In one study, without decision support patients with renal insufficiency received the appropriate dose only one-third of the time, while this fraction increased to approximately two-thirds with decision support, and patients with renal insufficiency were discharged from the hospital one-half day earlier. As of 2006, only about 15% of U.S. hospitals had implemented CPOE, but many more have plans to do so.

Another technology that can improve medication safety is bar-coding linked with an electronic medication administration record. Bar-coding can help ensure that the right patient gets the right medication at the right time. Electronic medication administration records can make it much easier to determine what medications a patient has received. Studies to assess the impact of bar-coding on medication safety are underway, and the early results are promising. Another technology that can be used to improve the safety of medication administration is "smart pumps." These are pumps that can be instructed in which medication is being given, and at what dose; if the nurse tries to administer too high a dose, he or she will receive a warning.

Non-technology-oriented interventions can also be highly effective. For example, having a pharmacist round with the team in the intensive care unit has been shown to decrease the ADE frequency substantially in that setting; this oversight is now a Joint Commission of Accreditation of Healthcare Organizations (JCAHO) requirement.

The National Picture around Safety Several organizations, including the National Quality Forum (NQF) and the JCAHO, have made recommendations about how to improve safety. In particular, the NQF has released recommendations to the country's hospitals about what practices will most improve the safety of care, which all hospitals are expected to implement (Table e1-1). Many of these practices arise frequently in routine care. One example is "readback," which is the practice of recording all verbal orders and immediately reading them back to the physician to verify the accuracy of what was heard. Another is to use only standard abbreviations and dose designations, since some abbreviations and dose designations are particularly prone to error; for example, 7U may be read as 70.

Measurement of Safety Measuring the safety of care is quite difficult and expensive, since adverse events are fortunately rare. Most hospitals rely on spontaneous reporting to identify errors and adverse events, but this approach has a very low sensitivity, with only ~1 in 20 ADEs reported. There are promising research techniques that involve searching the electronic record for signals suggesting that an adverse event has occurred, which will likely be routine in the future but are not yet in wide use. Claims data have been used to identify the frequency of adverse events; this approach works much better for surgical care than for medical care and still requires additional validation. The net result is that except for a few specific types of events, such as falls and nosocomial infections, hospitals have little idea about the true frequency of safety issues.

Nonetheless, all providers have the responsibility to report problems with safety as they are identified. All hospitals have spontaneous reporting systems, and if providers report events as they occur, these events can be used as lessons for subsequent improvement.

Conclusions about Safety It is now abundantly clear that the safety of health care can be improved substantially; as more areas are studied closely, more problems are identified. Compared to the outpatient setting, much more is known about the epidemiology of safety in the inpatient setting, and a number of effective strategies for improving safety have been identified and are being used increasingly. Some effective strategies are also available in the outpatient setting. Transitions appear to be especially risky. The solutions to improving care will often involve leveraging information technology, but they will also involve many other domains, such as use of human factors techniques, team training, and building a culture of safety.

QUALITY IN HEALTH CARE

Quality of care has remained somewhat elusive, although the tools for measuring it have increasingly improved. Selecting health care and measuring its quality is a complex process.

Quality Theory Donabedian has suggested that quality of care can be divided by type of measurement into structure, process, and outcome. *Structure* refers to whether or not a particular characteristic is present, e.g., whether a hospital has a catheterization laboratory or whether a clinic uses an electronic health record. *Process* refers to the way that care is delivered, and examples of process measures are whether a Pap smear was performed at the recommended interval or whether an aspirin was given to a patient with a suspected myocardial infarction. *Outcomes* refer to what actually happens, e.g., the mortality rate in myocardial infarction. It is important to note that good structure and process do not always result in good outcomes. For instance, a patient may present with a suspected myocardial infarction to an institution with a catheterization laboratory and receive recommended care, including aspirin, but still die because of their infarction.

Quality theory also suggests that overall quality will be improved more in the aggregate by raising the level of performance of all providers rather than finding a few poor performers and punishing them. This view suggests that systems changes are especially likely to be helpful in improving quality, since large numbers of providers may be affected simultaneously.

The theory of continuous quality improvement suggests that organizations should be evaluating the care they deliver on an on-going basis and continually making small changes to improve their individual processes. This approach can be very powerful if embraced over time.

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TABLE e1-1 SAFE PRACTICES FOR BETTER HEALTH CARE[a]

1. Create a health care culture of safety.
2. For designated high-risk, elective surgical procedures or other specified care, patients should be clearly informed of the likely reduced risk of an adverse outcome at treatment facilities that have demonstrated superior outcomes and should be referred to such facilities in accordance with the patient's stated preference.
3. Specify an explicit protocol to be used to ensure an adequate level of nursing based on the institution's usual patient mix and the experience and training of its nursing staff.
4. All patients in general intensive care units (both adult and pediatric) should be managed by physicians having specific training and certification in critical care medicine ("critical care certified").
5. Pharmacists should actively participate in the medication-use process, including, at a minimum, being available for consultation with prescribers on medication ordering, interpretation and review of medication orders, preparation of medications, dispensing of medications, and administration and monitoring of medications.
6. Verbal orders should be recorded whenever possible and immediately read back to the prescriber—i.e., a health care provider receiving a verbal order should read or repeat back the information that the prescriber conveys in order to verify the accuracy of what was heard.
7. Use only standardized abbreviations and dose designations.
8. Patient care summaries or other similar records should not be prepared from memory.
9. Ensure that care information, especially changes in orders and new diagnostic information, is transmitted in a timely and clearly understandable form to all of the patient's current health care providers who need that information to provide care.
10. Ask each patient or legal surrogate to recount what he or she has been told during the informed consent discussion.
11. Ensure that written documentation of the patient's preference for life-sustaining treatments is prominently displayed in his or her chart.
12. Implement a computerized prescriber order entry system.
13. Implement a standardized protocol to prevent the mislabeling of radiographs.
14. Implement standardized protocols to prevent the occurrence of wrong-site procedures or wrong-patient procedures.
15. Evaluate each patient undergoing elective surgery for risk of an acute ischemic cardiac event during surgery, and provide prophylactic treatment of high-risk patients with beta blockers.
16. Evaluate each patient upon admission, and regularly thereafter, for the risk of developing pressure ulcers. This evaluation should be repeated at regular intervals during care. Clinically appropriate preventive methods should be implemented consequent to the evaluation.
17. Evaluate each patient upon admission, and regularly thereafter, for the risk of developing deep vein thrombosis (DVT)/venous thromboembolism (VTE). Utilize clinically appropriate methods to prevent DVT/VTE.
18. Utilize dedicated anti-thrombotic (anti-coagulation) services that facilitate coordinated care management.
19. Upon admission, and regularly thereafter, evaluate each patient for the risk of aspiration.
20. Adhere to effective methods of preventing central venous catheter–associated bloodstream infections.
21. Evaluate each preoperative patient in light of his or her planned surgical procedure for the risk of surgical site infection, and implement appropriate antibiotic prophylaxis and other preventive measures based on that evaluation.
22. Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure, and utilize a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation.
23. Evaluate each patient upon admission, and regularly thereafter, for risk of malnutrition. Employ clinically appropriate strategies to prevent malnutrition.
24. Whenever a pneumatic tourniquet is used, evaluate the patient for the risk of an ischemic and/or thrombotic complication, and utilize appropriate prophylactic measures.
25. Decontaminate hands with either a hygienic hand rub or by washing with a disinfectant soap prior to and after direct contact with the patient or objects immediately around the patient.
26. Vaccinate health care workers against influenza to protect both them and patients from influenza.
27. Keep workspaces where medications are prepared clean, orderly, well lit, and free of clutter, distraction, and noise.
28. Standardize the methods for labeling, packaging, and storing medications.
29. Identify all "high alert" drugs (e.g., intravenous adrenergic agonists and antagonists, chemotherapy agents, anticoagulants and anti-thrombotics, concentrated parenteral electrolytes, general anesthetics, neuromuscular blockers, insulin and oral hypoglycemics, narcotics and opiates).
30. Dispense medications in unit-dose or, when appropriate, unit-of-use form, whenever possible.

[a]These 30 practices are the recommendations from the National Quality Forum (NQF) for improving the safety of health care; the NQF believes these should be universally utilized in applicable care settings to reduce the risk of patient harm. The practices all have strong supporting evidence and are likely to have a significant benefit.

A number of specific tools have been developed to help improve process performance. One of the most important of these tools is the Plan-Do-Check-Act cycle (Fig. e1-2). This approach can be used to perform what is called rapid cycle improvement for a process, e.g., the time for a patient with pneumonia to receive antibiotics after diagnosis. Often, specific statistical tools, such as control charts, are used in conjunction to determine whether or not progress is being made. Most medical care comprises one or many processes, making this tool especially important for improvement.

Factors Relating to Quality Many factors can decrease the level of quality, including stress to providers, high or low levels of production pressure, and poor systems, to name but a few examples. Stress can adversely affect quality because it can lead providers to omit important steps, as can a high level of production pressure. Low levels of production pressure can also sometimes result in worse quality, as providers may be bored or have little experience with a specific problem. Poor systems can have a tremendous impact on quality, and even extremely dedicated providers typically cannot achieve high levels of performance if they are operating within a poor system.

Data about the Current State of Quality A recent RAND study has provided the most complete picture of quality of care delivered in the United States to date. The results were sobering. The authors found that across a wide range of quality parameters, patients in the United States received only 55% of recommended care overall; there was little variation by subtype, with scores of 54% for preventive care, 54% for acute care, and 56% for care of chronic conditions, leading the authors to conclude that the chances of getting high-quality care in the United States broadly were little better than those of winning a coin flip.

Strategies for Improving Quality and Performance A number of specific strategies can be used to improve quality at the individual level, including rationing, education, feedback, incentives, and penalties. *Rationing* has been effective in some specific areas, such as convincing physicians to prescribe within a formulary, but it generally has been resisted. *Education* is effective in the short run and is necessary for changing opinions, but its effect decays fairly rapidly with time. *Feedback* on performance can be given either at the group or individual level. Feedback is most effective if it is individualized and if it is given in close temporal proximity to the original events. *Incentives* can be effective, and many believe that this will be a key to improving quality, especially if pay-for-performance with sufficient incentives is broadly implemented (see below). *Penalties* produce provider resentment and are rarely used in health care.

Another set of strategies for improving quality involves changing the systems of care. An example would be introducing reminders about which specific actions need to be taken at a visit for a specific patient, which is a strategy that has been demonstrated to improve performance in certain situations, e.g., in delivery of preventive services. Another approach that has been effective is the development of "bundles" or groups of quality measures that can be implemented together with a high degree of fidelity. A number of hospitals have now implemented a bundle for ventilator-associated pneumonia in the intensive care unit, which includes five measures, including, for example, ensuring that the head of the bed is elevated. The hospitals have found that they were able to substantially improve performance.

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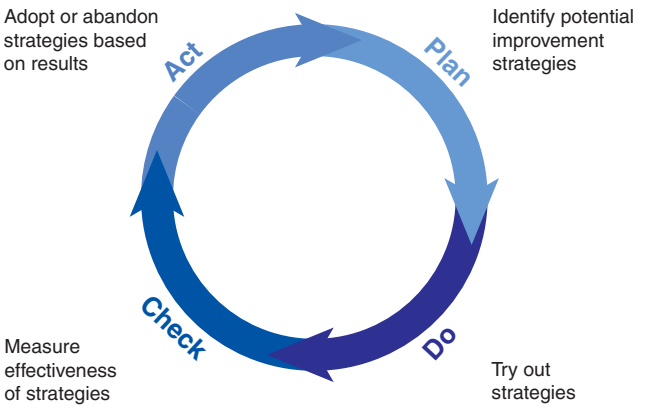

FIGURE e1-2 Plan-do-check-act (or PDCA) cycle. The PDCA cycle approach can be used to improve a specific process rapidly. First, planning is performed, and several potential improvement strategies are identified. Next, these strategies are trialed in small "tests of change." "Checking" is measuring whether or not they appeared to make a difference, and "act" refers to acting on the results.

Perhaps the most pressing need is to improve the quality of care for chronic diseases. The Chronic Care Model has been developed by Wagner and colleagues (Fig. e1-3); it suggests that a combination of strategies will be necessary, including self-management support, changes in delivery system design, decision support, and information systems, and that these must be delivered by a practice team composed of several providers, not just a physician.

Recent evidence about the relative efficacy of strategies in reducing hemoglobin A_{1c} (HbA_{1c}) in outpatient diabetes care (Fig. e1-4) supports this general premise. It is especially notable that the outcome was HbA_{1c}, as it has generally been much more difficult to improve outcome measures than process measures (such as whether a HbA_{1c} was performed). In this meta-analysis, a variety of strategies were effective, but the most effective ones were the use of team changes and use of a case manager. When cost-effectiveness is considered in addition, it appears likely that an amalgam of strategies will be needed. However, the more expensive strategies, such as use of case managers, will likely be implemented widely only if pay-for-performance takes hold.

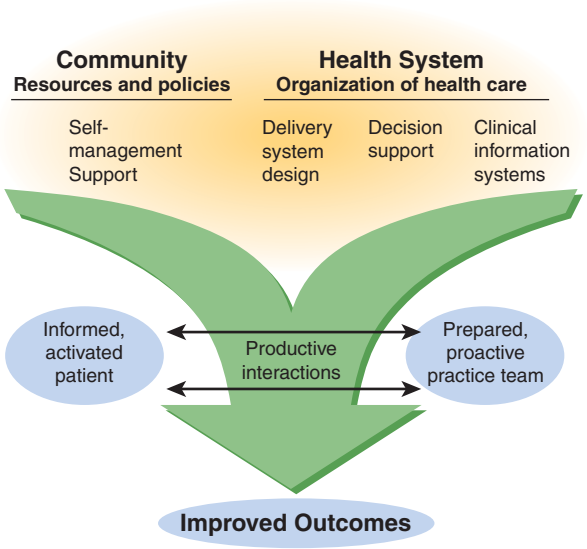

FIGURE e1-3 The chronic care model. The chronic care model, which focuses on improving care for chronic diseases, suggests that delivery of high-quality care demands a range of strategies that must closely involve and engage the patient, and, in addition, that team care is essential. *(From Wagner et al: Eff Clin Pract 1:2, 1998.)*

National State of Quality Measurement In the inpatient setting, quality measurement is now being performed by a very large proportion of hospitals for several conditions, including myocardial infarction, congestive heart failure, pneumonia, and surgical infection prevention; 20 measures are included in all. This is the result of the Hospital Quality Initiative, which represents a collaboration among many entities, including the Hospital Quality Alliance, the JCAHO, the NQF, and the Agency for Healthcare Research and Quality, among others. The data are housed at the Center for Medicare and Medicaid Services, which publicly releases performance on the measures on a website called *Hospital Compare*. These data are voluntarily reported and are available for a very high proportion of the nation's hospitals; they were first released in April 2006. Early analyses demonstrate that there is substantial regional variation in quality and that there are important differences among hospitals. Analyses by the Joint Commission for very similar indicators demonstrate that performance on measures by hospitals did improve over time, and that, as might be hoped, lower performers improved more than higher performers. Analogous national data for ambulatory care are not yet available, but a group called the Ambulatory care Quality Alliance (AQA) has been formed and is developing an analogous set of measures.

Public Reporting Overall, public reporting of quality data is becoming increasingly common. There are now commercial websites that have quality-related data for most regions of the country that can be accessed for a fee. Similarly, national data for hospitals are available. The evidence to date is that patients have not used such data very much, but that such data have had an important effect on provider and organization behavior. Instead, patients have relied on provider reputation to make choices. Part of the reason for this choice basis is that until very recently little information was available, and it was not necessarily represented in ways that were easy for patients to access. Many believe that as more information about quality becomes available, it will become increasingly central to patient choices about where to access care.

Pay-for-Performance Currently, providers in the United States get paid exactly the same amount for a specific service regardless of what quality care is delivered. The theory of pay-for-performance suggests that if providers are paid more for higher-quality care, they will invest in strategies that enable them to deliver that care. The current key issues in the pay-for-performance debate relate to (1) how effective it is, (2) what levels of incentives are needed, and (3) what perverse consequences are produced. The evidence about effectiveness is fairly limited to date, although a number of studies are ongoing. With respect to levels, most performance incentives around quality have accounted for merely 1–2% of total payment in this country to date, but in the United Kingdom, 40% of general practitioners' salaries have recently been placed at risk based on performance across a wide array of parameters. This has been associated with large improvements in reported quality performance, although it is still unclear as to what extent this represents better performance versus better reporting. The potential for perverse consequences exists with any incentive scheme. One problem is that if incentives are tied to outcomes, this introduces the incentive to transfer the sickest patients to other providers and systems. Another concern is that providers will pay too much attention to quality measures with incentives, and ignore the rest of the quality picture. The validity of these concerns remains to be determined.

CONCLUSIONS

The safety and quality of care in the United States could be improved substantially. A number of interventions are available today that have been demonstrated to improve the safety of care and should be used more widely; others are undergoing evaluation or will be evaluated. Quality could also be dramatically better, and the science of quality improvement is increasingly mature. Implementation of pay-for-performance should make it much easier for organizations to justify investments in improving these parameters, including health informa-

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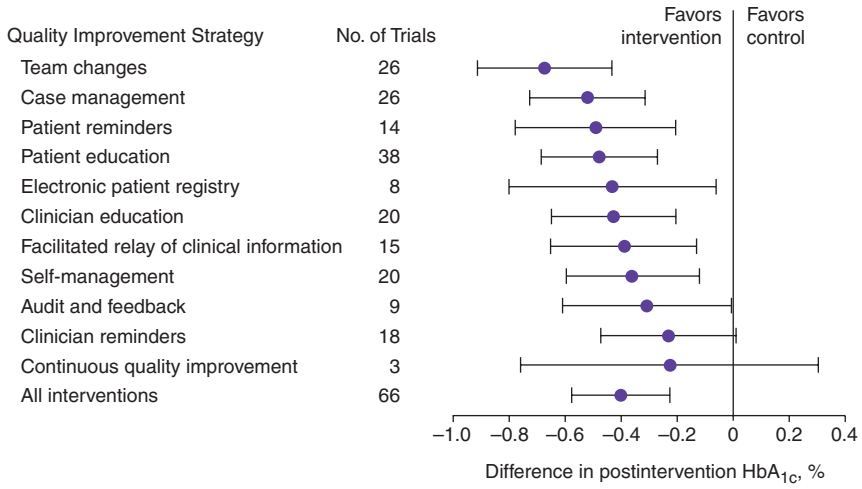

FIGURE e1-4 The efficacy of various strategies for improving diabetes care in outpatients. Shojania et al. performed a meta-analysis of evaluating the efficacy of strategies for reducing hemoglobin A_{1c} (HbA_{1c}) in diabetic outpatients; they found that team changes and case management had the largest impact on HbA_{1c}, although there was a trend toward improvement for many strategies. Interventions in which nurse or pharmacist case managers can make medication adjustments without awaiting physician authorization resulted in the largest reductions. *(From Shojania et al: JAMA 296:427, 2006.)*

tion technology; however, many will also require changing the structure of care, e.g., moving to a more team-oriented approach, and ensuring that the patients are more involved in their own care. The measures of safety are still relatively immature and could be made much more robust; it would be particularly useful if organizations had measures that they could use in routine operations to assess safety at reasonable cost. While the quality measures available are more robust than those for safety, they still cover a relatively small proportion of the entire domain of quality, and more need to be developed. The public and payers are now demanding better information about safety and quality, as well as better performance in these areas. The clear implication is that these domains will need to be addressed directly by providers.

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