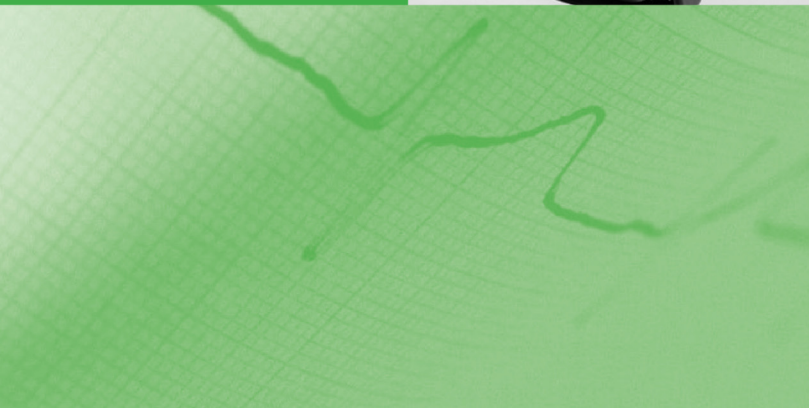


Patient  
Safety Event  
Reporting



# National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information

A CONSENSUS REPORT

The National Quality Forum (NQF) operates under a three-part mission to improve the quality of American healthcare by:

- building consensus on national priorities and goals for performance improvement and working in partnership to achieve them;
- endorsing national consensus standards for measuring and publicly reporting on performance; and
- promoting the attainment of national goals through education and outreach programs.

This work was conducted under a contract with the Department of Health and Human Services, Consensus-based Entities Regarding Healthcare Performance Measurement.

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# National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report

## Foreword

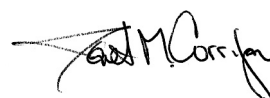
**HIGH-QUALITY HEALTHCARE** is safe healthcare. Public reporting of patient safety events is one avenue for improving healthcare safety. The primary aim of public reporting is to promote learning among providers and consumers regarding the nature and prevalence of safety risks.

This report, *National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information*, was developed to improve the quality of public reporting by providing guidance to those who sponsor and produce reports about patient safety events. It is applicable to public reports across all environments of care and to all report forms.

One of the earliest public reporting initiatives started in the 1980s when the precursor to the Centers for Medicare & Medicaid Services began reporting hospital mortality rates of Medicare patients. The National Quality Forum (NQF), itself, was later formed in response to the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry's report indicating that the first priority of healthcare must be to reduce healthcare errors. Since its formation, NQF has produced an array of products that focus on measuring, evaluating, reporting, and preventing patient safety events. The task of reporting is now facilitated by the use of widely accepted national data sources that are developed collaboratively across jurisdictions to enable compatibility.

These efforts are moving healthcare toward alignment of standards for accountability and public reporting, but the work is not finished. The goal of safer care will be realized when organizations responsible for public reporting align their efforts and work together to reduce patient safety events. The guidance contained in this report seeks to make a positive contribution toward that end. This report, however, will be useful only when those responsible for public reporting act on the recommendations detailed here so as to continue to add to the body of knowledge about public reporting.

NQF thanks the members of the Patient Safety Reporting Framework Steering Committee and NQF Members for their dedication to improving public reporting of patient safety information, which will lead to better healthcare for all Americans.



Janet M. Corrigan, PhD, MBA  
President and Chief Executive Officer

# National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report

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# National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report

## Executive Summary

**HIGH-QUALITY HEALTHCARE** is, first, safe healthcare. This report provides guidance that focuses on those who sponsor and produce public reports about patient safety events. It applies to public reports across all environments of care and to all report forms.

While the primary aim of public reporting is to facilitate consumer/patient decision-making, public reporting of patient safety events has the potential to serve multiple aims. It can promote learning among providers and consumers regarding the nature and prevalence of safety risks, and it can advance accountability of individual providers and organizations for safety. The aims of a particular report will drive its design and content, and it is important that reports be clear as to which aims they are designed to achieve.

The guidelines for publicly reporting patient safety event information presented herein are dynamic and should evolve as the science evolves. The framework is not meant to be approached as a set of guidelines to be addressed one after the other in the order presented. They should be used as part of a dynamic process.

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## National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information

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The seven guidelines listed below work together as an interconnected set.

- Identify the purpose of the report, its intended main consumer audiences, and how it will be made known to the audiences; also identify secondary audiences and how their unique needs will be addressed.
- Develop the report using a transparent process that involves consumers and other relevant stakeholders.
- The report should establish a context by describing what patient safety is, including understanding the nature of patient safety events, explaining where the measures are in their development or evolution (i.e., how the measures may or may not be used for comparison across organizations over time—their robustness/usefulness). Reporters should consider linking to well-accepted national sources such as the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), and NQF to accomplish this.

- Ensure that the measures included in a consumer-focused public report are meaningful to consumers, have transparent methodology, and meet widely accepted, rigorous criteria (i.e., important, scientifically acceptable, feasible, and usable).
- Present and explain the data clearly and objectively in ways that help consumers to understand and use the information. For each measure to be included, a determination should be made as to whether it is appropriately displayed as a rate, as low frequency, and, in some cases, should be included in a composite.
- Ensure that report design and navigation features enhance report usability. Web-based reports are recommended because of their design, display, and navigation capabilities.
- Regularly review and assess reports to ensure their effectiveness, usability, and currency.



# National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report

## Introduction

**HIGH-QUALITY HEALTHCARE** is, first, safe healthcare.<sup>1</sup> This report provides guidance to those who sponsor and produce healthcare quality and safety data reports. It draws on earlier National Quality Forum (NQF) work related to consumer-focused public reporting while focusing on the unique characteristics of patient safety event<sup>2</sup> reporting. It is intended to help report sponsors to ensure that the reports they issue are useful to consumers<sup>3</sup> in healthcare decisionmaking and useful to healthcare organizations, healthcare professionals, regulatory bodies, quality improvement organizations, and policymakers in promoting accountability and driving patient safety improvement.

This guidance applies to reports across all environments of care and to all report forms. Of note, a web-based report can be more easily used for such things as navigation, linkage to other sites, and drill down for explanatory or technical information.

Although the primary aim of public reporting is to facilitate consumer/patient decision-making, public reporting of patient safety events has the potential to serve multiple aims. It can promote learning among providers and consumers regarding the nature and prevalence of safety risks, and it can advance accountability of individual providers and organizations for safety. The aims of a particular report will drive its design and content, and it is important that reports be clear as to which aims they are designed to achieve.

The design of public reports pertaining to healthcare is a multifaceted task that should focus on the target audiences. This guidance considers the consumer to be the most important audience to reach and focuses on helping report sponsors to produce reports that the consumer can understand and use to make comparisons about the relative safety of the care provided by organizations and professionals to whom they entrust the care of themselves and their families. The science that supports effective public reporting is evolving; there is not yet a strong body of evidence that gives reporting organizations a formula for developing reports. This fact should not deter potential report sponsors from public reporting, but it should set a mandate for ensuring that development, testing, publication, and refinement of reports are focused on accurately representing the data in ways that are valid and useful to the target audiences. This focus should include evaluation of the outcomes of report publication, which may include improved consumer knowledge, improved provider outcomes and processes, and safer care.



Those responsible for this framework brought to bear their expertise; their understanding of the evidence related to patient safety event measurement, public reporting, and consumer engagement; and their experience with reporting and analyzing reports and report information in developing the guidance herein. No guidance related to public reporting will remain static over time. Public reporters and researchers are challenged to test both this guidance and the reports that are developed from its use as well as to monitor outcomes of other work in this area.<sup>4</sup> Part of that challenge is to report patient safety information that conveys valid, reliable data in a standardized way.

There are many efforts at patient safety reporting—both “reporting in” to regulatory and mandatory or voluntary systems and “reporting out” to the public. Although all of these efforts aim to improve the safety of healthcare, current reporting approaches risk confusion and misinformation. The goal of safer care will not be fully realized until reporting organizations align their efforts and move in a unified way toward reducing patient safety events. This guidance seeks to make a positive contribution toward that end.

## Background

Public reporting of patient safety information began as early as 1984, when the Health Care Financing Administration, now the Centers for Medicare & Medicaid Services (CMS), began reporting hospital mortality rates of Medicare patients.<sup>5</sup> However, it was not until 1998, when the President’s Advisory Commission on Consumer Protection and Quality in the

Health Care Industry published *Quality First: Better Health Care for All Americans*,<sup>6</sup> that concerted efforts to understand the issue truly began. In that report, the Commission concluded that the healthcare industry’s first priority must be to reduce the number of healthcare errors. It was out of that conclusion, and with that mandate, that the National Quality Forum (NQF) was formed. Since its formation, NQF has produced an array of products that focus on measuring, evaluating, reporting, and preventing patient safety events.<sup>7</sup> In 2002, NQF published a list of 27 adverse events in its report *Serious Reportable Events in Healthcare*,<sup>8</sup> setting out a course that continues to advocate for state and national reporting of adverse events to promote learning and the development of solutions. By identifying practices to prevent occurrence of adverse events, NQF’s *Safe Practices for Better Healthcare*,<sup>9</sup> first published in 2003, suggests additional measures. Also in 2003, NQF published *A Comprehensive Framework for Hospital Care Performance Evaluation*,<sup>10</sup> which provided a set of specific recommendations for reporting results to the public that spoke to the source and use of reports, the components of reports prepared for consumers, and the verification of results. The recommendations in that report remain useful and instructive to the current effort.

With the guidance and support of its member organizations, NQF has set standards for evaluating measures<sup>11</sup> for public reporting, and it has endorsed more than 90 performance measures that are directly related to patient safety as well as a tool for obtaining patients’ perceptions of their care.<sup>12</sup> It has endorsed reporting standards for a number of environments of care (e.g., hospitals, long-term care,

home care) and an array of healthcare professionals (e.g., physicians, nurses).

As individuals and organizations have begun to evaluate the science of patient safety event reporting, they have recognized issues unique to the field.

- **Low-frequency events:** Some events are serious but so low frequency that they should be reported simply as a number of events, not as a rate, nor should they be adjusted for volume or patient risk factors. There is currently no national consensus on which types of events are in this category, but events such as infant abduction or wrong patient surgery are commonly included. It is the report developer's responsibility to review proposed reportable events with appropriate stakeholders to determine which events should be reported as an unadjusted number of events rather than rates. It is anticipated that a national consensus will develop around some low-frequency events and appropriate reporting in the future.
- **Variability in consequences or harm:** Some events are, by definition, associated with significant harm (e.g., medication error leading to death). Others may be indisputable patient safety events but may not lead to any harm (e.g., retained needle, which does not require removal) or may lead to relatively transient harm (e.g., pressure ulcer, which is treated successfully before discharge from the facility). The same type of event (e.g., patient fall) may cause significant harm in one patient and no harm in another, for reasons of patient physiology, disease, and random chance, yet both events have the potential to flag a system in need of improvement.

Similarly, with increasing importance placed upon utilization of health information technology (HIT), it is now recognized that

events associated with use of electronic health information systems can be widely variable in terms of consequences and harm. Technology may reduce errors in some instances (e.g., errors associated with misinterpreted handwriting), while new potential sources of error may be introduced (e.g., use of dual—paper and electronic—systems that render both incomplete).

- **Lack of national consensus on appropriate volume- or risk-adjustment:** When rates are employed, it is not clear which rate format is optimal. For example, is it most useful to express rates of adverse events in terms of number per 1,000 patient (or device) days, days between events, risk-adjusted rates, etc.? Additionally, when some type of risk-adjustment strategy is indicated, there is not always consensus about the best methodology to use.
- **Problems of event identification:** Most adverse event data collection currently is dependent on recognition of the event and correct documentation. Organizations with a strong culture of safety and reliability, and greater readiness to report events, may perceive unfairness in public reporting. Nationally, events that do not cause harm (e.g., fall without injury) may be less likely to be recognized. Occurrences that do not reach the patient (near misses/close calls), such as a wrong dose of medication that is prepared in the pharmacy but is caught before leaving the pharmacy or the wrong site prepped but surgery not performed, are less likely to be reported, although they may flag a process in need of improvement.
- **Event-free intervals:** The relevance or usefulness of reporting intervals free of event occurrence (e.g., absence of bloodstream infections over a period of years) continues to be debated and remains an important issue for research and future consideration.

All of these are important components of patient safety information and should be explored within healthcare organizations. However, not all can be captured for public reporting.

The Institute of Medicine (IOM) has been a leader in these efforts by publishing a series of reports on quality and safety. In *To Err is Human: Building a Safer Health System*,<sup>13</sup> IOM notes that a mandatory reporting program for serious adverse events should be implemented nationwide, linked to accountability, and made available to the public. In *Crossing the Quality Chasm*,<sup>14</sup> IOM identifies six aims for improvement, the first of which is safety, and in *Patient Safety: Achieving a New Standard of Care*,<sup>15</sup> IOM presented a vision for patient safety reporting systems. The Patient Safety and Quality Improvement Act of 2005<sup>16</sup> codifies some of the IOM recommendations by setting expectations for confidentiality of patient safety information reported through patient safety organizations to a network of patient safety databases. In 2008, the Agency for Healthcare Research and Quality (AHRQ) issued its beta version of Common Formats for Patient Safety Organizations,<sup>17</sup> a set of reporting forms specifically for use by hospitals to confidentially report patient safety occurrences to federally listed patient safety organizations (PSOs) and available to any organization that desires to use them. The World Health Organization (WHO) continues development of its International Classification for Patient Safety,<sup>18</sup> a tool based on The Joint Commission's Patient Safety Event Taxonomy, which was endorsed by NQF in 2005.<sup>19</sup> Patient safety events are recognized as a national concern, and considerable effort has been invested in exploring them and designing systems for

external reporting of patient safety information. The federal sector, state governments, and nongovernmental organizations have focused on understanding, but not necessarily reporting, patient safety events. However, what such entities have done is instructive to the work of designing systems for public reporting. The National Healthcare Safety Network (NHSN) has done extensive work to standardize data and collect information about healthcare-associated infections (HAIs) for use in identifying trends that can be used by facilities or in aggregate, nationally. Of the 27 states requiring hospitals to report infections, the majority use the NHSN to do so.

The NQF report, *National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data*<sup>20</sup> concludes that there is a growing demand for public reporting of HAIs and other healthcare-associated adverse events. The patient safety reporting framework in this report provides guidance to meet this demand with regard to HAIs and other healthcare-associated events. The report further notes that the absence of agreed-upon standards for public reporting makes it difficult to compare or aggregate data that are reported to disparate databases. In asserting that consumers' need for actionable data must be met, the report recognizes that current measures are not ideal but points out that they will improve over time if reporting is implemented within a carefully constructed program. Similarly, the work done by organizations such as AHRQ with the Common Formats will likely help to add additional and more uniform sets of measures to the AHRQ Patient Safety Indicators and the safety measures promulgated by other organizations.

The impetus for public reporting of patient safety information is strengthened by evidence of the financial cost of unsafe care. NQF's *National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data* reports that "an estimated 2 million HAIs occur each year in the United States accounting for an estimated 90,000 deaths and adding \$4.5 billion to \$5.7 billion in healthcare costs."<sup>21</sup> The IOM report *Preventing Medication Errors* identifies error rates across a variety of settings and types and estimates that about 400,000 preventable adverse drug events (ADEs) occur each year in U.S. hospitals; another 800,000 occur in long-term care, and more than 500,000 occur among Medicare patients in outpatient settings. The report also notes that costs associated with preventable medication errors have not been well researched but conservatively estimates that the annual cost to hospitals of the 400,000 ADEs, in 2006 dollars, was \$3.5 billion.<sup>22</sup> While HAIs and preventable medication errors occur in relatively high numbers, they are only two of the many types of patient safety events that occur in healthcare settings. Healthcare costs are passed on to consumers in a number of ways—premiums, taxes, lost wages, and health threat, to name a few. As part of its value-based purchasing program, CMS limits payment for care related to a specified group of adverse events that occur in hospitals. Although the issue of cost is beyond the scope of this work, reporting that drives improvement in safety may also favorably impact healthcare costs.<sup>23</sup>

It is evident that there are significant direct and indirect costs associated with developing, publishing, and refining public reports. In addition to financial costs, there are considerable

costs in time and effort for production and maintenance of a public report that presents valid and reliable information, that is developed and tested with stakeholder input, includes data that has been determined to meet standard evaluation criteria, is updated to provide timely information, and is refined to ensure ongoing and improved value. Any effort that results in easy access to aggregated, reliable data that has been collected in standardized ways can help to further public reporting of comparable information and help to reduce the associated costs. The work of the organizations mentioned above and many others continues to move the field toward alignment of standards for accountability and public reporting, but the pace has not kept up with the need.

In 2007 NQF published *National Voluntary Consensus Standards for Hospital Care 2007—Guidelines for Consumer-Focused Public Reporting*.<sup>24</sup> The framework herein refines and builds upon the guidance provided in that document. It has been amplified and modified where necessary to reflect the unique attributes of patient safety event information. This report acknowledges that the science must continue to evolve and posits that organizations that promulgate public reports are uniquely positioned to add to the body of knowledge about what does and does not facilitate consumer understanding and provider improvement. They are challenged to do so. Because public reporting cannot achieve its potential unless the data in reports are robust, representative of the full range of events, and standardized and presented in an evaluable way, this report constitutes a call to action.

## Strategic Directions for NQF

The National Quality Forum (NQF) operates under a three-part mission to improve the quality of American healthcare by:

- building consensus on national priorities and goals for performance improvement and working in partnership to achieve them;
- endorsing national consensus standards for measuring and publicly reporting on performance; and
- promoting the attainment of national goals through education and outreach programs.

As greater numbers of quality measures are developed and brought to NQF for consideration, NQF must assist stakeholders in measuring and reporting “what makes a difference” and addressing what is important to achieve the best outcomes for patients and populations. An updated Measurement Framework, reviewed by NQF Members in December 2007, promotes shared accountability and measurement across episodes of care with a focus on outcomes and patient engagement in decisionmaking coupled with measures of the healthcare process and cost/resource use. For more information, see [www.qualityforum.org](http://www.qualityforum.org).

Several strategic directions have been identified to guide the consideration of candidate measures:

**DRIVE TOWARD HIGH PERFORMANCE.** Over time, the bar of performance expectations should be raised to encourage achievement of higher levels of system performance.

**EMPHASIZE COMPOSITES.** Composite measures provide much-needed summary information pertaining to multiple dimensions of performance and are more comprehensible to patients and consumers.

**MOVE TOWARD OUTCOME MEASUREMENT.** Outcome measures provide information of keen interest to consumers and purchasers, and when coupled with healthcare process measures, they provide useful and actionable information to providers. Outcome measures also focus attention on much-needed system-level improvements, since achieving the best patient outcomes often requires carefully designed care process, teamwork, and coordinated action on the part of many providers.

**CONSIDER DISPARITIES IN ALL WE DO.** Some of the greatest performance gaps relate to care of minority populations. Particular attention should be focused on identifying disparities-sensitive performance measures and on identifying the most relevant race/ethnicity/language socio-economic strata for reporting purposes.

These strategic directions are reflected in the framework for public reporting of patient safety information. Of particular import are the matters of improving the safety and reliability of America’s healthcare system and engaging its citizens.

## National Priorities Partnership

NQF seeks to endorse measures that address the National Priorities and Goals of the NQF-convened National Priorities Partnership (Partnership).<sup>25</sup> The Partnership represents those who receive, pay for, provide and evaluate



healthcare. The National Priorities and Goals focus on these areas:

- patient and family engagement,
- population health,
- safety,
- care coordination,
- palliative and end-of-life care, and
- overuse.

NPP recommends augmenting these six priorities with two additional areas of focus particularly relevant in this era of health reform: equitable access to ensure that all patients have access to affordable, timely, and high-quality care; and infrastructure supports (e.g., health information technology) to address underlying system changes that will be necessary to attain the goals of the other priority areas.

## Challenges and Opportunities

The evidence related to the value of public reporting remains mixed. Most of the studies to date have focused on hospitals, and there is support for the position that public reporting stimulates hospitals to make improvement efforts.<sup>26-29</sup> The effect on consumer education about quality and safety is less well demonstrated. One study states explicitly that poorly constructed report cards may impair consumer comprehension of their messages and may cause consumers to make decisions that are not consistent with their goals.<sup>30</sup> The organization of report cards and the way in which information is presented will influence the use of the reports. Although this presents a challenge overall, and with patient safety event information in particular, there is a body of evidence that provides

direction and specific recommendations for data display and explanation that is useful to consumer decisionmaking.<sup>31</sup>

### Challenges

The challenges in reporting information about patient safety events are many and complex. An overarching challenge is to design and implement a report that is appropriate for its purpose<sup>32</sup> and is of value to consumers. Although there is evidence that consumers want information about the performance of health-care organizations, there is also evidence that suggests that the information has little impact on consumers' healthcare decisionmaking.<sup>33</sup>

To generate a useful public report, the report sponsor must have access to complete and reliable data that are collected according to common definitions. There are challenges in meeting all of these criteria. Furthermore, data do not paint a complete picture of safety. At present, available measures of patient safety events focus on a few areas that, while important, do not reflect the full range of healthcare safety and more often are specified using administrative rather than clinical data.

Data are not always reliable or based on clear or consistent definitions. Public reports are typically populated with self-reported data. It is important to note that under-reporting has been demonstrated. These facts, coupled with the rarity of many patient safety events, should be weighed when considering the usefulness of data in measuring safety.<sup>34</sup> These facts also introduce an important challenge of unintended consequences. Invalid measures that are publicly reported may create misunderstandings or risks to patients, providers, and payers. Patients might choose a provider based on erroneous information. Providers might focus attention on

reported measures to the detriment of other areas and might avoid high-risk patients.<sup>35</sup> Payers might withdraw or provide rewards, drop providers, or send patients to lower-quality providers based on misinformation.<sup>36</sup> Reliance on self-reporting of adverse events, whether voluntary or mandatory, increases the challenge of ensuring that the reported information is accurate.

The universe of measures of patient safety events is heterogeneous. Some require risk adjustment, and others should not (or cannot) be risk adjusted. Some should be reported as raw incidence, and others should be reported as rates or otherwise adjusted for volume. For many events, including the NQF list of Serious Reportable Events (SREs), there are not sufficient numbers of fully specified measures to represent the safety spectrum. Although simple descriptions of some of the adverse events suggest that they are complete and clear, one needs only to look at how they are captured across report collection bodies or jurisdictions to see differences in definitions, which result in differences in reporting that preclude comparison. As one example, for CMS to use NQF's Serious Reportable Events as part of its value-based purchasing program, it needed to specify codes that go beyond the SRE specifications. One challenge is to provide guidance for a field of work for which major components have not been clearly defined, much less tested. Another is to make data become actionable information in a larger patient safety context.

Development of patient safety systems—including reporting systems—from provider organizations to states, regulatory bodies, and accrediting bodies is still in the early stages, and, for the most part, reporting has been limited to hospitals. Even for hospitals,

uniform reporting does not occur for various reasons, including lack of understanding about what constitutes a reportable event. For example, should only events resulting in harm be reported, or should no-harm events also be reported? Does level of harm make a difference? Although it may be clear that death due to a patient safety event should be reported, it is not always clear whether to attribute a death to a specific safety event, and definitions of harm below that threshold may vary. There is a trend toward improving the identification of harm events, in part due to a growing expectation for cultures that support error reporting for learning and improvement. With the availability of automated systems to facilitate the capture of events, reporting of both types and number has increased.

As noted, because adverse events suggest harm to patients, they are emotionally charged. Reporting such events with contextual information that helps the user to understand the data in a way that is useful for constructive decision-making is a challenge that will require careful work and consumer assistance.

In low-frequency events, the challenge becomes one of conveying meaningful information while at the same time maintaining patient confidentiality and providing enough data to allow for exploration of factors such as disparities. For example, some types of safety events may occur more frequently in certain populations, and the data should be available to explore reasons for this difference. Confidentiality must be protected, and this report assumes that any reporting organization will adhere to its obligations under the Health Insurance Portability and Accountability Act (HIPAA) and other legal requirements for protection.

Consideration has been given to near misses/close calls. The challenge inherent in



quantifying the level of potential harm, as well as in the varying definitions of near misses, precludes public reporting at this time. Any attempt to represent near misses in terms of impacts (e.g., fewer near misses implies safer care) could be misleading. Most organizations support a goal of reporting near-miss events as an important component of a culture of safety and high reliability. Because of the potential for learning from near misses and designing solutions to prevent adverse events, public reporting of near misses/close calls must continue to be an area for exploration and research. The potential for unintended consequences to occur as a result of public reporting is real and must be carefully considered. One such consequence could be the reluctance of providers to accept high-risk patients.<sup>37</sup> Another consequence could be the potential for loss of market share: Although one study shows that this was not the case, another study reports that the reputations of 24 hospitals that were included in a quality report were affected by the report.<sup>38</sup>

## Opportunities

There is an opportunity and an imperative to standardize and enhance patient safety reporting. Redundant, conflicting, or varying reporting requirements are associated with opportunity costs for measurement and data collection. They are also associated with real risks to the production of meaningful information and improved consumer understanding of safety. There are a number of well-accepted, mature, valid, reliable reporting systems both inside and outside government. Additionally, the AHRQ Common Formats for Patient Safety Organizations, provided for by the Patient Safety and Quality Improvement Act of 2005 and developed using databases through federal

partners such as CDC, including NHSN, CMS, and the Food and Drug Administration, hold promise for helping to standardize types of reported events, event and impact definitions, data to be reported, and approaches to analysis. An important principle for report sponsors is to make every effort to draw upon and harmonize with established and trusted sources wherever possible.

Public report sponsors have the opportunity to provide reports on patient safety that can educate consumers and drive improvement in safety. They should accept the challenge of providing balanced information in sufficient context to enable consumer understanding of safety and quality to lead to informed health-care choices, improvement, and appropriate accountability. This effort should include evaluation of the impact of the reports.<sup>39</sup>

Public reports, well constructed and rigorously controlled for clarity, validity, and reliability, can contribute to improved quality and safety that may enhance willingness to identify and report events. For those organizations that report events, require event reporting, or develop measures of events, there is an opportunity to improve and align existing measures. There is also an opportunity to improve the definitions and specifications of adverse events so that they meet standardized criteria for measures as well as to develop new and improved measures based on the NQF-endorsed<sup>®</sup> Safe Practices.

The way in which patient safety events are reported; e.g., by individual event, rates, or percentages, should be expected to change as the understanding of how best to convey the information is explored and better understood. With new knowledge, measure stewards/developers have the opportunity to continue to refine specifications of existing measures to ensure comportment with evidence of how best

to capture and report patient safety data as well as to develop new measures to do so. That same principle applies to the guidance in this report, which is acknowledged as dynamic.

Inherent in all of these opportunities is the opportunity to engage in “real-life” research to develop and improve measures and the quality of reports and to inform the understanding of what improves patient safety.

## National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information

### Overview of Endorsed Guidance

This work began by addressing a series of questions about what a framework for publicly reporting patient safety event information should encompass. Out of that activity, statements of purpose and a set of principles emerged along with a set of widely accepted working definitions drawn from organizations whose work encompasses patient safety.<sup>40</sup> Both the purpose and principles were revisited often and refined to ensure that they reflect the values and guidance in the framework. Because of their relevance to the NQF-endorsed *Guidelines for Consumer-Focused Public Reporting*,<sup>41</sup> those guidelines were affirmed as an appropriate starting point for patient safety event reporting. Changes have been made

to those guidelines to reflect the differences specific to patient safety reporting; however, the rationale underlying those guidelines is pertinent to this work, and the framework described in that report should be considered a companion to the framework for public reporting of patient safety event information. Indeed, it is contemplated that many public reports will include quality as well as patient safety data, and the guidance in this report, while highly focused on patient safety and patient safety reporting, is relevant to such reports.

The guidelines for publicly reporting patient safety event information presented here are the product of the Patient Safety Reporting Framework Steering Committee (Appendix A) in small groups and as a collective. They have been formed and refined through a series of teleconferences, an in-person meeting, and electronic interchanges. Steering Committee members would like reviewers and users of the framework to understand that the guidance is dynamic and should evolve as the science evolves. They recommend, in the strongest terms, that research should be undertaken to test the guidance and report findings. Additionally, they charge all users of the guidance to be continually alert to the potential for unintended consequences and to address promptly any that occur.

The framework is not meant to be approached as a set of guidelines to be addressed one after the other in the order presented. They should be used as part of a dynamic process that strives to meet the purposes and principles stated below.

## Purpose

This report provides a framework for publicly reporting patient safety event information—including events, indicators, and measures—about healthcare organizations to consumers.<sup>42</sup> It recognizes there are differences across environments of care that may need to be taken into consideration when reporting. To the extent that reporters become aware of such differences when constructing reports, they should account for the differences in their reports.

The framework is intended for use as a guide by those entities that currently provide public reports as well as those that will do so in the future. This includes public and private sectors that operate for profit or not-for-profit.

The purpose of this framework is to enable meaningful public reporting that:

- considers and clarifies organizational issues around measuring and evaluating patient safety event information including SREs and safety indicators;
- distinguishes reporting strategies that may need to differ based on the characteristics of event(s) being reported (e.g., SRE; commonly occurring versus low frequency/low volume);
- identifies an approach, including such procedures as validation and comparison strategies, to ensure honest, balanced reporting;
- designs or refines public reports to convey information about the safety of care delivered in ways that are comparative and are meaningful to the target audience(s) while at the same time clearly informing users of the report's intended use and its limitations; and

- increases consumer awareness and understanding of patient safety events by providing context and explanations.

## Guiding Principles

The following principles should guide the development and content of public reports about patient safety event information:

- Entities that provide public reports of patient safety information are accountable for the quality of the reports they produce, including the timeliness and accuracy of information and the relevance and usefulness of the information to the decisionmaking of consumers.
- Public reports of patient safety event information should heighten collective public awareness and concern about safety in a way that stimulates providers, healthcare organizations, and entities responsible for setting public policy to make improvements.
- Publicly reported information about patient safety events must be previewed for accuracy by those about whom it is reported, corrected as necessary, and then displayed in ways that facilitate appropriate and informed decisionmaking by consumers.
- To facilitate understanding and accountability, public reporters must use tested tools to properly convey information about the wide array of event characteristics, including those that occur frequently and those that occur rarely or with low frequency.
- The accuracy and completeness of information in public reports should be verifiable through means such as audits, cross-checks with multiple data sources, attestations by reporting organizations, and/or other means.

- Because the science that underpins public reporting is evolving, it is important that public reports are continually assessed for usefulness and validity and revised as the science improves.
- To advance improvements in understanding and improving patient safety, it is essential to bring uniformity to definitions, patient safety measurement tools, and approaches to analysis and classification of events.
- Information in public reports should be presented in a way that increases consumers' awareness and understanding of patient safety events, including preventability, by providing context, explanations, and information about their role in improving patient safety for themselves and others.
- Consumer involvement in the development of patient safety public reports is particularly important because of the significance of the information and its propensity to be highly technical in both terms and definitions. Translating this information into useful, actionable tools requires the active involvement of consumers in report construction.
- Patient confidentiality must be maintained.
- Complete transparency of methodology and sources should be required for all measures included in public reports.

The values outlined above form a call to individuals and organizations (consumers, healthcare providers and professionals, professional societies, data collectors and sources, public reporters, regulators, and policymakers) to collaborate in a serious effort to understand events, assume accountability for their roles and actions, and design national strategies to use data for accountability and learning to reduce the occurrence of adverse patient safety events.

Entities that produce public reports have a responsibility to establish high standards for independence, objectivity, and addressing conflicts of interest. These standards should govern development of the reports they produce and their actions in producing them. As reporting systems evolve and mature, it is expected that "gold standards" for safety event reporting will emerge. In order to maximize utility for the consumer, as well as minimize the burden to provider and healthcare organizations, report sponsors and producers are urged to utilize proven methodologies and formats.

## Framework for Public Reporting of Patient Safety Event Information

The intended users of this framework are entities that produce public reports for consumers, specifically reports that include patient safety event information. Patient safety events include a range of adverse events from infections to medical complications to errors and accidents in the care process.

For purposes of clarity, public report sponsors should explicitly state the purpose of the reports they produce. Whenever possible, those purposes should include all three of the recommended goals of accountability, learning, and consumer decisionmaking. Report sponsors should work diligently to ensure the accuracy, validity, reliability, and objectivity of the content of their reports and to ensure that the content is presented in ways that are evaluable by consumers.<sup>43,44</sup> A strong patient safety public report will provide consumers with information that is accurate and timely so they can make informed choices

about care and how to participate in that care to enhance its quality and safety. Report sponsors should also provide a way for consumers to contact the reporting entity with questions or comments.

It is incumbent upon report sponsors to recognize the potential impact of reports of patient safety events. Reports of harm associated with healthcare delivery, regardless of the extent, can be highly emotionally charged—to consumers, to healthcare professionals, and to healthcare organizations. The concerns range from vulnerability to harm to litigation. It is important to: 1) convey the patient safety information in an objective way after setting the context for use of the information; 2) provide information about why patient safety events

occur and what providers and patients are doing and can do to prevent safety events; and 3) provide information about what individuals can do if they believe they have experienced a patient safety event. With respect to the latter, a recommendation of this framework is that the report sponsor should urge the individual to contact the organization where the event is believed to have occurred. At this point in the evolution of safety cultures, it is expected that organizations will want to work directly with an individual to understand and address any concerns. Additionally, it is appropriate to include information about other organizations that are available to consumers to answer questions and address concerns (e.g., state licensing agencies, accrediting bodies, etc.).

## Table 1: National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information<sup>45</sup>

### GUIDELINES

1. Identify the purpose of the report, its intended main consumer audiences, and how it will be made known to the audiences; also identify secondary audiences and how their unique needs will be addressed.
  - 1a. Identify the nature and purpose of the report (what it will be about and what is to be accomplished by producing it). Whenever possible, the purpose should include accountability, learning, and consumer decisionmaking.
  - 1b. Identify the main consumer audiences for the report and describe their characteristics, their knowledge about the subject matter of the report, their information interests and needs, and how they will be expected to learn about and use the report. (In planning for use, provide for layering of information that permits the user to drill down to the technical details.)
  - 1c. Identify secondary audiences for the report, such as healthcare providers and policymakers, and describe how their report-specific interests and needs differ from those of the main consumer audiences. Determine how the report will accommodate the secondary audiences (such as allowing users to drill down to the technical details about measurement and statistical comparisons).

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## Table 1: National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information<sup>45</sup>

### GUIDELINES *(continued)*

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2. Develop the report using a transparent process that involves consumers and other relevant stakeholders.
    - 2a. Identify the various stakeholders for the report (these include, at a minimum, the developers and sponsors of the report, the main consumer audiences and organizations that represent these audiences, and the entities that are being measured and compared), and clarify their roles and responsibilities.
    - 2b. Establish governance and decisionmaking rules.
    - 2c. Provide an opportunity for the entities that are being measured and compared to preview their data and comment on the data's accuracy before the report is released; errors or misconceptions should be corrected and policies and procedures for mediation established.
    - 2d. Encourage organizations (healthcare organizations and/or providers) to describe, either as a part of or accessible from the public report, how these data may be used or have been used to improve safety.
    - 2e. Involve consumers in the development and refinement of the report by seeking their input into the report design, where appropriate, and getting their feedback on draft versions of language and data displays. Conduct usability/ease-of-use testing with consumers before the report is released, and then collect their feedback after the launch to help evaluate it.
- 
3. The report should establish a context by describing what patient safety is, including understanding the nature of patient safety events, explaining where the measures are in their development or evolution (i.e., how the measures may or may not be used for comparison across organizations over time—their robustness/usefulness). Reporters should consider linking to well-accepted national sources such as AHRQ, CDC, or NQF to accomplish this.
    - 3a. Define terms.
    - 3b. Explain adverse events in healthcare and how they can occur, and provide resources/links to consumer and patient-oriented resources (such as government and nonprofit sources) on topics such as infections, falls, pressure ulcers, safe surgery, medication use, and more.
    - 3c. Discuss preventability of patient safety events and how the consumer can learn more about best practices to improve safety and about their role in improving safety.
    - 3d. Explain how the report can be used to understand patient safety in healthcare organizations or providers.
    - 3e. Use consistent, simple, and familiar language to discuss safety and provide examples that will resonate with the main consumer audiences.

*more*



## Table 1: National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information<sup>45</sup>

### GUIDELINES *(continued)*

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4. Ensure that the measures included in a consumer-focused public report are meaningful to consumers, have transparent methodology, and meet widely accepted, rigorous criteria (i.e., important, scientifically acceptable, feasible, and usable).<sup>46</sup>
    - 4a. Provide context regarding the benefits and limitations of use of these data—make clear what they do and do not convey.
    - 4b. In choosing measures to be reported, take into account that the best measures:
      - i. are relevant to the healthcare-related concerns of the public;
      - ii. provide information that reflects the safety of care provided by the organizations included in the report (while patient safety measures may reflect harm, they may not reflect improvements that have been made to reduce recurrence, and organizations should be encouraged to provide data of the efforts to reduce recurrence.); and
      - iii. are objective, valid, reliable, methodologically sound, feasible, transparent, verifiable, and represent consensus among stakeholders, including consumers and professionals.
- 
5. Present and explain the data clearly and objectively in ways that help consumers to understand and use the information. For each measure to be included, a determination should be made whether it is appropriately displayed as a rate, as low frequency, and, in some cases, whether the measure should be included in a composite.
    - 5a. Help consumers to quickly and easily understand each measure and to use the information to aid in decisionmaking.
      - i. Display data in formats that have been shown to be evaluable. This means summarizing and displaying the data for the viewer in a way that facilitates interpretation (e.g., summary scores, labels, trends) without conveying misleading comparisons.
      - ii. To help users make correct interpretations, report measures in a consistent way so that, within a measure/group of measures, either a high score or a low score consistently indicates better performance.
      - iii. Make presentations of information more vivid and compelling by including anecdotes, stories, or case studies to illustrate the meaning of the data.
      - iv. Consider ancillary content to help consumers understand safe care (e.g., safe surgery checklist) and what they can do to contribute to improved safety.
    - 5b. Use approaches such as those listed below to present comparative patient safety information.
      - i. Use tools and methods such as rank ordering, color coding, or symbols that help users to discern meaningful performance variation and quickly determine their best options.
      - ii. When possible, include context for making comparisons and using the information.
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*more*



## Table 1: National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information<sup>45</sup>

### GUIDELINES *(continued)*

- iii. Where applicable and appropriate, provide risk-adjusted rates and grouping of information into categories such as “better” and “average” within standardized categories (such as by disease or by institution) and provide a simple explanation of why this was done (e.g., to make the comparisons fair and meaningful).
  - iv. Label indicators using everyday language (not clinical or technical terms).
  - v. Ensure that comparisons are reasonable and supportable.
  - vi. Whenever possible, limit the use of statistics and terms that are difficult for most consumers to understand.
- 5c. Composite measures, if used, should be clinically coherent, actionable, and transparent.
- i. Explain what a composite is and how it is constructed (in consumer language).
  - ii. Give examples to demonstrate how a composite may accurately reflect underlying safety or how it may fail to give an accurate depiction (e.g., if it averages widely varying results).
  - iii. Where measures are interpretable at the individual measure level, report all measures that comprise the composite without adding or deleting any individual component, or ensure transparency in the composite (at a layer down from the initial data display).
  - iv. Report results for the composite and for each component measure (at a layer down from the initial composite data display).
- 5d. Provide context for low-frequency events.
- i. Explain how low-frequency events are identified, collected, and displayed and how patient confidentiality is maintained.
  - ii. Discuss the use of low-frequency events in assessing quality and safety of healthcare provider.
  - iii. Retain and make accessible reports from year to year. In doing so, it would be appropriate to provide information about variation over time.
- 5e. Provide context for adverse events displayed by rates.
- i. Explain measures of adverse events that are calculated as rates.
  - ii. Discuss the use of rates in assessing quality and safety of a healthcare provider.
  - iii. Retain and make accessible reports from year to year. In doing so, it would be appropriate to provide information about variation over time.
- 5f. In providing contextual information/decision support:
- i. provide a clear contextual framework as part of the report introduction;
  - ii. make sure that key messages are included in the data display;
  - iii. make clear that reports of low-frequency/rare events are different from rates—distinguish between appropriate uses of different kinds of data;

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## Table 1: National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information<sup>45</sup>

### GUIDELINES *(continued)*

- iv. provide a specific explanation for any missing data and make the distinction clear between data that are missing because of small numbers (i.e., events that occur so infrequently that meaningful comparisons cannot be drawn from rate calculations) and data that are missing because of refusal to provide the data;
  - v. make information understandable by using everyday words and language;
  - vi. use consumer testing to verify that the language and displays provided in the report are easy for the intended consumer audiences to understand and use (in addition to English, provide content in the key languages of the consumer audiences);
  - vii. use most current data available, and display the dates/period that are covered by the data;
  - viii. provide context of comparison to peers, to self over time, and to optimum performance (policy goals); and
  - ix. clearly explain risk stratification, that is, where it is done, why it is important.
- 5g. In presenting technical documentation, address verifiability, reliability, validity, data sources, and data collection (e.g., self-reported versus IT system-generated; voluntary versus mandatory, etc.).
- i. Include detailed measure definitions, specifications, and risk-adjustment methods.
  - ii. Describe verifiability of the data (if any) through audits, reviews, cross-checking with other data sources, or attestation by the provider.
  - iii. Define data sources, quality control, and the data collection process.
  - iv. Explain whether data are collected as part of a legal or accreditation mandate, or on a voluntary basis.
  - v. Include resource information, when available, such as identification of the measure developer, sources of data, and interpretation guides.
  - vi. Provide complete details about methodology. *(The report should not use any measures or data that lack complete transparency as to methodology.)*
- 
6. Ensure that report design and navigation features enhance report usability. Web-based reports are recommended because of their design, display, and navigation capabilities. Design features should be used to:
- 6a. organize information in a way that lets users know what is available and lets them make their own choices;
  - 6b. provide an engaging format and include intuitive and consistent navigation tools that are placed in consistent locations;

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## Table 1: National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information<sup>45</sup>

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### GUIDELINES *(continued)*

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- 6c. make the report easy to skim and build in layering to provide the capability to drill down to information and to navigate back out;
  - 6d. seek feedback and test the design and navigation with the intended audiences;
  - 6e. provide users a way to print the information in understandable and usable formats;
  - 6f. make it easy to locate/access ancillary information (in a contextually relevant way); and
  - 6g. encourage consumer interaction through an easy-to-use comment feature (e.g., e-mails, FAQs, etc.).
- 
- 7. Regularly review and assess reports to ensure their effectiveness, usability, and currency.
    - 7a. Define the intended impact of the report, and measure usage/penetration and impact against that goal.
    - 7b. Use a combination of methods such as population-based surveys, focus groups, and direct consumer reports, which may be conducted internally or externally, to obtain and use feedback from the intended consumer audiences and the institutions that are the subjects of the reporting.
    - 7c. Involve stakeholders in revisions and seek their feedback after the report undergoes significant changes.
    - 7d. Use what is learned, including identification of unintended consequences of report publication, to help inform and drive the improvement and usefulness of performance measures and the field of consumer public reporting.
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# Guidelines for Public Reporting of Patient Safety Event Information

## Identify the Purpose, the Audiences, and How to Reach the Audiences

Report sponsors must be clear about the report's purpose and target audiences and how the target audiences are to be reached. The purpose of the report should be explicitly stated up front. This guidance suggests that the purpose of public patient safety reports should be to advance accountability, learning, and consumer decisionmaking and that consumers should be the primary audience. Other important audiences include state and federal government entities with healthcare safety responsibilities, healthcare providers, healthcare professionals, accrediting bodies, quality improvement organizations, and policymakers. Each of these groups will have unique needs that should be borne in mind, and each member of these groups will at various times assume different roles and perspectives, including that of consumer.

A web-based report is the most facile in terms of navigation within the report, links to other sites and sources of data and ancillary information, and ability to drill down to technical details of reported information and then easily return to the highest levels. However, not all public reporters have the considerable resources required to produce a web-based report, and not all consumers have access to computers. For that reason, this guidance does

not specify a web-based report as the standard for use, although some of the recommendations are most easily addressed in an electronic format.

**GUIDELINE 1.** Identify the purpose of the report, its intended main consumer audiences, and how it will be made known to the audiences; also identify secondary audiences and how their unique needs will be addressed.

- 1a. Identify the nature and purpose of the report (what it will be about and what is to be accomplished by producing it). Whenever possible the purpose should include accountability, learning, and consumer decisionmaking.
- 1b. Identify the main consumer audiences for the report and describe their characteristics, their knowledge about the subject matter of the report, their information interests and needs, and how they will be expected to learn about and use the report. (In planning for use, provide for layering of information that permits the user to drill down to the technical details.)
- 1c. Identify secondary audiences for the report, such as healthcare providers and policymakers, and describe how their report-specific interests and needs differ from those of the main consumer audiences. Determine how the report will accommodate the secondary audiences (such as allowing users to drill down to the technical details about measurement and statistical comparisons).

## Use a Transparent Process That Involves Stakeholders

All groups that are potential users of a public report about patient safety are also stakeholders in the process. Each stakeholder group will

have unique perspectives that can aid the report sponsor in determining what to include in the report, how to design the report, and how to best reach the target audiences. As the primary target audience, consumers are also the primary stakeholder, and it is essential that they be included in the planning. A diverse group of consumers can provide insights, offer suggestions for what will be meaningful, and provide feedback about ease of use and understanding of the data; however, accuracy and validity of data should be paramount in this assessment. As noted elsewhere, reports of patient safety event information will elicit emotional responses. Report sponsors should anticipate that and involve stakeholders, including the media, in the design of reports. Further, stakeholders can suggest ways to launch reports to generate interest and facilitate use without causing fear.

Organizations and professionals who submit data, regardless of source, should be given the opportunity to preview the data before reports are published and should be encouraged to provide information that puts the information in context. For example, it might be useful to include information about what steps have been taken to prevent the occurrence of specific types of events. Where trending is appropriate, the improvements consequent to such actions should become apparent. In determining a timeline for review and comment, it is important to balance the need for reasonable time for review against undue delay that might affect data currency.

Public reporting cannot achieve its potential unless the data that are presented are robust, consistent, and comparable, which is not

always the case. To ensure transparency, the report should provide information about the report sponsor's efforts to capture complete data. This should include an acknowledgement that the content of reports is dependent on the data that are available in the systems from which they are drawn. Further, the current state of patient safety event reporting by healthcare organizations and professionals precludes the ability to provide assurances that the information is fully, uniformly, and equally representative of all organizations, because it reflects a mix of voluntary and mandatory reporting and a lack of standardization and understanding of how to report certain types of events.

**GUIDELINE 2.** Develop the report using a transparent process that involves consumers and other relevant stakeholders.

- 2a. Identify the various stakeholders for the report (these include, at a minimum, the developers and sponsors of the report, the main consumer audiences and organizations that represent these audiences, and the entities that are being measured and compared), and clarify their roles and responsibilities.
- 2b. Establish governance and decisionmaking rules.
- 2c. Provide an opportunity for the entities that are being measured and compared to preview their data and comment on the data's accuracy before the report is released; errors/misconceptions should be corrected and policies and procedures for mediation established.
- 2d. Encourage organizations (healthcare organizations and/or providers) to describe, either as a part of or accessible from the public report, how these data may be used or have been used to improve safety.

- 2e. Involve consumers in the development and refinement of the report by seeking their input into the report design, where appropriate, and getting their feedback on draft versions of language and data displays. Conduct usability/ease-of-use testing with consumers before the report is released, and then collect their feedback after the launch to help evaluate it.

## Establish a Context by Providing Information About Patient Safety

In setting the context within which the information in the report should be considered, the report sponsor should provide information about the nature and types of patient safety events, including those discussed in the report and, possibly, those not appropriate for public reporting at this time. In setting the overall context for the report, report sponsors should speak to the following and, to the extent that clarity can be enhanced, provide examples:

- Some, but not all, patient safety events are preventable.<sup>47</sup> Some events, such as wrong-site surgery, simply should not occur. Others may not be under the complete control of the healthcare provider but should be reported and examined in terms of preventability.
- Some, but not all, events result in harm.
- Some, but not all, events result from error.
- Some, but not all, events can be reported using rates.
- Displaying results in rank order may be appropriate for some types of events. Ranking is irrelevant for those events that simply should not occur.

Report sponsors should provide information about the current state of understanding about patient safety events, such as the availability of patient safety event measures and the comparisons that can and cannot be made, the terms used, and the lack of consistent understanding of the terms within the patient safety community and across the broader healthcare and consumer communities. In providing context, the report sponsor should balance the inclusion of context with the need to make information accessible. Methods of doing this include such things as enabling “drill-down” for additional information and strategically placing “drop-down” or “pop-up” boxes that can be selected for additional information as desired.

Where the NQF-endorsed Serious Reportable Events<sup>48</sup> are used in reports, it should be noted that they are a subset of a broader set of adverse events. The majority of SREs relate to events that result in death or serious harm and, therefore, are relatively easy to identify and difficult to conceal. However, because they are not fully specified as measures, the way in which they are captured across jurisdictions will differ. This means that reports of their occurrence will not be based on standardized definitions or specifications.

**GUIDELINE 3.** The report should establish a context by describing what patient safety is, including understanding the nature of patient safety events, explaining where the measures are in their development or evolution (i.e., how the measures may or may not be used for comparison across organizations over time—their robustness/usefulness). Reporters should consider linking to well accepted national sources such as AHRQ, CDC, or NQF to accomplish this.

- 3a. Define terms.
- 3b. Explain adverse events in healthcare and how they can occur, and provide resources/links to consumer and patient-oriented resources (such as government and nonprofit sources) on topics such as infections, falls, pressure ulcers, safe surgery, medication use, and more.
- 3c. Discuss preventability of patient safety events and how the consumer can learn more about best practices to improve safety and about their role in improving safety.
- 3d. Explain how the report can be used to understand patient safety in healthcare organizations or providers.
- 3e. Use consistent, simple, and familiar language to discuss safety and provide examples that will resonate with the main consumer audiences.

## Use Measures That Are Transparent and That Meet Widely Accepted, Rigorous Criteria

Safety hazards and safety improvements are particularly difficult to measure. Pronovost et al. stated, “Most safety parameters are hard or impossible to capture as valid rates because events are uncommon or rare; few events have standardized definitions; surveillance systems depend upon self-reporting; denominators are largely unknown or poorly defined; and the time period for exposure is unspecified.”<sup>49</sup>

When there are well-established, well-recognized, methodologically sound, and well-accepted measures for reporting events, reporting entities that are using similar types of data should use those measures whenever

possible. Organizations that publicly report patient safety events should report only those events<sup>50</sup> and measures that have gone through a formal consensus development process. A consensus development process should include rigorous evaluation of the strength of the definition of the event or measure (according to, for example, NQF’s individual or composite measure evaluation criteria<sup>51</sup> and review and input by a wide range of healthcare stakeholders. Complete transparency is essential so that the result that occurs from application of a measure can be replicated.

At present some entities, including states and the federal government, collect information about adverse events using the NQF-endorsed SREs. When a patient safety event is reported for which there are no available measures, the event definition and parameters should be detailed. Additionally, it is important to provide information about timeframes in which patient safety events occur to ensure that context is transparent. Reporting patient safety event information in context is challenging but imperative. When reporting trends, it is important to recognize that specifications of measures change over time. Also, it is important to acknowledge that, with the current state of patient safety data collection, reported events, absent fully specified performance measures, will likely not conform to standardized criteria and definitions across organizations. For these reasons, among others, it is incumbent upon the reporter to provide context in explaining trends and organizational variation.

Public reporting of near misses/close calls is not recommended at this stage in the evolution of public reports. They are not clearly defined,



they are significantly under-recognized and under-reported, and there are no standard systems to classify them. Near misses/close calls are a fertile field for organizational focus in evaluating factors that predispose to error and constitute an essential data source for improvement. Measures should be developed, refined, and tested to make effective use of near miss/close call learning opportunities. It is possible that at some time they may meet appropriate criteria to be considered for inclusion in public reports.

**GUIDELINE 4.** Ensure that the measures included in a consumer-focused public report are meaningful to consumers, have transparent methodology, and meet widely accepted, rigorous criteria (i.e., important, scientifically acceptable, feasible, and usable<sup>52</sup>).

- 4a. Provide context regarding the benefits and limitations of use of these data—make clear what these data do and do not convey.
- 4b. In choosing measures to be reported, take into account that the best measures:
  - i. are relevant to the healthcare-related concerns of the public;
  - ii. provide information that reflects the safety of care provided by the organizations included in the report (while patient safety measures may reflect harm, they may not reflect improvements that have been made to reduce recurrence, and organizations should be encouraged to provide data of the efforts to reduce recurrence.); and
  - iii. are objective, valid, reliable, methodologically sound, feasible, transparent, verifiable, and represent consensus among stakeholders, including consumers and professionals.

## Present and Explain the Data

All information should be reported in a way that is understandable to consumers. However, the task of being clear about what patient safety data show and do not show is particularly challenging. Because such information will likely be used by consumers to evaluate whether they or their family will be safe in the care of an organization, the reporter is obligated to provide information that is clear, valid, and reliable. Further, the reporter should identify situations in which consumers may be at higher risk and provide ancillary resources to help consumers to use healthcare services effectively and to participate in improving the safety of their own care. For example, where surgical errors are reported, it would be useful to provide information about questions to ask if planning to have surgery, such as those provided by AHRQ in *Making Sure Your Surgery is Safe*.<sup>53</sup> The data may be displayed to show how an organization performs overall and over time.

Each report sponsor should use data responsibly to serve the overall goals of accountability, learning, and decisionmaking, being careful not to characterize or report events improperly. Explanations of the data should address differences in reporting and the display of low-frequency events as compared to more frequently occurring events. The interpretation of safety measures should be supported with trends, where feasible, and with access to technical details such as the consistency of data definitions and coding and the characteristics of data collection mechanisms.<sup>54</sup>

Low-frequency events, which are determined by relevant stakeholders to be events that should never occur, such as infant abduction or wrong-site surgery, are typically reported and displayed using methods such as the unadjusted, raw number of events or in some cases the number of days (or patient days) between events. It is usually not appropriate to express these types of events as rates.

More frequently occurring events, such as infections, can appropriately be reported with rates, risk adjustment, and trending. Such explanations should make clear whether comparisons are made among all providers, among peers, or to the organization's performance over time, or whether they speak to some theoretical optimum, which could be zero. It would be appropriate to note that the goal for preventable adverse events should be zero.

An overall obligation of public reporting is to help consumers understand how patient safety events happen. Reports about specific organizations should include an opportunity to provide information about what the organization is doing with its data to learn about and improve safety. This can be done by highlighting changes in the data over time and by conveying ancillary information about what the organization is doing to improve.

The use of composite measures<sup>55</sup> in patient safety event reporting carries a special set of challenges. Combining measures into a composite could offer enhanced insight into a domain of related practices, or it could obscure meaningful safety information. Combining measures related to similar types of events or processes (e.g., wrong patient, wrong site,

wrong procedure surgery events) may be useful. Combining events of unrelated processes (e.g., medication errors and pressure ulcers) may not be valid. Any aggregation of events and measures for reporting must be reviewed carefully to consider the ramifications of doing so. It is essential that the data for each component of a composite, as well as the aggregation methodology, are included in the technical details of the report so that the composite can be disaggregated for transparency and understanding.<sup>56</sup> It is of critical importance that the desire to convey a picture of overall safety in an organization by bundling a group of patient safety-related measures be tempered by the need to ensure that such measures have been determined to meet rigorous evaluation criteria both as a set and as individual measures. Further, the purpose and rationale for selecting and combining the components of a composite measure should be included. In fact, some measures are combined because they do not meet the criteria for a strong measure alone. This information is appropriate for those interested in the technical details of the report. The explanation of the purpose and use of composites, and its clarity as it is conveyed to consumers, will be challenging and should be tested for evaluability with consumers in advance of use in reports.

The issue of missing data is particularly challenging in patient safety event reporting. Public reports depend on the completeness and accuracy of the data that are reported to organizations that collect data about individual events by provider organizations. Reporting of certain events may be mandatory in some jurisdictions but voluntary in others. Additionally, to be reported, events must be recognized,

and those who recognize them must feel safe to report them within an organization and to relevant external agencies.

There is ample evidence that availability of complete and reliable patient safety event data is not uniform. In this context, the issue of identifying whether data are missing due to failure to report takes on a new dimension but does not remove the obligation. The report should discuss the likely reliability of reporting and the implications of missed recognition or reporting of events.

Sampling in data collection and reporting is discouraged because the occurrence and outcomes of most events cannot be adequately represented through this method. Therefore, all patient safety events should be reported.

Risk-adjustment strategies (e.g., risk models, risk stratification) deserve special consideration in patient safety. The risk-adjustment strategy should be transparent and should only be used when the characteristics to be adjusted have an impact on the occurrence of the adverse event and are present at the start of care.<sup>57</sup> Risk stratification enables reporting results by specific characteristics such as race, socioeconomic status, or gender. However, events such as child abduction or wrong-site surgery should usually not be risk adjusted.

Alternatives to risk adjustment, such as an adjustment that excludes the immunocompromised patient from measures of surgical-site infection, may be appropriate. In the foregoing example, exclusion criteria could be used to remove the immunocompromised patient from the population of interest.

Sources of data should be clearly identified and disclosed in reports. Distinctions about data obtained from voluntary as opposed to mandatory reports and self-reported as opposed to system generated should be made.

**GUIDELINE 5.** Present and explain the data clearly and objectively in ways that help consumers understand and use the information. For each measure to be included, a determination should be made whether it is appropriately displayed as a rate, as low frequency, and, in some cases, whether the measure should be included in a composite.

- 5a. Help consumers to quickly and easily understand each measure and to use the information to aid in decisionmaking.
  - i. Display data in formats that have been shown to be evaluable. This means summarizing and displaying the data for the viewer in a way that facilitates interpretation (e.g., summary scores, labels, trends) without conveying misleading comparisons.
  - ii. To help users make correct interpretations, report measures in a consistent way so that, within a measure/group of measures, either a high score or a low score consistently indicates better performance.
  - iii. Make presentations of information more vivid and compelling by including anecdotes, stories, or case studies to illustrate the meaning of the data.
  - iv. Consider ancillary content to help consumers understand safe care (e.g., safe surgery checklist) and what they can do to contribute to improved safety.

- 5b. Use approaches such as those listed below to present comparative patient safety information.
  - i. Use tools and methods such as rank ordering, color coding, and/or symbols that help users to discern meaningful performance variation and quickly determine their best options.
  - ii. When possible, include context for making comparisons and using the information.
  - iii. Where applicable and when appropriate, provide risk-adjusted rates and grouping of information into categories such as “better” and “average” within standardized categories (such as by disease or by institution) and provide a simple explanation of why this was done (e.g., to make the comparisons fair and meaningful).
  - iv. Label indicators using everyday language (not clinical or technical terms).
  - v. Ensure that comparisons are reasonable and supportable.
  - vi. Whenever possible, limit the use of statistics and terms that are difficult for most consumers to understand.
- 5c. Composite measures, if used, should be clinically coherent, actionable, and transparent.
  - i. Explain what a composite is and how it is constructed (in consumer language).
  - ii. Give examples to demonstrate how a composite may accurately reflect underlying safety or how it may fail to give an accurate depiction (e.g., if it averages widely varying results).
  - iii. Where measures are interpretable at the individual measure level, report all measures that comprise the composite without adding or deleting any individual component, or ensure transparency in the composite (at a layer down from the initial data display).
  - iv. Report results for the composite and for each component measure (at a layer down from the initial composite data display).
- 5d. Provide context for low-frequency events.
  - i. Explain how low-frequency events are identified, collected, and displayed and how patient confidentiality is maintained.
  - ii. Discuss the use of low-frequency events in assessing quality and safety of the healthcare provider.
  - iii. Retain and make accessible reports from year to year. In doing so, it would be appropriate to provide information about variation over time.
- 5e. Provide context for adverse events displayed by rates.
  - i. Explain measures of adverse events that are calculated as rates.
  - ii. Discuss the use of rates in assessing quality and safety of a healthcare provider.
  - iii. Retain and make accessible reports from year to year. In doing so, it would be appropriate to provide information about variation over time.
- 5f. In providing contextual information/ decision support:
  - i. provide a clear contextual framework as part of the report introduction;
  - ii. make sure that key messages are included in the data display;
  - iii. make clear that reports of low-frequency/rare events are different from rates—distinguish between appropriate uses of different kinds of data;

- iv. provide a specific explanation for missing data and make the distinction clear between data that are missing because of small numbers (i.e., events that occur so infrequently that meaningful comparisons cannot be drawn from rate calculations) and data that are missing because of refusal to provide the data;
  - v. make information understandable by using everyday words and language;
  - vi. use consumer testing to verify that the language and displays provided in the report are easy for the intended consumer audiences to understand and use (in addition to English, provide content in the key languages of the consumer audiences);
  - vii. use reasonably current data, and display the dates/period that are covered by the data;
  - viii. provide context of comparison to peers, to self over time, and to optimum performance (policy goals); and
  - ix. clearly explain risk stratification, that is, where it is done, why it is important.
- 5g. In presenting technical documentation, address verifiability, reliability, validity, data sources, and data collection (e.g., self-reported versus IT system-generated, voluntary versus mandatory, etc.).
- i. Include detailed measure definitions, specifications, and risk-adjustment methods.
  - ii. Describe verifiability of the data (if any) through audits, reviews, cross-checking with other data sources, or attestation by the provider.
  - iii. Define data sources, quality control, and the data collection process.
  - iv. Explain whether data are collected as part of a legal or accreditation mandate, or on a voluntary basis.
  - v. Include resource information, when available, such as identification of the measure developer, sources of data, and interpretation guides.
  - vi. Provide complete details about methodology. *(The report should not use any measures or data that lack complete transparency as to methodology.)*

## Ensure That the Report Design and its Navigation Features Enhance Usability

The guidance offered in this framework acknowledges the enhanced value that web-based reports offer in terms of design and navigation potential; however, the guidance is important regardless of the format selected. It will simply be more challenging when offered in other forms.

It is important to provide ancillary information about patient safety overall as well as information specific to different kinds of events. To ensure this occurs, two new items have been added to the expectations for report design and navigation. One stresses the importance of making ancillary information available in a contextually relevant way. For example, safe surgery information (e.g., checklist, questions to ask when planning surgery) should be included with information about surgical events. Providing consumers a way to ask questions and to obtain additional information is important for all quality and safety information, although the nature of patient safety concerns makes it especially important to stress this need. When providing a means to communicate, such as an e-mail option, it is important to ensure timely and accurate response to questions including, as relevant, a feedback

loop with the organizations about which the questions relate. It is essential also to use whatever information is gained for continuous improvement of reports.

**GUIDELINE 6.** Ensure that report design and navigation features enhance report usability. Web-based reports are recommended because of their design, display, and navigation capabilities.

Design features should be used to:

- 6a. organize information in a way that lets users know what is available and lets them make their own choices;
- 6b. provide an engaging format and include intuitive and consistent navigation tools that are placed in consistent locations;
- 6c. make the report easy to skim and build in layering to provide the capability to drill down to information and to navigate back out;
- 6d. seek feedback and test the design and navigation with the intended audiences;
- 6e. provide users a way to print the information in understandable and usable formats;
- 6f. make it easy to locate/access ancillary information (in a contextually relevant way); and
- 6g. encourage consumer interaction through an easy-to-use comment feature (e.g., e-mails, FAQs, etc.).

## Evaluate and Improve the Report

In issuing any public report of safety (or quality), it is important to be clear about what is expected to occur as a result of consumer use of the report and to assess the effectiveness in realizing goals outlined in the guidance specific

to consumer ease of use, understanding, and value in decisionmaking as well as value to the provider in their improvement efforts. In part, this is the question of whether the reporter simply wants to provide information or wants to make consumers more educated about safety and about how they can best make choices and influence safety outcomes. For that reason, the guidance goes beyond saying that assessments should be conducted. It stresses that the intended impact should be explicitly stated, and assessments should be measured against the stated goals. Such goals could include, for example, increased penetration and use of the report in a particular target audience, positive change in patient safety within and across organizations over time, or improved reporting and actual reduction in preventable events.

The role of stakeholders in the improvement of reports is essential, and that of the key audience is particularly important if reports are to be of value to consumers in their healthcare decisionmaking. The methods used to obtain feedback and evaluate impact may be accomplished through various methods including work done by the report sponsor or the work of independent evaluators/researchers. Report sponsors should provide for both active and passive consumer feedback through such things as surveys, focus groups, and direct consumer contact about concerns, questions, or events. With respect to the latter, the current state of event reporting will result in inconsistent reporting, and consumer reporting, although anecdotal, may help to uncover areas for improvement in data collection.



**GUIDELINE 7.** Regularly review and assess reports to ensure their effectiveness, usability, and currency.

- 7a. Define the intended impact of the report, and measure usage/penetration and impact against that goal.
- 7b. Use a combination of methods such as population-based surveys, focus groups, and direct consumer reports, which may be conducted internally or externally, to obtain and use feedback from the intended consumer audiences and the institutions that are the subject of the reporting.
- 7c. Involve stakeholders in revisions and seek their feedback after the report undergoes significant changes.
- 7d. Use what is learned, including identification of unintended consequences of report publication, to help inform and drive the improvement and usefulness of performance measures and the field of consumer public reporting.

## Additional Recommendations

Public reporting entities should apply the guidance in the framework and test its usefulness and consumer evaluability through various methods, including real-life testing, to advance the state of public reporting. Results should be reported through appropriate bodies and publications.

- Research and evaluation should be conducted to determine which events, measures, and aggregates of such events and measures convey a valid, reliable perspective of healthcare organization safety, including those related to intervals without occurrence of events (e.g., “days between” selected low-frequency adverse events).
- Research should be conducted to evaluate the impact of public reporting of patient safety information on patients, consumers, and healthcare institutions, which could then provide direction for future research and funding thereof by organizations such as AHRQ.
- Evaluate alignment of existing NQF-endorsed measures with the guidelines in this framework and address differences as appropriate.
- Development and testing of near-miss measurement should continue.
- Severity (harm) scales should be tested before use is recommended.
- The value of reporting population-level patient safety information should be tested.
- The guidance in the patient safety event reporting framework should be reviewed on a regular basis and revised as needed to reflect information gained from report testing and changes in technology.
- Organizations that collect patient safety reports from healthcare providers, design collection systems for such reports, design classification systems for event reporting, and other stakeholders should come together and begin to harmonize standardized systems for defining, measuring, reporting, analyzing, and classifying patient safety information in a way that produces greater data integrity, completeness, and reliability and, therefore, greater understanding of events, and reduces opportunity costs associated with these activities.
- Health information technology systems and any funds that become available to improve them should include provision for facilitating patient-safety-related data capture in ways that can be used for public reporting.




## Notes

1. Institute of Medicine, *Patient Safety Achieving a New Standard for Care*, Washington, DC: National Academies Press; 2004.
2. For purposes of this report, the term *patient safety event* is defined as an occurrence that reaches the patient whether or not it causes harm.
3. The term *consumers* is defined as patients (those currently using healthcare services) and potential patients (those who are making choices prior to using healthcare services) and their families. National Quality Forum (NQF), *National Voluntary Consensus Standards for Hospital Care 2007—Guidelines for Consumer-Focused Public Reporting: A Consensus Report*, Washington, DC: NQF; 2007.
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7. *National Voluntary Consensus Standards for Hospital Care 2007—Guidelines for Consumer-Focused Public Reporting* (2009); *National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data* (2008); *A Comprehensive Framework for Hospital Care Performance Evaluation* (2003); *A National Framework for Healthcare Quality Measurement and Reporting* (2002); *Standardizing a Patient Safety Taxonomy* (2006).
8. National Quality Forum (NQF), *Serious Reportable Events in Healthcare*, Washington, DC: NQF; 2002.
9. NQF, *Safe Practices for Better Healthcare*, Washington, DC: NQF; 2003.
10. NQF, *A Comprehensive Framework for Hospital Care Performance Evaluation: A Consensus Report*, Washington, DC: NQF; 2003.
11. The criteria for individual and composite measure evaluation are reported in *Composite Measure Evaluation Framework and National Voluntary Consensus Standards for Mortality and Safety—Composite Measures* (2009). Available at [www.qualityforum.org/Publications/Composite\\_Measures.aspx](http://www.qualityforum.org/Publications/Composite_Measures.aspx). Last accessed November 2009.
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18. Final Technical Report available at [www.who.int/patientsafety/taxonomy/icps\\_download/en/index.html](http://www.who.int/patientsafety/taxonomy/icps_download/en/index.html). Last accessed November 2009.
19. NQF, *Standardizing a Patient Safety Taxonomy: A Consensus Report*, Washington, DC: NQF; 2006.
20. NQF, *National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data: A Consensus Report*, Washington, DC: NQF; 2008.
21. NQF, *National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data: A Consensus Report*, Washington, DC: NQF; 2008.
22. IOM, *Preventing Medication Errors*, Washington, DC: National Academies Press; 2006.

23. Users may want to explore cost issues further and can find information in NQF's *Background Paper on Healthcare Cost and Price Transparency: Useable, Audience-Specific Information on Costs and Prices* (September 2007). Costs associated with state reporting are discussed in Rosenthal J, Booth M, Barry A, *Cost Implications of State Medical Error Reporting Programs: A Briefing Paper*, Washington, DC; National Academy of State Health Policy; 2001.
24. NQF, *National Voluntary Consensus Standards for Hospital Care 2007 — Guidelines for Consumer-Focused Public Reporting: A Consensus Report*, Washington, DC: NQF; 2008.
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39. NQF, Institute of Medicine, World Health Organization, Agency for Healthcare Research and Quality, The Joint Commission.
40. Rand Research Highlights, *Report Cards For Healthcare: Is Anyone Checking Them?* Available at [www.rand.org/pubs/research\\_briefs/RB4544/index1.html](http://www.rand.org/pubs/research_briefs/RB4544/index1.html). Last accessed January 2010.
41. NQF, *National Voluntary Consensus Standards for Hospital Care 2007 — Guidelines for Consumer-Focused Public Reporting: A Consensus Report*, Washington, DC: NQF; 2008.
42. The term *consumers* is defined as patients (those currently using healthcare services) and potential patients (those who are making choices prior to using healthcare services) and their families.
43. The principle of *evaluability* asserts that the weight given to an attribute in a choice is proportional to the ease or precision with which the value of the attribute (or a comparison of the attribute across alternatives) creates an affective (good/bad) feeling.
44. Hibbard JH, Slovic P, Peters E, et al., Strategies for reporting health plan performance information to consumers: evidence from controlled studies, *Health Serv Res*, 2002;37:291-313.
45. NQF's 2008 report, *National Voluntary Consensus Standards for Hospital Care 2007 — Guidelines for Consumer-Focused Public Reporting*, formed the basis for this guidance.

46. See NQF's individual and composite measure evaluation criteria in *Composite Measure Evaluation Framework and National Voluntary Consensus Standards for Mortality and Safety—Composite Measures: A Consensus Report*.
47. See Appendix C for definition of *preventable*. In using the term it will be necessary to provide caveats about how preventability was determined, including standardization of the approach used to make that determination.
48. Available at [http://qualityforum.org/Publications/2007/03/Serious\\_Reportable\\_Events\\_in\\_Healthcare-2006\\_Update.aspx](http://qualityforum.org/Publications/2007/03/Serious_Reportable_Events_in_Healthcare-2006_Update.aspx). Last accessed November 2009.
49. Pronovost, Sexton, Pham, et al., p. 169-179.
50. Events appropriate for reporting include those that result in serious harm, such as the NQF-endorsed Serious Reportable Events and The Joint Commission Sentinel Events, and other events indicative of patient safety compromises and represented by markers such as the AHRQ indicators. They include both process (e.g., handwashing) and outcome (e.g., HAIs) events as well as environmental events that affect multiple patients.
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52. See NQF individual and composite measure evaluation criteria in *Composite Measure Evaluation Framework and National Voluntary Consensus Standards for Mortality and Safety—Composite Measures: A Composite Report*, Washington, DC: NQF; 2009.
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# National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report

## **Appendix A**

### **NQF-Endorsed Patient Safety Measures, Serious Reportable Events, and Safe Practices**

*Endorsed as of October 2009.*

## Appendix A – NQF-Endorsed® Patient Safety Measures

A review of NQF-endorsed patient safety measures revealed 92 patient safety measures. Additionally, 35 measures related to mortality or readmission are potentially indicative of patient safety issues and are included here for that reason.

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>CENTRAL LINE (3)</b>			
139	Central line catheter-associated blood stream infection rate for ICU and high-risk nursery (HRN) patients	Percentage of ICU and high-risk nursery patients, who over a certain amount of days acquired a central line catheter-associated blood stream infections over a specified amount of line-days	S
298	Central line bundle compliance	Percentage of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place. The central line bundle elements include: <ul style="list-style-type: none"> <li>• Hand hygiene</li> <li>• Maximal barrier precautions upon insertion</li> <li>• Chlorhexidine skin antisepsis</li> <li>• Optimal catheter site selection, with subclavian vein as the preferred site for non-tunneled catheters in patients 18 years and older</li> <li>• Daily review of line necessity with prompt removal of unnecessary lines</li> </ul>	S-SP
464	Anesthesiology and critical care: prevention of catheter-related bloodstream infections (CRBSI) – central venous catheter (CVC) insertion protocol	Percentage of patients who undergo CVC insertion for whom CVC was inserted with all elements of maximal sterile barrier technique (cap AND mask AND sterile gown AND sterile gloves AND a large sterile sheet AND hand hygiene AND 2% chlorhexidine for cutaneous antisepsis) followed	S - SP
<b>FALLS (6)</b>			
35	Fall risk management in older adults: (a) Discussing fall risk; (b) Managing fall risk	Percentage of patients aged 75 and older who reported that their doctor or other health provider talked with them about falling or problems with balance or walking  Percentage of patients aged 75 and older who reported that their doctor or other health provider had done anything to help prevent falls or treat problems with balance or walking	S - SP, SRE
101	Falls: screening for fall risk	Percentage of patients aged 65 years and older who were screened for fall risk (2 or more falls in the past year or any fall with injury in the past year) at least once within 12 months	S - SP, SRE

*more*

<sup>a</sup> Key: **S**-Safety Measure; **SP**-Safety measure that corresponds to one or more NQF-Endorsed Safe Practice; **SRE**-Safety measure that corresponds to one or more NQF-Endorsed Serious Reportable Event; **M**-Mortality or readmission measures that may be indicative of patient safety issues; **Q/S**-Quality measures that may be relevant to patient safety.

## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>FALLS (6)</b> <i>(continued)</i>			
141	Falls prevalence	Percentage of patients during a certain # of days who fell	S - SP, SRE
202	Falls with injury	Percentage of patients during a certain # of days who fell and acquired an injury	S - SP, SRE
266	Patient fall	Percentage of ASC admissions experiencing a fall in the ASC	S - SP, SRE
537	Multifactor fall risk assessment conducted in patients 65 and older	Percent of home health episodes in which the patient was 65 or older and was assessed for risk of falls (using a standardized and validated multi-factor Fall Risk Assessment) at start or resumption of home health care	S - SP
<b>GENERAL PATIENT SAFETY COMPOSITES (2)</b>			
531	Patient safety for selected indicators	A composite measure of potentially preventable adverse events for selected indicators	S
532	Pediatric patient safety for selected indicators	A composite measure of potentially preventable adverse events for selected pediatric indicators	S
<b>HOSPITAL-ACQUIRED INFECTION (4)</b>			
304	Late sepsis or meningitis in very low birth weight (VLBW) neonates (risk-adjusted)	Percentage of infants born at the hospital, whose birth weight is between 401 and 1500 grams OR whose gestational age is between 22 weeks 0 days and 29 weeks 6 days, who have late sepsis or meningitis, with one or more of the following criteria: Bacterial Pathogen, Coagulase Negative Staphylococcus, Fungal Infection	S
431	Influenza vaccination coverage among healthcare personnel	Percentage of healthcare personnel (HCP) who receive the influenza vaccination.	S - SP
478	Nosocomial blood stream infections in neonates (NQI #3)	Percentage of qualifying neonates with selected bacterial blood stream infections	S
500	Severe sepsis and septic shock: management bundle	Initial steps in the management of the patient presenting with infection (severe sepsis or septic shock)	S
<b>MEDICATION MANAGEMENT (11)</b>			
19	Documentation of medication list in the outpatient record	Percentage of patients having a medication list in the medical record	S - SP
20	Documentation of allergies and adverse reactions in the outpatient record	Percentage of patients having documentation of allergies and adverse reactions in the medical record	S - SP

*more*



## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>MEDICATION MANAGEMENT (11)</b> <i>(continued)</i>			
22	Drugs to be avoided in the elderly: a. Patients who receive at least one drug to be avoided, b. Patients who receive at least two different drugs to be avoided.	Percentage of patients ages 65 years and older who received at least one drug to be avoided in the elderly in the measurement year Percentage of patients 65 years of age and older who received at least two different drugs to be avoided in the elderly in the measurement year	S - SP
419	Universal documentation and verification of current medications in the medical record	Percentage of patients aged 18 years and older with a list of current medications with dosages (includes prescription, over-the-counter, herbals, vitamin/mineral/dietary [nutritional] supplements) and verified with the patient or authorized representative documented by the provider	S - SP
486	Adoption of medication e-prescribing	Documents whether provider has adopted a qualified e-Prescribing system and the extent of use in the ambulatory setting	S - SP
487	EHR with EDI prescribing used in encounters where a prescribing event occurred	Of all patient encounters within the past month that used an electronic health record (EHR) with electronic data interchange (EDI) where a prescribing event occurred, how many used EDI for the prescribing event	S - SP
504	Pediatric weight documented in kilograms	Percent of emergency department patients < 18 years of age with a current weight in kilograms documented in the ED record	S
553	Care for older adults – medication review (COA)	Percentage of adults 65 years and older who had a medication review	S - SP
554	Medication reconciliation post-discharge (MRP)	Percentage of discharges from January 1 to December 1 of the measurement year for patients 65 years of age and older for whom medications were reconciled on or within 30 days of discharge	S - SP
555	Monthly INR monitoring for beneficiaries on warfarin	Average percentage of monthly intervals in which Part D beneficiaries with claims for warfarin do not receive an INR test during the measurement period	S
556	INR for beneficiaries taking warfarin and interacting anti-infective medications	Percentage of episodes with an INR test performed 3 to 7 days after a newly-started interacting anti-infective medication for Part D beneficiaries receiving warfarin	S

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## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>MENTAL HEALTH (2)</b>			
104	Major depressive disorder: suicide risk assessment	Percentage of patients who had a suicide risk assessment completed at each visit	S - SRE
111	Bipolar disorder: appraisal for risk of suicide	Percentage of patients with bipolar disorder with evidence of an initial assessment that includes an appraisal for risk of suicide	S - SRE
<b>MORTALITY (28)</b>			
119	Risk-adjusted operative mortality for CABG <sup>©</sup>	Percent of patients undergoing isolated CABG who die during the hospitalization in which the CABG was performed or within 30 days of the procedure	M
120	Risk-adjusted operative mortality for aortic valve replacement (AVR) <sup>©</sup>	Percent of patients undergoing AVR who die, including both 1) all deaths occurring during the hospitalization in which the [procedure] was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure	M
121	Risk-adjusted operative mortality for mitral valve replacement/repair (MVR)	Percent of patients undergoing MVR who die, including both 1) all deaths occurring during the hospitalization in which the [procedures] was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure	M
122	Risk-adjusted operative mortality MVR+CABG Surgery	Percent of patients undergoing MVR and CABG who die, including both 1) all deaths occurring during the hospitalization in which the [procedure] was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure	M
123	Risk-adjusted operative mortality for AVR+CABG	Percent of patients undergoing AVR and CABG who die, including both 1) all deaths occurring during the hospitalization in which the [procedure] was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure	M
133	PCI mortality (risk-adjusted) <sup>©</sup>	Percentage of PCI admissions who expired	M
161	AMI inpatient mortality (risk-adjusted)	Percentage of acute myocardial infarction (AMI) patients who expired during hospital stay	M
229	Heart failure 30-day mortality	Percentage of patients with AMI age 65 years and older, with hospital-specific, risk standardized, all-cause 30-day mortality (defined as death from any cause within 30 days after the index admission date) for patients discharged from the hospital with a principal diagnosis of HF	M

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## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>MORTALITY (28)</b> <i>(continued)</i>			
230	Acute myocardial infarction 30-day mortality	Percentage of patients with AMI age 65 years and older, with hospital-specific, risk standardized, all-cause 30-day mortality (defined as death from any cause within 30 days after the index admission date) for patients discharged from the hospital with a principal diagnosis of AMI	M
231	Inpatient pneumonia mortality	Percentage of patients with ICD-9-CM code of pneumonia as the principal diagnosis who were cases of in-hospital death among discharges	M
339	Pediatric heart surgery mortality (PDI 6) (risk adjusted)	Number of in-hospital deaths in patients undergoing surgery for congenital heart disease per 1000 patients	M
343	PICU standardized mortality ratio	The ratio of actual deaths over predicted deaths for PICU patients	M
347	Death in low mortality DRGs (PSI 2)	Percent of in-hospital deaths, age 18 years and older, in DRGs with less than 0.5% mortality rate	M
351	Death among surgical inpatients with serious, treatable complications (PSI 4)	Percent of in-hospital deaths for surgical discharges, age 18 years and older, with a principal procedure within 2 days of admission or elective, with enumerated complications of care listed in failure to rescue (FTR) definition (e.g., pneumonia, DVT/PE, sepsis, shock/cardiac arrest, or GI hemorrhage/acute ulcer)	M
352	Failure to rescue in-hospital mortality (risk adjusted)	Percentage of patients who died with a complication in the hospital	M
353	Failure to rescue 30-day mortality (risk adjusted)	Percentage of patients who died with a complication within 30 days from admission	M
354	Hip fracture mortality rate (IQI 19) (risk adjusted)	Percent of in-hospital deaths for discharges, age 18 years and older, with ICD-9-CM principal diagnosis code of hip fracture	M
358	Congestive heart failure mortality (IQI 16) (risk adjusted)	Percent of in-hospital death for discharges, 18 years and older, with ICD-9-CM principle diagnosis code of CHF	M
359	Abdominal aortic artery (AAA) repair mortality rate (IQI 11) (risk adjusted)	Number of deaths per 100 AAA repairs (risk adjusted)	M
360	Esophageal resection mortality rate (IQI 8) (risk adjusted)	Number of deaths per 100 esophageal resections for cancer (risk adjusted)	M
365	Pancreatic resection mortality rate (IQI 9) (risk adjusted)	Number of deaths per 100 pancreatic resections for cancer (risk adjusted)	M

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## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>MORTALITY (28)</b> <i>(continued)</i>			
369	Dialysis facility risk-adjusted standardized mortality ratio (32) Level	Risk-adjusted standardized mortality ratio for dialysis facility patients	M
467	Acute stroke mortality rate (IQI 17)	Percent of in-hospital deaths for discharges, 18 years and older, with ICD-9-CM principal diagnosis code of stroke	M
468	Pneumonia (PN) 30-day mortality rate	Hospital-specific, risk standardized, all-cause 30-day mortality (defined as death from any cause within 30 days after the index admission date) for patients discharged from the hospital with a principal diagnosis of pneumonia	M
530	Mortality for selected conditions	A composite measure of in-hospital mortality indicators for selected conditions	M
534	Hospital specific risk-adjusted measure of mortality or one or more major complications within 30 days of a lower extremity bypass (LEB)	Hospital specific risk-adjusted measure of mortality or one or more of the following major complications (cardiac arrest, myocardial infarction, CVA/stroke, on ventilator >48 hours, acute renal failure (requiring dialysis), bleeding/transfusions, graft/prosthesis/flap failure, septic shock, sepsis, and organ space surgical site infection), within 30 days of a lower extremity bypass (LEB) in patients age 16 and older	M
535	30-day all-cause risk-standardized mortality rate following percutaneous coronary intervention (PCI) for patients without ST segment elevation myocardial infarction (STEMI) and without cardiogenic shock	Hospital-specific 30-day all-cause risk-standardized mortality rate following Percutaneous Coronary Intervention (PCI) among patients aged 18 years or older without ST segment elevation myocardial infarction (STEMI) and without cardiogenic shock at the time of procedure	M
536	30-day all-cause risk-standardized mortality rate following Percutaneous Coronary Intervention (PCI) for patients with ST segment elevation myocardial infarction (STEMI) or cardiogenic shock	Hospital-specific 30-day all-cause risk-standardized mortality rate following Percutaneous Coronary Intervention (PCI) among patients aged 18 years or older with ST segment elevation myocardial infarction (STEMI) or cardiogenic shock at the time of procedure	M

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## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>PRESSURE ULCERS (9)</b>			
181	Increase in number of pressure ulcers	Percentage of patients who had an increase in the number of pressure ulcers	S - SP, SRE
187	Recently hospitalized residents with pressure ulcers (risk adjusted)	Recently hospitalized residents with pressure ulcers	S - SP, SRE
198	High-risk residents with pressure ulcers	Percentage of residents with a valid target assessment and one of the following inclusion criteria: 1. Impaired in mobility or transfer on the target assessment 2. Comatose on the target assessment 3. Suffer malnutrition on the target assessment who have pressure ulcers	S - SP, SRE
199	Average-risk residents with pressure ulcers	Percentage of residents with a valid target assessment and not qualifying as high risk with pressure ulcers	S - SP, SRE
201	Pressure ulcer prevalence	Percentage of patients with stage II or greater hospital-acquired pressure ulcers	S - SP, SRE
337	Decubitus ulcer (PDI 2)	Percent of surgical and medical discharges under 18 years with ICD-9-CM code for decubitus ulcer in secondary diagnosis field	S - SP, SRE
538	Pressure ulcer prevention included in plan of care	Percent of patients with assessed risk for Pressure Ulcers whose physician-ordered plan of care includes intervention(s) to prevent them	S - SP
539	Pressure ulcer prevention plans implemented	Percent of patients with assessed risk for Pressure Ulcers for whom interventions for pressure ulcer prevention were implemented during their episode of care	S - SP
540	Pressure ulcer risk assessment conducted	Percent of patients who were assessed for risk of Pressure Ulcers at start/resumption of home health care	S - SP
<b>RADIATION (2)</b>			
382	Oncology: radiation dose limits to normal tissues	Percentage of patients with a diagnosis of cancer receiving 3D conformal radiation therapy with documentation in medical record that normal tissue dose constraints were established within five treatment days for a minimum of one tissue	S
510	Exposure time reported for procedures using fluoroscopy	Percentage of final reports for procedures using fluoroscopy that include documentation of radiation exposure or exposure time	S

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## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>READMISSIONS (6)</b>			
329	All-cause readmission index (risk adjusted)	Overall inpatient 30-day hospital readmission rate	Q/S
330	30-day all-cause risk standardized readmission rate following heart failure hospitalization (risk adjusted)	Hospital-specific, risk-standardized, 30-day all-cause readmission rates for Medicare fee-for-service patients discharged from the hospital with a principal diagnosis of heart failure (HF)	Q/S
335	PICU unplanned readmission rate	The total number of patients requiring unscheduled readmission to the ICU within 24 hours of discharge or transfer	Q/S
336	Review of unplanned PICU readmissions	Periodic clinical review of unplanned readmissions to the PICU that occurred within 24 hours of discharge or transfer from the PICU	Q/S
505	Thirty-day all-cause risk standardized readmission rate following acute myocardial infarction (AMI) hospitalization	Hospital-specific 30-day all-cause risk standardized readmission rate following hospitalization for AMI among Medicare beneficiaries aged 65 years or older at the time of index hospitalization	S
506	Thirty-day all-cause risk standardized readmission rate following pneumonia hospitalization	Hospital-specific 30-day all-cause risk standardized readmission rate following hospitalization for pneumonia among Medicare beneficiaries aged 65 years or older at the time of index hospitalization	S
<b>RESTRAINTS (2)</b>			
193	Residents who were physically restrained daily during the 7-day assessment period	Percentage of residents on most recent assessments who were physically restrained daily during the 7-day assessment period	S - SRE
203	Restraint prevalence (vest and limb only)	Percentage of patients with vest and/or limb restraint on the day of the study	S - SRE
<b>SURGERY (5)</b>			
115	Surgical re-exploration	Percent of patients undergoing isolated CABG who require a return to the operating room for bleeding/tamponade, graft occlusion, or other cardiac reason.	Q/S
267	Wrong site, wrong side, wrong patient, wrong procedure, wrong implant	Percentage of ASC admissions experiencing a wrong site, wrong side, wrong patient, wrong procedure, or wrong implant.	S - SP, SRE
362	Foreign body left after procedure (PDI 3)	Discharges with foreign body accidentally left in during procedure per 1,000 discharges	S - SRE

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## Appendix A – NQF-Endorsed<sup>®</sup> Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>SURGERY (5)</b> <i>(continued)</i>			
363	Foreign body left in during procedure (PSI 5)	Discharges with foreign body accidentally left in during procedure per 1,000 discharges	S - SRE
452	Surgery patients with perioperative temperature management	Surgery patients for whom either active warming was used intraoperatively for the purpose of maintaining normothermia or who had at least one body temperature equal to or greater than 96.8° F/36° C recorded within the 30 minutes immediately prior to or the 15 minutes immediately after Anesthesia End Time	S - SP
<b>SURGICAL SITE INFECTION (15)</b>			
125	Timing of antibiotic prophylaxis for cardiac surgery patients	Percent of patients undergoing cardiac surgery who received prophylactic antibiotics within one hour prior to surgical incision (two hours if receiving vancomycin)	S
126	Selection of antibiotic prophylaxis for cardiac surgery patients	Percent of patients undergoing cardiac surgery who received prophylactic antibiotics recommended for the operation	S
128	Duration of prophylaxis for cardiac surgery patients	Percent of patients undergoing cardiac surgery whose prophylactic antibiotics were discontinued within 24 hours after surgery end time	S
130	Deep sternal wound infection rate	Percent of patients undergoing isolated CABG who developed deep sternal wound infection within 30 days post-operatively	S
264	Prophylactic intravenous (IV) antibiotic timing	Percentage of ASC patients who received IV antibiotics ordered for surgical site infection prophylaxis on time	S - SP
269	Timing of prophylactic antibiotics - administering physician	Percentage of surgical patients aged > 18 years with indications for prophylactic parenteral antibiotics for whom administration of the antibiotic has been initiated within one hour (if vancomycin, two hours) prior to the surgical incision or start of procedure when no incision is required	S - SP
270	Timing of antibiotic prophylaxis: ordering physician	Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics, who have an order for prophylactic antibiotic to be given within one hour (if fluoroquinolone or vancomycin, two hours), prior to the surgical incision (or start of procedure when no incision is required)	S - SP

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## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>SURGICAL SITE INFECTION (15)</b> <i>(continued)</i>			
271	Discontinuation of prophylactic antibiotics (non-cardiac procedures)	Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic antibiotics AND who received a prophylactic antibiotic, who have an order for discontinuation of prophylactic antibiotics within 24 hours of surgical end time	S - SP
299	Surgical site infection rate	Percentage of surgical site infections occurring within thirty days after the operative procedure if no implant is left in place, or within one year if an implant is in place in patients who had an NHSN operative procedure performed during a specified time period and the infection appears to be related to the operative procedure	S - SP
300	Cardiac patients with controlled 6 AM postoperative serum glucose	Percentage of cardiac surgery patients with controlled 6 a.m. serum glucose ( $\leq 200$ mg/dl) on postoperative day (POD) 1 and POD 2	S - SP
301	Surgery patients with appropriate hair removal	Percentage of surgery patients with surgical hair site removal with clippers or depilatory or no surgical site hair removal	S - SP
472	Prophylactic antibiotic received within one hour prior to surgical incision or at the time of delivery – cesarean section	Percentage of patients undergoing cesarean section who receive prophylactic antibiotics within one hour prior to surgical incision or at the time of delivery.	S - SP
527	Prophylactic antibiotic received within 1 hour prior to surgical incision SCIP-Inf-2	Surgical patients who received prophylactic antibiotics within 1 hour of surgical incision (2 hours if receiving vancomycin)	S - SP
528	Prophylactic antibiotic selection for surgical patients	Surgical patients who received recommended prophylactic antibiotics for specific surgical procedures	S - SP
529	Prophylactic antibiotics discontinued within 24 hours after surgery end time	Surgical patients whose prophylactic antibiotics were discontinued within 24 hours after surgery end time	S - SP

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## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>URINARY TRACT INFECTION (3)</b>			
138	Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients	Percentage of intensive care unit patients with urinary catheter-associated urinary tract infections	S
196	Residents with a urinary tract infection	Percentage of residents on most recent assessment with a urinary tract infection	S
453	Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2) with day of surgery being day zero	Surgical patients with urinary catheter removed on Postoperative Day 1 or Postoperative Day 2 with day of surgery being day zero.	S - SP
<b>VENOUS THROMBOEMBOLISM (11)</b>			
217	Surgery patients with recommended venous thromboembolism (VTE) prophylaxis ordered	Percentage of surgery patients with recommended Venous Thromboembolism (VTE) Prophylaxis ordered during admission	S - SP
218	Surgery patients who received appropriate venous thromboembolism (VTE) prophylaxis within 24 hours prior to surgery to 24 hours after surgery end time	Percentage of surgery patients who received appropriate Venous Thromboembolism (VTE) Prophylaxis within 24 hours prior to surgery to 24 hours after surgery end time	S - SP
239	Venous thromboembolism (VTE) prophylaxis	Percentage of patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time	S - SP
371	Venous thromboembolism (VTE) prophylaxis	This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after hospital admission or surgery end date for surgeries that start the day of or the day after hospital admission	S - SP

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## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>VENOUS THROMBOEMBOLISM (11)</b> <i>(continued)</i>			
372	Intensive care unit (ICU) VTE prophylaxis	This measure assesses the number of patients who received VTE prophylaxis or have documentation why no VTE prophylaxis was given the day of or the day after the initial admission (or transfer) to the Intensive Care Unit (ICU) or surgery end date for surgeries that start the day of or the day after ICU admission (or transfer).	S - SP
375	VTE discharge instructions	This measure assesses the number of patients diagnosed with confirmed VTE that are discharged to home, to home with home health or home hospice on warfarin with written discharge instructions that address all four criteria: compliance issues, dietary advice, follow-up monitoring, and information about the potential for adverse drug reactions/interactions	S - SP
376	Incidence of potentially preventable VTE	This measure assesses the number of patients diagnosed with confirmed VTE during hospitalization (not present on arrival) who did not receive VTE prophylaxis between hospital admission and the day before the VTE diagnostic testing order date	S - SP
434	Deep vein thrombosis (DVT) prophylaxis	Patients with an ischemic stroke or a hemorrhagic stroke and who are non-ambulatory should start receiving DVT prophylaxis by end of hospital day two	S - SP
450	Postoperative DVT or PE (PSI 12)	Percent of adult surgical discharges with a secondary diagnosis code of deep vein thrombosis or pulmonary embolism	S - SP
473	Appropriate DVT prophylaxis in women undergoing cesarean delivery	Measure adherence to current ACOG, ACCP recommendations for use of DVT prophylaxis in women undergoing cesarean delivery	S - SP
503	Anticoagulation for acute pulmonary embolus patients	Anticoagulation ordered for acute pulmonary embolus patients	S - SP

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## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>VENTILATOR (2)</b>			
140	Ventilator-associated pneumonia for ICU and high-risk nursery (HRN) patients	Percentage of ICU and HRN patients who over a certain amount of days have ventilator-associated pneumonia	S
302	Ventilator bundle	<p>Percentage of intensive care unit patients on mechanical ventilation at time of survey for whom all four elements of the ventilator bundle are documented and in place. The ventilator bundle elements are:</p> <ul style="list-style-type: none"> <li>• Head of bed (HOB) elevation 30 degrees or greater (unless medically contraindicated); noted on 2 different shifts within a 24 hour period</li> <li>• Daily "sedation interruption" and daily assessment of readiness to extubate; process includes interrupting sedation until patient follow commands and patient is assessed for discontinuation of mechanical ventilation; Parameters of discontinuation include: resolution of reason for intubation; inspired oxygen content roughly 40%; assessment of patients ability to defend airway after extubation due to heavy sedation; minute ventilation less than or equal to 15 liters/minute; and respiratory rate/tidal volume less than or equal to 105/min/L(RR/TV&lt; 105)</li> <li>• SUD (peptic ulcer disease) prophylaxis</li> <li>• DVT (deep venous thrombosis) prophylaxis</li> </ul>	S - SP
<b>WORKFORCE (3)</b>			
190	Nurse staffing hours - 4 parts	Percentage of daily work in hours by the entire group of nurses or nursing assistants spent tending to residents	S - SP
204	Skill mix (Registered Nurse [RN], Licensed Vocational/ Practical Nurse [LVN/LPN], unlicensed assistive personnel [UAP], and contract)	Percentage of patient care responsibilities covered in productive hours worked by nursing staff (RN, LPN, UAP, and contract)	S - SP
205	Nursing care hours per patient day (RN, LPN, and UAP)	Percentage of nursing care hours per patient day worked by nursing staff (RN, LPN, and UAP)	S - SP

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## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>MISCELLANEOUS (13)</b>			
263	Patient burn	Percentage of ASC admissions experiencing a burn prior to discharge	S - SRE
303	Late sepsis or meningitis in neonates (risk-adjusted)	Percentage of infants born at the hospital, whose birth weight is between 401 and 1500 grams OR whose gestational age is between 22 weeks 0 days and 29 weeks 6 days with late sepsis or meningitis with one or more of the following criteria: Bacterial Pathogen, Coagulase Negative Staphylococcus, Fungal Infection	S
344	Accidental puncture or laceration (PDI 1) (risk adjusted)	Percent of medical and surgical discharges under 18 years of age with ICD-9-CM code denoting accidental cut, puncture, perforation or laceration in any secondary diagnosis code	S
345	Accidental puncture or laceration (PSI 15)	Percent of medical and surgical discharges, 18 years and older, with ICD-9-CM code denoting accidental cut, puncture, perforation, or laceration in any secondary diagnosis field	S
346	Iatrogenic pneumothorax (PSI 6) (risk adjusted)	Percent of medical and surgical discharges, 18 years and older, with ICD-9-CM code of iatrogenic pneumothorax in any secondary diagnosis field	S
348	Iatrogenic pneumothorax in non-neonates (PDI 5) (risk adjusted)	Percent of medical and surgical discharges, age under 18 years, with ICD-9-CM code of iatrogenic pneumothorax in any secondary diagnosis field	S
349	Transfusion reaction (PSI 16)	Percent of medical and surgical discharges, 18 years and older, with ICD-9-CM code for transfusion reaction in any secondary diagnosis field.	S
350	Transfusion reaction (PDI 13)	Percent of medical and surgical discharges, under 18 years of age, with an ICD-9-CM code for transfusion reaction in any secondary diagnosis field	S
451	Call for a measure of glycemic control with intravenous insulin implementation	Intravenous insulin glycemic control protocol implemented for cardiac surgery patients with diabetes or hyperglycemia admitted into an intensive care unit	S - SP
488	Adoption of health information technology	Documents whether provider has adopted and is using health information technology. To qualify, the provider must have adopted and be using a certified/qualified electronic health record (EHR).	S

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## Appendix A – NQF-Endorsed® Patient Safety Measures

NQF #	MEASURE TITLE	MEASURE DESCRIPTION	CATEGORY <sup>a</sup>
<b>MISCELLANEOUS (13)</b> <i>(continued)</i>			
491	Tracking of clinical results between visits	Documentation of the extent to which a provider uses a certified/qualified electronic health record (EHR) system to track pending laboratory tests, diagnostic studies (including common preventive screenings) or patient referrals. The Electronic Health Record includes provider reminders when clinical results are not received within a predefined timeframe.	S - SP
501	Confirmation of endotracheal tube placement	Any time an endotracheal tube is placed into an airway in the Emergency Department or an endotracheal tube is placed by an outside provider and that patient arrives already intubated (EMS or hospital transfer) or when an airway is placed after patients arrives to the ED there should be some method attempted to confirm ETT placement	S
526	Timely initiation of care	Percent of patients with timely start or resumption of home health care	S

## Appendix A – NQF-Endorsed Serious Reportable Events in Healthcare<sup>b</sup>

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### 1. SURGICAL EVENTS

- A. Surgery performed on the wrong body part
- B. Surgery performed on the wrong patient
- C. Wrong surgical procedure performed on a patient
- D. Unintended retention of a foreign object in a patient after surgery or other procedure
- E. Intraoperative or immediately post-operative death in an ASA Class I patient

### 2. PRODUCT OR DEVICE EVENTS

- A. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility
- B. Patient death or serious disability associated with the use or function of a device in patient care, in which the device is used or functions other than as intended
- C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility

### 3. PATIENT PROTECTION EVENTS

- A. Infant discharged to the wrong person
- B. Patient death or serious disability associated with patient elopement (disappearance)
- C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility

### 4. CARE MANAGEMENT EVENTS

- A. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- B. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products
- C. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility
- D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility
- E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates
- F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility
- G. Patient death or serious disability due to spinal manipulative therapy
- H. Artificial insemination with the wrong donor sperm or wrong egg

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<sup>b</sup> See the full report for applicable care settings for each event, specifications, and additional background and reference material.

## Appendix A – NQF-Endorsed Serious Reportable Events in Healthcare<sup>b</sup>

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### 5. ENVIRONMENTAL EVENTS

- A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility
- B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances
- C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility
- D. Patient death or serious disability associated with a fall while being cared for in a healthcare facility
- E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility

### 6. CRIMINAL EVENTS

- A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider
  - B. Abduction of a patient of any age
  - C. Sexual assault on a patient within or on the grounds of the healthcare facility
  - D. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility
-

## Appendix A – NQF-Endorsed Safe Practices for Better Healthcare<sup>c</sup>

SAFE PRACTICE	PRACTICE STATEMENT
<b>Safe Practice 1: Leadership Structures and Systems</b>	Leadership structures and systems must be established to ensure that there is organization-wide awareness of patient safety performance gaps, direct accountability of leaders for those gaps, and adequate investment in performance improvement abilities, and that actions are taken to ensure safe care of every patient served.
<b>Safe Practice 2: Culture Measurement, Feedback, and Intervention</b>	Healthcare organizations must measure their culture, provide feedback to the leadership and staff, and undertake interventions that will reduce patient safety risk.
<b>Safe Practice 3: Teamwork Training and Skill Building</b>	Healthcare organizations must establish a proactive, systematic, organization-wide approach to developing team-based care through teamwork training, skill building, and team-led performance improvement interventions that reduce preventable harm to patients.
<b>Safe Practice 4: Identification and Mitigation of Risks and Hazards</b>	Healthcare organizations must systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm.
<b>Safe Practice 5: Informed Consent</b>	Ask each patient or legal surrogate to “teach back,” in his or her own words, key information about the proposed treatments or procedures for which he or she is being asked to provide informed consent.
<b>Safe Practice 6: Life-Sustaining Treatment</b>	Ensure that written documentation of the patient’s preferences for life-sustaining treatments is prominently displayed in his or her chart.
<b>Safe Practice 7: Disclosure</b>	Following serious unanticipated outcomes, including those that are clearly caused by systems failures, the patient and, as appropriate, the family should receive timely, transparent, and clear communication concerning what is known about the event.
<b>Safe Practice 8: Care of the Caregiver</b>	Following serious unintentional harm due to systems failures and/or errors that resulted from human performance failures, the involved caregivers (clinical providers, staff, and administrators) should receive timely and systematic care to include: treatment that is just, respect, compassion, supportive medical care, and the opportunity to fully participate in event investigation and risk identification and mitigation activities that will prevent future events.

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<sup>c</sup> See the full report for applicable care settings, specifications, and additional background and reference material.

## Appendix A – NQF-Endorsed Safe Practices for Better Healthcare<sup>c</sup>

SAFE PRACTICE	PRACTICE STATEMENT
<b>Safe Practice 9: Nursing Workforce</b>	Implement critical components of a well-designed nursing workforce that mutually reinforce patient safeguards, including the following: <ul style="list-style-type: none"> <li>• A nurse staffing plan with evidence that it is adequately resourced and actively managed and that its effectiveness is regularly evaluated with respect to patient safety.</li> <li>• Senior administrative nursing leaders, such as a Chief Nursing Officer, as part of the hospital senior management team.</li> <li>• Governance boards and senior administrative leaders that take accountability for reducing patient safety risks related to nurse staffing decisions and the provision of financial resources for nursing services.</li> <li>• Provision of budgetary resources to support nursing staff in the ongoing acquisition and maintenance of professional knowledge and skills.</li> </ul>
<b>Safe Practice 10: Direct Caregivers</b>	Ensure that non-nursing direct care staffing levels are adequate, that the staff are competent, and that they have had adequate orientation, training, and education to perform their assigned direct care duties.
<b>Safe Practice 11: Intensive Care Unit Care</b>	All patients in general intensive care units (both adult and pediatric) should be managed by physicians who have specific training and certification in critical care medicine (“critical care certified”).
<b>Safe Practice 12: Patient Care Information</b>	Ensure that care information is transmitted and appropriately documented in a timely manner and in a clearly understandable form to patients and to all of the patient’s healthcare providers/ professionals, within and between care settings, who need that information to provide continued care.
<b>Safe Practice 13: Order Read-Back and Abbreviations</b>	Incorporate within your organization a safe, effective communication strategy, structures, and systems to include the following: <ul style="list-style-type: none"> <li>• For verbal or telephone orders or for telephonic reporting of critical test results, verify the complete order or test result by having the person who is receiving the information record and “read-back” the complete order or test result.</li> <li>• Standardize a list of “Do Not Use” abbreviations, acronyms, symbols, and dose designations that cannot be used throughout the organization.</li> </ul>

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## Appendix A – NQF-Endorsed Safe Practices for Better Healthcare<sup>c</sup>

SAFE PRACTICE	PRACTICE STATEMENT
<b>Safe Practice 14: Labeling of Diagnostic Studies</b>	Implement standardized policies, processes, and systems to ensure accurate labeling of radiographs, laboratory specimens, or other diagnostic studies, so that the right study is labeled for the right patient at the right time.
<b>Safe Practice 15: Discharge Systems</b>	A “discharge plan” must be prepared for each patient at the time of hospital discharge, and a concise discharge summary must be prepared for and relayed to the clinical caregiver accepting responsibility for post discharge care in a timely manner. Organizations must ensure that there is confirmation of receipt of the discharge information by the independent licensed practitioner who will assume the responsibility for care after discharge.
<b>Safe Practice 16: Safe Adoption of Computerized Prescriber Order Entry</b>	Implement a computerized prescriber order entry (CPOE) system built upon the requisite foundation of re-engineered evidence-based care, an assurance of healthcare organization staff and independent practitioner readiness, and an integrated information technology infrastructure.
<b>Safe Practice 17: Medication Reconciliation</b>	The healthcare organization must develop, reconcile, and communicate an accurate patient medication list throughout the continuum of care.
<b>Safe Practice 18: Pharmacist Leadership Structures and Systems</b>	Pharmacy leaders should have an active role on the administrative leadership team that reflects their authority and accountability for medication management systems performance across the organization.
<b>Safe Practice 19: Hand Hygiene</b>	Comply with current Centers for Disease Control and Prevention Hand Hygiene Guidelines.
<b>Safe Practice 20: Influenza Prevention</b>	Comply with current Centers for Disease Control and Prevention (CDC) recommendations for influenza vaccinations for healthcare personnel and the annual recommendations of the CDC Advisory Committee on Immunization Practices for individual influenza prevention and control.
<b>Safe Practice 21: Central Line-Associated Bloodstream Infection Prevention</b>	Take actions to prevent central line-associated bloodstream infection by implementing evidence-based intervention practices.

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## Appendix A – NQF-Endorsed Safe Practices for Better Healthcare<sup>c</sup>

SAFE PRACTICE	PRACTICE STATEMENT
<b>Safe Practice 22: Surgical-Site Infection Prevention</b>	Take actions to prevent surgical-site infections by implementing evidence-based intervention practices.
<b>Safe Practice 23: Care of the Ventilated Patient</b>	Take actions to prevent complications associated with ventilated patients: specifically, ventilator-associated pneumonia, venous thromboembolism, peptic ulcer disease, dental complications, and pressure ulcers.
<b>Safe Practice 24: Multidrug-Resistant Organism Prevention</b>	Implement a systematic multidrug-resistant organism (MDRO) eradication program built upon the fundamental elements of infection control, an evidence-based approach, assurance of the hospital staff and independent practitioner readiness, and a re-engineered identification and care process for those patients with or at risk for MDRO infections. Note: This practice applies to, but is not limited to, epidemiologically important organisms such as methicillin-resistant <i>Staphylococcus aureus</i> , vancomycin-resistant enterococci, and <i>Clostridium difficile</i> . Multidrug-resistant gram-negative bacilli, such as <i>Enterobacter</i> species, <i>Klebsiella</i> species, <i>Pseudomonas</i> species, and <i>Escherichia coli</i> , and vancomycin-resistant <i>Staphylococcus aureus</i> , should be evaluated for inclusion on a local system level based on organizational risk assessments.
<b>Safe Practice 25: Catheter-Associated Urinary Tract Infection Prevention</b>	Take actions to prevent catheter-associated urinary tract infection by implementing evidence-based intervention practices.
<b>Safe Practice 26: Wrong-Site, Wrong- Procedure, Wrong-Person Surgery Prevention</b>	Implement the Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person™ Surgery for all invasive procedures.
<b>Safe Practice 27: Pressure Ulcer Prevention</b>	Take actions to prevent pressure ulcers by implementing evidence-based intervention practices.
<b>Safe Practice 28: Venous Thromboembolism Prevention</b>	Evaluate each patient upon admission, and regularly thereafter, for the risk of developing venous thromboembolism. Utilize clinically appropriate, evidence-based methods of thromboprophylaxis.
<b>Safe Practice 29: Anticoagulation Therapy</b>	Organizations should implement practices to prevent patient harm due to anticoagulant therapy.

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## Appendix A – NQF-Endorsed Safe Practices for Better Healthcare<sup>c</sup>

SAFE PRACTICE	PRACTICE STATEMENT
<b>Safe Practice 30: Contrast Media-Induced Renal Failure Prevention</b>	Utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure and gadolinium-associated nephrogenic systemic fibrosis, and utilize a clinically appropriate method for reducing the risk of adverse events based on the patient's risk evaluations.
<b>Safe Practice 31: Organ Donation</b>	Hospital policies that are consistent with applicable law and regulations should be in place and should address patient and family preferences for organ donation, as well as specify the roles and desired outcomes for every stage of the donation process.
<b>Safe Practice 32: Glycemic Control</b>	Take actions to improve glycemic control by implementing evidence-based intervention practices that prevent hypoglycemia and optimize the care of patients with hyperglycemia and diabetes.
<b>Safe Practice 33: Falls Prevention</b>	Take actions to prevent patient falls and to reduce fall-related injuries by implementing evidence-based intervention practices.
<b>Safe Practice 34: Pediatric Imaging</b>	When CT imaging studies are undertaken on children, "child-size" techniques should be used to reduce unnecessary exposure to ionizing radiation.

# National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report

## Appendix B Patient Safety Reporting Framework Steering Committee

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# National Voluntary Consensus Standards for Public Reporting of Patient Safety Event Information: A Consensus Report

## Appendix C Patient Safety-Related Concepts and Definitions

**IN AN EFFORT TO ENSURE** that the Steering Committee discussions reflected a common understanding of concepts, the group selected the following list of terms and definitions as concepts they would likely use during development of the framework. They are provided here so that framework users understand the concepts in the same way. For many of the concepts, there was more than one definition in use; therefore, the Steering Committee chose to give first consideration to definitions used by NQF.<sup>a</sup> Sources from which the definitions were drawn are listed with the definition.

**Measures** are numeric quantifications of healthcare quality.

**Frameworks** are conceptual models and organizing principles developed by NQF-convened Steering Committees to guide measurement development and reporting. Endorsed frameworks usually include guiding principles, domains, and subdomains.

**Practices** are a specific process or manner of providing healthcare services or organization-level activities that, when executed effectively, lead to improved outcomes.

**Serious Reportable Events** are adverse events that are preventable, serious, and unambiguous adverse events that should never occur.<sup>b</sup>

<sup>a</sup> Many of the NQF-accepted definitions included below are taken from other sources.

<sup>b</sup> Currently under review by Serious Reportable Events Steering Committee.

## Appendix C—Patient Safety-Related Concepts and Definitions

CONCEPTS	DEFINITION (source)
<b>Adverse drug event</b>	An adverse reaction to a drug or medication. ( <i>NQF Safe Practices for Better Healthcare—2009 Update</i> ) <i>FDA defines Adverse Drug Reaction as “An adverse drug reaction, also called a side effect, is any undesirable experience associated with the use of a medicine in a patient. Adverse events can range from mild to severe. Serious adverse events are those that can cause disability, are life-threatening, result in hospitalization or death, or are birth defects.”<sup>c</sup></i>
<b>Adverse event</b>	Any harm (injury or illness) caused by medical care. Identifying adverse events indicates that the care resulted in an undesirable clinical outcome and that the clinical outcome was not caused by an underlying disease, but does not imply an error, negligence, or poor quality care. ( <i>NQF Safe Practices for Better Healthcare—2009 Update</i> )
<b>Close call</b>	See <i>near miss</i>
<b>Composite measure</b>	A composite measure is a combination of two or more individual measures in a single measure that results in a single score. ( <i>NQF Composite Measure Evaluation Framework and National Voluntary Consensus Standards for Mortality and Safety—Composite Measures</i> )
<b>Consumers</b>	Patients (those currently using healthcare services) and potential patients (those who are making choices prior to using healthcare services) and their families.
<b>Culture of safety</b>	Safety culture and culture of safety are frequently encountered terms referring to a commitment to safety that permeates all levels of an organization, from frontline personnel to executive management. More specifically, “safety culture” calls up a number of features identified in studies of high-reliability organizations, organizations outside of healthcare with exemplary performance with respect to safety. These features include: 1) acknowledgment of the high-risk, error-prone nature of an organization’s activities; 2) a blame-free environment where individuals are able to report errors or close calls without fear of reprimand or punishment; 3) an expectation of collaboration across ranks to seek solutions to vulnerabilities; and 4) willingness on the part of the organization to direct resources to addressing safety concerns. ( <i>NQF Safe Practices for Better Healthcare—2009 Update</i> )

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<sup>c</sup> U.S. Food and Drug Administration, *An FDA Guide to Drug Safety Terms*. Available at [www.fda.gov/ForConsumers/ConsumerUpdates/ucm107970.htm](http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107970.htm). Last accessed January 2010.

## Appendix C—Patient Safety-Related Concepts and Definitions

CONCEPTS	DEFINITION (source)
<b>Disability</b>	A physical or mental impairment that substantially limits one or more of the major life activities of an individual. ( <i>NQF Serious Reportable Events in Healthcare 2006 Update</i> )
<b>Error</b>	Failure of a planned action to be completed as intended (error of execution) or use of a wrong plan to achieve an aim (error of planning); also includes failure of an unplanned action that should have been completed (omission). (Institute of Medicine Patient Safety, 2004.)
<b>Event</b>	A discrete, auditable, and clearly defined occurrence. ( <i>NQF Serious Reportable Events in Healthcare 2006 Update</i> )
<b>Harm</b>	Impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability and death. (WHO <sup>d</sup> )
<b>Healthcare-associated infection</b>	A localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) that 1) occurs in a patient in a healthcare setting (e.g., a hospital or outpatient clinic), 2) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission to the same setting and 3) if the setting is a hospital, meets the criteria for a specific infection site as defined by CDC. ( <i>NQF Safe Practices for Better Healthcare—2009 Update</i> )
<b>Healthcare facility</b>	Means any licensed facility that is organized, maintained, and operated for the diagnosis, prevention, treatment, rehabilitation, convalescence, or other care of human illness or injury, physical or mental, including care during and after pregnancy. Healthcare facilities include, but are not limited to, hospitals, nursing homes, rehabilitation centers, medical centers or offices, outpatient dialysis centers, reproductive health centers, independent clinical laboratories, hospices, and ambulatory surgical centers. ( <i>NQF Serious Reportable Events 2006 Update</i> )

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<sup>d</sup> World Health Organization (WHO), *The Conceptual Framework for the International Classification for Patient Safety, Version 1.1, Final Technical Report*, Geneva, Switzerland: WHO; January 2009. Available at [www.who.int/patientsafety/taxonomy/icps\\_full\\_report.pdf](http://www.who.int/patientsafety/taxonomy/icps_full_report.pdf). Last accessed December 2009.

## Appendix C—Patient Safety-Related Concepts and Definitions

CONCEPTS	DEFINITION (source)
<b>Hospital-acquired condition</b>	Medical condition not present prior to admission to a hospital. (NQF <i>Safe Practices for Better Healthcare—2009 Update</i> ) <i>The Center for Medicare and Medicaid Services (CMS) has defined hospital acquired conditions as “Events that are (a) high cost or high volume or both, (b) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines.”<sup>e</sup></i>
<b>Unintended consequences</b>	Unforeseen repercussions that follow and can overshadow the principal endeavor.
<b>Medical error</b>	The failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim. (NQF <i>Safe Practices for Better Healthcare—2009 Update</i> )
<b>Medication error</b>	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (NQF <i>Safe Practices for Better Healthcare—2009 Update</i> )
<b>Mitigation</b>	An action or circumstance which prevents or moderates the process of an incident towards harming a patient. (WHO)
<b>Near miss/close call</b>	An event that did not reach a patient. For example: discovery of a dispensing error by a nurse as part of the process of administering the medication to a patient (which if not discovered would have become an incident); discovery of a mislabeled specimen in a laboratory (which if not discovered might subsequently have resulted in an incident). (AHRQ Common Formats <sup>f</sup> ) <sup>g</sup>

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<sup>e</sup> Department of Health and Human Services, Overview of Healthcare Acquired Conditions, Available at [www.cms.hhs.gov/hospitalacqcond/](http://www.cms.hhs.gov/hospitalacqcond/). Last accessed August 2009.

<sup>f</sup> Agency for Healthcare Research and Quality, Common Formats for Patient Safety Organizations. Definition available at [www.psoppc.org/c/document\\_library/get\\_file?p\\_l\\_id=34330&folderId=44704&name=DLFE-2604.pdf](http://www.psoppc.org/c/document_library/get_file?p_l_id=34330&folderId=44704&name=DLFE-2604.pdf). Last accessed January 2010.

<sup>g</sup> Currently under review by Serious Reportable Events Steering Committee.

## Appendix C—Patient Safety-Related Concepts and Definitions

CONCEPTS	DEFINITION (source)
<b>Outcome</b>	In healthcare, an outcome may be measured in a variety of ways, but it tends to reflect the health and well-being of the patient and the associated costs of care. ( <i>NQF Safe Practices for Better Healthcare—2009 Update</i> )
<b>Patient</b>	A person who is a recipient of healthcare. (WHO)
<b>Patient safety</b>	The reduction and mitigation of unsafe acts within the health-care system, as well as through the use of best practices shown to lead to optimal patient outcomes. Freedom from accidental or preventable injuries produced by medical care. ( <i>NQF Safe Practices for Better Healthcare—2009 Update</i> )
<b>Patient safety event</b>	For purposes of this report, the term <i>patient safety event</i> is defined as an occurrence that reaches the patient, whether or not it causes harm.
<b>Preventable (event)</b>	Describes an event that could have been anticipated and prepared for, but that occurs because of an error or other system failure. ( <i>NQF Serious Reportable Events 2006 Update</i> )
<b>Quality of care</b>	Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. (IOM <i>To Err Is Human</i> , 1999)
<b>Reporting entities</b>	Organizations or agencies, public or private, that may perform functions such as establishing policies that guide the development of report content and format, report production and distribution, and tasks involving education and diffusion of information. Reporting entities can include, but are not limited to, organizations such as federal agencies (e.g., CMS, Agency for Healthcare Research and Quality), accrediting bodies (e.g., The Joint Commission, National Committee for Quality Assurance), community organizations, civic organizations, religious agencies, healthcare purchasers such as managed care plans, and quality improvement agencies such as the QIOs. ( <i>NQF: A Comprehensive Framework for Hospital Care Performance Evaluation</i> , 2003)

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## Appendix C—Patient Safety-Related Concepts and Definitions

CONCEPTS	DEFINITION (source)
<b>Root cause analysis</b>	A focused review of systems and processes to identify the basic or contributing factors that cause adverse events. ( <i>NQF Safe Practices for Better Healthcare—2009 Update</i> )
<b>Sentinel event</b>	An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called “sentinel” because they signal the need for immediate investigation and response. (The Joint Commission, 2001)
<b>Surgical site infection</b>	An infection that occurs within 30 days of an operative procedure (NQF <i>National Voluntary Consensus Standards for Reporting of Healthcare-Associated Infection Data</i> , 2008; CDC)

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