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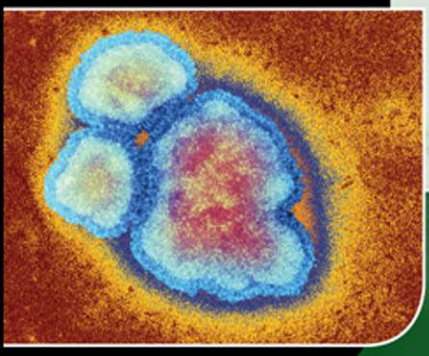

Pediatrics

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CURRENT Diagnosis & Treatment Pediatrics

TWENTY-SECOND EDITION

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Preface

The 22nd edition of *Current Diagnosis & Treatment: Pediatrics (CDTP)* features practical, up-to-date, well-referenced information on the care of children from birth through infancy and adolescence. *CDTP* emphasizes the clinical aspects of pediatric care while also covering important underlying principles. *CDTP* provides a guide to diagnosis, understanding, and treatment of the medical problems of all pediatric patients in an easy-to-use and readable format.

INTENDED AUDIENCE

Like all Lange medical books, *CDTP* provides a concise, yet comprehensive source of current information. Students will find *CDTP* an authoritative introduction to pediatrics and an excellent source for reference and review. *CDTP* provides excellent coverage of The Council on Medical Student Education in Pediatrics (COMSEP) curriculum used in pediatric clerkships. Residents in pediatrics (and other specialties) will appreciate the detailed descriptions of diseases as well as diagnostic and therapeutic procedures. Pediatricians, family practitioners, nurses and nurse practitioners, and other healthcare providers who work with infants and children will find *CDTP* a useful reference on management aspects of pediatric medicine.

COVERAGE

Forty-six chapters cover a wide range of topics, including neonatal medicine, child development and behavior, emergency and critical care medicine, and diagnosis and treatment of specific disorders according to major problems, etiologies, and organ systems. A wealth of tables and figures provides quick access to important information, such as acute and critical care procedures in the delivery room, the office, the emergency room, and the critical care unit; anti-infective agents; drug dosages; immunization schedules; differential diagnosis; and developmental screening tests. The final chapter is a handy guide to normal laboratory values.

NEW TO THIS EDITION

The 22nd edition of *CDTP* has been revised comprehensively by the editors and contributing authors. New references as well as up-to-date and useful Web sites have been added, permitting the reader to consult original material and to go beyond the confines of the textbook. As editors and practicing pediatricians, we have tried to ensure that each chapter reflects the needs and realities of day-to-day practice.

CHAPTERS WITH MAJOR REVISIONS INCLUDE:

3 Child Development & Behavior

6 Eating Disorders

9 Ambulatory & Office Pediatrics

10 Immunization

13 Poisoning

14 Critical Care

15 Skin

19 Respiratory Tract & Mediastinum

21 Gastrointestinal Tract

22 Liver & Pancreas

25 Neurologic & Muscular Disorders

26 Orthopedics

31 Neoplastic Disease

32 Pain Management & Pediatric Palliative & End-of-Life Care

33 Immunodeficiency

37 Genetics & Dysmorphology

38 Allergic Disorders

39 Antimicrobial Therapy

40 Infections: Viral & Rickettsial

41 Human Immunodeficiency Virus Infection

42 Infections: Bacterial & Spirochetal

43 Infections: Parasitic & Mycotic

CHAPTER REVISIONS

The 22 chapters that have been extensively revised, with new authors added in several cases, reflect the substantially updated material in each of their areas of pediatric medicine. Especially important are updates to the chapters on immunizations, diabetes, and endocrinology. The chapter on HIV includes current guidelines for prevention and treatment of HIV, and updates information on the new antiretroviral therapies that have become available. The chapter on immunizations contains the most recently published recommendations, discusses the contraindications and precautions relevant to special populations, and includes the new vaccines licensed since the last edition of this book. Chapters on Skin, Immunodeficiency, and Neoplastic Disease are markedly updated with the latest information. All laboratory tables in Chapter 46 Pediatric Laboratory Medicine, including Reference Ranges and Reference Intervals, have been updated. All other chapters are substantially revised and references have been updated. Nineteen new authors have contributed to these revisions.

ACKNOWLEDGMENTS

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Advancing the Quality and Safety of Care

1

Daniel Hyman, MD, MMM

While the history of the patient safety movement can be traced back to Hippocrates' famous dictum *primum non nocere* some 2500 years ago, the more modern safety effort was galvanized by the Institute of Medicine's (IOM) 1999 landmark report *To Err Is Human*. The most quoted statistic from this report, that between 44,000 and 98,000 Americans die each year as a result of medical error, was based upon studies of hospital mortality in Colorado, Utah, and New York and extrapolated to an annual estimate for the country. The IOM followed up this report with a second publication, *Crossing the Quality Chasm*, in which they said, *"Health care today harms too frequently, and routinely fails to deliver its potential benefits.... Between the health care we have and the care we could have lies not just a gap, but a chasm."* These two reports have served as central elements in an advocacy movement that has engaged stakeholders across the continuum of our healthcare delivery system and changed the nature of how we think about the quality of care we provide, and receive.

In *Crossing the Quality Chasm,* the IOM included a simple but elegant definition of the word "Quality" as it applies to health care. They defined six domains of healthcare quality: (1) SAFE—free from preventable harm, (2) EFFECTIVE—optimal clinical outcomes; doing what we should do, not what we should not do according to the evidence, (3) EFFICIENT—without waste of resources—human, financial, supplies/equipment, (4) TIMELY—without unnecessary delay, (5) PATIENT/FAMILY CENTERED—according to the wishes and values of patients and their families, (6) EQUITABLE—eliminating disparities in outcomes between patients of different race, gender, and socioeconomic status.

In the years since these two reports were published, the multiple stakeholders concerned about the effectiveness, safety, and cost of health care in the United States, and indeed throughout the world, have accelerated their individual and collective involvement in analyzing and improving care. In the United States, numerous governmental agencies, large employer groups, health insurance plans, consumers/patients, healthcare providers, and delivery systems are among the key constituencies calling for and working toward better and safer care at lower cost. Similar efforts are occurring internationally. Indeed, the concept of the Triple Aim is now being promoted as an organizing framework for considering the country's overall healthcare improvement goals.

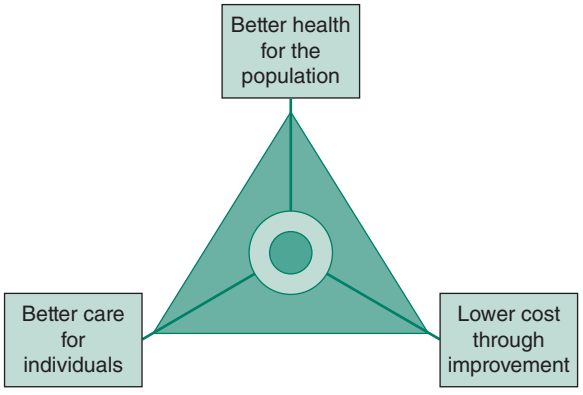
Committee on Quality Health Care in America, Institute of Medicine: *Crossing the Quality Chasm: a New Health System for the 21st Century.* Washington, DC: National Academy Press; 2001.

Kohn L, Corrigan JM: *To Err Is Human: Building a Safer Health System.* Washington, DC: National Academy Press; 2000.

CURRENT CONTEXT

The healthcare industry is in a period of transformation being driven by at least four converging factors: (1) the recognition of serious gaps in the safety and quality of care we provide (and receive), (2) the unsustainable increases in the cost of care as a percent of the national economy, (3) the aging of the population, and (4) the emerging role of healthcare information technology as a potential tool to improve care. These are impacting healthcare organizations as well as individual practitioners in numerous ways that can also be traced to expectations regarding transparency and increasing accountability for results. As depicted in Figure 1–1, the Triple Aim includes the simultaneous goals of better care (outcomes/experience) for individual patients, better health for the population, and lower cost overall. Practitioners and trainees must adapt to a new set of priorities that focus attention on new goals to extend our historic focus on the doctor/patient relationship and autonomous physician decision making. Instead, new imperatives are evidence-based medicine, advancing safety, and reducing unnecessary expense.

The impact of healthcare quality improvement will increasingly influence clinical practice and the delivery of pediatric



▲ **Figure 1–1.** Triple aim. (Adapted from the Center for Medicare and Medicaid Services.)

care in the future. This chapter provides a summary of some of the central elements of healthcare quality improvement and patient safety, and offers resources for the reader to obtain additional information and understanding about these topics.

To understand the external influences driving many of these changes, there are at least six key national organizations central to the transitions occurring.

1. Center for Medicare and Medicaid Services (Department of Health and Human Services)—www.cms.gov
   Center for Medicare and Medicaid Services (CMS) oversees the United States' federally funded healthcare programs including Medicare, Medicaid, and other related programs. CMS and the Veterans Affairs Divisions together now provide funding for more than one trillion of the total $2.6 trillion the United States spends annually on healthcare expense. CMS is increasingly promoting payment mechanisms that withhold payment for the costs of preventable complications of care and giving incentives to providers for achieving better outcomes for their patients, primarily in its Medicare population. The agency has also enabled and advocated for greater transparency of results and makes available on its website comparative measures of performance for its Medicare population. CMS is also increasingly utilizing its standards under which hospitals and other healthcare provider organizations are licensed to provide care as tools to ensure greater compliance with these regulations. It has adopted a list of hospital-acquired conditions (HACs) in 10 categories for which hospitals are no longer reimbursed. This list of HACs includes for 2013: foreign object retained after surgery, air embolism, blood incompatibility, stage III and IV pressure ulcers, falls and trauma, manifestations of poor glycemic control, catheter-associated urinary tract infection, iatrogenic pneumothorax, vascular catheter-associated infection, and surgical site infection or deep vein thrombosis/pulmonary embolism after selected procedures. It is worth noting that CMS is able to generate comparative national data only for its Medicare population because it, unlike Medicaid, is a single federal program with a single financial database. Because the Medicaid program functions as 51 state/federal partnership arrangements, patient experience and costs are captured in 51 separate state-based program databases. This segmentation has limited the development of national measures for pediatric care in both inpatient and ambulatory settings. Similarly, while the reporting of HACs is uniform across the United States for Medicare patients, in the Medicaid population it varies by individual state.
2. National Quality Forum—www.qualityforum.org/Home
   National Quality Forum (NQF) is a private, not-for-profit organization whose members include consumer advocacy groups, healthcare providers, accrediting bodies, employers and other purchasers of care, and research organizations. The NQF's mission is to promote improvement in the quality of American health care primarily through defining priorities for improvement, approving consensus standards and metrics for performance reporting, and through educational efforts. The NQF, for example, has endorsed a list of 29 "serious reportable events" in health care that include events related to surgical or invasive procedures, products or device failures, patient protection, care management, environmental issues, radiologic events, and potential criminal events. This list and the CMS list of HACs are both being used by insurers to reduce payment to hospitals/providers as well as to require reporting to state agencies for public review. In 2011, NQF released a set of 41 measures for the quality of pediatric care, largely representing outpatient preventive services and management of chronic conditions, and population-based measures applicable to health plans, for example immunization rates and frequency of well-child care.
3. Leapfrog—www.leapfroggroup.org
   Leapfrog is a group of large employers who seek to use their purchasing power to influence the healthcare community to achieve big "leaps" in healthcare safety and quality. Leapfrog promotes transparency and issues public reports of how well individual hospitals meet their recommended standards, including computerized physician-order entry, ICU staffing models, and rates of hospital-acquired infections. There is some evidence that meeting these standards is associated with improved hospital quality and/or mortality outcomes.
4. Agency for Healthcare Research and Quality—www.ahrq.gov
   Agency for Healthcare Research and Quality (AHRQ) is one of 12 agencies within the US Department of Health

and Human Services. AHRQ's primary mission has been to support health services research initiatives that seek to improve the quality of health care in the United States. Its activities extend well beyond the support of research and now include the development of measurements of quality and patient safety, reports on disparities in performance, measures of patient safety culture in organizations, and promotion of tools to improve care among others. AHRQ also convenes expert panels to assess national efforts to advance quality and patient safety and to recommend strategies to accelerate progress.

5. Specialty Society Boards
   Specialty Society Boards, for example, American Board of Pediatrics (ABP). The ABP, along with other specialty certification organizations, has responded to the call for greater accountability to consumers by enhancing its maintenance of certification programs (MOC). All trainees, and an increasing proportion of active practitioners, are now subject to the requirements of the MOC program, including participation in quality improvement activities in the diplomate's clinical practice. The Board's mission is focused on assuring the public that certificate holders have been trained according to their standards and also meet continuous evaluation requirements in six areas of core competency: patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and systems-based practice. These are the same competencies as required of residents in training programs as certified by the Accreditation Council on Graduate Medical Education. Providers need not only to be familiar with the principles of quality improvement and patient safety, but also must demonstrate having implemented quality improvement efforts within their practice settings.
6. The Joint Commission—www.jointcommission.org
   The Joint Commission (JC) is a private, nonprofit agency that is licensed to accredit healthcare provider organizations, including hospitals, nursing homes, and other healthcare provider entities in the United States as well as internationally. Its mission is to continuously improve the quality of care through evaluation, education, and enforcement of regulatory standards. Since 2003, JC has annually adopted a set of National Patient Safety Goals designed to help advance the safety of care provided in all healthcare settings. Examples include the use of two patient identifiers to reduce the risk of care being provided to an unintended patient; the use of time-outs and a universal protocol to improve surgical safety and reduce the risk of wrong site procedures; adherence to hand hygiene recommendations to reduce the risk of spreading hospital-acquired infections, to name just a few. These goals often become regulatory standards with time and widespread adoption. Failure to meet these standards can result in actions against the licensure of the healthcare provider, or more commonly, requires corrective action plans, measurement to demonstrate improvement, and resurveying depending upon the severity of findings. The JC publishes a monthly journal on quality and safety, available at http://store.jcrinc.com/the-joint-commission-journal-on-quality-and-patient-safety/.

Finally, advances in quality and safety will be impacted by the provisions of the American Recovery and Reinvestment Act (ARRA) and Patient Protection and Affordable Care Act (PPACA) enacted by the United States government in the past 2 years. These laws and their implications are only beginning to be understood in the United States. The landmark 2010 federal healthcare legislation will provide for near-universal access to health care, and now that the Supreme Court has upheld the law, states are beginning the process of creating healthcare exchanges or deferring to the federal government to do so. It is likely that changes in payment mechanisms for health care will continue irrespective of ARRA/PPACA, and current and future providers' practices will be economically, structurally, and functionally impacted by these emerging trends. Furthermore, changes in the funding and structure of the US healthcare system may ultimately also result in changes in other countries. Many countries have single-payer systems for providing health care to their citizens and often are leaders in defining new strategies for healthcare improvement.

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STRATEGIES AND MODELS FOR QUALITY IMPROVEMENT (QI)

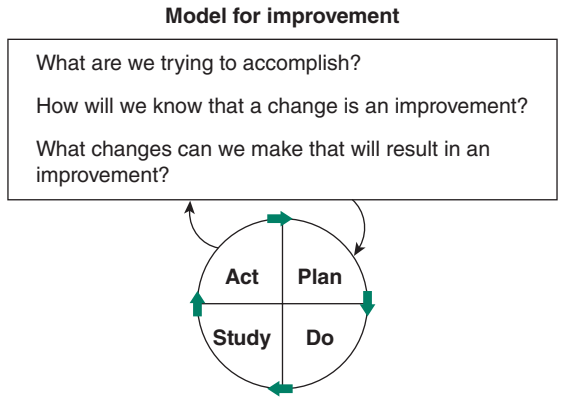
There are a number of commonly employed approaches to improving the quality of care in healthcare settings. This section highlights three representative approaches to conducting clinical improvement work, but they are by no means the only potential strategies that physicians and staff may see or utilize. The Model for Improvement is primarily emphasized because of its ease of adoption, and because it is the foundation for most improvement efforts included in the Maintenance of Certification program of the American Board of Pediatrics. Briefer summaries of Lean and Six-Sigma methods are also included, with listings of resources where the reader can find additional information.

"MODEL FOR IMPROVEMENT"

Widely taught and promoted by the Boston-based educational and advocacy organization the Institute for Healthcare Improvement (IHI), the Model for Improvement (MFI) is grounded in three simple questions that guide the work of the improvement leader and team. The model's framework includes an Aim statement, a measurement strategy, and then the use of "rapid cycle" changes to achieve the aim. The IHI web site, www.ihi.org, has an extensive resource library, and hosts an "Open School" that includes a QI/Patient safety modular curriculum for health professional students and their faculty at www.ihi.org/openschool.

AIM STATEMENT

The Aim statement answers the question, "What do we want to accomplish?" The measure question is "How will we know that a change is an improvement?" and the change component is focused on "What changes can we make that will result in improvement?" This model is represented in Figure 1–2.



▲ **Figure 1–2.** Model for improvement. (Adapted, with permission, from G. Langley, R. Moen, K. Nolan, T. Nolan, C. Norman, L. *Provost: The Improvement Guide: AIM model for Improvement.* San Francisco, CA: Jossey-Bass; 2009:24.)

Aim statements are a *written* description of what the team's improvement goal is, and also include information on who comprises the patient population and a time frame within which the improvement will be achieved. They identify a "stretch" but achievable improvement target goal, and, often, some general statement regarding how the improvement will be achieved. Aim statements are sometimes characterized using the mnemonic SMAART: Specific, Measurable, Achievable, Actionable, Relevant, and Timely. Aim statements should be unambiguous and understandable to the stakeholders, and are most likely to be achieved if they are aligned with the strategic goals of the team or organization.

For example, the following statement meets the criteria for a SMAART aim statement, *"We will reduce the frequency of emergency department visits and hospitalizations for patients with asthma seen at E Street Pediatrics by 25% by December 31, 2013."* Whereas, this next statement does not, *"We will improve the care for patients with asthma by appropriately prescribing indicated medications and better educating families in their use."*

The first example provides a specific measurable goal, a time frame, and clarity with respect to who the patients are. A 25% reduction in ED/inpatient asthma visits will require a change in the system for asthma care delivery for the entire population of children with asthma; that extent of level of improvement is a stretch, but it is much more achievable than a goal would be if it was set to "eliminate" such encounters. The second example is unclear in terms of the measure for improvement, the time frame for the goal to be met, and even the population in question. The statement provides some sense of processes that could be utilized to improve asthma care but is missing needed specificity.

MEASURES

Specific measures provide a means to assess whether or not the improvement effort is on track. Three types of measures are useful. *Outcome measures* answer questions concerning the healthcare impact for the patients, such as how has their health status changed? *Process measures* are related to the healthcare delivery system itself. They answer questions like how is the system performing? *Balancing measures* seek to identify potential unintended consequences that are related to the improvement effort being undertaken. Examples are helpful to contextualize these conceptual definitions.

Continuing with asthma as an example of the improvement effort, and utilizing the first aim statement example, here are some examples of measures that might be employed, and the type of measure each is.

Examples of measures for an asthma improvement project:

1. Proportion of children with an asthma severity assessment in their medical record in the past year (process).
2. Percent of children with asthma in the practice seen in the ED or hospitalized for asthma in the past 6 months (outcome).
3. Average difference in the time between the last office patient's scheduled appointment time and the actual office close time (balancing).
4. Staff satisfaction with their job (balancing).
5. Percent of children with persistent asthma, of any severity, prescribed a controller medication at their most recent visit (process).
6. Percent of children prescribed a controller medication who report taking their medicine (process—this one might seem surprising, but an outcome measures the health status of the patient, not the taking of a medication. One might argue that adherence to a treatment plan is an outcome of the work of the practice/practitioner prescribing the medication. It is more consistent, however, to consider the translation of the treatment plan into action as a part of the process of care, and that the health status or outcome measure will be improved by fully improving the measured processes of care, including patient adherence to the treatment plan.)
7. Percent of children in a practice asthma registry provided with a complete asthma action plan in the past twelve months (process).
8. Percent of children who missed any school days due to asthma in the past 6 months (outcome).

Measures are essential elements of any improvement work. It is a good idea to choose a manageable (4–6) number of measures, all of which can be obtained with limited or no extra effort, and with a mix of outcome, process, and balancing measures. Ideally, the best process measures are those that are directly linked to the outcome goal. The hypothesis in this specific example would be that assessing asthma severity and appropriately using controller medications and action plans would all contribute to reducing the number or frequency of missed school days and the need for ED/hospital utilization.

It is important to note that measurement in the setting of an improvement project is different from measurement in a research study. Improvement projects require "just enough" data to guide the team's continuing efforts. Often the results seen in a sequence of 10 patients is enough to tell you whether a particular system is functioning consistently or not. For example, considering measure example number 1, if in the last 10 patients seen with asthma, only two had their asthma severity documented, how many more charts need be checked to conclude that the system is not functioning as intended and that changes are needed? Other measures may require larger sample sizes, especially when assessing the impact of care changes on a population of patients with a particular condition. See Randolph's excellent summary for a fuller description of measurement for improvement.

CHANGES AND IDEAS

Once the team's aim is established and the measures are selected, the third component of the Model for Improvement focuses on what changes in the system must be made that will result in the targeted improvements. Here, the model draws from the field of industrial engineering and the work of improvement pioneers W. Edwards Deming and Walter Shewhart. To answer the question "What changes will result in improvement?", the improvement team should incorporate "Plan-Do-Study (or check)-Act" cycles, typically referred to as PDSA cycles. The cycles include the following steps.

Plan: What will we do that will likely improve the process measures linked to the outcome target goal? Who will do it? Where? When? How? How will the data be collected?

Do: Implementation of the planned change(s). *TIP!* It is good to make the change cycles as small as possible, for example, trying a new process on the next five patients being seen by one provider as opposed to wide scale implementation of a new chart documentation form across an entire clinic.

Study (or check): Once the small test of change is tried, its results are assessed. How many times did the process work as planned for the five patients included in the cycle?

Act: Based upon the results of the study of the cycle, recommendations are made as to what the next steps ought to be to achieve the goal. At this point, the cycle then resumes and planning begins for the next cycle.

Over the course of an improvement effort, multiple tests of change might be implemented for any or all of the process measures felt to be likely to impact the outcome measures relevant to the project.

The Model for Improvement has been used by improvement teams across numerous healthcare settings around the world. Further information about the model and examples can be found at www.ihi.org/openschool, or in *The Improvement Guide* (Langley et al).

The IHI Open School modules are an excellent online resource for clinicians interested in learning more about the fundamentals of quality improvement and patient safety. These educational lessons are free of charge to health professional students, residents, and university faculty members, and for a modest subscription fee to other clinicians. They are also free to healthcare practitioners in the developing world. An excellent original resource on implementing this model in clinical practice is in Berwick's summary article from 1998.

Berwick D: The science of improvement. JAMA 2008:299(10): 1182–1184.

Langley G, Moen R, Nolan K, Nolan T, Norman C, Provost L: *The Improvement Guide: AIM model for Improvement*. San Francisco, CA: Jossey-Bass; 2009:24.

Randolph G, Esporas M, Provost L, Massie S, Bundy D: Model for Improvement Part Two: *Measurement and Feedback for Quality Improvement Efforts*. Ped Clin N Am 2009;56(4): 779–798; Developing and Testing Changes in Delivery of Care Berwick, Donald M. MD, MPP. This paper is also available at http://www.acponline.org. Ann Intern Med 1998;128:651–656.

"LEAN"

Also grounded in industrial engineering, an increasingly popular method for driving improvement efforts in healthcare settings is "Lean" or "Lean processing." Early thinking about Lean processes is credited to the Toyota Manufacturing Company in Japan. The crossover to health care from manufacturing is a relatively recent phenomenon, but numerous hospitals and healthcare delivery settings, including individual clinics, have benefited from the application of these principles to their clinical operations. Lean improvement methods focus on reducing errors and variability in repetitive steps that are part of any process. In health care, examples of repeated processes would include how patients are registered and their information obtained; how medications are ordered, compounded, distributed, and administered; how consent forms are accurately completed in a timely manner prior to surgical procedures; and how antibiotics are reliably and efficiently delivered prior to surgical procedures.

Lean is a philosophy of continuous improvement. It is grounded in recognizing that the way we do things today is merely "current state." With time, effort, focus, and long-term thinking, we can create a "future state" that is better than the status quo. It does so by focusing on identifying the value of all steps in any process and eliminating those steps that do not contribute to the value sought by the customer, or in health care, the patient/family. In doing so, improvements in outcomes, including cost and productivity, and in clinical measures of effectiveness can be realized. See Young for an early critical assessment of the incorporation of Lean into healthcare settings.

There are four categories that describe the essential elements of Toyota's adoption of "Lean" as a management strategy. These four categories are: (1) *philosophy* (emphasize long-term thinking over short-term gain); (2) *process* (eliminate waste through very defined approaches including an emphasis on process flow and the use of pull systems to reduce overproduction, for example); (3) *people/partners* (respect, challenge, and grow staff); and (4) *problem solving* (create a culture of continuous learning and improvement).

There are a number of hospitals that have fully integrated Lean management as a primary basis for its organizational approach to improvement. Several were featured in a "White Paper" published by the Institute for Healthcare Improvement in 2005.

Going Lean in Health Care, Innovation Series White Paper. Institute for Healthcare Improvement; 2005. http://www.ihi.org/knowledge/Pages/IHIWhitePapers/GoingLeaninHealthCare.aspx.

Liker: *The Toyota Way*. Madison, WI: McGraw-Hill; 2004.

Young TP, McClean SI: A critical look at Lean Thinking in health care. BMJ Quality and Safety Health Care 2008;17:382–386.

"SIX SIGMA"

A third quality-improvement methodology also arose in the manufacturing industry. Motorola is generally credited with promoting Six Sigma as a management strategy designed to reduce the variability in its processes and thereby reducing the number of defects in its outputs. Organizations adopting Six Sigma as an improvement strategy utilize measurement-based strategies that focus on process improvement and variation reduction to eliminate defects in their work and to reduce cycle times, thereby increasing profitability and enhancing customer satisfaction. Sigma is the statistical measure of standard deviation and Motorola adopted Six Sigma as a performance indicator, promoting consistency of processes in order to have fewer than 3.4 defects per million opportunities. This performance goal has since become the common descriptor for this approach to improvement both in manufacturing and in service industries, including health care. Similar to Lean, the translation of business manufacturing strategies into health care has various challenges, but there are many processes that repeatedly occur in health care that can be routinized and made more consistent. Many healthcare processes fail far more frequently than 3.4 times per million opportunities. Consider pharmacy dispensing errors, medication ordering or administration errors, and patient-scheduling errors,

just to name a few. These are a few of many examples of processes that could potentially benefit from the kind of rigorous analysis that is integral to the Six-Sigma approach.

In a typical Six-Sigma structured improvement project, there are five phases generally referred to as DMAIC: (1) Define (what is the problem, what is the goal?), (2) Measure (quantify the problem and improvement opportunity), (3) Analyze (use of observations and data to identify causes), (4) Improve (implementation of solutions based on data analysis), and finally, (5) Control (sustainable change).

One of the central aspects of Six Sigma as an improvement strategy is its defined focus on understanding the reasons for defects in any process. By understanding these drivers, it is then possible to revise the approach to either the manufacturing process or the service functions in order to reduce these errors and failures.

"Lean-Six Sigma" is a newer entity that draws from both methodologies in order to simplify the improvement work where possible, but retain the rigorous statistical method that is a hallmark of Six-Sigma projects. Lean focuses on where time is lost in any process and can identify opportunities to eliminate steps or reduce time. Six Sigma aims to reduce or eliminate defects in the process, thereby resulting in a higher-quality product through a more efficient and lower cost process.

Regardless of the method used, improvement happens because an organization, team, or individual sets a goal to improve a current process through systematic analysis of the way things are done now, and then implementing planned changes to see how they impact the outputs or outcomes.

For additional information on Lean and Six Sigma, see www.isixsigma.com or www.asq.org/sixsigma.

Pande P, Holpp L: *What is Six Sigma?* New York, NY: McGraw-Hill; 2002.

PRINCIPLES OF PATIENT SAFETY (INCIDENT REPORTING, JUST CULTURE, DISCLOSURE, FMEA, RCA, RELIABILITY, CHECKLISTS)

Safe patient care avoids preventable harm; it is care that does not cause harm as it seeks to cure. The list of adverse events that are considered to be preventable is evolving. As mentioned earlier, both CMS and NQF have endorsed lists of various complications of care as being "never events" or "serious reportable events" for which providers are often now not reimbursed, and which are increasingly reportable to the public through various state transparency programs.

Irrespective of one's views about whether various complications are entirely preventable at the current state of science or not, these approaches reflect a changing paradigm that is impacting many aspects of healthcare delivery. Transparency of results is increasingly expected. Perspectives and data on how these kinds of efforts are impacting actual improvement in outcomes are mixed.

Given these trends, healthcare providers need to have robust systems for measuring and improving the safety of care provided to patients. The methods for improving quality reviewed above are frequently used to reduce harm, just as they can be used to improve effectiveness or efficiency. For example, hospitals attempting to reduce infections have successfully used these types of process improvement approaches to improve antibiotic use prior to surgical procedures or to improve hand hygiene practices.

Common patient safety tools are summarized here.

Incident-reporting systems: Efforts to advance safety in any organization require a clear understanding of the kinds of harm occurring within that organization, as well as the kinds of "near-misses" that are occurring. These reporting systems can range from a simple paper reporting form to a "telephone hot-line" to a computerized database that is available to staff (and potentially patients) within the organization. Events are traditionally graded according to the severity of harm that resulted from the incident. One example is the NCC MERP Index, which grades events from A (potential to cause harm) to I (resulting in patient death). Errors that are recognized represent only a fraction of the actual errors and near-misses that are present in the system. Incident-reporting systems depend upon people recognizing the error or near-miss, being comfortable reporting it, knowing how and when to report, and then actually doing so. It is no surprise therefore that estimates for how frequently incidents that could or should be reported into incident-reporting systems range from 1.5% to 30% depending on the type of adverse or near-miss event. "Trigger tools" (either manual chart reviews for indications of adverse events, or automated reports from electronic medical records) are increasingly being used to increase the recognition of episodes of harm in healthcare settings.

"Just culture": The effectiveness of incident-reporting systems is highly dependent upon the culture of the organization within which the reporting is occurring. Aviation industry safety-reporting systems are often highlighted for their successes over the past few decades in promoting reporting of aviation events that might have led to accidents. The Aviation Safety Reporting System (ASRS) prioritizes confidentiality in order to encourage reporting and protects reporters from punishment, with certain limitations when they report incidents, even if related to nonadherence to aviation regulations. Although the system is voluntary, more than 880,000 reports have been submitted and used by the Federal Aviation Administration to improve air travel safety.

In health care, the variable recognition of adverse events as well as any fear about reprisal for reporting events both work to reduce the consistent reporting of events. The concept of "just culture" has been promoted as a strategy to increase the comfort of staff members to report the occurrence of errors

or near-misses, even if they may have done something incorrectly. See the work of David Marx and the "Just Culture Community" for more information on how to evaluate error so as to support reporting and safer practices in organizations. A great deal more information about "just culture" principles is available at http://www.justculture.org.

Failure modes and effects analyses (FMEA): An FMEA is a systematic methodology used to proactively identify ways in which any process might fail, and then to prioritize among strategies for reducing the risk or impact of identified potential failures. In conducting an FMEA, which all hospitals are required to do annually, a team will carefully describe and analyze each step in a particular process, consider what and how anything might go wrong, why it would happen and what the impact would be of such failures. Like Lean and Six Sigma, the FMEA has been adopted into health care from its origins in military and industrial settings. The FMEA is an effective method for identifying strategies to reduce risks in healthcare settings, thereby protecting patients if interventions are put into place as a result of the analysis. A tool to use in conducting an FMEA is available from the IHI (http://www.ihi.org/knowledge/Pages/Tools/FailureModesandEffectsAnalysisTool.aspx). Their site includes additional information and resources about the FMEA process.

Root-cause analyses (RCA) (post-event reviews): As contrasted with the proactive FMEA process, an RCA is a retrospective analysis of an adverse occurrence (or near-miss) that has already happened. It too is a systematic process that in this case allows a team to reach an understanding of why certain things occurred, what systems factors and human factors contributed to the occurrence, and what defects in the system might be changed in order to reduce the likelihood of recurrence. Key to an effective RCA process, and similar to the principles discussed above related to "just culture," RCAs are designed not to ask who was at fault, but rather what system reasons contributed to the event. "Why," not "who," is the essential question to be asked. The answer to the question "why did this occur" almost invariably results in a combination of factors, often illustrated by a series of pieces of Swiss cheese where the holes all line up. Taken from the writings of James Reason, the "Swiss Cheese Model" illustrates the many possible system failures that can contribute to an error, and contributes to identifying potential system changes that reduce the risk of error recurrence. Strategies for approaching retrospective RCA are available at http://www.ncbi.nlm.nih.gov/pmc/articles/pmc1117770.

Communication and team training: Because failures of communication are the most common identified factors in the analysis of reported serious healthcare events, many healthcare organizations have incorporated tools from other industries, particularly aviation, in order to enhance patient safety. As a result of the knowledge gained through analysis of tragic aviation accidents, the airline industry implemented methods like crew resource management training to ensure that communication among cockpit team members is effective and clear, thereby reducing risk of air accidents. Similar methods have been used to train teams in operating rooms, delivery rooms, and other team-based settings. Most of these curricula include a few common elements: introductions to be sure all team members know one another's name, promoting the likelihood of speaking up; leader clarity with team members about the expectation that all will speak up if anyone has a concern; and structured language and other tools like verbal read-back of critical information to ensure clarity in interpersonal or interdisciplinary communications. Such training also seeks to flatten the hierarchy, making it more likely that potential risks or problems will be identified and effectively addressed. Common tools used in promoting effective team communication include structured language like SBAR (Situation, Background, Assessment, and Recommendation), taken from the navy, to promote clarity of communication.

A number of resources exist in the public domain to support better teamwork and communication. One good place to start is the TeamSTEPPS program from the Agency for Healthcare Research and Quality. It can be found at http://teamstepps.ahrq.gov/.

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The Newborn Infant

2

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The newborn period is defined as the first 28 days of life. In practice, however, sick or very immature infants may require neonatal care for many months. There are three levels of newborn care. Level 1 refers to basic care of well newborns of 35 weeks' gestation or more, neonatal resuscitation, and stabilization prior to transport. Level 2 refers to specialty neonatal care of premature infants greater than 1500 g or more than 32 weeks' gestation. Level 3 is subspecialty care of higher complexity ranging from 3A to 3D based on newborn size and gestational age, availability of medical subspecialties, advanced imaging, pediatric ophthalmology, pediatric general surgery, cardiac surgery, and extracorporeal membrane oxygenation. Level 3 care is often part of a perinatal center offering critical care and transport to the high-risk mother and fetus as well as the newborn infant. A level 4 center has additional capabilities to care for complex surgical conditions including cardiac surgery with bypass.

THE NEONATAL HISTORY

The newborn medical history has three key components:

1. Maternal and paternal medical and genetic history
2. Maternal past obstetric history
3. Current antepartum and intrapartum obstetric history

The mother's medical history includes chronic medical conditions, medications taken during pregnancy, unusual dietary habits, smoking history, occupational exposure to chemicals or infections of potential risk to the fetus, and any social history that might increase the risk for parenting problems and child abuse. Family illnesses and a history of congenital anomalies with genetic implications should be sought. The past obstetric history includes maternal age, gravidity, parity, blood type, and pregnancy outcomes. The current obstetric history includes the results of procedures during the current pregnancy such as ultrasound, amniocentesis, screening tests (rubella antibody, hepatitis B surface antigen, serum quadruple screen in the second trimester or first trimester ultrasound screening for nuchal translucency coupled with measurement in maternal serum of human chorionic gonadotropin and pregnancy-associated plasma protein A to screen for genetic disorders, HIV [human immunodeficiency virus]), and antepartum tests of fetal well-being (eg, biophysical profiles, nonstress tests, or Doppler assessment of fetal blood flow patterns). Pregnancy-related maternal complications such as urinary tract infection, pregnancy-induced hypertension, eclampsia, gestational diabetes, vaginal bleeding, and preterm labor should be documented. Significant peripartum events include duration of ruptured membranes, maternal fever, fetal distress, meconium-stained amniotic fluid, type of delivery (vaginal or cesarean section), anesthesia and analgesia used, reason for operative or forceps delivery, infant status at birth, resuscitative measures, and Apgar scores.

ASSESSMENT OF GROWTH & GESTATIONAL AGE

It is important to know the infant's gestational age because normal behavior and possible medical problems can be predicted on this basis. The date of the last menstrual period is the best indicator of gestational age, if known, and if menses were regular. Fetal ultrasound provides supporting information. Postnatal physical characteristics and neurologic development are also clues to gestational age. Table 2–1 lists the physical and neurologic criteria of maturity used to estimate gestational age by the Ballard method. Adding the scores assigned to each neonatal physical and neuromuscular sign yields a score corresponding to gestational age.

Disappearance of the anterior vascular capsule of the lens is also helpful in determining gestational age. Until 27–28 weeks' gestation, the lens capsule is covered by vessels; by 34 weeks, this vascular plexus is completely atrophied. Foot length, from the heel to the tip of the longest toe, also correlates with gestational age in appropriately grown infants. The foot measures 4.5 cm at 25 weeks' gestation and increases 0.25 cm/wk until term.

If the physical examination indicates a gestational age within 2 weeks of that predicted by the obstetric dates, the gestational age is as assigned by the obstetric dating. Birth weight and gestational age are plotted on standard grids (Figure 2–1) to determine whether the birth weight is