TAHOE FOREST HOSPITAL DISTRICT

Board Quality Committee

Aug 20, 2015 at 12:00 PM - 01:30 PM

Eskridge Conference Room

Meeting Book - 2015 Aug 20 Board Quality Committee

AGENDA

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5. APPROVAL OF MINUTES

a) 06/09/2015 Quality Committee_DRAFT Minutes Page 5

6. ITEMS FOR COMMITTEE DISCUSSION AND/OR RECOMMENDATION

6.1. Quality Committee Goals 2015 Page 8

6.2. Patient & Family Centered Care (PFCC)

6.2.1. Patient & Family Advisory Council Update
* No related materials

6.3. TFHS Web Site Quality Information Update
* No related materials
visit website at:
http://www.tfhd.com/quality-staging081015.asp

6.4. Lean Training Program

a) Lean Overview2015 Page 9

b) IHI Comparing Lean and QI White Paper 2014 Page 24

6.5. Board Quality Education

6.5.1. Patient Safety/Medication Error Reduction Program Survey

a) GACHRLS-Entrance-List Page 54

b) GACHRLS-MERP-Entrance-List Page 56

6.5.2. National Quality Forum (2015) - Performance Measurement for Rural Low-Volume Providers.

a) Rural_draft_report_for_comment060115 Page 57

b) Rural_health_presentation_slides_07292015 Page 98

7. INFORMATIONAL REPORTS/MATERIALS

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TAHOE FOREST HEALTH SYSTEM

QUALITY COMMITTEE AGENDA

Thursday, August 20, 2015 at 12:00 p.m.
Eskridge Lobby Conference Room, Tahoe Forest Hospital
10121 Pine Avenue, Truckee, CA

1. **CALL TO ORDER**

2. **ROLL CALL**
   Greg Jellinek, M.D., Chair; John Mohun, Board Member

3. **CLEAR THE AGENDA/ITEMS NOT ON THE POSTED AGENDA**

4. **INPUT – AUDIENCE**
   This is an opportunity for members of the public to address the Committee on items which are not on the agenda. Please state your name for the record. Comments are limited to three minutes. Written comments should be submitted to the Board Clerk 24 hours prior to the meeting to allow for distribution. Under Government Code Section 54954.2 – Brown Act, the Committee cannot take action on any item not on the agenda. The Committee may choose to acknowledge the comment or, where appropriate, briefly answer a question, refer the matter to staff, or set the item for discussion at a future meeting.

5. **APPROVAL OF MINUTES OF: 6/9/2015** ..... ATTACHMENT

6. **ITEMS FOR COMMITTEE DISCUSSION AND/OR RECOMMENDATION**

6.1. **Quality Committee Goals 2015** ..... ATTACHMENT
Committee will review and provide updates related to 2015 committee goals.

6.2. **Patient & Family Centered Care (PFCC)**

6.2.1. **Patient & Family Advisory Council Update**
An update will be provided related to the activities of the Patient and Family Advisory Council (PFAC).

6.3. **TFHS Web Site Quality Information Update**
Committee will review and provide input related to the Tahoe Forest Health System web site quality information.

6.4. **Lean Training Program** ..... ATTACHMENT
An update will be provided about the Lean training program that TFHD staff has been participating in. This has been funded through a grant from the National Rural Health Resource Center and the CHA Flex Grant.

6.5. **Board Quality Education** ..... ATTACHMENT
The committee will review and discuss topics for future Board quality education.

6.5.1. **Patient Safety/Medication Error Reduction Program Survey**
The Committee will be provided education related to the General Acute Care Hospital (GACH) Relicensing Survey which incorporates elements of the former stand-alone Medication Error Reduction Plan (MERP) survey and Patient Safety Licensing Survey (PSLS).

6.5.2. **National Quality Forum (2015) - Performance Measurement for Rural Low-Volume Providers.**
A Department of Health and Human Services report for review to discuss key learning points for our organization.

7. **INFORMATIONAL REPORTS/MATERIALS**
7.1. Quality Committee Charter..... ATTACHMENT

8. **REVIEW FOLLOW UP ITEMS / BOARD MEETING RECOMMENDATIONS**

9. **NEXT MEETING DATE**
The date and time of the next committee meeting will be proposed and/or confirmed.

10. **ADJOURN**

*Denotes material (or a portion thereof) may be distributed later.

Note: It is the policy of Tahoe Forest Hospital District to not discriminate in admissions, provisions of services, hiring, training and employment practices on the basis of color, national origin, sex, religion, age or disability including AIDS and related conditions.

Equal Opportunity Employer. The meeting location is accessible to people with disabilities. Every reasonable effort will be made to accommodate participation of the disabled in all of the District's public meetings. If particular accommodations for the disabled are needed (i.e., disability-related aids or other services), please contact the Executive Assistant at 582-3481 at least 24 hours in advance of the meeting.

TAHOE FOREST HEALTH SYSTEM

QUALITY COMMITTEE
DRAFT MINUTES

Tuesday, June 9, 2015 at 12:00 p.m.
Eskridge Lobby Conference Room, Tahoe Forest Hospital
10121 Pine Avenue, Truckee, CA

1. **CALL TO ORDER**
Meeting called to order at 12:04 p.m.

2. **ROLL CALL**
Board: Greg Jellinek, M.D., Chair; John Mohun, Board Member

Staff: Jake Dorst, Interim CEO; Judy Newland, CNO/COO; Janet Van Gelder, Director of Quality; Dr. Peter Taylor; Dr. Shawni Coll; Dr. Jay Foley; Paige Thomason, Director of Marketing; John Rust, Director of Emergency Service; and Patricia Barrett, Clerk of the Board

3. **CLEAR THE AGENDA/ITEMS NOT ON THE POSTED AGENDA**

4. **INPUT – AUDIENCE**
None.

5. **APPROVAL OF MINUTES OF: 4/14/2015**

ACTION: Motion made by Director Mohun, seconded by Director Jellinek, to approve minutes of April 14, 2015. Approved unanimously.

6. **ITEMS FOR COMMITTEE DISCUSSION AND/OR RECOMMENDATION**

6.1. **Quality Committee Goals 2015**

Discussion took place related to how the Quality Committee goals tie to the triple aim and ACO value base system changes.

The Quality goal pertaining to service lines and how it relates to finance was discussed. A recommendation was made to have the goal state that "in collaboration with the Finance Committee, the Quality Committee will review [a minimum number of] service line opportunities to evaluate cost of care, quality, and satisfaction, to assure value based care."

Discussion took place related to outmigration and whether a related goal would be appropriate for the Quality Committee to adopt. Following discussion it was agreed that the issue of outmigration will be brought to the Board for determination as to which committee if any should take lead on assessing the issue.

Committee Recommendation: Committee recommends board approval of the Quality Committee 2015 Goals.

6.2. **TFHS Quality Strategic Plan Goals**

Director of Quality reviewed the quality focused strategic plan goals. It was noted that the strategic plan that is in place will remain and be sustained until a new CEO is in place to lead a review.

6.3. **Medical Staff Strategic Plan Update**

Dr. Shawni Coll provided a review of the medical staff goals noting that the Patient service and quality goal tie to the Districts' strategic goal.

6.4. **TFHS Web Site Quality Information**

Topic moved to top of agenda following 6.5

Paige Thomason, Director of Marketing, provided an overview of the TFHD website quality components.

The website has not been updated recently and will be updated in the next week or so. It was noted that the HCAPs reflect most recent data available and a suggestion was made to make reference to it being the most updated data to clarify the delay in available data.

The CNO provided background related to the Committee's decision to provide more detail by providing graphs rather than hyperlink to the data sources only. A recommendation was made to include the hyperlink should a member of the public wish to obtain additional information.

Discussion took place related to the infection rates which reflect a 2012 date. Moving forward the data will be updated annually after the data is reviewed through the Committee.

Discussion took place related to what quality measures should be shared and it was agreed that only items that are statistically significant should be shared.

Dr. Coll recommends greater promotion of 5 star rating and other such recognitions. A recommendation was made to add additional text to the website and to include a link for more information.

Discussion took place related to website activity/click-throughs and a recommendation to have staff review how people are utilizing the site to determine what data and form of presentation are working.

Director Jellinek recommends reaching out to division leaders to help identify what type of data should be included on the website; noting it should tie to core measures at a minimum.

6.5. **Patient & Family Centered Care (PFCC)**

6.5.1. **Patient & Family Advisory Council Update**

Topic moved to the top of the agenda.

Patient Advocate, Trish Foley, provided an update related to the Patient and Family Advisory Council.

The Council meets on a monthly basis and two meetings have taken place thus far. The council is made up of four active members (1 male and three females of approximately the same age) and two additional members are receiving training. The council is currently looking for additional members and opportunities to provide greater diversity are being considered.

Director Mohun inquired as to whether the implementation of the PFAC had an impact in obtaining or retaining the CMS 5-star rating. It was noted that the award was based on data in place prior to the program and the program will assist with retaining the rating.

Director Jellinek inquired about what demographics should be considered for participation on the council. The panel interviews each candidate.

Community input:
Ronda Brooks inquired as to whether the council involves former patients or family members.

Discussion took place related to the criteria outlined for the program participation.

6.6. **Lean Training Program**
Director of Quality provided an update related to recent webinar Lean training participated in by 20-30 staff members. An all-day in-person training occurred on May 15th with Dr. Bilson and a half day training for directors is being pursued.

6.7. **Board Quality Education**
Director of Quality reported that Horty Springer conducted a one hour education webinar last week and the Board was provided information and invited to participate. The webinar reviewed 10 items related to physician specialty organizations. The takeaway from the webinar is that TFH is doing a pretty good job.

Discussion took place related to medical staff discussions pertaining to volumes.

Director Mohun recommended the committee read a 2014 article related to alignment of physicians and will provide details to the Director of Quality.

7. **REVIEW FOLLOW UP ITEMS / BOARD MEETING RECOMMENDATIONS**
Outmigration review
Goal Approval

8. **NEXT MEETING DATE**
The date and time of the next committee meeting will be proposed and/or confirmed.

9. **ADJOURN**
Meeting adjourned at 1:35 p.m.

Board Quality Committee Goals 2015

1. Provide appropriate resources to assist the Patient & Family Advisory Council (PFAC) improvement initiatives.

2. Monitor quality and patient safety metrics and support processes, with a focus on outliers, to achieve top decile performance.

3. Provide direction on the Quality and Service elements of the Health System strategic plan and the Quality Assurance/Performance Improvement (QA/PI) Plan.

4. Share quality and service metrics with the community through multi-media venues (i.e., web site, public speaking, social media, quarterly magazine, newspaper articles, etc.).

5. Utilize Just Culture principles when notified of sentinel/adverse events, including the disclosure of medical errors, and when patients share their experience.

6. Request that the Quality Department evaluate Patient Satisfaction survey vendors and determine if a change in vendor is warranted.

7. Prepare for Critical Access Hospital's participation in CMS Hospital Value-Based Purchasing program through the monitoring of Clinical Process of Care, Patient Experience, and Outcome measures.

Lean Healthcare SHIP Lean Training and Mini- Project

RE-THINKING HEALTHCARE
IMPROVING PATIENT CARE THROUGH DESIGN

Introduction to Lean Thinking

Healthcare in America

As a percentage of its gross domestic product (GDP), the U.S. spends more on healthcare than any nation in the world. According to a 2012 report from the Organization for Economic Cooperation and Development (OECD), the U.S. annually spends 17.6% of its GDP providing healthcare services. This compares with 12% for the Netherlands, the country with the second largest annual spend on healthcare services as a percentage of GDP, and an average of just 9.5% of GDP for other OECD countries.

At the same time, the rising cost of healthcare has not directly resulted in better patient care or improved patient outcomes. According to the same OECD report data, while average life expectancy in the U.S. has increased by almost nine years since 1960, the current U.S. average of 78.7 years is a full year below the OECD country average of 79.8 years. Further, according to a landmark study conducted by the Institute of Medicine, preventable medical errors are estimated to result in as many as 98,000 patient deaths each year, with a projected annual cost as high as $29 billion.

Medical mistakes are believed to be one of the leading causes of death in the U.S., on a par with automobile accidents, breast cancer and AIDS. In this context, healthcare institutions and professionals are exploring innovative approaches and methods that reduce preventable medical errors, improve patient care and safety and decrease healthcare costs. Increasingly, healthcare institutions are implementing lean operational principles and practices pioneered at Toyota and other industrial companies in the 1990s. By applying lean methodologies to existing systems and procedures, healthcare institutions are achieving significant improvements in patient safety while also reducing costs.

Issues and Challenges in Healthcare Today

No other industry places as high a premium on quality of service as healthcare. Leading companies in other industries often boast that their service quality differentiates them from competitors. But only in healthcare does quality of service have a direct impact on the health and safety of those served. Indeed, service quality that does not meet the minimum required standards of healthcare providers can mean the difference between life and death.

Given the essential requirement of quality of care in the healthcare industry, one would reasonably expect healthcare providers to lead the way in initiating and maintaining effective quality management systems. In fact, healthcare industry leaders have worked for decades to improve patient care through a myriad of quality programs. Unfortunately, many of these quality improvement efforts have fallen short of expectations.

One measure of this shortfall is the human and financial cost from deaths and illnesses attributable to medical errors. According to one study, approximately 200,000 Americans die each year from preventable medical errors and facility-acquired illnesses, at a direct cost of nearly $20 billion. In addition, the broader economic impact from medical errors may well approach $1 trillion annually when lost economic productivity due to death or illness is calculated.

The healthcare environment is also increasingly unsafe not just for patients but for healthcare workers as well. In 2011, one of out every 20 full-time U.S. healthcare workers experienced a nonfatal injury or illness, an incident rate second only to workers in agriculture, forestry, fishing and hunting occupations.

During that year, healthcare workers reported more than 631,000 incidents of injuries or illnesses in connection with their work. One estimate puts the cost of worker injuries and illnesses in the healthcare workplace at over $10 billion annually.

These and other statistics clearly illustrate the human and financial consequences when healthcare institutions fail to consistently deliver the highest possible quality of care to patients. They also highlight some of the inherent limits in healthcare's traditional approach to quality improvement. These limits include: a reliance on a host of individual projects, rather than a coordinated system-wide approach to quality improvement; a quality strategy formulated and handed down from senior management without input from the employees responsible for service delivery; and the failure to properly align an institution's approach to quality improvement with its mission and strategy.

The American healthcare industry is currently undergoing an unprecedented transformation, as healthcare providers are actively engaged in efforts to bring their practices into compliance with the requirements of the 2011 Patient Care and Affordable Care Act. As a result, healthcare providers are under pressure to increase access and reduce costs while improving the quality of patient care.

Successfully overcoming the limitations of legacy quality programs while also addressing today's challenges requires new approaches to quality improvement, approaches that can directly lead to better quality of care through improved work flow and increased operating efficiencies.

The Origins of Lean Principles

Modern quality management programs are rooted in pioneering research conducted more than 100 years ago by Americans Frederick Winslow Taylor and Walter Shewhart. Taylor focused on studying existing workflow processes, experimenting with alternative processes that removed unnecessary or inefficient activities and adopting those processes that resulted in consistent production quality and improved worker productivity. Shewhart was the first to implement statistical process control, a quality control method in which data are regularly analyzed in order to identify anomalous production patterns.

Many of the efficiency assessment methods championed by Taylor and implemented by automotive icon Henry Ford in the U.S. were studied by manufacturers in other countries, including Sakichi Toyoda, a Japanese entrepreneur and textile manufacturer. Toyoda's efficiency investigations were later applied by his son, Kiichiro Toyoda, the founder of Toyota Motor Corporation, initially in the 1930s and especially in the late 1940s and 1950s. Around the same time, Edwards Deming, an advocate of Shewhart's quality control theories, was invited to Japan by the Japanese Union of Scientists and Engineers to train engineers and managers on statistical process control methods.

Deming later worked with a number of Japanese corporations and lectured extensively in Japan, resulting in the widespread application of these principles. At Toyota, it is Taiichi Ohno who is widely credited with developing the Toyota Production System (TPS) in the 1950s and 1960s. Based largely on Shewhart's and Deming's production efficiency principles, the TPS is a comprehensive, systemic approach to manufacturing that reduces or eliminates waste and production inconsistencies to maintain or increase value to customers.

The TPS also embraces a number of underlying principles, including the value of organizational learning as a tool for fostering continuous improvement. The principles and practices collectively known as lean production (or lean, for short) are largely derived from the philosophy and approach embodied in the TPS.

The promise of more efficient production with reduced overhead costs has spurred interest in lean principles for more than 20 years, and lean thinking has been successfully adopted and adapted by a wide range of international corporations at facilities worldwide. Increasingly, lean principles and practices are being applied in non-production environments as diverse as software development and education. More recently, efforts to introduce lean principles in healthcare have gained considerable traction, as healthcare institutions and providers seek initiatives that move beyond the limits of traditional production efficiency or quality improvement programs. Indeed, lean initiatives in healthcare

offer the potential to achieve quality of care objectives, improve patient and worker safety, speed delivery of medical services, and lower costs.

Lean in Practice

At its core, the lean approach focuses on customer value by improving processes to reduce waste and eliminate inefficiencies. Regardless of the specific setting in which a lean thinking is espoused, the application of lean is based on the following five defining principles:

1. **Specify value** — Define value from a customer's perspective. Learn what a customer values, and how their experience could be improved to support the best outcome.

2. **Identify value stream** — Evaluate how all the steps of a process or procedure should be organized to deliver a seamless customer experience; eliminate any steps that do not directly contribute to achieving that goal.

3. **Flow without interruptions** — Whenever possible, eliminate waste between steps of a process so that a product or service is delivered as efficiently as possible.

4. **Customer "pulls" services** — Allow the customer to receive or request products or services if and when needed; do not push a product or service that a customer is not ready to receive.

5. **Pursue perfection** — Continuously adapt to an ever-changing environment and customer needs in order to deliver a product or service of the highest possible quality.

The application of lean principles depends on an organization's commitment to continuously improving the value provided to a customer. In practice, a lean improvement system uses science-based problem-solving methods to identify root cause issues, and applies improvement tools to create new standard procedures that reduce waste and improve quality. The effectiveness of new procedures is monitored to assess results and changes are incorporated to further improve the process.

The most successful lean initiatives are: implemented by front-line employees, supported by organization leaders, are coached by staff Lean experts; and are consistent with an organization's mission and strategy. They are systematic, not project driven and are not a reaction to a specific condition or event. Taking this approach, the application of lean principles contributes to the creation of an organizational culture in which continuous improvement is the rule and not the exception.

An essential element of an effective, lean-driven culture is lean leadership. Lean leadership is the commitment of an organization's leaders to empower its employees to continuously identify and implement changes that will improve customer value. In the most successful examples, lean leadership starts at the highest levels of an organization and requires a willingness to ask questions rather than provide answers so that others can develop and implement effective and lasting changes based on their direct experience.

Lean leadership also requires an ongoing commitment to training and development so that all employees have the knowledge and the skills necessary to identify root cause issues and to implement changes that improve value. Finally, lean leaders must make sure that the mission and values of their organizations are aligned with the goal of increasing customer value through continuous improvement.

Lean principles and practices are being successfully applied in daily processes used by healthcare leadership and staff at a number of healthcare institutions. In one rural hospital, for example, lean principles have been applied as part of an effort to eliminate medication errors. The hospital estimated that nearly one-third of pharmacy staff time was spent resolving problems related to incomplete, unclear or illegible medication orders, placing patients at risk and costing approximately $155,000 per year just to clarify problem medication orders.

In this instance, the application of lean principles resulted in process changes to post-operative and medicine unit orders. These changes have reduced the average amount of time required to process a medication order to less than five minutes. More important, the changes have dramatically reduced the number of medication orders placed on hold for further clarification, from 2% of all orders to just 0.02%.

Problems with post-operative medication orders have dropped from 34% to 10%, thereby decreasing the amount of time patients wait to receive medication following surgery. And the percentage of unclear post-operative medication orders has been reduced by 42%. These improvements have also resulted in a reduction in the time hospital pharmacists spend resolving problems with medication orders, allowing them to focus more time on value-added activities.

A Business Case for Lean in Healthcare

The application of lean principles and practices in healthcare settings can dramatically improve the delivery of patient services and the quality of patient care. But lean initiatives in healthcare can also provide important business advantages for healthcare institutions, including the following benefits:

- Improved patient outcomes — Lean initiatives can increase value for patients by providing better healthcare services that more effectively treat medical conditions and reduce rates of recurrence. Such results can prevent unnecessary readmissions and the associated added costs or reduced reimbursement rates.

- Increased patient satisfaction — Patients are becoming more knowledgeable consumers of healthcare services. Satisfied patients are more likely to remain with healthcare providers who provide quality services in a timely manner and are less likely to change healthcare providers.
- Reduced operating costs — Lean initiatives typically result in greater operating efficiencies that lead to reduced staffing and facilities requirements. Employees can be deployed to perform more value-added functions and facilities can be redesigned to offer new or expanded services.
- Stronger financial performance — By increasing productivity and reducing costs, healthcare institutions can achieve stronger financial results, thereby building a more solid financial base and providing financial resources for further investment.
- Greater employee engagement — Lean initiatives depend on empowering employees to increase patient value. Empowered employees are more engaged, and are likely to exhibit higher levels of job satisfaction. These results can lead to increased employee retention and reduced turnover rates.

Unlike other quality improvement initiatives, efforts based on lean principles are not capital intensive. Instead, they are built on alignment of an entire workforce focused on continuously improving patient value. Successful lean initiatives stimulate service improvements that benefit patients as well as the healthcare institution and its employees, often with little or no direct financial investment.

The business of healthcare is undergoing a significant transformation as healthcare institutions and leaders seek innovative ways to improve quality of service and reduce costs. Traditionally applied in production settings, lean principles and practices are now being implemented in non-production related settings including healthcare environments.

Lean offers significant advantages over legacy quality improvement models by increasing efficiency and reducing waste while simultaneously improving quality of patient care. With its focus on increasing value, lean has the potential to help balance the cost associated with healthcare, increase the job satisfaction of healthcare professionals, and fundamentally improve the health of our communities.

Eight Wastes in Healthcare

Waste is any element of a process that does not add value to a service or outcome, but increases cost. In the healthcare context, value is defined as the provision of customer / patient service and satisfaction. Any activity, which doesn't contribute to this, is classified as waste.

Identifying the eight wastes can help to achieve improvement in healthcare by enabling staff to examine their own workplace and eliminate wasteful activity. This improves the patient experience as well as giving front line staff more time to reinvest in services. As waste is a symptom rather than the root cause of problem, it indicates problems within the system or organization.

Typically in a healthcare process, 95 percent of a total activity is non-value-add. The concept of Lean is to eliminate the waste and the non-value-add activities. Removing waste in a process requires intuition, creativity, courage, and strength. By developing and executing Lean strategies, a cultural shift in your organization will begin to take place. You will notice that it is much easier to institute change, provoke thought and leadership from all team members, and develop efficiencies you never believed to be possible.

The term "waste" encompasses an array of definitions for hospitals and health systems, including wasted time, finances, steps and human potential, to name a few.

1. **Defects.** This includes all time spent doing something incorrectly and inspecting or fixing errors. One example of defect waste is the time spent looking for an item missing from a surgical case cart.

2. **Over-production.** This includes doing more than what is needed by the patient or doing it sooner than needed. A broad example of this is the performance of unnecessary diagnostic procedures.

3. **Transportation.** Unnecessarily moving patients, specimens or materials throughout a system is wasteful. This type of waste is evident when the hospital has a poor layout, such as a catheter lab located a long distance from the emergency department.

4. **Waiting.** Waiting for the next event to occur or the next work activity can eat up time and resources. Patients waiting for an appointment is a sign of waste, as is employees waiting because their workloads are not level.

5. **Inventory.** Hospitals create waste when they incur excess inventory costs, storage and movement costs, spoilage and waste. One example is letting supplies expire and then disposing of them, including out-of-date medications.

6. **Motion.** Do employees move from room to room, floor to floor and building to building more than necessary? That accounts for one type

of waste. Lab employees may walk miles per day due to a poor hospital layout, for example.

7. **Over-processing.** This describes work performed that is not valued by the patient or caused by definitions of quality that aren't aligned with patient needs. One example is extra data stamps put onto forms, but that data never being used.

8. **Human potential.** This waste is caused when employees are not engaged, heard or supported. Employees may feel burnt out and cease sharing ideas for improvement.

Eliminating waste along entire value streams, instead of at isolated points, creates processes that need less human effort, less space, less capital, and less time to make products and services at far less costs and with much fewer defects, compared with traditional business systems. Organizations are able to respond to changing customer desires with high variety, high quality, low cost, and with very fast throughput times. Also, information management becomes much simpler and more accurate.

The Concept of Flow

Do patients, providers and staff want to wait in your hospital? No, of course not, ideally, they want to go from one process to the next process - never having to wait. They want, and need, service to flow. Because waits, delays, and cancellations are so common in health care, patients, providers and staff assume that waiting is simply part of the care process.

When patients, providers and staff have to wait, then the flow of the value stream has stopped. Basic to Lean is to create processes where there are no stoppages or interruptions. By removing wasteful or non-value activities properly, and increasing the value for the client, we are able to reach this ultimate goal of flow.

The term ‘flow’ describes the progressive movement of people, equipment and information through a sequence of processes. In healthcare, the term generally denotes the flow of patients between staff, departments and organizations along a pathway of care.

Flow is not about the what of clinical care decisions, but about the how, where, when and who of care provision. How services are accessed, when and where assessment and treatment is available, and who it is provided by, can have as significant an impact on the quality of care as the actual clinical care received.

The concept of using flow to improve care has received increasing traction within healthcare, especially in relation to reductions inpatient waiting times for emergency and elective care. Awareness has been growing of the

ideas, first tested in other industries, and results that organizations have generated by applying flow thinking to their organizations.

The goal of flow is to eliminate the use of batching and queuing within a process. Processes that use batches and queues produce multiple wait times and interruptions. The US healthcare system is built on batch and queue systems. A patient who feels sick calls his physician and makes an appointment. At the appointed date and time, he arrives at the provider's office and waits to be seen. Upon examination, the doctor may recommend the patient see a specialist, have laboratory tests performed, and even begin taking a prescribed medication. Each step entails waiting for a service or product to be delivered.

Batches and queues are also evident in processes involving reimbursement, coding, and chart review. Even electronic health record systems, promised to streamline healthcare, rely on some form of batching and queuing. For example, a patient's phone message and request for appointment may be stored in a queue on the toolbar of the physician's computer. If the physician reviews his queue before going home and calls back only those patients that he thinks are the most severe, the system actually impedes providing needed treatment in the timeliest manner.

The ultimate goal of flow is to ensure that a process is continuously worked on until it is complete. For the patient, this means receiving the care he or she needs without waiting, interruptions, and suffering unnecessary pain.

By enabling stakeholders to more easily understand the issues, they can more readily identify and link root causes of issues to specific activities and steps within a process. This also assists with prioritizing process improvements. Whereas traditional people and process improvement tends to focus on a single process, value stream mapping provides a complete end-to-end perspective.

Understanding patient flow requires looking at the whole system of care, not just in isolated units. Reducing variation in flow has been shown to improve overall patient flow. Providing patients with timely access to appropriate care is an essential element of high quality care, because when care is provided is often as important as what care is provided.

As the national policy agenda focuses more strongly on integration between primary care, acute services and social care, the need to understand and improve how patients flow through systems is more important than ever. High-profile cases of failures in the timeliness and quality of care serve as warnings as to the painful consequences of poor quality systems and processes.

The Voice of the Customer

Every organization serves a unique need for the customer. And a key feature that differentiates a successful organization from a not so successful organization is that a successful one listens to what the customer needs and creates products and services that exceeds the expectations. Healthcare attracts the most dedicated, well-intentioned professionals who truly care about the well being of their customers, the patients.

However, unlike other service organizations (think hospitality industry), the healthcare professionals will tell you what they think their customers want and need, but will often fail to directly ask what their patients *actually* want by determining the Voice of the Customer.

The impact of customer satisfaction on profitability is widely researched and reported. For every patient complaining, there are 20 more who do not complain, but will not return. Understanding the patient's wants has an immense implication on the satisfaction, retention, staff morale and profitability of an organization.

In health care, the 'customer' perspective has historically been gathered mainly as a risk management or public affairs activity to reduce the possibility of costly litigation or negative media exposure. This focus on mitigating negative patient feedback began to evolve as the quality improvement (QI) movement took hold in the early 2000's. Quality Improvement science has evolved the concept of customer satisfaction to a more holistic view, often called the 'Voice of the Customer' (VOC).

The VOC is the idea that the wants and needs of the customer are central to any business or service. In Lean methodology, anything done by an organization that does not provide value to the customer is waste and should be minimized or eliminated. Regardless of the type of QI science utilized, a truly QI focused organization has a strong, fundamental link to the VOC.

Too many people consider only the voices of external customers (in health care, the external customer is the patient). To design something that is truly patient-friendly, designers must take into consideration all of the customers, both internal and external. In health care, this means creating processes that take the needs of the patients and their loved ones, housekeepers, nurses, physicians, and lab technicians into consideration.

Considering the needs of internal customers can also mean involving people in the Quality Improvement (QI) initiative or 'redesign' that are not normally involved in direct health care delivery. These internal customers should be included as they are passionate about the care and services they provide and are up to date on new ideas in their fields. These individuals may play a

significant role in creating new and innovative solutions to QI concerns. Incorporating the voice of these innovative internal customers moves QI beyond just meeting current customer expectations and the prevention of problems to truly customer focused service delivery.

Some common Lean tools used to elicit the Voice of the Customer in healthcare are surveys, customer complaints data base, focus groups, Kano Model analysis, leadership patients rounds (management by walking around), process observations (watching the actual process), encounters based on "moment of truth" (Carlzon defines moment as truth as the point where the customer interacts with the organization and forms an impression on the quality of the service provided), mystery shopper, Critical to Quality Trees, Quality Function Deployment (QFD) and some proprietary off-the-shelf packages.

To truly create high-quality, focused health care that is meaningful to patients, we must ask patients (external customers) what it feels like to seek and receive health care and related services. We have to ask health care providers (internal customers) what it feels like to provide health care services. We must engage all health care customers in the quality improvement process to improve health care delivery. Establishing a formal connection to the VOC by actively engaging customers in ongoing quality committees or patient advisory groups ensures there is a constant flow of information both to and from the customer. Only by listening to customers can we hope to meet their needs.

Lean Culture Transformation

Lean is often perceived as a 'toolbox' of concepts and methodologies that are implemented and tailored to an organization. While this is statement true, it is only a small step on the Lean journey to operational excellence. Organizations stand little chance of implementing Lean unless they have paid at least equal (or more) attention to creating the right culture, and the conditions and circumstances, which can become the foundation for implementing change. Just imagine what you could achieve if your organizational culture actively welcomed change.

Consider how easy it would be to install the training, the techniques, the methodologies and the common language that accompanies any Lean strategy, if staff at all levels chose to perceive the change as an aid to their work, rather than as a hindrance and distraction from their daily, weekly and monthly targets. The organizational culture determines the success of Lean or any other change initiative. Sometimes the biggest problems facing implementation of Lean thinking have nothing to do with the tools, but rather the behaviors inherent in the organization's culture. Nothing changes until behavior changes.

Managing transitions organizations are social systems composed of conflicting interests focused on working to ensure that strategic goals are achieved. Culture change is about driving performance across the organization to exceed customer expectations. Change is not just a technical-rational process. It is a behavioral, emotional and political process.

Most organizational cultures exist by accident or default. The original owners or architects who created the organization ensured that their values of transacting operations were central to 'how things get done.' This became their culture, but over time and with key players and new actors entering the scene the organizational culture changes over time.

Leadership for change is perhaps the most important aspect of implementing a Lean management system. This calls for leaders to lead the change, not manage it. It is driven by behaviors like coaching, modeling, mentoring and empowering. It is leadership taking the responsibility for the transformation and actively crafting the organizational culture. It is leadership establishing the behavioral expectations and driving accountability to those expectations.

Everyone in the organization must first understand the need for change and then embrace their role in that change model. The model must be driven by the empowerment to solve staff's own problems and be recognized for those efforts.

Lean can be a major strategic initiative focused on major cost efficiencies managed from the top of the business, or it can evolve in smaller discrete initiatives lower down in the organization. The preferred route of a 'top down' approach will have a major positive impact. If managed effectively, 'Lean' can be the major philosophy uniting the organization in a relentless drive for improvement.

In other words, Lean only works from the top down and the bottom up. Strong leadership support from the top to create the right conditions and expectations and strong grassroots involvement from the front-line staff to make it all happen. The goal of developing a lean culture is to create an army of problem solvers includes everyone in the organization pulling the rope in the same direction.

Lean Data and Metrics

Successful implementation of Lean principles requires a systematic method of information and data collection. Clearly stated metrics and appropriate data collection will drive successful lean project implementation.

While the general principles of Lean management are increasing value and eliminating waste, Lean has five performance measures organizations should be aware of to best leverage this strategy:

1. Human development. Human development is the engagement of all stakeholders in the improvement process. Lean engages people in daily problem solving and furthers their involvement in running the business as opposed to a top down approach.

2. Quality. The second performance area is quality, as Lean projects aim to improve quality by eliminating unnecessary processes. As hospitals focus more on quality and patient safety, they may turn to Lean to guide quality improvement initiatives.

3. Service. The service dimension of Lean relates to on-time delivery — such as the ease of scheduling an appointment at the hospital, a short wait time for services and smooth patient flow between departments. This area of performance is a way that hospital organizations and clinics can differentiate themselves in a competitive environment, and how they can attract more patients to their facility.

4. Cost. Cost, which is tied to productivity, is an element of Lean that is becoming more important today in an environment of reduced reimbursement. Lean process improvement can decrease costs by eliminating unnecessary steps and increasing productivity. Lean practices may also help hospitals cut costs without needing to lay off employees.

5. Growth. Hospitals need to implement a growth strategy concurrently with a Lean approach to optimize the benefits of Lean processes. As Lean streamlines processes, staff who may not be needed for certain processes can be redeployed to other areas, such as expanded services. By pursuing a growth strategy, hospitals can reinvest the savings achieved through Lean to continuously improve — one of the tenets of Lean.

In addition, Lean Thinking places a strong emphasis on measuring, evaluating, and communicating performance results. In this context, metrics enable organizations using Lean to:

- Identify and target the right problems during Lean events and projects
- Evaluate potential process improvements and select appropriate actions for implementation
- Establish baselines for process performance and track progress over time
- Understand and communicate the results (outcomes) of Lean
- Inform and monitor efforts to deploy Lean throughout an organization

There is always a scale by which we measure the success of our endeavors and someone is always keeping score. For managers, this means there is a scale by which the consequences of our decisions and actions are measured. Our hope is that the results of our efforts are favorable for those who entrust us with decision-making authority. In a profit seeking organization, the shareholders, employees and customers measure the outcomes of the decisions we make and the actions we take. In government, this task is given to the voting public. For non-profits, managers are brought to account by fundraisers, contributors and the beneficiaries of the organization's services.

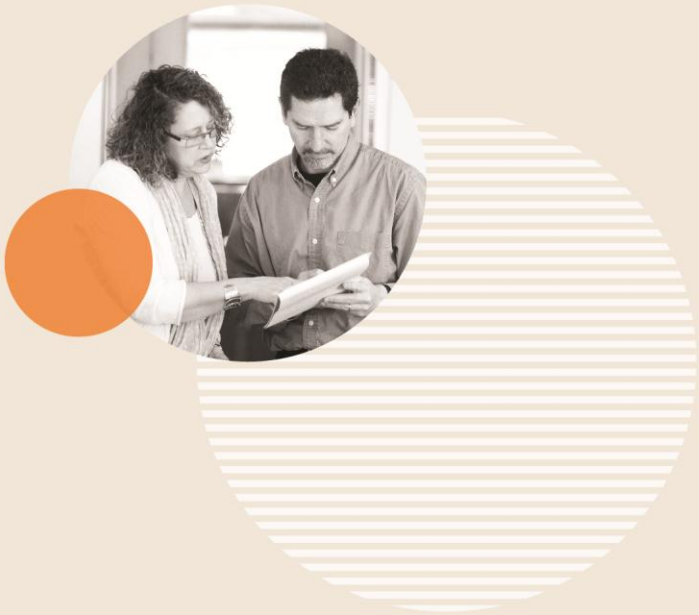
In our world of healthcare, the ultimate trust is that which exists between our patients and us. When they require care, they rely on us to provide the right diagnosis, early and timely treatment, and the best conditions for a complete recovery. And yes, they too are keeping score. Now, more than ever, the healthcare industry needs to embrace the economic value proposition of improving productivity.

For the past 20 years, the healthcare has experienced negative productivity growth. The economic consequences of this type of performance are stunning. The bottom line is that until true health care cost reform becomes a reality, these pressures will continue to cause problems for providers, for people's health care and for the nation's economy. Healthcare organizations should use these pressures as motivation to embark upon a relentless pursuit of ever-increasing productivity.

Institute *for* Healthcare Improvement

WHITE PAPER

Comparing Lean and Quality Improvement



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In their role as consulting Improvement Advisors to IHI, the authors are long-standing practitioners of the IHI approach to quality improvement who recognize the fundamental compatibility and potential synergies between the IHI approach and Lean as ways of perceiving, understanding, and influencing the progress of health care systems seeking to provide excellent patient care in a fast-changing environment.

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Executive Summary

In the past 25 years, improvement in health care has grown from demonstration projects into a worldwide movement. Dominant in this movement has been an improvement approach grounded in the work of Walter Shewhart, W. Edwards Deming, Joseph Juran, and Associates in Process Improvement, and shaped in practice by the staff and faculty of the Institute for Healthcare Improvement (IHI). Today, this "IHI approach" to quality improvement (referred to as "IHI-QI" throughout this paper) provides a framework for thousands of improvement practitioners around the globe. Meanwhile, many people in health care have heard about Lean and the Toyota Production System (TPS) as a powerful method for improvement and cost reduction in manufacturing, and about its notably successful application in health care by influential organizations such as Virginia Mason Medical Center and ThedaCare.

People often want to know about the relationship between IHI-QI and Lean, and how they can best utilize one or both approaches to improve their own care systems. This white paper aims to address these issues, and argues that because IHI-QI and Lean are complementary ways of approaching improvement, it is not necessary to choose one over the other as a guide to action.

Furthermore, integrating perspectives and lessons from the two approaches has the potential to strengthen both Lean and IHI-QI. As practitioners of IHI-QI, the authors see specific Lean lessons worth adopting, like the Lean requirement to ground analysis and improvement in the workplace, with expectations for all levels of a management hierarchy to engage in standard work and continuous improvement. For practitioners of Lean, we believe that IHI-QI offers diverse conceptual frameworks for managing change, techniques for implementing changes in complex systems, program formats for spreading change, and learning models that have been developed and implemented in a broad array of health care settings.

This paper begins with a brief overview of the issues and some key definitions, followed by more detailed descriptions of Lean and IHI-QI. For each approach, we discuss the key conceptual foundations, the principles that lead the way to improved system performance, the project roadmaps typically followed under each approach, and the tools that characterize them in practice. We also point out the fundamental congruence between the two approaches, as well as key differences. Finally, we suggest ways that practitioners of both Lean and IHI-QI can use the principles and methods of the other to extend their capabilities. Appendix A provides additional detail about the intertwined histories of Lean and IHI-QI.

After reading this paper, you will have clear answers to the following questions:

- What are the basic concepts and principles of IHI-QI and Lean?
- How are they similar (in history and approach)? How are they different?
- For what purposes is IHI-QI the most appropriate approach? For what purposes is Lean the best approach?

Overview

"Do not seek to follow in the footsteps of the old masters.
Seek instead what the old masters sought." –Basho (1644-1694)

In her 2012 keynote presentation at the Institute for Healthcare Improvement (IHI) National Forum on Quality Improvement in Health Care, IHI CEO Maureen Bisognano said that everyone in health care should have two jobs: to do the work and to improve how the work is done.

In that simple statement, Bisognano posed a transformational challenge to health care organizations struggling to meet the increasing demands of the marketplace to provide excellent patient experience, and make a meaningful impact on the health of the patients they serve. Following in the footsteps of other industries, they must somehow figure out ways to define the work — of everyone, including senior executives, point-of-care staff, clinicians, and those in support roles — to deliver excellent care and services ("doing the work"), while simultaneously designing systems and processes that build in continuous improvement ("improving how the work is done").[1]

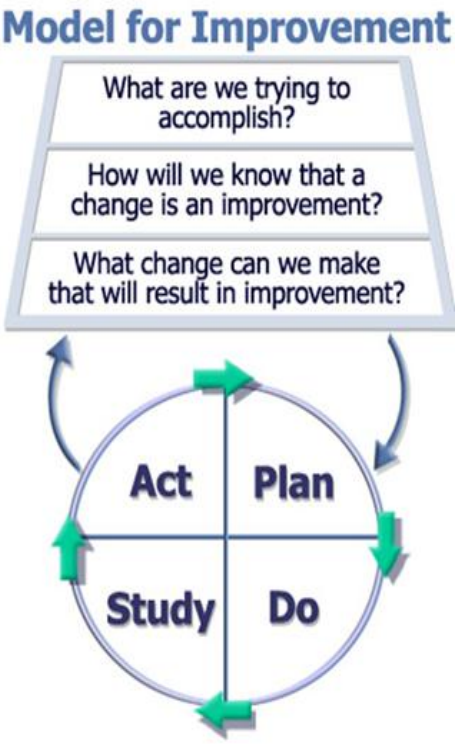
How can this be accomplished?

This white paper describes two distinct but related approaches to Bisognano's challenge. We refer to these approaches as the "IHI approach" to quality improvement (which, for the purposes of this paper, we shorten to "IHI-QI") and "Lean." We take "IHI-QI" to mean the approach to quality improvement developed by Associates in Process Improvement and promulgated by IHI, grounded in the work of Walter Shewhart, W. Edwards Deming, and Joseph Juran. IHI-QI emphasizes rapid-cycle testing in the field in order to learn which interventions, in which contexts, can predictably produce improvements. By "Lean" we mean the integrated principles, methods, and tools that have developed from the Toyota Production System to optimize the performance and management of value-producing systems.

The effort to improve quality in US health care has spread well beyond the "early adopter" phase of the 1990s. At that time, the Institute for Healthcare Improvement took the lead in promoting and translating industrial quality improvement methods to health care practitioners in a determined effort to close the "chasm" between unreliable common care practices and the evidence-based guidelines emanating from medical science.[2] In the 25 years since the seminal book *Curing Health Care* was published,[3] health care quality improvement has become a worldwide movement, and in the US has gained urgency from policy reforms by payers, governments, and professional standards bodies that increasingly insist on management of outcomes and documented efforts to constrain costs and improve value. These trends show every indication of accelerating in coming years.

IHI has been guided by a close relationship with Tom Nolan, Ron Moen, Lloyd Provost, and their colleagues at Associates in Process Improvement (API) that began in 1992.[4] That collaboration has resulted in wide-scale application of IHI-QI in health care worldwide. The IHI approach is informed by the work of Shewhart and Juran and is based on the application of Deming's System of Profound Knowledge. The specific methods of IHI-QI have evolved, based on learning from their application within health care by API, Improvement Advisors, IHI Fellows, faculty and staff, strategic partners, as well as thousands of participants in IHI projects and initiatives. IHI's clinical and technical leaders learned quality improvement from API, who in their turn worked closely with Deming.

Figure 1. The Model for Improvement



Developed by Associates in Process Improvement

IHI-QI is a vibrant discipline. It has not ossified into dogma, thanks in good measure to the diversity, energy, and idealism of its adherents, and to the "open source" approach that IHI has promoted with regard to methods and content. IHI faculty have been encouraged to candidly share their best ideas, in the belief that the field can most rapidly and effectively advance health care quality through collaboration. Together, the IHI community has grown in an atmosphere of transparency and a spirit of "all teach, all learn."

IHI-QI is often confused with one of its core elements, the Model for Improvement (see Figure 1).[5] The Model — three clarifying questions and the Plan-Do-Study-Act (PDSA) cycle — has formed the mainstay of IHI's teaching and improvement methodology over the years. But despite its fame, and despite its manifest utility in almost any life situation, the Model for Improvement is not synonymous with IHI-QI.

The Model for Improvement, developed by Associates in Process Improvement, is a general-purpose heuristic for learning from experience and guiding purposeful action. More simply, it is an "algorithm for achieving an aim" at any scale. As a tool for gaining practical knowledge, it represents a radical distillation of pragmatic epistemology into a habit of immediate, sequential testing of changes. One objective of this paper is to reconsider the Model for Improvement in its proper place, as a pervasive guide for action within the larger context of IHI-QI.

At present, Lean tools and methods are rapidly gaining adherents among aspiring health care improvers. As health care leaders have embraced the results-oriented discipline of industrial quality improvement, interest in more effective management systems has increased. The Toyota Production System (TPS), in particular, has received much attention. TPS is rooted in the innovations of Taiichi Ohno and colleagues in Toyota factories starting soon after the end of World War II. Adaptations of TPS are widely known by reference to one of its key principles of practice, "Lean" — the drive to devise nimble tasks, processes, and enterprises that maximize value and minimize waste in all its forms. Leading health care organizations, notably Virginia Mason Medical Center in Seattle,[6] ThedaCare in Wisconsin,[7] and the Pittsburgh Regional Health Initiative in Pennsylvania,[8] have adopted TPS as their model for management and improvement, with widely recognized success.

Which Is "Better"?

The recent upsurge in adoption of Lean methods in health care settings, following on the wide dissemination of IHI-QI over the past 25 years, has led some people to ask, "Which is better, the IHI approach or Lean?" Certainly, the choice of methodology can be challenging for organizational leaders with limited knowledge of both approaches, who look to the literature, the testimony of colleagues, or current fashion to decide how to build their organization's improvement capacity. The choice of Lean or IHI-QI may well be seen as a Big Decision, with serious risks and expensive

consequences. The decision is made no easier by the narrow interests and elaborate technical language of consultants and vendors promoting their own particular approaches and skill sets.

But the question is a canard, equally contrary to the spirit of both traditions. A critical comparison of the origins, core principles, methodological roadmaps, and tool sets of IHI-QI and Lean reveals them to be harmonious in conception and complementary in practice. Instead of an "either-or" choice, we suggest that there is much for leaders to gain by considering both IHI-QI and Lean in light of the needs of the new health care marketplace, with a clear view of the complementary strengths and applications of each, appreciating the profound compatibility of their philosophies and approaches.

Describing the IHI Approach to Quality Improvement and Lean

Methodologies, like children, are ultimately shaped by their parents and by the tasks they are set to accomplish. IHI-QI and Lean share a close family history, arising out of pragmatic philosophy, the scientific method, statistical process control, and practical line-level industrial engineering. However, these siblings were separated at birth and reared by practitioners from different cultures and neighborhoods — the Japanese factory floor versus American industry. They have enjoyed frequent family visits along the way.

Lean and the Toyota Production System

A journey to discover the origins of Lean might begin with a tour of Henry Ford's automobile assembly plant in Highland Park, Michigan, in 1914, where the system he called "flow production" incorporated many features we now associate with Lean and TPS.[9,10] Or, one might pinpoint the moment in Nagoya, Japan, in 1946, when Taiichi Ohno assumed control of the machine shop at Toyota's Honsha assembly plant and began to assemble the elements of what would become the Toyota Production System (TPS). Ohno detailed standardized work for each job in the shop, and began to experiment with physical configurations and job pacing that minimized queues and time between operations, signaling systems that allowed upstream operations to respond quickly to downstream conditions, and worker training that emphasized awareness and individual responsibility for quality and problem solving.[11] Under Ohno's leadership over the following decades, the core principles and techniques that became TPS were elaborated and codified.

In a profound sense, TPS embodies an aim — an ideal of how a value-focused production system should behave, and the components, connections, and attributes it must have in order to behave that way. Steven Spear (IHI Senior Fellow, MIT Sloan School faculty, and noted Lean expert) summarizes the ideal production system in terms of outcomes:[12]

- The output is defect free.
- The product or service is delivered in response to customer need (i.e., on demand, "pull" system).
- The response is immediate.
- Products or services are provided one by one, in the unit size of use (i.e., tailored to the identified needs of the consumer).

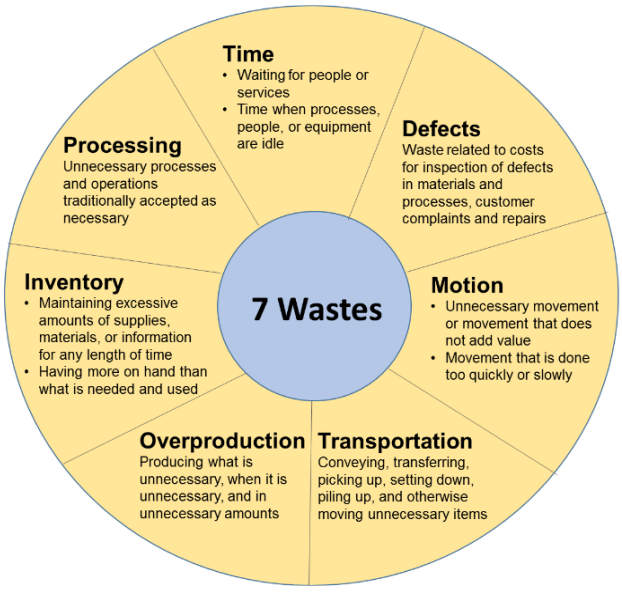
- Work is done without waste.
- Work is done safely.
- Work is done securely.

The core principles of TPS are apparent in Lean production systems that approach this ideal. Toyota's website says that TPS is built on two concepts: *jidoka* ("automation with a human touch") and *Just-in-Time*. *Jidoka* means "when a problem occurs, the equipment stops immediately, preventing defective products from being produced." By extension, *jidoka* signifies continuous inspection built into every process — automated when possible, but always foremost in the awareness of operators, who are charged with recognizing and addressing problems immediately by means of *kaizen*. (See Appendix B for a glossary of common Lean terminology.)

Kaizen means "continuous improvement"; it also refers to the local experimentation (aka "PDSA testing") undertaken to mitigate production problems at the front line.[13] Detailed standardization of tasks refined via *kaizen* means that ever smaller deviations in methods and quality can be discerned as problems, then quickly corrected, thus leading to ever greater consistency of product and conformance to specifications.[14]

Just-in-Time (JIT) describes the ideal functioning of the production system. It means that "each process produces only what is needed by the next process in a continuous flow," reducing to an absolute minimum the time between recognition of customer desire and its fulfillment by the process. "Customers" in this sense include the next process in the production chain as well the ultimate consumer of the product or service.[14] Pursuit of JIT production engages a set of principles for standardizing, integrating, and coordinating operations within and between processes across the entire enterprise. Fundamental among these are *value* and its converse, *waste*.

Figure 2. Toyota Production System Seven Wastes



Value is "expressed in terms of a specific product (i.e., a good or service) that meets the customer's needs at a specific price at a specific time."[15] Value is created by the production system; any aspect of production that does not contribute to value is *waste*: wasted material, wasted time, items held in queues or inventories, wasted human effort, and so on (see Figure 2 for the TPS Seven Wastes[16]: time, defects, motion, transportation, overproduction, inventory, processing). Maximizing value requires minimizing waste. The term "Lean" acknowledges the drive to eliminate waste from the system, and thus produce maximum value at minimum cost.[17]

The production process — from the customer's signaled need to production to consumption — is called the *value stream*, and includes both the production process and the information flows that control it. The ideal value stream behaves as a single "super-organism," responding rapidly and flexibly to customer demand and changes in external conditions (though poorly designed Lean systems are prone to disruption if too tightly adapted to anticipated conditions[17]).

Key principles such as *standardized work*, *flow*, *heijunka* (load leveling), and calculating *takt time* and *cycle time* guide system improvements to increase integration, coordinate activity, and minimize waste. *Poka-yoke* (mistake-proofing) devices, beginning with simple checklists, integrate error prevention and real-time inspection into standard work in order to make errors less likely and, when they occur, instantly visible before they become defective products.[18]

Communication within and among processes is the nervous system for rapid, responsive action. A *kanban* is a token that signals to an upstream process that product is needed, and to a downstream process that it has been delivered, thus enabling the customer to "pull" product in single units from the producer. *Visual controls* allow operators and supervisors to sense the current state of the system, so that they can coordinate their actions in real time with upstream and downstream conditions and resolve discontinuities. An *andon* is a signal that a problem has occurred, and may halt the process (even an entire factory) while a remedy is found, thus avoiding the waste that would result from sending a defective product down the line.[15]

The TPS features and principles noted above constitute an integrated "template" for designing a production system that conforms to the Lean ideal. In IHI-QI terms (described in further detail below), they are *change concepts* that serve to prompt improvers to identify specific ideas for designing processes and addressing problems using disciplined empirical techniques.

It is important to note that TPS is a *production* system. Its ideal outcomes, change concepts, and tools are adapted to reduce waste and variation in systems where the concept of a value stream applies. Certainly, health care systems include a great many production processes, from clinic visits to medication administration in hospitals to support functions such as pharmacy management. However, it is prudent to recognize the degree to which the TPS template must be altered to fit the very diverse and complex world of health care, where prevention, patient care, and payment are typically the responsibility of multiple business entities, and where patients themselves are intrinsic "producers" of their own outcomes.

For example, Spear employs the principle of "reducing ambiguity" as a key Lean change concept for standardizing care processes to improve safety.[19] In its efforts to apply TPS, Virginia Mason Medical Center (VMMC) found that translating the concept of *jidoka* into the realm of medication errors and adverse events presented a host of definitional problems that resulted in the Patient Safety Alert, a declared signal of an error that could endanger patient safety and a set of procedures for rectifying the error without actually halting patient care.[20] Similarly, VMMC invented the "flow station" to help eliminate waste and improve flow in the hospital workplace where, in contrast to an assembly line, the providers, not the patients, are constantly on the move.[20]

Even the concept of "value" must shift when transposed into health care.[21] In TPS, value is defined in terms of customers' willingness to pay.[22] In health care, John Toussaint, former CEO of ThedaCare, writes that "looking for what is truly of value in a process is an emotionally loaded exercise. Not only do physicians embrace different methods and measures, there is often a good deal of ego invested in those methods. At ThedaCare, therefore, teams examining a process for improvement are continually reminded to consider the patient first."[7]

Jim Womack, founder of the Lean Enterprise Institute, stresses that the core health care value stream is the individual patient's "journey" over the course of an illness, surgery, chronic disease, pregnancy, end of life, or myriad episodes or conditions. The similar journeys of many patients call for "service line" value streams that flow across traditional departmental and organizational boundaries, supported by common resources and infrastructure. Since "value" depends in part on the unique circumstances and needs of each patient, such standardized processes of care must

include features that allow them to adapt in real time to individual patient needs throughout the journey, while maintaining the reliable consistency required by evidence-based practice. Care systems that are responsive at this level require tightly integrated care teams for whom continual awareness of individual patients' needs and front-line *kaizen* are essential.[1]

Lean follows a "roadmap" for bringing a production system into conformance with an ideal state like that defined in TPS. As described by Womack and Jones in *Lean Thinking*, the route has five waypoints:[15]

1. Specify the value desired by the customer.
2. Identify the value stream for each product providing that value and challenge all of the wasted steps (generally nine out of ten) currently necessary to provide it.
3. Make the product flow continuously through the remaining value-added steps.
4. Introduce pull between all steps where continuous flow is not possible.
5. Manage toward perfection so that the number of steps and the amount of time and information needed to serve the customer continually fall.

As they follow the roadmap, practitioners use the Lean "toolkit" to guide their journey. *Value stream maps* detail the steps in a process along with the associated information flow and data to quantify waste, cycle time, and other process characteristics. A supervisor seeking to rectify a production problem "goes to the *gemba"* (workplace) for a firsthand view of the situation before undertaking any *kaizen*. *Spaghetti diagrams* reveal wasted physical motion; *5-S* is a set of ideas for organizing tools and materials to eliminate the waste of excess inventory and searching for needed items. A team seeking to improve a process beyond incremental changes may engage in a *kaizen event* (aka "rapid improvement event"), an intensive sequence of value stream mapping, process redesign, data collection, and testing intended to generate rapid, radical improvement.

Similar to the Model for Improvement used in IHI-QI, the A3 approach used in Lean is a general method for defining a problem and goal for improvement, targeting candidate changes, and planning a series of tests to settle on workable "countermeasures." A3 and the Model for Improvement share a common motivation: to provide a method for everyone, not just staff specialists, that is as simple as possible and can be applied anywhere in an organization.[23] The method takes its name from an A3 (297 x 420 mm) size sheet of paper, which must fit the entire plan. A3 was devised by Toyota engineers as part of their preparation at Toyota Motor Company to compete for the JUSE Deming Prize, awarded in 1965. They needed a way to demystify the work of the quality expert so that problem solving could become an integral part of everyone's daily work, at all levels of the organization.[1] By relying on a standard format with diagrams that everyone can understand, A3's requirement of a single page forces succinct summary and focus on the most important aspects of the problem and its resolution. In similar fashion, improvement science practitioners often employ structured forms to guide PDSA planning and execution. Table 1 matches elements of the A3 approach with the components of the Model for Improvement.

Table 1. Lean A3 Problem-Solving Approach Mapped to the Model for Improvement

Component of Model for Improvement	Component of A3 Problem Solving
AIM: What are we trying to accomplish?	Eliminate or at least reduce the gap between current state and standard performance or between current state and ideal state.
MEASURES: How will we know that a change is an improvement?	Specify one or more measures that characterize the current state and the ideal state (e.g., with respect to quality, cost, timing or safety). Specify the goal as target level(s) of the measure(s).
CHANGES: What change(s) can we make that will result in improvement?	Develop one or more changes from investigation of current state combined with Lean concepts (e.g., eliminate waste).
PDSA: Carry out Plan-Do-Study-Act (PDSA) test cycle(s) to increase the degree of belief in the change(s) that can improve performance (i.e., get closer to the aim). Revise the change(s) or the method, or abandon the change(s) based on data.	Test the changes to confirm that they reduce or eliminate the gap between current state and ideal state (Plan-Do-Check-Act). Revise or augment the changes as needed to achieve the goal.

At its highest level, Lean extends the concepts and methods of the production system into a holistic conception of the organization, its context, culture, and management. In *The Machine That Changed the World,* Lean is described as a product development process, a fulfillment process from order through production to delivery, a supplier management process, a customer management process, and a general management process. John Toussaint, former CEO of ThedaCare, calls Lean an "operating system."[24] In this view, TPS principles extend outward from the core value stream to shape management, support functions, supply chains, and customer experience beyond the mere receipt of a product or service.

In a Lean enterprise all levels of management, from line supervisors to the CEO and board of trustees, must conform their own work to the key principles of TPS, including standardized daily work, sensitivity to operational quality, constant readiness to detect and address problems in real time, and providing coaching and leadership in Lean thinking and methods to staff.[25] In this way improvement becomes integrated into the daily functions of all staff, not just managers and quality specialists. In their 2013 article, Toussaint and Berry say that Lean applied to health care reflects "an organization's cultural commitment to applying the scientific method to designing, performing, and continuously improving the work delivered by teams of people, leading to measurably better value for patients and other stakeholders."[26]

The IHI Approach to Quality Improvement

For the purposes of this paper, we refer to IHI-QI as the approach to improvement developed by Associates in Process Improvement and promulgated by IHI, grounded in the work of W. Edwards Deming, with roots reaching deep into pragmatic philosophy, systems theory, Walter Shewhart's statistical treatment of quality, human psychology and logic, and the scientific experimental method.[27]

IHI-QI draws a fundamental distinction between the system to be improved and the techniques and methods used to improve it. IHI-QI seeks to formulate and codify generalizable knowledge that, when applied in other systems, can yield predictable improvements.[27-29]

All improvement requires that changes be made in the system (though to be sure, not all changes are improvements). Building on the knowledge of subject matter experts, improvers target changes that are predicted to lead to improvement in a specific system. These changes are then tested and amended through iterative Plan-Do-Study-Act (PDSA) cycles to produce sustainable improvement. Such changes comprise the "content" of improvement.

In health care, a primary source of content is clinical science: the body of theory and evidence that links clinical assessments and treatments with desirable outcomes. Content knowledge is exercised by those who work in the system with firsthand knowledge of its purpose, processes, and dynamics. IHI-QI in a particular system is guided by a content theory that justifies particular changes by their anticipated impact on results.

IHI-QI does not confine itself to any particular content area or production system. Its chief concern is with how theories and techniques offered by various disciplines can be brought to bear on a given system under specific conditions with a sufficient degree of belief that they will achieve the desired improvements.[30,31] Success in such endeavors requires *will*, the moral engagement and energetic action to improve; *ideas* for changes that can be tested, adapted, and ultimately implemented; and *execution*, the techniques and methods that translate theory into actual improvement.[32] In Deming's terminology, the knowledge that builds will, generates ideas, and guides execution is "Profound Knowledge."

Profound Knowledge stresses that predictably successful improvement requires skills and knowledge that extend across a wide range of disciplines in four interdependent domains: Appreciation for a System, Theory of Knowledge, Psychology, and Understanding Variation.[33] In Deming's words, Profound Knowledge "provides a map of a theory by which to understand the organizations that we work in."[34]

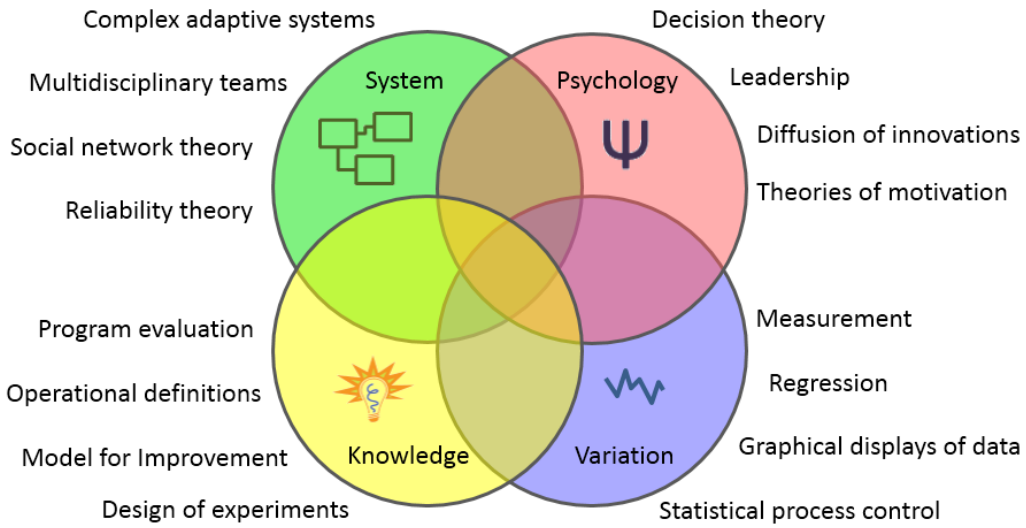
- *Appreciation for a System* is a matter of understanding the purpose of the enterprise and the interoperations among its parts — physical, social, and functional.[35] Systems thinking embraces the causal influences and feedback loops that enable (or impede) enactment of the organization's aim, its capacity for improvement and propensity to change, and the qualities it must exhibit in order to achieve its aim. Such systems, animated by human beings, are by nature complex and adaptive, and thus resist efforts to improve them through simplistic "top-down" directives.[36]
- *Theory of Knowledge* refers to the development of practical knowledge of "what works." It is grounded in predictions about the results to be achieved through system changes. Knowledge is gained through a process of stating a theory, making a prediction based on the theory, comparing observations with predictions, and revising or abandoning the theory accordingly.[33] Thus the science of improvement is deeply concerned with the nature of learning and with ways to foster, maintain, and accelerate learning in practice. The Model for Improvement is both an expression of the theory of knowledge and its most fundamental technique. The explicit goal of the science of improvement is to increase such knowledge.
- *Psychology* deals with the behavior of humans as social actors, their interactions with one another, and their interactions with the systems of which they are a part. Intrinsic personal motivation is fundamental to improvement, and the factors that mobilize and sustain the will to improve are vital for successful initiatives. Biases in people's perception and interpretation

of others' behavior, for example, "attribution error," have important implications for leaders working to develop a blame-free culture of improvement.[37] Care systems, to be truly reliable, must compensate for the shortcomings of human memory and attention, and for people's naïve decision-making "heuristics."[38-41] Techniques to assess and balance factors such as temperament, motivation, and emotion are critical for the operation of well-functioning teams.[42]

- *Understanding Variation* requires the recognition that variability — both among entities and over time — is an inherent characteristic of any system. Measures and data are useful to guide future action, provided we can discern patterns in such variation and respond appropriately. Shewhart's theory of variation, made operational by control charts, provides the foundation. The key concept of Shewhart's theory is the distinction between common cause variation produced by a stable, predictable process and special cause variation that results either from unstandardized, uncontrolled operations or from intentional process changes.[43]

In working to improve a system, IHI-QI practitioners employ an array of conceptual frameworks and methods drawn from many disciplines in order to understand and influence complex adaptive systems such as health care organizations. Selection of methods will vary greatly depending on the scope, scale, and context of the work. Figure 3 matches a few of these frameworks with the domains of Profound Knowledge to which they mainly pertain, with the caveat that there is much overlap; for example, a framework such as "leadership" finds relevant principles in all four domains.

Figure 3. Conceptual Frameworks Associated with Deming's Four Domains of Profound Knowledge



The search for conceptual frameworks that can be usefully brought to bear on improvement is ongoing. Emerging fields such as social network analysis, predictive modeling based on large data sets, and decision theory offer tantalizing frameworks for innovation not only in care processes, but also for informing execution models that are increasingly effective for improvement.

The Model for Improvement is the engine that propels Profound Knowledge from a static catalog of interesting ideas into a dynamic program of learning and action. The Model represents a

ceaseless quest for practical, functional knowledge gained from hands-on experience in execution. Set a goal and measure it. Select a change idea, make a prediction, and try it out. What worked? Why? Under what circumstances? Will it work next time? Revise and try again. The Model drives improvement at all levels of scale, from the most minute adjustment of standard work, to the process redesigns of improvement teams, to the initiatives that aim to transform the health care systems of entire countries.

Productive testing requires good ideas about how to change the system. Such ideas may arise from the insights of those who work in the system (especially those with line-level point-of-care experience), or they may come from observation of another system that has demonstrated a better approach to the problem. Directed creativity techniques like those of Edward deBono[44] or the IDEO Corporation[45] can help teams generate innovative ideas for changes.

The authors of *The Improvement Guide* advocate for *change concepts* as a way of targeting ideas for change related to an improvement aim. They explain that "a change concept is a general notion or approach found to be useful in developing specific ideas for changes that lead to improvement."[5] Improvers are prompted to think of an aspect of the system that needs change, then select a change concept that describes the needed improvement and use it to provoke an idea. For example, a data team working to increase their efficiency might consider the change concept "eliminate things that are not used," review its current work process, and discard a monthly report that is no longer needed by its original consumer. Such change concepts are represented by TPS principles such as *eliminate waste*, *Just-in-Time*, *jidoka*, and *poka-yoke*. A number of TPS change concepts appear in *The Improvement Guide*'s Appendix A.

IHI-QI initiatives are designed to fit the topic, scope, and scale of work at hand. Based on the design of IHI educational offerings, Collaboratives, and spread initiatives, and much hands-on experience, the authors of this white paper have outlined a series of steps that describe a "generic" IHI-QI initiative (see Table 2). This sequence is a bit of a "deli menu" — no diners are expected to consume all the items, and the sequence of dishes is certainly not obligatory. No improvement team would execute these steps in a fixed order, but instead would work up and down the list as the initiative is planned and enacted.

Table 2. Steps in a "Generic" IHI-QI Initiative

Step	Elements
1. Plan the initiative	• Create an explicit theory of what improvement you intend to obtain in the system and how you intend to go about it.
1a. Content theory and aim	• Identify the system to be improved (e.g., patient population, sites, unit of adoption). Assemble evidence, develop guidelines and protocols, identify key outcomes, and express the desired future state of the system. • Assess the gap in current performance. • Use a driver diagram to capture the content theory and target key processes needed to achieve the aim. • Develop a formal aim statement: "how much, by when, for whom." • Identify and operationalize outcome and process measures.

Step	Elements
1b. Execution theory and plan	• Select a format for the initiative (e.g., "fast-track improvement," single-process improvement, Breakthrough Series Collaborative, spread initiative) based on aim, scope of the system, and specificity of content. • Plan for data collection, analysis, and feedback. • Assess the internal and external contexts, and figure out how to influence them. • Assemble a team. • Plan activities (e.g., webinars, site visits, *kaizen* events, coaching). • Assess the needs of customers and staff. • Develop an evaluation plan and metrics that can provide concurrent feedback and track the inevitable adaptations of methods that occur in every initiative. • Develop a timeline and tactical plan.
2. Develop, test, and pilot changes	• Assess the current system structure and performance using control charts, system diagrams, Pareto charts, process maps, or other tools. • Identify relevant change concepts and exemplar systems. • Use change concepts or directed creativity to develop and prioritize change ideas. • Use PDSA cycles to develop, test, and pilot changes under diverse conditions, to gain confidence that they will work as predicted and refine where necessary. • Use measurement to monitor progress, identify problems, and promote adoption.
3. Implement, sustain, and control	• Implement successful changes throughout the local system. • Test and implement necessary support functions, including training, job descriptions, human resources, information technology, etc. • Establish a long-term measurement plan to monitor for sustainability. • Institute a quality control regime.
4. Spread changes throughout the extended system	• Define the scope and unit of spread. • Devise measures of spread. • "Package" content for easy implementation by new teams. • Develop communication and measurement systems and technical support. • Monitor and adapt.
5. Evaluate and "pass forward"	• Use statistical analysis, after-action reports, surveys, etc., to evaluate the effectiveness of the initiative, its interventions, team operations, and the role of context. • Celebrate success. • Codify learning to inform future improvers.

IHI-QI has flourished in the complex world of health care, with its many independent constituencies, disparate traditions, and often competing institutions. Its eclectic, overarching approach to improvement has fostered a generation of innovation and adaptation. Over the years, practitioners working across the broad IHI-QI field have extended the range of tools and methods to include driver diagrams, Failure Modes and Effects Analysis,[46] the MUSIQ survey of project

context and organizational QI readiness,[47] Elias Porter's SDI psychological profile inventory,[48] and many others. In the spirit of Deming's Profound Knowledge, they have assimilated useful constructs and methods from a wide array of other disciplines, including aviation, reliability science, social psychology, social network theory, Everett Rogers' *Diffusion of Innovations*,[49] and behavioral economics.[50]

IHI has led the development and adaptation of program formats for organizing people to engage in improvement, including the Breakthrough Series Collaborative,[51] R&D methods for developing new processes (e.g., 90-Day R&D projects), the IHI Framework for Spread,[52] as well as campaigns designed for large-scale dissemination of evidence-based clinical practices (e.g., the 100,000 Lives Campaign). The IHI Open School, with its online curriculum, an international network of local chapters, and web-based resources, is designed to inculcate IHI-QI in the next generation of practitioners.

Comparing IHI-QI and Lean

The above descriptions reflect strong congruence between Lean and IHI-QI:

- Both approaches recognize the purpose of the system — defined from the customer's perspective — as the starting point for improvement.
- Both approaches take the well-being, morale, and dignity of people working in organizations as both ethical and instrumental objectives.
- Both approaches emphasize the design and continual refinement of processes as the way to reduce variation and increase value in outcomes.
- Lean and IHI-QI both rely on general principles (in IHI-QI terminology, "change concepts") to guide the identification of candidate changes and solutions. They share many improvement tools and methods.
- Both emphasize the use of error proofing and inspection (including probabilistic sampling) in process design in order to improve reliability and reduce the rate of defects.
- Both approaches provide a simplified heuristic for defining quality problems on small and large scales, identifying candidate changes, and testing them to arrive at workable solutions. For IHI-QI, the heuristic is the Model for Improvement; for Lean, the A3 approach to problem solving.
- For both, the daily application of experimental methods by line-level staff to recognize workplace problems and identify useful changes (*kaizen*, PDSA) is the driving mechanism of sustainable improvement.
- Both recognize that measured feedback is an essential component of successful improvement efforts.
- Both see the ultimate work of improvement as transforming the culture of the organization from one based primarily on personal accountability to one based on cooperative understanding of system purpose, dynamics, and operation.

To be sure, there are differences between Lean and IHI-QI as these approaches are typically employed in health care. Table 3 highlights aspects of Lean and IHI-QI where the two approaches diverge. Appendix A provides additional detail about the intertwined histories of Lean and IHI-QI.

Table 3. Key Differences Between Lean and IHI-QI

Aspect	Lean	IHI-QI
Purpose	• Maximize customer-specified value of products or services. • Value includes cost, timeliness, absence of defects, and product or service features.	• Formulate and codify generalizable knowledge that yields predictable improvement in outcomes when applied in diverse systems. • When applied in health care, aims ideally balance patient experience, cost, and population health.
Origins	• Originated by engineers and managers working within an automotive manufacturing system. • Lean has since been extended with methods and principles for application in other contexts, including more recently in health care.	• Developed primarily by consultants working first in automotive and electronics manufacturing, and elaborated in health care systems by the IHI community.
Focus and scope	• Methods are specialized for repetitive product production within a single enterprise (including suppliers and customers); generalized to services and clinical care (with adaptations).	• Approach is abstract, includes methods for problem/aim definition applicable to any system. • Many initiatives are concerned with spread of evidence-based practices across health care systems and coalitions of enterprises.
Key principles guiding improvement	• "Value" definition provides criteria; value stream describes process. • Ideals and change concepts inherent in TPS form an integrated "template" that prompts ideas for problem mitigation and guides *kaizen* (continuous improvement).	• Profound Knowledge and the Model for Improvement apply to any system. • Program theory provides the aim and change concepts to guide testing. • Metrics provide criteria. • Iterative PDSA cycles are used in diverse conditions to develop, test, implement, and spread robust changes.
Measurement and data	• Data relevant to the process operations are embedded in the value stream as visual controls and charts showing performance over time. • Qualitative data, rooted in direct observations, is the basis for problem mitigation.	• Measures are defined as a component of content theory. • Organizational dashboards monitor performance at all levels. • PDSA-level measures evaluate changes. • Common vs. special cause variation distinctions help guide management decisions. • Run and control charts with decision rules are used to evaluate the significance of changes.

Aspect	Lean	IHI-QI
		• Qualitative data are essential for interpreting changes in context. • Data provides feedback to teams, typically tracing improvement over time.
Integrating improvement into daily work	• *Jidoka* requires constant detection and remediation of defects at the lowest possible level of the organizational hierarchy. • Managers at all levels have a key role as teachers of improvement. • Standardization and visual controls reduce complexity, thus increasing mental capacity of people to improve.	• Improvement efforts are organized around projects with time-bound goals. • Methods for implementing changes as standard work describe adoption, scale-up, and adaptation of support processes.
Primary approach to reducing variation	• Standardized work is developed by line-level staff and supervisors. • Continuous *kaizen* based on Lean change concepts to incorporate *poka-yoke* features refines standard work to reduce process variation empirically.	• Statistical process control retrospectively identifies special causes to be eliminated, to stabilize the process; redesign a stable process using the Model for Improvement based on change concepts. • Reliability theory provides change concepts to reduce errors and defects in real time.
Role of managers and executives in improvement	• Managers and executives have standard work processes, and the primary role as coaches for frontline staff. • Improvement is integrated with standard work.	• Executive sponsors are seen as necessary for initiative success. They remove barriers and support the frontline project team.

Summary and Implications

Lean and the principles of TPS are in no way antithetical to the IHI approach to quality improvement, and vice versa. Lean is, in a sense, a complex and deep "application" of Profound Knowledge, a particular deployment of improvement in the realm of production systems, though it was not purposely conceived as such.

IHI-QI is a general approach that guides the development and application of execution theories across a range of specified contexts to realize clearly stated goals. We can consider Lean and TPS to be an example of such an execution theory. The TPS package of interdependent change concepts was originally developed to optimize manufacturing production systems. It represents a "template" for improving such systems, with a set of predefined aims, change concepts, implementation roadmap, and tools. Its validity has been empirically well established in the marketplace by

competitive manufacturing firms seeking to maximize value. Lean extends the principles of TPS into a general system of distributed management.

The application of TPS and Lean in other types of systems such as health care requires adaptation of the original template to divergent organizational structures whose aims, customers, contexts, and cultures may range very far indeed from Ohno's machine shop at Nagoya. Each new application subjects TPS/Lean to a new test of its validity, where the domains, principles, and methods of improvement science come into play. The further the system of application diverges from manufacturing production, as in health care, the more the template must be adapted to yield predictable improvements.

Lean is well on its way to being validated in health care, in the sense that we can identify systems that have deployed and adapted Lean systematically and demonstrated improved performance, sustained over a period of years, that they attribute to the use of Lean principles. Practitioners of IHI-QI should recognize Lean thus applied as a success story in the larger improvement mission to develop and spread successful execution models. Improvement practitioners should seek to recognize the range of systems and contexts in which Lean is useful, and the modifications needed to adapt it when context requires.

In the view of the authors, a major lesson that IHI-QI practitioners can take from deployments of Lean in health care is its insistence that the *gemba* (the workplace) is the fundamental locus of sustainable improvement, and that point-of-care preoccupation with continuous improvement based on standard work is essential for success.

This is where the "two jobs" of everyone in health care — to do the work and to improve how the work is done — come together.

- Every person in the organization has a necessary role to play. IHI-QI initiatives typically focus on line-level processes, but too often fail to develop and integrate standard work for supervisors and executives that, in Lean, are essential to transforming the organizational culture.
- In Lean, improvement is the responsibility of the line-level work team, not specialized quality professionals or consultants. An essential component of Lean transformation is process definition and improvement by the work team in the workplace; IHI-QI initiatives typically advocate the use of cross-functional teams. IHI-QI practitioners struggling to achieve sustainable change would be well advised to explore ways to bring the improvement initiative to the workplace, instead of (or in addition to) using a quality department staff person to "drive" the project or bringing team members offsite for training and coaching. The microsystem school of health care improvement has heard this message loud and clear; it describes an improvement roadmap that concentrates on work team assessment, development, and continuous improvement.[53]
- IHI-QI practitioners should insist that they themselves, along with the leaders of the organizations with whom they work, go to the *gemba* to observe. Leaders will observe their teams in action. IHI-QI practitioners will observe the viability of their execution theory in action. Both will be better prepared to coach about improvement, and better able to adapt improvements as required.
- In complementary fashion, Lean practitioners can benefit from the diverse conceptual frameworks, program formats for spreading change, evaluation models, and practical

experience that IHI-QI offers regarding the deployment of improvement initiatives across a broad array of complex settings.

Creating a truly Lean health care organization requires a transformational commitment by leadership, followed by a steadfast, long-term commitment to building improvement capability throughout the management hierarchy. And not only capability — Lean also demands that roles, attitudes, and job descriptions are redefined at all levels of the organization. This kind of large-scale change is formidable. It is the kind of work that practitioners of IHI-QI have engaged in for the past quarter century and more. From the viewpoint of IHI-QI, a Lean deployment represents an organization-level improvement initiative that embraces a particular execution model. Planning and evaluation of Lean deployments from the IHI-QI perspective can lead to principles and practices that may accelerate the adoption of Lean in new environments, and suggest testable ideas for adapting of the Lean/TPS "template" to the unique challenges of complex health care systems.

For example, with adapted change packages and team support methods, the Breakthrough Series Collaborative model could provide a workable platform for the deployment of Lean among frontline staff and supervisors. Principles and tactics of adoption and spread could subsequently inform the systemwide transformation of organizations to a Lean culture. The design and implementation of theory-driven measurement systems can inform initiatives promoting the adoption and impact of Lean practices. Ultimately, it may be that models such as the Learning Healthcare Organization, and related principles such as the IHI Triple Aim, can extend the TPS template and change concepts to better apply in health care.[54]

For both traditions, the future is about learning what works to improve value for patients. This mutual goal, pursued with a pragmatic spirit of shared learning, can help health care practitioners and improvers work together toward "doing the work and improving the work."

Appendix A: Origins and Historical Linkage of the IHI Approach to Quality Improvement and Lean

Lean and the "IHI approach" to quality improvement (IHI-QI) share common roots in the industrializing world of the early 20th century, and have traced intertwined histories ever since.

Toyota Corporation was first established in 1918 as Toyoda Cotton Spinning and Weaving Company by Sakichi Toyoda.[55] Key principles of the Toyota Production System, including *flow* and *jidoka* — which originally denoted a loom that would stop automatically if the thread broke — had their origins in these early textile operations.[22] Toyota Motor Company, Ltd., was established as a separate entity out of Toyoda Automatic Loom Works in 1937.[55]

In the first half of the 20th century, Toyoda leaders, in keen competition with American and British textile firms, observed and creatively adapted methods from foreign manufacturing. Sakichi Toyoda, and later his son Kiichiro, regularly toured factories in Europe and the US.[55] A translation of *Principles of Scientific Management* by Frederick Taylor, the first celebrity management consultant, appeared in Japan in 1913.[56] Taylor's methods focused on process standardization, careful measurement, and field experimentation as keys to improving production efficiency. Taylor trained Japanese managers in his seminars in the US, while scientific management was popularized in Japan by Ueno Yoichi, a consultant for Kyochokai, a semi-governmental think tank. Ueno's concepts of waste — *muda*, *mura*, and *muri* — were anathema to the ideal of efficiency, and later appeared as key concepts of the Lean value stream.[56] Henry Ford's innovation of the moving assembly line, which enabled production to flow, was an important feature of Toyota's initial automobile venture. Taichi Ohno even drew inspiration from the American supermarkets of the 1950s for the *kanban* control method that is an essential feature of Just-in-Time production.[22]

Meanwhile, Walter Shewhart, a physicist working at Western Electric Bell Labs in the 1920s, was creating a functional conception of quality based on statistical distributions and the pragmatic principles of prediction and experimentation. Shewhart defined the quality of a product in terms of its future utility:

> "The judgment that the quality of any thing is such and such is from a practical viewpoint equivalent to a judgment that it will be such and such. Moreover, such a judgment is based upon… evidence obtained through certain operations on the thing or similar things in the past and implies that certain experience will result if certain operations are carried out on the thing in the future… Hence we shall consider the first origin of standards of quality… as relating past to future experience."[57]

W. Edwards Deming, a statistician, was a colleague and student of Shewhart at Western Electric. In his work at the US Department of Agriculture, Deming combined Shewhart's ideas with emerging principles in experimental design that he had absorbed while studying with R.A. Fisher at University College in London; a job at the US Census Bureau provided the opportunity to extend Shewhart's thinking beyond production systems into service operations. Following World War II, Deming was recruited by General Douglas MacArthur's occupation administration to advise the

Japanese census. While there he established relationships with engineers, who later founded the Japanese Union of Scientists and Engineers (JUSE).[58]

Shewhart invented statistical process control (SPC) charts, and with them the notion of common and special cause variation that related process standardization to the discovery of defects. Quality control could now cease to be a matter of merely inspecting for defective product, and become a continuing search to identify and eliminate the underlying causes of poor quality. Improvement for Shewhart progressed in an iterative cycle of "specification, production, inspection"; Deming refined the cycle into "design, production, sales, and market research." Deming introduced the cycle in Japan in 1951, where it became "Plan-Do-Check-Act," the essence of *kaizen* (continuous improvement) and a fundamental principle of both Lean and, as "Plan-Do-Study-Act," the Model for Improvement.[13,59]

Development of the Toyota Production System beginning in the 1950s took place in a vigorous, rapidly expanding industrial environment. While American industry, unchallenged in the postwar era, concentrated on economies of scale and cultivation of worldwide markets, Japanese companies re-engaged in broad adoption of quality control and improvement methods under the leadership of JUSE, with the aim of closing a perceived nine-fold productivity gap between American and Japanese industry.[9,60]

Both Deming and Joseph Juran, another student of Shewhart at Western Electric, took part in lectures and visits sponsored by JUSE starting in the 1950s. Deming's 1951 lectures focused on Shewhart's statistical methods. JUSE engineers soon concluded that a more comprehensive approach to quality improvement was required, and in 1954 invited Juran to deliver lectures on quality management. In subsequent years JUSE promoted education, research, and applications of quality, out of which emerged a general body of methods and concepts that JUSE called Total Quality Control (TQC), later modified and renamed Total Quality Management (TQM).[61] TQC was actively practiced at Toyota during the postwar years, and formed the ground in which TPS took root.[22,62] Deming's legacy in Japan derives from his 1950s interactions with JUSE. In 1951 JUSE established the Deming Prize, awarded annually for excellence in quality improvement. In a 1991 speech Shoichiro Toyoda, then Chairman and former President of Toyota, remarked that "every day I think about what he meant to us. Deming is the core of our management."[63]

Anxiety over the ascendancy of Japanese industry in the 1970s, due in large measure to the superior quality of Toyota automobiles and other Japanese products, led to a renewed interest in quality methods among American manufacturers. In 1980, a TV special, "If Japan Can, Why Can't We?," launched Deming on a late-life career of consulting to US firms.

In Fremont, California, the New United Motor Manufacturing, Inc., a joint venture between Toyota and General Motors, brought Toyota know-how to running a car factory in the United States in 1984. Two years later, Toyota opened an assembly plant in Kentucky. Knowledge of the Toyota Production System began to spread among Americans, who gained firsthand experience with Toyota and its supply chain. Toyota attracted the attention of researchers, including James Womack, at the International Motor Vehicle Program at MIT. Womack led the research team that coined the term "lean production" to describe Toyota's business system. Womack left MIT in 1991, and in 1997 established the Lean Enterprise Institute, which is today a leading purveyor of TPS philosophy and methods.

In 1987, Dr. Donald Berwick, then a Boston pediatrician, and A. Blanton Godfrey, then CEO of The Juran Institute, launched the National Demonstration Project on Quality Improvement in Health Care (NDP) with funding from the John A. Hartford Foundation. Twenty-four health care

organizations joined with industrial engineers in an attempt to answer the question, "Can the tools of modern quality improvement, with which other industries have achieved breakthroughs in performance, help in health care as well?"[3] The QI methods taught in the NDP were from the Total Quality Management tradition of Joseph Juran.[3] One outcome of the NDP was the founding of the Institute for Healthcare Improvement in 1991, the same year that Tom Nolan, an original member of Associates in Process Improvement (API), assumed what was to become a guiding role in IHI's mission of spreading improvement techniques in health care. IHI's early focus had been on general QI methods and tools education for health care professionals; in the mid-1990s, with the support of Nolan, attention turned to setting specific aims for improvement of the health care system[64] and developing methods to pursue them. Notable among them is the Breakthrough Series Collaborative, a multi-team project format for spread originally conceived by Berwick and Paul Batalden. The first Collaborative, focused on reducing the rate of cesarean sections, kicked off in 1994.

Tom Nolan, Ron Moen, and Lloyd Provost met when the three worked as statisticians for the US Department of Agriculture in the early 1970s. All three then pursued careers in the private sector. In 1981 Moen was hired by General Motors (GM) to be the point of contact with Deming, who had been retained as a consultant to the automaker. Nolan and Provost left their employers to consult with GM at this time and, with Moen, began working together as Associates in Process Improvement. Eventually, all three worked with Deming in his national seminar series from 1980 until Deming's death in 1993.[65] During the 1990s Moen, Provost, and Tom Nolan were joined in API by Kevin Nolan, Jerry Langley, and Cliff Norman. Together they continued to develop Deming's "Plan-Do-Study-Act" cycle into the Model for Improvement, adding the three guiding questions and insisting on prediction as a necessary starting point for useful tests.[59] API had observed that frequent, rapid testing was a characteristic of successful improvement efforts; in refining the Model for Improvement, they sought to simplify the core approach to its absolute essentials — aim, feedback, changes, and testing loop — to make it applicable in any setting, by anyone.[4] *The Improvement Guide*, written by API authors and first published in 1996, presented the Model for Improvement, a core element of IHI's approach to quality improvement.[4,5]

Since 1995, API has worked closely with IHI to extend and adapt the IHI approach to quality improvement to the distinctive needs of the health care industry. An important focus of this work has been developing program formats (e.g., Breakthrough Series Collaborative, spread initiatives, Campaigns, deep dives, educational and professional development training programs) in order to support the many health care systems implementing their own local improvement initiatives with whom IHI and API work. In the process, IHI and API have adapted a wide range of conceptual frameworks as a source of program interventions. For example, Everett Rogers' theory of the diffusion of innovations[49] informed the program strategies that appear in IHI's spread models. Political campaigns were a source of inspiration for the IHI 100,000 Lives Campaign.

Appendix B: Glossary of Common Lean Terminology

This list of terms is adapted from the IHI white paper, *Going Lean in Health Care*.[66]

5-S	Sort, Simplify, Sweep, Standardize, Self-Discipline: A visually-oriented system for organizing the workplace to minimize the waste of time.
Andon	A system that signals process defects as they occur, and empowers the operator to halt production until the problem is corrected.
Flow	The progressive achievement of tasks along the value stream so that a product proceeds from design to launch, order to delivery, and raw materials into the hands of the customer with no stoppages, scrap, or backflows.
Gemba	The "workplace," where value is created (e.g., managers "go to *gemba*" to observe production firsthand; the best ideas for improvement come from direct observation).
Heijunka	"Load leveling," or reducing the wasted overcapacity required to accommodate fluctuations in demand by managing demand or increasing the flexibility of production.
Jidoka	"Automation with a human touch" (involves appropriate use of automation, continuous inspection, and a halt to the production process when a defect is detected).
Just-in-Time	A system for producing and delivering the right items at the right time in the right amounts. The key elements of Just-in-Time are flow, pull, standard work, and *takt* time.
Kaizen	Continuous, incremental improvement of an activity to create more value with less waste.
Kanban	A signal, often a card attached to supplies or equipment, that regulates pull by signaling upstream production and delivery.
Poka-yoke	"Mistake-proofing": Process features that prevent, signal, or correct human errors as they occur, before they cause a process defect.
Pull	A system of cascading production and delivery instructions from downstream to upstream activities in which nothing is produced by the upstream supplier until the downstream customer signals a need; the opposite of push.
Standard work	A precise description of each work activity specifying cycle time, *takt* time, the work sequence of specific tasks for each team member, and the minimum inventory of parts on hand needed to conduct the activity.
***Takt* time**	Sets the pace of production to match the rate of customer demand; the "heartbeat" of the production system. *Takt* time is the available production time divided by the rate of customer demand. For example, if customers demand 240 widgets per day and the factory operates 480 minutes per day, *takt* time is two minutes.

Value	Value is expressed in terms of a specific good or a service which meets the customer's needs at a specific price at a specific time.[15] Value is created by the production system; any aspect of production that does not contribute to value is waste.
Value stream	The specific activities required to design, order, and provide a specific product or service — from concept launch, to order, to delivery into the hands of the customer.
Visual control	Signals placed in the workstream or environment that indicate the current state of the process, used to guide actions to be taken.
Waste	Anything that does not add value to the final product or service, in the eyes of the customer; an activity the customer wouldn't want to pay for if they knew it was happening.

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California Department of Public Health
Center for Health Care Quality
Licensing & Certification Program

General Acute Care Hospital Relicensing Survey

NAME OF FACILITY	DATE	NAME OF TEAM COORDINATOR

The team leader will work with the facility staff to determine which documents/items the team needs immediately and which ones are needed within a few hours. Please provide the following:	REQUESTING	RCV'D
1. **Hospital Policy and Procedures:**		
a) Infection control policy (**HSC §1255.8**).		
b) Environmental Services Policies that address cleaning/disinfection (**HSC §1255.8**).		
c) Patient safety plan (**HSC §1279.6 & HSC §1279.7(e)**).		
d) Immunizations/Vaccinations - staff & patient (**HSC §1288.7(a)** & **HSC §120392.9**).		
2. **Hospital Written Reports:**		
a) Infection surveillance & prevention program's written report, required every 3 years, & required annual updates, with revisions, if necessary (**HSC §1288.6**).		
b) Hospital strategic plan (**HSC §1288.6**).		
c) Seasonal influenza plan with disaster plan revisions for a pandemic influenza component (**HSC §1288.7(b)**).		
(d) Process for reimbursing patients for excess amounts paid on their bills, including interest owed by the hospital. (**HSC §127440**).		
4. **Healthcare Staff/ Employee Records:**		
a) Credentialing file evidence of infection surveillance, prevention, & control training attendance for the physician who has been designated as a hospital epidemiologist/infection surveillance, prevention and control committee chairperson (**HSC §1288.95(a)**).		
b) Facility infection control training program for all types of staff, which includes annual and after policy changes (**HSC § 1288.95**)		
(c) List of charity care and discount payment patientrs including outpatient services (last 3 months) (**HSC § 1288.95 (a)**).		
7. **Nutrition/Dietary Services:**		
a) Organizational Chart of Nutrition Services		
b) Personnel file of Director of Food Services (**HSC §1265.4**).		
c) Job Descriptions: Manager of Dietetic Services, Manager of Food Services and Chief Clinical Dietitian, Dietetic Technicians (if applicable)		
d) Menus for the Week: including extensions		
e) Meal and Nourishment Schedules		
f) Current Patient Diet List		

General Acute Care Hospital Relicensing Survey

Documents	REQUESTING	RCV'D
6. **Additional Items:**		
a) Current inpatient census		
b) Hospital floor plan or stacking diagram.		
c) List of key hospital personnel with phone numbers and roles.		
d) Hospital organization chart to include governing body and officers.		
e) List of current program flexibility(s)		
f) Medical Staff roster to include allied health and mid-level practitioners.		
g) List of all service locations.		
h) List of contracted services.		
i) Governing Body Bylaws/Rules and regulations.		

California Department of Public Health
Center for Health Care Quality
Licensing & Certification Program

GENERAL ACUTE CARE HOSPITAL RELICENSING SURVEY

ENTRANCE DOCUMENTS/DATA REQUEST FOR MEDICATION ERROR REDUCTION PLAN (MERP) AND PHARMACEUTICAL SERVICES

NAME OF FACILITY	DATE	NAME OF SURVEYOR

The survey process will include the California Code of Regulations Title 22, Chapter 1 and Health and Safety Code Section 1339.63. Please have available items one through three as soon as possible.

Please provide the following documents/data directly to the Pharmaceutical Consultant of the survey team:	RECEIVED √	NOTE
1. Policies and procedures related to:		
• Medication errors (e.g., reporting and analysis)		
• Medication administration (including medication administration times)		
• Emergency medication use (crash carts, malignant hyperthermia carts, etc.)		
• Automated dispensing cabinets (ADCs) including overrides and discrepancies		
• Drug storage (refrigerators, warmers, unit stock, etc.)		
• High risk medication use (transdermal fentanyl, insulin, droperidol, propofol, etc.)		
• Patient Controlled Analgesia (PCA)		
2. The current MERP and evidence of annual reviews since the previous MERP survey.		
3. List of patients that have received any of the following medications within the last 30 days: PCA delivered drugs, transdermal fentanyl, droperidol, insulin drip, heparin drip, rescue (reversal) agents, e.g., naloxone, D50W.		
4. Medication error summary reports and trends analysis since the last MERP survey.		
5. Multidisciplinary MERP committee meeting minutes and Pharmacy and Therapeutics (P&T) Committee meeting minutes since the last MERP survey.		
6. Preprinted or computer order sets for titrating medications (insulin drip, heparin, etc.).		
7. All adverse events since the last MERP survey, resulting in patient death or serious disability directly related to a contaminated drug, device, or biologic; use or function of a device other than is intended (where "device" refers to equipment associated with medication delivery); medication error or hypoglycemia (see H&SC 1279.1 [b][2][A],[b][2][B],[b][4][A], and [b][4][D].		

NATIONAL QUALITY FORUM

Performance Measurement for Rural Low-Volume Providers

Draft Report for Comment

June 1, 2015

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Executive Summary

Providers in rural areas face a number of challenges when it comes to delivery of healthcare in general and in performance measurement and quality improvement in particular. Rural areas are incredibly diverse: many are relatively close to urban or suburban areas, while others are relatively far, and others quite remote. Geographically isolated rural areas typically have relatively fewer healthcare settings and providers than non-isolated areas, and may have lack of information technology capabilities and difficulties due to transportation. Those who serve in small rural hospitals and clinician practices typically have multiple, disparate responsibilities claiming their time and attention (e.g., direct patient care, business and operational responsibilities), and consequently, often have limited time, staff, and/or finances available for quality improvement activities. Many rural areas also have a disproportionate number of vulnerable residents (e.g., economic or other social disadvantages, those in poor health, and those with poor health behaviors). This heterogeneity has particular implications for healthcare performance measurement, including limited applicability of measures that are appropriate for non-rural areas. Moreover, rural providers often may not have enough patients to achieve reliable and valid performance measurement results. While many of these challenges are not necessarily limited to rural areas, their impact on quality measurement and improvement likely is exacerbated in rural areas.

Although rural hospitals and clinicians do participate in a variety of private-sector, state, and federal quality measurement and improvement efforts, many Centers for Medicare & Medicaid Services (CMS) quality initiatives systematically exclude rural hospitals and clinicians from participation because they are paid differently than other providers. This exclusion may impact their ability to identify and address opportunities for improvement in care and result in a lack of easily-accessible information about provider performance for rural residents. Moreover, exclusion of rural providers from the CMS quality programs prevents rural providers from earning payment incentives that are open to non-rural providers.

Given the recent legislative actions by Congress and the Department of Health and Human Services' (HHS) accelerated timeframe for achieving value-driven healthcare (i.e., paying providers based on quality and cost rather than on quantity), it is now even more essential to integrate rural providers into Medicare quality improvement programs.

In 2014, HHS tasked the National Quality Forum to convene a multistakeholder Committee to identify challenges in healthcare performance measurement for rural providers and to make recommendations for mitigating these challenges, particularly in the context of CMS pay-for-performance programs. The specific objectives of this project are to:

- Make recommendations regarding measures appropriate for use in CMS pay-for-performance programs for rural hospitals and clinicians
- Make recommendations to help mitigate measurement challenges for rural providers, including the low-case volume challenge
- Identify measurement gaps for rural hospitals and clinicians

Providers of interest for the project include Critical Access Hospitals (CAHs), Rural Health Clinics (RHCs), Community Health Centers (CHCs), small rural hospitals, small rural clinical practices, and the clinicians who serve in these settings.

In addressing the objectives of this project, the 20-member Committee made the following recommendations:

- Make participation in CMS quality improvement programs mandatory for all rural providers but allow a phased approach for full participation across program types
- Use measures for rural providers that explicitly address low case-volume
- Use guiding principles for selecting quality measures that are relevant for rural providers
- Use a core set of measures, along with a menu of optional measures for rural providers
- Consider measures that are used in Patient-Centered Medical Home models
- Consider rural-relevant sociodemographic factors in risk adjustment
- Create a MAP workgroup to advise CMS on the selection of rural-relevant measures
- Pursue continued alignment of measurement efforts for rural providers
- Fund development of rural-relevant measures. The Committee identified the following topic areas as some of the most impactful for rural providers at this time:
    - Patient hand-offs and transitions
    - Alcohol/drug treatment
    - Telehealth/telemedicine
    - Access to care and timeliness of care
    - Cost
    - Population health at the geographic level
    - Advance directives/end-of-life
- For rural providers, create payment programs that include incentive payments, but not penalties
- Offer rewards for rural providers based on achievement or improvement
- Encourage voluntary groupings of rural providers for payment incentive purposes
- Fund additional work to consider how peer groups for rural providers should be defined and used for comparison purposes
- When creating and using composite measures, ensure that the component measures are appropriate for rural (particularly low-volume) providers

Lastly, the Committee provided additional recommendations that would benefit other quality measurement and improvement efforts for both rural and non-rural providers:

- Relax requirements for use of vendors in administering Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys and/or offer alternative data collection mechanisms
- Facilitate quicker and broader access to performance scores and to Medicare data for quality improvement purposes
- Facilitate inclusion of CMS data into all-payer databases

Many of the above recommendations are applicable not only to CMS quality improvement initiatives, but also to efforts of other stakeholders, including various public- and private-sector entities.

Project Overview

Healthcare performance measures increasingly are being used by both public and private purchasers and insurers for various types of accountability applications, including accreditation, network inclusion/exclusion, public reporting, and payment incentive programs. For those providing care in rural areas, however, participation in performance measurement and improvement efforts may be especially challenging. Although rural hospitals and clinicians do participate in a variety of private-sector, state, and federal quality measurement and improvement efforts, many Centers for Medicare & Medicaid Services (CMS) quality initiatives systematically exclude rural hospitals and clinicians from participation.

In 2014, the Department of Health and Human Services (HHS) contracted with the National Quality Forum (NQF) to convene a multistakeholder Committee to identify challenges in healthcare performance measurement for rural providers and to make recommendations for mitigating these challenges, particularly in the context of pay-for-performance programs operated by CMS.

Background and Context

With the publication of the Institute of Medicine's (IOM's) landmark reports *To Err is Human* and *Crossing the Quality Chasm* in 1999 and 2000, respectively, Americans became aware of the serious deficiencies in the safety and quality of America's healthcare system. These reports prompted numerous and varied efforts across a multitude of stakeholder groups to improve healthcare quality and safety. An essential component of these improvement efforts is the performance measurement enterprise: the development, implementation, and use of performance measures for assessing care quality, safety, cost, and efficiency.

More recently, the Affordable Care Act mandated the creation of a National Strategy for Quality Improvement in Health Care (the "National Quality Strategy" or NQS). The NQS articulated three objectives for healthcare quality improvement (the "triple aim"): better care, affordable care, and healthy people and communities. To achieve these objectives, the NQS identified the following six priorities: reducing harm to patients, facilitating communication and care coordination, empowering patients and families to be involved in their care, implementing evidence-based prevention and treatment, promoting healthy behaviors and environments at the community level, and implementing new healthcare delivery models that simultaneously reduce costs and improve quality.[a] Together, these objectives and priorities serve as the "blueprint" for healthcare performance measurement in the U.S.

The ultimate goal underlying healthcare performance measurement is to improve the quality of care delivered to patients and their families, and ultimately, to improve their health. Performance measurement results are used for a variety of purposes, including:

[a] Robert Wood Johnson Foundation (RWJF). *What is the National Quality Strategy?* Princeton, NJ:RWJF; 2012.

- internal quality improvement efforts by clinicians, hospitals, nursing facilities, health plans, etc.
- public reporting to inform healthcare consumers and aid in decisionmaking
- accreditation and certification
- healthcare network inclusion, exclusion, or tiering decisions
- various types of payment incentive programs by both public and private payers

CMS, the nation's largest healthcare insurer and purchaser, has instituted many setting- and provider-based programs aimed at driving healthcare improvement, increasing transparency, and influencing payment.[b] Earlier programs have run the gamut from encouraging voluntary participation in reporting performance results to CMS (often through financial incentives) to publicly reporting quality measure results to applying negative payment adjustments (i.e., "penalties") if results are not reported. More recently, programs created under the Affordable Care Act have instituted payment adjustments, including bonuses and sometimes penalties, based on results of both quality and cost measures (i.e., pay for performance).

However, many of the CMS quality improvement programs systematically exclude certain facilities and clinicians for programmatic, methodological, or other reasons. For example, many of the CMS hospital-based programs exclude facilities that are not paid through the Inpatient Prospective Payment System (IPPS). Similarly, the CMS clinician-based programs currently exclude providers who are not paid under the Medicare Physician Fee Schedule (e.g., those providing services through Federally Qualified Health Centers [FQHCs]). Moreover, those hospitals and clinicians that do not meet requirements for a minimum number of cases may not be able to participate fully in the various CMS programs (for example, their results would not be publicly reported).

A large proportion of the hospitals, clinics, and clinicians that are excluded from these CMS quality programs operate in rural areas. Therefore, many care providers serving rural communities do not receive financial incentives and comparative performance data that are provided through the programs for the purpose of spurring improvement. Moreover, rural patients and their families may not have access to publicly-reported performance results for many of their healthcare providers.

As CMS programs and policies evolve, however, it is likely that many more rural providers will be subject to CMS pay-for-performance (P4P) programs. For example, although program expansion for non-prospective payment system (PPS) hospitals is not imminent, the Affordable Care Act mandates a demonstration program to inform how typically-excluded facilities can participate in the Hospital Value-Based Purchasing (HVBP) program. Also, under current rule, only physicians in practices with 100 or more eligible professionals are included in the Value-Based Payment Modifier (VBPM) program for 2015; however, this program will be extended to all fee-for-service Medicare clinicians (both physicians and non-physicians) by 2018.

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[b] Goodrich K, Garcia E Conway PH. A history of and a vision for CMS quality measurement programs. *Jt Comm J Qual Patient Saf*. 2012; 38(10):465-470.

In January of 2015, HHS unveiled its goals and a timeline for "rewarding value" rather than volume. Specifically, it aims to have 30 percent of Medicare payments in alternative payment models (e.g., Accountable Care Organizations (ACOs), primary care medical home (PCMH) models, bundled payment arrangements) by the end of 2016 (50 percent by the end of 2018) and to link 85 percent of Medicare fee-for-service payments to quality by 2016 (90 percent by 2018) through programs such as the HVBP and the Hospital Readmissions Reduction Program.

In April of 2015, Congress passed the Medicare Access and CHIP Reauthorization Act (MACRA), which repealed the Medicare's Sustainable Growth Rate formula (created to contain the growth of Medicare spending on physician services). Beginning in 2019, physicians and other eligible professionals will participate in one of two payment pathways:

- *Merit Based Incentive Payment System (MIPS*), which will adjust fee-for-service payments with a bonus or penalty, depending performance on quality, resource use, clinical practice improvement activities, and meaningful use of electronic health record systems. This program will consolidate the current Physician Quality Reporting System (PQRS), Value-Based Payment Modifier (VBPM), and Meaningful Use programs
- *Alternative Payment Model (APM*), which will provide bonus payments for clinicians who participate in a qualified APM in which providers will take on substantial financial risk

It is unclear at this time the extent to which these two new policy changes will affect rural providers.

While many stakeholders desire the eventual participation of currently-excluded rural providers in CMS quality improvement programs, including P4P programs, the very rurality of these providers may pose significant measurement and design challenges for the various programs. These rural providers are influenced by both the geography and the culture of the areas and populations they serve. Regardless of the methodology used to define the rural population of the U.S.,[c] statistics indicate that those living in rural areas may be more disadvantaged overall than those in urban or suburban areas, particularly with respect to sociodemographic factors, health status and behaviors, and access to the healthcare delivery system.[d] For example, people in rural areas are more likely than others to have lower incomes, lower educational attainment, higher unemployment rates, and higher rates of poverty.[e] According to data

[c] Depending on the definition, as few as 10 percent, or as many as 28 percent, of Americans live in rural areas. See: Hart LG, Larson EH Lishner DM. Rural definitions for health policy and research. *Am J Public Health*. 2005; 95(7), 1149-1155. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449333/pdf/0951149.pdf; Last accessed January 2015. Crosby RA, Wendel ML, Vanderpool RC, et al. *Rural Populations and Health: Determinants, Disparities, and Solutions*. San Francisco, CA: John Wiley & Sons; 2012.

[d] However, it should be noted that rural areas are heterogeneous, and there may be substantial variation from one area to the next.

[e] U.S. Department of Agriculture State Fact Sheets website. Available at http://www.ers.usda.gov/data-products/state-fact-sheets/state-data.aspx?StateFIPS=00. Last accessed January 2015.

from the *2014 Update of the Rural-Urban Chartbook,*[f] those in rural areas are, in general, more likely to be older (i.e., ages 65 and above).[g] Rural residents also are more likely to engage in certain riskier health behaviors, such as smoking among adolescents and adults and leisure-time physical inactivity, and have higher overall mortality in all age categories (i.e., children and young adults, working-age adults, and those 65 and older), compared to those in other geographical areas. Healthcare provider shortages, as well as limited availability of other resources such as technological expertise and transportation networks in rural areas, also affect how care is delivered (e.g., transfer of high-acuity patients to other facilities for specialty care). Moreover, many rural providers face challenges in quality measurement and associated accountability efforts because of low patient volume, which can impact the reliability, validity, and utility of performance metrics.

Project Objectives and Approach

The specific objectives of this project are to:

- Make recommendations regarding measures appropriate for use in CMS pay-for-performance programs for rural hospitals and clinicians
- Make recommendations to help mitigate measurement challenges for rural providers, including the low-case volume challenge
- Identify measurement gaps for rural hospitals and clinicians

Providers of interest for the project include[h]:

- Critical Access Hospitals (CAHs)
- Rural Health Clinics (RHCs)
- Community Health Centers (CHCs)
- Small rural hospitals
- Small rural clinical practices
- Clinicians who serve in these settings

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[f] There is some indication, however, that relatively fewer of the "oldest old" (i.e., those 85 and older) live in rural areas. See MedPAC. Serving rural Medicare beneficiaries. In: *Report to the Congress: Medicare and the Health Care Delivery System.* Washington, DC:MedPac;2012:115-137..

[g] There is some indication, however, that relatively fewer of the "oldest old" (i.e., those 85 and older) live in rural areas. See MedPAC. Serving rural Medicare beneficiaries. In: *Report to the Congress: Medicare and the Health Care Delivery System*. Washington, DC:MedPac;2012:115-137.

[h] A glossary of terms that provides definitions for these providers, as well as other terms used throughout this report, is included in Appendix A.

NQF convened a 20-member multistakeholder Committee to accomplish the purpose and objectives of the project. Committee members were appointed based on their expertise and experience in statistical methodology, delivery of health care in rural areas, and/or implementation of quality performance measurement programs. Committee members include representatives from various stakeholder groups including private insurers, purchasers, payers, employers, consumers, Medicaid program staff, as well as providers from CAHs, RHCs, CHCs, and small rural hospitals and clinician practices (see Appendix C). The timeline for the project is included in Appendix B.

To help inform the Committee's deliberations regarding salient measurement issues that are associated with providing healthcare in rural areas, NQF conducted an environmental scan to identify performance measures and measurement efforts that are being used by both public and private entities to assess and influence rural providers and to identify and describe how these measures and programs are being used and validated to accurately reflect quality, cost, and/or resource use. To inform this environmental scan, NQF reviewed relevant peer-reviewed and grey literature and publicly available repositories of measures (including NQF's portfolio of measures). NQF also sought input from the NQF members and key informants. Key results from the scan included a catalogue of more than 1000 hospital- and clinician-level performance measures, which were tagged according to selected condition or topic areas, rural relevancy, and use in various Federal quality improvement programs. Measures were tagged as relevant for rural providers based on both published and on-going efforts to identify measures useful and meaningful for CAHs and RHCs.

Key Issues Regarding Measurement of Rural Providers

Throughout the project, the Committee identified several key issues and challenges that can negatively influence quality measurement and/or improvement activities for rural providers, most of which are interrelated to a greater or lesser extent. These include:

- ***Geographic isolation*.** Although not all rural areas are geographically isolated, many are. This isolation can result in limited availability of healthcare providers, including specialists and post-acute care providers, difficulties with transportation, and lack of broadband access that can severely limit information technology capabilities. It also can negatively impact the amount of support available from referral, academic, or other leadership centers that might otherwise supply significant medical, educational, or other resources.
- ***Small practice size***. Many rural hospitals and clinician practices tend to be small and these often have limited time, staff, and/or finances available for quality improvement activities including data collection, management, analysis, reporting, and improvement. In many rural areas, there is a limited supply of individuals with specialized technological skills (e.g., ability to use EHRs or registries for measurement calculation/improvement) and/or quality improvement skills to use measurement results to drive improvements in care. Lack of financial resources also impacts ability to invest in HIT infrastructure and in quality improvement initiatives. Finally, those who serve in small hospitals and practices often have multiple, disparate responsibilities (e.g., direct patient care, business and operational responsibilities, etc.) that compete with quality improvement activities.

- ***Heterogeneity*.** There is incredible heterogeneity across rural areas of the U.S. While many rural areas are relatively close to urban or suburban areas, many are not, and in fact, many are quite remote[i]. Many rural areas, particularly frontier areas, must contend with seasonal hazards that impact care provision. As noted earlier, many rural areas (although not all) also have a disproportionate number of vulnerable residents (e.g., economic or other social disadvantages, those in poor health, those with poor health behaviors, etc.). This heterogeneity is a particular issue for healthcare performance measurement, with implications regarding the applicability of measures or measure sets, adjustment of measures for patient characteristics, reliability of measures, and use of measures. This heterogeneity in setting and patient population also drives diversity among providers, which has implications when comparing providers for accountability purposes.
- ***Low case-volume*.** Many rural providers do not have enough patients to achieve reliable and valid measurement results. This may be particularly true for certain condition-specific measures and/or providers in more isolated rural areas. Relatedly, many rural providers may not offer a full suite of healthcare services. (e.g., some small hospitals or CAHs may not do surgery, have ICUs, etc.) and thus some measures used in various quality improvement programs may not be applicable.

The Committee acknowledged that most of these challenges are not limited to rural areas, but members believe that their impact on quality measurement and improvement likely is exacerbated in rural areas.

The Committee also noted several additional challenges that arise due to the way CAHs, RHCs, and CHCs are paid for services provided to Medicare beneficiaries. Although CAHs bill Medicare Part A for their services like other hospitals, the payment is cost-based versus based on diagnosis-related groups (DRGs). There is anecdotal evidence that the diagnostic and procedural coding for CAHs may not be as accurate as that done in hospitals that are paid based on DRGs; moreover, there is concern that patients seen in CAHs may have relatively higher acuity than is indicated through the diagnosis codes that are documented. However, if coding is not accurate, comparison of provider performance may not be accurate when claims-based measures are used. This may be exacerbated for outcome measures that are risk-adjusted using diagnostic and/or procedural data.

RHCs also are paid on a cost-basis through the Medicare Part B trust fund, although they actually submit Medicare Part A claims. However, because the services are billed through Part A, services are described using revenue center codes rather than through CPT codes that are used by most other clinicians when they submit Part B claims. Thus, most of the performance measures specified for clinicians using claims data may not be applicable to clinicians in RHCs because the measures are specified using CPT codes (unless the RHCs are also reporting CPT codes as well as revenue center codes). Also, clinicians working

[i] The Federal government distinguishes between various "levels" of rurality. "Frontier" areas are the most remote and sparsely populated rural areas. Depending on the definition used, between 5.6 and 9.9 million Americans live in frontier areas.

in RHCs occasionally provide services that fall outside those covered by RHCs (e.g., more extensive diagnostic services) and these are billed to Medicare Part B. Thus, these clinicians may provide some services that could be reported to CMS programs such as Physician Quality Reporting System (PQRS), but the bulk of the services they supply is not captured in PQRS. As with RHCs, CHCs bill Medicare Part A primarily (although some services are billed through Part B); thus, it is unclear the extent to which current claims-based measures can be used for these providers.

Recommendations

After discussion of many of the rural health and setting-specific challenges related to performance measurement of rural providers, the Committee agreed that their recommendations should, at minimum, address the following four key issues:

- Low case-volume
- Need for measures that are most meaningful to rural providers and their patients and families
- Alignment of measurement efforts
- Mandatory versus voluntary participation in CMS quality improvement programs

The Committee offered their recommendations under two key assumptions. First, past experience of quality measurement and improvement efforts can be used to inform future efforts for rural providers, many of whom have, to date, been excluded from CMS quality initiatives. Second, the design of current CMS quality programs (including how measures are developed, selected, and used and how payment incentives are allocated) should not constrain recommendations for future measurement and improvement efforts for rural providers.

As should be expected, because many of the challenges of measurement for rural providers are interconnected, so also are many of the recommendations to address these challenges. Consequently, the order of the recommendations should not be construed as a listing of "most important to least important" recommendations. Instead, they should be considered a compendium of policy recommendations that are, to a large extent, interdependent. Importantly, many of the recommendations made by the Committee directly address the low case-volume challenge, while several others address this challenge indirectly.

Make participation in CMS quality improvement programs mandatory for all rural providers but allow a phased approach for full participation across program types

As mentioned earlier, many rural healthcare providers are systematically excluded from participation in various CMS quality improvement programs. Specifically, CAHs are not mandated to report quality measure data for the Hospital Compare program, although they can *voluntarily* submit data for public reporting through this program. CAHs, are, however, completely excluded from the Inpatient Quality Reporting (IQR), Outpatient Quality Reporting (OQR), and Hospital VBP programs because they are not

paid under the Medicare's hospital IPPS. Likewise, clinicians who practice solely in RHCs and CHCs are not eligible to participate in the PQRS, Physician Compare, or VBPM programs.[j] Moreover, rural providers in these or other settings (i.e., small hospitals or small practices) may be unable to fully participate in these programs on a measure-by-measure basis due to low case-volume.

Because these rural providers are systematically excluded from these highly visible quality improvement programs, there is some concern that they may be less likely to implement comprehensive quality measurement efforts, thus impacting their ability to identify and address opportunities for improvement in care. Exclusion from such programs also may imply, inadvertently, that measurement and improvement efforts on behalf of rural residents are unimportant to the U.S. healthcare system as a whole. Exclusion from these programs also results in a lack of easily-accessible information about provider performance for rural residents. Not only does this lack of data deny many rural residents the ability to choose providers based on performance, it also may suggest, again inadvertently, that rural providers cannot provide high-quality care and consequently drive the outmigration of patients from rural hospitals and practices. In such cases, rural residents may decide to seek care from non-rural providers, which may increase the burden of rural residents (e.g., having to drive further to obtain care) and could also negatively impact the financial viability of rural providers. Finally, exclusion of rural providers from the CMS quality programs also prevents rural providers from earning payment incentives that are open to non-rural providers. Accordingly, the Committee recommended that CMS should not only allow participation in quality initiative programs for all rural providers, but should make such participation mandatory. ***This recommendation for mandatory participation for all rural providers is, however, contingent on uptake of several of the other Committee recommendations, particularly those related to measure selection and use, payment incentive options, and alignment*.**

The Committee recognized that requiring participation of all rural providers across all of the various CMS programs, including the pay-for-performance programs, cannot and should not be implemented immediately. This is due to a variety of factors, including the relative inexperience of many rural providers in federal quality measurement efforts, constrained resources of many rural (particularly small) providers, and the low case-volume challenges inherent in many measures included in current CMS programs. Accordingly, the Committee strongly supported the use of a phased approach for including CAHs, RHCs, and CHCs in CMS quality improvement programs.

One option might be to begin including rural providers in pay-for-reporting programs and then gradually transition to public reporting and then, perhaps, to pay-for-performance programs. Such a phased approach would be consistent with past CMS policy for providers in other settings. For example, in the PPS hospital setting CMS instituted pay-for-reporting programs to incentivize providers to report quality data on a set of performance measures. At about the same time, CMS also began to publicly report

[j] These clinicians can participate in these programs when they provide services outside of the RHC and CHC settings. Similarly, clinicians providing outpatient services in CAHs can participate in PQRS going forward, even if he/she has reassigned billing rights to the CAH.

measure results in order to provide information to consumers, payers, purchasers, and other stakeholders to help inform their decisionmaking regarding healthcare issues. Subsequently, CMS implemented a value-based payment program whereby hospitals received incentives based on their performance on certain quality and cost measures. Over time, CMS has changed the incentive structure so that negative payment adjustments ("penalties") are applied if providers fail to report quality data, reach a performance threshold, or show improvements in their performance score (depending on the particular program). For PPS hospitals, this transition from pay-for-reporting to value-based purchasing with both positive and negative payment adjustments has been underway for more than a decade. CMS has implemented a similar, though not quite identical path, for clinicians paid through the Medicare Physician Fee Schedule (as well as for providers in other post-acute care/long-term care settings), although the timeframe has been relatively more aggressive. As noted earlier, the evolution of value-based payment incentive programs for clinicians will continue with implementation of the MACRA.

Committee members recognized, however, that many rural providers (e.g., those CAHs who have been voluntarily reporting performance scores for public reporting through Hospital Compare) may not need or want a formal phased approach that transitions through types of programs. One solution would be to mandate participation in an overall quality improvement program, but to structure the rewards in a hierarchical manner (e.g., providers who simply report performance scores to CMS would earn a certain bonus amount, those who allow their scores to be publicly reported would earn an additional amount, and those whose performance meets a certain threshold for achievement and/or improvement would earn an even higher bonus).

Use measures for rural providers that explicitly address low case-volume

The key measurement challenge facing rural providers, no matter the setting, is the likelihood of low case-volume for many measures used in current CMS quality improvement programs. As already mentioned, potential solutions to this problem are weaved throughout many of the Committee's recommendations. Additional recommendations by the Committee specific to this challenge include:

- ***Use measures that are broadly-applicable across rural providers***. The Committee identified several topic areas (e.g., vaccinations, screening, blood pressure control, diabetes control, medication reconciliation) that would apply to a large proportion of patients served by rural providers. Such measures should be considered for use in core and optional measure sets available to rural providers (a recommendation described later in this report).
- ***Consider measures that reflect the wellness of the community***. Because many factors affect community wellness, population-based measures do not assess performance of individual providers, although they may sometimes be used for individual clinician-level or facility-level accountability. Although these types of measures address one of the triple aims of the National Quality Strategy (i.e., increasing the health of the population), the Committee did not support use of such measures for in pay-for-performance initiatives for rural providers. However, members did recognize the usefulness of population health measures for internal quality improvement purposes at the provider level. Because the denominator for these kinds of measures is a particular sub-population (e.g., community, region, age-based group, etc.) there typically would be no difficulty in terms of case-volume.

- ***Reconsider exclusions for existing measures***. Many measures, often for valid reasons, exclude large numbers of patients. As an example, the HCAHPS measures exclude patients who are residents of nursing facilities or who receive hospice care due to the difficulty in collecting data from these patients and the concern that they may conflate their hospital experiences with those of the nursing facility or hospice. However, for rural providers with very small patient panels, the exclusion of these patients exacerbates the low case-volume challenge, as potentially many otherwise eligible patients are not surveyed. Measure developers should consider the impact of low case-volume for certain providers when developing and revising measures.
- ***Consider development and use of measures that are constructed using continuous variables.*** Measuring an aspect of care using a continuous variable rather than a binary variable may require a smaller sample size to detect meaningful differences between providers. Examples of this type of measure would be assessing the time until a medication is given rather than just whether or not a medication was given or measuring the number of preventive services received rather than whether or not preventive services were received. Note, however, that care should be taken when considering such measures for rural providers (particularly timing measures), as such measures would be sensitive to outliers and because the environmental context could potentially invalidate comparisons between providers.
- ***Consider development and use of ratio measures.*** Ratio measures are measures where the numerator is not necessarily a part of the denominator. For example, in a measure of bloodstream infections, the number is the number of bloodstream infections but the denominator may be the number of days where the patient has a central line. These kinds of measures could circumvent the low case-volume problem because each patient could contribute many "units" to the denominator.

It should be noted that the above recommendations will not necessarily eliminate the low case-volume challenge for all rural providers, but they are options that may ameliorate the problem to some extent for some providers.

Use guiding principles for selecting quality measures that are relevant for rural providers

The Committee did not perceive creating lists of specific measures for use in CMS accountability programs as within their purview during this current project, particularly as the specific measures may vary based on provider (hospital vs. clinician) and use (e.g., pay for reporting vs. for performance), and because measures may "transition" from one use to another over time as experience builds. Instead, Committee members identified several principles[k] that should be used by CMS or other stakeholders when selecting measures for inclusion in quality improvement programs that are appropriate for rural healthcare providers. Many of the principles are consistent with the criteria used by NQF to evaluate individual candidate performance measures for potential endorsement. The NQF measure evaluation criteria reflect desirable characteristics of performance measures and are used to determine the

[k] Note that the Committee made additional, separate recommendations related to many of these principles.

suitability of measures for use in both internal quality improvement efforts and in accountability applications, including pay-for-performance. Several of the principles also are consistent with the measure selection criteria used by the Measure Applications Partnership (MAP), an NQF-convened mulitstakeholder group that is charged with providing recommendations to HHS on the selection of quality performance measures for at least 20 federal quality improvement programs. The MAP criteria are intended to assist the MAP with identifying characteristics that are associated with ideal measure sets used for public reporting and payment programs.

The following table lists the Committee's suggested principles for selecting measures to be used to assess performance of rural providers. The table indicates whether the principle is currently included as part of the NQF's endorsement criteria, the MAP's measure selection criteria, both, or neither. It should be noted that although many of the principles overlap with NQF endorsement or MAP criteria or are applicable across multiple settings and providers (not just rural providers), there often is a particular rural perspective that should be considered in the measure selection process.

Table 1: Principles for selecting measures to assess performance of rural providers

Principles	NQF Endorsement Criteria	MAP Measure Selection Criteria
Address the low case-volume challenge. Because many rural areas will have small sample sizes that will impact measure reliability, measures used for rural providers should be broadly applicable for most rural providers.		
Facilitate fair comparisons for rural providers. Because of the heterogeneity of rural providers as well as challenges (e.g., distance) that are particularly relevant to rural (as opposed to urban or suburban) providers, selected measures must allow for fair comparisons between providers. This can be accomplished either through the construction of the measure itself (e.g., through appropriate case-mix adjustment) or through program policy such as establishing appropriate peer groups for comparison, or both.		
Address areas of high risk for patients. The Committee noted that some care processes should "just happen" regardless of provider or size of patient panel and these should be prioritized for selection into quality improvement programs (e.g., medication reconciliation).		

Principles	NQF Endorsement Criteria	MAP Measure Selection Criteria
Support local access to care. To the extent possible, the Committee favors use of measures that promote provision of care at the local level. The Committee recognized that such measures may not yet exist (e.g., telehealth measures). They also noted that such measures may not necessarily be appropriate for individual providers, but instead be better suited for "higher" levels of analysis such as health plans, ACOs, or even geographic populations.		
Address actionable activities for rural providers. It is important to realize that not all medical conditions or procedures are addressed by all rural providers and therefore many measures may not be appropriate for use with rural providers. Additionally, some activities (such as triage and transfer) may be more common among rural providers. Some Committee members suggested that measures selected for use for providers who are new to quality measure reporting should be completely within the control of the provider (e.g., process measures vs. outcome measures). However, the Committee did not reach consensus on this aspect of selection, as many outcome measures certainly can be influenced, if not directly controlled, by providers. Moreover, improvement activities initiated as a consequence of outcome measures necessarily require local solutions.		
***Be evidence-based*.** Measures should be supported by empirical evidence demonstrating clinical effectiveness and a link to desired health outcomes.	X	
Address areas where there is opportunity for improvement. In some cases, measures that are “topped out” in some areas of the country may still offer opportunity for improvement in rural areas and thus these should be considered for selection into programs for rural providers.	X	
Be suitable for use in internal quality improvement efforts. Because the primary goal of measurement is to improve the quality of care received by patients and their families, rural providers should be able to use measures selected for various external programs in their own internal quality improvement efforts.	X	

Principles	NQF Endorsement Criteria	MAP Measure Selection Criteria
Require feasibility for data collection by rural providers. Because of resource constraints, the data collection process can be overly burdensome for many rural providers. Thus, measures selected for use in CMS programs should rely on data that are readily available or are feasible to collect (e.g., in structured data fields in EHRs). In addition to reducing the burden of reporting, ease of data collection can also facilitate internal quality improvement efforts because often the same staff members who collect the data also implement improvement activities.	X	X
Exclude measures that have unintended consequences for rural patients. Measures that could potentially hinder access to healthcare in rural communities should not be selected for use in quality improvement programs.	X	X
Be suitable for use in particular programs. All measures have strengths and weaknesses, but there is general consensus that only the "strongest measures" (in terms of evidence, reliability, validity, etc.) should be used in pay-for-performance programs. Relatedly, measures selected for particular programs ideally should be diverse in type and in terms of burden required of rural providers. Moreover, they should be useful for the programs for which they are selected (for example, measures used for public reporting should be meaningful for consumers and purchasers who use the results for decisionmaking).		X
Select measures that align with other programs. Alignment with other programs will help reduce measurement burden for rural providers; this will be particularly relevant for rural providers with severe financial or staff constraints.		X
Support the triple aim. Measures chosen for use in CMS programs should support each of the aims for the National Quality Strategy (NQS): better care, healthy people/healthy communities, and affordable care. Because many rural communities have a high percentage of socially, economically, or medically disadvantaged residents, measures that support the aim of creating and maintaining healthy communities may be particularly salient.		X

Use a core set of measures, along with a menu of optional measures, for rural providers

As noted earlier in this report, there is tremendous heterogeneity in the services that are delivered by rural providers as well as in the patients they serve. For example, some CAHs provide surgical care while others do not; similarly, some providers may serve a substantial number of patients with diabetes, while others may serve very few. For example, only 76 percent of rural hospitals with 25 or fewer beds perform inpatient surgery, compared to 93 percent of rural hospitals with 26-50 beds; also, less than 20% of the smallest hospitals have Intensive Care Units (ICUs), while more than 90% of hospitals with more than 50 beds offer this care. [I]

To address this heterogeneity, Committee members recommended use of a core set of measures in CMS programs for rural providers (ideally, no more than 10-20) and that this core set be supplemented by a menu of optional measures that can be used as applicable. Measures in the core set should be cross-cutting rather than disease-specific (e.g., address primary and preventive care), while measures in the optional set would allow the flexibility needed to tailor measurement based on the types of patients served and the types of services offered. Moreover, the number of measures available in the optional set must be large enough—and the number of measures to be reported on must be small enough—that providers with even the smallest case volumes should be able to find applicable measures. A key advantage of use of a core set of measures is that users of measures would be able to compare all rural providers across a small set of measures.

The Committee noted that a variety of measure types (including structural, process, outcome, patient experience, and composite measures) should be available in these core and optional sets. While members agreed that outcome measures are particularly desirable, they noted that low case-volume may be a particular challenge for some providers, depending on the measure. However, they also recognized that patient experience measures (one type of patient-reported outcome measure) might be particularly relevant for rural providers and would likely not suffer as badly from low case-volume challenges, as they are typically not condition- or service-specific. However, the Committee recognized the potential data collection burden and cost implications for these kinds of measures.

Finally, the Committee also recommended that measures used in the core and optional sets use a variety of data collection strategies and data sources, so that the burden of data collection is minimized. The Committee specifically cautioned against including measures in the core and optional sets that rely on the efforts of few individuals. This recommendation is particularly relevant for very small practices that have limited staff (e.g., nurses who have the expertise to abstract data for measurement but who must also provide direct patient care).

[I] The 21st Century Rural Hospital. A Chart Book. March 2015. Available at: http://www.shepscenter.unc.edu/wp-content/uploads/2015/02/21stCenturyRuralHospitalsChartBook.pdf

Measures included in such a core set should be broadly applicable to a majority of patients in rural settings, and measures chosen by providers from the optional set should be those for which they have a large enough patient pool. Examples of measures that would be appropriate for the core measure set would include screening, immunization, or medication reconciliation measures. While this would not necessarily solve the low case-volume problem for all rural low-volume providers, it would greatly reduce the number of providers who have too few patients for reliable and valid measurement.

Interestingly, use of a core set of measures was advocated in an April, 2015 report released by the Institute of Medicine. This report, *Vital Signs: Core Metrics for Health and Health Care Progress,* recommended a set of 15 "core measures" that will provide consistent benchmarks for health progress across the nation and improve system performance in the highest-priority areas. Additional "related priority measures" also were identified for each of the core measures. The core measures included, among others, well-being, addictive behavior, care access, preventive services, and patient safety (these also were identified by the Committee as priority areas for rural-relevant measurement; see below).

Consider measures that are used in Patient-Centered Medical Home models

Because much rural healthcare involves the delivery of primary care, and because many public and private efforts currently are directed towards the establishment of PCMHs, the Committee recommended particular consideration of measures used in PCMH models. Many such measures exist, conform to the principles cited above, and are already in use by many rural providers (thus reducing the burden of data collection). Examples of such measures include those focused on breast, cervical, and colorectal cancer screening, poor control of HbA1c, blood pressure control, and pneumonia vaccination.

Consider rural-relevant sociodemographic factors in risk adjustment

In response to recommendations by a multistakeholder panel of experts in healthcare performance measurement and disparities, NQF recently lifted, for a 2-year trial period, a previous prohibition against including sociodemographic (SDS) factors (e.g., age, race, ethnicity, income, educational attainment, primary language, etc.) in risk adjustment (also known as case mix adjustment) of healthcare performance measures.

Because many patients served by rural providers are socially and/or financially disadvantaged, the Committee applauded this change in policy, seeing it as a way to facilitate more valid comparisons among rural providers. In addition to many of the factors already identified by NQF's SDS Expert Panel (income, education level, insurance status), the Committee also recommended that the following rural-relevant SDS factors be considered in potential risk adjustment methodologies:

- Distance to referral hospital
- Time of travel to referral hospital or physician office
- Availability of other healthcare resources in the area (e.g., primary care provider density, availability of home health, nursing facilities, or hospice)
- Shortage area designations defined by HRSA (i.e., Health Professional Shortage Area, Medically Under-Served Areas, Medically Under-Served Populations)
- Frontier area designations

Some members of the Committee also noted that the size of the medical staff reflects the availability of resources and therefore might merit consideration in risk-adjustment methodologies. However, the size of the medical staff is not a patient-related factor and therefore may not be appropriate for case-mix adjustment of healthcare performance measures. Similarly, it is unclear whether other factors such as seasonality (which is important in rural areas where weather can severely restrict travel) are appropriate for case-mix adjustment.

Relatedly, the Committee also recommended that at least one rural health expert be empanelled on the yet-to-be-formed NQF Disparities Committee, the formation of which was recommended by NQF's SDS Expert Panel. The work of the NQF Disparities Committee will be to monitor implementation of the revised policy, monitor for unintended consequences (particularly for disadvantaged patients and safety net providers), assess trends in disparities, review and provide guidance related to methodologies for adjustment and stratification (e.g., use of community factors, collection of standard sociodemographic data), and help ensure that social and demographic disparities in care do not get overlooked, but rather remain an integral part of quality measurement. This Committee will have the expertise needed to determine if the above-listed factors would be suitable for case-mix adjustment. Inclusion of at least one rural health expert on this panel will ensure that disparities among rural residents are considered and that non-rural experts can benefit from knowledge and practices used in rural health care delivery (for example, race and ethnicity data are routinely collected by HRSA through the Uniform Data System). This Committee—particularly with the inclusion of at least one rural health expert—will be able to consider and provide specific guidance about how the challenge of low case-volume can be balanced, or possibly mitigated, by appropriate risk-adjustment for rural providers.

Create a MAP workgroup to advise CMS on the selection of rural-relevant measures

Under the assumption that CMS eventually will mandate participation of CAHs, RHCs, and CHCs in their quality improvement programs, the Committee strongly recommended that experts in rural health be given a role in the selection of measures to be used in such programs. Specifically, the Committee recommended that a Rural Health workgroup be added to the Measure Applications Partnership (MAP). The MAP utilizes a two-tiered organizational structure whereby setting- or population-specific workgroups review and provide recommendations on measures for relevant programs and/or provide input on measurement gaps and areas for measure refinement and development. Current workgroups exist to provide input on the selection and coordination of measures for hospitals, clinicians, and post-acute and long-term care providers, as well as input on measures and issues related to the quality of care for Medicare/Medicaid dual eligible beneficiaries. Recommendations from the individual workgroups are then reviewed and approved by the MAP Coordinating Committee prior to submission of the recommendations to HHS. This Rural Health Workgroup would function in a manner similar to that of the MAP Dual Eligible Beneficiaries Workgroup, which is tasked with providing recommendations on issues related to the quality of care for beneficiaries who are dually eligible for both Medicare and Medicaid. Activities of this workgroup include identifying a set of the best available measures to address the needs of this unique population, identifying persistent measure gaps, and addressing measurement topics relevant to vulnerable individuals, including quality of life, person- and family-centered care, shared decisionmaking, and functional outcomes. Ideally, a MAP Rural workgroup would reflect the

various types of rural providers, including those from CAHs, RHCs, CHCs, and small PPS hospitals and clinician practices, and reflect the diversity of the rural population in the U.S. (e.g., rural-adjacent areas, frontier areas, heavily minority areas, etc.). This MAP workgroup also would use the measure-selection principles cited above when making its recommendations to HHS.

Pursue continued alignment of measurement efforts for rural providers

Lack of alignment in quality measurement was one of the key challenges for rural providers that was identified by the Committee. Accordingly, the Committee strongly recommended continued efforts to align both measures and data collection efforts, as well as improvement and informational resources.

Specifically, the Committee emphasized the need for a uniform set of measures that can be used, at minimum, across HHS programs (particularly CMS and Health Resources and Service Administration [HRSA] programs), and, to the extent possible, across other programs including those used by private payers, credentialing and accrediting bodies, etc. This recommendation is in alignment with the IOM's April 2015 recommendation for a streamlined set of measures to provide benchmarks for health progress across the nation. Members also noted a need for measures that can be used across multiple healthcare settings (e.g., in both ambulatory and hospital settings). For example, measures such as medication reconciliation would apply to both settings and would incentivize improved communications and patient safety. Measures across hospital settings may also be particularly helpful for CAHs because they often provide services (e.g., physical therapy, occupational therapy, imaging) that are typically provided in an outpatient setting in non-rural areas.

The Committee also recognized that data collection can be particularly burdensome for rural providers, either because small rural providers may not have the staff needed to collect data (e.g., for measures that require laborious abstraction from medical records) or because they may not have the resources (financial, staff expertise, etc.) to invest in or maximize use of sophisticated HIT systems that would facilitate calculating and reporting of quality measures. Committee members therefore recommended that HHS work to develop standardized processes so that data that are used for various purposes (e.g., Hospital Compare, HRSA's Medicare Beneficiary Quality Improvement Project, The Joint Commission accreditation) would have to be reported by providers only once. Note that this recommendation can be operationalized only if there is alignment of the measure sets for the various purposes. The Committee also recommended that HHS provide additional financial or other resources to assist rural providers in their data collection and reporting activities.

The Committee reiterated that many rural providers will continue to require technical assistance in order to facilitate their participation in federal programs (e.g., advice on data collection/reporting, improvement science, etc.). While members acknowledged that CMS and other federal offices already provide this kind of assistance (e.g., through the Quality Improvement Organization program under CMS, the Flex program under HRSA, etc.), they recommended that such resources be aligned across HHS to more efficiently and effectively provide support to rural providers. Such assistance will be particularly critical for those that are (or will be) new to quality measure reporting and/or to small providers who do not have sufficient staff expertise for measurement and improvement. The Committee also reiterated

that performance measures used by those offering technical assistance services should be aligned to the extent possible. Notably, a quality provision in the MACRA legislation specifically includes support for technical assistance to help practices with 15 or fewer clinicians implement the MIPS or transition to APMs.

Finally, the Committee recommended that departments within HHS that work with rural providers (e.g., CMS, HRSA, etc.) collaborate to provide opportunities for rural health stakeholders, as well as HHS staff, to interact and to obtain information regarding various departmental programs, policies, and initiatives relevant to quality measurement. In addition to providing a needed informational "one-stop shop" for rural providers, such alignment of informational resources across HHS could enable creation of more compatible policies across departments that would, in turn, be more beneficial to rural providers than policies that are discordant.

Fund development of rural-relevant measures

The Committee recommended that CMS fund the development and/or modification of measures that are particularly relevant to, and appropriate for, rural providers (especially for low-volume providers). The Committee recognized that in some cases, de novo measure development is needed, but in other cases, modification of existing measures to make them appropriate for use by rural providers may be needed. The Committee identified the following rural-relevant topic areas for potential measure development or modification at this time:

- ***Patient hand-offs and transitions***[m]. The Committee acknowledged that there are already several quality measures that address hand-offs and transitions, but agreed that additional measures are needed for rural providers. The Committee specifically noted the need for measures that assess the appropriateness of transfers (i.e., that transfers are made for the right reasons). They also suggested a need for measures that assess whether transfers are made at the appropriate time. However, they also recognized the difficulties inherent in measures of transfer timeliness for rural providers (for example, if a facility does not have an ICU, a patient may be kept, appropriately, for a longer period in the Emergency Department). The Committee also acknowledged the fact that successful hand-offs and transfers require coordination between providers and that limitations in healthcare infrastructure often hinders rather than facilitates coordination.
- ***Alcohol/drug treatment.*** Because substance abuse is highly prevalent in many rural areas, measures that focus on alcohol and drug screening and treatment are highly relevant for rural providers. The Committee agreed that measures of alcohol and drug screening are already available but noted that substance abuse measures focused on effective interventions that can be provided at the primary care level should be developed, particularly as the options for substance abuse treatment often are limited in rural areas.

[m] The Committee agreed that grouping hand-offs and transitions as a single topic area is appropriate, although they clarified that hand-off measures assess provider-to-provider communication whereas transition measures assess the movement of patients from one setting of care to another.

- ***Telehealth/telemedicine***. Currently, no measures focused on telehealth or telemedicine are endorsed by NQF. Because telehealth and telemedicine are tools that allow greater access to care, they are of particular importance to rural residents. However, the Committee in general agreed that it may be too early for development of quality measures that focus on telehealth/telemedicine. Members noted that simple structural measures of telehealth or telemedicine likely would not be helpful, in part because implementing this type of care delivery requires cooperation between providers (e.g., a primary care provider in a rural area and a specialist outside that particular area), leading to potential difficulties with attribution, and because currently there are state-specific requirements that may make consistent measurement difficult. The Committee also agreed that condition-specific telehealth/telemedicine measures are not needed (e.g., assessing blood glucose control for diabetes patients who participate in telehealth/telemedicine). However, members did agree that current measures (including disease-specific measures) should be specified so that care delivered via telehealth/telemedicine is "counted" in the measures. Finally, the Committee agreed that use of telehealth/telemedicine should be incorporated into measures of access to care.
- ***Access to care and timeliness of care***. Although a few quality measures endorsed by NQF can be considered access to care measures (e.g., those assessing follow-up care), the Committee agreed that additional measures of access to care are needed. While access to care measures may not always be considered "quality measures" per se, they provide a needed complement to other measures of care quality. However, while agreeing with the importance of access to care, the Committee did express concern that use of access to care measures may be problematic for rural providers, particularly if used in payment programs (e.g., potential for a payment penalty if obstetric services are not provided). The Committee considered timeliness of care to be another way of assessing access to care. While there are several NQF-endorsed timeliness measures, members noted that many of these are condition-specific and thus subject to low case-volume. They also noted that timeliness of care measures could be used to assess productivity, which may not always equate to quality, particularly in rural areas.
- ***Cost***. The Committee was somewhat conflicted about the need for additional cost measures for rural providers. On one hand, members recognized the need for cost information in the context of pay-for-performance programs, and noted that because many rural providers are paid by CMS through cost-based reimbursement schemas rather than through Medicare prospective payment structures, the current cost measures cannot be applied to those providers. They also noted that costs generated by primary care providers in rural areas may not be comparable to costs generated by primary care providers in non-rural areas because rural primary care providers typically provide more services themselves rather than referring to specialists. They also noted that comparing the costs of low volume rural to high volume urban providers is inappropriate given diseconomies of scale in rural areas that are a consequence of providing local access to care. On the other hand, they expressed concern that a focus on cost measures might detract from promoting development of needed quality measures. The Committee also discussed patient out-of-pocket costs, and agreed that while this can be a barrier to seeking care and therefore a potential factor that should be considered in risk-adjustment approaches, development of specific measures of out-of-pocket costs is not needed.
- ***Population health at the geographic level***. As noted earlier, the Committee agreed that population health measures are important and, moreover, could potentially resolve the low-case volume issues that are associated with disease-specific measures. Members acknowledged several potential difficulties inherent in such measures, including cultural influences that impact

healthcare decisions, availability of community resources, feasibility of data collection, and appropriate use of such measures. In general, the Committee recognized the need for shared accountability across multiple stakeholders (e.g., individuals, communities, healthcare providers, etc.) in order to improve population health, but did not support the use of such measures in pay-for-performance programs for individual hospitals and clinicians (at least until attribution issues are properly addressed). Instead, they supported a "stepwise" approach to the use of population health measures. For example, members were, for the most part, supportive of the use of such measures at higher levels of analyses (e.g., the ACO level). They also recommended development of measures that assess provider engagement in population health efforts, as such measures could be used to incentivize participation in wellness activities and programs.

- ***Advance directives/end-of-life***. The Committee agreed on the need to promote engagement in shared decisionmaking regarding end of life care planning and suggested that measures regarding advanced directives or physician orders for life-sustaining treatment (POLST) measures be developed. The Committee noted that advanced care planning is needed for all adults, not just older adults, and not just for those nearing end of life. The Committee also noted the impact of limited access to hospice or other care alternatives in many rural areas should be considered when developing measures that assess end-of-life care.

Committee members noted that the intent behind this list is to encourage research and development of measures that can be used to populate the previously-recommended core and optional measure sets for rural providers. However, they also emphasized that development of new measures should not lead to an increased measurement burden. The Committee also cautioned that any measures developed to address the above topic areas may not be appropriate for all types of programs at all times. For example, some may be appropriate for immediate inclusion in pay-for-performance programs, while others may never be appropriate for such programs and others may become appropriate for such programs only after providers gain experience with them in other ways.

For rural providers, create payment programs that include incentive payments, but not penalties

Many rural providers operate on a relatively thin financial margin, with little room to absorb payment reductions (or "penalties") without concomitant reductions in staff and/or services. Additionally, RHCs and CHCs, as well as many CAHs and small rural hospitals and clinician practices, operate in federally- or state-defined shortage areas (e.g., Health Professional Shortage Areas or Medically Underserved Areas) and may be considered part of the nation's healthcare safety net. Thus, the Committee agreed that quality program policies should be crafted so as not to potentially compromise this safety net through application of payment penalties. Accordingly, Committee members recommended that, for the foreseeable future, CMS payment incentive programs for rural providers should be designed to provide "bonus" payments only, not penalties.[n] Such a policy would incentivize reporting and improvement but would preserve the rural providers' safety net role in the communities they serve. Members noted that such a policy would make the Committee's recommendation of mandatory participation in CMS quality programs more palatable to those rural providers who have been excluded from CMS programs to date.

[n] This method is currently used in the Value-Based Payment Modifier program for small physician practices.

They also noted that because per capita health care expenditures for rural residents generally are lower than for those in other areas, "bonus" payments for rural providers should be feasible. Finally, members noted that CMS precedent for not applying penalties in quality improvement programs (e.g., for many years, PQRS offered only positive incentives; currently the VBPM program does not apply penalties to physicians in very small practices.

Offer rewards for rural providers based on achievement or improvement

Pay-for-performance programs often are designed to reward providers based on achievement of some threshold value (e.g., a national benchmark value) or on demonstration of a certain amount of improvement since a baseline period, even if they have not attained a particular measurement threshold. However, characteristics of patients in rural areas (e.g., health behaviors, cultural norms, sociodemographic factors, distance from providers) may constrain the ability of rural providers to achieve threshold values for certain quality measures. Similarly, rural providers may be unable to attain a certain level of improvement for some measures, either because they already have a very high performance (therefore making incremental improvement difficult) or because of low case-volume (in which case, achieving a statistically significant improvement may be difficult, if not impossible). Accordingly, the Committee recommended that pay-for-performance programs for rural providers should incorporate both an achievement component and an improvement component. The Committee noted that CMS' design of the HVBP offers a precedent for this type of arrangement.[o] Members cautioned that because low case-volume is a particular challenge for many rural providers, any requirement for statistically significant improvement would have to be carefully considered.

Encourage voluntary groupings of rural providers for payment incentive purposes

While the Committee agreed that detailed CMS feedback regarding performance scores should be provided at the clinician level (as is done currently in the Medicare FFS Physician Feedback Program), members were much more critical of holding individual clinicians accountable in pay-for-performance programs, particularly for rural and/or small volume providers who often have significant resource constraints and challenges with low case-volume. Instead, the Committee recommended that CMS should encourage rural providers to establish collaborative groups, as desired, for payment incentive purposes. Entry into such groups should be completely voluntary. Moreover, the groups should not be limited to clinicians only, but should be open to CAHs, RHCs, and CHCs, as well as to small rural hospitals and clinician practices. Establishment of such groups could accelerate quality measurement and improvement efforts and could help address the low case-volume challenge. Because programmatic safeguards would have to be put in place to ensure that gaming is minimized during the formation of these provider groups, Committee members suggested that HHS support this effort through establishment of a grant or pilot project.

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[o] For each of the various measures included in the program, hospitals receive a score based achievement or improvement, whichever is higher. The total performance score for each hospitals is calculated as a weighted sum of measures scores for four domains (clinical process of care, patient experience of care, outcome, and efficiency).

Fund additional work to consider how peer groups for rural providers should be defined and used for comparison purposes

Another key concern of the Committee, particularly in the context of pay-for-performance programs, is how to ensure fair comparisons for rural providers. While the issue of fair comparisons is relevant to non-rural providers, the Committee emphasized the difficulties in identifying appropriate comparison groups for rural providers due to the heterogeneity of the patients, service offerings, and overall circumstances surrounding care delivery in rural areas. In general, the Committee favored use of peer groups to assure "like-to-like" comparisons. Suggestions for defining peer groups included comparing providers with similar service lines or capabilities (e.g., those providing surgical services or those with ICU capacity), those with similar geographic isolation profiles, and/or those with similar patient characteristics.[p] There was less enthusiasm for comparison within provider type (e.g., CAH to CAH) because of heterogeneity within provider types (e.g., a 5-bed CAH may be much different than a 25-bed CAH) or lack thereof (e.g., there may be few real differences in primary care provided by RHCs, CHCs, or small clinical practices). There was also resistance to comparing providers solely on a regional basis. The Committee also recognized that for some measures (typically outcome and cost/resource use measures), appropriate statistical case mix adjustment could potentially reduce the need for peer group comparisons, but noted that more study is needed to better understand this complex issue. Finally, after a considerable amount of discussion around this issue, the Committee acknowledged the need for additional consideration of this topic and recommended that CMS fund efforts to define and use appropriate comparison groups for rural providers.

When creating and using composite measures, ensure that the component measures are appropriate for rural (particularly low-volume) providers

Committee members noted that creating a composite performance score from disparate individual measures, as is currently done in some CMS programs, may be particularly problematic for rural providers, either because they do not offer services assessed by the individual measures or have very few patients who "qualify" for some of the individual measures. For example, in some programs, such as the Hospital Acquired Condition (HAC) Reduction program, if a provider cannot report on one or more of the measures in a domain, then the score for that provider depends more heavily on the other measures in that domain (or in other domains). The Committee therefore recommended that if CMS uses a composite measure approach to assess provider performance, such composite measures should be comprised of individual measures that are applicable to rural (particularly low-volume) providers. Preferably, all providers would be assessed on the same measures within the composite; at minimum, providers should be assessed on the same number of measures in the composite (so that no one

[p] A recently-developed taxonomy of population and health-resource characteristics for rural areas may also inform efforts to define peer groups for rural providers. This taxonomy uses variables such as hospital and nursing facitli bed counts, the number of primary care and specialist physicians and other clinicians, demographic data including race, poverty level, and insurance status, and age to classify 10 different Primary Care Service Areas. See http://cph.uiowa.edu/rupri/Place/taxonomy.html.

measure is more heavily weighted for one provider than another). Individual measures used in such composites ideally would come from the core and optional measure sets that are specifically selected for rural providers as recommended by the Committee (see above).

Additional recommendations

The Committee provided additional recommendations that would benefit other quality measurement and improvement efforts for both rural and non-rural providers, as follows:

- ***Relax requirements for use of vendors in administering CAHPS surveys and/or offer alternative data collection mechanisms*** (e.g., similar to CART tool for hospitals). CAHPS surveys obtain patient-reported feedback on their experiences with care; these data are used to compute performance results regarding access to care, patient-provider communication, and shared decisionmaking, among others. Currently, collection of CAHPS data requires use of approved data collection vendors, which can be prohibitively expensive for many rural providers. The Committee noted that many hospitals use the CMS Abstraction and Reporting Tool (CART), a free tool for submitting process measure data to CMS. Thus, Committee members recommended that a similar tool/process be developed to allow reporting of CAHPS data to CMS.
- ***Facilitate quicker and broader access to performance scores and to Medicare data for quality improvement purposes***. Committee members applauded "feedback reports" provided as part of the Physician Feedback of Quality Resource and Use Reports (QRURs)/Value-Based Payment Modifier program (for clinicians) and the Medicare Shared Savings Program (for ACOs), noting that these data allow for the identification of patients in a service area, as well as the types, locations, sources, and, sometimes, costs of care provided to their patients. The Committee recommended that this kind of data be provided to all providers as quickly as possible in order to improve the care coordination for patients, reduce the overall cost to Medicare, and drive overall improvement efforts. Relatedly, the Committee also recommended that CMS facilitate faster cycle time between actual performance and use of performance data in programs. Currently performance results used in CMS improvement programs may be 2 years or more out of date (e.g., data used in 2015 programs reflect care provided in 2013 or earlier). Such long look-back periods hinder receipt of rewards for more recent improvements in care.
- ***Facilitate inclusion of CMS data into all-payer databases***. The Committee agreed that the growth of large multi-payer databases is likely to increase and that the inclusion of Medicare data (and allowing use of such data by multiple stakeholders) would help to mitigate the low case-volume challenge and may help to facilitate alignment of measurement efforts across payers.

Vignettes

(NOTE: These will be scattered throughout the report, probably as side-bar "boxes").

Vignette #1

Recently a single mother brought her 18-month old daughter to a walk-in clinic in a small, remote community. The mother told the physician assistant (PA) that the baby had stopped using her arm and appeared to be in pain when her shirt was being changed. The mother did not report a specific injury but did say that the baby tended to fall a lot. Based on the mother's description, the presentation symptoms, and the baby's age, the PA diagnosed "nursemaid's elbow", a common upper-extremity injury in children between the ages of one and five. The PA tried the standard treatment (a manipulation to "pop" the displaced ligament back into place). Unfortunately, the treatment, which was quite painful to the baby, was unsuccessful, indicating that the diagnosis was incorrect. The PA then ordered x-rays, which required a long drive to the nearest facility with radiology services. Results from the x-ray indicated early healing of both radius and ulna fractures. The PA splinted the baby's arm then referred her to an orthopedic surgeon for evaluation. The surgeon applied a cast, but because he recognized the injury as consistent with abuse fracture, initiated an evaluation by Child and Family Services and arranged for the baby's grandmother to provide care pending the outcome of the evaluation. Fortunately, the fractures healed uneventfully and the abusive family situation was corrected.

Small rural hospitals and CAHs often lack specialty care, particularly for general surgery, obstetrics, and orthopedic surgery. As in the above case, when the only orthopedist is located more than 100 miles away, the doctor must work closely with local primary care providers (PCPs) to deliver high-quality musculoskeletal care. As an example of this provider-to-provider collaboration, one hospital developed a monthly musculoskeletal quality/feedback conference, using a case-study approach to provide local PCPs the needed education to help them recognize and treat many common musculoskeletal conditions. The above story was used at one of the quality meetings, prompting a rich discussion of the proper evaluation of upper extremity injuries in young children, appropriate work-up of nursemaid’s elbow, and recognition of abuse injuries, including the common radiographic patterns of non-accidental fractures. As a group, everyone agreed on a “low-threshold” policy for orthopedic referral when non-accidental trauma is even remotely suspected. The group also agreed that, unless the history and clinical presentation of a nursemaid’s elbow is obvious, x-rays of the extremity would be obtained before attempting treatment.

Vignette #2

Often, trade-offs occur in rural Emergency Departments (EDs). One particular ED is located in a CAH in northeastern Maine. The hospital is one of two hospitals in the county, providing care for a relatively older population of 33,000 individuals. The nearest tertiary care hospital is 100 miles away and is accessible only by a secondary rural road. The hospital is served by Life Flight of Maine, which functions with two helicopters for all 40 hospitals in the state. Unlike many rural EDs that are staffed entirely by nurse practitioners and PAs, this particular ED has around-the-clock physician staffing.

One night, when the hospital's orthopedic surgeon was away for a conference, an 88-year-old woman, the matriarch of a large family fell in the middle of night and fractured her hip. Her fracture was diagnosed in the ED and her pain was subsequently managed, but she had to be transferred to the

tertiary care hospital for surgery because the orthopedic surgeon was out of town. This transfer required a long, painful ambulance ride to a setting unfamiliar and inconvenient for both the patient and her family. Unfortunately, her son, who lived with his wife and three children only a few miles from his mother, was killed when his car slid on the snow covered road as he was on his way to visit his mother.

Treatment options for heart attack include IV thrombolytic therapy or invasive cardiac catheterization. While both have relatively comparable outcomes, cardiac catheterization is preferred but requires admission to a tertiary care facility. Because occasionally the IV thrombolytic therapy fails to open the artery, in most rural hospitals patients are immediately transferred (often via helicopter, to minimize the time of transfer) after being given the IV medication. A 56-year-old man presented to this ED in January with chest pain and shortness of breath and was diagnosed with the most dangerous type of heart attack within minutes of arrival. Unfortunately, weather conditions prevented the helicopter flight, and the patient died while awaiting transport.

Vignette #3

Two years ago, the smallest and most rural of the 12 clinics in an ACO in Nebraska added a care coordinator position to help patients with post-discharge follow-up after hospital admissions and ED visits. Addition of this position has improved the care provided to their patients, in large part because they are now able to correct medication errors for their patients who have been hospitalized. In fact, the quality gains have been so apparent that they have added a second care coordinator position. The care coordinators from all 12 clinics use an online discussion board to share success stories and discuss common problems and solutions. This clinic has some of the best quality performance results of all the clinics to date and the care coordinators' experiences demonstrate that small, rural primary care clinics can implement needed quality improvement infrastructure.

Vignette #4

Operating Community Health Center in in rural North Dakota can be challenging. For example, the scope of clinical practice is wide: it is not unusual to provide care for those with mental illness, heart disease, diabetes, cancer, and routine acute illnesses all in the same day. Providers at the clinic often deal with emergency situations; for example, not long ago the doctors helped to stabilize a gentleman with chest pain (who drove 45 minutes to get to the clinic) before he was transferred to a larger center for additional care. It is not unusual to provide advanced care for patients with rare or serious conditions. For example, one physician had to administer an experimental medication because the nearest specialist who could deal with the patient's condition is 8 hours away. Providers routinely manage patients with severe depression and schizophrenia because there is a 6-month wait time to see a psychiatrist. The doctors at the clinic also see patients who are in a nursing home, hospitalized, or enrolled in hospice. Despite these clinical challenges, the clinic staff is committed to quality measurement and improvement. They report quality data to multiple organizations, including the federal government. They have received multiple awards for management of patients' chronic illnesses. But because they are small and isolated, they must wear many quality improvement "hats", including that of data collector, IT specialist, metric analyzers, and improvement coordinator.

Vignette #5

Small clinician practices in rural areas face similar challenges to those of Rural Health Clinics and Community Health Centers, particularly when located in areas that are more remote. A typical Monday morning in such practices may include the doctor's early arrival (after being on-call over the weekend) to catch up medication orders, phone calls, lab reviews, and charting; a huddle with staff to discuss any follow-up needs from the previous week or weekend; troubleshooting the EHR; meeting with a payer to negotiate fee schedules; and, finally, seeing patients. The doctor often will spend the evening doing other administrative and quality improvement activities. Small rural practices usually do not have the resources to hire a formally trained financial officer, care coordinator, quality improvement coordinator, bookkeeper, compliance administrator, or technology expert. As more and more private and public payers use performance measurement results for payment purposes, the burden of data collection and reporting dramatically increases, particularly when measures used for different purposes are not aligned.

Vignette #6

One Rural Health Clinic in a central Mississippi serves a socio-demographically vulnerable population in a designated Health Professional Shortage Area. Certified Nurse Midwives (CNMs) play an important role in these clinics by providing maternity care as well as other primary care services. Near the end of a recent well woman visit, the CNM planned to discuss the patient's BMI (27+, categorized as overweight) and the need for weight loss and increased physical activity, as well as several other preventive health issues. However, before she could begin the discussion, the patient requested medication to stimulate her appetite. She shared that she felt “too skinny and needed to thicken up”. In trying to explain the lack of medical indication for such a medication and the health risks associated with overweight and obesity, the patient reiterated her belief that she needed to gain weight. With continued discussion, this patient revealed various cultural reasons for wanting to gain weight. In the rural south, cultural norms and beliefs can be strong determinants of health, necessitating considerable educational and preventive care efforts by providers in these areas.

Appendix A. Glossary of Terms

Critical Access Hospital (CAH) – CAH is a hospital certified under a set of Medicare Conditions of Participation (CoP), which are structured differently than the acute care hospital CoP. Some of the requirements for CAH certification include: having no more than 25 inpatient beds; maintaining an annual average length of stay of no more than 96 hours for acute inpatient care; offering 24-hour, 7-day-a-week emergency care; and being located in a rural area, usually, although not always, at least 35 miles drive away from any other hospital or CAH.[a]

Community Health Center (CHC) – CHCs serve communities with limited access to health care. Health center program fundamentals include the following: located in or serve a high need community; governed by a community board; provide comprehensive primary health care; provide services available to all; and meet other performance and accountability requirements. There are three types of health centers including, grant-supported federally qualified health centers, non-grant-supported health centers, and outpatient health programs/facilities operated by tribal organizations. [b]

Frontier Areas – In general, frontier areas are sparsely populated rural areas that are isolated from population centers and services. Definitions of frontier for specific state and federal programs vary, depending on the purpose of the project being researched or funded. Some of the issues that may be considered in classifying an area as frontier include: population density, distance from a population center or specific service, travel time to reach a population center or service, functional association with other places, availability of paved roads, and seasonal changes in access to services.[c]

Health Professional Shortage Areas (HPSAs) – Health professional(s) shortage area means any of the following which the Secretary of HHS determines has a shortage of health professional(s): (1) An urban or rural area (which need not conform to the geographic boundaries of a political subdivision and which is a rational area for the delivery of health services); (2) a population group; or (3) a public or nonprofit private medical facility.[d]

Hospital Acquired Condition (HAC) Reduction program – The HAC Reduction program is a pay-for-performance and public reporting program that supports the broader public health imperative to raise awareness and reduce the incidences of preventable HACs by applying evidence-based clinical guidelines. HACs are high-cost and/or high-volume conditions that occur during a hospital stay, result in

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[a] HRSA. http://www.hrsa.gov/healthit/toolbox/RuralHealthITtoolbox/Introduction/critical.html

[b] HRSA. About Health Centers. http://bphc.hrsa.gov/about/

[c] Rural Assistance Center- http://www.raconline.org/topics/frontier#definition

[d] HPSA Designation Criteria. Available at http://bhpr.hrsa.gov/shortage/hpsas/designationcriteria/designationcriteria.html

higher costs of care, and can reasonably be prevented if evidence-based care is provided. Pressure ulcers, various surgical site infections, and injuries sustained in falls or other traumatic events are examples of HACs that are included in this program. Hospital performance under the HAC Reduction Program is determined based on a hospital's Total HAC Score, which can range from 1 to 10. The higher a hospital's Total HAC Score, the worse the hospital's performance under this program. [e]

Hospital Compare website – The Hospital Compare provides information on how well hospitals provide recommended care to their patients to help consumers make more informed healthcare decisions about where to receive healthcare. Hospital Compare allows consumers to select multiple hospitals and directly compare performance measure information related to heart attack, heart failure, pneumonia, surgery, and other conditions.[f]

Hospital Inpatient Quality Reporting (IQR) program – IQR is a pay-for-reporting and public reporting program that authorizes CMS to pay hospitals a higher annual update to their payment rates if they successfully report designated quality measures. This program was authorized by the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003.[g]

Hospital Outpatient Quality Reporting (OQR) program – OQR is a pay-for-reporting program with performance information reported on the Hospital Compare website. The goals of the program are to establish a system for collecting and reporting on quality performance of hospitals that offer outpatient services such as clinical visits, emergency department visits, and critical care services.[h]

Hospital Value-Based Purchasing (HVBP) program - HVBP is a pay-for-performance program that aims to improve healthcare quality by providing incentive payments to hospitals that meet or exceed performance standards. Hospitals are scored based on their performance on each measure within the program relative to other hospitals, or on how their performance on each measure has improved over time. Four domain-level scores (clinical process of care, patient experience of care, outcome, and efficiency) are calculated from scores of measures that make up the domains. Scores from each domain

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[e] CMS.gov. Hospital-acquired conditions (present on admission indicator) website. Available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html. Last accessed January 2015.

[f] CMS.gov. Hospital Compare website. Available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalCompare.html. Last accessed January 2015.

[g] Centers for Medicare & Medicaid (CMS) website. . Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU.html. Last accessed December 2014.

[h] CMS.gov. Hospital outpatient quality reporting program website. Available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalOutpatientQualityReportingProgram.html. Last accessed January 2015.

are weighted and summed to determine the total performance score. Measures selected for the HVBP program must be included in IQR and reported on the Hospital Compare website for at least one year prior to use in the HVBP program.[i]

Medically Underserved Area – Medically underserved areas/populations are areas or populations designated by HRSA as having too few primary care providers, high infant mortality, high poverty or a high elderly population.[j]

Medicare and Medicaid EHR Incentive ("Meaningful Use") program – MU provides incentives to eligible professionals, eligible hospitals, and CAHs as they adopt, implement, upgrade, or demonstrate meaningful use of certified EHR technology. The goal of this program is to promote the widespread adoption of certified EHR technology by providers and to incentivize the "meaningful use" of EHRs to improve quality, safety, efficiency, and reduce health disparities, engage patients and their families, improve care coordination, and maintain privacy and security of patient health information.[k]

Medicare Shared Savings Program (Shared Savings Program) – This program aims to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce unnecessary costs. Eligible providers, hospitals, and suppliers may participate in the Shared Savings Program by creating or participating in an Accountable Care Organization (ACO). The Shared Savings Program will reward ACOs that lower their growth in Medicare spending while meeting performance standards on quality of care and putting patients first. Participation in an ACO is purely voluntary.[l]

Physician Compare – A federal website that reports information on physicians and other clinicians. The purpose of the website is public reporting of information and quality measures that are meaningful to patients.[m]

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[i] The FY 2015 IPPS/LTCH Final Rule *Fed Registr* 2014;79:49853-50449. Available at https://federalregister.gov/a/2014-18545 . Last accessed January 2015.

[j] HRSA. http://muafind.hrsa.gov/

[k] CMS.gov. Eligible hospital information website. Available at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Eligible_Hospital_Information.html. Last accessed January 2015.

[l] CMS.gov. Shared savings program website. Available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/. Last accessed January 2015.

[m] CY 2015 Revisions to payment politics under the Physician Fee Schedule and other revisions to Medicare Part B (CMS-1612-P). Fed Registr. 2014;79:67547-68010. Available at https://www.federalregister.gov/articles/2014/11/13/2014-26183/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-clinical-laboratory. Last accessed January 2015.

Physician Quality Reporting System (PQRS) – PQRS is a reporting program that uses a combination of incentive payments and payment adjustments to promote reporting of quality information by eligible professionals (EPs) who satisfactorily report data on quality measures for covered Physician Fee Schedule (PFS) services furnished to Medicare Part B Fee-for-Service (FFS) beneficiaries. All PQRS measures will be used for public reporting on Physician Compare and for the quality component of the Value-Based Payment Modifier.[n]

Rural – This term has been defined in many ways, most often in terms of non-urban status. The Federal Office of Rural Health Policy (FORHP) defines rural as located outside a Metropolitan Statistical Area (MSA), or located in a rural census tract of a MSA as determined under the Goldesmith Modification or the Rural Urban Commuting Areas. [o]

Rural Health Clinic (RHC) – RHC is a federally qualified health clinic certified to receive special Medicare and Medicaid reimbursement. RHCs are required to be staffed by a team that includes one mid-level provider, such as a nurse practitioner (NP), physician assistant (PA), or certified nurse midwife (CNM), that must be on-site to see patients at least 50 percent of the time the clinic is open, and physician (MD or DO) to supervise the mid-level practitioner in a manner consistent with state and federal law. RHCs are only required to provide outpatient primary care services and basic laboratory services and must be located within non-urban rural areas that have health care shortage designations. [p]

Small Hospital – A hospital defined as 49 available beds or less, as reported on the hospital's most recently filed Medicare Cost Report. [q]

Small Clinician Practice – For the purposes of this report, small clinician practices are defined as those with <10 eligible professionals.

Telehealth – The use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration is called telehealth. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.[r]

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[n] CMS.gov. Physician quality reporting system website. Available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/. Last accessed January 2015.

[o] HRSA. How is rural defined? http://www.hrsa.gov/healthit/toolbox/RuralHealthITtoolbox/Introduction/defined.html

[p] HRSA. http://www.hrsa.gov/healthit/toolbox/RuralHealthITtoolbox/Introduction/ruralclinics.html

[q] HRSA. Small Rural Hospital Improvement Program (SHIP) http://www.hrsa.gov/ruralhealth/about/hospitalstate/smallimprovement.html

[r] HRSA. Telehealth. Available at: http://www.hrsa.gov/ruralhealth/about/telehealth/

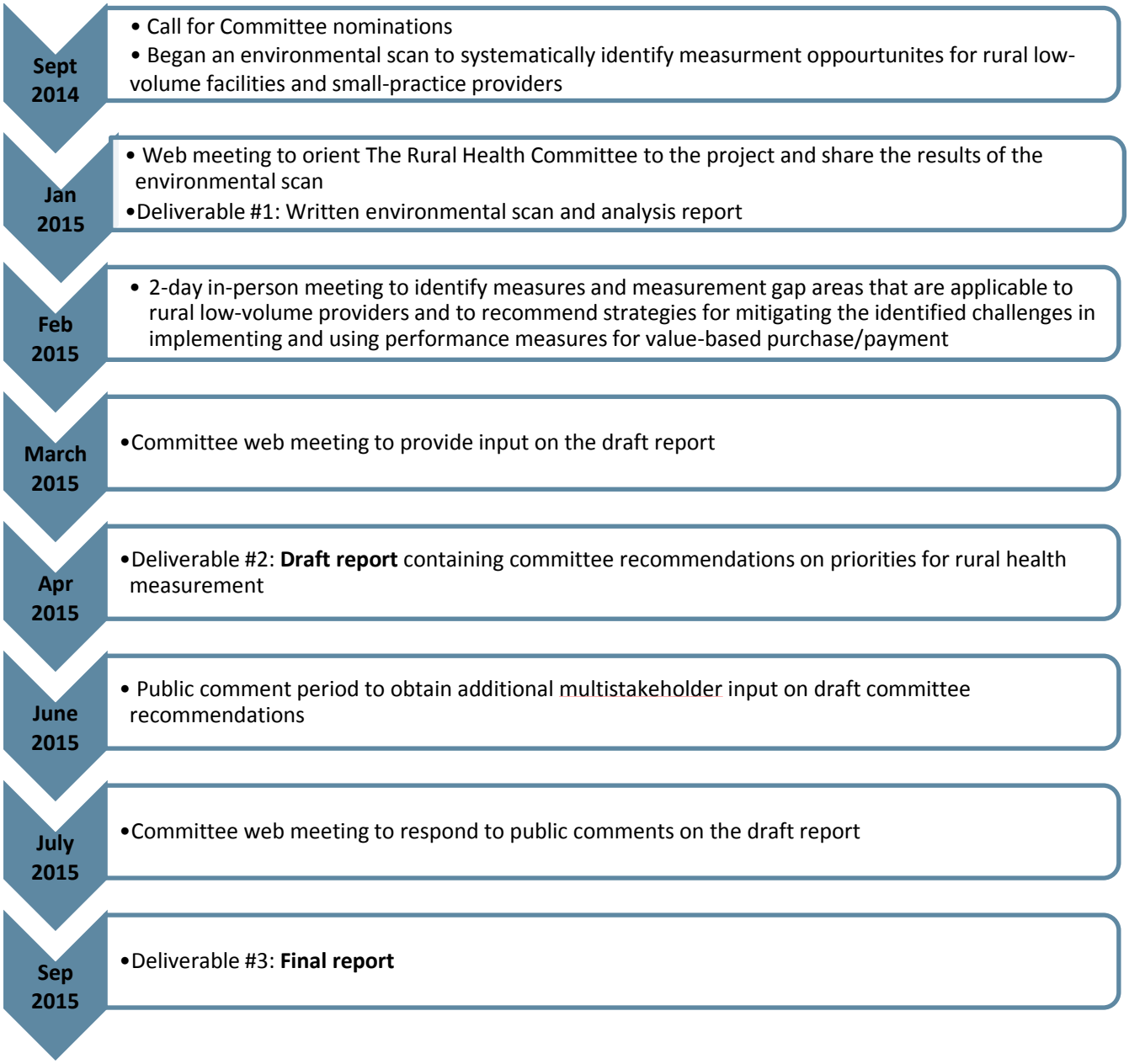
Telemedicine – For purposes of Medicaid, telemedicine seeks to improve a patient's health by permitting two-way, real time interactive communication between the patient, and the physician or practitioner at the distant site. This electronic communication means the use of interactive telecommunications equipment that includes, at a minimum, audio and video equipment.[s]

Value-Based Payment Modifier – The VBPM program (also known as the Value Modifier) is a pay-for-performance program that provides differential payment to physicians or physician groups who are paid under the Medicare Physician Fee Schedule (PFS). The payment adjustments are calculated based upon the quality of care furnished compared to the cost of care during a performance period. High-quality and/or low-cost groups can qualify for upward adjustments in payments, while low-quality and/or high-cost groups or groups that fail to satisfactorily report measures to PQRS are subject to downward adjustments in payment. This program will be implemented in several phases. In 2015, the Value Modifier will be applied to physicians in practices of 100 or more eligible professionals (EPs), based on their 2013 performance. In 2016, the Value Modifier will be applied to physicians in practices of 10 or more EPs, based on their 2014 performance. Beginning in 2017, the Value Modifier will be applied to all physicians, regardless of group size (although groups with <10 EPs will not be subject to negative payment adjustments). In 2018, the Value Modifier also will be applied to non-physician EPs.[t]

[s] Medicaid.gov. Available at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html

[t] CMS. Value-Based Payment Modifier. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html#What is the Value-Based Payment Modifier (Value Modifier)

Appendix B: Project Timeline



Appendix C. Rural Health Committee Members

COMMITTEE MEMBERS	
Kelly Court, CPHQ, MBA – co-chair	Wisconsin Hospital Association
Ira Moscovice, PhD – co-chair	University of Minnesota School of Public Health
Ann Abdella	Chautauqua County Health Network
Michael Baer, MD	AmeriHealth Caritas Pennsylvania
Tonya Bartholomew, OTR	Platte Valley Medical Clinic
John Gale, MS	University of Southern Maine
Aaron Garman, MD	Coal Country Community Health Center
Gregory Irvine, MD	St. Luke's McCall Orthopedics Clinic
Jason Kessler, MD	Iowa Medicaid Enterprise
Jason Landers, MBA	Highmark West Virginia
Bruce Landon, MD, MBA, MSc	Harvard Medical School
Jonathan Merrell, RN, BSN, MBA, IA	Indian Health Service
Guy Nuki, MD	BlueWater Emergency Partners
Kimberly Rask, MD, PhD	Alliant Health Solutions
Robert Rauner, MD, MPH	SERPA-ACO
Sheila Roman, MD, MPH	Independent consultant
Susan Saunders, MSN, CNM, WHNP-BC	American College of Nurse-Midwives
Stephen Schmaltz, MS, MPH, PhD	The Joint Commission
Tim Size, BSE, MBA, Doctorate Humanities (Honorary)	Rural Wisconsin Health Cooperative
Brock Slabach, MPH, FACHE	National Rural Health Association

DEPARTMENT OF HEALTH AND HUMAN SERVICES REPRESENTATIVES	
Girma Alemu, MD, MPH	Health Resources and Services Administration
Kristin Martinsen, MPM	Health Resources and Services Administration
Megan Meacham, MPH	Health Resources and Services Administration
Curt Mueller, PhD	Health Resources and Services Administration
Martin Rice, MS, RN-BC, CPHIMS	Centers for Medicare & Medicaid Services

NATIONAL QUALITY FORUM STAFF	
Helen Burstin, MD, MPH	Chief Scientific Officer
Severa Chavez	Project Analyst
Mitra Ghazinour, MPP	Project Manager
Karen Johnson, MS	Senior Director
Marcia Wilson, PhD, MBA	Senior Vice President

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Healthcare Performance Measurement for Rural, Low-Volume Providers

Karen Johnson
Mitra Ghazinour
Severa Chavez

NATIONAL QUALITY FORUM

Committee Web Meeting
July 29, 2015

Rural Health Committee Members

Kelly Court, Wisconsin Hospital Association	**Bruce Landon**, Harvard Medical School
Ira Moscovice, University of Minnesota School of Public Health	**Jonathan Merrell**, Indian Health Services
Ann Abdella, Chautauqua County Health Network	**Guy Nuki**, BlueWater Emergency Partners
Michael Baer, AmeriHealth Caritas Pennsylvania	**Kimberly Rask**, Alliant Health Solutions
Tonya Bartholomew, Platte Valley Medical Clinic	**Robert Rauner**, SERPA-ACO
John Gale, University of Southern Maine	**Sheila Roman**, Independent consultant
Aaron Garman, Coal Country Community Health Center	**Susan Saunders**, American College of Nurse-Midwives
Gregory Irvine, St. Luke's McCall Orthopedics Clinic	**Stephen Schmaltz**, The Joint Commission
Jason Kessler, Iowa Medicaid Enterprise	**Tim Size**, Rural Wisconsin Health Cooperative
Jason Landers, Highmark West Virginia	**Brock Slabach**, National Rural Health Association

Objectives

- Review public comments received on the draft report
- Discuss any potential revisions to the Committee's recommendations and/or the draft report based on the comments received
- Discuss potential next steps for rural health performance measurement

Comments Received

Comments

- Comments received from 16 organizations
- Overall, most commenters were supportive of the project, recommendations, and the key issues identified for rural providers
- Particular support for recommendations regarding alignment, core set, MAP workgroup, addressing low case-volume, mandatory participation, no financial penalties
- However, some concern with mandatory participation and core sets

Discussion of Comments Received

Not necessarily supportive of mandatory participation

- Concern that this can have a negative impact on patient access to services (as providers are often overworked) (ID#4)
- Current programs not a good fit (ID#11)
- Premature
  - Unless the many technical challenges of measuring the quality of rural low-volume providers accurately are addressed. (ID#5)
  - Need more input to determine a reasonable starting point (ID#22)

Should the Recommendations be Prioritized, Sequenced, and/or Given a Timeline?

- Three commenters suggested a need for a prioritization, sequencing, and/or timeline
- PROs
  - Would give "shape" or focus to recommendations
  - Potentially address concerns about mandated participation
  - Would help to clarify next steps
- CONs
  - Many rural providers already included in incentive programs
  - Several recommendations reflect "continuous" action (e.g., measure development, selection, alignment) that may not be amenable to sequencing

Not necessarily supportive of the core set, as written

- Core set with same measures reported by all providers (ID#6)
  - Concern that the core set might be irrelevant to some providers
    - » Instead, reframe like Vital Signs report (i.e. "consistent goals and objects for improvement")

How should the core set discussion be modified?

- Clarify that the core sets would differ by setting (i.e., hospitals would have a different set than clinics)
- Currently recommend cross-cutting rather than disease-specific measures
  - Should measures that reflect conditions of highest occurrence within rural areas be considered? (ID#8, #20, #36)
  - Or would this be more appropriate for the optional set?

Should, and if so, how, might some discussion of community providers be incorporated?

- In the context of population heath and wellness of the community
  - measurement (ID#16)
  - collaborative groups (ID#30)
  - Incentives for providers to participate with/leading (ID#31)
- At minimum, addition of text noting the contributions of community providers when measuring population health?

Is there any desire to recommend different standards for rural providers?

- Adjusting measurement benchmarks (ID#2, #8)
- Less reporting of measures (ID#8)

Is there any desire to say more about alignment?

- Alignment without standardization (ID#12)
- More about alignment of measures with private payers (ID#12)

Additional questions to consider

- Any additional recommendations regarding low case-volume?
  - Aggregating data for several facilities (ID#23)
  - Other suggestions noted in Environmental Scan
  - Formation of a methods workgroup to addresses the low case-volume problem (ID#31)
- Any additional recommendations regarding the CAHPS surveys?
  - Allowing potential alternatives (ID#19)
  - Relaxing requirements for use (ID#27)

Additional questions to consider

- Is there a common definition for swing beds? Does anyone know if these typically are excluded from measures? (ID#1)
- Include housing security and food security as potential SDS adjustors? (ID#4)
- Additional principle for selection: measure across the continuum of care? (ID#17)
- Anything more specific in the report about measurement for the healthcare exchanges or for Medicaid managed care? (ID#12)

Some comments illustrate need additional clarity in the report

- Commenters assumed that:
  - All rural providers are employed in CAHs, RHCs, for FQHCs (ID#3)
  - All rural practices are low-volume (ID#3)
  - The committee has recommended a separate set of measures for rural providers (ID#8)
  - The Committee has recommended that CMS augment existing programs (and mandate participation in those) rather than designing new programs (ID#11)
- Staff will provide additional text in the report to address these misconceptions

How Else Should the Report be Modified?

- Potentially, group the recommendations in some way?
  - For example: measurement, selection, payment
- Other thoughts?

Potential Next Steps

Public Comment

Project Next Steps

Next Steps

- **September 9, 2015:** Presentation to CMS
- **September 14, 2015:** Final report due to HHS

Thank you!

Quality Committee Charter

Tahoe Forest Hospital District is committed to performance excellence, to delivering the highest quality care and service, and to exceeding the expectations of our patients, physicians, employees, and community. This committee will provide leadership, oversight, and accountability for organization wide quality improvement processes and programs. We will regularly assess the needs of our stakeholders, evaluate proposed quality initiatives, openly debate options, and assure the production of an organization wide strategic plan for quality. We will set expectations, facilitate education, and support the monitoring of the quality of care, service excellence, risk reduction, safety enhancement, performance improvement, and healthcare outcomes. Because of our efforts Tahoe Forest Hospital District will be the best place to receive care, the best place to work, the best place to practice medicine, and a recognized asset to all in our community.