The more I know, the less I sleep

Global perspectives on clinical governance

KPMG International

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“The more I know, the less I sleep.”

This great quote, from a former colleague Dr. David Rosser, Executive Medical Director of the University Hospitals Birmingham in the UK, nicely alludes to the mix of anxiety, curiosity and desire associated with the quest to provide great quality care. This report, and research conducted by KPMG’s Global Healthcare practice on clinical governance and ‘high reliability’ healthcare organizations, is both timely and necessary.

Timely, because of a number of high-profile and widely reported problems in healthcare delivery in various parts of the world. Necessary, because healthcare still has too many of the characteristics associated with an old-fashioned, individual, craft-based system which no longer sits well with what we know works better in the 21st century: teamwork, safety and improvement science, executed on an industrial scale.

As individuals, we would not fly if the current random quality control systems at work in healthcare were adopted by the aviation industry. We have identified four essential elements for healthcare improvement that have been adopted decades ago in other industries. These elements — a culture devoted to quality, accountability, standardized processes and measurement — need to be systematically applied to healthcare. No matter how laudable, our global research suggests that regulation often gives more assurance to politicians and officials than it does improvement for patients. In short, it is necessary but never sufficient.

Real, sustainable change comes from the organizations and hardworking staff that deliver care to patients. Pleasingly, we have found that a number of high-performing organizations encourage patients to become active partners in their care, thereby creating more value.

It’s odd that something so important and personal as healthcare doesn’t have widely acknowledged or adopted ‘industry standards’ of inspection, reporting and improvement. It is high time a debate be started in healthcare to explore whether we should professionalize our best endeavors.

This report also looks at some national and regional attempts to make comparisons easier so that boards and professionals can hold themselves to account in a much more transparent fashion for patients and members of the public alike. Independent assurance is important but delivering quality improvement inside — and across — organizations is mission critical. Through our global roundtable discussions with high-performing practitioners, it is clear that strong purpose, enduring values, great leadership and a restless curiosity to improve truly distinguish excellence.

Finally, as information systems develop and become more reliable and robust, there is a great opportunity for healthcare and life sciences organizations to exploit their growing repositories to capitalize on the ‘Big Data’ trends that have been embraced and exploited by other sectors. We are currently in the foothills of this development but it will come and we should be ready to apply this to the benefit of patients and wider population health.

I’d like to thank the practitioners and guests who participated in this global study and hope you enjoy the report and feel inspired to make a difference.

Dr. Mark Britnell
Chairman, Global Health Practice, KPMG International, and Partner, KPMG in the UK
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Executive summary

In the quest to improve healthcare, increasing attention is being paid to gaining control over quality, by making care safe, effective, timely and centered on patient needs. Payers, regulators and governments are also seeking evidence of safe, high-quality care, yet reporting that paints a meaningful picture that is open to sector-wide comparison does not yet exist.

This report shows that a relentless focus on accurately reported outcomes of care is the critical glue that can bring together patients, professionals, providers and those paying for and regulating care.

About this report

This report is based on a literature review and more than 20 interviews conducted with leading C-level leaders of world-class providers in the US, UK, India, Germany, Australia, Canada and Singapore. Roundtable discussions were organized based on the preliminary results in Sydney, Amsterdam, Lausanne and Boston.

These roundtable discussions were used to test, validate and further develop the findings in this report. Thanks to all those who gave their valuable time.

Marc has been in leading healthcare consulting roles for over a decade and his pioneering work on commissioning, purchasing and operations has produced dramatic advances in achieving better outcomes at lower costs. Marc is a Principal and Head of Strategy and Transformation Health for KPMG in the US and a member of the Global Center of Excellence for Healthcare.

‘In control’

What do the interviewees mean:
— methodically measuring care outcomes
— understanding the key drivers of these outcomes
— understanding how to make these outcomes best of class
— systematically preventing avoidable harm to patients.

‘High reliability’ organizations

The definition of a high reliability organization extends beyond patient safety to encompass quality care — and ultimately value.
Clinical and corporate governance: delivering quality reliably

In a ‘high reliability’ organization, excellence is planned, rather than accidental. Outcomes are methodically measured and understood, and safety is an absolute priority. Quality is a thread running through the entire institution from the ground floor to the boardroom, encompassing core processes and measurement systems. Evidence shows that outcomes improve dramatically as quality becomes everyone’s responsibility and not just the domain of individual clinicians.

Even the most advanced organizations acknowledge that they are on a journey to achieving high reliability and need to address four essential building blocks: (1) a culture devoted to quality; (2) responsibility and accountability of staff; (3) optimizing and standardizing processes and (4) measurement of performance.

1. A culture devoted to quality

A number of hospitals around the world have allowed themselves to develop cultures of ‘normalized deviance,’ where below average performance becomes the norm, people are afraid to speak out and leaders are either unaware of or deny failure. Such weaknesses have led to high-profile incidents. In a culture of excellence, on the other hand, the board leads by example, sets the tone at the top and refuses to accept anything but the highest standards. No individual can feel that he or she is above the rules, and leaders must have the courage to challenge anyone in the organization, including clinicians and administrators.

Although the organization exercises zero tolerance for safety breaches and diversion from standards and procedures, failures or errors are not blamed on single individuals (unless in cases of individual rule-breaking, for example) but, rather, viewed as vital learning experiences. Most importantly, healthcare providers must acknowledge mistakes and poor practices, and empathize with patients and their families. In building such a culture, boards may need to go through formal training that emphasizes their role in overseeing quality and safety.

2. Responsibility and accountability

Defined individuals should be responsible for the clinical and financial outcome of patient pathways and accountable to senior management. All information should be distilled as it flows upwards, to keep leaders informed but not overwhelmed with data, with appropriate levels of detail for each audience. In some of the best examples, quality and safety are built into the strategic goals and become a central part of all board meetings, supported by robust internal audits to verify the established high standards of governance, as with financial audits, are consistently applied.

3. Optimizing and standardizing processes

Doctors have typically been deeply resistant to standardization, believing that every patient is unique. However, such an individual-by-individual approach actually increases the likelihood of errors. Leading providers have achieved dramatic results by implementing standard guidelines and operating procedures, increasing patient survival rates and cutting the cost of care significantly.

The path to standardization can, however, be slow and painful, with staff at all levels reluctant to change behavior, resulting in a frustrating lack of compliance. Clinical leaders must be relentlessly vigilant in checking and double-checking adherence to protocol, making those on the front line directly accountable and stressing that guideline adherence is not a loss of professional autonomy, merely a replacement of pure individual autonomy by more collective autonomy. Results should be fed back to the pathway owners, whose task is to continuously improve the performance and thus the quality of care.

Information technology (IT) plays a vital role in measuring outcomes and improving processes. However, some of the most impressive breakthroughs have occurred in organizations where the IT infrastructure was still unsophisticated, so technological limitations are no reason for inactivity.

4. Measurement

Leading healthcare organizations measure quality relentlessly, with systematic reporting and monitoring, real-time feedback, and regular benchmarking against peers and industry best practices. This inquisitiveness extends to understanding the drivers behind low- or high-scoring measures. Staff at all levels are encouraged not just to measure, but to measure the outcomes that matter most to patients.

Once a standardized database has a critical mass, it can be a big catalyst for improvement, as clinicians see what works and what does not. Published performance data also breeds competition, as clinicians strive to be at the top of the rankings, which again raises standards.
The journey towards a ‘high reliability’ organization

Despite representing many of the world’s foremost healthcare organizations, none of the leaders interviewed for this paper were confident that their institutions had reached a state of ‘high reliability,’ which entails a journey through four phases (see page 17).

<table>
<thead>
<tr>
<th>Reliability stage</th>
<th>Phase 0</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
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<tbody>
<tr>
<td>Description</td>
<td>Unrestrained individual autonomy of professionals</td>
<td>Constrained individual autonomy</td>
<td>Constrained collective autonomy (teams)</td>
<td>Teams with strong situational awareness</td>
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<td>$&lt;10^{-2}$</td>
<td>$&lt;10^{-3}$</td>
</tr>
<tr>
<td>Translation to care</td>
<td>Healthcare as craft</td>
<td>Watchful professional</td>
<td>Collective professionalism</td>
<td>High reliability care</td>
</tr>
</tbody>
</table>

Range in which most current healthcare practices operate

Source: KPMG International, 2013

A strong focus on quality care will raise clinical standards and reduce costs. Ultimately, one of the best ways to demonstrate control over quality care is to produce consistently excellent outcomes over time.

Becoming a high reliability organization will not happen overnight, and all the leaders contributing to this paper acknowledge that their organizations have some way to go. The journey involves four stages (see page 17 for more detail) with most current providers operating within Phase 0 and 1, which are characterized by a lack of standardized measurements and controls, with individually operating clinicians dominating the culture.

Over time, with the right culture and strategy established by the board, quality and safety take on greater importance and gradually become institutionalized. By Phase 2, key outcomes and their drivers are routinely measured and reported, and a zero tolerance culture predominates, with clear responsibility for outcomes. In Phase 3 — which is likely to apply only to specific departments such as intensive care — there is a total focus on preventing failure and continuously improving care.

System governance: assuring quality

In recent years, the stakes for sound reporting have risen. This puts pressure on providers, but also on regulators and payers/commissioners. The response has been to increase the range and volume of activities that providers have to publicly report, including quality and patient safety.

Despite the time and effort that goes into compiling, submitting and analyzing such data, negative events continue to happen. Regulators and providers need to reassess what goes into reports, so that the content offers a meaningful and accurate picture that signals serious failings, as well as being a driver for improved standards.

The tension between internal and external reporting

As the volume of required measures rise, healthcare providers feel under siege, forced to allot more and more valuable staff time to compiling reports, rather than providing care. Worse still, many believe that much of the data required for external reporting is of little
or no use, as it concerns detailed, low-level activities that offer no indication of overall performance.

The way forward here lies in a relentless focus on reporting the key outcomes that matter from the patient’s perspective. In many cases, establishing and reporting on these measures is simpler than is often assumed.

**Making measurements simpler and more relevant**

Much of current regulatory reporting centers around processes and activities. However, there is growing agreement that the most important measures are outcomes, such as survival, quality of life, minimal symptoms and exacerbations, or a return to full physical fitness. Key measures are often already available for common conditions such as diabetes, breast cancer and hip arthrosis, but are also required for patients with co-morbidities and frail elderly patients.

Healthcare boards, patients, payers, governments and other stakeholders need to shift their focus towards this goal, with internationally standardized measures the ultimate aim; areas such as oncology and cardiovascular surgery are leading the way. With a more focused set of measures, it should be easier to assess whether an organization is in control of quality and benchmark against peers. Of course, this aim introduces a key challenge, as care often involves several different care providers, with limited ability to exchange and use data. But in the 21st century, not having oversight over patient outcomes over the total episode of care can no longer be seen as acceptable.

**Assuring the reliability of reports**

The collection and presentation of healthcare data lags behind that of financial data, with insufficient guidelines, lack of standardized procedures, and little or no segregation of duties between recording and reporting. Software is also relatively unsophisticated and, with few controls, much of the information is not dependable. Instances of ‘massaging’ data have been observed, further reducing trust in the numbers.

Independent assurance can help verify the reliability of quality measures, and internal and external audits are becoming more commonplace in some countries. To meet such scrutiny, healthcare organizations will have to govern clinical activity with the kind of controls that are standard in financial reporting, including penalties for incomplete or inaccurate submissions. Reliability can be tested by verifying consistent applications of established controls as well as looking for unexpected patterns and volume of co-morbidities and, for example, making comparisons with similar organizations.

**Assuring safety**

In the wake of a number of incidents, patient safety is high on regulators’ agendas, with hospitals and healthcare providers under pressure to prove that they have preventive measures in place, and can act quickly should any incidents occur. However, safety is proving a headache for public reporting, as negative outcomes are often too rare to be statistically valid, and too diverse to be measured cost-effectively.

Measuring harmful incidents can be useful for internal purposes, but patients, citizens and payers are typically uninterested in lengthy lists of what could go wrong. Arguably, certification is the way forward for this domain of quality, as it can assure common standards across all providers. Several safety-specific accreditation schemes exist and are emerging in Canada, the US and Australia, helping to create some common standards.

**The time to act is now**

Regulatory demands are likely to change significantly as providers and payers acknowledge the need to converge internal and external measurements and reporting around what is best for the patient.

Standardized outcome measures should emerge at an international level, and safety should rise up the agenda. Auditing quality should become more regular and adopt the same standards as financial assurance to give regulators, providers, patients and other stakeholders confidence in the accuracy and completeness of the levels of quality and safety being achieved and reported.

The organizations studied in this paper are all making progress along the path to ‘high reliability,’ and in the following pages we explore how they have adopted some or all of these actions.

> The path towards defining, monitoring and reporting on quality outcomes is evolving quickly. In order for boards to fulfill their fiduciary obligations, they need to make this a high priority or they may be putting patients unnecessarily at risk and sustaining an environment that fosters inefficient operations.

Marc Scher, Partner, KPMG in the US
Introduction

The healthcare sector is still exploring how best to provide oversight and assurance, govern, as well as measure and monitor quality and safety. This report examines the emerging leading practices from some global best-in-class providers and thought leaders. In studying how successful organizations are developing their clinical and corporate governance, it becomes apparent that for a board to be ‘in control’ means having a culture devoted to quality, responsibility and accountability of staff, optimized and standardized processes, and systematic, real-time measurement.

Boards, C-suite executives, providers/ payers and regulators have spent decades developing the processes and activities associated with managing and reducing costs. However, this research reveals they have much less experience and available guidance for quantifying, measuring and reporting the quality of patient outcomes in terms of safety, effectiveness, patient satisfaction and timeliness. Where other industries have introduced rigorous controls and reporting requirements, healthcare is still evolving its governance of quality care.

Today, high-profile incidents are pushing quality to the top of the agenda. The troubles at the UK’s Bristol and Mid Staffordshire hospitals, the Walter Reed Army Medical Center neglect scandal in the US, and the Garling inquiry into New South Wales Public Hospitals in Australia all demonstrate what can happen when outcomes are not closely measured, monitored and reported. The tragedy of these cases is compounded by the fact that staff and patients’ concerns were ignored, due to a widespread culture of denial and lack of attentiveness to patient welfare.

If health organizations want to consistently provide quality care, they need to address two levels of governance.

1. Clinical and corporate governance: delivering quality reliably
How can leaders gain more control over quality care? And how can boards provide better financial and clinical oversight to ensure their organizations provide high-quality care?

2. System governance: assuring quality
How can payers/commissioners and regulators/governments reassure the public and stakeholders that they are buying and overseeing quality care? How can they obtain the data to measure and report on quality standards without creating a huge administrative burden?

The four dimensions of quality

| Safe       | — Avoid harm to patients |
| Effective  | — Provide clinically proven services to all who benefit; refrain from providing services to those not likely to benefit |
| Patient-centered | — Show respect for patient preferences and needs, with patient values guiding all clinical decisions |
| Timely     | — Reduce waiting times and (potentially harmful) delays |
Few, if any, of the world’s healthcare leaders would claim that their organizations are fully ‘in control.' Even those widely acknowledged as shining examples of best practice admit that they have some way to go in understanding what drives outcomes, and how to measure quality and avoid harm to patients.

Mike Harper, Executive Dean of Clinical Practice of the US-based Mayo Clinic, explains: “Compared to the average, we’re doing pretty well; we score on the top of most lists. But are we ‘in control’ yet? No. Are we where we want to be? No. But we’re on our way. We score very high on all of these measures, yet we can do better.”

In a high-risk environment such as healthcare (and, indeed, in aviation, chemical processing and nuclear power), the aim is to become a ‘high reliability’ provider that is focused on consistently excellent outcomes along with prevention of failure. Such organizations align their leadership, core processes and measurement systems, with clear lines of accountability and a common mind-set from the ground floor to the boardroom.

The predominant culture within many providers is one of individual professional autonomy, where clinical excellence is the sole responsibility of doctors, and boards have little influence over quality. Consequently, processes are error-free only 80 percent of the time, outcomes are variable, and patients frequently suffer harm. And without formal monitoring of outcomes, such a state is either unknown or tolerated as the norm. Conversely, once safety and clinical excellence are given higher priority, and responsibility for quality shifts from individuals to multifunctional teams, outcomes improve dramatically and harm rates decline. High reliability organizations typically experience zero errors in more than 99.5 percent of care processes.1

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<table>
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**Base error rate of each step**

**How small errors contribute to unreliability:** Even at seemingly low error rates per step, more complex processes with multiple steps have unacceptably high error rates. In healthcare, error rates run at above 1 percent per step, evidence that organizations are not ‘in control.’


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The definition of a high reliability organization extends beyond patient safety to encompass quality care — and ultimately value.

Many healthcare providers lack even the basic building blocks of culture, responsibilities and accountability, process optimization and standardization, and measurement. As they progress to a state of high reliability, each of these blocks has to mature individually and become interdependent with the others, which is no small task, even for the more renowned organizations.

“We are moving towards a more fully integrated operating model, fighting the disintegrating pull of continuous specialization,” says Mayo Clinic’s Mike Harper. These sentiments are echoed by Ralf Kuhlen, Chief Medical Officer of Helios Kliniken, a German hospital chain with an explicit, public focus on clinical excellence. “Much of this isn’t very sexy. It is the small stuff that matters the most, and it is sometimes hard to get everyone to focus on that.”

What distinguishes these providers is their willingness to push back the frontiers to integrate necessary changes encompassing the building blocks.

Quality has a clear monetary value, with 40 percent of patients coming from outside the country, high quality is essential for continued economic growth.

Dr. Fawzi Al-Hammouri
CEO, The Specialty Hospital, Jordan
Building block 1 — A culture devoted to quality

All the leaders involved in this report highlighted the importance of a quality-oriented culture, not just among leaders but throughout the organization. Continuous measurement and a clear sense of accountability are intrinsic values rather than imposed obligations. This manifests in: trust and respect for each other’s roles (especially between managers and professionals); a constructive approach to errors that does not seek to blame individuals; and a sense of belonging to a team coupled with a drive to excel and not accept complacency.

Staff is urged to recognize soft signals, such as stress, or a reluctance to speak up. There is also a zero tolerance to any breaches of safety, especially from individuals that feel they are above the rules. Leaders may have to confront entrenched attitudes among medical professionals in particular, while also questioning their own assumptions over safety and behavior.

Building a culture tuned to quality takes time and calls for collective effort and common goals. The board’s role is crucial and goes beyond the creation of organizational structures and reporting lines. Board members will have to reverse their traditional deference to professionals, and take an active involvement in defining and measuring quality and safety, and acting upon any poor examples, to boost awareness.2

As with all high-performance cultures, leadership has to demonstrate an aversion to being average, and a willingness to empathize with patients, families and the involved professionals following incidents where patients have been harmed. Embracing the right values is every bit as important as reporting structures and dashboards, and sets an example for the entire organization, as Georgina Black, head of KPMG Health in Canada explains: “The tone at the top from the board and senior management is crucial. The board needs to be informed, engaged and asking questions of management. Management in turn needs to treat quality as a core business of the organization and set a culture that promotes trust, inquiry, transparency, collaboration, ongoing learning and excellence. Structured methods of learning enable front line staff to inspire each other and exemplify the drive to excellence.”

Much of this isn’t very sexy. It is the small stuff that matters the most, and it is sometimes hard to get everyone to focus on that.

Ralf Kuhlen
Chief Medical Officer,
Helios Kliniken, Germany

Defining ‘culture’

It is useful to define what we mean by culture: Hofstede defines culture in organizations as the collective mental programming that distinguishes one group or organization from another. Here, we are interested in a mental programming tuned to quality.

Bad habits can become the norm

“Being satisfied with average can lead one to slowly start to accept the most appalling levels of quality,” says Malcolm Lowe-Lauri of KPMG in Australia. “As minor breaches of standards become gradually accepted, so major failures follow.” This ‘normalized deviance’ led to disasters as varied as the NASA Challenger Shuttle and the UK’s Mid Staffordshire Hospitals. The reports coming out of the system merely confirmed that the organizations were not doing too badly, yet this concealed the fact that no one was prepared to ask aggressive, challenging questions that would keep everyone on their toes.

Examples of normalized deviance are: low hand washing compliance before patient contact, or minimal/zero consultant oversight of hospital care on weekends. The culture of tolerance makes it easy for such organizations to slide further downhill, with individuals believing that “rules are for others.” Without strong examples from senior role models, any corrective patient safety initiatives are doomed to failure.

A lack of response to organizational deviance at a community and regulatory level has similar dire consequences, with members unlikely to fear any punishments for violating formal standards of behavior.3

1 For an in-depth discussion, see: Baker, G. et al. (2010). Effective governance for quality and patient safety in Canadian healthcare Organizations, Ontario/Alberta. Canadian Health Services Research Foundation and Canadian Patient Safety Institute.


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Building block 2 — Responsibility and accountability

Without a clear vision of how to use measurements, even the best metrics are of little value.

“The more I measure, the less I sleep” notes David Rosser, Executive Medical Director of University Hospitals Birmingham, UK. “Even if you would know what to measure, you lie awake thinking about what to do with this data. You can’t just throw it back at your doctors; you have to make it live for them and be actionable.” Hospitals need to clarify responsibility for outcomes and reporting structures, so that the board can identify who is accountable and measure his or her performance. As Mary Jo Haddad of SickKids Hospital emphasizes: “Jobs and roles have to be crystal clear, and that’s often not the case.”

As a starting point, patient pathways through the organization should have identifiable owners and teams, in the same way that units such as wards, intensive care and emergency have clear lines of responsibility. When these owners — professionals and managers — are accountable for their performance, the organization has a basis for continuous quality and cost improvement.

Progressing through the stages — penetrating the concrete floor

“Mintzberg (1998)” used the ‘concrete floor’ as a metaphor to describe the separation between clinical and managerial perspectives in most healthcare provider organizations. “Beneath it, the clinicians work away delivering their services, driven primarily by professional specializations, which are in turn driven by sophisticated technologies. Above it, senior managers advocate and negotiate with one another, and manage the non-clinical operations when they are not, of course, engaged in one of their perpetual — and often fruitless — reorganizations.” The ‘concrete floor’ indicates a misalignment of perspectives, objectives and values, and a communication and cultural disconnect between those working on either side of the concrete floor. In the context of delivering value, there is a real risk of separation into different emphases — financial and operational in the management world above the concrete floor, and clinical value for the individual patient below it. Perhaps an extreme example of such a concrete floor is evident in the findings of the Francis inquiry into failings at the Mid Staffordshire NHS Foundation Trust in England (2010, 2013).

Dr. Panigrahi
Head of Medical Operations, Fortis Healthcare, India

We don’t operate with a standard, top-down recipe book. Top clinicians are the crucial element, and they have to become owners, to ensure that the standard is a joint endeavor rather than a management initiative.


The power of having the board on board. Institute for Healthcare Improvement; 2011.
By making outcomes the most important objective, the board sets the tone and oversees the quality strategy and implementation, underpinned by the proper metrics, with the Chief Executive Officer (CEO) and other executives fully accountable. An internal audit function augments such an approach, to monitor and improve governance processes, risk management and quality control. In this way, clinical governance should mirror financial governance, as David Dalton of Salford Royal Foundation Trust, UK explains: “The system for quality governance is built into our Trust’s annual plan. Each of the risks are rated, and responsibility for monitoring and management is allocated on the basis of the level of risk involved, with the most critical sitting with the entire board, then the Chief Exec and so on. Quality and safety are a key part of all board meetings, and we’ve trained all board members. These topics constitute about a third of the agenda and time, and they are usually the first part of the meeting.”

A streamlined upward flow of the most important measures can keep everyone informed and avoid information overload, with appropriate levels of detail for each audience.

King’s College Hospital NHS Foundation Trust, UK, has a well-developed approach, says Tim Smart, CEO: “We now have a Quality and Governance Board committee, on which I sit, in addition to Finance, Workforce and so forth. That committee has several feeder committees — which I don’t attend — which cover all the subtopics, and are in turn fed by the ward and unit management.”

Successful healthcare organizations no longer develop measures from the top down and recognize that those at the front line know what is most important to track. “In the old days, quality governance staff were on the sidelines and not respected nor attended to,” says David Rosser of University Hospitals, Birmingham, UK, “We’ve changed that, making the quality of the work the central responsibility of our core lines. You have to make them accountable, and measure and monitor their work in a very timely way. That creates the drive.”

“A zero tolerance for complacency is crucial. Look at our mandate: we take care of sick kids, and every kid that comes through these doors should and will receive exemplary care. We have created an open, transparent, trusting culture, and if something goes wrong we delve into it, report on it, learn from it, and share these lessons.”

Mary Jo Haddad
President and CEO,
SickKids Hospital, Toronto

A commitment to improvement

In the German Helios hospital chain, data is reported from each clinic’s medical director to the regional level, and then up to headquarters. “We go through reporting cycles like that every two months,” explains Ralf Kuhlen, Chief Medical Officer. “We found ourselves scoring ‘average’ on stroke outcomes, for example, and that was simply not good enough. So we picked that up, went into the best- and least-performing clinics, learned what worked and what didn’t, and improved our overall performance.”

“Everybody has to participate, and we follow-up on problematic scores and enforce agreed quality measures, such as the usage of general surgery checklists. We have made it very clear, at all levels, who is responsible for such measures. Those are ‘must dos’; when you don’t, you’re not working with us.”

Global perspectives on clinical governance

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A UK perspective

In top-performing providers, internal auditors not only scrutinize financial reporting and governance processes, but also look at the way that quality is reported and governed. In some cases, there is a focus on data quality, which is arguably a key foundation of quality governance. Reliability and validity of reported quality data is often poor, something that is touched upon later in this document.

In the UK, the Quality Governance Framework tests the ‘robustness’ of quality governance in providers that either want to achieve ‘Foundation Trust’ status or, alternatively, are experiencing quality problems. This framework was developed by Monitor, the regulator, and is explicitly multidimensional, touching on several building blocks. Boards first have to provide a self-certification statement showing compliance with the framework standards (to demonstrate that the board is in control of quality), after which an external assessment can take place. The framework, with which KPMG in the UK has extensive experience, is divided into four domains.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Capability and culture</th>
<th>Processes and structure</th>
<th>Measurement</th>
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<tbody>
<tr>
<td>1a Does quality drive the Trust’s strategy?</td>
<td>2a Does the board have the necessary leadership, skills and knowledge to ensure delivery of the quality agenda?</td>
<td>3a Are there clear roles and accountabilities for quality governance?</td>
<td>4a Is appropriate quality information being analyzed and challenged?</td>
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<tr>
<td>1b Is the board sufficiently aware of potential risks to quality?</td>
<td>2b Does the board promote a quality-focused culture throughout the Trust?</td>
<td>3b Are there clearly defined, well understood processes for escalating and resolving issues and managing performance?</td>
<td>4b Is the board assured of the robustness of information relating to quality?</td>
</tr>
<tr>
<td>3c Does the board actively engage patients, staff and other key stakeholders on quality?</td>
<td>4c Is the information on quality being used effectively?</td>
<td></td>
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</tbody>
</table>

The internal auditors at KPMG in the UK take a mixed approach to data gathering and assessment.

— **Checking information:** the focus of policies; minutes of relevant committees; testing information flow from the floor/ward to the board level.

— **One-on-one interviews with executive and non-executive board members:** observing the board and the way decisions are made; time spent on quality and the interactions between executive and non-executive members (understanding the degree to which behavior is defensive, open and challenging, and the extent to which individuals are held to account).

— **Focus groups of staff to provide a view from the hospital floor:** do staff feel able to report? Is there an open, transparent listening culture?

— **Whistle-blowing:** is there a procedure in place? Do staff know about it and has it ever been used?

— **Risk registers and board assurance frameworks:** how are these updated, who owns the risks and what is being done to mitigate these risks?

— **Seeking information from other sources (regulatory and others):** mortality indices; serious untoward incident reports; action plans; staff and patient surveys; complaints; how are all these addressed if there are any adverse findings or trends?

— **Interview local stakeholders:** including clinical commissioning groups.

The framework helps bring these strands of information together through a scoring mechanism, which signals areas of concern over governance arrangements.

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Global perspectives on clinical governance

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Building block 3 — Optimizing and standardizing processes

When every surgeon uses his or her own preferred operating technique, there is a higher chance of misunderstandings and errors. In a ‘high reliability’ organization, on the other hand, measurement, roles and culture are all aligned with standard pathways and operating procedures, which can reduce complexity and variation, improves cooperation and communication, and enhances quality.

With a higher level of scrutiny and double-checks, processes can become far more resilient. Front line professionals are responsible for confirming that guidelines are being followed, and have the capability and will to intervene should they fear that this is not happening.

Standard operating procedures should be embedded in the workflow, which is an approach that has produced tremendous results for Intermountain Healthcare.

Based in Utah, US, Intermountain has pioneered the integration of standard processes and measurement of outcomes, as Dr. Brent James, Chief Quality Officer explains: “We blended the guidelines into the flow of clinical work at the bedside, and added it to the checklists, order sets and clinical flow sheets that the clinicians already routinely used to deliver care. Guidelines are typically forgotten half of the time, so we made these automated pathways the default way of doing things around here.”

In the UK, University Hospitals Birmingham’s IT system has similar, constant checks on whether crucial process steps are made, guidelines are followed, and medications are given. In some cases, innovations can be very simple, as proven by Helios Clinics’ ‘Stroke Box,’ which put all the material needed for acute stroke treatment (syringe, anti-thrombolytic drug, checklist) in one container, automating the process and increasing compliance to guidelines.

Average is not good enough

According to Malcolm Lowe-Lauri, KPMG in Australia: “All too often, benchmarks in healthcare measure against the average. If I’m average, it’s typically considered okay. Yet we should be aiming at the leading edge.” Mary Jo Haddad of SickKids Hospital concurs: “We all have to feel the innate urge to learn, to become better. You have to be willing to take smart risks. A manager with a poor performance measure should share this with his or her team. The emergency team should be asking: ‘How come surgery had better performance than us this year?’ We are not going to let that happen again!’ If all my indicators are meeting target, then the targets are probably set too low.”

Devolving responsibility is key to the approach — so is staff and doctor participation. Dena Van Den Bergh, Director: Quality Leadership and IT, Netcare Limited, South Africa says: “We have moved away from physician ‘buy-in’ to one where they get involved early and take on leadership roles in improvement. Doctors increasingly step forward for this — ‘they are hungry for data that supports improvement, it’s not about incentives’.”

Guidelines are typically forgotten half of the time, so we made these automated pathways the default way of doing things.

Dr. Brent James
Chief Quality Officer, Intermountain Healthcare, US
“You have to build in mechanisms for people to find and follow those guidelines,” argues Mary Jo Haddad, President and CEO of Toronto’s SickKids Hospital. “Translating requires a clear message and a clear understanding of the target, and crystal clear roles and responsibilities.” This is where the different building blocks come together. The compliance with and outcomes of the care paths are measured, with results fed back to the ‘owners,’ who monitor and constantly improve the value delivered by the care path. “Once you have the process in place, and you measure the outcomes and close the feedback loop, you improve the guidelines as well.”

The Mayo Clinic’s Mike Harper also emphasizes the importance of evidence-based, user-friendly processes, infused with the newest insights from the ongoing measurement and improvement cycles. “We call this our ‘knowledge-to-delivery engine.’ By using all of Mayo’s expertise to filter internal and external information and knowledge, we arrive at optimal processes, which are made actionable in dynamic care pathways that are constantly updated with new knowledge. This is the upgraded Mayo philosophy that is fit for our larger scale and technology-supported, as if you have the power of all of Mayo behind you.”

As Ralf Kuhlen of Helios notes, there is a history of deep resistance towards ‘standardization’ in healthcare: “In Germany, the medical specialist is still very much his or her own boss. We are told that every patient is unique and that standards do not work for doctors.” Despite some regional differences, such observations were recognized by everyone we interviewed for this report. However, leading doctors do recognize that standardization can go hand-in-hand with clinical expertise and judgment, an observation made many times by the surgeon and writer Atul Gawande. To achieve true excellence, an organization first needs a standard as a basis for continual improvement. This standard operating procedure remains the default, liberating practitioners to focus on the truly unique aspects of any given case.

**Standardization and clinical excellence are natural bedfellows**

Opponents of clinical care pathways argue that they stifle individual judgment, losing the ‘art’ of medicine. Yet, in the same way that improvisational jazz is based upon standard chords and melodies (actually called ‘standards’), it is by mastering the ‘standards’ that one learns to improvise. Subtly deviating from the standard at the right time, in the right way, turns the standard into art. True professional excellence is achieved through standards; not in spite of them.

**Intermountain Healthcare: saving lives, reducing costs**

By introducing standard workflow guidelines, and measuring outcomes, Intermountain Healthcare has made dramatic and continuous improvements. For patients who were most seriously ill with acute respiratory distress syndrome, the rate of guideline variances dropped from 59 percent to 6 percent within just four months. Patient survival increased from 9.5 percent to 44 percent, physicians’ time commitments fell by about half, and the total cost of care decreased by 25 percent. This approach has since been extended to cover 104 clinical processes that account for the vast majority of the care within Intermountain’s care delivery system, with a similar degree of success. The group is now widely regarded as one of the top, high-value providers in the US, achieving excellent outcomes at low costs.

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7 For example: (2012) The checklist, big med. Restaurant chains have managed to combine quality control, cost control, and innovation. Can health care? The New Yorker.
Building block 4 — Measurement

All the organizations taking part in our discussions share an obsession with measurement, as Mayo Clinic’s Mike Harper succinctly explains: “We aim to religiously and relentlessly measure and re-measure.”

State-of-the-art internal dashboards are commonplace, along with process and outcome measures from the ward-level up, covering a wide range of quality outcomes, prevention practices, re-admissions, length-of-stay and throughput time data, and compliance with protocol. Many measures are real-time and automatically fed to professionals and — where relevant — higher management tiers and, ultimately, the board. Data is fed back to the owners of clinical pathways to enable continuous improvement.

Quality dashboards

In most leading organizations, those responsible for specific care processes — and the individuals they report to — have internal quality reporting and monitoring systems. These provide general oversight at the highest levels, and can investigate the drivers behind low- or high-scoring measures. By benchmarking against peers, they use an internal clinical intelligence platform, constantly updated, to close any performance gaps at the point of care.

The Mayo care process model

The Mayo Clinic is developing a bank of care processes, which is their term for care pathways. “These care processes should be used 80 percent of the time, and we measure that,” says Mike Harper, Executive Dean of Clinical Practice. “This is key to how we manage and control quality. We now have 75 - 125 care process models, including frequently asked questions (FAQs) for the experts to review, comment on and accept.” They then integrate these guidelines into the workflow: “For example, we have experts on prolonged cardiac QT syndrome, and need to spread their knowledge around the organization. You have to detect this condition on the ECG, because outcomes can be disastrous if you don’t spot it, and medications can make things worse if you don’t know the patient has it. Despite creating a rule for the emergency room, people ignored the rule, and non-experts didn’t know what to do with the alarm. So we added more explanation to the rule, a set of FAQs detailing when to refer, and when to do something else — and many people still got the wrong medications and/or were not referred to the cardiologist. Finally, we built the rules into the order system and inserted checks into the medication system, so that technology ensures that you will remember, bringing the number of mistakes down to zero.”

Source: UHB/KPMG International Hospital Benchmarking tool

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The search for new and better measures never ceases, according to David Rosser, Executive Medical Director of University Hospitals Birmingham, UK. “We are not sure that we are measuring what we should be measuring as best as we can.”

This outlook is shared by Mary Jo Haddad, President and CEO of SickKids Hospital in Toronto: “Everybody wants to measure everything. That is in the culture of our organization. We measure, create score cards, dive deeper. We are constantly trying to figure out what’s most important to measure. The leadership task is to keep focusing, connect the measurement with the core organizational goals and priorities and ultimately measure what matters.”

Interestingly, these organizations do not fall into the trap of over-measurement that has jammed the work schedules of many hospitals, causing project overload. “For us,” says David Dalton, CEO of Salford Royal Foundation Trust, UK, “measurement and improvement is not a project: it is an integrated part of everyday work.”

Measurements are only relevant when they relate to patient outcomes, as Mary Jo Haddad of SickKids Hospital observes: “A key example is in pediatric cardiac surgery. We started a database to measure outcomes of this type of surgery almost 20 years ago. That has helped create an improvement in outcomes across the world; it is truly incredible to have been a part of that. It all started with a professional with a drive for excellence; someone who had seen kids die and wanted to change that. From there on he began to build a registry of cardiovascular outcome data, and reach out to colleagues, to get them on board. All this was driven by a professional passion.”

“We’ve started with a few specialties,” concurs Dr. Panigrahi, Head of Medical Operations of Fortis Healthcare. “Three outcomes are being tracked and measured — percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) in Cardiac Sciences and total knee replacement (TKR) in Orthopedics. We have also become part of an international registry for acute myocardial infarction (AMI), where we are looking at how they are managed. This is under the aegis of the International Consortium for Health Outcome Measurement (ICOHM). For all AMI cases we measure 30-day outcomes, one-year outcomes, and revascularization outcomes. For cardiac surgery, we have adopted the Euroscore, a standardized outcome measurement methodology. For hip or knee replacement, we look at the outcomes after one year. We pick from available US and European metrics. We start with new measures, learn to work with them, make them robust and then we move further.”

All those involved in our interviews agree that IT infrastructure is key to the success of dashboards. However, these pioneers do not let technology gaps such as interoperability or incomplete electronic records hold them back, observes: “A key example is in pediatric cardiac surgery. We started a database to measure outcomes of this type of surgery almost 20 years ago. That has helped create an improvement in outcomes across the world; it is truly incredible to have been a part of that. It all started with a professional with a drive for excellence; someone who had seen kids die and wanted to change that. From there on he began to build a registry of cardiovascular outcome data, and reach out to colleagues, to get them on board. All this was driven by a professional passion.”

The power of benchmarking
Forward-thinking organizations aim to benchmark themselves internationally, to learn from best practice around the world. In partnership with University Hospitals Birmingham, UK, KPMG has developed an International Hospital Benchmark (IHB), which helps hospitals compare quality and safety, productivity and efficiency, and financial performance with one another. This tool is part of KPMG’s commitment to the sector to help increase the effectiveness and efficiency of clinical governance. It allows point-of-care benchmarking and data-exploration at both the hospital and the diagnosis level, using sophisticated web-based technology. See page 15 and pages 23–24 in this report for illustrations of what the tool can do. For more information on IHB, contact healthcare@kpmg.com, or your national practice leader.
The journey towards ‘high reliability’

Despite representing many of the world’s foremost healthcare organizations, none of the leaders interviewed for this paper were confident that their institutions had reached a state of high reliability, which entails a journey through four stages:

<table>
<thead>
<tr>
<th>Reliability stage</th>
<th>Phase 0</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td>Unrestrained individual autonomy of professionals</td>
<td>Constrained individual autonomy</td>
<td>Constrained collective autonomy (teams)</td>
<td>Teams with strong situational awareness</td>
</tr>
<tr>
<td><strong>Reliability level</strong></td>
<td>&gt;10⁻¹ (&lt;80% error-free)</td>
<td>&lt;10⁻¹</td>
<td>&lt;10⁻²</td>
<td>&lt;10⁻³</td>
</tr>
<tr>
<td><strong>Translation to care</strong></td>
<td>Healthcare as craft</td>
<td>Watchful professional</td>
<td>Collective professionalism</td>
<td>High reliability care</td>
</tr>
</tbody>
</table>

Range in which most current healthcare practices operate

**Phase 0**

In this initial phase, care may be excellent but not consistently so, with no real board oversight over quality and a lack of control over clinical risks. Outcomes are not uniformly measured nor reported, and quality is not central to the culture. Responsibility for outcomes is poorly defined, with few protocols centered around patients.

**Phase 1**

Many providers in developed markets are at this stage, where safety and clinical excellence enters the agenda, along with a growing acknowledgment that progress is dependent upon systems rather than individuals. Measurement of outcomes is more common but not yet standard, and attention to quality is becoming more systematic, from the board down to the ground floor, with higher prevalence of (and adherence to) protocols and checklists, to improve outcomes.

**Phase 2**

Only the most advanced organizations have reached Phase 2, where key outcomes and their drivers are routinely measured and reported, and aligned with the board’s quality objectives. The culture is intolerant of breaking basic rules, yet also takes a blame-free, learning approach to errors. Individuals have clear responsibility for care paths, while departments handling parts of care also have their own measures, and monitor the impact of their performance upon overall patient outcomes.

**Phase 3**

Phase 3, ‘high reliability’ care, is achieved only in some instances, where the standards become so high that preventing failures becomes the leading drive. In healthcare, probably only high-risk environments like the OR, ICU and the ED require such a mind-set and corresponding ‘failsafe’ organization of the work.

Becoming a Phase 2 or even Phase 3 organization is a high ambition — but the public demands it, and the business case is clear for both those delivering and receiving or contracting the care. Becoming ‘in control’ of quality, we see time and time again, creates a much stronger grasp on expenditures as well. Ultimately, delivering high-quality care is why most providers and professionals stepped into the business in the first place.
As payers, patients, governments and regulators demand to know more about care delivery and quality, providers are seeking reliable and meaningful metrics. Many healthcare leaders perceive a disconnect between the internal drive for excellence and external requests for measurement and assurance, viewing the latter as unnecessary administration. In the quest to become high-reliability organizations, a greater focus on care outcomes can help providers to align these two tasks by reducing complexity and increasing transparency to the benefit of all stakeholders.

The one exception to this call for a shift towards outcome measures is safety. Although measurement enhances safety, measuring the successful avoidance of catastrophic events such as wrong-side surgery, complications and medication errors is not a feasible way towards assurance. In common with other high-risk industries, certification is often the preferred way forward, coupled with careful oversight and engaged clinicians.

The tension between internal and external reporting

Many executives contributing to this paper noted the constant tension between how they felt their organization should be held to account and how their health organizations actually judge them. There was virtually unanimous concern over the increasing number of measures, most of which are felt to be largely irrelevant. Leaders acknowledge the rights of patients and payers to know the outcomes that matter to them, yet also feel that the incessant demands for information can actually hold back rather than stimulate transparency and accountability.

These views were largely consistent across different healthcare organizations and geographies. “We have to report on well over 300 measures, a number that is rapidly expanding each year,” says the Mayo Clinic’s Mike Harper, referring to requests coming from different sources...
such as regulators, accreditation agencies and state departments of health. “We play the game, but the regulators and payers often do not coordinate their efforts nor focus on the things that we think represent ‘value.’ It takes a lot of manpower to cobble together the information.” This includes time spent working with on-site inspections and survey teams that aim to dive deeper into the data, to discover whether the organization is compliant with accreditation standards and other regulations.

A lack of focus

The UK’s Mid Staffordshire NHS Foundation Trust Public Inquiry revealed shockingly low standards of care that were allowed to persist over many years. As the Francis inquiry report concludes, the checks and balances of the healthcare system took much effort and many meetings, but ultimately did not address the underlying problem. According to Malcolm Lowe-Lauri of KPMG in Australia and previous CEO of University Hospitals of Leicester, UK: “The regulators were too remote and working at a too detailed level. They turn up a day late and a dollar short; not because of a lack of detail, but because of a lack of focus on what really matters.”

The outcomes that matter

Professionals and scientists are used to discussing those outcomes — known as ‘primary endpoints’ — that really matter to patients with a specific or multiple conditions. These endpoints are an excellent starting point for measuring broader outcomes. For stroke care, for example, the status 90 days after the onset of stroke is seen as the ‘primary outcome measure,’ on the road to optimum recovery. For rheumatoid arthritis patients, the most important intermediate goal — a strong predictor of long-term outcomes — is controlling the disease activity, as measured by the disease activity score, achievable through a few questions and one blood test.9, 10

Any organization basing its clinical measurements on inadequate internal administrative data and external regulatory requirements — rather than on intermediate and final clinical, cost, and service outcomes built around specific clinical care processes — will fail in its attempts to manage care delivery.

Dr. Brent James
Chief Quality Officer,
Intermountain Healthcare, US

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The leaders interviewed felt that, at best, half of the information they reported was meaningful — and some felt that none was of any use. In addition to the administrative costs, these tasks send out confusing and potentially demotivating messages to healthcare professionals, as Mary Jo Haddad of Toronto’s SickKids Hospital points out: “We’ve been working on measurement for a long time. Too often, policy-makers come up with new measures that do not have any relevance to us. In Ontario, for example, we are required to report on a number of key measures, a number of which are not overly relevant to children’s hospitals. I would rather report on the key indicators that are relevant to us, yet those won’t be taken into account. Measurement must be meaningful to impact positive change and improvement. Measuring irrelevant items may actually hurt what we are trying to do, by diminishing staff engagement and even undermining the board’s authority, which is perceived as micromanaging. The unintended consequences of such wrongly focused messages are huge.”

A further criticism is the low level of granularity of many measures, requiring reports, audits and inspections on outcomes of a particular treatment in great detail. Many providers feel that such data does not paint a picture of the overall value of care being delivered, a point emphasized by Haddad: “We are dwelling in all these overly detailed measures, while we should be focusing at the right level. I’d like the regulators to demand that we establish, for all our fields, the key outcome measures and linked targets and then publish the outcomes reliably and verifiably.”

“Measurement must be meaningful to impact positive change and improvement.”

Mary Jo Haddad, President and CEO, SickKids Hospital, Toronto
Making measurements simpler and more relevant

Some of the most important measures — for both internal and external use — are those that capture the overall outcomes of the care. To a diabetic patient, for example, the Hb1Ac (an intermediate outcome measure) is not a meaningful goal in itself; the true objective is to combine a full life with as few symptoms, exacerbations and long-term complications as possible. Similarly, for acute stroke or cancer patients, the core goals are survival, optimal recovery and, ultimately, quality of life.

Once hospitals are able to reliably measure and report these outcomes, and demonstrate improvements over time, there is no need to publicly report a plethora of process and intermediate measures. Healthcare boards, patients, payers, governments and other stakeholders around the world will likely no longer be interested in processes for patient centeredness, timeliness and effectiveness; they will just want to know whether providers are delivering best possible outcomes.

This is a new approach and, not unexpectedly, the sector is still trying to define the key outcomes and find ways to measure these effectively.

“Ideally, internationally standardized measures would work best,” argues Ralf Kuhlen of Germany’s Helios Kliniken. “In that way, everyone would be doing the same; we could compare outcomes, and we could really bring medicine forward.” In the absence of such measures, Helios has developed its own set of measures based on hospital administrative data, with an emphasis upon key outcomes. This is published annually for every clinic that is part of the Helios group.

We need competition on outcomes, not on the metrics!

Dr. Panigrahi
Head of Medical Operations,
Fortis Healthcare, India

Until recently, real outcome measures were rare

Processes are the most common measurements because they are easier to measure and do not require detailed risk-adjustment. Measuring outcomes, on the other hand, means gathering data from a variety of different care providers that are often not connected. Providers usually do not have access to data from other systems; even clinical registries only follow the patient as far as the reach of the relevant profession goes. Payers will have data that transcend organizational boundaries, but until recently, these sources were rarely combined.

External agencies have been focused primarily on the quality of care that a provider delivers, rather than on the quality of care a patient receives. The latter is a tougher challenge, as care is typically received from more than one provider.
Nevertheless, progress on outcome measurement is promising. In oncology and cardiovascular surgery, standardized outcome measures are becoming available through internationally coordinated clinical registries. For acute cardiovascular, chronic and elective care, the Dutch Health Insurers’ association has used its all-payer database to work with leading professionals to establish key outcome measures for conditions such as strokes, AMI and Parkinson’s disease. By combining this work with patient-reported outcome measures, it is possible to establish the key outcomes — including the appropriateness of interventions. In some of the leading US Accountable Care Organization (ACO) developments, payers and providers are combining administrative databases with clinical registries to improve the validity of measured outcomes.

For providers, such measures should ensure attention on those outcomes that matter most, feeding directly to internal improvement efforts, and freeing time traditionally spent on reporting unwanted metrics. The new, limited set of outcome measures would more reliably demonstrate the organization’s level of control.

Does the increase in improving compliance with process measures translate into improved outcomes?

The NHS in England introduced a new policy relating specifically to venous thromboembolism (VTE) and pulmonary embolisms (PE). It required all hospitals in the country to complete a clinical risk assessment of 90 percent of their patients who were admitted to determine if they were at risk of developing a VTE or PE. This process measure was designed and enforced through policy, with financial penalties for non-compliance, in the hope that if patients were deemed to be at risk the appropriate steps would be taken, reducing clinical risk and improving outcome.

The graphs show how each hospital performed against the process measure and when they achieved the 90 percent mandated target.
Clinical risk assessment for VTE over time in England

Graph showing the change in uptake for VTE risk assessment for trusts in England.

**Conclusion:** Following the new targets on VTE risk assessment in 2010, 96 percent of trusts managed to achieve the 90 percent target by April 2012.

Source: Healthcare Evaluation Data (HED), developed by Quality and Outcomes Research Unit, University Hospitals Birmingham, 2013.
Adequate benchmarking, as made possible by the KPMG UHB benchmarking tool, demonstrates how improved process measures do not always yield the outcomes hoped for. Some hospitals who achieved the process measure target early actually had worse outcomes than in previous years. The ability to track long-term patient outcomes at disease level to refine clinical processes is paramount. The benchmark also allows hospitals to study whether the cost of implementing the process measure policy translated into saving lives. What would be better to report on and more meaningful: the process measure or the outcomes?

Graph showing the percentage of VTE risk assessment compliance by hospital from April 2013 to August 2013.

Conclusion: 99 percent of all hospitals in England were compliant with the 90 percent assessment rate in the indicated time period.

Source: Healthcare Evaluation Data (HED), developed by Quality and Outcomes Research Unit, University Hospitals Birmingham, 2013.

But what about the outcomes?

Graph showing the number of PE-related deaths per year from 2001 – 2013.

Conclusion: The number of PE-related deaths has continued to rise from 2001 onwards. For related literature see Lester W. et al, (2013). Fatal VTE associated with hospital admission: a cohort study to assess the impact of a national risk assessment target. Heart BMJ, (published online first).

Source: Healthcare Evaluation Data (HED), developed by Quality and Outcomes Research Unit, University Hospitals Birmingham, 2013.
Assuring the reliability of reports

If stakeholders are to act on and pay for the reported outcomes, these outcomes should be available, reliable and valid. Currently, however, there is an acknowledged lack of clear definitions, registration and handling procedures, and reporting guidelines. Data is often not gathered in a standardized manner, and there is no segregation of duties in data recording and reporting. Systems used for recording and reporting are typically unsophisticated and lack the kinds of double entry facility seen in the general ledger of financial accounts.

Consequently, most publicly reported outcome data is still unreliable, especially when compared to the financial performance of healthcare organizations which have strong internal and external controls that assure the accuracy of data. The conclusions from an earlier study by KPMG in the US on quality reporting are still valid. “There is no consistency and no assurance in the accuracy of information.”

With few standards for registration, case-mix correction, data handling, indicator calculation and publication, and an absence of controls, any data published is not truly dependable.

In the rush to request data, governments, payers and regulators are often failing to question whether reports can be trusted. Indeed, there have been cases where data has been massaged to improve scores, such as in the Netherlands, where some hospitals’ reported breast cancer recurrence scores were lower than the numbers sent to the clinical registries. Such ‘gaming’ becomes noticeably more prevalent when professionals and providers question the relevance of particular reports.

For an in-depth analysis and an example of what a core-set of outcome measures look like, please see KPMG’s accompanying report, Measuring the Value of Healthcare Delivery at kpmg.com/healthcare.

Poor measures lead to gaming

The Hospital Standardized Mortality Rate (HSMR) was developed over a decade ago to capture the quality of a hospital in a single number. The HSMR looks at the number of people that die in the hospital in relation to the number of people that would be expected to die, taking into consideration the case-mix of patients. The validity of HSMR has been increasingly challenged, partly due to coding differences that create large fluctuations in the score, and partly because of the huge variation in patients and care in different hospitals. Yet the UK, for example, still publishes scores prominently, and hospitals are criticized for above-average HSMR rates. Deserved skepticism can lead to hospitals massaging their figures to achieve a more desirable score.

**Three steps to reliable reporting**

1. **Adequate and complete registration (including registration of risk-adjustment variables)**
2. **Adequate calculation of measure (including exclusion rules in population definition)**
3. **Adequate reporting (truthful, with audit trail)**

**Assuring pay-for-performance quality scores:**

The BMJ Informatica Contract+ tool is used by UK general practitioners (GPs) to score quality points, which determine their pay-for-performance. The system signals when actions such as tests and other activities have to be undertaken, and quality ‘points’ can be earned by improving the quality of care. The system registers the points, adds the information to the electronic patient record, and generates internal reporting data, such as points totals, and guidelines on improving scores. With one click of a button, the points earned are submitted to the (and in principle accepted by) NHS.

KPMG in Australia’s Malcolm Lowe-Lauri feels that gaming is not the biggest concern: “The main problem is poor data and poor completion of records — with little or no punishment for such failings.”

Ekkehard Schuler, Head of Quality Management of Helios Kliniken, agrees: “In Germany, mortality figures are compiled by the government. Due to the missing data, however, nobody really uses this information.”

To counter such problems, regulators are carrying out independent, sometimes ad hoc checks on the reliability of reports. In the Netherlands, the Visible Care program (a government-run initiative to stimulate public reporting from healthcare providers) has created a system of red, orange and green flags to indicate whether reported scores are valid and reliable.

“In Germany, mortality figures are compiled by the government. Due to the missing data, however, nobody really uses this information.”

**Ekkehard Schuler,**

Head of Quality Management, Helios Kliniken, Germany
Assuring quality in the UK National Health Service (NHS)

Since 2009, external auditors have had to confirm that specific quality indicators are accurate and that the content of the ‘Quality Account’ offers a balanced view of the provider’s performance. The five characteristics of good data quality are:

— **Governance**: to support data quality and give assurance over the data reliability.

— **Policies**: to support good information management, helping data security and accuracy.

— **Systems and processes**: well-designed performance information systems ensure data quality and inform providers and boards to take action.

— **People and skills**: staff and board members need the right skills and capabilities to review and challenge reported data.

— **Data use and reporting**: transparent reporting promotes data quality and enhances public accountability.

A 2010 audit of 32 providers conducted by KPMG in the UK found that each required improvement against every one of the criteria reviewed. Data use and reporting was the only area with satisfactory performance — and only in the acute hospital setting. The main factors hindering good data quality were data management and information systems. There were varied levels of sophistication and investment in data systems, and a lack of consistent definitions where a single provider spanned different hospital sites. Systems were creaking under the weight of data measured and measures to report, with limited investment in appropriate staff and systems. Nevertheless, some good practice did emerge, notably:

— information assurance maps, to track data quality across indicators, systems and time

— assurance on data management built into other routine business processes, including clinical audit or performance review processes, to filter and routinely assure critical information for decision-making

— a forum of combining clinical, statistical and informatics professionals, to assess and improve the management and presentation of healthcare outcome data.

As Neil Thomas (KPMG in the UK) says: “This experience demonstrates how a regulator and auditor can work together to drive improved governance arrangements in provider organizations.”


This experience demonstrates how a regulator and auditor can work together to drive improved governance arrangements in provider organizations.

Neil Thomas, Audit Partner, KPMG in the UK

**Reliable data entry?**

The most vital moment in data assurance is the point of data entry. At the bottom line, the professional or administrator entering the diagnosis, procedure code or other piece of clinical information has to register this data reliably. Professionals or administrators can test reliability through a variety of methods: looking for unexpected statistical patterns; checking how many co-morbidities are registered (too few suggest improper coding); checking audit trails; enforcing separation of registration/reporting duties; and comparing data with other information entered elsewhere. By making adequate data entry a priority, organizations have a better chance of both producing meaningful outcomes to drive decision-making and satisfy regulators.
Internal and external auditors are also frequently asked to assess the accuracy and completeness of reporting, drawing on their extensive experience with financial reports. Their efforts are aided by the rapid growth in literature on quality reporting, with regulation in Canada, the UK, Portugal, the US and elsewhere creating new requirements for data assurance.

In the UK, all NHS providers must publish an annual set of public Quality Accounts that is independently checked, with a director’s statement confirming balance and accuracy. To meet international auditing standards, such a confirmation requires auditors to look at the design of data systems, walk through the operations, identifying and checking audit trails, verifying the existence of proper internal controls, and performing sample tests to assure accuracy.

As Neil Thomas, an audit partner with KPMG in the UK, comments: “This involves a deep dive into the surrounding data and reports, to ask questions such as: “What was reported? Were all serious patient complaints and harm in the report? Were in-depth investigations conducted on why the processes or outcomes of care failed?”

To satisfy the regulators' scrutiny, the board and internal auditors should be engaged early to help ensure that the report content has passed through sufficient reviews to reflect all aspects of performance before being subject to the external audit. Although quality data assurance is on the agenda in the US, Anthony Monaco, an advisory partner with KPMG in the US, says that: “As yet, there is no standardized approach or clear external audit role.”

Providers will have to balance the need for assured data reliability with the resources required to achieve such a goal. One way to achieve greater efficiency is to concentrate on those outcome measures that matter most to patients. Smart use of IT can also help, with certified software making data gathering and reporting both faster and more accurate and reliable, enabling checks of calculation methods and inclusion and exclusion rules. Smart IT can thus help with the second and third step in reliable reporting. The first step, the moment of data entry itself, then becomes the remaining, key step where reliability is at stake, and further assurance may be required.

Assuring the quality of reported data: ‘Meaningful Use’ certification in the US

‘Meaningful Use’ is a US incentive program to stimulate adoption of electronic health records (EHR). Providers receive funds when they prove they meaningfully use the EHR. This involves maintaining an active medication list for every patient; recording essential data items in a standardized way; keeping data secure; and calculating and submitting certain quality metrics in a standard manner. The software must pass standardized and partly automated stress tests, after which the certified software is included in a national register, releasing the incentive payments. Such certification helps to assure reliability of particular quality metrics, as they are all calculated and submitted in the same manner.

(For an example of such a test, see: http://www.healthit.gov/sites/default/files/170.314c1-c3cqms_2014_tp_approvedv1.2.pdf)
Assuring safety

Measuring non-catastrophic ‘negative’ outcomes (such as pressure sores, in-hospital falls, infections, medication errors and readmissions) can be done and is a foundation of safe and high reliable care. Yet there are an infinite number of things that can go wrong, and properly reporting all of these — in a reliable way, properly corrected for the case-mix of the population — would be a very costly endeavor, adding to the administrative burden for providers, and ultimately not realistic.\textsuperscript{12,13,14} (Not surprisingly, many of the critical comments of the health providers referred to these types of public measures.)

In addition, a core focus of ‘patient safety’ is avoiding catastrophic, rare events (like wrong-side surgery, foreign objects left in the body after surgery, serious medication errors, and so forth).\textsuperscript{15} Reporting on such events reliably is statistically impossible. Also, the safety precautions should be such that the risk of such event occurring is as minimal as possible, and that when it occurs, the organization will act swiftly and decisively, deal with the patient (and family) with respect, and prevent further harm to the patient as well as to future patients.

Resorting to publicly reporting on care bundles (how many patients received all necessary steps of a carepath) is not a solution either, since the list of such processes is equally enormous. Measuring key bundle compliance for internal purposes is crucial, but citizens and payers are not interested in long lists of things that (almost) went wrong. Too much focus on this also disempowers professionals and providers rather than supports them, tapping both moral and real resources that could have been spent more wisely.

Certification is arguably the most effective way to reassure the public that care is safe, and organizations such as the US Joint Commission, Accreditation Canada, DNV and the Australian Commission on Safety and Quality in Health Care have all introduced programs in recent years. Not all of these programs have incorporated the state-of-the-art risk management insights, however. Ideally, the certification process would focus on how far a particular organization has proceeded on the path to becoming a high reliability organization (which stage of reliability is achieved), zooming in on whether the organization is building the right structures and processes, and, crucially, the right culture.

As leaders seek to create a safe organization, they need to ensure that they:

1. measure the right processes and safety-outcome measures at the right level
2. align these measures with clear responsibilities and accountabilities for safety, both for the patient-focused pathways and the central units, such as intensive care and wards
3. combine zero tolerance with an openness to learning, and to collectively discussing process failures, near misses and patient harm
4. make processes ‘fail-safe,’ and owned by staff with appropriate authority.

\textsuperscript{15} Facts about the Sentinel Event Policy. The Joint Commission; 2009.

“Not dying is not the best measure of quality in surgery. We are beginning to see registries of patients and outcome information that are true windows into the quality of the procedure that was performed.”

Dr. Cynthia Ambres
Partner, KPMG in the US

BMJ Outcomes journal

Supported by KPMG International, the British Medical Journal (BMJ) is currently working on a new initiative to provide a journal and repository for publication of outcome measures to help facilitate discussion and support the consolidation of knowledge in this area. The aim is to create an international forum for debate and consolidation of knowledge on how to measure the key outcomes that matter for patients, professionals, providers, payers and the public.

Hopefully, BMJ Outcomes will contribute to a growing body of evidence and industry best practice in the approach to outcomes measurement at an individual, organizational, regional, national and international level.

“Certification is arguably the most effective way to reassure the public that care is safe.”

Dr. Marc Berg
Principal, KPMG in the US

Global perspectives on clinical governance

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Conclusion

As healthcare organizations strive to gain control over quality, they can expect the journey towards ‘high reliability’ to take them through various stages, with the pursuit of excellence and safety gradually becoming systematic, towards a culture obsessed with outcomes and safety — and the measurement of these factors.

Responsibility for quality will likely become less reliant on individuals and more on teams. Staff should learn to embrace standardized processes trading individual for collective autonomy, leading to improved outcomes and a sharp decline in harm rates.

Regulatory demands are expected to change significantly, as providers, payers and governments acknowledge the need to converge internal and external measurements and reporting around the key outcomes that matter most to the patient.

These outcome measures should become increasingly internationally standardized — as guidelines increasingly are also. Quality audits will likely become the norm and adopt the same standards as financial assurance, to give regulators, patients and other stakeholders confidence that reports accurately reflect real performance. Likewise, certification should focus primarily on the safety of care, assuring error rates much lower than we are now used to.

Path towards high reliability

The organizations studied in this paper are all making progress along the path to high reliability and have adopted some or all of the following actions:

01 Embrace the four building blocks of measurement, responsibilities and accountability, culture, and process optimization and standardization.

02 Measure the outcomes that matter most to patients, and the contributing processes and intermediate outcomes.

03 Assign individuals responsibility for clinical and financial outcomes of defined care processes.

04 Align measurement processes with care pathways and lines of reporting.

05 Create a culture that is zero tolerant to complacency, but also open and just, committed to excellence and joint learning.

06 Adopt the appropriate information technology (IT) to optimize measurement and processes, but being careful not to let the lack of a proper IT infrastructure act as an excuse for inactivity.

07 Focus external reporting on important patient outcomes, rather than on detailed processes and protocols.

08 Continually seek ways to risk-adjust measurements, to enable better benchmarking.

09 Provide independent assurance over the reliability of quality measures, via internal and external audits, applying established assurance principles.

10 Choose certification as an appropriate way to assure safety, rather than public reporting of negative outcomes.
How KPMG can help

Helping to assure reliability in the public quality report

Good clinical governance requires boards to pay at least as much attention to quality issues as is paid to financial issues, and to publicly account for outcomes in these two fields in the same way.

Industry best practices for quality reporting should therefore consist of a periodically and publicly issued report that contains information that is relevant for all the stakeholders:

— that aligns objectives and information from the patient’s perspective for professionals and providers, being held to account
— that gives a true and fair view of all the relevant matters concerning the quality of care, which means that unfavorable data are also incorporated in the report
— that is based on routine-based measurement of relevant data, that are subject to internal controls, comparable with internal controls used for financial data
— that is the subject of an external audit, and for which an auditor’s report is issued.

Although there are no global standards for quality reporting in healthcare, global standards for giving assurance on non-financial reporting, such as quality data, do exist and are used in several countries where external audits and reporting on selected clinical data is required.

About KPMG

KPMG’s 3,200 global healthcare professionals, combined with the Healthcare Center for Excellence, have the appropriate experience to assist organizations with evaluating their governance over quality data, including the processes used to capture and report on that data both for internal and external stakeholders.

Furthermore KPMG’s Healthcare professionals can also test the clinical systems and provide assurance over the completeness and accuracy of this data. For more information, please contact one of the partners listed on the back cover of this report or healthcare@kpmg.com.
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Thought Leadership

We invite you to visit KPMG Global Healthcare (kpmg.com/healthcare) to access our global thought leadership. Here you can gain valuable insights on a range of topics that we hope add to the global dialogue on healthcare. Should you prefer a printed copy of the publication, please email us at healthcare@kpmg.com.

What Works: Creating new value with patients, caregivers and communities
Globally some parts of healthcare are beginning to make the changes that will involve patients, caregivers and communities more fully in their own healthcare. Using our experience across the world, this report outlines the answers that you need to fully realize the value inherent in better patient involvement and communities to improve care.

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kpmg.com/valuebasedcare

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