QUALITY ASSURANCE AND MANAGEMENT

Edited by **Mehmet Savsar**

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Preface

Quality is one of the most important factors when selecting products or services. Consequently, understanding and improving quality has become the main issue for business strategy in competitive markets. The need for quality-related studies and research has increased in parallel with advances in technology and product complexity. Quality engineering and management tools have evolved over the years, from the principles of "Scientific Management" through quality control, quality assurance, total quality, six sigma, ISO certification and continuous improvement. In order to facilitate and achieve continuous quality improvement, the development of new tools and techniques are continually required.

With the initiation of "Scientific Management" principles by F. W. Taylor in 1875, productivity became a focus in dealing with complex systems. Later, systematic inspection and testing of products were started by AT&T in 1907. After the introduction of control chart concepts by W. A. Shewhart in 1924 and acceptance sampling methodology by H. F. Dodge and H. G. Romig in 1928 at Bell Labs, statistical quality control tools became widely used in industry. After 1950, total quality control concepts were introduced by several pioneers including A. V. Feigenbaum. In addition to development of several new quality control tools and techniques, use of design of experiments became widely used for quality assurance and for improving quality. In 1989, Motorola Company initiated six sigma concepts to assure high quality for complex electronic products and related systems. After 1990, ISO 9000 quality certification programs were introduced and became widespread in many organizations. American Society for Quality Control became American Society for Quality to put emphasis on quality improvement.

Quality terminologies are varied and often used interchangeably. In particular, quality assurance and quality control are both used to represent activities of a quality department, which develops planning processes and procedures to make sure that the products manufactured or the services delivered by organizations will always be of good quality. However, there is a difference between the two. In particular, while quality assurance is process oriented and includes preventive activities, quality control is product oriented and includes detection activity, which focuses on detecting the defects after the product is manufactured. Thus, testing a product is in quality control domain and is not quality assurance. Quality Assurance makes sure that the right

things are done in the right way. It is important to make sure that the products are produced or the services are provided in good quality before they are tested in the final stage of production. Once in final stage, there is no way to recover the costs that are already incurred due to bad quality. Quality assurance is therefore an area that needs to be studied and investigated in more detail with respect to various production processes, and service activities. Quality assurance is widely applied in such areas as industrial manufacturing, healthcare, medical areas, software, education, transportation, research, government activities, and other service industries.

The purpose of this book is to present new concepts, the state-of-the-art techniques, and advances in quality related research. Novel ideas and current developments in the field of quality assurance and related topics are presented in different chapters, which are organized according to application areas. Initial chapters present basic ideas and historical perspectives on quality, while subsequent chapters present quality assurance applications in education, healthcare, medicine, software development, service industry, and other technical areas. This book is a valuable contribution to the literature in the field of quality assurance and quality management. The primary target audience for the book includes students, researchers, quality engineers, production and process managers, and professionals who are interested in quality assurance and related areas.

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Contents

1

Five Essential Skills for 21st Century Quality Professionals in Health and Human Service Organisations

Cathy Balding
Qualityworks P/L and La Trobe University
Australia

1. Introduction

Society's demand for quality in all spheres has never been higher. In health and human services industries in particular, consumers and funding bodies demand both technical excellence and outstanding customer service. Industries such as health, aged care and community services are struggling to meet these challenges, as the numbers of consumers grow, technology adds new a layer of complexity that solves some problems and creates others, and staff are expected to provide excellent customer service as well as technically effective services. The role of the quality improvement professional in these organizations is expanding in line with these growing expectations and has never been more important. Traditional quality systems focused on compliance and monitoring are no longer sufficient to create an excellent consumer experience, and quality managers need to add to their skills base to effectively support their organizations in this rapidly evolving environment. This chapter proposes five essential skills for quality professionals in the new millennium that build on, and go beyond, those associated with traditional monitoring and improvement, and are essential for taking organizations beyond compliance to transformation of the consumer experience. The five essential skills for 21st century quality managers discussed in this chapter are:

1. Support robust quality governance
2. Work effectively in complex systems
3. Develop a balance of rule based and proactive approaches to quality
4. Develop strategic quality plans
5. Create impact and improve outcomes through sustained systems change

The content is derived from the literature and from the author's 20 years experience working as a quality manager and with quality managers in health and aged care.

2. Support robust quality governance

Transforming the consumer experience cannot be achieved without effective governance for quality. We now need quality governance and systems that address the impact we have on our consumers – not just the outcomes we achieve. People across the organisation, from the

boardroom to the customer interface, need to be clear on their individual responsibility for the quality of the services they provide and supported to enact it. Quality managers must be able to work with governing bodies and executives to design and develop systems that support staff to fulfil their responsibilities. This section discusses the governance systems required to enable and empower personnel across the organisation to enact their role in creating high quality services every day.

2.1 Understanding and implementing quality governance

The concept of quality governance is a relatively recent phenomenon. When the author started working as a quality manager in the 1980s, we thought that if we were accredited, doing some auditing and clinical review and engaging staff in quality projects then we were doing well. We knew that leadership was important, but we didn't know how important it was or indeed how best to lead. It took various studies and inquiries into suboptimal care and adverse events in healthcare to demonstrate that safe and high-quality care in a complex environment requires more than good staff trying hard. Clinical governance largely emerged from the findings of public inquiries into poor care that found that the majority of these organisations were not the victims of deliberately negligent practitioners. What they lacked were systems: for including consumers in their care, for supporting staff to provide quality care, for clarify accountabilities and for measurement and improvement. Nor did they exhibit consumer and safety-oriented cultures, with 'blame and shame' the common response to adverse events and passive response to data indicating suboptimal results. (Hindle et al., 2006)

Of course, quality care can't be achieved without good staff doing their best. But to create great care consistently, healthcare staff also need sturdy organisational supports behind them. Staff are 'front of house' – out there working with the customers. Governance is 'back of house' – the behind-the-scenes systems that support staff and enable them to provide a great consumer experience. To make the components of great care happen for every consumer, every day you'll need to ask:

- What do we currently have in place that supports great care as we've defined it?
- What do we need to enhance/change to achieve our quality goals?
- What new processes/supports do we need that we don't currently have?

Providing safe, quality care and guarding against organisational weaknesses that allow poor care requires commitment and accountability to be embedded in the organisational structures and culture, but also requires a targeted plan. Setting goals and targets for the quality of care your organisation wants to deliver, and implementing strategies to achieve them is part of the governance of any health or aged care organisation. The emergence of clinical governance over the past decade has been healthcare's approach to providing this accountability, planning and support. In aged and primary care, this can be reframed using more appropriate terms such as 'quality governance' or 'care governance'. The key components of governance can be organised into four generic cornerstones:

- strategic leadership, planning and culture
- consumer participation
- effective and accountable workforce
- quality and risk systems.

The importance of a quality governance system cannot be overstated; it provides the foundation for the myriad pieces of a quality system and gives people a role in that system, which in turn makes the implementation of the various governance systems easier.

2.1.1 Clarifying accountabilities for creating safe, quality care

The concept of governance arose from the need to ensure greater and clearer accountability for the quality and safety of care experienced by the consumer. This is still a work in progress in healthcare. There are many health service organisations in which individuals are not aware of the clear, specific, personal responsibility they have for the quality of care and services they provide. This makes it difficult for staff to carry out their responsibilities, and even harder to create a consistently safe, quality experience for consumers. Governance is where the governing body, executives and managers play their critical role in creating safe, quality care. The executive must translate the strategic quality goals into operational plans and strategies to facilitate their implementation as part of organisational business. Those on the frontline of care create the consumer experience, but the organisational supports for this must come from the top, as staff require leadership, policy, systems and an investment of time and resources to implement the strategies. And, of course, the quality manager provides technical support across the organisation to enable staff to fulfil their responsibilities. An example of generic governance roles for quality care is described in Table 1.

2.1.2 Developing dynamic quality committees

Another aspect of accountability is the way in which committees support the quality system. Driving the achievement of the quality plan through line management will generally occur in partnership with working groups or committees, particularly where implementation requires cooperation across staff groups or services. When committees are action focused they are invaluable in tracking and driving progress with the quality goals. When committees are just information recipients, staff will have difficulty understanding their purpose - and may try to avoid them. Quality managers need to be alert to directionless committees - and get them on track before they erode the credibility of the quality system. Committees should take an active role in quality goal monitoring and action at the local department/service level (where they might take responsibility for driving one component of a goal) right through to board committee level (which monitors progress with achieving the quality goals). Committees that have an explicit responsibility for achieving a quality goal are more likely to be proactive decision makers and less likely to be passive recipients of information.

To be useful, committees need a clear purpose and something that they are responsible for so they can make decisions and take action. Giving a quality committee responsibility for driving and monitoring a quality goal, objective, strategy or governance support will add some life and energy to proceedings. A clear purpose also helps determine a committee's agenda and membership. Quality committee agendas can be structured according to the quality goals and their objectives and components, which makes it easier to see how data monitoring and improvement activities link to the achievement of great care. All reporting should help a committee determine if progress is being made towards implementing governance cornerstones or achieving the relevant quality goals. Committee membership is

always tricky to get right. Members can be invited on the basis of who has to be on this committee - there will always be political and relationship imperatives in a complex system - and who you need on the committee to fulfil its purpose. Some members may need to be there because they are decision makers and have formal power. Depending on the committee's role, you may also want people with informal power - the influencers. If the committee is responsible for addressing improvement in a particular area of the organisation, you will need some who have a deep understanding of the relevant systems, relationships and mental maps. Everyone on a quality-related committee should understand its purpose and exactly what each of their roles is - be it sharing their knowledge, experience or influence - and be invited to contribute to discussions and decisions on that basis.

Organisational level	Quality Governance Responsibilities
Governing Body Accountable for the quality of care, services and consumer experience	• Make the achievement of great care a priority • Set strategic direction and the line in the sand for the quality of care and services to be achieved • Lead a just, proactive culture • Ensure management provides the necessary system supports and staff development to provide great care for each consumer, and monitors progress towards achieving the strategic quality goals
Chief Executive and Executives Accountable for and lead great care and services	• Make the achievement of great care a priority • Set strategic goals for great care and operationalise them through effective governance, resources, data, plans, systems, support, tools, policy and people development • Monitor and drive progress towards the strategic quality goals • Develop a thinking organisation and a just culture, wherein staff are supported to take a proactive approach to achieving safe, quality care and services
Directors and Managers Responsible for the quality of care in each service	• Make the achievement of great care a priority and take a proactive approach to achieving it • Operationalise the strategic quality goals by translating them into local initiatives • Understand the key organisational safety and quality issues and the broader quality agenda • Monitor and drive progress by implementing the drivers of great care within their services • Develop staff and systems to create quality care and services for each consumer • Make the right thing easy for staff to do
Clinicians and Staff Responsible for quality of care at point of care	• Make evaluation and improvement a routine part of care • Develop, implement and evaluate initiatives to contribute to the organisational quality goals • Support and enable all staff to create great care • Create a great experience for each consumer through positive behaviours and attitudes and a proactive approach

Table 1. Examples of governance roles in creating quality care (Australian Commission on Safety and Quality in Healthcare [ACSQHC], 2010; Victorian Quality Council [VQC], 2003)

2.2 Work effectively in complex systems

Organizations providing human services are complex systems. They have a large number of inputs and processes, and are continually exposed to outside pressures and influences. It is imperative that quality managers working in these environments understand how these systems work to be successful. This section explains what complex systems are, how they work and, most importantly, why these things are important for quality managers, because of the way they directly impact on the pursuit of high quality services in an organisation. Working in a complex system, but treating it as if it is a simple or complicated system, makes it difficult to achieve consistently high quality services. Change and improvement in complex systems require a particular approach, tailored to the unique characteristics of the complex environment.

2.2.1 An overview of some key complex systems characteristics

Complex systems operate according to distinctive and often counter-intuitive rules. It is important that quality managers understand these rules and, in particular, their implications for creating change and improving safety and quality. Traditional, production line approaches to quality are only half the story in a complex environment such as a health or aged care service.

All complex systems have a goal, which may be as simple as survival, or maintaining the current situation. Be prepared for push back from the system if you interfere with it achieving its goal. Systems enjoy their status quo and strive to maintain it. If you change one part of the system, this will result in resistance from the other parts of the system it is linked to because it means they will have to change as well. The more parts of the system there are and the more possible connections between them, the harder it is to change and the easier it is to create chaos (Meadows, 2008). So whenever you take action within a complex system, there will be side effects. These may be positive or negative, depending on your perspective. In our health services, we usually expect that effect will follow cause. This is production line thinking. We recognise these as false conclusions when we can't then replicate the same result in another part of the organisation. The result may have been due to the natural variation inherent in every system. Or it may have been due to your intervention - but this intervention won't work the same way in another part of the system. Generally speaking, real change in complex systems requires a lot of different parts of the system to be working towards the same change.

A complex system acts like a web of elastic bands so that when you pull one piece out of position it will stay there only for as long as you exert force on it. When you let go, you may be surprised and annoyed that it springs back to where it was before. In addition, a complex system may or may not be stable. Stable complex systems that have not been subject to a lot of change become more resistant to change as time goes on. All of us have experienced this in organisations, where one service or department has somehow escaped the force of change experienced by other parts of the organisation. When their turn comes, they find change very difficult. In an unstable system, however, pressure to make changes can cause the system to burst like a balloon. If the system is under a lot of pressure routinely, this may only take a small trigger, just as a small crack in a dam can lead to its collapse because of the constant pressure of water behind it. So if you put an unstable system under enough pressure for long enough, it can suddenly disintegrate.

Despite these characteristics, complex systems work because people make them work. But to do this, processes in the system are often changed as the system evolves, and then the relationships between the processes have to change to keep the system working. The relationship between different parts of the system determines how the system overall works, so each process change, however minor, can affect the behaviour of the whole. This is an important point! All processes in a system are interdependent and they all interact. The key to change is not to just focus on one process in isolation, but to look at how it relates to the other processes in the system. Systems can also become self-organising and can generate their own hierarchies of power and influence. These hierarchies may not be the same as those seen on your organisational chart. Each person, wherever they sit in the system, has the power to affect the way the system behaves. Relationships within each subsystem are denser and stronger than relationships between subsystems. For example, there are likely to be more interdependencies and networks up and down a silo in a health service than across and between silos. Interaction within the silos occurs mainly between members of the same professional group: nurses interacting with nurses, and doctors interacting with doctors. These tribes give the people within them an important sense of belonging but it can be hard to break down the walls and build bridges between them (Braithwaite, 2010).

Complex systems do not necessarily operate according to the policies of the organisation. On the contrary, complex systems can be exceedingly policy resistant. This resistance particularly arises when an introduced change threatens the goal of the system or when policies are implemented that are not based on the reality and unwritten rules of those having to implement them. We've all experienced policies developed on the run, or even painstakingly over a long period, that have only been partially adhered to by those they were designed for. If there is too great a mismatch between the policy requirements and the way that things really get done or the goals of the system, the policy will generally fail. At worst, people will disregard it; at best, they will work around it to meet their goals of getting their work done in the most effective, efficient and easiest way – a way that has probably been crafted over time and is protected by and embedded in the way the system operates and the unwritten beliefs of those who work within it. The way in which policy is implemented can also influence the degree to which it is enacted as intended. Poor implementation opens up a policy to all sorts of change and interpretation by those using it. This may drive policy enactment to drift away from the original intention.

The importance of quality professionals being able to adjust to and deal with these characteristics cannot be underestimated. It can mean the difference between the creation of consistently safe and quality services, and implementing monitoring and improvement with few gains. The implications of these complex systems characteristics are discussed throughout the remainder of this chapter.

2.3 Develop a balance of rule based and proactive approaches to quality

Human services have traditionally relied on rules to enforce standards and ways of working. But, as we can see from the characteristics of complex systems, more than traditional approaches are required to create consistently safe and high quality health and human services. Of course some rules and standardization are important, but too many rules can do as much damage as too few. Staff work around rules that are not a good fit for their environment and all systems and procedures gradually erode in complex systems,

where they are open to a myriad of influences and changing circumstances. What is required is a balance of rules, systems and thinking, proactive staff.

Improving reliability through systems that force and guide safe decisions, provide backups, remind staff of preferred behaviour and catch fallible humans when they make a mistake, are key aspects of creating safety. In fact, their use is in its infancy in healthcare - compared to other high-risk industries - and there would probably be significant benefit in fast-tracking the implementation of proven safety systems. Rule-based decision making, such as the use of protocols and checklists is also extremely useful in many situations; for example, by inexperienced practitioners who are learning standard procedures for frequent high-risk situations. Standard procedures can be useful for experts as well - particularly if they find themselves in a situation that they do not often experience (Flin et al, 2008). Not all aspects of standardisation and reliability are foolproof, however, and there is danger in thinking that they are a set and forget solution to safety. There are many reasons for this in a complex system. Remember the 'policy resistant' aspect of complex systems? Complex systems - and the people working within them - do not always respond well to overly restrictive rules, and they may react in unexpected ways. Creating a standardized approach, unless based on a forcing function, does not guarantee that it will be followed. And forcing functions, while useful in creating safety, can give rise to complacency and a lack of staff alertness. So standardisation is *one* answer to improving safety and quality, but not the *only* answer.

Why is this? We often find that there is such a strong emphasis on procedures, checklists and protocols that organisations attempt to write one for every eventuality. But it is almost impossible for a procedure to be written for every situation in a complex system, and unlikely that staff will refer to all procedures if there are too many of them (Amalberti et al, 2006). Reliability in high reliability organisations is accomplished by standardisation and simplification of as many processes as possible. But your health service is a dynamic organism with a high level of variability, production pressure, professional autonomy and rapid creation of new knowledge. Not everything can be fixed and standardised so when trying to reduce variability and improve reliability, it is better to focus on the variation that is creating real problems, rather than variation more broadly. All safety policies have a natural lifespan as the context around them is constantly changing. The challenge of creating and maintaining safety within this context requires a mix of standardisation and proactive, flexible, thinking solutions.

Over reliance on rule-based decision making is another flaw in mechanistic approaches to safety and quality in health services. It may cause a degree of skill decay; if an unexpected and unfamiliar situation arises and no rule exists, will the person making the decisions be able to formulate an effective course of action? (Flin et al, 2008). Protocols too may reduce or discourage the ability of people to be proactive, practice situational awareness, identify deviations from normal situations - in short, to think for themselves (Dekker, 2005). Bad decisions can also occur in rule based situations if the wrong rule or protocol is selected. It is human nature to prefer a familiar rule, whether or not it is the right one to match the situation in which the decision maker finds themselves. A mechanistic rule-based approach to safety is based on the premise that safety is the result of people following procedures, but staff work around rules and procedures that do not meet their needs for efficiency and streamlining. Developing checklists and protocols in response to risks may provide a sense of action having been taken, but can send the message that reliable, safe care requires

nothing more than insisting upon routine standardised procedures. Nothing threatens safety like the belief that the problem is solved (Bosk et al, 2009).

2.3.1 Moving beyond standardisation to create safety and quality

When developing safety policies and protocols, it is better to give staff fewer rules that can be reliably followed around the clock than to write 'perfect' protocols based on ideal conditions that require workarounds to fit the situation at 11pm on a Saturday night. Try to resist the pressure to develop a new rule in response to every adverse event or root cause analysis finding because you'll end up with a mix of 'should follow' and 'must follow' rules that will muddy the safety waters. 'Should follow' rules that have little credibility or apparent consequence are unlikely to be followed in a messy, high-risk, high-stress environment, so why bother? Erosion of compliance with 'should follow' rules can, in turn, negatively influence compliance with the more important 'must follow' rules. When people are violating a protocol, find out why! It may be for a good reason and may give you an insight into what's going on in practice – and what's required to improve. Use observation and discussion to work out what's really happening. And when introducing a new protocol to reduce a risk, do the troubleshooting around whether or not it's likely to be followed, before people's lives depend on it. Quality managers who understand and can explain the value of not constraining the system any more than necessary, and who encourage challenging a new protocol with 'why won't it work?' and 'how are people likely to work around it?' are more likely to effect positive change in their organisation's approach to safety and quality than those obsessed with rules and compliance.

Another strategy for creating safety and quality in complex organizations is to develop the resilience of the staff. Resilience engineering is a concept derived from human factors engineering – the discipline that studies the interface between machines and systems and human beings, and improves design so that humans can operate safely and effectively. From a human factors perspective, resilience refers to the ability, within complex and high-risk organisations, to understand how failure is avoided and how to design for success. It describes how people learn and adapt to create safety in settings that are fraught with gaps, hazards, tradeoffs and multiple goals. Resilience can be described as a property of both individuals and teams within their workplace (Jeffcott et al, 2009). It fits well with James Reason's observation that his 'Swiss Cheese Model of Accident Causation' (Reason, 2008). requires another slice of cheese – cheddar, not Swiss – at the end of the line. This slice represents humans as the final barrier and defence against unsafe situations turning into harm, when all other systems fail. Practising resilience requires organizations to investigate how individuals, teams and organisations monitor, adapt and act effectively to cope with system failures in high-risk situations, and to apply and develop these lessons.

In the end, rules don't create safety – people do. Quality care and services are created by systems and standardisation, and also by proactive staff working in partnership with consumers to create the organisation's vision for great care. Building resilience is a component of this approach that combines elements of creating safety, human factors, high performing teams, job satisfaction and empowerment in a way that may assist with winning the hearts and minds of the staff at point of care. These are the staff we ultimately depend on to create and deliver the safety and quality of care we want our consumers to experience every day.