

# Developing a Quality Management System

An operating system for a quality-driven learning organisation



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# Executive Summary

**Internationally there is recognition that a holistic quality management system (QMS) approach will enable healthcare organisations to meet the needs of their populations and continuously improve the care and experience provided. In NHS Wales, the Duty of Quality was introduced in 2023 through the Health and Social Care (Quality and Engagement) (Wales) Act 2020<sup>1</sup> and requires Welsh NHS bodies to establish an effective QMS where appropriate focus is placed upon Quality Control, Quality Planning, Quality Improvement and Quality Assurance.**

The 90-day cycle methodology was used to explore how high performing organisations manage for quality – identifying universal findings across all the organisations, a summary of what a QMS can achieve and the importance of the role of the Board. The findings informed the development of a QMS Framework for healthcare which has supported the development of the Duty of Quality and includes:

- **A definition of quality:** Continuously, reliably and sustainably meeting the needs of the population that we serve (aligned to the Duty of Quality).
- **A definition of QMS for NHS Wales:** An operating framework to continuously, reliably and sustainably meet the needs of the population we serve.
- **Descriptions of the four aspects within a QMS:** Quality Planning, Quality Improvement, Quality Control and Quality Assurance and examples of tools and resources that can be used to support their implementation.
- **Descriptions of the organisation enablers for a QMS:** leadership, workforce and culture; learning, improvement and research; whole system approach; and, information (aligned to the Duty of Quality Standards).
- **A methodology to implement and embed a QMS:** an adaptation of Quality as an Organisational Strategy (QOS) informed by the experience of piloting the approach at directorate and organisation level.

## Executive Summary (continued)

The Juran Trilogy – with the addition of Quality Assurance – provides the key aspects for quality management. The connectivity and inter-dependency between the aspects and their activities and tools is what enables the organisation to be quality-driven and have the continuous internal and external feedback that supports continuous improvement. However, the addition of a methodology for implementation alongside attention to the key enablers is key to the sustainability and success of a QMS.

The QMS Framework outlined in this paper focuses on the design of an organisation management system and how it can enable the delivery of the highest quality care. It provides an approach that can build on work already underway within an organisation and can be used at local team, directorate, organisational or national level and could be applied in clinical or non-clinical settings. It can support organisations to consider how to effectively begin to embed a sustainable operating system to lead and manage for quality.

# Background

**In recent years, significant focus has been placed globally upon the quality of healthcare services, with a recognition of the gap between the quality of services received by populations and the potential to deliver safer care and better patient outcomes.**

In 2013, responding to the Francis Inquiry report, Professor Don Berwick called upon NHS leaders and senior government officials to 'place the quality and safety of patient care above all other aims for the NHS' (2: p.41). International thinking and research into the impact of Quality Improvement has shifted in this arena to acknowledge that traditionally conceived Quality Improvement in itself is insufficient to tackle the challenges we face<sup>3</sup>.

There is recognition that Quality Improvement can solve complex adaptive problems in healthcare – but as part of a Quality Management System (QMS) that aims to meet the needs of service users whilst improving the quality of care, reducing costs and ensuring sustainability<sup>4,5</sup>. This sentiment is echoed internationally with the Institute for Healthcare Improvement (IHI) advocating for a holistic approach to managing quality, where 'quality is the organisational strategy, not merely a component of the strategy' (6: p.5).

A holistic approach to managing for quality can be achieved through a QMS: a 'consistent and coordinated approach to planning, improving, controlling and assuring high quality care' (7). While QMS is a relatively new concept in healthcare, its origins stem from manufacturing and management, and in particular the work of Joseph Juran<sup>8</sup> and W. Edwards Deming<sup>9</sup>. Juran's Quality Trilogy – Quality Improvement, Quality Control and Quality Planning – often forms the basis of a QMS. Additionally, a fourth component – Quality Assurance – is deemed crucial in healthcare to evaluate system performance and identify any gaps where the service is not meeting customer needs<sup>4,6</sup>.

Policymakers across the UK have called upon the principles of the Juran Trilogy to drive forward the quality agenda. In Wales, the Quality and Safety Framework<sup>10</sup> outlined how NHS organisations should consider Quality Improvement as part of the whole quality cycle, reviewing and developing a fully-functioning QMS, aligned to the Quality Trilogy – along with Quality Assurance. More recently, the Duty of Quality was introduced in 2023 through the Health and Social Care (Quality and Engagement) (Wales) Act 2020<sup>1</sup>.

Recognising that managing quality requires a system-wide approach, the Duty requires Welsh NHS bodies to establish an effective QMS where appropriate focus is placed upon Quality Control, Quality Planning, Quality Improvement (the Juran Trilogy) and Quality Assurance.

Similarly, in England, NHS IMPACT (Improving Patient Care Together) calls for organisations to develop a management system that aligns strategy, vision and purpose<sup>11</sup>. Healthcare Improvement Scotland places a learning system at the heart of its QMS Framework, which is also built from the Juran Trilogy<sup>12</sup>.

While the theory of QMS is increasingly documented in the literature, what does it look like when applied in practice? This paper outlines Quality, Safety and Improvement's journey as a learning organisation and aims to share the learning from developing a QMS over the last five years (first as Improvement Cymru and now as Quality, Safety and Improvement). Recognising that a QMS is ever evolving as our contexts change, experiential learning is shared from leaders and organisations that have faced significant challenges in recent years, including: post-pandemic recovery, staff burnout and moral injury, workforce shortages, budget constraints and the increasingly complex needs of the population.

The paper is structured in three parts:

1. Learning from high-performing organisations
2. Developing a QMS Framework
3. Summarising the learning

## Who We Are

**On 1 April 2024, Improvement Cymru became the Quality, Safety and Improvement (QSI) directorate of the newly formed NHS Wales Executive which is a national support function.**

NHS Wales Executive aims to drive improvements in the quality and safety of care – resulting in better and more equitable outcomes, access and patient experience, reduced variation, and improvements in population health.

# Part 1 – Learning from High-Performing Organisations

**In 2023, Kedar Mate’s keynote address at the IHI Forum outlined four ages of quality<sup>13</sup>. The first age relates to alignment with, and achievement of, basic minimum standards, advancing into the second age where evidence and measurement are used to ensure delivery of evidence-based care.**

The third age concerns collaborative improvement where improvement in quality is accelerated by working together. Mate notes it is only high-performing organisations that reach the fourth age of true ‘systemness’, where quality is embedded in all that the organisation does, and can be scaled, spread, and, critically, sustained.

In 2019, Improvement Cymru began a journey to shift its approach to quality from the third age to the fourth age. To understand more about how this shift could be achieved, the Carnegie Foundation’s 90-day cycle methodology (also used by IHI) was utilised to determine how high-performing organisations manage for quality<sup>14</sup>. An understanding of the barriers and the enablers was assessed, together with the role of the organisation’s Board and the methodology used to deliver and achieve whole system quality.

This paper has been shaped by stakeholder interviews across the UK nations, thematic analysis of 15 expert interviews (UK and USA) and a review of the quality management literature including:

- 443 abstracts
- 40 original research papers, covering 21 organisations
- 14 national and international case-study reports.

## 1.1 High-level universal findings

High performing health care organisations were defined as those that ‘have created effective frameworks and systems for improving care that are applicable in different settings and sustainable over time’<sup>15</sup>.

For high-performing organisations that manage quality holistically:

1. They recognise that truly embedding quality takes a long time (findings suggest 10 or more years), it is challenging, and failure is inevitable.
2. One system-wide approach to managing for quality is chosen and universally embraced.
3. The focus on managing quality can be triggered by external or internal influences but is always led by the CEO and Board.
4. Requires leadership at all levels and continuity of leadership is key. Where continuity is not possible, it is important for new leaders to adopt and maintain the agreed approach.
5. Quality is managed by viewing the organisation as a system (how all the different parts of the organisation connect and interlink). Quality is not a directorate.
6. The need to undertake Quality Planning, Quality Control and Quality Improvement, as well as the need to include Quality Assurance for complex healthcare organisations is fully recognised and implementation approaches do not separate these aspects.
7. Improvement is one part of a wider framework for managing quality.
8. Quality Control is a function of the frontline – leadership uses Quality Improvement and Quality Planning to provide assurance.
9. There is openness and transparency using time series data, where data is used for learning, not judgement.
10. A focus on understanding their systems and the design of the processes within them enabled a shift in culture and empowerment of staff

**“[QMS] never stops, it’s not one of these things that you can do and then just forget about it and go on to the next project. So I think we’re always trying to refine and fine tune it and learning from other people”**

- Expert interview participant – hospital CEO for over 30 years



By analysing the literature and from extensive stakeholder engagement, definitions of quality and QMS for NHS Wales were developed, as follows:

**Definition of quality:** Continuously, reliably and sustainably meeting the needs of the population that we serve (aligned to the Duty of Quality).

**Definition of QMS for NHS Wales:** An operating framework to continuously, reliably and sustainably meet the needs of the population we serve.

## 1.2 Managing Quality - What can be achieved?

**The impact of managing for quality has been extracted from the literature and includes:**

1. A reliable system that places the needs and experiences of citizens and staff at its core.
2. Improvements in the Quadruple Aim<sup>16</sup> and a focus on measurable results.
3. An understanding of the current system and the identification of opportunities for improvements.
4. Improved organisation reputation – becoming a place where people want to be cared for and want to work.
5. A shared focus and purpose on the common vision and mission – people challenge legacy work, identify misaligned activities and understand what is expected of them.
6. A culture of safety for citizens and staff underpinned by predictability and reliability in the system that enables prioritisation, learning and robust process improvement.
7. Sustainability and clearly defined work and processes.
8. A stronger relationship between the executive and frontline staff and ownership of quality at every level – generated through common ambition, transparency and visibility, improved experience and support for the 'right work'.

## 1.3 What is the role of the Board?

In addition to the above evidence about the components of a QMS and what it can achieve, it is clear that a systematic approach to managing quality holistically also relies upon a key number of enablers (described in more detail in Part 2):

- Knowledge, skills and infrastructure
- Leadership, culture and behaviours
- A method for managing quality

In terms of leadership, culture and behaviours, it is apparent that the Board plays a critical role in driving and supporting an organisation-wide approach to managing quality.

**“It’s important that the Board, first of all understand[s] what its overall purpose is and secondly have the shared view of what quality means. And as part of that shared view it is actually testing it with the views of the people that the organisation serve[s]. The patients, the families, the local community, the frontline staff”**

- Expert interview participant – Chief Executive

The key components for the Board are:

1. Setting a clear vision and mission underpinned by well-defined organisational priorities for improvement with measurable goals (qualitative and quantitative) – providing constancy of purpose and focus on quality as the core business.
2. Ensuring an organisation-wide strategy is in place to systematically implement the improvements.
3. Ensuring active and meaningful support and resource is in place for the QMS Framework enablers to deliver the strategy.
4. Knowledge and understanding of the organisation’s overarching mission, vision and key metrics; the system-wide improvement approach; and how quality is defined within the organisation in relation to its customers and stakeholders.
5. Identify and periodically review areas that require improvement or redesign and make decisions on resources, capacity and capability.

6. Be visible in supporting and championing quality – through walk rounds, visits, awards and involvement in improvements.
7. Use qualitative and quantitative measures alongside citizen, stakeholder and staff stories to personalise quality and facilitate the alignment of the entire organisation around the quality of care.
8. Create and model a culture that is ambitious and encourages inquiry and improvement.
9. Have a strategic macro-focus on the vision, mission and goals of the organisation through a workplan and reporting structure focused on quality and the delineation of quality issues between the Quality Committee and Board.
10. Ensure overarching alignment of macro-strategies e.g. human resources, finance, to enable quality.
11. Fulfil its governance and advisory role by understanding when the data shows variation from what the organisation is meant to be achieving and setting the organisation the challenge of fixing this at the front line.

**“I think the biggest success I can remember in some organisations, was that the Board learnt about variations, they learnt to look at data differently. They began to understand variations, and how variation informs action, it almost brought me to tears, happy tears, For the first time a Board started asking questions differently”**

- Expert interview participant – Improvement Advisor and Quality Consultant

# Part 2 – Developing the QMS Framework

Following the literature search, expert interviews and stakeholder engagement, a framework was developed (Figure 1) to illustrate the components of a QMS for healthcare.

It was designed for use across NHS Wales to enable a strategic, system-wide approach to achieve the Quadruple Aim<sup>16</sup> and embed the values of NHS Wales by planning and managing quality-driven services to meet the needs of citizens and stakeholders.



**Figure 1 - The initial QMS Framework (version 1)**

As shown in Figure 1, the framework comprised the Juran Trilogy – Quality Planning, Quality Control and Quality Improvement – with Quality Assurance added following the precedent set by other high-performing, quality-driven organisations. It distinguishes between quality control and quality assurance – concepts which have, at times, been conflated within the health and care landscape.

The definitions for each aspect are:

<b>Quality Planning</b>	<b>Quality Improvement</b>
<p><b>A process for leadership to annually plan and prioritise the design and redesign of processes, services and products, allocate resources and identify capacity and capability to meet population needs.</b></p> <p>It includes:</p> <ul style="list-style-type: none"><li>• A relentless focus on customer need, staff wellbeing and culture informed by internal and external feedback.</li><li>• Purpose aligned to need and integrated into daily work and improvements.</li></ul>	<p><b>Standardised training and coaching approach incorporating established methodologies for continuous improvement for our populations.</b></p> <p>It includes:</p> <ul style="list-style-type: none"><li>• Development of improvement skills throughout the organisation, from Board to frontline, with a small cadre of experts to support.</li><li>• Improvement designed and delivered as close to the frontline as possible by those involved with its delivery – staff, service users, family and carers.</li></ul>
<b>Quality Control</b>	<b>Quality Assurance</b>
<p><b>Connected daily operational management to monitor and maintain quality, including the use of real-time measures over time.</b></p> <p>It includes:</p> <ul style="list-style-type: none"><li>• Those closest to the work develop standardised processes to ensure reliability and reduce variation.</li><li>• Making real-time corrections to processes if required and clear escalation routes if necessitated.</li><li>• Visual management to focus efforts and identify issues early.</li></ul>	<p><b>A process to ensure that the system is operating effectively and providing quality care in line with standards, guidelines and policy.</b></p> <p>It includes:</p> <ul style="list-style-type: none"><li>• Provides a clear line of sight across the organisation and identifies gaps against the purpose and customer need.</li><li>• Reviewing data retrospectively.</li><li>• Can be both internal and external.</li></ul>

Examples of tools and process that support each of the aspects are detailed below. For a QMS to be effective, these tools and processes need to connect to each other within and across the four aspects – their interconnectivity is essential to drive and align the focus on quality.

Quality Planning	Quality Improvement
<ul style="list-style-type: none"> <li>• Service User and Staff feedback (e.g. surveys)</li> <li>• Stakeholder mapping</li> <li>• Dashboard of process, outcome and balancing measures</li> <li>• Strategic Planning Process and resource allocation (workforce, finance)</li> <li>• Strategic Improvement Priorities</li> <li>• Pathway or service models and specifications</li> <li>• Strategic partnerships</li> <li>• Commissioning and hosting arrangements</li> </ul>	<ul style="list-style-type: none"> <li>• Standardised methodologies appropriate to the problem (e.g. Lean, Model for Improvement)</li> <li>• Theory of Change</li> <li>• Change Package</li> <li>• Consideration of the 'soft' and 'hard' side of the change</li> <li>• Data collection and analysis over time (e.g. Statistical Process Control charts)</li> </ul>
Quality Control	Quality Assurance
<ul style="list-style-type: none"> <li>• Data visualisation over time (e.g. visual management boards)</li> <li>• Escalation processes</li> <li>• Communication (e.g. SBAR; huddles)</li> <li>• Standardised Operating Procedures</li> <li>• Real-time feedback</li> <li>• Simple process fixes (e.g. Plan-do-check-adjust cycles)</li> </ul>	<ul style="list-style-type: none"> <li>• Suite of outcome measures aligned to purpose</li> <li>• Inspections and Reviews</li> <li>• Audits</li> <li>• Incident and risk management (e.g. Datix)</li> <li>• Guidelines and good practice (e.g. NICE; Royal Colleges)</li> <li>• Compliance with legal requirements and Escalation Framework</li> </ul>

## 2.1 QMS enablers at every level of the organisation

A simple focus on Quality Planning, Quality Control, Quality Improvement and Quality Assurance alone is not sufficient to deliver quality-driven services to meet the needs of citizens and stakeholders. Additional factors impact the success of the implementation of a QMS such as culture, structure and leadership, information analysis and knowledge management, workforce and resource management<sup>17-19</sup>. As such, key enablers informed by the literature included: knowledge, skills and infrastructure; leadership, culture and behaviours; and a method for managing quality.

### Knowledge, skills and infrastructure

**Having a clear organisational development strategy that focuses on improvement and system expertise to make quality-driven changes throughout the system.**

#### Knowledge

The knowledge that is needed to enable quality-driven services:

1. The Board needs knowledge and understanding of the organisation's chosen improvement approach and methodologies, its definition of quality and key metrics.
2. Leaders need subject matter expertise as well as knowledge and understanding of the aim of their organisation and how their organisation works, understanding of variation and an appreciation of the psychology of change.
3. Staff need 'hands on' knowledge and experience of the day-to-day processes and systems that work together to meet customer needs, the organisation's improvement methodology and how to implement small incremental changes through, for example, Plan-Do-Study-Act (PDSA) cycles.

**"Improvement is the how, quality is what you are trying to deliver..."**

- Expert Interview Participant - National Quality Director

## Skills

Skills in improvement and data are taught at appropriate levels to all staff across the organisation to enable quality-driven decision making and an understanding of what is happening in the system:

1. The Board needs skills to review data and engage with executives about trends in relation to meeting customer needs.
2. Leaders need skills to understand how system-wide priorities are being met, and to make resource and planning decisions.
3. Staff need skills to understand, on a daily basis, if their work is in control, including being able check if a process is in control using data and to act to minimise unwarranted variation and improve processes when required.

The above skills (at all levels) should be complemented by planning skills so that business planning can be undertaken alongside planning and managing improvement efforts and their outcomes. This will also require support from strategies for quality, communications and capability building.

**“Capacity building is [...] the most important thing you can do, so teaching people the toolkit and the behaviours appears to be pretty much the most important thing you can do.”**

- Expert Interview Participant - National Quality Director



## Infrastructure

We learnt that the infrastructure to support quality management should ideally comprise:

- A system map of the organisation – to help understand the connections and dependencies that support or inhibit work to meet citizen, stakeholder and staff needs.
- Daily management systems with visual management boards and tiered huddles to create communication and transparency, help solve problems, escalate issues, share accountability and enable alignment with other work and to overarching mission and priorities.
- System for continuous real-time feedback from staff, citizens, stakeholders and partners alongside data and horizon scanning insights and intelligence.
- Tiered measurement system to escalate Quality Control issues and show how the system is performing.
- Improvement hub or network to enable the systematic upskilling of staff in a standardised improvement methodology.
- A system for identifying and learning from improvements that have worked and those that have not.
- Standard operating procedures to define and share what to do and how to do it – reducing variation and quality issues.

**“The infrastructure that works best is that learning system that sits at the centre, you need to absolutely have the systems, the models, the processes in place to help you do it. You need to be absolutely aligning resources to whatever the improvement work needs to be, but also within it we need to understand the data”**

- Expert Interview Participant - National Improvement and Safety Associate Director

## Leadership, culture and behaviours

**Creating the conditions for a learning and improving environment that supports and enables staff and aligns all activities to the overarching mission and priorities.**

### Leadership

- Consistent, visible leadership and communication that reinforces the priorities and pace is vital. Pay attention to the data and 'soft signals' of quality – give attention to the things that matter as people follow the attention of the leaders.
- Leaders model behaviours that support quality, promote the chosen improvement approach and methodologies methodology and encourage inquiry at the front line.
- Quality becomes the core strategy – use it as a system to identify priorities and resource them effectively.
- Celebrate successes, learn from failures and stop doing things that are misaligned or do not work.
- Drive Quality Planning focused on what matters most, informed by feedback and focused on strategic improvements – with the aligned leadership, resources, capability and culture to enable implementation

**“Our job as leadership is really to create the environment, create the opportunities, create the time, space and empower staff to be the best people they can be. And ultimately, it’s not really rocket science. It’s harder to do than say”**

- Expert Interview Participant - Chief Executive

## Culture

A culture of quality requires cultivation at all levels of the organisation and can be supported through:

- Integrating the aims and vision into daily work with frontline efforts connected to overarching goals.
- Creating capacity for learning and spread through a consistent training and coaching approach that incorporates recognised methodologies for improvement and aligns with the vision, culture and operating philosophy.
- Recognising that improvement needs to include a balance of large-scale breakthrough improvements (e.g. system redesign) alongside bottom-up incremental changes.
- Promoting the health and wellbeing of staff and creating a healthy workplace environment.
- Supporting teamwork and promoting a culture of respect, integrity, trust and open communication.
- Paying attention to the emotional and psychological safety of everyone within the organisation. Creating an environment and culture where staff feel able and supported to try new approaches and learn from times when things do not turn out as expected.

**“Quality is not something separate to what I do. It’s that definition of what culture is”**

- Expert Interview Participant - Chief Executive

**“Quality management can be a hugely powerful vehicle for developing a culture within your organisation which is attractive to all staff. [...] the biggest thing I think that has contributed towards our reputation is the fact that we’re on the same page, patients and clients, the safety, quality and experience of how we deliver services around that, they’re absolutely the biggest priority of our organisation”**

- Expert Interview Participant - Chief Executive

## Behaviours

To instil quality at the heart of the organisation, behaviours need to support and enable quality by:

- Focusing on system issues rather than 'people' issues – considering the design of services and processes as the cause of poor quality, and its solution.
- Recognising and celebrating success and learning from failure.
- Embedding coaching into management practice and compassionate leadership.
- Recognising the contribution of all staff to the quality agenda.
- Supporting citizens, carers and communities to co-produce care.
- Engaging and involving citizens, staff and partners in a meaningful way in the design and delivery of care to ensure care and services truly meet their needs.
- Valuing, listening to and supporting staff with the skills, resources and permission to improve their own work and take ownership of the quality they deliver.

**“So personal and public involvement becomes absolutely critical. And I think our team are a lot better at it. But they have a bit to go I would say at involving users in the development of service changes. But particularly how we drive forward Quality Improvement. [...] Those with the lived experience are now trained and are part of the team supporting current mental health patients. It was a co-design programme.”**

- Expert Interview Participant - Chief Executive

## A method for managing quality

**Enabling the systematic application of the QMS Framework within an organisation (not just projects) to achieve the desired outcomes, experience and value that matter to citizens, stakeholders and staff.**

'Quality as a Business Strategy' was most frequently cited through our expert interviews as a proven method for helping organisations to transform their approach to enable them to meet stakeholder needs and become high-performing quality-driven organisations.

The methodology (outlined further in section 2.2) provides a structured approach to enable organisations to focus upon learning, planning and actions under the banner of quality. It describes an approach to leading organisations based on W. Edwards Deming's belief that leaders required a new theory of management and a strategy built on quality.

Such focus on quality becomes the means to accomplish other goals, such as financial, growth or sustainability goals but it is fundamentally about organisational continuous improvement.

**"A very big part of quality management systems is the idea of understanding the system that you are, how it is set and designed and how it runs."**

- Expert Interview Participant - Quality Consultant



**Figure 2 The updated (version 2) QMS Framework: an operating framework to continuously, reliably and sustainably meet the needs of the population we serve.**

The initial QMS Framework was developed and iterated with stakeholder engagement, particularly through involvement within the health and care policy landscape in Wales.

The Health and Social Care (Quality and Engagement) (Wales) Act became law in 2020 and came into force in 2023. The Act comprises four key components, one of which is a Duty of Quality which places a legal obligation upon NHS bodies in Wales and Ministers to deliver and improve quality-driven services. The Duty of Quality included its own definition of quality, which was developed from the research.

New national quality standards were also created in the Duty which comprised six domains of quality – safe, timely, effective, efficient, equitable and person-centred (STEEEP) and six quality enablers – which were adapted from the initial framework and are reflected in the revised Framework (Figure 2).

## 2.2 Implementing a QMS

Quality as a Business Strategy (20) – later renamed Quality as an Organisational Strategy (QOS) – was developed by the Associates in Process Improvement to help organisations achieve system transformation and embed continuous Quality Improvement, based on Deming’s Chain Reaction<sup>9</sup>.\*

QOS offers an operating system for an organisation to embed quality and operate as a system for continuous improvement.

**“In healthcare the problem is people are exposed to quality through projects and through this emergence of quality in healthcare that is much more as a separate thing. Whereas people in business, quality was the way you do business. [...] a lot of times in hospitals there are quality people, there are quality activities, there is quality stuff. But it is not necessarily the way that the organisation is managed or run.”**

- Expert Interview Participant - Quality Consultant

QOS has been used by quality-driven organisations for a number of years, including those that have won quality awards such as the Baldrige Award<sup>21</sup>. It comprises five key activities for leaders:

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\* A newer version of Quality as a Business Strategy (20) has recently been published. Details are included in the ‘Further resources’ section of this paper.

**1. Understand your purpose.** What need in the system does your organisation meet? Develop a purpose statement, including your mission, vision and values. This purpose should then guide and focus the organisation's work.

**2. Organisation viewed as a system.** How does your organisation operate as a system? This step involves mapping your processes and categorising them as driver, mainstay or support processes. These are defined as:

- **Driver processes** – designed to prepare organisations to meet customer need. This includes strategic planning, customer feedback, horizon scanning and information collection systems.
- **Mainstay processes** – what is actually done to meet customer needs. This comprises the products and services delivered by the organisation.
- **Support processes** – everything else that helps meet customer needs, including recruitment, financial management, communications and workforce development.

Importantly, these distinctions are not hierarchical – support processes are as important as mainstay and driver processes; all of them work together as a system to help achieve the overall purpose of meeting the wider system need.

**3. System to obtain information.** How does your system obtain relevant information in relation to the need your organisation is meeting? First, you need to identify who your customers are (current and future) and then develop systems to gather needs-focused information. You may wish to consider gathering information from staff, suppliers, regulations and the marketplace.

**4. Planning for improvement.** There are two categories of planning – planning to operate the system and planning to improve the system – and this step relates to the latter. The goal here is to take the information gathered from your 'system to obtain information' and, based on these inputs, accelerate the organisation's performance by developing strategic objectives<sup>20</sup>. You'll then need to identify the products, services and/or processes that need to be designed or redesigned to meet the strategic objective. Importantly, a strategic objective should not sit with one individual; achieving the objective will require work from across your system, and your plan for improvement will need to be coordinated with the organisation's budget, strategy and business functions.

**5. Managing improvement.** How does your organisation manage individual and team improvement efforts? Leaders need to provide provision (e.g. training) to ensure staff have the necessary improvement capability. This should be coupled with use of a standardised methodology for all your improvement efforts. Leaders may need to help remove barriers, as well as provide guidance, sponsorship and recognition<sup>20</sup>.

This approach was utilised to support QMS development within Improvement Cymru and within an organisation consecutively. In the two areas it was employed through a linear approach, and an agile approach, exploring and developing each of the activities with system-leaders in the organisations.

### Learning from implementation of QOS

- There are several helpful exercises to create and integrate your QMS. They do not need to be completed in a linear fashion – build on the plans and work already underway in your organisation.
- The use of a defined method provided collective focus and commitment by the Leadership Team – and involvement of the next tier of leaders can also help expedite efforts and socialise the approach.
- The principles of the methodology are translatable to the culture and context of UK health and care, but the application needed contextualising.
- The focus on system and process design as opposed to a focus on the people working within the system shifted the quality conversation and approach.
- A broader consideration of improvement methodologies beyond the Model for Improvement will support application of the principles in UK health and care organisations.
- The methodology could be more agile and simplified for use at scale in healthcare organisations in the UK.
- Language and definitions are incredibly important to ensure everyone has a common understanding and focus.
- Do not create a separate QMS identity and programme – it is about applying the principles to how you improve existing ways of working.
- Use outputs that are ‘good enough’ and iterate as you learn from your QMS.
- An adaption of the methodology could align the work of Deming and Juran.



## 2.3 Methodology for operating a QMS

Based on learning in-action and reflections, a more simplified approach was adopted placing greater focus on the four aspects of Quality Planning, Quality Control, Quality Improvement and Quality Assurance and their interdependence (Figure 3). This was in recognition of the context and language already in use in NHS Wales regarding Quality Management Systems. Bridging the theoretical approaches of Joseph Juran (the Juran Trilogy) and W. Edwards Deming (the origins of QOS) was achieved by drawing upon their similarities – a proactive approach to quality management through an appreciation of the system and a focus on prevention of defects rather than just detection; a focus on senior leader commitment and promotion of a culture of quality; and, a requirement for continuous improvement, enabling an approach relevant to NHS Wales<sup>8,9</sup>. The revised methodology overlays the 5 activities from QOS onto the Juran Trilogy – with the addition of Quality Assurance. It draws in learning regarding quality control and quality assurance, which do not feature in QOS as its focus is primarily operating for continuous improvement.

The methodology was adapted from QOS and built on the learning from applying QOS in two settings - directorate level (Improvement Cymru) and organisational level. The methodology can be used at organisation, directorate or team level. It focuses on drawing together existing systems such as finance, operations and human resources into one management system for quality that meets the needs of the population the organisation is serving. The methodology pays attention to the systems and processes within an organisation and how they can be improved to enable care to be of the highest quality.

### Quality Management System

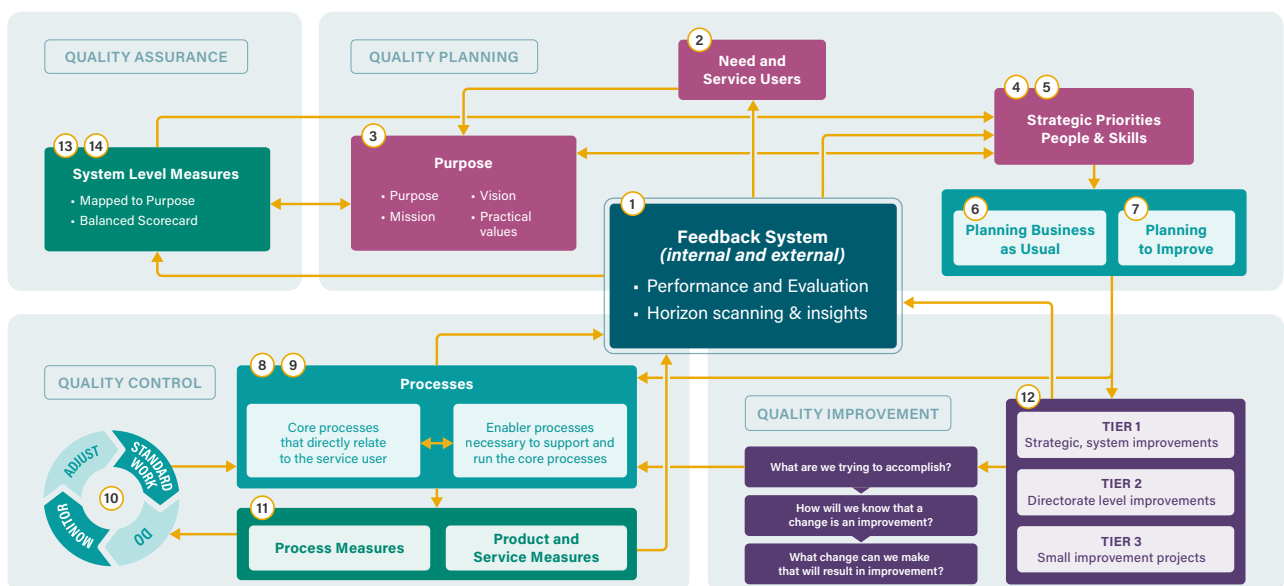


Figure 3 The method for operating a QMS (adapted from <sup>20</sup>)

Feedback sits at the heart of the system. Core to the method is an effective feedback system that ensures the organisation is clear on what it needs to respond to with Quality Planning. This feedback system can include horizon scanning, insight generation, policy context, population needs and current organisational performance. As indicated by the arrows across the diagram, the linkages and a continual use of feedback enable the operating model to put quality at its core:

- Quality Planning is driven by feedback and aligned to purpose and supports leaders to distinguish between business-as-usual and strategic improvements that need to be prioritised, resourced and sponsored.
- Quality Improvement activities are tiered into those that can be undertaken at project, directorate or system level.
- Quality Control includes processes to monitor processes and keep them reliable on a daily basis and staff are empowered to make adjustments if needed.
- Quality Assurance mechanisms are streamlined to focus on what is needed for an organisation to be assured of in line with its purpose.

The methodology provides equal weighting for the four aspects of Quality Planning, Quality Improvement, Quality Control and Quality Assurance. However, by drawing them together with feedback at the core, it offers an operating model to enable organisations to continuously improve. It also offers a way for organisations with mature quality improvement hubs or teams to connect improvement programmes and projects into the other three aspects to enable a continuous and sustainable focus on quality. The methodology essentially connects the four aspects to enable an organisation to improve its own system and ways of working.

## 2.4 Where to start?

From learning to date, it is recommended to begin in Quality Planning with point 1 with feedback enabling a clear understanding of need and guiding leaders in their strategic identification and planning of the services and processes that will continue to operate as business-as-usual with ongoing monitoring and real-time adjustments (Quality Control) and those that will need to be designed or redesigned (moving into Quality Improvement), to ultimately assure the quality of the services provided (Quality Assurance). However, recognising that organisations are not static and will already have a number of the tools in place, the methodology is agile and can be started from any of the aspects.

Recognising that healthcare organisations are large, complex systems and the QMS methodology will be new, it can be used at directorate or service level in the first instance to pilot the approach and gain confidence before considering application at organisational level.

The questions below provide helpful guidance for each aspect – drawing out the key components to consider in a system that is designed for quality.

## Quality Planning

1. Has something in our internal processes or external environment signalled a change?
2. Does the signal indicate a change in the need or in our customers?
3. Does the signal indicate our purpose needs to change?
4. What does the leadership need to do to get the system ready to meet the need?
5. Do we need to change our plans to achieve the outcomes we need?
6. Planning to operate:
  - Which processes are meeting expectations and where they need to be?
  - What people do we need and what skills capacity and capabilities do they need to have?
7. Planning to Improve:
  - Which new processes, products or services need to be designed and why?
  - Which existing processes, products or services need to be redesigned and why?

## Quality Control

8. Do we have a standardised process in place to manage daily work?
9. Are our processes operating as we need and delivering the products and services we need?
10. What isn't working as it should be and can be improved by those closest to the work?
11. What is our data telling us isn't working as it should be and needs to be escalated for improvement support?

## Quality Improvement

12. Has the improvement resulted in the products and services achieving the intended outcome and meeting the need?

## Quality Assurance

13. Are we assured of our performance over time?

14. Are we assured that we have the necessary culture, people, infrastructure and improvement programmes to deliver on the outcomes?

The questions above provide a guide for an organisation that is already operating and has some of the components in place to build on. For organisations that are in the early stages of being established, we have a distinct set of questions to help you build your QMS. This can be found in Appendix C: Questions to guide the development of a new QMS.

# Part 3 – Summarising the Learning

**A QMS can enable healthcare organisations to successfully – and measurably – meet the needs of their service users and staff and continually improve the quality of services provided.**

The Juran Trilogy – with the addition of Quality Assurance – provides the key aspects for quality management. It is the connectivity and inter-dependency between the aspects, including the associated activities and tools, that enable the organisation to be quality-driven. Quality control (daily management of work) and quality assurance (largely external, infrequent and retrospective) should be recognised as distinct and complementary aspects. Most importantly, each of the quality aspects are dependent upon, and need to be driven by, a central feedback system where learning and insights from internal and external stakeholders helps to support continuous improvement. Finally, introducing an implementation methodology and paying attention to the key enablers at every level of the organisation is critical for the sustainability and success of an effective QMS.

We have tested our QMS framework and methodology at both directorate level (Improvement Cymru) and organisational level, and found it offers an approach that can support organisations in their pursuit of quality. It also provides an approach for organisations to systematise the requirements for an annual quality report and 'Always On' reporting as detailed in the Duty of Quality.

Organisations at the start of their QMS journey should build on the systems and processes already in place and always consider, regardless of the methodology used, the enablers and culture that need to be wrapped around the methodology.

Implementing a QMS at any level provides insights and strategic alignment that fundamentally ensures that the needs of the population are met. It results in staff being supported by a system and processes that enable them to reach their full potential and do their best at work. Fundamentally, it provides an operating system for continuous improvement so that an organisation can both meet the needs of the population it serves - and be accountable to it.

## Learning so far – principles

- The QMS Framework can be used at local team, directorate, organisational or national level and could be applied in clinical or non-clinical settings.
- Ensure clear understanding of Quality Control and Quality Assurance.
- Quality Control and Quality Planning is often the greatest area of work and where the biggest impact can be achieved.
- Quality Improvement will have the greatest impact when it is directed by Quality Planning, with results in sustained Quality Control.
- The language and concepts can be overwhelming and confusing – simplify as much as possible.
- A common language and priorities are key.
- Much of the approach has its foundations in management principles.
- Find the approach or method that works for you and stick to it.

## Learning so far – implementation

- The building blocks are often in place – implementation is about the connectivity.
- The approach needs to be led by the executive team, but implementation sits at the tier below and must be aligned to ‘bottom-up’ opportunities and initiatives.
- Incorporate the methodology but avoid labelling it as a separate initiative.
- Learn and refine as you go – ‘good enough’ outputs can be iterated over time.
- Constant feedback that informs the QMS is essential – and acting upon this.
- Measurement over time and connected throughout the organisation is key – with national and local systems in place to support.
- There is a need to align the measures required by organisations to self-assure their focus on quality with external reporting requirements.
- Alignment of purpose and strategic improvement efforts offers the greatest opportunity for impact.
- A complete QMS will evolve over time – some elements will be more mature than others.
- Start small or focus on one aspect (Quality Planning, Quality Control, Quality Improvement, Quality Assurance) – do not attempt all the pieces at once; whilst there is interdependency, the approach needs to be practical.
- An assessment tool to understand organisational readiness and assess progress is beneficial in this space.

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## Appendix A: Key attributes of organisations managing quality holistically

Throughout the 90-day learning cycle, the following attributes (which informed the high-level findings) were demonstrated by high-performing quality-driven organisations.

Attribute	Example Organisation where demonstrated
Customer-led definition of quality	Southcentral Foundation (US)
Quality as a core strategy across the system, implemented using a proven method for managing quality	Jönköping County Council (Sweden); Mecklenburg Emergency Medical Services Agency (US)
Clear alignment of citizen need, vision, mission, values, goals and strategies across the organisation	Hill Country Memorial Hospital (US)
System level measures and a shift from audit to time series data	Memorial Hermann Health System (US)
Everyone must be involved in making improvements every day to shift from projects and rate-limited improvements (dependent on trained staff) create a culture of improvement	Catalysis / ThedaCare (US)
Real time data collection at the frontline to guide improvement – Quality Control at the frontline	Intermountain Health (US)
Skills and capability for the management of quality at all levels including a standardised approach to improvement	Virginia Mason Institute (US)
Consistent, visible and visionary leadership	Jönköping County Council (Sweden)
Value staff wellbeing and experience	South Eastern Health and Social Care Trust (Northern Ireland, UK)
Clear vision and a small number of aligned strategic goals	Hill Country Memorial Hospital (US)
All work aligns to common goals	Veterans Health Administration (US)
Effective methods to scale up and spread	Jönköping County Council (Sweden)
Standardised processes and guidelines for daily work	Intermountain Health (US)

Leadership skilled in improvement at all levels creates a learning and improving culture across clinical and non-clinical services	Catalysis / ThedaCare (US)
Co-producing care with citizens and staff	Jönköping County Council (Sweden)
Quality improvement and Quality Control should happen as close to the work as possible	Jönköping County Council (Sweden)
Leadership opportunities to learn from others through visits	East London NHS Foundation Trust (England, UK)
Board assurance requires system and quality knowledge alongside a culture and infrastructure that enable a clear line of sight	John Hopkins Medicine (US)
Focus on system issues and variation in care processes – rather than people	Intermountain Health (US)

## Appendix B: Further details relating to 90-day learning cycle

### National & international case studies:

- Catalysis / ThedaCare (US)
- Cincinnati Children’s Hospital (US)
- East London NHS Foundation Trust (UK)
- Hill Country Memorial Hospital (US)
- Intermountain Health (US)
- John Hopkins Medicine (US)
- Jönköping County Council (Sweden)
- Mayo Clinic (US)
- Memorial Hermann Health System (US)
- NYU Langone Medical Center (US)
- Southcentral Foundation (US)
- St. David’s HealthCare (US)
- Veterans Health Administration (US)
- Virginia Mason Institute (US)

### Interviews with senior leaders from:

- Advancing Quality Alliance (AQuA) (England, UK)
- Greater Baltimore Medical Centre (US)
- Healthcare Improvement Scotland (Scotland, UK)
- Mecklenburg Emergency Medical Services Agency (US)
- Public Health Wales NHS Trust Board (Wales, UK)
- South Eastern Health and Social Care Trust (Northern Ireland, UK)
- Willamette Valley Medical Center (US)
- Quality management experts in healthcare (n=8)

## Appendix C: Questions to guide the development of a new QMS

### Understanding the big Picture

- What do we know about the internal and external environment?
- What is the data telling us?
- What needs have we identified?

### Purpose

- Who are we serving?
- What is our purpose?
- What value do we add for them?
- What do we measure to tell us we are accomplishing our purpose?

### Practical values

- What values do we collectively need in order to achieve our purpose?

### Products and services

- What products and services do we have that help us achieve our purpose?
- What products and services do we need to design or redesign to help us achieve our purpose?

### Processes

- How are work processes linked to make the system achieve its purpose effectively?
- What 20% of processes do we depend upon to accomplish our purpose?

### People

- What roles and responsibilities do we need to fill and what kinds of people do we need to fill them?
- What skills do they need to have?
- How should we interact as we work to achieve our purpose?
- How does the current culture support a QMS and how can our efforts to improve/maintain our culture align?

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