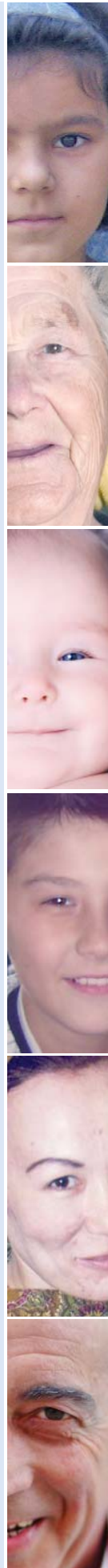


Guidance on developing quality and safety strategies with a health system approach





Guidance on developing
quality and safety strategies
with a health system
approach

Quality and safety have been recognized as key issues in establishing and delivering accessible, effective and responsive health systems. The regionally shaped guidance document covers the development of national quality and safety strategies suited to local circumstances (from formulation to continual review and renewal in successive phases).. The five chapters : 1) explain how a quality strategy can contribute to meeting challenges faced by health services/ health systems; 2) set a common background for quality principles and perspectives (patient, professional, management quality); 3) consider five types of national strategies showing choices about legislation, measurement, action programmes and improvement policies.; 4) provide practical steps on how to develop a strategy for different situations, and 5) show how a quality and safety strategy strengthens health systems..

The brief glossary, the quality assessment tool and the framework for using dedicated research in decision making provided in the appendices, aim to assist in the process.

Keywords

QUALITY OF HEALTH CARE – STANDARDS
SAFETY
STRATEGIC PLANNING
DELIVERY OF HEALTH CARE – METHODS
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Foreword

Evidence has proven that health systems must be strengthened to face current and future challenges in maintaining and increasing the health status of populations and their quality of life.

Working towards the implementation of the Millennium Development Goals and the 'health for all' objectives, WHO aims to provide approaches and tools which will help countries improve their own health systems, engaging Member States in a constructive dialogue.

The most effective strategies are those which are research-based as well as politically and economically feasible. WHO support draws on already existing quality and safety initiatives and dedicated scientific research focused on problems and solutions, to inform the quality strategy decision-making and prioritization processes.

The aim of this guidance is to help national policy advisers and policy makers to create and implement a national quality strategy, drawing attention to the need for sustainable longer term public health measures, which are sometimes overlooked.

National and regional quality and safety strategies include actions for building knowledge about quality problems and solutions, and actions for planning and implementing solutions at different levels of the health system. They target the needs of the population at large, with emphasis on poor and marginalized (vulnerable) populations, which have poorer access to care.

Effective quality and safety improvement is the result of many activities using systematic methods over a period of time. The development of tailored strategic plans and interventions plays an important role in creating conditions to stimulate and guide the various stakeholders to improve quality of performance and resource use. Establishing such strategies aims to institutionalise improvement work so that it survives particular governments.

We wish to thank the many parties who contributed important ideas and insights to this guidance.

Dr Valentina Hafner
WHO Regional Office for Europe

Executive Summary

This guidance addresses senior health policy makers, advisers and quality leaders. It aims to give independent and research based guidance for developing national quality and safety strategies suited to local circumstances.

The guidance covers all phases of strategy development, from formulation through to continual review and renewal in successive phases.

Chapter 1 explains how a quality strategy can contribute to resolving the challenges faced by health services and health systems.

Chapter 2 gives concepts and principles for leaders to understand some of the choices they face. Advice and representations can be biased towards particular actions, therefore it is important to be aware of existing choices and where to find out more.

Chapter 3 considers five types of national strategies aimed at professionals, managers of health care organizations, medical products and technologies, patients and financiers. It shows choices leaders have about legislation and regulation, measurement initiatives, action programmes, and improvement policies.

Chapter 4 provides practical steps on how to develop a strategy for different situations.

Chapter 5 shows how a quality and safety strategy strengthens health systems – a priority for many Member States.

The appendices give resources which readers might find helpful in developing a strategy.

Why does a country need a quality and safety strategy?

The public holds governments accountable for the quality of health care. There is growing evidence of suboptimal outcomes because patients are not provided in a timely way with appropriate treatments and because of poorly organized health care services.

Comparisons of quality of care show major differences between countries. Many health providers are dissatisfied with their conditions of work and are ready for changes which allow them to give better care. There is evidence that quality methods can help to solve these and other challenges faced by low and high income countries alike.

However, money can be wasted on methods and approaches which are not appropriate for the country or problems, by poor implementation, by inadequate data to assess if actions are working, or by not sustaining efforts which take time to produce results.

A carefully developed strategy creates the conditions providers need to improve quality, in part by mobilizing and coordinating many different contributors to the task. It can ensure the right approaches for the circumstances, that there are structures, resources and skills to test and make the changes needed, and that there are regular reviews and renewals.

What is quality and safety and how is it best developed?

Reaching agreement about what we mean by “safety and quality” is an important step.

There are many definitions which can help this process so as to define safety and quality in a way which communicates to people what the strategy is about and makes clear what the strategy will cover and what it will not.

One general definition which has proved useful for strategy development in various resource settings makes quality a function of the way resources are used, not necessarily a result of how many resources are used.

“A quality health service is one which organizes resources in the most effective way to meet the health needs of those most in need, for prevention and care, safely, without waste and within higher level requirements”.

This definition recognizes the need for safe care and for higher-level laws stating high level standards and human rights. It also covers the three perspectives on quality:

- patient quality (what patients want and experience);
- professional quality (what patients need and following best practice) and
- management quality (efficiency and meeting regulations). Improvement means defining and measuring aspects of each and setting standards.

Most strategies aim to improve the services which a patient receives in a health care facility (the **healthcare service perspective**). But we know that the most unsafe periods of care are transition points between professions and services and many quality problems occur at the boundaries between services. There is therefore a choice to define quality and safety as how well different services work together for an entire episode of care (the **system of care/continuity of care perspective**). Even broader than this, some strategies aim to improve services to citizens who are not yet patients and define the quality of a health system as including prevention and health promotion services to populations (the **health system quality perspective**). This assumes that a high quality and safe system makes services accessible to those who most need it, does not put people at risk of avoidable harm and maximizes health output influenced by health care on population level.

Those formulating the strategy may choose which of these perspectives to take and what the objectives of the strategy should be.

General approaches

Choosing the types of approach will be an additional challenge.

A common view considers that the best way to improve quality is to allocate **more resources** to health care. Any strategy will need resources for specialists, quality structures and training in methods to improve quality. In some situations it might require refurbishment or update of lacking or unsafe equipment and facilities. But often more resources are taken to build “more of the same” and this can sometimes lead to dangerous and ineffective healthcare services: located in the wrong place for population needs, not integrated with the other care which a patient needs, etc.

A second common view is that what is needed to improve safety and quality is **large scale health care reform**. Nearly all health care reforms carry with them a declaration that the objective is to improve quality. Reforms and reorganizations can be a successful approach, for example by changing financing systems, redistribution of resources across the system, or decentralizing decision-making. However, large scale reorganizations often divert time, attention and money from local small-scale improvement and distract energies from the sustained approach which is needed. It may be that micro-reorganization, and not macro restructuring, would be the most effective approach according to context, using quality methods described below.

A third view is that what is needed is to **strengthen management** by training and recruiting for professional and business managers and by better management structures and processes for accountability. More resources and reorganizations often fail to improve quality because managers do not have sufficient skills. They are not able to efficiently use the available assets or coordinate the restructuring process in beneficial ways. Furthermore the management of professional organizations such as health care services demands specific competencies. Strengthening skills contributes to laying the basis for managers to use specific safety and quality improvement methods.

Specific quality and safety approaches

Improving quality requires the knowledge, choice and use of specific methods adjusted to local circumstances. There are four broad categories of methods.

1. *Strengthen the role of patients/consumers and citizens.* The consumer approach can be enhanced through consumer protection or patients' rights regulations, or through programmes to involve patients and communities in improving safety and quality in different ways. Some see co-payments by patients as a means of involvement.
2. *Regulation and assessment of health professionals and services.* A regulatory background and dedicated agencies (governmental or nongovernmental organizations) can institute accreditation and licensing services to providers. This may or may not involve making public lists of those licensed or accredited.
3. *Applying standards or guidelines locally.* Implementation will require systems to supervise and encourage compliance (all external assessment processes use standards). This applies more to how local management defines safety and quality standards and ensures they are followed using quality management systems. This method can use agreed standards or guidelines developed by national or international bodies.
4. *Quality problem-solving teams.* The teams work on specific problems using simple methods ("quality tools") which they have been trained to use. Examples are a team in a health centre working on appropriate prescription of antibiotics or improving medical records, or district officers working on the problem of lack of transport and resources for supervision. Sometimes methods are used by teams to describe and improve processes or patient pathways.

There will be many different views and ideas about "the best approach", in part because of the genuine uncertainty about which is right for a country at a given time, and in part because different groups promote different approaches.

Which approach – or combination of approaches – to take depends in part on leader's assessment of the causes of safety problems and poor quality, and whether to take a whole system approach

or focus on specific services. Again, this is as much a technical analysis as it is an assessment of what different parties whose cooperation will be needed consider to be the causes of unsafe care and poor quality. Part of the strategy may be to educate about or negotiate perceptions of causes and the best solutions, using what is known from existing evidence and research performed elsewhere, and in a country's own context.

Who are the key stakeholders in a health care system that a quality strategy should address and what are the key components?

Health care systems have a complex socioeconomic structure with various stakeholders, each with their own roles and interests and multiple interactions.

Some elements however, are common in all health care systems.

- There are specific *occupations* (professions) recognized as being key to delivering health care such as physicians, nurses and allied health professionals, and the medical knowledge on which they base their work is largely universal.
- There are specific *organizations* (services) where health care is provided through the combination of professionals, medical products and technologies in an organizational setting such as hospitals or health care centres.
- There are specific *medical products* and *technologies* applied in health care delivery such as pharmaceuticals and medical devices.
- There are *patients* demanding and/or needing the services provided by professionals and organizations, based on a common understanding of illness and disease, and using the various products with the intention to stay healthy, to get better and/or to prevent further disabilities or discomfort.

Quality and safety strategies particularly address the interaction of professionals, organizations and products with the patients that use them. The quality and safety strategies are aimed at optimizing the performance of the providers in assuring the demands and needs of the users related to the ultimate aim of achieving the users' highest potential level of health.

In addition other stakeholders play an important role such as financiers (for example health care insurers), employers, industry, media and government on regional and local levels. These also have a major impact on how the health care system functions and how national quality and safety strategies work out in practice. Especially the financing of health care can constitute an important incentive or disincentive towards quality.

Thus, from a governmental perspective, national strategies should also consider these other stakeholders, who indirectly influence the primary processes of care delivery, to ensure that they will promote quality and safety through their role across the health care system.

In summary the main stakeholders a national quality and safety strategy should address are professionals, health care organizations, medical products and technologies, patients and financiers.

Key components of national quality and safety strategies aimed at health care professionals, health care organizations, medical products and technologies, patients and financiers

Different strategies are thus needed to address different components of the health care system: professionals, organizations, medical products and technologies, patients and citizens, and the financiers of health care. The government role in strategies aimed at each element covers legislation and regulation; monitoring and measurement; assuring and improving the quality of individual health care services; and assuring and improving the quality of the health care system as a whole. These roles can be fulfilled by using a mix of the quality approaches described earlier.

For addressing professionals possible strategies include training and continuous medical education, working conditions that facilitate learning, certification/revalidation, development and implementation of practice guidelines, explicit description of professional competencies, performance-measurement, peer-review, setting norms and standards dealing with professional misconduct, registering of types and numbers of professionals, medical workforce planning, task-substitution amongst professionals, the introduction of new professions.

For addressing health care organizations possible strategies include licensing, performance indicators, accreditation/certification, risk-management, adverse event reporting, nationally standardized data bases, quality improvement and safety programmes, accreditation of integrated delivery systems, organizational innovation.

For addressing medical products and technologies possible strategies include regulation of market entrance, regulation and monitoring of risks, technology assessment and an overall national innovation strategy.

For addressing patients, possible strategies include legislation on patient rights, patient/community participation, systematic measurement of patient experiences, publicly available performance information and health promotion policies.

For addressing the financiers, possible strategies can focus on the valuing of quality in monetary terms, the production of performance information, financial incentive structures that promote quality and safety and the issuing of national performance reports.

What is the best way to formulate and implement a strategy?

Where should we start? Which of the many problems should we address? Should we use one specific method for this problem, or a general approach such as accreditation which might address many problems? The answer is to start by creating the best process for answering these questions: combine the stakeholders who make the changes and evidence about problems and solutions. Make a structure and process which outlasts individuals and ensures regular review and renewal of the strategy. A country serious about improving quality and strategy will go beyond a paper strategy. It will have people working in a structure, with skills and allocated resources and following a process which includes regular reviews and renewal.

The process will cover: a) formulation, implementation and renewal of the strategy, b) who should be involved, c) how to reach agreement on improvement priorities. Research suggests success is more likely when the strategy is choosing improvements which can be carried out in

the local context, and is using systemised experience to inform choices and to progress implementation. Appendix 3 shows how to draw on research to inform strategy development stages.

There are certain principles which should guide strategy development (section 4.1), and approaches to decide priorities for the strategy (section 4.2). These apply to the different phases which a strategy will move through, where strategy reviews build on what has been achieved in earlier phases.

A strategy moves a country through quality development phases: it develops patient's and provider's understanding of quality, experience with quality methods and the country's capability to implement quality programmes and actions.

Example of possible priorities in different phases

Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Develop awareness in patients, citizens, health providers and politicians	Develop institutions to protect the public from poor quality	Establish a core set of standards.	Start projects to test methods for more difficult cross-profession/service problems	Evaluate experience to date and plan future strategy based on current problems and experience of the most cost effective approaches.
Collect information about quality problems and relevant solutions	Require health providers to assign senior personnel responsible for quality	Evaluate methods for external assessment of providers.	Test process improvement methods	
Select relevant quality methods and approaches to promote	Develop quality training linked to real projects	Evaluate and publicize the demonstration projects	Introduce quality costing methods	
Issue plan for action for consultation with stakeholders	Establish pilot projects to test quality methods and demonstrate what can be achieved	Develop methods for patients to contribute to improvement	Link quality, finance and production in performance measurement of services	
Engage health and management profession associations, the independent sector and the research community	Develop and test a core set of standards (with different levels of achievement)	Improve routine data on quality	Address financial disincentives to quality improvement	
	Establish a patient rights law or policy		Develop a national report on health system performance including performance on quality and safety	

The content for each phase depends on the level of resources, quality experience and implementation capacity, but also on other factors including the type of health system and degree of consumerism in the country, which can change significantly over time.

The aim is to decide, at each stage of development, how to use resources in the best way both to make the biggest improvements to quality and to build the quality change capacity. It is not about making the perfect decision, but to avoid major mistakes like choosing a problem or a solution which uses time and money with few results, and discredits the strategy. Inappropriate choices are more likely if those developing the strategy do not look widely enough and do not gather sufficient information about the range of problems, solutions and approaches which might be appropriate for the country's level of resources and quality change capability. The involvement of too few, too many stakeholders (that might not be directly concerned or have

conflicting interests) can also produce confusion, rather than objectively seeking answers to the question, “what would make the biggest difference for patients for the resources at this phase of our development?”

The right data to monitor progress need to be chosen, collected and used in annual reviews.

How does a quality and safety strategy strengthen a country’s health system and contribute to health?

Quality and safety methods strengthen the health-enhancing aspects of health care and health systems. Safety methods reduce the chances that health care will endanger health. Quality methods improve the outcomes of health care services which are valued by individuals and populations.

Quality and safety strategies strengthen health systems by increasing the contribution of health services and health systems to the highest attainable level of health of individuals and populations.

The five strategic strands described below target different stakeholders and correspond to the six building blocks for health system strengthening proposed by WHO:

1. *Good health services deliver effective, safe, good quality personal and non-personal health interventions to those that need them, when needed, with minimum waste of resources and optimal efficiency.* This can be achieved by applying the quality perspectives and using the methods described (chapter 2).
2. *An operational health information system ensures the production, analysis, dissemination and use of reliable and timely information on health determinants, health system and status.* Collecting and using data is an essential part of modern quality improvement actions – to prioritize what to work on and to assess if changes have made an improvement. This aspect is described for each of the five national strategies proposed (chapter 3).
3. *Well adjusted health services ensure equitable access to essential medical products and technologies of assured quality, safety, and efficacy, and their scientifically sound and cost-effective use.* The national quality and safety strategies for medical products and technologies described (chapter 3) aim to assure quality and safety before using a product and to assess medical technologies, especially when linked to the use of practice guidelines (as described in the national quality and safety strategy targeted at professionals).
4. *A well performing health workforce is one which works in ways that are responsive, fair and efficient to achieve the best health outcomes possible, given available resources and circumstances (i.e. staff is sufficient, fairly distributed, competent, responsive and productive).* The national strategies aimed at professionals (chapter 3) show ways in which human resource management can ensure numbers and mix of professionals.
5. *A good health financing system secures adequate funds for health in ways that ensure people can use the health services they need, and are protected from financial catastrophe or impoverishment associated with their payment. It provides incentives for providers and users to enhance efficiency of access and delivery.* The national quality and safety strategy towards financers (chapter 3) addresses this building block and focuses on how to provide more efficient care and choice of incentives.

6. *Leadership and governance combines development of strategic policy frameworks with effective oversight; coalition-building; regulation; attention to system-design, and accountability.* National quality and safety strategies are a more concrete operational representation of this building block (chapter 3). Governance and leadership are specifically addressed in relation to national quality and safety strategies (chapter 4).

The insights provided in this report on the possible components and ways of developing and implementing a national health system strategy on quality and safety should prove beneficial to policy leaders and decision makers. National choices will always be context specific but these should be embedded in the overall approaches of health system strengthening.

1. Why does a country need a quality and safety strategy?

1.1 Introduction

This guidance has been developed to provide independent and research based guidance for developing a national quality and safety strategy which is suited to a country's situation. It is targeting senior health policy makers and advisers; and quality leaders involved in the process of strategy development and decision making.

Based on existing dedicated evidence, research and experience, it briefly describes:

- the benefits which a successful strategy will bring for patients, citizens, health care providers and others;
- the choices about how to define and improve quality and safety;
- the contents of a strategy addressing the various stakeholders in the health care system;
- how to develop a successful strategy; and
- how quality and safety improvement strengthens a health system and is essential to creating better health for all.

1.2 The challenge and the way forward

Quality and safety improvement contributes to meeting the challenges confronting countries. People are expecting more from healthcare and have changing health needs. Costs are rising and there are skill shortages and increasing labour and patient mobility. There is more evidence that some healthcare is harmful or ineffective (IOM 2001, McGlynn et al 2003, Nolte et al 2008), and that resources are often wasted (Øvretveit 2003, 2005).

However, all countries have professionals, managers, patients, financiers and others who want to improve safety and quality, and many ideas about how to do so. The purpose of this document is to help national and regional leaders to develop a strategy which supports the enthusiasts for improvement and protects the public from the unsafe. Research and experience have discovered general principles for a strategy to be successful in most countries. There is also knowledge about what is specific to and needed in different types of health system and resource settings. This knowledge is tentative and changing, so no detailed prescriptions can be given. Much depends on leader's and organization's competence to apply the principles wisely, appropriately, and persistently.

Quality and safety in healthcare can be confusing for both non-experts and experts. There are technical terms from the quality and safety sciences and practices. But terms are used in different ways. This is because some ideas and ways of defining quality suit the interest of different groups: quality is political. This is one reason why an independent guide is needed, and one which is realistic about the challenges.

There are many ideas about what we mean by quality and "the best approach", and many strong interest groups pressuring for particular approaches. There is little strong evidence to show which approach is best in which situation. Leaders do not need to be experts, but do need to know that there are different approaches, and that modern methods are about organizing and

using resources more effectively. As such, quality improvement is as much about management as it is about health professional's skills.

This document gives simple guidance without being simplistic, shows some of the choices, and directs leaders to resources which are based on sound research or good experiential evidence. It differs from other documents by combining these elements, so that it:

- integrates patient safety as part of quality and gives equal balance to patient, professional and management perspectives;
- views safety and responsiveness to patients needs and dignity as following from human rights declarations;
- guides how to improve both health service and health system quality;
- includes the quality of primary, secondary, public health and community services;
- describes how to gain support and contributions from key national stakeholders;
- provides recent knowledge about effective actions at levels above the hospital level which improve quality;
- provides specific but flexible guidance for different resource settings with different change-capacity and competence for quality improvement and concentrates on implementable strategies; and
- is designed for the various countries showing the learning and help which countries can give and receive from others.

Service Safety: providing a service which does not harm a patient or a health care provider and which increases people's trust and confidence in the service

Service Quality: organizing available resources in the most effective way to meet important health needs safely, without waste and within legal and regulatory requirements.

System Quality: ensuring access to and coordination of separate services through combining services in the most effective way to provide service quality for patients throughout their illness episode and to enhance population health.

Quality policy: general principles and expectations governing action to ensure service and system quality.

Quality strategy: coordinated actions over time by government and others to create the best conditions for health care organizations to improve quality.

1.3 Why does a country need a quality policy and strategy?

Quality healthcare – which also includes safe healthcare – is not a luxury. Indeed, low resource countries are discovering that quality methods used in the right way may become very effective in making better use of resources and initiate improvements which are greatly valued by patients (Berwick 2004; Øvretveit & Serouri 2007).

Quality healthcare can lower costs and advance human rights and can therefore contribute to the best attainable level of health (including its social dimension) and wealth of a country. A well-developed quality policy and strategy will reduce the obstacles to improvement and will mobilize stakeholders to act towards attaining higher quality services.

1.3.1 The economics of quality

There is a high economic and human cost to poor quality. Research shows on average that one in ten patients suffers an adverse event in hospital (Hospitals for Europe working party on quality care in hospitals 2000), and that some events lead to higher costs in extra care. Approaches to improving quality are not always about spending more on health care but about using resources more effectively. This requires investment of time in the planning process (what to do/ how to do), a close follow up on implementation (what was done) and the evaluation of expected change (how it works).

The “economics of quality” include ideas about how to ensure that resources are used effectively, and also highlight how to save money using the right methods.

Providers or other stakeholders can waste funds and time using quality methods which are not effective or not well applied to the context. In particular situations, the seed investment might not be available even for methods proven to improve quality and reduce costs on the long run.

Additionally, there are health financing methods that do not reward providers for higher quality performance: if a provider succeeds in attracting more patients and in being able to treat them more quickly, the financing system then might not pay for each extra patient treated. However this tries to limit the risks of increased patient turn-over, keeping the balance with considered quality and safety standards of practice.

Quality improvement methods can save money for a service and a health system, but this is not guaranteed – a quality strategy should create the conditions which increase the chances of the right methods being chosen and used successfully.

1.3.2 Safe quality care is a human right

According to the World Health Organization’s constitution, “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being”. This implies several obligations for the Member States, which have to: implement the right to health care by adopting measures aimed at achieving universal access and refraining from systemic discrimination to care, as well as to preconditions for health (including environmental regulations etc).

Acknowledging that health is a pre-condition for the enjoyment of all other fundamental rights and liberties emphasizes the responsibility and accountability of Member States in providing individuals with living conditions compatible with health, and guaranteeing access to and quality of health care on the basis of their needs.

1.3.3 The public expects safe, quality health care

The quality of health of care is a growing political issue, regardless of whether services are provided by government or independent providers. The public expects their government to assure the quality of health care, and policy-makers seek credible, effective and low-cost ways to do so. Just as patients want a quick solution such as a medication, so too do policy makers, but quality improvement takes time. There is often pressure on policy makers to take quick action, but this may not be effective or may even be counter-productive.

A well formulated quality policy and strategy is not only effective in the short term, but can ensure the sustained and persistent actions which are needed for substantial improvements.

There is growing evidence of waste in healthcare because patients are given treatments which they do not need, and because of poorly organized health systems.

Many health providers are dissatisfied with their conditions of work and are ready for change which allows them to give better care.

There is evidence that quality methods can help to solve these and other challenges faced by low and high income countries alike.

The public expects governments to ensure safe, accessible and good quality health care.

1.3.4 Why do we need a national strategy?

In many countries there is an agreement that something must be done to improve quality. A strategy is a process not an end product – a way of agreeing what is to be done and by whom, and of ensuring that quality work is carried forward, regardless of particular individuals

An overall strategy gives a statement of intent by those committed to taking action and stimulates others to start working on quality actions. It can provide a useful “rallying point” and organizing force, coordinating quality work by different organizations.

Money and time can be wasted on methods and approaches which are not appropriate for the country or problem, by poor implementation or by not sustaining efforts which take time to produce results.

A carefully developed strategy creates the conditions which providers and others need to improve quality.

There is no one approach or strategy which works in all situations, but there are principles which can help to develop a strategy suited to a particular region's situation.

Although there are benefits, there are costs and challenges. The history of the quality and evidence based medicine movement shows how difficult it can be to initiate change in health care. Implementing safety interventions can be a time consuming and lengthy enterprise, sometimes only partially successful, even when health personnel are strongly motivated. The advantage of independent research-based guidance is that it gives a balanced picture of what would be needed to improve quality and safety, taking into account context variability.

A quality and safety strategy brings many benefits. It is needed to ensure that the right actions are taken for the circumstances and that these actions are continued and renewed over time. Experience shows that without a consistent strategic approach, time and resources can be wasted on erroneous actions. The content issues (chapter 3) and principles (chapter 4) further described are meant to assist in developing tailored national/regional strategies, adapted to local existing circumstances. The main choices that strategy leaders will face are briefly described in the next chapter.

2. What is quality and safety and how is it best developed?

2.1 General principles of quality improvement – old and new

Since the beginning of time, the help people could get for their suffering depended in part on access to someone who could help them, such as how far they had to travel, and what they gave in return for the help. Improving access continues to be one element of quality improvement, now using different approaches that have been tested, proven to work and implemented widely.

One of the earliest principles of health care was “first, do no harm”, leading health care providers and their professional associations to work for centuries in developing skills to ensure safe and quality care. Methods to ensure the competence of individual providers continue to be a main part of the modern approach to safety and quality improvement.

Increasingly, the care a patient receives depends on how the system is organized and the organizational conditions under which the provider performs: it depends on the provider getting the right information, being referred the type of patient she/he can help, as well as access to drugs and other supplies. The modern approach views the source of quality and safety as being as much about how care is organized as it is about the individual provider’s skills. Management, working with the health care professionals who know the details of every day’s work, can re-design and improve work and information flows.

Patient safety draws on theories and experience from other industries which found that error and adverse events are the cumulative result of a number of causes and rarely due to individual negligence. The modern approach directs investigation beyond the visible event towards possible underlying causes in the way the task is structured, and in the physical and social environment. It leads to solutions in changing the task, environment and systems as well as training. This approach differs from the human tendency to blame individuals for failure, and from the emphasis which professions place on the individual as the source of quality.

Quality improvement is a developing body of knowledge and practice with origins in a different set of sciences than safety improvement. However, quality and safety sciences are being combined in health care and share many of the same principles: an organization and systems approach, collecting data and testing changes before making them widespread, the need for standards and a standardized approach for some tasks. Furthermore safety becomes one of the quality dimensions, with improvement founded on scientific evidence and methods systematically applied in real work settings.

There are more challenges to introducing this modern approach to safety and quality in health care than in other industries. The view that the individual is the source of safety and quality is strongly held. There is a corresponding tendency to use training and discipline to prevent and solve problems. The standardization of processes (often necessary) is resisted, and it is sometimes difficult to tell whether standardization is truly inappropriate. There is also organizational and cultural inertia, as well as the increasing pressure of work for health care providers. This makes it difficult for health care professionals and managers to turn from treating patients to spending time on “organizational issues” which they are often not trained to do and do not see as necessary to their work.

Existing challenges further enhance the need for change, and new integrated approaches and methods are necessary and beneficial for all.

A quality strategy will need to promote the following principles of quality improvement throughout a health system:

- Multiple stakeholder approach
 - patient focused: actions and changes should be assessed against whether these reduce suffering and are accepted by patients;
 - shared responsibility: for safety and quality improvement, with each group contributing with specific responsibilities;
- Evidence based
 - fact based action: locally-collected data used to prioritize which problems to work on and to check the results of change (use graphs to better understand the data);
 - use knowledge of effectiveness: improvements are best made by using approaches/methods and changes to organizations which have been shown to be effective;
- Systematic application to the local situation
 - local adaptation: use changes proven to be effective elsewhere but adapt the change to your local setting characteristics;
 - a systematic approach to change with simple methods: use the facts to plan what to do, carry out the change, check the results, and then decide further action (the “plan, do, check, act” cycle);
- Organization and attitude change
 - systems and organizational change: the most effective improvements involve changing procedures and the way care is organized. Asking people to work harder or be more careful is an important but additional measure, which cannot work alone;
 - attitudes and culture change: improvement requires providers to put their patients first, and their social setting to encourage provision of quality care. Attitude and culture change takes time, leadership and many different coordinated actions.

There is broad agreement on the above principles, but beyond this there are different views on which other principles should also be included. Some consider these to be essential for effective improvement:

- ‘Project team’ process improvement
 - project team based change: there is a view that change at all levels is best devised and implemented by a team of people who understand what happens at present and how to make a change, supported by a facilitator helping with the choice of methods that the team can use to be more effective;
 - process change: describes the steps in a process or patient pathway over time and changes parts of these to make it work better;
 - statistical process control: collects and analyses data using special methods and graphs to determine if the introduced change(s) lead(s) to significant improvement.

2.2 Perspectives and definitions of quality and safety

What do we mean by the quality of a health service or of a health system? There are different “schools of thought”, each with their own set of terms. The aim of this chapter is to provide leaders with some understanding of these and existing choices.

Each profession, management and others have different views. Leaders will also need to guide a common understanding and agreement between different parties about what they are aiming to achieve together. Commonly used definitions of quality provide a starting point.

One general definition which has proved useful for strategy development in various settings, independently of their level of resources, states that. “*A quality health service is one which organizes resources in the most effective way to meet the health needs of those most in need for prevention and care, safely, without waste and within higher level requirements*” (Øvretveit 1992)

This definition underlines that quality is resulting from the way resources are used, and not from how many resources are available. The definition recognizes the need for safe care, higher-level laws and human rights. It also covers the three stated entry points to quality: patient, professional and management quality.

2.3 Three perspectives on quality and safety

2.3.1 *The “Healthcare service” perspective*

This first perspective focuses on the quality and safety of services received by a patient who is under health care. It is often viewed along the three entry points (Øvretveit 1992) listed below.

- *Patient quality*: the service provides patients with what they want and expect, during and after the service.
- *Professional quality*: the service follows procedures and methods which are thought to be most effective in meeting patient’s clinical needs, as assessed by health professionals.
- *Management quality*: the service uses available resources in the best way to achieve patient and professional quality, without waste and within higher level requirements.

These three dimensions can be in conflict. Patients’ expectations may be different to their needs as assessed by professionals. Both can be in conflict with higher level requirements or available resources. A quality service uses methods to balance these three cross cutting features. For example, professionals work with patients to agree the best treatment.

Some quality methods can improve all three dimensions at the same time by changing the way services are organized: one example is process and pathway improvement carried out by a quality project teams which improves the different stages of a patients “journey” through a service or system (Langly et al 1997).

These correspond to three of the five types of national strategies described in chapter 3, which focus on patients, professionals and the management of health care institutions. The other two strategies in chapter 3 address the “organization of resources”, through the use of medical products and technologies and funder’s actions.

The three dimensions also give a basis for measuring progress in improving quality – one of the things which a quality strategy needs to do.

- Patient safety and quality can be measured through complaints, level of satisfaction, and claims related data at a service level.
- Professional safety and quality can be measured by assessing which patients do not get professionally appropriate prevention services or treatments, or by collecting indicators of clinical outcome and error reports.
- Management safety and quality can be measured by unit costs, length of stay, and measures of waste. Many error reports indicate lack or failure of dedicated management systems.

These three key features are usefully combined with three other ways of considering quality:

- the inputs and structure of quality (e.g. how many personnel and which skill mix, how responsibilities are distributed etc);
- the process (e.g. which actions are taken); and
- the outcomes (e.g. results for patients and others). It takes time to see results of quality actions on patient outcomes, so there is a need to also assess whether there are inputs and structures, as well as whether the right things are done (processes) which are likely to lead to patient outcomes (Donabedian 1980) .

A key part of the quality approach is to collect data about identified key features using different quality data collection and presentation methods. Collected data can be used to compare providers, or to compare the changes in safety and quality of each provider over time. This gives both providers and strategy managers information for judging the effects of changes and deciding future action. Choice of the right measures and data use are an essential part of the quality approach at all levels and a number of methods exist which are easy to use. (Langly et al 1997).

Most quality strategies aim to improve the quality of specific health services. However, many quality problems occur when patients move between services. Hence a wider definition of quality will look at the system in its entirety.

System Quality: ensuring that separate services combine in the most effective way to provide service quality for patients throughout their illness episode and transitions within health care, ultimately enhancing populations' health.

2.3.2 The "System-of-care" perspective

The above definition gives a wider perspective for a quality strategy to take. It looks beyond what happens to patients within a healthcare service facility and addresses safety and quality of care from and between many services.

Patients may be pleased with the quality of care of a specific service, but are often unhappy about what happens in their transfer to another service. Many are harmed because health related needed information is often not properly passed on to the next receiving service, or due to failure

of referral to the right service. The quality of care for a patient depends as much on how the services connect with each other as it does on how well the patient is treated within each service.

The quality of a health system is more than the sum of the quality of separate services: it depends on good coordination at the clinical and higher levels, especially where prevention is concerned.

2.3.3 The “Populations’ public health” perspective

An even broader perspective views health system quality and safety as more than providing health care to patients already in contact with services (Klazinga et al 2001).

It includes services reaching out to people who do not ask for services but may need services more than those who arrive at the door of the health unit. These may be poor or vulnerable people, homeless, or marginalised groups.

It also includes services to maintain the health of people with long term illness and often involves health services working with others to promote health and prevent illness.

Public health system quality: how well combined services reach out and are accessible to people with health needs or at risk (who do not ask for services, but may be in greater need of caring, curative or preventive services than those who do use services).

There are choices about which perspective and definition of quality and safety to use. There is a choice whether to concentrate on specific health service quality for patients, which may be appropriate at an early stage; or whether to concentrate on system of care quality; or whether to choose a more public health type of definition. The choice will focus the quality strategy.

2.4 Approaches to improving quality

There are as many different views about the best way to improve quality as there are definitions. Those developing a strategy will need to debate the different ideas below, and possibly develop a strategy which includes elements of each. The first three approaches are generic.

2.4.1 More resources

Many think the best way to improve quality is to put more money into the system. The extra money could be used to employ more doctors, nurses and other healthcare workers, to increase pay and buy more drugs and equipment. Sometimes this is necessary.

However “more of the same” might not be the best way to improve quality. Some healthcare services are dangerous and ineffective. Some are in the wrong place for population needs, or do not integrate with the other care which a patient needs. Expanding the existing system without changing it might not be the best use of scarce resources.

2.4.2 Reform

Reorganization changes the work done and where it is done. Examples are closing some facilities and transferring the resources which are released to other facilities, or decentralizing decision-making, or reallocating personnel.

However, large scale reorganizations often divert time, attention and money from local small-scale improvement and distract energies from the sustained approach which is needed

Changes to financing methods can give incentives which reward rather than penalize quality practices – for example, allowing personnel to use savings from more effective prescribing to improve their service. Also, direct payment incentives for better quality can be effective (Custers et al 2006, 2008).

2.4.3 Strengthen management

More resources and reorganizations often fail to improve quality because managers do not have sufficient skills. They are not able to use the resources or implement the reorganization in ways which benefit patients.

Developing manager's skills is one way to improve quality and may bring bigger improvements than more specialized approaches to quality. Strengthening management also involves developing management processes for motivation, supervision, control and action, all of which can support quality improvement and are often a necessary precondition for more specialized approaches.

2.4.4 Use quality methods

All the above are “generic approaches” to quality improvement and can be successful if carried out in the right way. However, a fourth approach is to use specific quality methods which have proven successful in certain settings when applied properly.

It is important that strategy developers are aware of the different quality approaches, the choices they face, and that there is no strong evidence that one is more effective than another in all situations. The quality methods listed below cover external quality assessment, standard-based quality management, team-based problem solving and approaches for patient and community participation.

Quality methods approach 1: patient and community participation or direction

This approach includes:

- a national statement about what patients have a right to expect from a healthcare provider;
- community participation (each level), giving feedback about quality of services and working with providers to make improvements, as well as helping with public health interventions; and,
- surveys of patients to discover what they do and do not like about health related services, deciding subsequent priorities for action, and using problem solving methods to improve services from the patient's perspective.

Work would be needed to find the best ways to introduce this approach, building on local culture and existing structures (e.g. local health committees). This approach can be used for individual

services as well as for improving how services connect and for the functioning of health care systems (see chapter 3).

Quality methods approach 2: external regulation and assessment

This approach aims to develop different national systems for awarding certificates of competence to practitioners or facilities, for licensing practitioners or facilities to operate, and for accrediting facilities to show the level of quality they have achieved (Shaw, C & Kalo, I (2002)). It includes: peer review, certification, licensing and accreditation.

The objectives range from reducing harm to patients from incompetent practitioners and dangerous services to improvement in quality and safety of care through the incentives of external recognition. The disadvantages are that these can be unpopular with many practitioners and services, can take time and bureaucracy to implement, and the resources might be better used for other measures to improve quality.

Organizational accreditation could be part of a national quality programme, but establishing a full accreditation scheme for health facilities might not be appropriate at the early stage of quality improvement or in low resource settings.

Schemes for certification, licensing and peer review should be explored where a country does not have such schemes. The various approaches towards quality assessment can be made part of national legislation or regulation as described in chapter 3.

Quality methods approach 3: local standard-based quality management

All external assessment processes use standards. However, a standards based approach can be used locally and on its own without being part of peer review, certification, licensing and accreditation.

Standards for how to provide effective and safe care are defined and communicated, and are used as a yardstick to monitor and measure the quality of care. Guidelines are one example, but there are many other types of standards. Personnel are helped to follow standards through training, job aids and supervision. The process is documented and where standards are not followed, supervisors and managers bear the responsibility for taking corrective action. In addition, standards are defined for management activities and service performance (Øvretveit & Serouri 2007).

A standards-based approach entails the following phases.

- Develop standards which will ensure effective and safe care and which are feasible, given the resources available.
- Implement standards: communicate and supervise the standards, and document where standards are not met.
- Take corrective action where practice falls below standards using problem solving methods.

In some countries this approach has been used partially, omitting the last phase (corrective action and problem solving).

The advantages of this approach are that it is easy to understand and can be implemented through an already existing management structure with advice and support, and also developing/refining this structure. The disadvantages are that the management and supervision structure might not be strong enough to communicate and uphold standards, or there may not be the resources for supervision or for effective action if/ when practice falls below standard.

Evidence that care does not reach basic standards when apparently nothing can be done damages morale and raises anxiety. However, many problems can be solved if local managers have the authority and the right attitude, and use quality problem solving methods. One approach is to test this standards-based approach using a quality management system in selected areas. The standards-based quality management methods are related to quality monitoring and measurement as described in chapter 3.

Quality methods approach 4: local project teams working on quality-problems

A common approach is focused on setting up quality problem-solving teams which work on specific problems using simple methods (“quality tools”) which they have been trained to use. Examples are a team in a health centre working on over-prescription of antibiotics or improving medical records, or district officers working on the problem of lack of transport and resources for supervision. Methods for process or patient pathway improvement also can be very effective (Langly et al 1997), as well as teams implementing simple safety methods to improve communications or find and solve the root causes of a safety problem.

The advantages are that this would allow some units to quickly solve priority quality problems. It could also improve personnel morale and pride and develop professionals’ abilities to work in teams. The disadvantages are that it only impacts a few problem areas, and teams would spend time learning the methods before producing results. Experience elsewhere shows that regular facilitation and management support is needed for the teams to be successful otherwise the training and time of the team is fruitless.

A team-based problem solving approach is used within individual health services as well as for problems concerning continuity of care for patients over a number of services.

There will be different views about which approach (nationally and locally) should form the main parts of a quality strategy. But often a strategy emphasizes one or more approaches because the conditions needed for each are slightly different.

Strategy developers will need to create a process for deciding which approaches the strategy will promote, drawing on more recent evidence of which has been successful in situations similar to those in their region and as described in chapter 4.

The four approaches described above can be combined, but there is a risk of confusing providers about what quality is about. Choosing one or more approaches requires translation and adaptation to the local situation and culture. The first two approaches often need a different kind of government involvement (legislation, regulation, standard setting and monitoring) than the latter two approaches which mainly require government to stimulate and facilitate team problem solving and patient/community participation.

However, for all of these methods to work, health workers need to feel that high or low quality makes a real difference to them. Quality methods were developed for services which wanted to

keep and attract more customers. Are there incentives for workers and managers to spend time learning on using quality methods? The financial and social context of health services influences how effective different approaches are. The approach of a tax-based public system with budgets for providers not related to the number of patients they treat, will need to be different from the approach where providers' gain is related to the number of patients they serve.

3. Who are the key stakeholders a national strategy should address and what are the key elements of a quality and safety strategy?

The ultimate aim of health systems is to maximize the potential health of individuals and populations. The provision of health care services, together with genetic, behavioural and environmental factors, is an important part of achieving that goal (Lalonde 1973, Mackenbach 1996). Alongside the goal to achieve health, there are system goals related to equity (health for all) and goals related to an adequate use of resources (efficiency). This mixture of health, costs and distributive goals is captured in the various international attempts of WHO, OECD, World Bank etc, to assess health system performance.

National quality and safety strategies are an inherent part of the overall system performance and have more recently also become of interest from an European Union perspective (Legido-Quigley et al 2008). Quality and safety strategies mainly focus on the optimization of health services performance towards individuals and populations' needs (existing and perceived) given the resources available, which implies that notions such as the effectiveness, responsiveness and efficiency of services are the main focus. This chapter will describe the key elements of national quality and safety strategies in health care by addressing the main components that in their interaction constitute health care: professionals, services, medical products and technologies and patients.

Health care systems are complex social systems with various stakeholders, each with their own roles and interests and multiple interactions. However, some elements are common in all health care systems.

- There are specific *occupations* (professions) recognized as being key to delivering health care such as physicians, nurses and allied health professionals, and the medical knowledge on which they base their work is largely universal.
- There are specific *organizations* (services) where health care is provided through the combination of professionals, medical products and technologies in an organizational setting such as hospitals or health care centres.
- There are specific *medical products* and *technologies* applied in health care delivery such as pharmaceuticals and medical devices.
- There are *patients* demanding and/or needing the services provided by professionals and organizations, based on a common understanding of illness and disease, and using the various products with the intention to stay healthy, to get better and/or to prevent further disabilities or discomfort.

Quality and safety strategies particularly address the interaction of professionals, organizations and products/technologies with the patients that use them. The quality and safety strategies are aimed at optimizing the performance of providers in meeting the demands and needs of users, with the ultimate aim of reaching/maintaining users' highest potential level of health.

These common elements can be used in targeting national quality and safety strategies:

1. National quality and safety strategies aimed at health care professionals
2. National quality and safety strategies aimed at health care organizations

3. National quality and safety strategies aimed at medical products and technologies
4. National quality and safety strategies aimed at health care users

In addition to professionals, organizations, medical products, technologies and patients, other stakeholders play an important role in shaping health care systems such as parties involved in the overall financing of health care, the financers (for example health care insurers, employers, government on national, regional and/or local level) or actors such as the media or industries marketing new health related products. These other actors also have a major impact on how the health care system functions and how national quality and safety strategies work out in practice. Especially the financing of health care can constitute an important incentive or disincentive towards quality. Thus, from a governmental perspective, national dedicated strategies can also target these other actors to enhance promotion of quality and safety through their role in the health care system. This yields a fifth type of national quality and safety strategies targeted at *financers*.

5. National quality and safety strategies aimed at health care financers

The role of national governments in health care differs from country to country. Apart from having an overall legislative responsibility for the health of the population, governments have a say in the financing, ownership and regulation of health care.

Furthermore, even if government has a major role in the actual provision of health care, there are different parts of the government organization involved, and responsibilities may be delegated to various geographical locations.

Considering the major differences between the 53 Member States of the WHO European region, the following description of the 5 strategies uses rather generic terms, recognizing that further detailing is needed based on the specific characteristics of and governance models in individual national health care systems. However, the generic elements seem universal and relate to:

- I. Legislation and regulation (formulation and enforcement of laws and regulatory requirements)
- II. Monitoring and measurement (national data bases with relevant information to monitor and assess various aspects of health and health care functioning).
- III. Assuring and improving the quality and safety of individual health care services (quality and safety of services provided through individual professionals, individual institutions and with the use of specific technologies and devices).
- IV. Assuring and improving the quality of the health care system (health care system performance as a whole, addressing issues such as continuity and timeliness of care delivery to those in need).

These functions can be fulfilled by using a mix of the quality improvement approaches previously described.

The 5 types of national strategies targeted at professionals (3.1), health care organizations (3.2), medical products and technologies (3.3), patients (3.4) and financers (3.5) will be addressed through the functions that governments can fulfil with respect to legislation and regulation (I), monitoring and measurement (II), assuring and improving the quality of individual health care services (III) and the health care system as a whole (IV). Various combinations of quality

improvement approaches (quality assessment, standards-based quality management, team problem solving, patient and community participation) are suitable for these functions as part of the respective national quality strategies.

3.1 National quality and safety strategies aimed at health care professionals

The essence of the health care profession is an occupation that entails the application of specific knowledge and skills with a specific attitude. The knowledge largely has a scientific basis and the skills need considerable training. Thus professions in health care are linked to the growing body of medical knowledge and techniques on the one hand and professional and societal norms on the other.

A professional in health care is, delivering services through intensive human interaction. Because of the nature of this work, mutual trust between the health care professional and the patient is essential and thus the application of professional knowledge and skills is embedded in a set of professional norms.

Quality and safety as such are core values of professions in health care, and the classical principles of doing no harm and preserving life are as old as the medical and nursing professions. Traditionally governments have assured the quality and safety of professionals in health care through regulatory frameworks on their occupation and on their mandatory training. However, with the rapid changes in knowledge and techniques, the professional quality of can no longer be assured by merely awarding diplomas and titles after completion of training. Continuous medical education has become the norm and additional mechanisms such as re-validation or re-licensing have been put in place. For these mechanisms it is essential to assess the performance of individual professionals and here again countries have come up with various types of regulations varying from mandatory Continuous Medical Education, peer-review and all sorts of individual performance assessment schemes. With this, the various competencies of professionals have been made more explicit. Several European countries are in the process of adapting the Canadian CanMed model for describing the necessary competencies in their professionals (Borleffs&Cate 2004).

A debate has been going on in medical journals over the past years with respect to professional norms and standards and the new role of professionals, particularly in relation to issues such as quality and safety (Physician Charter 2002, Carroll & Quijada 2004).

Partly initiated by health workforce problems, countries have started looking at questions such as whether the mix of professionals working in their health care systems is still optimal for the type of health care problems they need to address. Various new professions have emerged such as physician assistants and nurse practitioners. These initiatives towards substitution of tasks and professional roles within the health care workforce are also part of the general agenda to improve the quality of health care in a given country.

Generic elements of national quality and safety strategies aimed at professionals seem to be:

Legislation and regulation

- Ia Legislation on and regulation of the various types of professionals and their training (use of titles and the related mandatory training)
- Ib Legislation on and regulation of re-validation of professionals (assuring that all professionals who are actually practising have the necessary up-to-date competencies).
- Ic Legislation on and regulation of professional norms and standards (often in close cooperation with the national professional bodies of physicians, nurses and allied health professionals)
- Id Legislation on and regulation of misconduct of professionals

Monitoring and measurement

- IIa Monitoring the total number of recognized professionals – national professionals register
- IIb Stimulating data collection that helps to enhance performance measurement.

Assuring and improving the performance of individual professionals

- IIIa Stimulating professional approaches towards peer-review and learning through systematic self evaluation and CME.
- IIIb Stimulating the uptake of new knowledge through practice guideline development programmes
- IIIc Stimulating working conditions both in time and culture that facilitate professional learning by addressing good performance as well as errors and shortcomings

Assuring and improving the performance of health care professionals as a whole

- IVa Adequate human resource planning (health workforce planning) in health care
- IVb Adequate description of the set of competencies corresponding to the various types of professionals
- IVc Development of policies on task substitution among existing professions and introduction of new professions.

3.2 National quality and safety strategies aimed at health care organizations

Health care organizations, with the hospital as the best known exponent, can deliver a variety of health care services which usually entail a mixed input of professionals and technology. Prevention, diagnosis, therapy and rehabilitation are some of the main headings under which the services can be grouped, but a grouping according to specialties (surgery, paediatrics, cardiology etc.) or setting (clinical care, day-care, ambulatory care) is also possible.

The history of the modern hospital as a health care service goes back to the end of the 19th century when technological innovations such as narcosis and X-rays were embedded in former nursing institutions and thus became a working place for a growing number of medical specialties (<http://en.wikipedia.org/wiki/Hospital>). This history is relevant as in the 21st century,

also led by technological innovations in diagnostics and therapeutics as well as in communication technologies, the rationale for the hospital organization is shifting again.

Clinical care is shifting to day care and in many countries of the WHO European region ambulatory services constitute a large volume of hospital activities. Quality and safety strategies are related to these changes in the structure of the hospital organization. In general, many quality improvement efforts are focusing on care process-reengineering, managing risks and improvement of communication. As with the national strategies for professionals, quality and safety strategies for health care organizations focus on legislation, monitoring, individual service improvement and whole system improvement, thus resulting in a mixture of laws, data-collection efforts, stimulation programmes and national organizational innovation strategies.

The following generic elements can be recognized:

Legislation and regulation

- Ia Legislation on and regulation of the various types of health care organizations and related services.

Legislation determining the specific requirements for organizations that provide specific services through specific professionals (i.e. hospital, primary care centres, mental health care institutions) and the *licensing* of these organizations and related services .

- Ib Legislation on and regulation of specific aspects of health care *services* that pose a risk for patients (e.g. radiology, nuclear medicine, handling of human tissue, disposal of hospital waste, fire-regulations, etc)

Monitoring and measurement

- IIa Use of hospital performance indicators

Over the past ten years many initiatives have been taken on the measurement and reporting of performance indicators on health care organizations. A national quality and safety strategy can drive the indicator agenda by promoting the development and use of a valid set of performance indicators. Important choices in this process are whether the indicators should be limited to quality and safety issues or should be integrated in a broader set of information on organizational performance, and which indicators are in the public domain versus indicators to be used primarily for internal learning. The WHO Performance Assessment Tool for quality improvement in Hospitals (PATH) project is an example of an indicator project for hospitals that works with a broad set of tools with the primary aim of internal learning (WHO PATH 2007). A precondition for defining performance indicators is the availability of nationally standardized administrative and medical databases ((Veillard et al 2005, Groene et al 2008).

- IIb Linking the agenda of organizational performance indicators to the broader agenda of electronic (medical) records and *systematic collection of health care information*.

Measurement of quality and safety aspects is largely dependent on the quality of the hospital information systems and the level of (national) standardization. For medical information, ICD9 or 10 coding is essential for making international comparisons possible.

Assuring and improving the quality and safety of individual health care services.

IIIa *Accreditation and/or certification systems*

These systems have been implemented in most countries to assure the quality of health care services. WHO reports have described in detail the various programmes (Shaw 2006). Over the past years accreditation work has given more emphasis to safety aspects and various programmes are at present combining regular site-visits with periodic reporting on performance indicators. National strategies can promote the use and focus of accreditation programmes. At present there is no clear evidence indicating which accreditation model is the most effective but there is evidence that increased external pressure on hospitals is associated with more mature hospital quality improvement systems and desired outputs (policy brief MARQuIS project 2006)

IIIb *Stimulation of specific quality improvement and safety programmes*

As described elsewhere in this report various national concerted initiatives have been initiated to enhance quality and safety improvement. Notably programmes promoted by the US Institute of Health care Improvement, quality collaborations and the safety initiatives of the World Alliance for Patient Safety all aim at involving health care organizations in common activities, based on mutual learning and patient empowerment, to achieve local improvement.

Assuring the quality and safety of health care services as a whole

IVa *Accreditation and/or certification of integrated health care delivery systems*

One of the strategies to assure the quality and safety of care for patients in contact with various services is to approach a set of services (for examples a group of GP's, a hospital, a nursing home and home care services) as a single integrated delivery system. Accreditation/certification can be executed on this level, together with the measurement of relevant population based performance indicators. In Europe this approach is not common practice yet although various countries have adapted an integrative approach for the assessment of quality and safety in primary care (for example primary care trusts in the UK).

IVb *Strategies to promote innovation in the organizational formats through which services are delivered*

Substitution of tasks amongst services (for example transfer wards between hospital and nursing homes) can be combined with the introduction of new services (for example stroke services or integrated services for chronic diseases such as diabetes, heart failure and chronic obstructive pulmonary disease). Many of these services have been proven to deliver better quality (Brown 1996) but further implementation is often hampered by existing regulation and financing focused on existing services.

A national quality and safety strategy should include policies to facilitate the development of effective integrated service delivery models.

3.3 National quality and safety strategies aimed at medical products and technologies

The health care system, together with professionals and organizations, is characterized by the consumption of large quantities of medical products and technologies. Pharmaceuticals make up a considerable part of these, but medical devices and even health care information products such as related websites can also be included here. A national quality and safety strategy also entails the assurance of the quality of these products. This is especially warranted for those products that can pose a serious risk for the health of individual patients when not appropriately used. In general the market of pharmaceuticals is regulated and monitored but the markets of medical devices, self-tests and health care information are less transparent and get less attention from policy makers.

Legislation and regulation

- Ia Legislation on and regulation of the entrance on the health care market of pharmaceuticals, medical devices, and specific forms of medical information.
- Ib Legislation and regulation that enforces governments to intervene when products already allowed on the health care market pose a health threat.

Monitoring and measurement

- II Information systems to signal potential problems related to the use of specific products such as pharmaceuticals and medical devices.

Usually the reporting of side-effects of pharmaceuticals is in place, however reporting systems on failures of medical devices/technologies are less common. National strategies can enforce the culture and communication structures for reporting.

Assuring and improving the quality of individual medical products and technologies

- III Stimulating evaluation of the use and effectiveness of specific products

Although a large number of trials is conducted before new products, particularly pharmaceutical products, for specific indications are systematically introduced, less is known about the actual effect of these products in real life situations. Also, decision making on reimbursement of specific new products from collective financing sources is quite often based on technology assessment reports made at one specific moment in time.

National bodies that systematically assess the available evidence (e.g. NICE in the UK) can be of particular use in this process. The evaluation of new products should continue after their introduction to assure their quality and safe use. Policy makers could consider preliminary decisions for introduction that could be enforced after a specified period of time, based on real life data. In this way a more continuous approach towards quality improvement, i.e. a more effective use of a new product, could be secured.

Assuring the quality and safety of medical products and technologies

- IV Health care products should be part of the overall national innovation strategy. In many countries the introduction of new products comes from outside the country. This is partly a result of the fact that the research and development industry for

pharmaceuticals and medical devices has gradually shifted to specific geographical areas.

To assure the quality and safety of health care products it also seems advisable that the national innovation agenda incorporate local health care product needs.

3.4 National quality and safety strategies aimed at patients

The achievement of highest attainable health of individuals and populations is the ultimate aim of health care. It is therefore obvious that the patients themselves are an integral part of experienced quality and safety related processes. Thus a national strategy should also address the patient as the ultimate recipient of care and judge of quality. This national quality and safety strategy runs in parallel with the overall strategies aimed to strengthen the role of patients in health care systems. This can be realized through legislative support but also by many other initiatives to improve the health literacy of citizens, improve risk-awareness and improve self reliance.

Generic notions of national quality and safety strategies aimed at patients follow:

Legislation and regulation

- Ia Formal recognition of individual *patient rights* on issues such as health information, privacy, informed consent, shared decision making.
- Ib Formal participation of *patients/consumers* in the design and evaluation of health services

Monitoring and measurement

- IIa *Monitoring of patient experiences*
- IIb Transparent and public *performance information* on which patients can base their judgement and selection of health care providers
Assurance and improvement of quality and safety with respect to individual services and general services seen as a whole.

All strategies that enforce the real involvement of patients, and described above under I and II, will enhance quality and safety.

III and IV Bearing the public health goal in mind this particular strategy should also address the strengthening of health promotion and prevention by assuring that these are an integral part of all healthcare activities (WHO Health Promoting Hospitals network).

3.5 National quality and safety strategies aimed at financiers

Quality and safety are “produced” in the interaction between health care providers and patients, but the financing context influences both. Financing systems result in incentives and these may influence essential aspects such as the time available for a consultation, the effect of co-payment on the timeliness of visiting a physician or the extent to which certain diagnostic tests are performed or drugs are prescribed. Incentive structures vary between countries and settings but

especially during the past ten years various experiments have been set up to link performance to payment (Mannion & Davies 2008, Custers et al 2008). Thus a national strategy on quality and safety should also address the way the financing influences quality improvement efforts.

I. Through legislation and regulation the purchasers of health care can be put in a position where they inherently value purchasing quality and safety alongside incentives that drive volume and cost concerns.

II. Through the active use and publication of *performance information* on health care services with respect to quality and safety.

Financers/purchasers can use this information as part of performance management. Furthermore, in systems fostering purchasers' competition, availability of public information on their successfulness can be a driver for their own accountability

III. Financers can focus on specific quality elements and set targets for providers through quality improvement funds. Thus the financer becomes an integral player in quality improvement programmes.

IV. To assure that the interactions between purchasers and providers ultimately result in strengthening populations' health, governments can produce *national performance reports*. Based on recorded trends and international comparisons these can be used for strategic orientation in the field of quality and safety and help identify directions requiring further attention.

In addition the (*financial*) *incentive system* could be designed in such a way that it pays to deliver good quality care.

In the development of national quality and safety strategies the following provisional checklist could be considered as emerging from this chapter.

Professionals: training, re-validation, norms and standards, misconduct, register of profession, performance-measurement, peer-review, CME, practice guidelines, working conditions that facilitate learning, human resource planning, professional competencies, task-substitution, new professions.

Health Care Organizations: licensing, regulation of risks, performance indicators, systematic collection of health care information, accreditation/certification, quality improvement and safety programmes, accreditation of integrated delivery systems, organizational innovation.

Medical products and technologies: registration and validation, market entrance, regulation of risks, technology assessment, overall national innovation strategy

Patients: patient rights, patient/community participation, monitoring of patient experiences, performance information, health promotion

Financers: appraising quality, performance information, incentives, national performance reports

4. What is the best way to formulate and implement a strategy?

Where should we start? Which of the many problems should we address? Should we use one specific method for this problem, or a general approach such as accreditation which might address many problems? The answer is to start by creating the best process for answering these questions:

- Combine the stakeholders who make the changes and evidence about problems and solutions.
- Make a structure and process which outlast individuals and ensure regular review and renewal of the strategy.

A country committed to improving quality and safety will not only have a paper strategy. It will have people working in a structure, with skills and allocated resources, and following a process which includes regular reviews and renewal.

Previous chapters gave guidance about the contents of a strategy and how to choose what is right for a specific time and situation. This chapter considers how to create a process for developing a strategy, which covers how to formulate, implement and renew a strategy, who should be involved, and how to reach agreements about what to focus on (improvement priorities).

Research suggests success is more likely by following principles described below. It shows how to choose improvements which can be made successfully, adapted to the country situation, and how to use published and local research and systematized experience to make strategies more successful. Countries which have a strategy can be more successful if they add elements which are missing from their national processes and structures – most typically better coordination of initiatives can increase benefits for patients.

The focus is a comprehensive strategy covering all patient groups, institutions and areas, rather than a strategy for a particular service. However, the discussion is also relevant for a specific strategy, including one for a level lower than national such as for a particular institution.

4.1 What are the principles which guide strategy development?

Research into country quality strategies shows not only that the contents are different, but that the way countries develop a quality strategy differs – in how the strategy was formulated in the early stages, and in how it was reviewed, redirected or forgotten (Shaw & Kalo 2002). Some are formulated and driven by top-level groups in a ministry. Some evolve in a more complex way through interaction between stakeholder groups reaching agreement about different actions at different times. Research so far has no definitive answer as to whether one way is more effective than another for a particular country at a particular time.

However, research and experience do suggest principles which, if followed, are likely to result in a successful strategy – one which is implementable and brings benefits for patients and health care providers. These principles are:

- **Leadership:** leadership by an institution capable of securing and coordinating the contributions of different actors (this may be government, but it may be a national quality institution)

- **Different institutions and levels:** action by many parties at each level of the health system is needed to improve quality
- **Stakeholder participation:** those who think they will gain or lose need to take part in different ways, especially those who will themselves need to change
- **Different methods:** are needed to get and continue the contribution of different parties (including incentives, laws, directives, education)
- **Realistic and motivating expectations:** quality and safety are best improved by systematic actions which also assess results – there is a need for visible short term results but also long term changes
- **Priorities and phases:** priorities need to be set to support development and to monitor step wise implementation (what to focus on first, and in later phases)
- **Informed by research and data:** politics, values and interests of different groups will influence choice of priorities and strategy implementation, but data about problems and effectiveness of solutions, as well as local research into pilot schemes and good practices, must also inform choices
- **Results monitoring and review:** annual reviews and renewal are needed, based on carefully chosen short term monitoring data which show progress in implementation and likely results.
- **Institutionalised structures and processes:** are needed to make the strategy live beyond particular individuals and to ensure review and renewal to suit changing situations.
- **Resources and capabilities:** little will happen unless resources to develop quality improvement capabilities are found.

The way in which the strategy is developed also indirectly communicates ideas about the philosophy of quality and safety which the country will pursue: will it be through legal or regulatory measures, will it be only through non-directive positive encouragement, will it be through participatory negotiation at each step? The following expands on some of the above principles before considering how to prioritize and how to combine politics and a systematic and evidence-based approach.

4.1.1 Leadership

The public expects governments to take action in sustaining quality and safety improvement of health care. The credibility and ability of government to mobilize the different contributors to develop and sustain a quality strategy vary from country to country. Governments may lead through coordinating and initiating the actions of others, or by taking the first steps with public services to set an example. As more countries decentralize healthcare, there is an increased need to work through motivation, incentives, regulation and persuasion rather than through direction. More will happen if others are motivated and willingly play a part, but supportive legislation and dedicated regulation, as described in the last chapter, retain an important role

In practice, leading a quality strategy often involves forming a core top level government team reporting to or involving the minister of health. A top level steering committee bringing together key government and non-government members as well as different advisory groups and networks is needed to form a “quality leadership system”. The work and membership of these groups will change at different phases of the development of the strategy. The top-level core

group needs to keep constant oversight to ensure the different groups and activities are coordinated and not in competition or conflict.

4.1.2 Different institutions

To improve healthcare related services in a country, different contributions are needed from a number of existing and new institutions. Countries have various types of health systems where governments finance or provide differing amounts or levels of services.

Governments through their regulatory function will need to incorporate quality and safety perspectives and coordinate their role with others who carry out different forms of regulation.

Research shows that the way healthcare is financed significantly helps or hinders quality improvement. Accordingly, funding agencies will need to include quality considerations in how they finance healthcare.

Educational institutions will need to develop skills in quality improvement for different groups, and quality management must be added to existing curricula.

Health care professional associations usually have a long history of actions for developing the quality of their members' practice. They can introduce new quality methods for analysing and improving health care organization.

4.1.3 Resources and capabilities

Strategies remain in their paper format when needed resources are not allocated and capacities not developed.

Government is one source: time is needed develop the strategy as well as to secure funding for the development process, which may include special funds for projects.

If savings are to be made using quality methods then investment is needed to develop the capability to make improvement effectively. Capabilities are the ability of individual and organizations to apply quality ideas and methods and to carry through change. Some organizations or health systems have limited experience and capability to carry through effective change.

A strategy needs to build both specialist quality expertise and a change capacity in the health care system. This allows the strategy to later address more complex problems.

An evidence informed strategy

Evidence about effective treatments

Evidence about effective interventions to organizations which improve quality and safety

Data (including experiential evidence collected systematically):

- about strategy actions: progress, expected impact and results
- from pilot testing

4.1.4 Data, evaluation and continual renewal

Over the years a quality strategy will go through different phases, starting with initiation, then active local projects and programmes, then further phases which build on the growing experience and capacity to make changes.

Any strategy is more successful with two types of evaluation and review.

- The first is **assessing strategy implementation and short term results**. This means defining which data will show progress in implementing aspects of the strategy at regular intervals (including establishing structures and processes) and give indications of short term and long term results. Data covers in this case a range of information including reports of cross-sectional informed observers, project meetings as well as statistical data. “It is too early to be clear about the results” does not mean that no fact based assessment can be made about progress. “No clear data yet” means that there has been a failure to define, before an action, which short term data will give some indication, and to collect these data. The choice is not between no data and a research report in three years.
- The second type of evaluation is **pilot testing using the quality cycle** to learn which changes or approaches are most effective before fully adopting them. This cycle involves assessing, planning, testing, and reviewing national actions and helps to plan more effective further action.

Pilot testing example: Patient complaints and estimation of avoidable deaths lead to an assessment which shows these could be due to poor standards of care and lack of training. Solutions may be to strengthen licensing and establish facility accreditation. The cost and the effectiveness of these interventions for the country may be unknown and there may be other solutions. Planning would involve deciding which actions to take and trying them on a local small scale, using simple research to then decide which actions are most effective on a national scale for the country in the future.

The pilot testing example in the box illustrates the cycle for one problem. The cycle can be used to collect information to assess which are the most serious national quality and safety problems, prioritize and test different actions and then revise the national strategy.

Pilots need to be conducted before being implemented country-wide, but sometimes the political timetable does not correspond to the logical one. Pilot testing needs to align with the political timetable.

4.2 Deciding priorities

The most important and difficult decision is what to focus on, when initiating but also when renewing a strategy. There are so many different improvements which are needed. A successful strategy is one which focuses on a few achievable objectives. The choice of objectives needs to be made by considering:

Evidence

- Data on the size, severity, and human and economics consequences of the problem
- Information on solutions, and assessments of whether the solutions can be implemented in the situation and will produce results found elsewhere

Expertise and change capability

- Whether there is expertise available about how to implement the change, including how to collect data to assess results (nationally, and locally)
- Whether those who will need to change and manage the change are capable of doing so (e.g. are there many other changes and has their “change coping capacity” reached a limit)

Politics and values

- Whether enough of the right people value the possible results and the means of implementation
- Agreement, commitment and motivation by a sufficient number of those who will need to change and to manage the change (typically doctors, nurses and managers).

A problem may be significant, have an effective solution, and there may be experience and capability available to implement it. But if the problem and solution do not align with the politics and values of the key individuals and groups, nothing will happen. This is likely even in countries where implementation goes through legal or top-down methods. Non-alignment is sometimes overcome by presenting the issue in a way which shows benefits to the key stakeholders, or by education.

Another drawback can come from involving too many stakeholders with competing agendas, when each tends to argue for objectives to their own benefit. It can be difficult to agree priorities and the risk is a strategy which has too many objectives, many of which cannot be achieved in a reasonable time given the resources and competencies available. Multiple stakeholder approach may incur the risk of failure to prioritize or the setting of unachievable priorities. A strategy which is not implemented will make future strategies more difficult to carry out.

The way to develop a successful strategy is to create a process which educates those most important to its implementation about the above principles for success. It allows debate about the evidence, negotiation, and ultimately agreement, and builds motivation and commitment to action.

4.3 Priorities and phases in quality development

A strategy leads a country through different phases in its ‘quality development’. In the early phases, the quality of services is lower, as is the capacity to make quality change, mainly because there is less experience and expertise. A strategy develops both the level of quality of services and the “quality change capacity” at each level of the system and of the country as a whole.

A key consideration for the starting point is to what extent the country has the necessary preconditions for applying quality methods in the general organization, management and institutions of its health system. In some countries with an underdeveloped health system, quality

might be best improved by strengthening management and organization reporting and accountability processes. Some quality methods and approaches make assumptions that there are already certain capacities and institutions in place. With little supervision, some of the quality approaches will not be implemented or sustained. In some countries, introducing effective practitioner licensing or regulating pharmaceuticals may improve quality more than more sophisticated organizational approaches which would be difficult to implement appropriately.

A strategy moves a country through quality development phases: it develops patient's and provider's understanding of quality, experience with quality methods and the country's capability to implement quality programmes and actions.

Example of possible priorities in different phases

Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
Develop awareness in patients, citizens, health care providers and politicians	Develop institutions to protect the public from poor quality	Establish a core set of standards.	Start projects to test methods for more difficult cross-profession/service problems	Evaluate experience to date and plan future strategy based on current problems and experience of the most cost effective approaches.
Collect information about quality problems and relevant solutions	Require health providers to assign senior personnel responsible for quality	Evaluate methods for external assessment of providers.	Test process improvement methods	
Select relevant quality methods and approaches to promote	Develop quality training programmes linked to real projects	Evaluate and publicize the demonstration projects	Introduce quality costing methods	
Issue plan for action for consultation with stakeholders	Establish pilot projects to test quality methods and demonstrate what can be achieved	Develop methods for patients to contribute to improvement	Link quality, finance and production in performance measurement of services	
Engage health and management profession associations, the independent sector and the research community	Develop and test a core set of standards (with different levels of achievement)	Improve routine data on quality	Address financial disincentives to quality improvement	
			Establish a patient rights law or policy	

The aims and contents for each phase do not only depend on the level of resources, quality experience and implementation capacity. They depend on other factors and especially the type of health system and degree of consumerism in the country. For some countries, a national data measurement system for comparing the quality of providers might not produce any significant change in quality for patients. Other actions might be more cost-effective: a patient's rights law, a profession-led improvement programme, or an accreditation scheme.

However, significant improvements for patients might result from making comparative data public, if purchasers and patients would use these quality data to choose providers of care, and if the country has the expertise and resources to implement an effective measurement system.

Example of phases in strategy development

The UK is an example of a country which has used different actions at different phases, such as patients' charters, accreditation, inspection, and process improvement. Each phase has been possible because of what was achieved before. In addition, the first steps were possible only because of general reforms in the health system which introduced public competition and management strengthening. In 1998 the UK started a national quality strategy for health services which built capacity and experience in how to implement large scale programmes, and allowed learning about their effectiveness for different purposes in the country at the time.

To choose which actions are appropriate to the country at one time it is helpful to learn from countries with similar health systems, wealth levels, and levels of understanding of quality amongst patients and providers.

For governments first introducing a quality strategy, the aims could be:

- To outline the new institutions and support structures which will carry forward and sustain quality improvement;
- To describe the role of different partners in improving healthcare; to draw together activities and ideas;
- To provide a vehicle for a coordinated and sustained programme of quality improvement, and
- To indicate the first steps to be made and responsibilities for action. This would need to draw on extensive consultation with stakeholders.

In phase 1 an "initial framework" would not give details or timetables. These would be developed by a national health quality committee and partners, as they draw on the lessons from experiments and from the deeper knowledge gained from education about quality methods and programmes. The features of a later and more detailed plan could be:

- Encouragement for professional and other bodies to exercise leadership in raising quality and professionalism.
- Developing and testing specific quality methods such as team problem solving or a quality management system in selected areas. The plan would outline how these experiments would be evaluated, the approach revised for more widespread use, and how a central quality unit would spread the approach to other areas.
- Establishing demonstration sites to give examples of how investment in personnel and management systems can improve quality for low costs.
- Development of new incentives and motivation for health personnel which would reward quality improvement.
- External review processes such as peer review and stronger regulation of the quality of private practitioners and services through more effective inspection, certification and licensing of practice (not just facilities and equipment), with formal procedures for appeal and protection against corruption.

And, if they are not addressed by other reforms in the country:

- Programmes upgrading the skills of all health personnel, modernizing training and training institutions, including training in quality standards and attitudes;
- Upgrading equipment and supplies, with adequate accountability for their use through supervision and auditing processes;
- A review and rationalization of health facilities so as to be more oriented and accessible to the needs of the population.

Some of the above could be carried out with no extra resources, but many activities would require additional and continuing resources. Experience shows that programmes which start with special funding decline once this funding is stopped: funding is not transferred to the main budgeting system and managers are not able or willing to divert even a small percentage of funding from operational healthcare to quality activities.

Savings can come from changes made as a result of using quality methods, but experience shows that careful management is required to ensure this, and that some resources can be wasted on ineffectual quality activities. At an early phase a country's regions can allocate a percentage of their budgets to quality activities and appoint quality coordinators. Once they have demonstrated results and quality is incorporated in operational plans, these regions then can become eligible for training which could be partially funded at national level.

A key issue in later phases is to finance the spread of a developed effective quality system after testing. Some financing for upgrading skills, equipment and supplies can come from funds released through closure of some facilities, reduction of waste through quality standards and methods, and by increased user fees through higher attendance as a result of higher quality services.

Quality change capacity: the ability to design a solution for the problem and implement it in a way which improves quality in a visible or measurable way.

This capacity depends on the amount of resources allocated, on expertise and experience using quality methods to implement change effectively in the situation. It refers to quality units and teams at each level of the health system, but also how these units and teams work together across levels and sectors.

Quality change capacity also refers to ordinary health workers understanding of and attitude to quality: motivation towards improvement and knowledge of quality methods form part of a country's quality change capacity.

A higher "quality change capacity" will be needed for more complex changes, and also if there are other reforms or changes competing for time and attention.

4.4 When to renew or redirect a strategy?

One difficult choice at annual reviews of a strategy is whether to keep pursuing a particular initiative which is not showing results. Is lack of results due to the actions which are ineffective, or because it takes time to get results, or because the wrong things are being measured?

Quality improvement takes time and resources can be wasted by abandoning an approach just when results are beginning to be produced. Persistence with any approach can be more important for results than choosing “the right approach”.

There is no definitive answer about whether to change an initiative. The only clear guidance is to pilot-test what can be tested before making it part of a wider strategy, ensure good data is collected about the degree of implementation and indicators of possible later results, and continually raise the question, “is this approach effective or should we try something else?”.

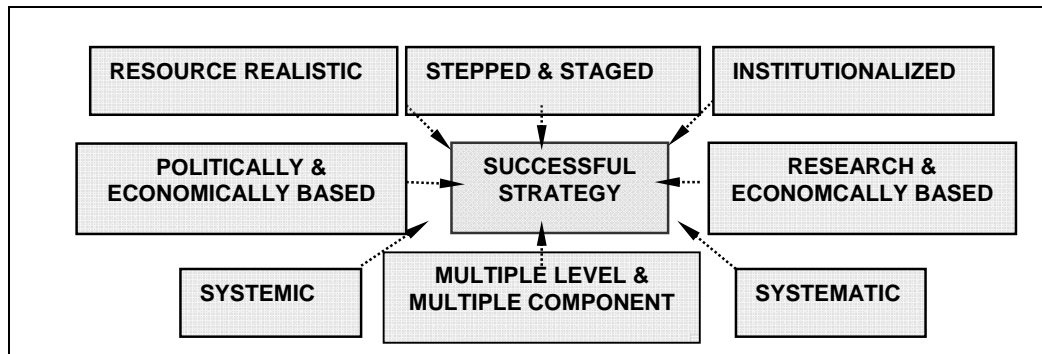
Strategies need timetabled review points and indicators of effectiveness and renewal otherwise they will lose direction and relevance.

Questions to ask when formulating and reviewing strategy:

- What is the information about the size and severity of these problems?
- How can we improve our information to help prioritize problems and measure our progress in solving them?
- How can we gain more information about strategies in situations similar to our own, and about their effectiveness?
- How can we ensure that evidence of the effectiveness of actions on quality is made part of our decision-making at different stages, rather than just reacting to problems or political demands?
- Which approach are we using now and would there be value to making more use of other approaches?

4.5 Successful strategy development

It is impossible to do everything at once, and it is better to do a few things well so as to build sound knowledge and capacity for future action. This means prioritizing problems and solutions. This chapter proposes combining a political and a technical approach by educating stakeholders to choose effective and implementable solutions. Prioritization is made easier by recognizing that some problems are more easily solved later when expertise and knowledge has been developed or more resources may be available.



The aim is to decide, at each stage of development, how to use resources in the best way to make the biggest improvements to quality and to build quality change capacity. The aim is not to make the perfect decision, but to avoid major mistakes in choosing a problem or a solution which uses time and money for few results, and discredits the strategy. Wrong choices are more likely if those developing the strategy do not look widely enough and do not gather information about the range of problems, solutions and approaches which might be appropriate for the country's level of resources and quality change capability. Following the quality cycle above, seeking out good information about problems, solutions and possible approaches helps to make better priorities for what the strategy should focus on. The right data to indicate progress needs to be collected and used in annual reviews.

Making strategy mistakes is more likely if too few stakeholders and expert advisers are involved or consulted. Too many, and the wrong ones, can also produce strategy mistakes: many will be representing different views and interests rather than neutrally seeking answers to the question, "what intervention would make the biggest difference for patients and match resources available at this phase of our development?"

Strategy success index: how high does your strategy score on these elements:

A successful strategy meets the following requirements:

Politically-based: the strategy development and implementation process engages key stakeholders and enlists them in the common aim with their different contributions (multiple stakeholders). The process presented and allowed research and evidence to be discussed and allowed conflicts to be minimized between what is politically feasible and what the research and evidence indicates. The cost and savings of the strategy are estimated and tracked and a defined budget allocated and its use reported.

Scoring: The strategy does not address this at all = 0. Does this well = 5.

Resource-realistic: how well has the strategy provided extra resources for developing expertise in quality, time for personnel to give to improving quality, and finance for investment in change. Score: No provision = 0. Could not be better in this respect = 5.

Staged and phased: the strategy phases in quality actions and initiatives according to the resources and knowledge at any one time, and to complement other reforms and priorities at that time.

Scoring: The strategy does not address this at all = 0. Does this well = 5.

Institutionalised: the strategy will survive individuals, because it is established as a national policy, a central policy of all organizations, and has a structure and process for implementation which has defined responsibilities including reporting and accountability. It also actively creates a quality and safety culture.

Scoring: The strategy does not address this at all = 0. Does this well = 5.

Systemic: the strategy takes into account the systemic nature of a service (outcomes for patients depend on how the parts relate – changing one part has many effects which are difficult to predict). It uses tests actions and pilot schemes on a small scale before changes are fixed and spread.

Scoring: The strategy does not address this at all = 0. Does this well = 5.

Multi-level and multiple component: the strategy describes actions at each level of the system and the actions to remove hindrances and give support which the level above takes to provide the facilitating context for the level below.

Scoring: The strategy does not address this at all = 0. Does this well = 5.

Systematic: The strategy ensures the use of proven quality tools and methods such as PDCA or RCA to ensure that the time given to quality work is effective.

Scoring: The strategy does not address this at all = 0. Does this well = 5.

Research- and evidence-informed: the strategy uses and requires at certain points research into effectiveness, data about local problems and measures for feedback about the effectiveness of change in the process of improvement.

Scoring: The strategy does not address this at all = 0. Does this well = 5.

The degree to which the strategy meets these requirements indicates the chances of the strategy to be successful and sustained. Strategies scoring less than 40% of the possible total are unlikely to be successful, and strategy success can be increased by working on areas with low scores to decide actions which could increase the score.

5. Conclusion

This document gives guidance for developing a research-informed but politically and economically feasible quality and safety strategy. It starts by showing why a strategy is needed and the need to agree a definition for and ways to measure quality. The test of a quality service and health system is whether it uses its resources most effectively to give those who most need health care what they need, safely and in a way that they find acceptable.

The aim of a quality strategy can be to develop system quality so that separate services work together to ensure continuity for patients and provide health promotion and prevention services. Beyond general principles, there are different views about the best way to improve quality, in part because of a lack of strong evidence about which approach is effective in different settings. However, recent knowledge does make it possible to provide guidance to those developing a quality strategy which is based on research and experiential evidence.

There is no “road map” for a strategy which all European countries can follow because their situation changes and because we do not know exactly which approaches work best in which situations. Developing a strategy starts with plans and continually re-plans after the experience of implementing changes. There are principles and requirements which increase the chances of the persistent, consistent and sustainable strategy which research suggests is required.

Strategy development takes a country through different stages in gaining experience and building capacity to implement programmes. Effective change and capacity development goes through a cycle of assessing, planning, acting, reviewing and reassessing.

Research and experience show that a strategy is more likely to be successful if it is:

- made by combining research evidence with negotiations with key stakeholders so that it is appropriate and acceptable for the local situation,
- implemented in stages which are suited to the resources available and to the knowledge and experience in the country about quality.

The choice of which actions to use in the strategy depends on the situation in the country. Different approaches are needed in competitive systems than those needed in a system where there is no competition for patients, which may in part be due to the lack of alternative services, and in part due to financing systems encouraging providers to treat more patients. Other considerations in formulating the strategy include the degree of patient and provider awareness of quality problems and methods, the level of development of the health system, and the local and national capability to implement different actions.

A quality and safety strategy strengthens a country's health system

The guidance also contributes to advancing the recent WHO health system strengthening strategy (WHO's framework for action 2007). The guidance is also based on research which shows that healthcare quality and safety methods strengthen the health-enhancing aspects of health care and health systems in general. Safety methods reduce the chances that health care will endanger health. Quality methods improve the outcomes of health care services which are valued by individuals and populations. Quality and safety strategies strengthen health systems by

increasing the contribution of the health service and health system to the health of individuals and populations (WB report 2008).

The five national strategies described target different stakeholders and correspond to the six building blocks for health system strengthening proposed by WHO:

1. Good health services are those which deliver effective, safe, good quality personal and non-personal health interventions to those that need them, when needed, with minimum waste of resources. This can be achieved by improving the three dimensions of quality described, and using the suggested quality methods.
2. A well-functioning health information system is one that ensures the production, analysis, dissemination and use of reliable and timely information on health determinants, health system and status. Collecting and using data is an essential part of modern quality improvement – to prioritize what to work on and to assess if changes have made an improvement. This aspect is described for each of the five proposed national concurring strategies. The quality and safety of a country's health system will be clearer as a result of both WHO and OECD work on including these aspects in new data collection systems.
3. A well functioning health system ensures equitable access to essential medical products and technologies of assured quality, safety, efficacy and cost-effectiveness, and their scientifically sound and cost-effective use. The national quality and safety strategies for medical products and technologies described aim to ensure quality and safety requirements before using a product and to evaluate the use of medical technologies, especially when linked to the use of practice guidelines as described in the national quality and safety strategy targeting health care staff.
4. A well performing health workforce is one which works in ways that are responsive, fair and efficient to achieve the best health outcomes possible, given available resources and circumstances, i.e. there is sufficient staff fairly distributed; they are competent, responsive and productive. The national strategies aimed at professionals underline how human resource management can ensure the right number and mix of professionals.
5. A good health financing system raises adequate funds for health in ways that ensure that people can make use of the services they need and are protected from financial catastrophe or impoverishment associated with having to pay for them. It provides incentives for providers and users to be efficient. Quality is defined to prioritize those most in need and shows that many obstacles to access are avoidable. The national quality and safety strategy targeting financiers addresses this building block and focuses on how to provide more efficient care and ensure the right incentives.
6. *Leadership and governance involves ensuring that strategic policy frameworks exist and are combined with effective oversight, coalition-building, regulation, attention to system design, and accountability.* The national quality and safety strategies presented are a more concrete operationalization of this building block and also describe in more detail how governance and leadership can be addressed specifically in relation to national quality and safety strategies.

Through four functions, governments can enact the five strategies: legislation and regulation, monitoring and measurement, assuring the improvement of individual health care services and assuring improvement of the health system as a whole. Each of these functions are relevant for all five strategies and in many aspects government is the only stakeholder in a health care system who can enforce them. How governments of European Member States enact these various

functions as part of the five strategies differs from country to country. It is only recently that health system performance is supported by performance reports including indicators on quality and safety. A recent OECD report showed a varied relative performance of countries with respect to quality on various domains such as vaccination, acute care, cancer care and chronic care (OECD Health at a Glance 2007). Likewise the systematic sharing of experiences in national quality and safety strategies between countries should be placed high on the agenda. This could help to channel the limited energy available for quality and safety improvement efforts in the most optimal direction. National strategies addressing professionals, health care organizations, medical products and technologies, patients and financiers should thus be positioned at centre stage in strengthening quality and safety of health care systems.

6. Appendices

6.1 Appendix 1: Glossary of health service and system quality definitions

A comparison of quality aspects covered by different definitions

Donabedian 1988	Maxwell 1992	NHS 1997	Council of Europe 1998	NLHI of JCAHO 1999	IOM 2001	WHO 2006
Effectiveness	Effectiveness	Effectiveness	Effectiveness	Effectiveness	Effectiveness	Effectiveness
Efficiency	Efficiency	Efficiency	Efficiency	Efficiency	Efficiency	Efficiency
Access	Access	Fair Access	Access	Access	-	Access
Safety	Respect	-	Safety	Safety	Respect/Safety	Safety
Appropriateness	Appropriateness	-	Appropriateness	Appropriateness	-	-
Equity	Equity	-	-	-	Equity	Equity
-	-	Timeliness	-	Timeliness	Timeliness	-
-	Acceptability	-	Acceptability	-	-	Acceptability
-	Choice/ Availability of information	Patient care experience	Patient satisfaction	-	Responsive ness/ patient centeredness	Patient centeredness
Health improvement	Technical competence	Health improvement	Efficacy	-	-	-
-	-	-	-	Availability	Continuity	-
-	Relevance	-	Assessment	Prevention/ early detection	-	-

Basic concepts of quality (WHO 2006)

Effective: delivering health care that is adherent to an evidence base and results in improved health outcomes for individuals and communities, based on need;

Efficient: delivering health care in a manner which maximizes resource use and avoids waste;

Accessible: delivering health care that is timely, geographically reasonable, and provided in a setting where skills and resources are appropriate to medical need;

Acceptable/patient-centred: delivering health care which takes into account the preferences and aspirations of individual service users and the cultures of their communities;

Equitable: delivering health care which does not vary in quality because of personal characteristics such as gender, race, ethnicity, geographical location, or socioeconomic status;

Safe: delivering health care which minimizes risks and harm to service users.

6.2 Appendix 2: Quality Strategy Assessment Tool

This tool helps national leaders to develop a quality strategy for the country. It asks questions about subjects which research and experience has shown to be important to consider in developing a successful quality strategy, and which are discussed in the main text of this guidance document. It can be used to:

- Increase the awareness of whoever completes the questionnaire about the current starting point and context for quality improvement and about the institutions and processes which need to be developed.
- Gather information, by asking different parties to complete and return the questionnaire and analysing the responses to form a picture of the current situation with respect to factors important for quality and ideas about how to move forward.

The tool is useful when used as preparation for meetings to discuss strategy development so as to help ensure a sufficiently wide range of relevant issues and approaches are discussed. Different participants have different answers to each question. Comparing answers helps to clarify differences in understanding of terms and also to identify the evidence each is using to form their views and which information is missing and needed. The tool can be used in this way for internal ministry meetings and for larger stakeholder group meetings to prepare participants for the meeting. In the meeting it can be used to enable sharing of different views and evidence. It can be also used by a visiting external group to frame their data gathering and assessment to the ministry or others.

Part 1: General features of the country health system relevant to choosing a strategy approach

- Type of system
 - What percentage of primary and hospital healthcare is public or private in a) financing, b) provision.
 - Is there high or low competition for patients and in which sectors?
 - Are there alternative primary or hospital services for most patients in a) rural, b) urban areas?
 - Do providers lose money if they attract and treat fewer patients?
- Funding
 - For the next five years, how much extra or fewer resources will be available to the health system?
 - Where could funds to invest in quality improvement come from? (new or reallocated finance)
- Level of development of management and systems
 - What is the general level of management skills and management systems?
 - Is there a culture of supervision and accountability or of high independence for professionals?

- Quality awareness, attitudes and culture
 - How much are the public aware of and concerned about the safety and quality of services?
 - How much time do providers spend, or would spend working on quality improvement?
 - What is the degree of knowledge and concern about safety and quality among top national leaders who influence what happens in the health system?
 - Are there many different terms used in discussion about quality impeding on the consistency of communication?
 - Are any future action to improve quality looked at with scepticism, and if so which and why?
- Current changes
 - What are the key changes which providers need to spend time on and adjust to over the next five years?
 - How could quality improvement contribute to current reforms and other changes?
- Research capacity and use
 - Is there capability for quality and safety research and support to policy-makers and providers in their quality improvement?
 - How much is research and evidence valued and used in decision making in health care?
 - Are there other countries with similar health systems which we could learn from which are further along the “quality journey”, or with whom we could form a partnership to share experience and resources?
- Process for developing the strategy
 - Are the key stakeholders that will be affected by and are needed to contribute to the strategy sufficiently involved?
 - Do the stakeholders know enough about the problems and different solutions and approaches which could be used in the strategy?
 - Is there a plan for steps, times and responsibilities for formulating, implementing and reviewing the strategy?

Part 2: Checklist for the five national strategies on quality and safety

Please provide for each question below a yes or no answer. If yes, please expand on the nature and scope of the arrangements in place in your country

1. National quality and safety strategies aimed at health care professionals
 - Do you have legislation and regulation for different professions (physicians, nurses, para-medical professions) practising in health care in your country and their required training?

- Do you have legislation and regulation in place on the revalidation of professionals practising in health care in your country to assure that they have the necessary up-to-date competences?
 - Do you have legislation and regulation in place in your country to assure professional norms and standards?
 - Do you have legislation and regulation in place in your country to signal and deal with misconduct amongst professionals?
 - Does your country have registries in place that monitor the number of trained and practising professionals?
 - Does your country have mechanisms in place to monitor the performance of professionals?
 - Does your country have programmes in place for peer-review and Continuous Medical Education (CME)?
 - Does your country have programmes for the development of (national) practice guidelines?
 - Does your country have policies in place to ensure working conditions that facilitate professional learning for professionals?
 - Does your country have national policies for medical workforce planning in health care (Health Manpower Planning and Management) in place?
 - Does your country have policies in place through which the necessary competences for the various professions are described systematically?
 - Does your country have policies in place on task substitution between professions and on the introduction of new professions?
2. National quality and safety strategies aimed at health care organizations
- Do you have legislation and regulation on the various types of health care organizations (licensing)?
 - Do you have legislation and regulation on specific services that pose a risk to patients (i.e. radiology, nuclear medicine, laboratory, human tissues, disposal of hospital waste, fire-regulations etc) and could you provide a list of the various domains covered?
 - Does your country use performance indicators on the quality of hospital care?
 - Does your country have a policy to improve the quality of health care data in general and the medical record in particular?
 - Does your country use accreditation/certification programmes and to which type of services do they apply?
 - Does your country have national support programmes for quality improvement and safety in health services?
 - Does your country use accreditation/certification programmes for integrated delivery systems (i.e. focussing on the cooperation between various types of services and continuity of care)?

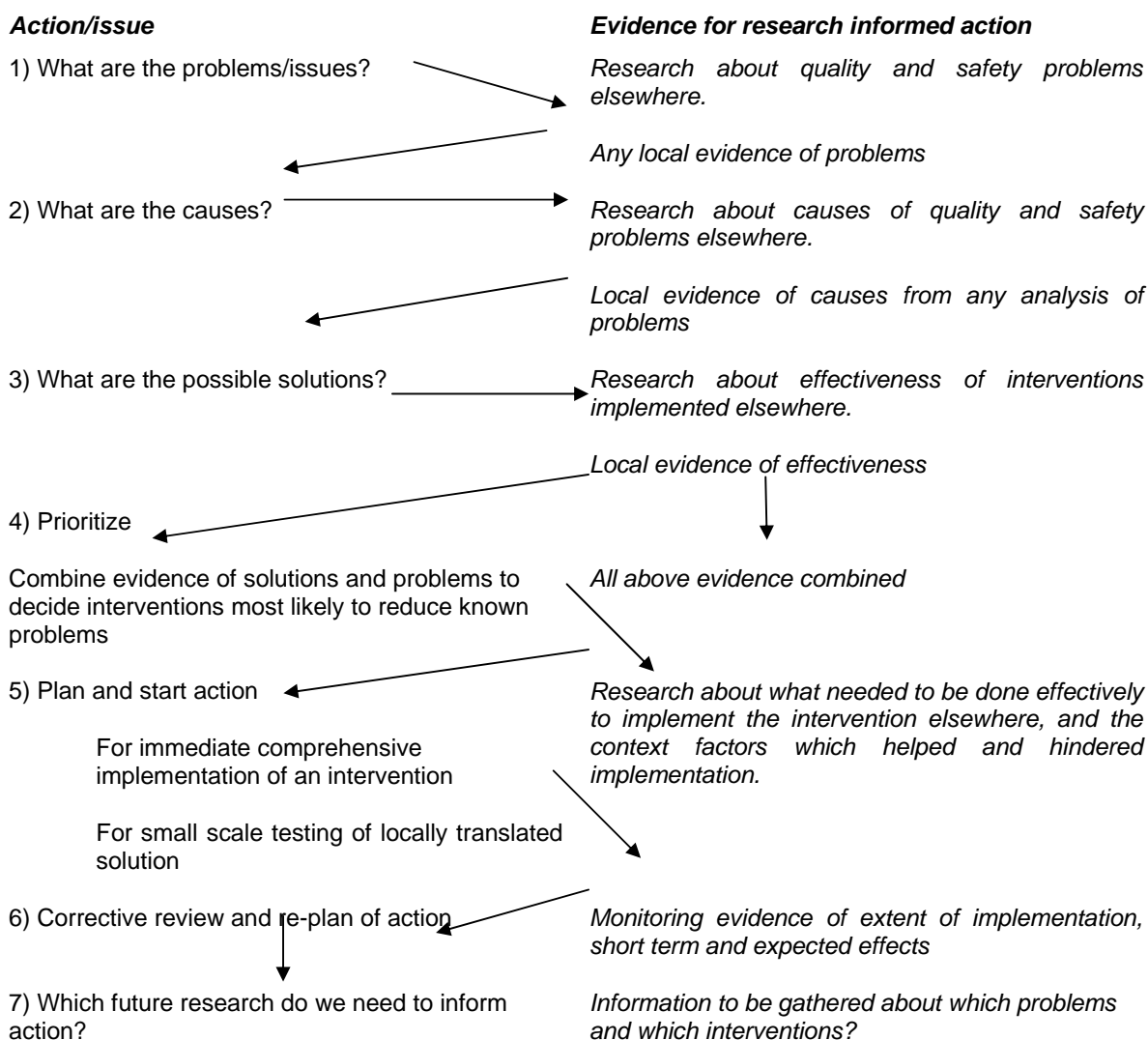
- Does your country have policies that promote the introduction of innovative organizational formats through which services are delivered?
3. National quality and safety strategies aimed at medical products and technologies
- Does your country have legislation and regulation on the entrance to the health care market of new medical products and technologies?
 - Does your country have legislation, monitoring and regulation in place to signal and act towards unsafe situations with respect to medical products and technologies?
 - Does your country have specific technology assessment programmes in place that are used for decision making on the appropriateness of medical products and technologies, including reimbursement through collective financing arrangements?
 - Does your country have a national policy in place to promote innovation towards medical products and technologies that address the national needs?
4. National quality and safety strategies aimed at patients
- Does your country have legislation and regulation on patient rights?
 - Does your country have legislation and regulation on the participation of patients/consumers/ community in the design and evaluation of health services?
 - Does your country have mechanisms in place to systematically monitor patient experiences?
 - Does your country have measurement mechanisms in place to publish public performance information that can be used by patients to judge and select providers?
 - Does your country have national programmes in place for health promotion?
5. National quality and safety strategies aimed at financiers
- Does your country have legislation and regulation in place that stipulate financiers (purchasers) of health care to value quality and safety?
 - Does your country have measurement mechanisms in place that allow financiers to assess the performance of health care providers and to include quality and safety notions in their purchasing role?
 - Does your country have specific (financial) incentives in its health care system aiming at quality and safety?
 - Does your country produce regularly a national report on the performance of the health care system as a whole with respect to quality and safety?

Please note that all questions posed above are rather generic. This is done deliberately to limit the number of questions to the major elements of national quality and safety strategies. This way the person using the “check-list” will keep the overview of the main elements of national strategies without getting lost in details. On each of the topics raised above (like accreditation, guidelines, workforce planning, patient rights, etc) more detailed assessments are possible and often more specific WHO guidance is available.

6.3 Appendix 3: Using quality and safety research in decision making – a framework

Improving quality and safety is first and foremost an economic and political programme, both at the national and local level. However, research can be used to decide and carry actions so that they are more effective than if they were made only pragmatically and on political or economic grounds.

The following framework shows the role of research to inform action, and applies for decision making at the national and local levels (e.g. hospital or unit level). Three types of “evidence” are considered: evidence about problem size and severity (e.g. adverse drug events); evidence or reliable reported experience about the effectiveness of intervention-actions to reduce the problem (e.g. changing confusing labelling); and evidence or reliable reported experience about how to implement the intervention-actions (e.g. how to reach agreements with drug makers through national standing committees and other actions).



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The world health report 2000. Murray et al. (report introduces the concept of quality alongside responsiveness to assess and rank overall health systems performance)

A background for national quality policies in health systems. Charles Shaw and Isuf Kalo WHO Regional Office for Europe 2002 (a general introduction and overview of existing national quality policies and a self assessment questionnaire focusing on underlying values of policies, support structures, statutory mechanisms, external quality assessment and improvement programmes and resources)

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