

Principles for Developing Clinical Quality Standards in Low and Middle Income Countries

A Guide

Version 2



June 2015

ABOUT THIS DOCUMENT

This guide defines the principles for developing evidence-informed, clinical quality indicators known as quality standards and describes the processes and methods involved. It is designed to help low and middle income countries (LMICs) that are moving to universal health coverage (UHC) develop robust and measurable criteria, derived from evidence-informed guidance, to improve the quality of patient care.

This document has been adapted from the National Institute for Care and Excellence (NICE) Quality Standards Process Guide (NICE 2014b), which details how quality standards are developed for the National Health Service in the UK. The document also draws on examples from our experiences of adapting this NICE model to develop quality standards for improving maternal care in Kerala, India (Government of Kerala et al. 2013) and for stroke care in Vietnam (Ministry of Health et al. 2013), in partnership with respective policymakers and stakeholders such as clinicians. We recognise that countries have different health systems with different needs, with different political and socio-cultural factors underlying policy and clinical decisions; and decision-makers will need to contextualise the process of quality standards development to their local setting. However we hope this guide provides a useful roadmap for policy makers and others who are responsible for establishing quality improvement programmes and who drive quality initiatives in their locality.

The methods for developing Quality Standards are evolving, so this guide is work in progress. It will be reviewed regularly as our experience of developing Quality Standards in LMICs evolves. We welcome constructive comments, suggestions or examples from users which will help improve the content of this document.

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ABBREVIATIONS

BIA	Budget impact analysis
CoI	Conflict of interest
CEA	Cost-effectiveness analysis
CT	Computerised tomography
HBP	Health benefits plan
HTA	Health technology assessment
KFOG	Kerala Federation of Obstetricians and Gynaecologists
MoH	Ministry of Health
MSA	Medical Services Administration (Ministry of Health, Vietnam)
NRHM	National Rural Health Mission
NI	NICE International
NICE	National Institute for Health and Care Excellence
OECD	Organisation for Economic Co-operation and Development
RSBY	Rashtriya Swasthya Bima Yojna
QS	Quality standard
TIA	Transient ischaemic attack
UHC	Universal health coverage
VND	Vietnamese Dong
WHO	World Health Organisation

1 Introduction

1.1 What are quality standards?

Measuring and monitoring quality of care is increasingly recognised by healthcare payers and providers throughout the world as means of improving health services and outcomes (Campbell et al. 2015). Quality has been considered an overarching consideration of Universal Health Coverage (UHC) (Kieny 2015). Countries moving towards Universal Health Coverage (UHC) are especially concerned as they seek to provide services that are affordable and equitable while increasing the quality of care patients receive (Mate et al. 2013), and to manage common challenges such as overcrowding and overuse of inappropriate treatments. Whilst there have been many initiatives worldwide around health financing and health systems reforms, questions of how to measure and improve quality, what to measure, and what all this means in clinical practice, are under-researched and under-addressed by the global development community. Likewise, the financial aspect of quality improvement initiatives is also little discussed, with health technology assessment (HTA) and health benefits plans (HBPs) not always explicitly addressing quality.

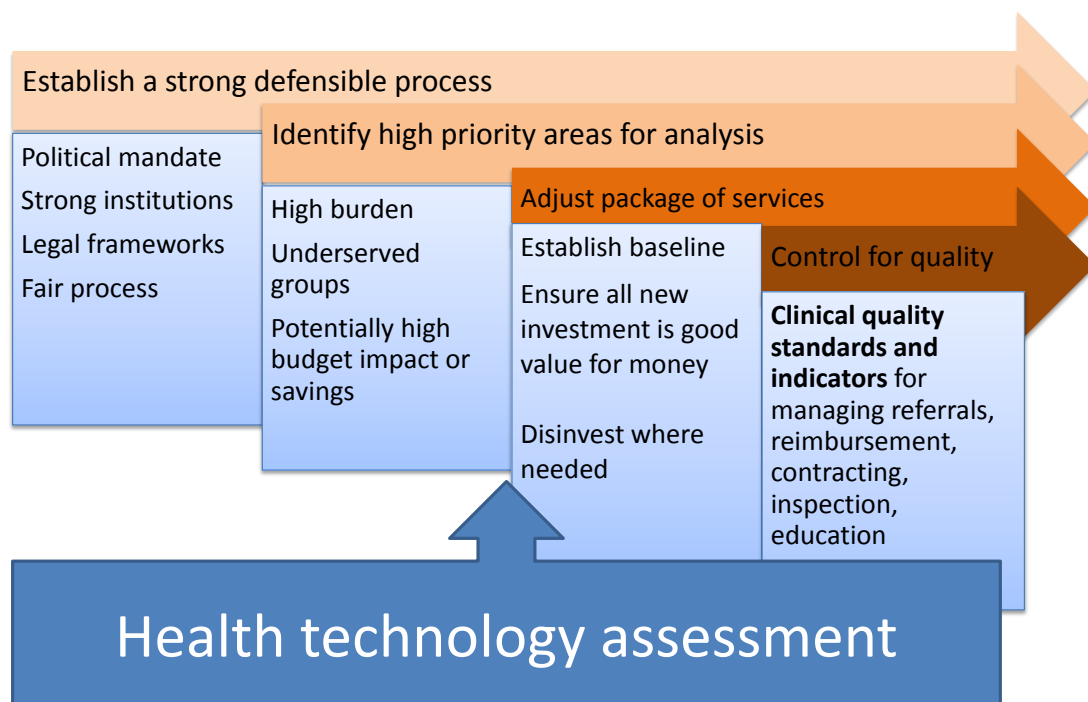
Quality standards are an important aspect of priority-setting in health, as an approach to support the delivery of the best possible health outcomes within a given budget. They are concise sets of prioritised statements designed to drive measurable quality improvements within a particular area of health or care (NICE 2015b). They:

- are derived from high quality evidence, accompanied by measurable indicators, and are developed in consultation with relevant parties
- provide explicit benchmarks for assessing actual care performance and improving practice
- inform payment mechanisms and incentives, in the context of health insurance, health benefits packages, and pay-for-performance frameworks
- interface closely with other quality improvement initiatives, including clinical audit.

1.2 Quality standards in the context of priority-setting, health technology assessment, and health benefits plans

Quality standards can be considered as important components of HTA. HTA seeks to compare the clinical, economic, and socio-ethical issues around different health interventions, through a systematic, deliberative and participatory process¹, in order to help decision makers make informed decisions on what interventions to offer in what context. Quality standards follow these procedural principles of HTA; they are also a tool for translating recommendations for cost-effective interventions into implementable and measurable clinical and organisational activities (Campbell et al. 2015).

Figure 1. Quality standards are an important tool for quality improvement within the framework of HTA. Adapted from Sadanandan, R.: *Health Technology Assessment : an evidence-informed approach to designing, adjusting and applying Benefits Packages*, presentation at Better Decisions for Better Health Workshop, New Delhi, Oct 2014.



HBP are increasingly being considered and implemented by LMICs as an explicit means of priority-setting in health (Glassman et al. 2015). An HBP is a description of “services, activities and goods reimbursed or directly provided by publicly funded statutory/mandatory insurance schemes or by national health services” (Velasco Garrido et al. 2006). At core, benefits plans describe not only “what” is to be provided but also “to whom” and “in what circumstances” (Rumbold et al. 2012), and should be underpinned by robust processes and methods to enable efficient use

¹ Adapted from EUNetHTA definition: <http://www.eunetha.eu/about-us/faq#t287n73>

of the limited resources available and encourage an appropriate level of health care quality. Thus quality standards, alongside HTA and clinical guidelines, are important tools for supporting both the efficiency and quality of services and technologies available in a benefits plan.

Topic selection for and development of quality standards, like HTA and HBPs, should not be a one-off activity (Glassman et al. 2015). Rather, they should be part of a process that is documented (for example, in a process and methods guide), followed, sustained, reviewed and improved upon. Quality standard topics should be expanded over time to address the ongoing needs and priorities of the health system, and quality standards themselves should also be subject to a process of regular review as new clinical and economic evidence emerges over time.

1.3 Why quality standards?

Quality standards provide health policymakers, health insurers, service providers, healthcare professionals and patients with definitions of what high quality healthcare looks like in practice; and related performance measures that are reliable and meaningful to the local setting in which they are used.

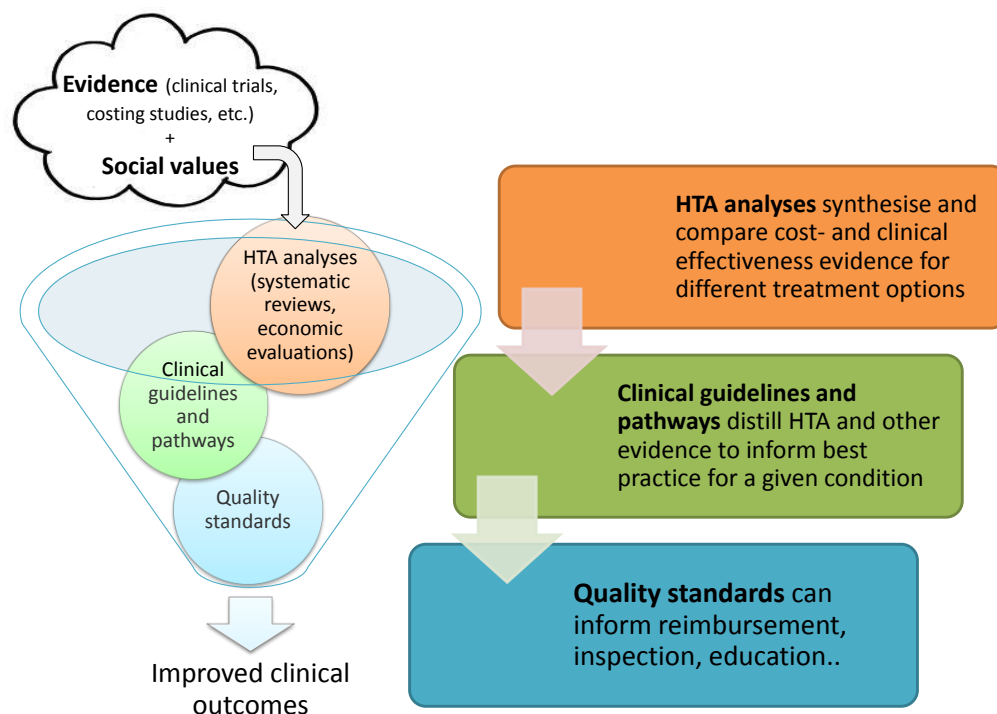
- **Payers** (governments, health insurers, and often patients themselves) may use quality standards to ensure that high quality patient care is delivered, and measurable indicators for setting reimbursement benchmarks and targets.
- **Regulatory bodies** can monitor the quality of care as described in quality standards through national audit or inspection. Quality standards could be included in provider accreditation schemes, to cover the clinical dimensions of quality (in addition to the structural, staffing and safety components of accreditation schemes).
- **Provider organisations** (such as hospitals, primary care centres) can use quality standards to provide high quality patient care and to monitor quality improvements, to show through quality accounting reports that high-quality care is being provided, and highlight areas for improvement, or to show successful performance
- **Healthcare professionals** (doctors, nurses, pharmacists, allied health professionals) can use Quality Standards to audit their practice. Quality standards can also be incorporated into the educational curricula and professional development frameworks for healthcare professionals, including validation criteria.
- **Patients** and the public can use quality standards as a source of information about the quality of care they and their families can expect to receive from their healthcare provider.

Since quality standards are developed locally², they apply only to the context for which they were intended. Potential users will need to decide on their own local needs and priorities, and consider establishing their own local service agreements or policies.

1.4 Definitions

There are many terms to define documents or related initiatives in the field of evidence-informed quality improvement. Often these terms are used interchangeably and may be confusing. Figure 4 illustrates the relationship between evidence, HTA analyses, clinical guidelines, pathways and quality standards; and we clarify some of these terms below.

Figure 2. From evidence to quality standards.



Quality standards: Concise statements with related indicators designed to drive and measure priority quality improvements within a particular area of care. The term 'quality standards' can also be a collective noun, referring to a set of individual standards (each with its own statement and measures) for a specific disease or condition, usually in a standalone document. For clarity, we shall refer to such a standalone set of quality standards as 'QS', as in 'the QS for Stroke'.

² "Locally" may include: a country, region (state or province), groups of institutions (for example networks of primary care centres), or individual establishments (for example hospitals)

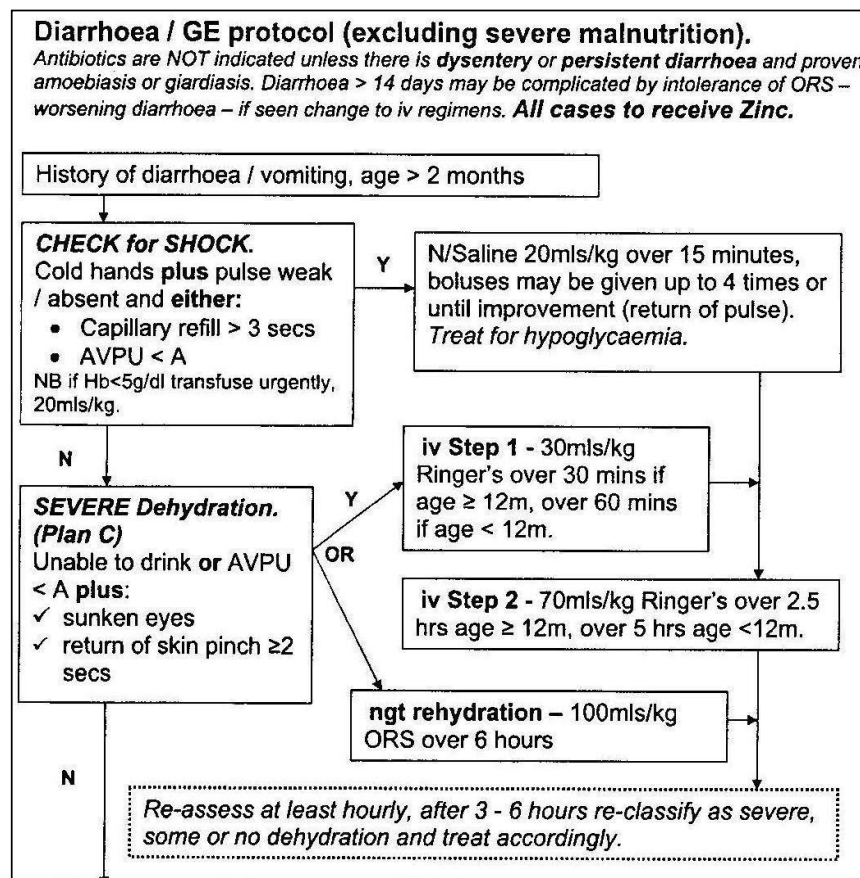
Clinical guidelines: Also known as ‘guidelines’, ‘clinical practice guidelines’, ‘evidence-based guidelines’ or ‘standard treatment guidelines’ (STGs), these are standalone documents containing “a set of recommendations on the appropriate treatment and care of people with specific diseases and conditions, based on the best available evidence.” (NICE 2014a) Guidelines help healthcare professionals in their work, but they do not replace their knowledge and skills. Clinical guidelines provide generic recommendations in the form of statements. For example (NICE 2011):

NICE recommendation: “When considering a diagnosis of hypertension, measure blood pressure in both arms.

- If the difference in readings between arms is more than 20 mmHg, repeat the measurements
- If the difference in readings between arms remains more than 20 mmHg on the second measurement, measure subsequent blood pressures in the arm with the higher reading”

Protocols: Also known as *medical protocols* or *algorithms*, these define the practical steps that healthcare providers should be taking when treating patients, within a specific or local clinical setting (for example, within a specific hospital). Protocols usually build on clinical guidelines recommendations and tend to be more restrictive or prescriptive. They are often presented visually as algorithms (flowcharts), such as that in Figure 3.

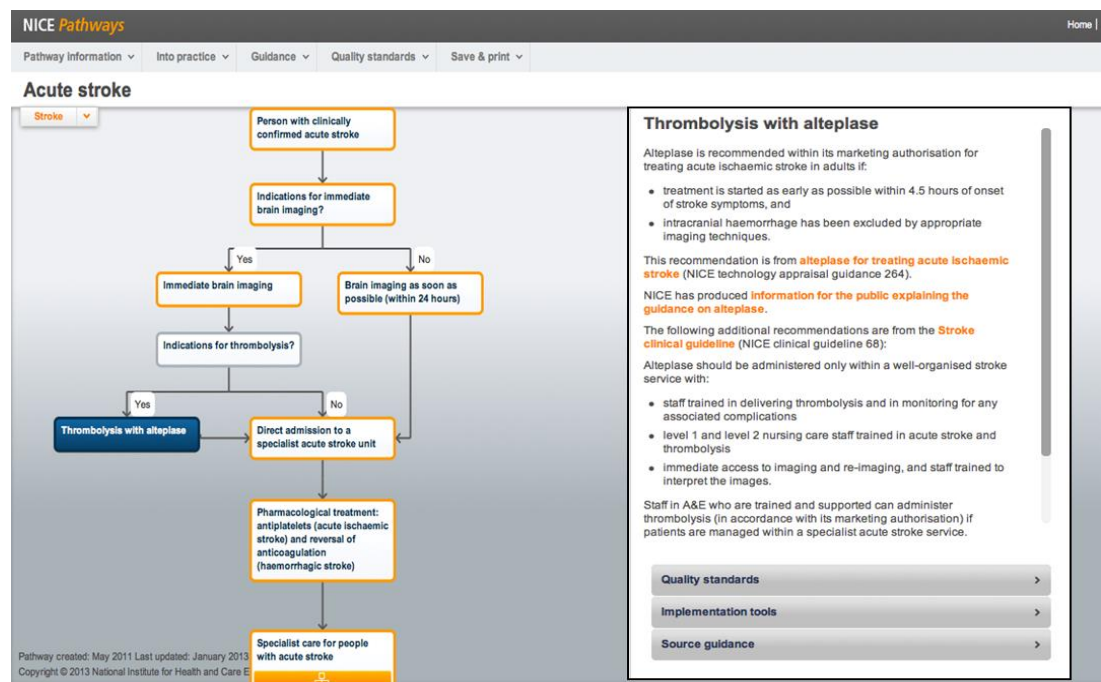
Figure 3. Basic Paediatric Protocols for diarrhoea and gastroenteritis, Kenya (Ministry of Health (Government of Kenya) 2010)



Clinical pathways: usually refers to the sequence of practices, procedures and treatments that should be used with people with a particular condition to improve their quality of care. Synonymous terms are often used, such as: *integrated care pathways, critical pathways, care plans, care pathways, care maps, collaborative care pathways*. They support the translation of clinical guidelines or protocols into clinical practice (detailing the local structure, systems and time-frames) (OpenClinical 2013); and like protocols, are typically prescriptive. For example, the clinical pathways developed by RSBY, India's government-funded health insurance scheme for the Below Poverty Line population, define each step empanelled hospital providers must follow and evidence in order to be reimbursed for providing a particular surgical procedure (NICE International 2014a).

Note that 'Pathways' produced by NICE in the UK are neither clinical pathways in the strictest sense, nor a standalone piece of guidance or a quality improvement tool. Rather, NICE Pathways are interactive tools that collate and represent related pieces of NICE guidance within and across clinical topics, in an accessible and visual format (for example, Figure 4).

Figure 4. NICE Pathways for Acute Stroke (NICE 2010).



2 What makes quality standards?

2.1 Key principles

Quality standards are based on several core principles, in that they:

1. describe an **aspirational but achievable level of best practice**, in terms of patient safety, clinical effectiveness, and patient experience, across a clinical condition or care pathway
2. are derived from **clinical recommendations based on best available, relevant evidence**, for example clinical guidelines such as NICE guidelines, WHO guidelines, guidelines adapted from high quality international guidelines, or other sources such as local guidelines accredited through trustworthy processes (for example the NICE accreditation process; see also 4.5.1) (NICE 2015a), including cost-effectiveness evidence where available;
3. aim to **maximise impact** in terms of efficiency, effectiveness and ethical considerations, prioritising quality improvement in areas where existing clinical practice is likely to be poor, highly variable, or disadvantages particular populations (see 2.1.1);
4. are produced through a **deliberative, transparent and participatory process** with all the interested parties, for example government, clinicians and professional organisations, health insurers, and service users (patients and carers) and other members of civil society;
5. are **reviewed regularly** as clinical guidelines are updated in light of new clinical and economic evidence.

Note that quality standards *do not* typically describe minimum standards; nor do they review or re-assess the underlying evidence base, as this should already have been considered within the source guidelines.

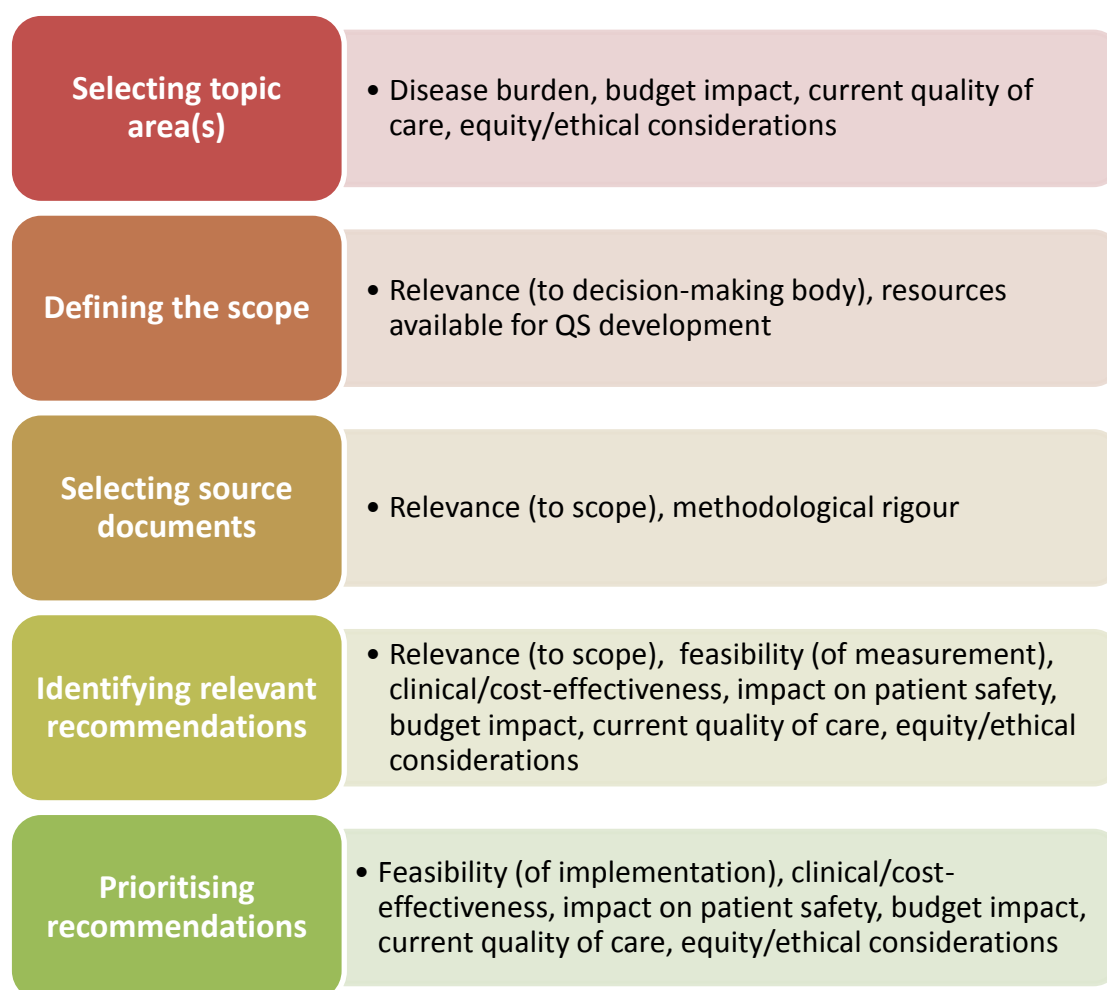
2.1.1 Prioritising quality standards for maximum impact

Throughout the various steps of QS development, prioritisation will be important in order to maximise the impact of the end product (**Error! Reference source not found.**). This may mean focusing on particular areas with evidence of or consensus on:

- high burden of disease

- high budget impact and associated problems of cost containment/cost escalation for payers; or high out-of-pocket payments and associated impoverishment for patients
- current poor quality, ineffective or highly variable care, particularly with regards to patient safety, clinical effectiveness, and patient experience
- significant regional variations in clinical practice, access to services, or health outcomes (especially in aspects of care that are not widely provided or not considered to be standard practice, but that are feasible)
- other social and ethical value considerations, for example favouring particular disadvantaged or marginalised population groups
- likelihood that changes to practice will be implementable and that quality improvement will be achievable.

Figure 5. Multiple stages through QS development and associated prioritisation criteria, following the principles of efficiency, effectiveness, and equity



2.2 Components of a quality standard

There are two main components to a quality standard: the **quality statement** and the **quality measure**. Other related sections provide more specific information to help users understand how the quality standard is constructed and what it means for different groups or audiences. A quality standard typically comprises the following:

- Quality statement(s)
- Rationale
- Quality measures
- What the quality statement means for each audience
- Source guidance
- Data sources
- Social and equality considerations
- Budget impact analysis.

2.3 Quality statements

Quality statements are sentences that describe high-priority areas for quality improvement, in a clear and concise way. In some circumstances, statements may describe basic requirements of care where there is significant concern that such care is not provided in all services.

Each QS usually contains 6–8 quality statements (up to 15, to ensure they can be implemented) with related measures. Each statement should usually specify one requirement for high-quality care, to make it easier for users to interpret, implement and measure the quality standard. However, in some circumstances it may be necessary to include more than one requirement within one quality statement, when they are closely linked (for example, if treatment options are dependent on the results of prior diagnostic testing or assessment; or where the quality statement describes a package of services with multiple core components), and individual statements describing these separately may lack clarity. Table 1 gives examples of how guideline recommendations from NICE, UK Royal College of Physicians (Royal College of Physicians 2012), and WHO (World Health Organisation 2012) have been translated respectively into quality statements in the UK, Vietnam (Ministry of Health et al. 2014), and Kerala, India (Government of Kerala et al. 2013).

Table 1. Clinical guideline recommendations and associated quality statements

Guideline recommendation(s)	Quality statement
Stroke: Diagnosis and initial management of acute stroke and transient ischaemic attack (TIA) Brain imaging should be performed immediately⁽¹⁾ for people with acute stroke if any of the following apply: • indications for thrombolysis or early anticoagulation treatment on anticoagulant treatment • a known bleeding tendency • a depressed level of consciousness (Glasgow Coma Score below 13) • unexplained progressive or fluctuating symptoms • papilloedema, neck stiffness or fever • severe headache at onset of stroke symptoms ⁽¹⁾ <i>The Guideline Development Group felt that 'immediately' is defined as 'ideally the next slot and definitely within 1 hour, whichever is sooner', in line with the National Stroke Strategy.</i>	QS for Stroke, NICE Patients with acute stroke receive brain imaging within 1 hour of arrival at the hospital if they meet any of the indications for immediate imaging
Acute management of stroke • Patients who need ongoing inpatient rehabilitation after completion of their acute diagnosis and treatment should be treated in a specialist stroke rehabilitation unit, which should fulfil the following criteria: • it should be a geographically identified unit • it should have a coordinated multidisciplinary team that meets at least once a week for the interchange of information about individual patients • the staff should have specialist expertise in stroke and rehabilitation • educational programmes and information are provided for staff, patients and carers • it has agreed management protocols for common problems, based on available evidence. Source: (Royal College of Physicians 2012)	QS for Stroke, Vietnam Patients with suspected stroke are assessed and managed in a specialist stroke unit that meets at least Bronze* criteria, by a doctor with specialist expertise in stroke and other appropriately trained staff within 24 hours of admission to hospital, and by all relevant members of the multidisciplinary rehabilitation team within 72 hours, with documented multidisciplinary goals agreed within 5 days. *'Bronze' and other criteria for stroke units are specified in an accompanying definitions section.
Active management of third stage of labour • The use of uterotonics for the prevention of PPH during the third stage of labour is recommended for all births • Oxytocin (10 IU, IV/IM) is the recommended uterotonic drug	QS for Post-Partum Haemorrhage, Kerala Women who have given birth either vaginally or by caesarean

for the prevention of PPH • In settings where oxytocin is unavailable, the use of other injectable uterotonics (if appropriate ergometrine / methylergometrine or the fixed drug combination of oxytocin and ergometrine) or oral misoprostol (600 µg) is recommended. Source: (World Health Organisation 2012)	are offered a bolus dose of Oxytocin, Ergometrine or Prostaglandin F2 Alfa at the time of delivery of the shoulder or within 1 minute of the delivery of foetus to prevent post-partum haemorrhage and to assist delivery of the placenta.
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Quality statements are usually accompanied by a ‘rationale’ section, in the form of a paragraph explaining the basis for making the statement, for example the following from the NICE Quality Standard on Heavy Menstrual Bleeding (NICE 2013):

Quality statement

Women with heavy menstrual bleeding and a normal uterus or small uterine fibroids who choose surgical intervention have a documented discussion about endometrial ablation as a preferred treatment to hysterectomy

Rationale

Some women with heavy menstrual bleeding and a normal uterus or small uterine fibroids may choose surgery if they do not wish to have drug treatment or if drug treatment is contraindicated or fails to adequately control their symptoms. Endometrial ablation is a less invasive surgical procedure than hysterectomy, is associated with fewer complications and can be performed as day surgery. It is important that all women have the opportunity to discuss the risks and benefits of both endometrial ablation and hysterectomy to enable them to make an informed decision about which intervention is most appropriate for them. Evidence suggests that women who live in poorer areas are more likely to undergo hysterectomy rather than endometrial ablation compared with women who live in more affluent areas.

2.4 Quality measures

Quality measures are quantitative measures of care quality or service provision specified in the quality statement, and comprise three components: **structure**, **process** and **outcome measures** (see 0 for more details). They accompany each quality statement and are drafted after the wording of the quality statement has been agreed.

Quality standards can drive improvement by setting the expected degree of achievement in the measures of care processes that are considered to be linked to health outcomes. In practice, it is usually easier to use process measures, as proxies of health outcomes; relevant health outcomes may be difficult to measure reliably at the local level, especially for long-term or rare outcomes.

All quality measures are specified in the form of a numerator and a denominator which define a proportion (numerator/denominator). The numerator is assumed to be a subset of the denominator population. Below is an example of an outcome quality measure for Active Management of Third Stage of Labour (AMTSL) (Government of Kerala et al. 2013):

The proportion of women who experience an estimated blood loss equal to or more than 500 ml during and/or following a vaginal delivery

Numerator – the number of women giving birth vaginally receiving AMTSL who experience an estimated blood loss equal to or more than 500 ml during and/or following a vaginal delivery in the hospital

Denominator – all women giving birth vaginally, who receive AMTSL in the hospital

2.5 Budget impact analysis

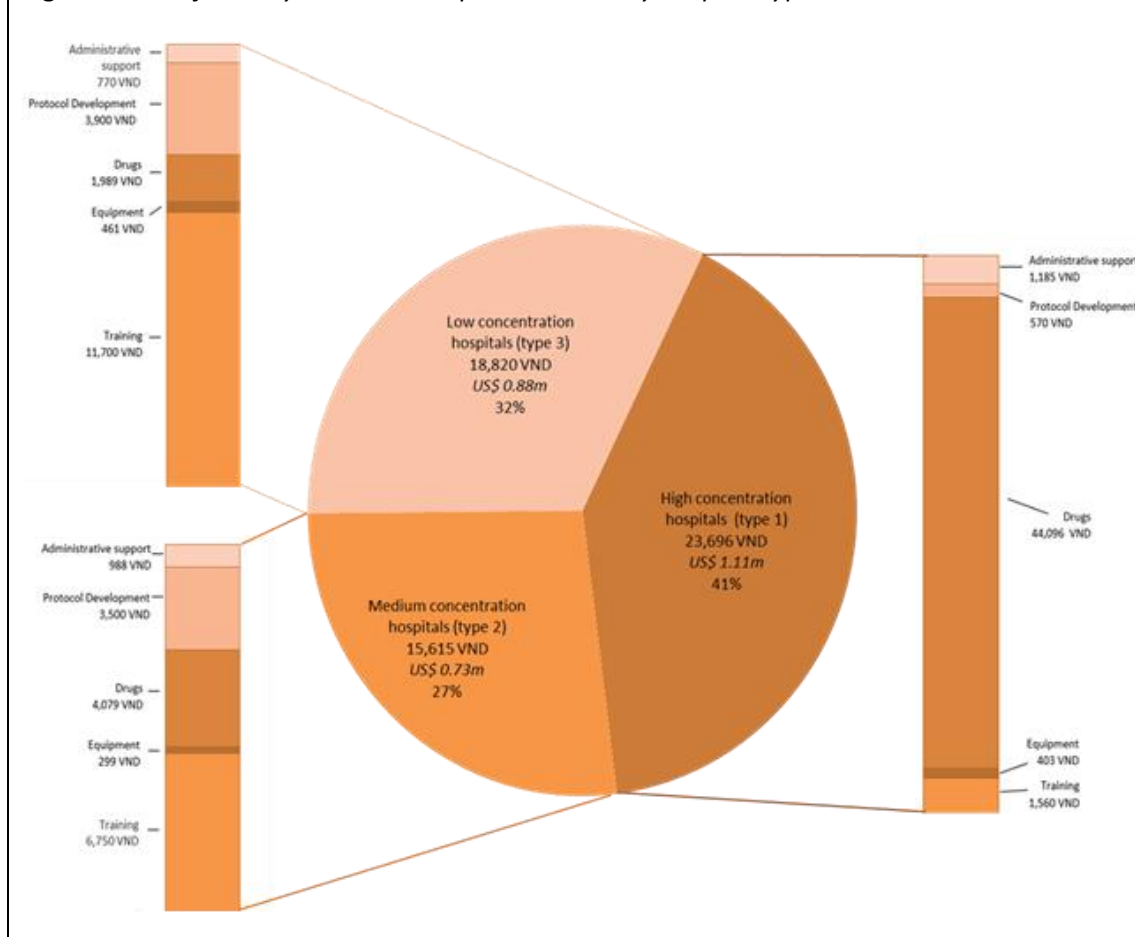
A QS document is usually accompanied by a budget impact analysis (BIA), which identifies the key cost drivers and estimates costs of implementing the changes required for achieving the standards at the national and sub-national (including local) levels. This analysis highlights potential savings from implementing the QS, as well as areas where investment is needed upfront, with the aim of assisting planning and implementation by policymakers as well as local hospital managers. In high income countries, quality standards should ideally be budget neutral; however in LMICs where there are spare resources, this may be best invested in improving quality of care through implementing quality standards.

Table 2. Excerpt from a budget impact analysis of implementing QS for Stroke in Vietnam.

Cost drivers The cost drivers identified for the purposes of this analysis are training, equipment, drugs, protocol development and administrative support. [Figure] shows the distribution of costs across hospital types, and in stacked bars shows how the costs for each hospital type is distributed across the cost drivers... A large proportion of the costs associated with implementing the Qs in Type One hospitals can be attributed to the cost of thrombolysis. Per-facility costs in many instances are significantly higher in Type One compared to Type

Two or Three hospitals, however, as there is a relatively small number of Type One hospitals the total costs are much smaller. Further, as the costs associated with achieving a basic level of care are independent of the actual patient flow, training is a substantial cost associated with rolling out the standards in Type Two Type Three hospitals.

Figure: *Costs of Quality Standards implementation by hospital type and cost driver*



BIA is different from cost-effectiveness analysis (CEA), which provides estimates of the health effects relative to cost effects and which underpins clinical guideline recommendations. In other words, a cost-effective intervention may nonetheless have a large or a small budget impact when implemented through the respective quality standard.

3 Who is involved in developing quality standards?

3.1 QS development: A participatory, multi-disciplinary exercise

Several groups contribute to developing a QS document, each with distinct areas of responsibility. Altogether these groups combine the inclusive participation of policy, clinical, technical and administrative inputs that the QS needs. Table 3 lists the different groups, their responsibilities, and how they interact.

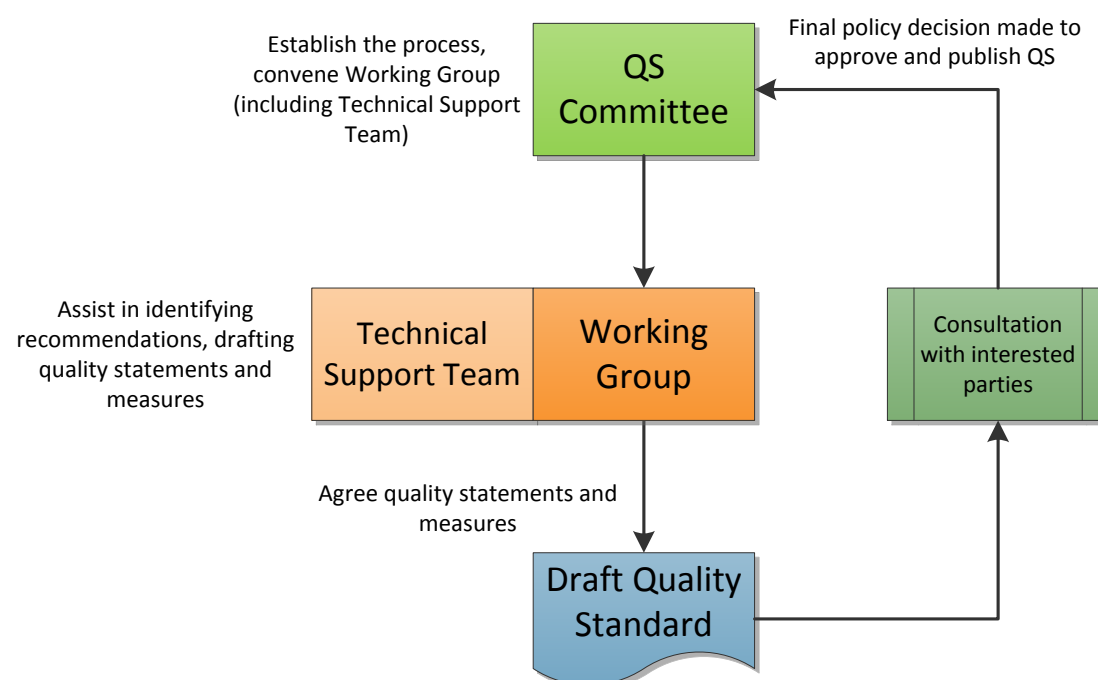
Table 3. Groups involved in developing a QS, and core responsibilities.

Group and composition	Responsibilities
QS Committee , a decision-making committee convened by a policymaking/regulatory/payer body (such as the Ministry of Health, other relevant authorities or independent agencies including health insurers). Such body usually holds the budget for implementing quality improvement.	• Select topics for QS development • Approve or ratify the QS • Oversee and regulate implementation of the QS
Working Group to develop the QS, led by a Chair and comprising topic experts (doctors, nurses, and clinicians from allied health professions), pharmacists, hospital managers, as well as a Technical and Administrative Team (see below).	• Identify relevant source clinical guidance for the QS • Discuss and select clinical recommendations to be included • Review and finalise the draft QS • Respond to consultation comments
Technical Support Team produces technical work as part of the Working Group, and may include specialists in: epidemiology, public health, evidence-based medicine, health economics, accountancy, clinical audit, implementation; alongside project managers and administrative staff	• Provide technical and administrative support to the QS Committee and the Working Group • Undertake epidemiological and routine data analysis, present results to the wider Working Group • Assess quality of clinical guidance for QS • Prepare meetings and documents for the Working Group • Draft QS and present to the wider Working Group • Undertake budget impact analysis
Broader interested parties who may offer their input through consultation (but do not sit on the QS Committee or Working Group). These can include healthcare professionals, patient groups, and other	• Review the QS agreed by the Working Group • Endorse and disseminate the QS (for example, through events or publications by professional

members from civil society.	organisations)
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The relationship between the various groups involved in QS development is illustrated in Figure 4. Note that this is only one possible model for QS development, which has been successful in our experience in various settings such as Kerala, India, and Vietnam. Nonetheless, any model for QS development will require a close working relationship between the policy decision makers and a well-resourced advisory team with the relevant technical and administrative expertise.

Figure 6. Links between the different groups involved in the QS development.



3.2 QS Committee

Quality standards have implications for the decision-making bodies responsible for planning and financing healthcare services, and setting regulatory mechanisms. Often, responsibility for planning, financing and regulation falls on the Ministry of Health, social insurance agency (national or local), or the health insurer. They will need to establish an ongoing mechanism to approve the published QS, oversee their implementation, and measure performance. Decision-making bodies may also be involved upstream, in selecting the topics for QS, based on the needs of their populations and healthcare systems.

To undertake the above tasks, it is recommended to establish a QS Committee in a relevant department of the Ministry of Health (or the payer/insurance organisation). If a committee or similar group already exists with responsibility for quality of care, it could take on the additional task of overseeing the ongoing topic selection,

development and implementation of QS. Alternatively, the responsibility may be devolved to an independent agency mandated to develop QS on behalf of the decision maker.

Whatever the model, members of the QS Committee should be familiar with quality improvement issues and understand the benefits of quality standards as well as the challenges of introducing them into practice in their own healthcare system (for example, investment needed in purchasing equipment; training capacity; information requirements).

It is desirable for the QS Committee to have membership from a broad range of interested parties. These may include: policymakers, health insurers, professional groups representing different sectors (including primary care and hospitals) and disciplines, health managers, health information specialists, health economists, accountants, as well as service users, patients, and other members from civil society.

3.3 Working Group

The Working Group will be primarily responsible for developing the QS according to the process and methods set by the QS Committee. Aside from the Technical Support Team, the Working Group will likely to be a topic expert group relevant to the selected clinical topic. It should involve input from key relevant interested parties, including practicing healthcare professionals from a range of care settings (including primary care and hospitals) and relevant disciplines (medical doctors with different specialties, nurses, generalists, family physicians, pharmacists, and other relevant allied health professionals such as clinical psychologists, physiotherapists), health insurers, managers, health information specialists, and service users (patients and carers)³. Policymakers may also be involved.

As countries should ideally be anticipating an ongoing programme of quality improvement centred around QS, a standing Working Group could also be considered as part of this process. This means the Working Group would comprise of a majority of standing members from a range of disciplines as described above, and they would bring (and develop) quality improvement expertise in developing QS for a range of clinical topics, with a small number of condition-specific clinical experts brought into the Working Group as required for each QS. The NICE Quality Standards Advisory Committee (QSAC) in the UK operate through a similar model (NICE 2015b).

3.3.1 Chair of the Working Group

³ There may be circumstances where key non-governmental agencies working with patients may need to be included in the group. This is at the discretion of each country and should be considered on a case by case basis

The Working Group should have a Chair who will lead the discussions. The Chair is typically an eminent and respected clinical leader, usually (but not necessarily) with both professional clinical and academic expertise on the selected clinical topic. He or she should have sufficient authority to help the Working Group work collaboratively, ensuring a balanced contribution from all members, and be impartial in order to encourage constructive debate. The Chair should have experience in leading clinical guideline development and quality improvement activities, ideally at a national level.

3.3.2 Members of the Working Group

Generally speaking, the composition of the Working Group should reflect the goals of the QS within the specific local context of the healthcare system, and ideally include representation among the different audiences to whom the QS is expected to apply. For example, Vietnam's geographic spread, and its distinctive tiered hospital system (where each of the district, provincial and central levels will have different quality improvement needs, clinical and administrative capacities) (Ministry of Health et al. 2014), meant that the QS for Stroke needed to recruit Working Group members from the three hospital levels and across North, South and Central Vietnam. In Kerala, India, where the majority of births took place in private hospitals (International Institute for Population Sciences 2008), it was important that the Working Group for the maternal mortality QS included clinicians from both private and public providers. In general, it is desirable for all members to have some understanding (and preferably experience) of clinical guideline development or clinical quality improvement. Table 4 shows the composition of Working Group for the QS for maternal care in Kerala (Government of Kerala et al. 2013).

Table 4. Organisations and affiliations in the Working Group for the QS for maternal care in Kerala

Organisation	Position
Government of Kerala	Secretary Health & Family Welfare
National Rural Health Mission	State Mission Director
National Rural Health Mission	Scientist C
Prof & Head, OBGYN, Govt. Medical College, Trivandrum; SAT Hospital	Professor; Head of Obstetrics & Gynaecology
KFOG; Mother Hospital & Raji Nursing Home, Thrissur; Kerala Federation of Obstetrics and Genecology (KFOG)	Consultant Obstetrician Gynaecologist

SUT Academy of Medical Sciences; KFOG; Thekkekappil House, Chalakuzhi lane, Trivandrum	Professor; Head of Department of Obsterics & Gynaecology
Health Services	Director
Medical Education	Director
Achutha Menon Centre for Health Science Studies. SCTIMST	Scientist C
Nursing Council	Trainer, facilitator

An ideal workable size for a Working Group is around 15 – 20 people, excluding the Technical Support Team, for example as suggested by NICE International for the QS for Stroke in Vietnam (Table 5). This would balance the opportunity for individuals to contribute effectively with the need for a broad range of experience and knowledge. That said, the QS for Stroke was ultimately developed successfully with a much larger Working Group of over 25 people, partly reflecting the QS Committee’s priorities in ensuring a wider representation of disciplines, hospital tiers and geography across Vietnam. Such large groups might in practice require some more creative methods of group facilitation and engagement, for example using breakout sessions (see 3.3.2).

Table 5. Suggested composition of QS for Stroke Working Group in Vietnam, as suggested by NICE International, and actual composition

Suggested composition
• Emergency care/ICU doctor (3) (one for each: district, provincial and central hospital) • Neurologist (3) (one for each ; district, provincial and central hospital) • Neurosurgeon (1) • Cardiologist (1) • Radiologist/neuroradiologist (1) • Pharmacist (1) • Nurse/stroke nurse (1) • Patients or carers (Vietnam Association Against Stroke; Vietnam Stroke Association) (2) • Hospital manager (3) (one for each: district, provincial and central hospital) • Health economist (1) • Programme Manager (1) • Representatives from Vietnam Social Security, Medical Services Administration, Department for Planning and Financing, Vietnam Health Economics Association, Health Strategy and Policy Institute, and NICE International

3.4 Technical Support Team

The Technical Support Team will prepare and present technical briefings, that will inform the QS Committee as well as the Working Group in their decisions throughout QS development. The Technical Support Team is considered to be part of the Working Group and should be involved in all Working Group meetings and discussions. The team should work to job descriptions specifying their responsibilities and tasks as outlined in Table 3

This team would ideally include a range of technical skillsets such as:

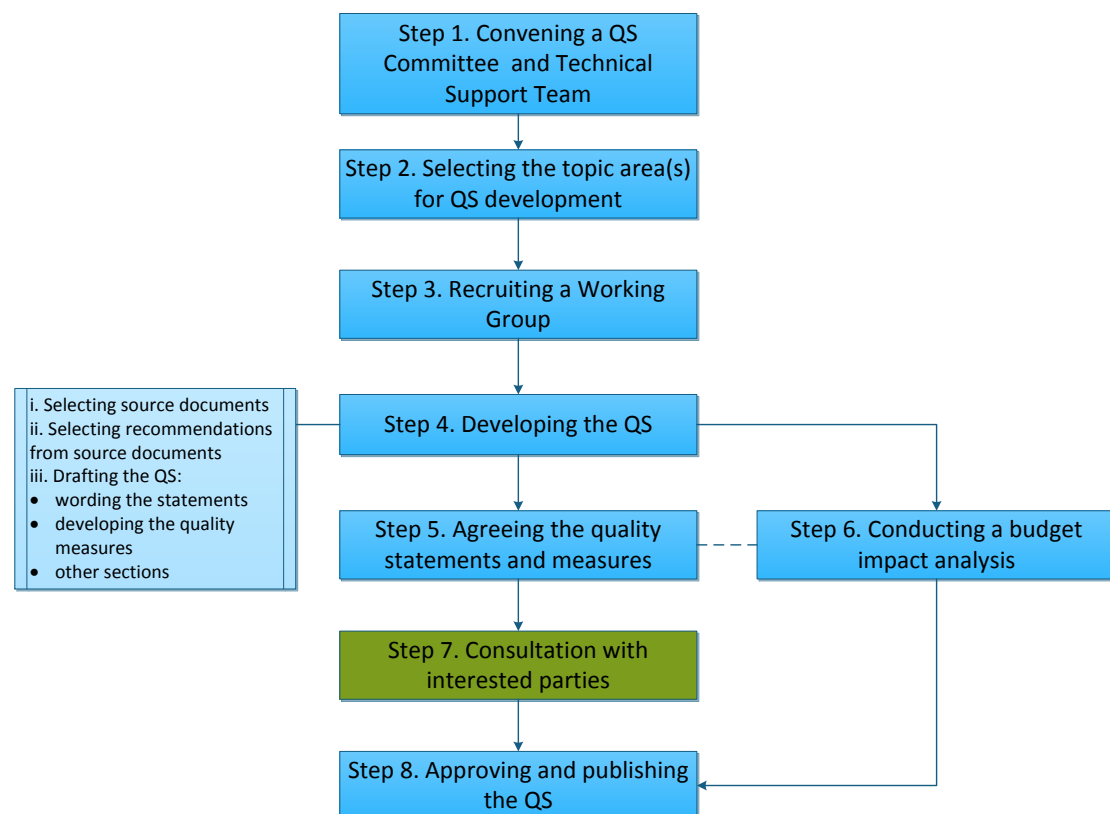
- evidence-based medicine, including clinical guideline appraisal, development or adaptation
- health economics, including cost-effectiveness analysis and budget impact analysis
- clinical audit
- quality improvement and implementation
- impact evaluation
- administrative skills, including project management and logistical support.

4 Process for developing and approving quality standards

4.1 Overview

Developing and approving a QS document goes through a number of interlinked activities with various parties involved. It can be thought of as an iterative process, particularly for the Working Group which will engage in a number of meetings to agree on major decisions about the content of the QS, with technical and administrative work being carried out in the background between meetings by the Technical Support Team. Throughout the process, the Technical Support Team will be working closely with key members of the Working Group (particularly its Chair). Figure 7 shows an overview of the whole process. Timelines may vary but should not usually take longer than 6-9 months, in order to keep the momentum.

Figure 7. Process for developing and approving QS



Moreover, QS development is also iterative in the sense that it begins with the broad context of the entire health system and all possible health conditions that could be covered; through topic selection to focus on one clinical topic, which then gets defined further into various clinical areas, each of which will have been covered by various relevant source clinical guidelines with various recommendations, which will have to be further sifted, and so on. At each iteration, there is a process of prioritisation and deliberation, in keeping with the core principles of quality

standards (see 2.1). All this ideally results in an end product which will contain focused and specific quality statements and measures, that will be implementable in clinical practice.

4.2 Convening a QS Committee and Technical Support Team (Step 1)

The QS Committee should be convened by decision-making body (MoH, payer, etc.) to set out the process and methods, select the topic area for QS development, approve the QS, oversee and drive implementation (see 3.2). A Technical Support Team should also be recruited by the decision-making body, on advice from the QS Committee, to begin conducting the early technical and administrative work towards QS topic selection (see 3.4).

4.3 Selecting the topic area(s) for QS development (Step 2)

Topic selection by the QS Committee forms an important part of the QS development process, because limited resources in a health system should be prioritised in disease areas or populations where improvement gains in terms of patient outcomes and efficiencies are likely to be greatest. This should consider the prioritisation criteria listed in **Error! Reference source not found.**

4.3.1 Data sources to inform topic selection

Data may originate from global reports on major burden of disease from international agencies, for example WHO, World Bank, Organisation for Economic Co-operation and Development (OECD) reports, and the Disease Control Priorities project, and country-specific epidemiological studies including household surveys. Below is an example of this type of data (NICE International 2014b).

Recent national assessments of mortality and causes of death in Viet Nam have identified stroke as the leading cause of death in both men and women (6). These data were used in the 2008 Viet Nam Burden of Disease and Injury Study, which found that chronic diseases were responsible for 66% of the overall disease burden in men and 77% in women (7). Although this magnitude of chronic disease burden was similar to that of developed countries (8), the magnitude of burden from stroke was substantially higher in Viet Nam, where stroke caused the greatest burden of all diseases and injuries in 2008."

From : Hoy D, Rao C, Nhung NT, Marks G, Hoa NP. Risk Factors for Chronic Disease in Viet Nam: A Review of the Literature. Prev Chronic Dis 2013;10:120067.

(6) Ngo AD, Rao C, Hoa N, Adair T, Chuc N. Mortality patterns in Vietnam, 2006: Findings from a national verbal autopsy survey. BMC Res Notes 2010;3:78.

(7) Nguyen T, Tran K, Bui N, Vos T, Ngo D, Nguyen T. Viet Nam Burden of Disease and Injury Study 2008. The University of Queensland and Hanoi School of Public Health; 2011.

Local information and experience from experts will also guide this topic selection process. Basic local epidemiological data (trends in mortality and morbidity) and other outcomes should be utilised, as well as routine data from regular reporting systems, audit and reviews collected by MoH authorities or health insurance bodies, hospitals, NGOs or other appropriate organisations in the country. The following is an excerpt of the local data used to inform the topic for the Quality Standard on maternal care in Kerala (Government of Kerala et al. 2013):

To obtain a clearer understanding of the current maternal mortality patterns and practice we collected background material from the Ministry of Health & Family Welfare and clinical lead obstetricians and administrator colleagues in Kerala. Data included basic local epidemiological data (trends in maternal mortality) and other outcomes; data from regular reporting systems; maternal deaths' audit, confidential review of maternal death concentrating on specific events / problems and levels of variation in access and in outcomes; and existing relevant guidelines / standards / pathways prepared by obstetricians and healthcare professionals in Kerala. An important source document was the Confidential Enquiry into Maternal Deaths (1).

(1) *Second Report of Confidential Review of Maternal Deaths, Kerala. Why mothers die, Kerala – 2006-2009; published by Kerala Federation of Obstetrics and Gynaecology, 2012.*

The Technical Support Team will collect and analyse the data, and summarise them in briefing papers that will be presented to the QS Committee for discussion. This can be conducted through a meeting or workshop to identify one or two key priority areas which are likely to meet the prioritisation criteria listed in **Error! Reference source not found..**

At the meeting, briefing papers and other summaries of evidence can be supplemented with presentations from experts or relevant policy makers, to help focus the discussions. Table 6 shows an example of such presentations used to inform QS topic selection on improving maternal care in Kerala (Government of Kerala et al. 2013).

Table 6. Data presentations at the first workshop to prioritise topic for Quality Standard for maternal care, Kerala, June 2012

<i>Presentation Title</i>	<i>Presenter</i>
Maternal death Situation Analysis in Kerala	Director of Health Services, Government of Kerala
Analysis of maternal death audits	Demographer, Directorate of Health Services; Government of Kerala
Developing guides on maternal care	Kerala Federation of Obstetricians & Gynaecologists
Preventable maternal mortality	Head of Dept of Obstetrics & Gynaecology, Medical College Trivandrum
Why mothers continue to die: Confidential review of maternal deaths	Kerala Federation of Obstetricians & Gynaecologists
At the workshop, postpartum haemorrhage (PPH) was identified as the leading cause of maternal death in Kerala (19.4%). It was agreed that PPH could be prevented through improved services and training. A plan was drawn outlining which elements of care to prevent and treat post-partum hemorrhage should be covered in the Quality Standard.	

4.3.2 Defining the scope of the QS

As part of the topic selection process, it may be useful for the QS Committee (with support from the Technical Support Team) to draft and agree on a **scope** for the QS. The scope will provide an overview of what the QS will and will not cover specifically within the broad area of the selected clinical topic, as to provide clear guidance to the Working Group in developing the QS, and to ensure that the end product will be focused and fit-for-purpose for the specific needs of the decision-making body.

For example, if stroke is identified by the QS Committee as a priority clinical topic for QS development, there will need to be decisions on whether the scope will be limited to hospital care for stroke or also include primary care services; and also whether acute stroke and rehabilitation will both be covered. A formal, well-defined scope will help to set clear expectations around the size of the work, reduce the likelihood of disagreements during QS development, minimise the technical work required to search and manage irrelevant source documents and recommendations, and ensure that the QS will be of a reasonable size and developed within the given time and resources.

4.4 Recruiting a Working Group (Step 3)

A Working Group (see 3.3) comprising a Chair, expert members on the clinical topic (whether by clinical, technical or policy experience on a day-to-day basis) should be recruited by the decision-making or payer body on advice of the QS Committee, to develop the QS. Working Group members should ideally be recruited through open advertisements and the press, although this may often not be possible in many LMICs. QS Committee members may need to be pragmatic in engaging contacts through their professional networks.

4.4.1 Declaration of interests

All Working Group members should declare any interests they may have in becoming involved in the QS development work, including funding from, employment in or ownership of shares in the healthcare industry (including pharma companies, private healthcare providers and insurers). Acknowledging that the private healthcare industry plays an important role in many LMICs and indeed may be an important end user of the QS, declaring interests openly nonetheless helps to avoid public concern that links with the healthcare industry or other relevant interests might unduly influence the work of the QS.

Declaring such an interest wouldn't necessarily preclude someone from being a Working Group member, but the person might be asked to leave the room during certain parts of a meeting where there might be a significant conflict of interest. If a person's interest is so significant that it could affect their objectivity throughout the development of a QS, it is unlikely that person would be invited to join the group. An example of a declaration of interest form can be found in Appendix C.

4.5 Developing the QS (Step 4)

This will take place in several stages, requiring regular input from the Working Group, checking with expert interested parties, and input from the QS Committee for approval of the final product. The Technical Support Team will assist with managing the meeting and preparing briefings/papers for the group.

4.5.1 Selecting source documents

Relevant evidence-based clinical guidelines form the basis from which to build the QS. These may be internationally produced clinical guidelines or guidelines from reputable national guidelines' programmes, professional societies or national government programmes. They can also be locally developed guidelines, or that have been adapted for local use from international documents (such as NICE: <http://www.nice.org.uk/guidance/published?type=guidelines>, WHO: <http://www.who.int/publications/guidelines/atoz/en/>). For international guidelines, there are dedicated guidelines databases such as the US National Guidelines Clearinghouse (<http://www.guideline.gov/>).

A key principle of quality standards is that the statements should be based on evidence-informed recommendations (see 2.1). The relevant guidelines or other guidance identified should comply with internationally recognised criteria for methodological rigour (for example the AGREE II criteria, <http://www.agreetrust.org>) to ensure that they are of sufficient quality and have addressed issues of applicability. It is preferable to use a limited number of guidelines to limit the burden of work and focus only on the documents that are most relevant to local practice.

Note that in the UK, NICE Quality Standards are based on clinical guideline recommendations that were (generally, though not always) made on the basis of cost-effectiveness in the NHS setting (NICE 2014a). In principle, NICE quality statements should be budget neutral when implemented in the NHS, where based on recommendations with cost-effectiveness considerations. Where UK or indeed international guidelines are adapted into Quality Standards for use in LMICs, cost-effectiveness cannot always be assumed as costs and resource use will vary across country settings.

4.5.2 Identifying relevant recommendations from source documents

Not all recommendations in the selected guidelines will be relevant for developing the QS. This depends on the breadth of the guidance and how much of the pathway of care they cover. For example, if the QS Committee has decided that the scope of the QS should be restricted to the diagnosis of patients with suspected stroke in a hospital emergency department, then guidance on palliative care for stroke, or prevention of stroke in primary care will not be relevant.

The searching, assessment and sifting of guidelines, and the identification of relevant recommendations should be carried out by the Technical Support Team, with advice from the rest of the Working Group.

There is no standard process for selecting recommendations, but again the overarching criteria for prioritising high impact recommendations, listed in **Error! eference source not found.**, can be used as a guide. It is advisable for the Technical Support Team to document the rationale and evidence sources for considering particular recommendations (as in Table 7), and to present these to the Working Group and inform the prioritisation process (4.5.3).

Table 7. Identified clinical recommendations on nutrition screening and swallowing checks, for the QS for Stroke in Vietnam.

Clinical recommendations [source]	Rationale
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NICE/NICE accredited UK guidelines 4.17.1A Patients with acute stroke should have their swallowing screened, using a validated screening tool, by a trained healthcare professional within 4 hours of admission to hospital, before being given any oral food, fluid or medication, and they should have an ongoing management plan for the provision of adequate hydration and nutrition. <i>[RCP, NICE 1.6.1.1]</i> 4.17.1.B All patients should be screened for malnutrition and the risk of malnutrition at the time of admission and at least weekly thereafter. Screening should be undertaken by trained staff using a structured assessment such as the Malnutrition Universal Screen Tool (MUST). <i>[RCP]</i> Vietnamese guidelines <i>[108 Military Hospital Guidelines]</i> 2.11 Increase metabolism, nourishment Evaluate swallowing disorders when do oral feeding to avoid food getting into respiratory system which causes complication of choking and aspiration pneumonia. Feeding through the gastric sonde with liquid nutrients, enhances body metabolism, prevent gastritis. <i>[Bach Mai Hospital Guideline]</i> <i>Swallowing checks only mentioned as part of indication for aspirin:</i> III.1. If there is no bleeding on CT brain scan but contraindications to thrombolysis, aspirin may be considered after assessing patient swallowing. Then switch to an appropriate specialist for further treatment	Checking stroke patients' swallowing and nutritional needs are relatively simple interventions that have a major impact in reducing mortality (Bray et al. 2013), and can potentially be delivered by non-specialist staff in any hospital setting. A study of a central hospital in Vietnam found that only 1 in 10 stroke patients received any swallowing check (despite almost all receiving a CT scan) (Tirschwell et al. 2012), suggesting that swallowing checks may not be part of routine clinical practice even at central level.
<i>Sources</i> (NICE 2008;Royal College of Physicians 2012;Thong 2015;Ton 2009)	

4.5.3 Prioritising recommendations

Once the Technical Support Team has identified clinical recommendations that are relevant for the scope of the QS, the Working Group will need to select a subset of recommendations to be developed into quality standards. The prioritisation process should be based on broadly similar principles as before (see **Error! Reference source not found.**), i.e. focusing on the recommendations that would have the most impact on area of poor current care or high variation, but also importantly considering practical implementation and feasibility issues, including feasibility of measuring the structure and process.

During the Working Group meeting, the Technical Support Team may present the relevant clinical recommendations, from various source documents, that span the

various key clinical areas defined by the scope (for example, ranging diagnosis of acute stroke, acute management, early rehabilitation, to overall service organisation issues). The Working Group will then discuss these recommendations, with the objective of reaching a consensus on a shortlist of clinical recommendations that will be taken forward for development into quality standards.

There are various possible models for consensus building, which may be employed flexibility depending on the circumstances, including the size, personal and cultural dynamics of the Working Group. Breakout sessions may work well for larger Working Groups in providing more opportunities for individual group members to contribute to the wider discussion, as in the example below from Vietnam.

Consensus building through breakout group discussions, in the first workshop on QS for Stroke in Vietnam

Working Group members reviewed a shortlist of clinical recommendations for the acute care of stroke, identified from the UK NICE / Royal College of Physicians guidelines and various Vietnamese guidelines, from the priority clinical areas highlighted identified by the Working Group the day before.

Members broke into small groups of 5, to discuss what quality standards for stroke care they would like to see. One rapporteur from each group reported their key discussion points to the wider group; the Working Group then collectively discussed each issue.



The Working Group reached consensus on the following clinical areas to take forward for development into QS: organisation of stroke units,

thrombolysis, brain imaging, management of transient ischaemic attacks (TIAs), early mobilisation, swallowing checks, technical transfer, staff training, public awareness, and secondary prevention.

On the organisation of stroke units, for example, the Working Group agreed on the following:

- Stroke units should be geographically separate from existing hospital departments (e.g. ED or ICU), and provided in all hospital tiers
- All stroke units should be able to provide both acute care and early rehabilitation from the first hour, with a multidisciplinary team including a specialist stroke doctor / neurologist, rehabilitation nurse and other therapists
- Hospitals without the capacity to provide safe thrombolysis should not provide it; conversely a district hospital that does meet standards should be allowed to
- Stroke units can provide good care even without thrombolysis; but there should be a mechanism for assessing indication, and referring on to another hospital for thrombolysis if necessary.

Irrespective of the method for achieving consensus, the Chair will play a particularly important role throughout, in ensuring that different voices from around the table are heard, providing succinct summaries of the key discussion points to facilitate the deliberative process, and highlighting the decision and action points for the Working Group. The discussions should be recorded by the Technical Support Team in order to document how the Working Group came to specific decisions, and in order to defend them in the future.

4.5.4 Drafting the quality standard

Quality statements will be derived from guidance recommendations where there is evidence (from data, or collective experience or knowledge) that current practice does not align with the recommendations, or where there is variation in the implementation of the recommendations (see also **Error! Reference source not found.**). The statements will therefore cover areas where quality can be improved, and where quality statements and measures could be used to support quality improvement initiatives.

Ahead of the Working Group meeting, the Technical Support Team may start drafting the quality statements that make up the QS, with advice from the Working Group Chair. They can present the draft quality statements together with briefing papers for consideration by the Working Group (see Section 5.5).

Wording the quality statements

Each quality statement should specify one requirement for high-quality care or service provision (for example, a single intervention, action or event), to make it easier for users to interpret, implement and measure the quality standard. The statement may also specify the timeframe in which the clinical activity is expected to be achieved and measured.

In some circumstances, a quality statement may include more than one intervention or action when these activities are closely linked, or individual statements describing these separately would lack clarity. For example, a quality statement specifying high-quality post-diagnostic follow-up may simultaneously describe what is required of the diagnostic test as well as the various treatment options that follow depending on the outcome of the test; or a quality statement around rehabilitation may describe both the requirements for a rehabilitation plan as well as the actual rehabilitation interventions. Here are some examples from the QS for Stroke in Vietnam:

Patients with suspected stroke arriving at a hospital with facilities to provide thrombolysis are admitted directly to a specialist stroke unit and assessed for thrombolysis, receiving it within 4.5 hours of stroke onset if clinically indicated.

Patients with acute stroke have their swallowing screened by specially trained healthcare staff within 4 hours of admission to the hospital, before being given any oral food, fluid or medication; and have an ongoing management plan for the provision of adequate nutrition.

Quality statements are not verbatim restatements of the relevant source guideline recommendations. A quality statement may map onto clinical guideline recommendations from one or more guidelines, and may be derived by rewording one or more recommendations into a single statement. Table 1 (page 11) shows how various quality statements are built from guideline recommendations.

Developing the quality measures

The **structural measures** will list the necessary practical arrangements for implementing the quality standard. These arrangements should be visible and measurable, for example display of flowcharts on the walls of the delivery ward, or the physical presence of chairs for early mobilisation of people with stroke.

Figure 8. Protocols and equipment introduced into maternity wards for implementation of the QS in Kerala.



The **process measures** will be specified in the form of a numerator and a denominator which define a proportion (numerator/denominator). The numerator is assumed to be a subset of the denominator population. For example, if a quality measure is made up of:

- **(Numerator)** The number of women who have received a bolus dose of Oxytocin
- **(Denominator)** the number of women giving birth

The correct **proportion** is the number of women who have delivered who have also received a bolus dose of oxytocin.

The **outcome measures** will also be specified as a numerator, a denominator, and a proportion in the same format as process measures. Note that many quality standards will not include outcome measures (for example, where these are not easily measurable or attributable to the intended change in clinical activity).

Table 8. Example of a Quality Measure for vaginal deliveries for statement 1. Active Management of Third Stage of Labour (AMTSL) (Government of Kerala et al. 2013)

Structure:
a) Evidence of agreed guidelines or protocols in the hospital for the active management of the third stage of labour

- b) Display of flow charts based on agreed guidelines, protocols or clinical pathways in the labour room
- c) Evidence of availability of Oxytocin, Ergometrine and PG F2 Alfa at the place of delivery
- d) Evidence of suitable storage facilities (refrigerator) for the drugs
- e) Evidence of equipment for measuring blood loss

Process measure:

Proportion of women giving birth vaginally who receive the Oxytocin, Ergometrine or PGF2 Alfa during third stage management of labour during the month

Numerator– the number of women giving birth vaginally receiving Oxytocin, Ergometrine or PGF2 Alfa during the third stage of labour in the hospital during the month

Denominator– all women giving birth vaginally in the hospital during the month.

Outcome measure:

Proportion of women who experience an estimated blood loss equal to or more than 500 ml during and or following a vaginal delivery

Numerator– the number of women giving birth vaginally receiving the AMTSL who experience an estimated blood loss equal to or more than 500 ml during and or following a vaginal delivery in the hospital.

Denominator– all women giving birth vaginally, who receive AMTSL in the hospital.

Other sections

In addition, each statement will be accompanied by

- Definitions of the terms used
- Implications of implementing the quality standard, for different audiences (service providers, healthcare professionals, payers, patients, service users, policy makers)
- Sources of data for measurement (for example registers, databases both national and local)
- Guidance used to underpin the quality standard (for example, guideline from which the recommendations were sourced)
- Specific considerations for individual groups, where relevant, for example tribal or ethnic minority groups

Examples of quality statements from Vietnam (QS for Stroke) and Kerala (QS for post-partum haemorrhage) can be found in Appendix B.

4.6 Agreeing the quality statements and measures (Step 5)

The Working Group will discuss the draft QS at a dedicated workshop. The Technical Support Team will provide background documentation and briefing papers to the Working Group, to enable them to see the sources used to build the quality statements and measures. This will include assessment of the quality of the source guidelines used, and relevance of the guidance to the local context. It may also include estimates of the budget impact of implementing the quality standards.

The Technical Support Team will present the quality statement, quality measures and other components of the quality standards, and each will be discussed in turn. The Working Group will consider the draft quality statements against the presented evidence. It may refine the wording of the statement and other components of the quality standards in light of the discussion. It is important that the Working Group does not review or redefine the evidence base (for example guideline recommendations) from which the quality statements are derived (see 2.1).

This stage will often lead to passionate debate as the group tackles complex issues of care practice and members express their differing perspectives. As previously noted, various possible models for consensus building may be employed flexibly by the Working Group Chair (see 4.5.3). The Chair's role will be critical at this stage to ensure that the debate is orderly, fair and constructive, so that the group will be able to achieve a consensus. Excerpts of discussions that took place to agree the quality statement on Active Management of Third Stage of Labour (AMTSL) in Kerala are presented as follows:

Examples of practical issues discussed during development of a quality statement

Draft quality statement: Women who have given birth are offered a bolus dose of uterotonic drugs to reduce haemorrhage and assist delivery of placenta within one minute (or at the delivery of the shoulder)

What practical issues should we consider regarding scope and content of the statement?

- **Timing of administration of the drug?** Can we measure / record both administration and timing? History of practitioners holding off administering for fear of retention- so important to emphasise and ensure adequate training of staff especially in cases where drugs are not administered
- **Are these the right drugs?** Inclusion/exclusion criteria for drugs. Place? Oxytocin – *no need for combination drug as this is not available in Kerala.*

Misoprostol? (consider different side effect profile when deciding on appropriate drug) e.g warning for Ergometrine / but cheaper and available
– Will we measure which drug were administered?

- **Clinical care:** Quantifying the measure of blood loss is not part of current practice in Kerala but the use of pads in hospitals can be introduced as a practice to measure blood loss. Disposable pads may carry additional cost
- Proportion of women who have given birth experiencing an estimated blood loss of over 500 ml after vaginal birth could be a key clinical measure
- **Local data collection:** May need to develop a new form to collect additional process and outcome data and to redesign the labour registers
- Data are currently being recorded in different formats – Some hospitals already record some of the QS indicators in the register, others don't.
- May need to interrogate pharmacy records for re assessing use of intravenous drugs
- Data may be available but need to be aggregated from other sources
- **Training:** The change in practice would require additional training of all maternity staff.

Once the quality standards are agreed, it may be helpful for the Technical Support Team to outline the considerations around feasibility of implementation for each quality standard, which will help the QS Committee at the later stage of piloting the QS (see Section 5). For example, Table 10 (page 51) sets out the potential extent to which the QS for Stroke could be implemented in practice, within the various categories of hospitals in Vietnam, based on known policy, administrative and other practical constraints.

4.7 Conducting a budget impact analysis (Step 6)

The Technical Support Team will undertake a BIA for the QS, usually in parallel with QS development. The BIA will identify the key cost drivers, and considering a range of local costs related to current practice (services provided, medicines, staffing, etc.), together with data on epidemiology, volume of patients, resource utilisation, current infrastructure and capacity, and clinical outcomes where relevant to costing (such as length of stay). Data may be drawn from a variety of sources; and in LMICs where published or routinely collected data may be scarce, informal data sources play a useful role.

The estimates made by the BIA at this stage will be national or sub-national (e.g. state-level) aggregate estimates as applicable to the remit of the QS. These can only be estimates, as different jurisdictions and healthcare facilities in any country or state will inevitably have different baseline levels of resource use and standards of current practice. To assist in local planning, local hospital managers or policymakers will need to apply the BIA using locally relevant estimates, in order to generate local estimates of the budget impact at the individual hospital level (see 5.3). Primary data collected through auditing as part of QS implementation (see 5.3.1) can in turn also improve the national aggregate estimates in the nationwide BIA.

4.8 Consultation with interested parties (Step 7)

Once the Working Group has agreed the QS, interested parties not previously involved in its development should be invited to comment on it. Interested parties could include payers, healthcare providers, pharmaceutical and devices companies, relevant professional bodies, patient and carer organisations, and other members of the general public or civil society. The aim of this consultation may include obtaining feedback on how the quality statements and accompanying measures will work in practice.

This consultation can be carried out through various different methods, interviews, surveys, or workshops depending on the specific objectives of the consultation, the nature of the QS topic, and available time and resources. The process needs to be closely managed, and participating parties fully informed so they understand what the QS aim to achieve, and the purpose of their input in the consultation.

The Technical Support Team will collate feedback from the consultation. The Working Group will review this information and make the necessary changes or refinements to the QS, documenting its response to the issues raised.

4.9 Approving and publishing the QS (Step 8)

In the final stage, the Working Group will send to QS Committee for approval:

- The final QS
- The budget impact analysis
- Comments from the consultation, and responses to these comments

The QS Committee will review the QS and decide whether to approve it. The QS Committee will ensure that the development process for the QS has been followed correctly (preferably following an established process and methods guide), including the Working Group responses to consultation with interested parties. It will also quality assure the content of the QS by scrutinising the sources of information

underpinning it. In addition, it will examine the budget impact analysis carried out by the Technical Support Team on behalf of the Working Group.

Key members of the Working Group, including the Chair and the Technical Support Team, should attend the meeting to answer any questions the QS Committee may have. In the case of the QS for Stroke in Vietnam, the committee was convened by the Director of the Medical Services Administration, and included key members of the Working Group (including the Chair), to sign off the QS.

Once the QS Committee has approved the QS, it can be published and disseminated through appropriate channels. The QS Committee should consider a coordinated dissemination and communication plan, working with professional associations, patient groups and the media, in a way that is appropriate within the country context.

5 Preparing for QS implementation and piloting

5.1 General principles of implementation

Implementing the QS will require changes in how practice is structured and delivered. This will need detailed planning and preparation. There will be different implementation models that are workable, depending on the local circumstances. These will include whether existing quality strategies and quality initiatives could be leveraged, and the readiness or capacity of the local health system (in terms of available financial, structural and human resources) to initiate change.

Regardless of the model, there are some general principles of good practice, that should maximise the likelihood of a successful implementation:

- Start small, and aim for **incremental progress**;
- **Prioritise** to maximise impact (see **Error! Reference source not found.**);
- **Engage and involve all relevant interested parties** with a role to play in implementation (including policymakers, hospital managers, and clinicians on the ground) as early as possible in the process, to maximise all parties' ownership of quality improvement
- **Monitor, measure, and record** practice and outcomes, including a baseline measurement of current practice, as well as throughout implementation, in order to test and understand the impact of quality improvement activities, and to provide lessons for further improvement.

In this section, we outline a general approach to QS implementation, which begins with a limited pilot, based on the experiences of NICE International in planning for the implementation of the QS for Stroke in Vietnam, and for the QS for maternal care in Kerala:

1. Planning
2. Inception (pre-implementation)
3. Pilot implementation
4. Post-implementation and wider rollout

Following the Plan-Do-Study-Act framework (NHS Institute for Innovation and Improvement 2008), a QS pilot would be a proof-of-concept to test its feasibility in practice, and to learn lessons that would facilitate its scaling up. The full proposed implementation plan for the QS for Stroke in Vietnam can be found in Appendix D.

5.2 Planning for implementation

During QS development, the Working Group will have discussed practical issues of implementation, as will have the QS Committee in approving the final version. The

Technical Support Team may have explored the potential feasibility of each of the quality standards (see Table 10). Consultation with interested parties (see 4.8) should also have highlighted potential challenges in applying the QS in practice. Finally, the BIA will have highlighted resource implications (see 0).

5.2.1 Phased implementation

A phased implementation may be envisaged, starting with a pilot in a small number of hospitals within a province before a full roll out across the state or country. Selecting suitable pilot sites will be an important activity during this planning stage, and feasibility will be a major consideration here, as the aim will.

QS implementation could also be phased in the sense that the pilot could start with the most impactful and feasible subset of the quality standards before more quality standards are adopted incrementally. Again this could be determined locally using some of the prioritisation criteria mentioned in **Error! Reference source not found.**, hether through a formal gap analysis or audit, or through consensus involving the local interested parties. For example, as was recommended for the QS for Stroke in Vietnam (D.3), implementation could in the short term focus on the quality standards that are relatively easily achievable through staff training and one-off procurement of equipment and materials, with likely sustained impact; and in the medium and longer term, the focus could shift to quality standards requiring system reorganisation.

5.3 Inception (pre-implementation) activities

A number of activities will need to take place in preparation for the QS pilot implementation. These may include:

- Any necessarily policy or administrative steps; for instance a circular from the Ministry of Health, or contractual arrangements with the pilot hospitals
- Developing standard operating procedures (SOPs, i.e. specifications for each quality statement and measure), training materials and protocols, clinical protocols and tools (such as screening instruments)
- Developing data collection tools, and conducting baseline assessments (see 5.3.1, page 40)
- Developing tools for local BIA (such as Excel spreadsheet templates for use at the hospital level), and conducting local BIA using locally relevant cost and resource use estimates
- Identifying local priorities for implementation
- Staff recruitment, training, and procurement to enable implementation of quality standards

The following box and Table 9 outline the experience of planning for the implementation of the QS in Kerala, currently being piloted in 8 hospitals (6 public and 2 private):

A planning workshop to discuss the implementation plan was held with the Working Group in December 2012. It was chaired by the Principal Health Secretary for Kerala, the Director of the National Rural Health Mission (NRHM). An implementation plan was drawn. Issues regarding implementation were discussed (data collection procedures, documents, training issues). Responsibilities for tasks leading to the pilot implementation were outlined and timelines drawn. These activities, responsibility and timelines are shown in Appendix 5. The following core tasks in Table 9 needed to be put into place for the start of the pilot implementation on 1 April 2013.

Table 9. Core tasks for preparing the implementation of the QS in Kerala.

Core tasks	Description
Orientation meeting	An information meeting held by the NRHM director with directors of pilot hospitals to explain the QS work
Quality Standard document	The document for the launch
Needs assessment	Each pilot hospital conducted an inventory of equipment, staffing and other components needed for the QS implementation to identify gaps in existing resources. The needs assessment proforma is presented in Appendix Error! Reference source not found..
Design baseline data collection forms	Data collection proforma to collect retrospective baseline data on QS indicators in pilot hospitals
Labour registers – design and printing	Redesigning existing labour registers to collect data for QS indicators. Data to be collected is shown in Appendix Error! Reference source not found..
Flow charts design and printing	Posters representing the QS to be posted in labour wards
Training	2-day training sessions for all frontline maternity staff (400) in the pilot hospitals
Human resources	Staff redeployment needed to ensure adequate capacity to implement QS (e.g

	2-hour observation post-delivery)
Procurement	Procurement of equipment, materials and drugs needed

5.3.1 Baseline assessment

Since a key objective of quality standards is to measure and drive improvement, a reliable and valid baseline assessment will be absolutely crucial to successful implementation. Possible approaches could include:

- general organisational audit; for example, a snapshot of each hospital's stroke service structure, patient caseload, and staffing levels and competencies
- tailored organisational audit, specific to the quality measures defined in the QS, and
- patient-level audit, through case review.

Such an assessment can form the basis of a formal gap analysis at each implementation site to determine local priorities for implementation, whether for the purposes of the pilot or were the QS to be subsequently more widely implemented. It will also strengthen the cost and resource use estimates for updating the BIA (see 4.7).

Depending on the needs of interested parties, available resources (time, financial, and human resources) and information systems, not all of audit approaches may be useful or feasible in this initial pilot stage. For example, for a small-scale QS pilot, it may not be necessary to conduct a case review of individual patient notes, although any data gaps in the baseline organisational audit may inform future improvements to address data collection and monitoring needs at the patient-level.

If resources allow, it is also be helpful to conduct baseline assessments at both pilot and non-pilot sites, as to allow more robust analysis of the effect of implementing the QS on process and clinical outcomes, even if a randomised controlled trial of implementation were not possible. As a rule of thumb, baseline data should span at least 3 months prior to the start of implementation, though longer is preferable. For example, for more sophisticated analytic techniques such as interrupted time series regression, data spanning at least 12 months pre-intervention is the generally accepted requirement (Wagner et al. 2002).

5.4 Piloting the QS

Piloting the QS provides valuable information about its applicability in practice, allowing identification of problems not previously recognised. Regular auditing and

reporting from pilot sites and regular follow-up will therefore be essential, including a record of reported challenges and suggestions for improvement from staff at pilot sites.

In Kerala, pilot hospitals collect monthly data on all indicators of the QS from their delivery register, and send the aggregated data to the NRHM. Monthly review meetings are held to monitor progress with the pilot implementation and to collect feedback from the hospitals. The meetings are chaired by the Principal Secretary, with input from the NRHM Mission Director and Lead KFOG. Staff from the pilot Hospitals present their data, and issues are discussed openly. Minutes are kept by the NRHM staff.

Appendix A. Example of selected slides for introductory training to Quality Standards

What are quality standards?

Quality standards are a concise set of evidence-informed statements, designed to drive and measure priority quality improvements, within a particular area of care (e.g. acute management of stroke).

Quality Standards define what clinicians should aspire to and what patients should expect

Quality statement from NICE QS: Stroke (2010)

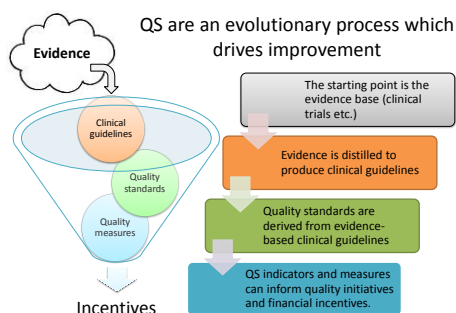
Patients with acute stroke have their swallowing screened by a specially trained healthcare professional within 4 hours of admission to hospital, before being given any oral food, fluid or medication, and they have an ongoing management plan for the provision of adequate nutrition.

Quality Standards aim to improve quality and reduce variation

1. **Markers of high quality care** (*not* minimum standards!) in terms of: *clinical effectiveness, safety, and patient experience*
2. Focus on areas **where sub-optimal clinical practice is common**
3. Derived from **best available evidence**, e.g. WHO, NICE, other local guidance
4. **Aligned with government/payer priorities**
5. **Produced collaboratively** with stakeholders (policymakers, payers, hospital managers, clinicians, service users, professional/patient organisations).

Quality Standards do *not*:

- Review or re-assess the underlying evidence base
- List *all* necessary components of acceptable care



Quality statements describe what high-quality care looks like in practice

- **Implementable:** Clearly set out key infrastructural and clinical requirements
- **Measurable:** Can be developed into **quality measures**.
- **Timeframe** is usually specified

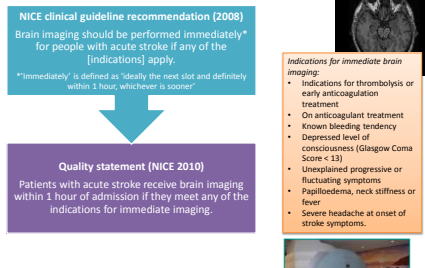
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3. Derived from **best available evidence**, e.g. WHO, NICE, other local guidance
4. **Aligned with government/payer priorities**
5. **Produced collaboratively** with stakeholders (policymakers, payers, hospital managers, clinicians, service users, professional/patient organisations).

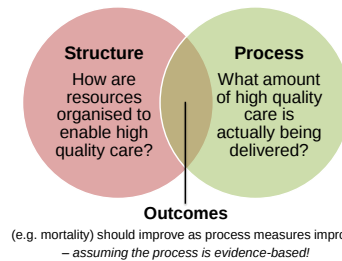
Quality statements describe what high-quality care looks like in practice

- **Implementable**: Clearly set out key infrastructural and clinical requirements
- **Measurable**: Can be developed into **quality measures**.
- **Timeframe** is usually specified

Quality statement for stroke developed from NICE guideline



Quality measures assess quality of healthcare provision (as specified in quality statement)



Quality measure for stroke: Structure

What are the resources, and how are they organised to ensure patients can receive brain imaging within 1hr of admission?

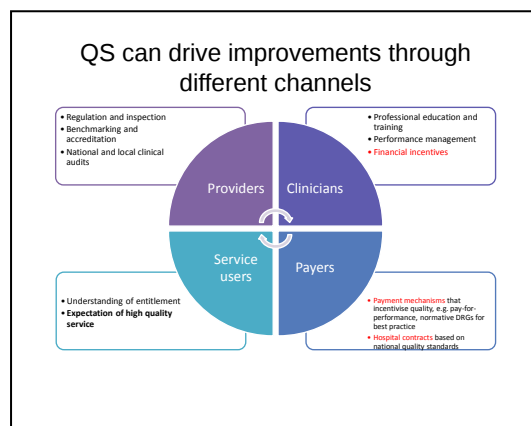
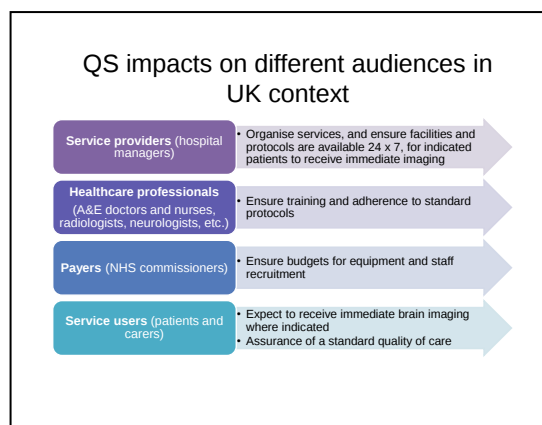
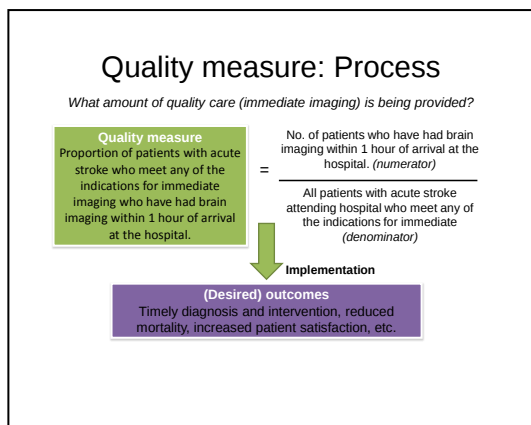
- Are there protocols or clinical pathways in the hospital for managing acute stroke, from admission to A&E onwards?
- Are brain imaging facilities (equipment and personnel) available 24x7, and organised to prioritise acute stroke patients?



Quality measure: Process

What amount of quality care (immediate imaging) is being provided?

Quality measure Proportion of patients with acute stroke who meet any of the indications for immediate imaging who have had brain imaging within 1 hour of arrival at the hospital.	=	No. of patients who have had brain imaging within 1 hour of arrival at the hospital. (<i>numerator</i>) All patients with acute stroke attending hospital who meet any of the indications for immediate (<i>denominator</i>)
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Appendix B. Examples of quality standards in Vietnam and India

B.1. QS for the hospital management of stroke in Vietnam

B.1.1 *Transient ischaemic attack (TIA)*

Quality statement 3

People with TIA (whose symptoms have fully resolved) are considered as medical emergencies, assessed and treated by a healthcare professional with expertise in neurovascular disease within 24 hours, and started on aspirin treatment immediately.

Quality measure – structure

- Evidence of locally agreed protocols for the assessment and treatment of TIA as medical emergencies within 24 hours, and not necessarily as inpatients
- Availability of staff with expertise in neurovascular disease
- Availability of aspirin

Quality measure – process

a)

Numerator: The number of patients treated as medical emergencies, and assessed and treated by a healthcare professional with expertise in neurovascular disease within 24 hours of arrival at the hospital.

Denominator: The number of patients with TIA admitted to the hospital.

b)

Numerator: The number of patients started on aspirin treatment immediately.

Denominator: The number of patients with TIA admitted to the hospital who do not have contraindications to aspirin.

What quality statement means for each audience

Ministry of Health: Ensure that training programmes and standards for healthcare professionals include recognition of stroke risk following TIA (for example, using the ABCD2 tool), and treating TIAs as emergencies.

Provincial health departments: Ensure the resources for hospitals to assess and treat TIA as medical emergencies.

Hospitals: Ensure the appropriate skillset and resources to assess and treat TIA as medical emergencies, and not necessarily as inpatients.

Healthcare staff: Ensure adherence to training and protocols to assess and treat TIA as medical emergencies, and not necessarily as inpatients.

Payers (Vietnam Social Security, other health insurers, patients who pay for a service): Can use adherence to QS to inform payment.

Patients with TIA: Can expect to be assessed and managed as an outpatient medical emergency, and started on aspirin immediately.

Definitions

TIAs, by definition, can only be diagnosed in people whose neurological symptoms have fully resolved. They are associated with a very high risk of stroke in the first month after the event and up to 1 year afterwards.

Validated tools for identifying people at high risk of stroke following a TIA include the ABCD2 score (Age, Blood Pressure, Clinical Features, Duration of Symptoms, Diabetes).

Determining stroke risk following a TIA using the ABCD2 score. Reproduced from NICE Clinical Knowledge Summaries for Stroke and TIA.

How should I assess the ABCD2 score?

Use the ABCD² scoring system to help assess the risk of stroke early after a transient ischaemic attack:

A — age: 60 years of age or more, 1 point.

B — blood pressure at presentation: 140/90 mmHg or greater, 1 point.

C — clinical features: unilateral weakness, 2 points; speech disturbance without weakness, 1 point.

D — duration of symptoms: 60 minutes or longer, 2 points; 10–59 minutes, 1 point.

D — presence of diabetes: 1 point.

Points from the individual items are added to give the ABCD² score.

People with a score of 4 or more are regarded as being at high risk of an early stroke.

The ABCD² scoring system excludes certain populations who may be at particularly high risk, such as:

People who have had two or more transient ischaemic attacks (TIAs) within 1 week — they are

at higher risk for early stroke.

People on anticoagulation treatment — brain imaging is required to exclude intracranial bleeding.

They also may not be relevant to people who present days after a TIA.

Data sources

- Baseline audit for stroke QS pilot
- Local data collection

References

Josephson, S.A. et al. (2008) Higher ABCD2 score predicts patients most likely to have true transient ischemic attack. *Stroke*, 39, 3096 – 3098.

NICE (2009) Stroke and TIA – NICE CKS. Assessing the ABCD2 score. <http://cks.nice.org.uk/stroke-and-tia#!scenario recommendation:2>

Royal College of Physicians (2012) National Clinical Guidelines for Stroke, 4th Edition. RCP, London.

B.2. QS for post-partum haemorrhage and hypertensive disorders of pregnancy⁴

B.2.1 Management of the third stage of labour

Quality statement

Women who have given birth either vaginally or by caesarean are offered a bolus dose of Oxytocin, Ergometrine or Prostaglandin F2 Alfa at the time of delivery of the shoulder or within 1 minute of the delivery of foetus to prevent post-partum haemorrhage and to assist delivery of the placenta.

Definitions

Third stage of labour: from the time of delivery of the foetus to the complete delivery of the placenta.

Active management of the third stage of labour: Steps to reduce post-partum haemorrhage:

1. Use of uterotonic drugs
2. Early delivery of placenta by controlled cord traction, after ensuring uterine contraction and giving counter pressure to prevent inversion of uterus

⁴ Government of Kerala in collaboration with the National Rural Health Mission, the Kerala Federation of Obstetrics & Gynaecology and NICE International. Improving maternity care in Kerala. Quality standards for post-partum haemorrhage and hypertensive disorders of pregnancy. First Edition, 15 January 2013

Oxytocin, Ergometrine are Uterotonic Drugs

Dose:

- Oxytocin 5U IV or 10U IM; (prefer the 5 units slow iv bolus injection)
- Ergometrine 0.2 mg IM (contra indicated in women with hypertension and heart disease)
- PGF2 Alfa 125 micro gram IM (contraindicated in women with H/O asthma)

Quality Measure

Structure:

- a) Evidence of agreed guidelines or protocols in the hospital for the active management of the third stage of labour
- b) Display of flow charts based on agreed guidelines, protocols or clinical pathways in the labour room
- c) Evidence of availability of Oxytocin, Ergometrine and PG F2 Alfa at the place of delivery
- d) Evidence of suitable storage facilities (refrigerator) for the drugs
- e) Evidence of equipment for measuring blood loss

Process measure:

VAGINAL DELIVERIES

Proportion of women giving birth vaginally who receive the Oxytocin, Ergometrine or PGF2 Alfa during third stage management of labour during the month

Numerator– the number of women giving birth vaginally receiving Oxytocin, Ergometrine or PGF2 Alfa during the third stage of labour in the hospital during the month

Denominator– all women giving birth vaginally in the hospital during the month.

CAESAREAN DELIVERIES

Proportion of women giving birth by caesarean section who receive Oxytocin, Ergometrine or PGF2 Alfa as part of active management of third stage of labour during the month

Numerator– the number of women delivering by caesarean section receiving the Oxytocin, Ergometrine PGF2 Alfa as part of active management of third stage of labour

Denominator– all women giving birth by caesarean section

Outcomes:

VAGINAL DELIVERIES

Proportion of women who experience an estimated blood loss equal to or more than 500 ml during and or following a vaginal delivery

Numerator– the number of women giving birth vaginally receiving the AMTSL who experience an estimated blood loss equal to or more than 500 ml during and or following a vaginal delivery in the hospital.

Denominator– all women giving birth vaginally, who receive AMTSL in the hospital.

CAESAREAN DELIVERIES

Proportion of women who experience an estimated blood loss equal to or more than 1000 ml during and after caesarean section, except in women with placenta praevia accreta.

Numerator– the number of women delivering by caesarean section and experiencing an estimated blood loss equal to or more than 1000 ml during and after caesarean section in the hospital except the ones with placenta praevia accreta

Denominator – all women giving birth by caesarean section in the hospital except those with placenta praevia accreta.

What the quality Statement means for each audience

Service Providers: Ensure adequate human resources, equipment, drugs and supplies to provide 24 X 7 services and to measure blood loss.

Healthcare Professionals: Training and adherence to standard protocols.

Payers: (government, health insurers, women giving birth who pay for service): Ensure a quality standard is in place and is being followed before they pay for services.

Data sources

- Local data collection in the standard labour room register
- Consider developing appropriate checklists/audit forms as part of this Quality Standard for use by local facilities, inclusion in DHS survey, in Kerala Accreditation Standards Criteria for providers and in Confidential Maternal Death Review
- Monthly reporting forms for National Rural Health Mission

Source guidance

- KFOG obstetric management protocols, second edition 2012; published by Kerala Federation of Obstetrics and Gynaecology. P 109-111
- Second Report of Confidential Review of Maternal Deaths, Kerala. Why mothers die, Kerala – 2006-2009; published by Kerala Federation of Obstetrics and Gynaecology, 2012. P 80
- National Institute for Health and Clinical Excellence. Intrapartum Care, Care of healthy women and their babies during childbirth; 2007
- World Health Organisation. WHO guidelines for the management of postpartum haemorrhage and retained placenta; 2012
- Royal College of Obstetricians and Gynaecologists. Green-top guideline No 52, Prevention and management of post-partum haemorrhage; 2009

Appendix C. Sample declaration of interests form

Before joining the QS Working Group, you should declare any interests you have that could affect your membership

What is a 'declaration of interests'?

It is the process by which a Working Group member registers any commercial or financial interests that might affect their objectivity (for instance if they carry out work for, or their organisation receives funding from the healthcare industry). These might create a conflict of interest and could affect the independence of any quality standard to which the person contributed.

Why is this important?

Declaring interests helps to avoid public concern that links with the healthcare industry or other relevant interests might unduly influence the work of the quality standard. It ensures that such interests are openly and publicly declared. Declaring such an interest wouldn't necessarily preclude someone from being a Working Group member, but the person might be asked to leave the room during certain parts of a meeting where there might be a conflict of interest.

If a person's interest is so significant that it could affect their objectivity throughout the development of a quality standard (for instance if they work for or have a significant number of shares in a drug company, or their organisation receives funding from a drug company), then even if he or she receive no personal benefit from such interest, it is unlikely that person would be invited to join the group.

Definitions

Healthcare industry: Any companies, partnerships or individuals involved with the manufacture, sale or supply of health technologies (medicines, equipment etc.) that are, or may be used by the healthcare service in the country.

Personal interest: Payments directly to an individual from the healthcare industry or related trade associations (e.g. through consultancy work, fee-paid work or direct share-holdings).

Non-personal interest: Payment which benefits a department or organisation for which a person has managerial responsibility, but is not received by the person themselves. For example, charitable organisation might receive sponsorship or educational grants from drug companies, which might be considered as affecting the objectivity of people working for the organisation.

Name:.....

☐

Do you have any interest to declare: Yes

No

☐

If 'Yes' Please list below any interests you want to declare

.....

Appendix D. Proposed implementation plan for the QS for Stroke, Vietnam, by NICE International

D.1. Where will the QS ultimately be implemented?

The QS should eventually be implemented in all hospitals in Vietnam where acute stroke is managed, from district level hospitals to specialist central hospitals, and including private hospital facilities. However, differences in the administrative and technical classes of hospitals means that some hospitals will be able to implement the QS more rapidly and without major reorganisation or costs, while others may need substantial changes to clinical practice, organisational environment, and existing payment and activity regulation policies.

The maximum potential for implementing each QS in hospitals by administrative type and class, under current Ministry of Health policies, is shown in Table 10.

Table 10. Potential for implementing each QS within different hospital categories.

Quality Standard	Central Hospital		Provincial Hospital		District Hospital		Private
	Specialised	Level I & II	Level I & II	Level III	Level I & II	Level III	
<i>No. in Vietnam</i>	3	22	62	268	17	516	
QS1: Trained Staff	✓	✓	✓	✓	✓	✓	✓
QS2: Imaging	✓	✓	✓	✓	✗	✗	Hospital decision
QS3: TIA	✓	✓	✓	✓	Referral	Referral	Competency dependent
QS4: Stroke Units	Gold	Gold	Gold	Silver	Bronze	Bronze	Bronze at minimum
QS5: Dignity	✓	✓	✓	✓	✓	✓	✓
QS6: Thrombolysis	✓	✓	✓	✗	✗	✗	Competency dependent
QS7: Early Mobilisation	✓	✓	✓	✓	✓	✓	✓
QS8: Swallowing and Nutrition	✓	✓	✓	✓	✓	✓	✓
QS9: Prevention (lifestyle advice)	✓	✓	✓	✓	✓	✓	✓
QS10: Secondary Prevention (medication)	✓	✓	✓	✓	✓	✓	✓
QS11:	Hub	Hub	✓	✓	✓	✓	✓

Telemedicine							
QS12: Disseminating Expertise	Hub	Hub	Hub / Recipient	Hub / Recipient	Recipient	Recipient	Hospital decision
QS13: Screening (emergency response)	✓	✓	✓	✓	✓	✓	✓
QS14: Public Awareness	✓	✓	✓	✓	✓	✓	✓
QS15: Monitoring Quality of Care	✓	✓	✓	✓	✓	✓	✓

D.2. Selection of pilot hospital

For maximum likelihood of impact and sustainability, NI recommends a phased approach to implementation, beginning with a pilot in a very small number of hospitals (up to 2). Following the Plan-Do-Study-Act framework, the pilot would be an opportunity to test the feasibility of the QS in practice, to test its impact, and to learn lessons that would facilitate its scaling up to the entire country.

Hospital A and **Hospital B** are identified as potential pilot sites for the Stroke QS:

- **Hospital A:** As a central hospital, Hospital A is considered a centre of excellence and, in principle, not administratively restricted from implementing any of the 15 quality statements. The Stroke QS Committee involved staff from Hospital A whom have made important contributions to the development of the Stroke QS. Hospital A already plays an active role in hospital quality improvement and technical transfer (e.g. for satellite hospitals), and has also received the informal backing from MOH officials.
- **Hospital B:** Although situated in an urban centre, Hospital B is classified as a provincial hospital. It has 700 beds, housing 70-80 stroke patients at any given time (approx. 1,000 per year) with average length of stay of 14 days. A clinician from Hospital B was actively involved in developing the QS as a member of the QS Committee. Senior hospital staff expressed plans to establish a stroke unit, which would probably have to start at Bronze level; they have the infrastructure and skilled doctors, but would need to integrate the skills from different disciplines for stroke care, particularly nurses.

Although we recommend piloting in a maximum of 2 hospitals, in principle other hospitals could participate in auditing under the auspices of wider MSA quality improvement activities. The pre-implementation training events could also include representatives from other hospitals (e.g. nearby provinces), as an opportunistic way of widening the impact of quality improvement initiatives beyond the pilot site, subject to MSA being able to secure funding sources to bring in external participants.

D.3. Phased implementation of the QS

Implementation of the QS could be phased in the following manner:

1. **Training:** patient experience, clinical outcomes
2. **System reorganisation:** internal (e.g. stroke unit), external (e.g. telemedicine, referrals), human resources
3. **Monitoring and audit**

D.4. Prioritisation of QS to be implemented in the pilot

A small subset (4-5) of the QS should be initially piloted, focusing on the quality statements likely to have a high impact in terms of changing current practice and improving patient outcomes.

While a formal gap analysis could be one approach to guide prioritisation, NICE International recommends that for the purposes of the pilot, implementation activities should primarily focus on:

5. Patients with stroke are treated with dignity, including their hygiene maintained, provided care to prevent and manage pressure ulcers, and given privacy.
7. Patients with acute stroke (ischemic and haemorrhagic) are mobilised and helped to sit up as soon as they are awake, unless medically unstable; and supported to stand and walk as soon as possible.
8. Patients with acute stroke have their swallowing screened by specially trained healthcare staff within 4 hours of admission to the hospital, before being given any oral food, fluid or medication; and have an ongoing management plan for the provision of adequate nutrition.
10. Patients after stroke are offered appropriate medication to reduce risk of future strokes.

Based on the evidence, NHS clinical experience and our understanding of the Vietnamese health system, these are the low-cost, high-impact interventions that are relatively easy to implement and feasible for all hospitals (with relatively little system re-organisation required), and yet could make a substantive difference to clinical outcomes in terms of patient experience, mortality and length of stay.

Where current infrastructure and administrative positioning within the health system allows, **QS2: Imaging** and **QS4: Stroke units** could be considered in the next phase of the pilot.

2. Patients with suspected stroke receive brain imaging within 1 hour of arrival at the hospital if they meet any of the indications for immediate imaging, or within 24 hours if they do not meet any indication for immediate imaging.

4. Patients with suspected stroke are assessed and managed in a specialist stroke unit that meets at least Bronze criteria, by a doctor with specialist expertise in stroke and other appropriately trained staff within 24 hours of admission to hospital, and by all relevant members of the multidisciplinary rehabilitation team within 72 hours, with documented multidisciplinary goals agreed within 5 days.

D.4.1 Baseline assessment

MSA, with NI support, is developing a tailored organisational audit tool specific to the 15 quality statements, which will be used to conduct a baseline assessment for the pilot hospitals. This could form the basis of a formal gap analysis were the QS to be more widely implemented, as well as that of a stroke audit programme at the national level.

For the purposes of a small-scale pilot of the Stroke QS, it is not necessary to conduct a case review of individual patient notes, although any data gaps in the baseline organisational audit may inform future improvements to address data collection and monitoring needs at the patient-level.

D.5. Project plan for pilot implementation

Activity	Date	Who is responsible
Identify subset of 4-5 high-priority quality statements for pilot implementation	Month 1	MSA with NI support
Develop organisational audit tool for the QS	Month 1	MSA with NI support
Collate tools and resources for implementation, based on NICE and NHS experience	Months 1 – 2	NI
Adapt and translate selected tools: timelines, audit tool, training tools	Month 1 – 4	MSA with NI support
Approach relevant decision-makers in potential pilot hospitals	Month 2	MSA
Scheduled structured meeting with pilot hospitals to discuss specifics of pilot activities	Month 3	MSA and pilot hospitals
MSA agrees terms of reference with pilot hospitals	Month 4	MSA and pilot hospitals

Conduct baseline organisational audit at pilot hospitals	Months 4 – 5	MSA and pilot hospitals
Secure funding and organise QS training event for pilot hospitals	Months 4 – 5	MSA
Identify and recruit participants within pilot hospitals for training	Month 5	MSA and pilot hospitals
Conduct staff training for selected subset of QS	Month 5	NI Clinical Experts
Begin pilot implementation	Month 6	Pilot hospitals

Appendix E. Examples of data collection tools for QS implementation

E.1. QS for the hospital management of stroke in Vietnam

E.1.1 Acute organisational audit tool for stroke adapted for use in Vietnam

This tool was presented by NICE International at the second Stroke QS workshop in Hanoi, March 2014.

Instructions

This proforma should describe your stroke services as on the date of completion. Please complete all questions. Data collected from this proforma will form a useful baseline on which to drive quality improvement, for example to inform the implementation of the Ministry of Health Quality Standards for the Hospital Management of Stroke in Vietnam.

This proforma was adapted from the UK Sentinel Stroke National Audit Programme (SSNAP) with the involvement of one of its authors Professor Tony Rudd, chair of the UK Intercollegiate Stroke Working Party.

Basic organisational information

1.1 Please give the full name of your hospital.

1.2 Hospital level

☐ Central ☐ Provincial ☒ District ☐ Private

☐ Other (please specify)

1.3 MoH technical classification

☐ Specialised ☐ Class I ☐ Class II ☐ Class III

☐ Class IV ☒ No official classification

Caseload

1.4 What is the total number of stroke patients in the hospital at the time this form is completed?

1.5 What is the total number of patients with confirmed or suspected TIA in the hospital at the time this form is completed?

1.6 How many stroke patients are in neurology beds at the time this form is completed?

1.7 How many stroke patients are in stroke beds at the time this form is completed?

1.8 How many stroke patients are in general medical beds at the time this form is completed?

1.9 How many stroke patients are in ICU beds at the time this form is completed?

1.10 How many stroke patients are on other wards at the time this form is completed?

1.11 How many stroke patients are on each ward? (must add up to the total for 1.10):

Coronary care unit

Care of the elderly ward

High Dependency Unit

Generic rehabilitation unit

Other Name(s) of ward(s):

1.12 What is the total number of patients with stroke for the year 1 January 2013 – 31 December 2013?

1.13 How many doctors, at what grades, are assessing or treating patients with stroke?

Title and grade of staff		Number of staff	
Title and grade of staff		Number of staff	
Title and grade of staff		Number of staff	

Acute presentation

Brain imaging

2.1 Does your hospital have a CT scanner? ☐ Yes ☐ No

2.2 Does your hospital have an MRI scanner? ☐ Yes ☐ No

2.3 How many stroke patients received brain imaging during 1 January 2013 – 31 December 2013?

a) CT

b) MRI

5.4.1.1.1.1.1 Only answer 2.4 to 2.5 if you have answered 'Yes' to 2.1 or 2.2.

2.4 Is there immediate access to scanning (CT or MRI) for urgent stroke patients (as defined by the MoH Quality Standards⁵)? ☐ Yes ☐ No

⁵ Indications for immediate imaging (within 1 hour) are any of the following:

- indications for thrombolysis or early anticoagulation
- on anticoagulant treatment
- a known bleeding tendency
- a depressed level of consciousness (Glasgow Coma Score below 13)
- unexplained progressive or fluctuating symptoms
- papilloedema, neck stiffness or fever
- severe headache at onset of stroke symptoms.

2.5 What level of brain imaging service (CT or MRI) does your hospital offer?

- a) Weekdays: Number of hours per day
- b) Saturdays: Number of hours per day
- c) Sundays and public holidays: Number of hours per day

5.5 Thrombolysis

2.6 Does your hospital currently provide thrombolysis? ☐ Yes ☐ No

2.7 How many patients were thrombolysed during 1 January 2013 – 31 December 2013?

5.5.1.1.1.1.1 Only answer 2.8 to 2.10 if you have answered 'Yes' to 2.6

2.8 What level of thrombolysis service does your hospital offer?

- a) Weekdays: Number of hours per day
- b) Saturdays: Number of hours per day
- c) Sundays and public holidays: Number of hours per day

2.9 Who initially assesses patients for thrombolysis at your hospital? (Answer for 'normal hours' and, if applicable, 'out of hours' and select all that apply)

Title and grade of staff ☐ Normal hours ☐ Out of hours

Title and grade of staff ☐ Normal hours ☐ Out of hours

Title and grade of staff ☐ Normal hours ☐ Out of hours

2.10 Who makes the final decision that a patient should be given thrombolysis at your site? (Answer for 'normal hours' and, if applicable, 'out of hours' and select all that apply)

Title and grade of staff ☐ Normal hours ☐ Out of hours

Title and grade of staff ☐ Normal hours ☐ Out of hours

Title and grade of staff ☐ Normal hours ☐ Out of hours

Early management

2.11 Are patients routinely screened for swallowing problems before feeding?

☐ Yes ☐ No

2.12 If yes, who does this screening? (You may enter more than one staff group.)

Title and grade of staff

Title and grade of staff

Title and grade of staff

2.13 On average, how many days after admission would stroke patients be got out of bed?

Assessment wards taking stroke patients

3.1 How many days per week would a stroke patient be seen by a stroke specialist senior doctor?
(e.g. enter '7' if the patient would be seen on every day that they are in the ward, even if patients in the ward for 7 days)

Stroke units

4.1 Does your hospital have a stroke unit? ☐ Yes ☐ No

5.5.1.1.1.2 Only answer 4.2 to 4.7 if you have answered Yes to 4.1:

4.2 How many beds are in the stroke unit?

4.3 How many members of clinical staff, at what grades, are employed in the stroke unit?

Title and grade of staff Number of staff

Title and grade of staff Number of staff

Title and grade of staff Number of staff

Title and grade of staff Number of staff

Title and grade of staff Number of staff

4.4 How many days per week is there a stroke specialist senior doctor ward round for these beds? (If there is more than one location for these beds, please give an average, e.g. if there are 20 beds overall and 10 have ward rounds 7 times a week and the other 10 have ward rounds 5 times a week, you should put '6'.)

4.5 How many of the following nursing staff are there usually on duty at 10am for these beds? (Enter 0 if no staff of

that grade.)

a) Qualified nurses: Weekdays , Saturdays , Sundays and public holidays

b) Care assistants: Weekdays , Saturdays , Sundays and public holidays

4.6 How many nurses are usually on duty for these beds at 10am who are trained in the following? (Enter '0' if none.)

a) Swallow screening: Weekdays , Saturdays , Sundays and public holidays

b) Stroke assessment and management: Weekdays , Saturdays , Sundays and public holidays

4.7 How many hours of junior doctor time are there per week in total for all stroke unit beds?

Other stroke care models

Secondary prevention

5.1 Does your hospital have any system for giving information to or supporting stroke patients to reduce lifestyle risk factor (exercise, smoking, diet, weight and alcohol)?

☐ Yes ☐ No

Community rehabilitation

5.2 Do you have access to any rehabilitation in the community after the patient has been discharged?

☐ Yes ☐ No

5.3 Do you send stroke patients to any other inpatient facility for further rehabilitation?

☐ Yes ☐ No

TIA/Neurovascular service

6.1 Do you routinely admit patients with TIA as inpatients?

☐ Yes ☐ No

6.2 Do you have a neurovascular clinic?

☐ Yes ☐ No

If yes:

- a) How many clinics within a 4 week period?
- b) How many new patients were seen during the past 4 weeks?
- c) What is the current average waiting time for an appointment? days

Other hospitals / units in the stroke pathway

7.1 How many other locations, providing bed-based rehabilitation (i.e. community hospital beds, intermediate care beds, rehab stroke unit beds, generic rehab beds), take at least 10 patients at year with a primary diagnosis of stroke from your hospital, i.e. the patients are transferred from your hospital?

7.2 Does your hospital have regular, stroke-specific educational meetings?

☐ Yes ☐ No

5.5.1.1.1.3 7.3 If yes, to whom are these meetings open to? (Please tick all that apply.)

☐ Staff that assess or manage stroke patients

☐ All staff in this hospital

☐ Staff in other hospitals

E.2. QS for post-partum haemorrhage and hypertensive disorders of pregnancy, Kerala, India⁶

E.2.1 Template for needs assessment in the pilot hospitals

Hospital	
Type of institution • Medical college • District hospital, • Taluk Hospital, • Community Health Centre	
Total number of deliveries in the past 3 months	
Human resources • Use human resources questionnaire	

⁶ Government of Kerala in collaboration with the National Rural Health Mission, the Kerala Federation of Obstetrics & Gynaecology and NICE International. Improving maternity care in Kerala. Quality standards for post-partum haemorrhage and hypertensive disorders of pregnancy. First Edition, 15 January 2013

• Sara questionnaire (adapted for local use)	
Infrastructure • Number of labour cots • Space for IV stage observation Y/N • High dependency care Y/N • Fridge Y/N	
Equipment (functioning) <i>Specify if each of these is available</i> • Delivery Set • Episiotomy kit • Forceps delivery kit • Vacuum extractor metal • Silastic vacuum extractor • Blood pressure apparatus • Sthethoscope • Cardiac monitor adult • Pulse oxymeter • Nebulizer • Weighing scale (adult) • CPAP machine • Head box for oxygen • HP meter • Glucometer • Female airway • Electronic Weighing scale for measuring blood loss • Suction apparatus (electrical) • Suction apparatus (foot) • Wall clock • Torch • Emergency call Bell • Oxygen supply (central) • Telephone • Autoclave drums • Railed cot • Gowns for doctors & nurses & mothers • Washable slippers	
Disposables <i>Specify if each of these is available</i> • Mat • Cord clamp	

• Dee Lee's Mucus trap • Neoflon (intravenous catheter) 24 G • Micro drip set with & without burette • Blood transfusion set • 3 way stop cock • Suction catheter size 2.5, 3, 3.5 mm • Sterile gloves and drapes • Chemical disinfectants • Glucostix & Multistix strips (in container) • Cotton, surgical gauze • Normal saline, 10% Dextrose infusion bottle • Sanitary pads Drugs • Ergometrine • Oxytocin • Prostaglandin F2 alpha • Blood products : packed red blood cells, fresh frozen plasma or cryoprecipitate and platelets • Labetalol (tablets) • Alphadopa and labetalol • Nifedipine • Labetalol (IV) • Hydralazine (IV) • Magnesium sulphate	
Documentation requirements • Appropriate labour register • Monthly return forms • Case notes	

E.2.2 Template for patient-level audit (labour register), including data required for QS indicators

Serial Number monthly/annually	
IP Number	
Name of patient	
Address	
Age	
Name of husband/Mother/Guardian	
Date and time of admission	
Gest. Age (Wks & days)	
Presentation	
Date & time of delivery	
Type of delivery (Vaginal or CS)	
Induction of labor (Y/N)	

Assisted delivery (forceps.vacum) Y/N	
Pre eclampsia (Y/N)	
Maternal death (Y/N)	
oxytocin Y/N	Quality Statement 1
ergometrine Y/N	
PGF2 Alpha Y/N	
Blood loss vaginal	Quality Statement 2
< 500 ml	
Equal or > 500 ml	
Blood loss C section	
< 1000 ml	
Equal or > 1000 ml	
For vaginal deliveries If = or more than 500ml blood loss transfusion /blood products (Y/N)	Quality Statement 3
For C-Section If more than 1000ml blood loss blood transfusion/blood products (Y/N)	
Transferred/referred to ICU Y/N	Quality statement 4
Acute circulatory failure Y/N	
Organ failure Y/N	
Transfusion Y/N	
Previous CS (Y/N)	Quality statement 5
Myomectomy (Y/N)	
Diagnosed Placenta Pravia (Y/N)	
History of hypertension during pregnancy (Y/N)	Quality statement 6
On hypertensive treatment (Y/N)	Quality Statement 7
History of albuminuria during pregnancy Y/N	
Severe hypertension immediately post-partum (Y/N)	Quality statement

	8
CVA (Y/N)	
Eclampsia (Y/N)	
Ocular complications (Y/N)	
neurological complications (Y/N)	
Labetalol (Y/N)	
Hydralize (Y/N)	
Induction of labor	Quality statement 9
Magnesium sulphate Y/N	Quality Statement 10
Observation every 30 minutes for 2 hours	
BP	
Pulse rate	
Palour	
ABD for abdominal palpation and fundal position	
Expressed blood loss	
Blood loss vaginal	
< 500 ml	
Equal or > 500 ml	
Blood loss C section	
< 1000 ml	
Equal or > 1000 ml	

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