

# Principles for developing clinical Quality Standards in low and middle income countries

**A Guide**

***Version 1***

**NICE** National Institute for  
Health and Care Excellence

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NICE International



## ABOUT THIS DOCUMENT

This guide defines the principles for developing clinical Quality Standards and describes the processes and methods involved. It is designed to help low and middle income countries that are moving to Universal Health Coverage 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<sup>1</sup>. It also draws on examples from our initial experiences of developing a Quality Standard for improving maternal care in Kerala, India<sup>2</sup> and for stroke care in Vietnam<sup>3</sup>. We recognise that individual countries will have specific requirements and procedures and may need to adjust the process to fit 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 low and middle countries evolves. We welcome constructive comments, suggestions or examples from users which will help improve the content of this document.

We are grateful to all the colleagues who contributed in some way to the development of this guide.

### Acknowledgements:

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<sup>1</sup> NICE Health and Social Care Directorate Quality standards Process guide (August 2013). London: National Institute for Health and Care Excellence. Available from: [www.nice.org.uk](http://www.nice.org.uk)

<sup>2</sup> 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

<sup>3</sup> <http://www.nice.org.uk/about/niceinternational/projects/NICEInternationalVietnam.jsp>

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## ABBREVIATIONS

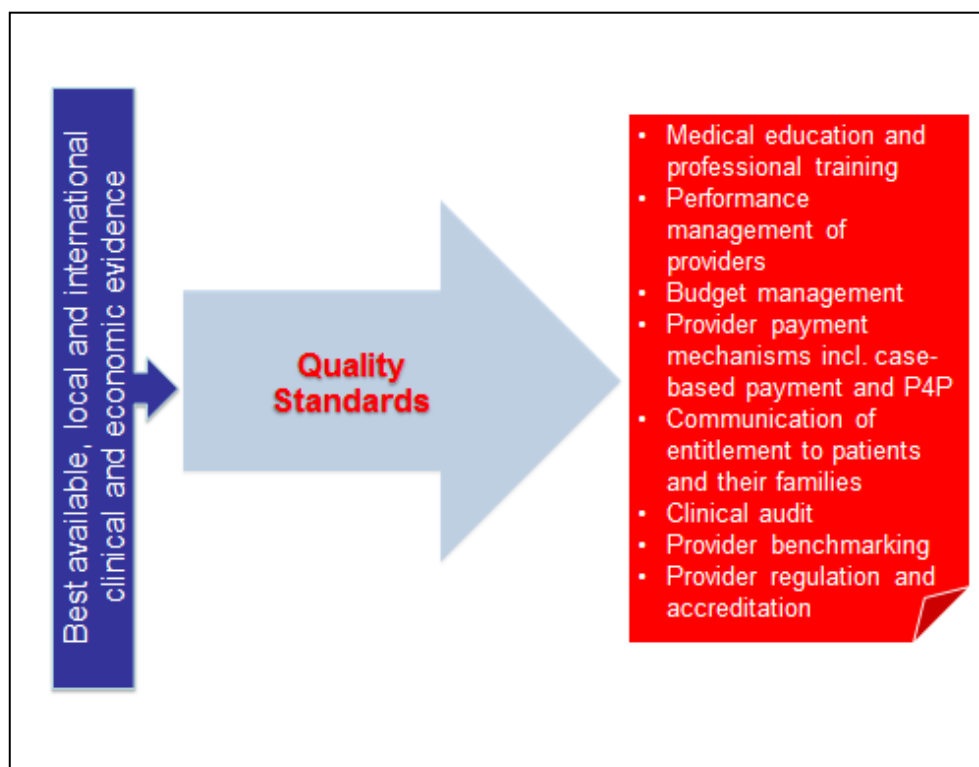
BIA	Budget Impact Analysis
CoI	Conflict of Interest
CEA	Cost-Effectiveness Analysis
KFOG	Kerala Federation of Obstetricians and Gynaecologists
MoH	Ministry of Health
NRHM	National Rural Health Mission
NICE	National Institute for Health and Care Excellence
OECD	Organisation for Economic Co-operation and Development
QS	Quality Standard
UHC	Universal Health Coverage
WHO	World Health Organisation

## 1 Introduction

Measuring and monitoring the quality of care has become a key priority for payers, providers and patients throughout the world as a means of improving health services and outcomes. 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<sup>4</sup>.

Quality Standards are derived from high quality evidence, accompanied by measurable indicators, and developed in consultation with relevant local groups. They are increasingly used as tools to provide explicit benchmarks against which actual care performance can be assessed and improvements to services put into practice. They can inform payment mechanisms and incentives, in the context of healthcare insurance and Pay for Performance frameworks. They also interface closely with other quality improvement initiatives, including clinical audit. The relationship between evidence, quality standards and other quality improvement activities is illustrated in Figure 1.

**Figure 1. Quality Standards linking evidence and quality improvement**



<sup>4</sup> Mate KS, Sifrim ZK, Chalkidou K, Cluzeau F, Cutler D, Kimball M, Morente T, Smits H, Barker P. Improving health system quality in low- and middle-income countries that are expanding health coverage: a framework for insurance. *Int J Qual Health Care*. 2013 Oct;25(5):497-504. doi: 10.1093/intqhc/mzt053. Epub 2013 Aug 19.

A key purpose of Quality Standards is to clarify what quality care is, by providing governments, health insurers, service providers, professionals and patients with definitions of high quality health care, and performance measures that are reliable and meaningful to the local setting in which they are used.

- **Payers** (governments and health insurers) may use the Quality Standards to ensure that high quality care is delivered to patients, and measurable indicators for setting reimbursement benchmarks and targets.
- **Regulatory bodies** can monitor the quality of care as described in a Quality Standard 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** (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
- **Health professionals** (doctors, nurses, pharmacists, allied health professionals) can use Quality Standards to audit their practice and governance or could use the reports or in professional development and validation
- **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 locally<sup>5</sup>, 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.

### 1.1 Defining the terms

There are many terms to define documents or related initiatives in the field of quality improvement. Often these terms are used interchangeably and may be confusing. Below we clarify the terminology.

***Clinical guidelines:*** “A set of recommendations on the appropriate treatment and care of people with specific diseases and conditions, based on the best available

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<sup>5</sup> “Locally” may include: a country, region, groups of institutions (for example networks of primary care centres) or individual establishments (for example hospitals)

evidence”<sup>6</sup>. Guidelines help healthcare professionals in their work, but they do not replace their knowledge and skills. Clinical Guidelines are also known as “guidelines”, “clinical practice guidelines” and “Standard Treatment Guidelines”. Clinical guidelines provide generic recommendations in the form of statements. For example:

**WHO recommendation:** *“The use of uterotonics for the prevention of PPH during the third stage of labour is recommended for all births. (Strong recommendation, moderate-quality evidence)”*<sup>7</sup>

**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”*<sup>8</sup>

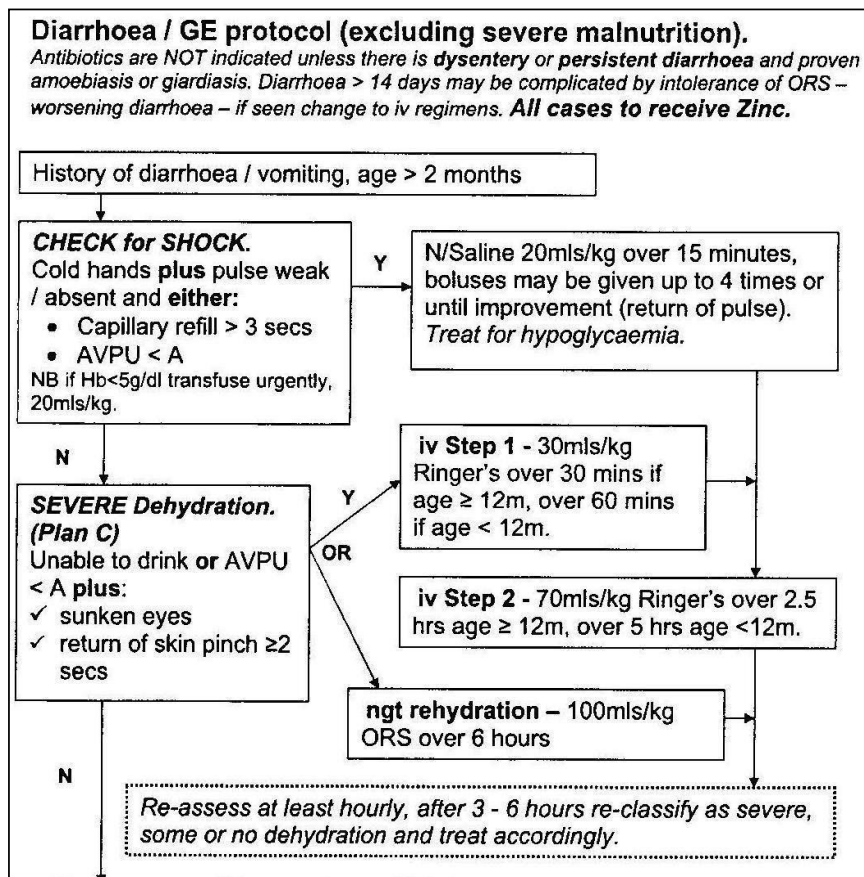
**Protocols:** Locally and practice focused they describe the steps taken to treat patients to make them acceptable to the healthcare providers within a specific clinical setting (stepwise approach). They usually build on clinical guidelines recommendations and may be more restrictive. Often called 2medical protocols they are often presented as algorithms. Below is an example from the Ministry of Health. Basic Paediatric Protocols. Kenya: Government of Kenya, 2010.

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<sup>6</sup> Adapted from : NICE, The guidelines manual <http://publications.nice.org.uk/pmg6> ;30 November 2012

<sup>7</sup> WHO recommendations for the prevention and treatment of postpartum haemorrhage, World Health organisation, 2012.  
[http://apps.who.int/iris/bitstream/10665/75411/1/9789241548502\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/75411/1/9789241548502_eng.pdf)

<sup>8</sup> NICE, CG127 hypertension, 2011. <http://guidance.nice.org.uk/CG127>



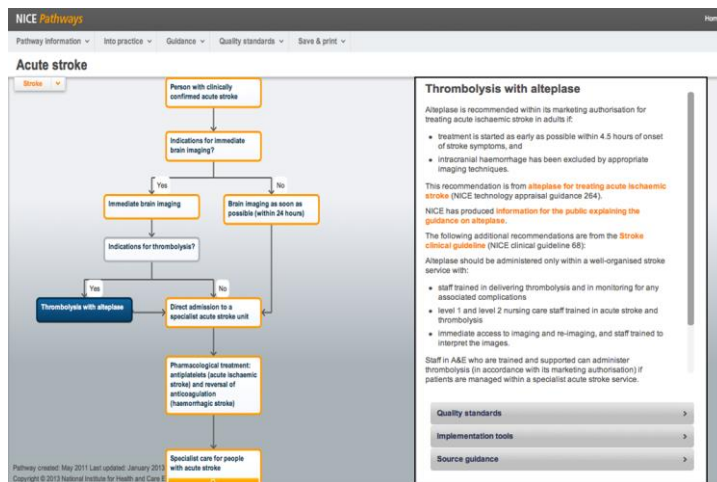
**Clinical pathways:** usually refers to the sequence of practices, procedures and treatments that should be used with people with a particular condition to improve their quality of care. Synonym terms are often used such as: 'integrated care pathways', 'Critical Pathways', 'Care Plans', 'Care Pathways', '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)<sup>9</sup>

NICE Clinical pathways are "interactive tools for health and social care professionals providing fast access to NICE guidance and associated products". Below is an example of such pathways<sup>10</sup>

<sup>9</sup> <http://www.openclinical.org/clinicalpathways.html>

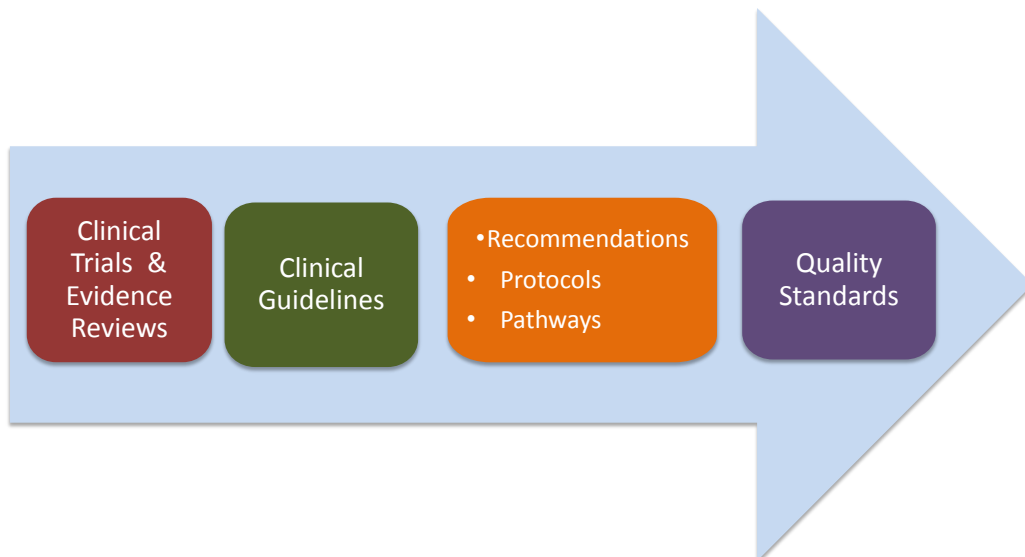
<sup>10</sup> NICE Hypertension pathways, 2010. <http://publications.nice.org.uk/stroke-quality-standard-gs2>





The relationship between evidence, clinical guidelines, other quality documents and quality standards is shown in Figure 2.

**Figure 2. The linking process: from evidence to Quality standards**



## 2 Key principles of Quality Standards

Quality Standards (QS) are a concise set of statements and related measures

designed to drive and measure priority quality improvements within a particular area of care. They describe what high-quality care looks like across three dimensions of quality: patient safety, clinical effectiveness, patient experience. They set an aspirational but achievable level of performance that healthcare professionals, healthcare organisations and payers should aim for. In that sense they act as markers of high-quality patient care across a clinical condition or care pathway. They are based on the following core principles:

- They are derived from the **best available evidence**, for example clinical guidelines such as NICE guidelines, WHO guidelines, guidelines adapted from high quality international guidelines or other sources accredited through trustworthy processes (for example the NICE accreditation process)<sup>11</sup> including local guidelines
- They are produced **collaboratively** with all the interested parties (for example government, clinicians and professional organisations, health insurers) and service users (patients and carers)
- They are developed through a **transparent process**
- They are **reviewed regularly**.

*Quality Standards do not:*

- review or re-assess the underlying evidence base
- provide specific details about how a service is organised or operates

### 3 What makes 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 QS are constructed and what they mean for different groups or audiences. Box 1 lists the various components typically included in a Quality Standard.

#### Box 1. Components of a Quality Standard

Clinical topic  
Quality statement(s)  
Rationale  
Quality measures  
What the quality statement means for each audience  
Source guidance  
Data sources  
Social and equality considerations

### 3.1 Quality statements

Quality statements are descriptive, qualitative statements (sentences) that are clear and concise, and describe high-priority areas for quality improvement. They are aspirational (they describe excellence) but are achievable. 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 set of Quality Standards 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, although in some circumstances two requirements for high-quality care may be allowed in one statement, when they are closely linked (for example, if treatment options are dependent on the results of prior diagnostic testing or assessment) and individual statements describing these separately would lack clarity.

Table 1 shows an example of recommendations from the WHO guidelines for the prevention and management of postpartum haemorrhage (PPH) and retained placenta<sup>12</sup>, and the corresponding quality statement for the Active Management of Third Stage of Labour (AMTSL) developed in Kerala<sup>13</sup>.

**Table 1. Guideline recommendations and quality statement. Example from Active Management of Third Stage of Labour (AMTSL)<sup>14</sup>**

WHO recommendation	Kerala quality statement
<ul style="list-style-type: none"><li>• The use of uterotonics for the prevention of PPH during the third stage of labour is recommended for all births</li><li>• Oxytocin (10 IU, IV/IM) is the recommended uterotonic drug for the prevention of PPH</li><li>• If intravenous oxytocin is unavailable, or if the bleeding does not respond to oxytocin, the use of intravenous ergometrine, oxytocin-ergometrine fixed dose, or a prostaglandin drug (including sublingual misoprostol, 800 µg) is recommended.</li></ul>	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.

<sup>12</sup> World Health Organisation. WHO guidelines for the management of postpartum haemorrhage and retained placenta; 2012

<sup>13</sup> 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. (Quality Statement 1)

Quality statements should be accompanied by a 'rationale' section in the form of an explanatory paragraph that provides the basis for making the statement. Box 2 shows an example of a quality statement with its rationale.

**Box 2. Quality statement and rationale from the NICE Quality Standard on Heavy Menstrual Bleeding<sup>15</sup>**

**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.

**3.2 Quality measures**

Quality measures are quantitative measures that assess the quality of care or service provision specified in the quality statement, and consist of three components: include three components: **structure**, **process** and **outcome measures** (see 5.4.5 for more details). They accompany each quality statement and are drafted after the wording of the quality statement has been agreed.

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<sup>15</sup>Heavy menstrual bleeding, NICE quality standard 47. September 2013  
<http://publications.nice.org.uk/heavy-menstrual-bleeding-gs47/quality-statement-5-access-to-endometrial-ablation>

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 outcome, because few outcome measures can be used at local level to assess the quality of care reliably, or they may be long-term outcome measures.

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) <sup>16</sup>:

**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

### 3.3 Budget impact analysis

Quality Standards are accompanied by a budget impact analysis (BIA), which considers the cost of implementing the changes required in order to achieve the quality standard at a local level<sup>17</sup>. This analysis highlights potential savings, as well as areas where investment is needed upfront to ensure changes are made in line with the requirements of the Quality Standards (see 5.7). This will inform the strategy for implementing the Quality Standard in practice. In high income countries, Quality Standards should ideally be budget neutral; however in low and middle income countries where there are spare resources, this may be best invested in improving quality of care through implementing Quality Standards.

BIA is distinct from a 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 recommendation may

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<sup>16</sup> 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. (Quality Statement 1)

<sup>17</sup> <http://www.nice.org.uk/usingguidance/implementationtools/costingtools.jsp?domedia=1&mid=20742FE7-19B9-E0B5-D40CB19ACF2E52E7>

nonetheless have a large or a small budget impact when implemented through the respective Quality Standard.

#### 4 Who is involved in developing Quality Standards?

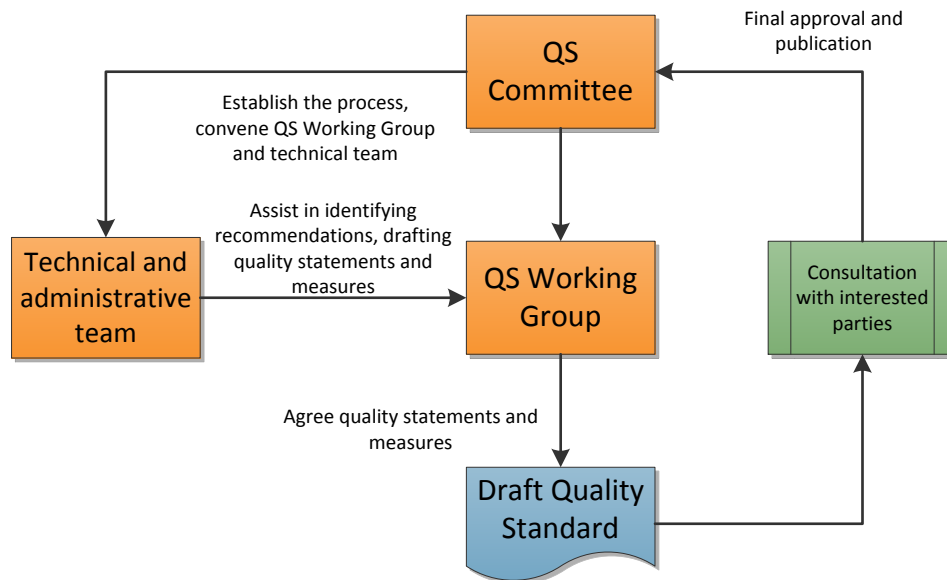
Several groups contribute to developing a quality standard, each with distinct areas of responsibility. Altogether these groups combine the policy, medical, technical and administrative inputs (inclusive participation) that the QS needs. Table 2 lists the different groups, their responsibilities, and how they interact.

**Table 2. Groups involved in developing a QS, and core areas of responsibility**

Groups	Responsibilities
<ul style="list-style-type: none"> <li>Decision making committee (“QS Committee”) convened by Ministry of Health or an independent agency or a healthcare insurer, or relevant authorities (MoH/Payers/agency), responsible for regulating, signing off and overseeing the implementation of the standard, including holding the budget for implementing quality improvement</li> </ul>	<ul style="list-style-type: none"> <li>Prioritise topics and areas of improvement for QS development</li> <li>Approves/ratifies the QS</li> </ul>
<ul style="list-style-type: none"> <li>Technical and administrative team at MoH (or an independent agency or a healthcare insurer). This team can include epidemiologists/public health staff, health economist or accountants, and project managers/administrative staff</li> </ul>	<ul style="list-style-type: none"> <li>Provide technical and administrative support to the QS Committee and the working group</li> <li>Undertake epidemiological and routine data analysis, present results to committee</li> <li>Assess quality of clinical guidance for QS</li> <li>Draft QS and present to the Working Group</li> <li>Undertake budget impact analysis</li> <li>Prepare documents with the Chair of the Working Group</li> </ul>
<ul style="list-style-type: none"> <li>Working Group to develop the QS: topic experts (e.g. doctors, nurses), pharmacists, hospital managers, administrator</li> </ul>	<ul style="list-style-type: none"> <li>Guide the work of the technical and administrative team</li> <li>Help identify relevant clinical guidance as source documents for the QS, and selects recommendations</li> <li>Review and finalise draft QS</li> <li>Respond to consultation comments</li> </ul>
<ul style="list-style-type: none"> <li>Broader interested parties who may offer their input through consultation (but do not sit on the QS Committee). These can be professionals and/or patient groups.</li> </ul>	<ul style="list-style-type: none"> <li>Review the QS agreed by the Working Group</li> </ul>

The relationship between the various groups involved in QS development is illustrated in Figure 4.

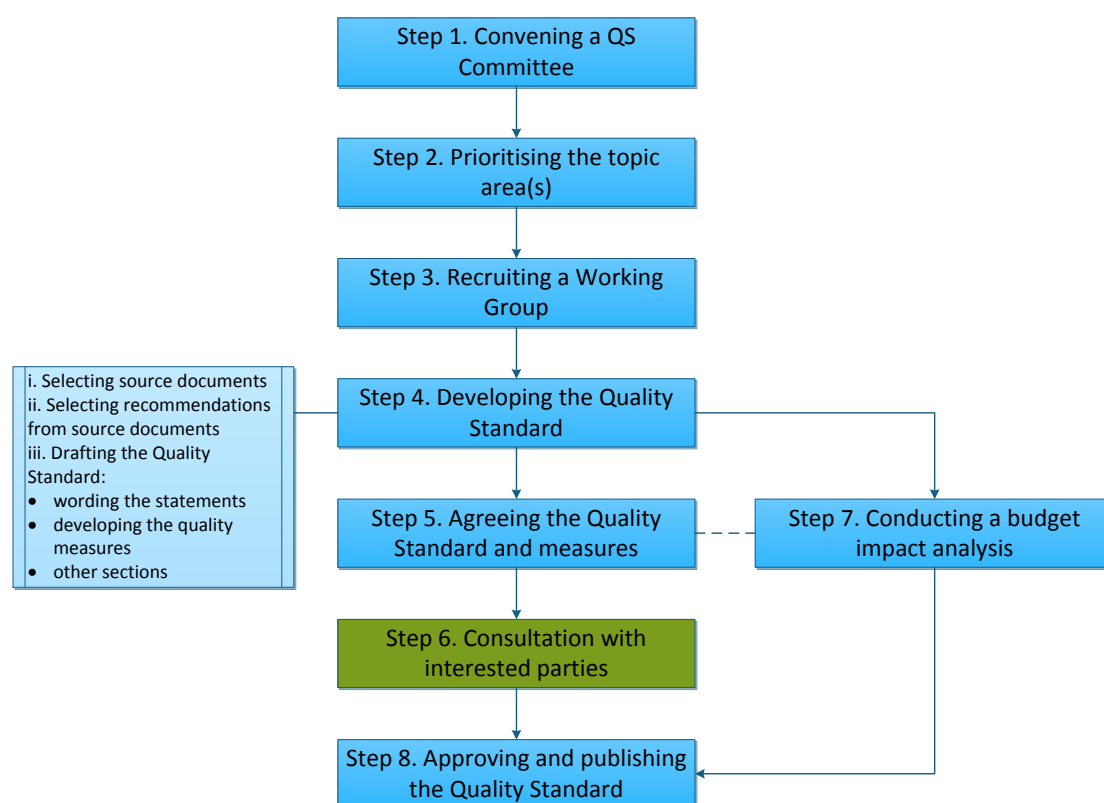
**Figure 4. Links between the different groups involved in the QS development**



## 5 Process for developing and approving a Quality Standard

Developing and approving a Quality Standard goes through a number of steps and distinct but interlinked activities with the various groups involved in some way throughout the process. Timelines may vary but should not take longer than 6 months to keep the momentum. Figure 5 shows an overview of the process and timing. This is indicative and will vary depending on individual circumstances.

**Figure 5. Overview of the Process for developing a Quality Standard**



### 5.1 Convening a QS Committee (Step 1)

Quality Standards are aimed at improving the quality of care and have implications for those that deliver the relevant services, as well as those responsible for planning and financing these services and for setting regulatory mechanisms. Often, responsibility for the planning, financing and regulation of services falls on the Ministry of Health, social insurance agency (national or provincial), or on the health insurer who will have to establish a mechanism to approve the published Quality Standards, oversee their implementation and measure performance. Ministries of Health and payers may also be involved upstream, in selecting the topics for Quality Standards, 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). The role of the QS Committee will be a) to identify and select the topic for developing the QS and 2) to approve the QS developed by the Working Group (see 5.5). If a committee or similar group already exists with responsibility for quality of care, it can take on the additional task of overseeing the development and implementation of Quality Standards. Alternatively the responsibility may be



devolved to an independent agency mandated to develop QS on behalf of the Ministry (or payer).

Whatever the model, members of the QS Committee should be familiar with quality improvement issues and understand the benefits of QS 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). Appendix 1 shows selected slides that can be used as initial training for the QS Committee and also for the QS Working group (5.3). It would be desirable for the QS Committee to have membership from a broad range of interested parties. These may include: policy makers, health insurers, professional groups (hospital or primary care), health managers, health information specialists, health economists, accountants as well as service users/patients.

## 5.2 Prioritise the topic area(s) for the Quality Standard (Step 2)

Selecting the topic to develop a Quality Standard forms an important part of the process, because limited resources in a health system should be prioritised in areas where improvement gains in terms of patient outcomes and efficiencies are likely to be greatest. Criteria such as current poor quality or ineffective care, high burden of disease, significant regional variations in health outcomes, or problems of cost containment or cost escalation should be considered in the selection process.

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. Box 3 shows an example of this type of data.

### Box 3. Example of data used for selecting topic for a QS on stroke in Vietnam<sup>18</sup>

"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.*

<sup>18</sup> <http://www.nice.org.uk/aboutnice/niceinternational/projects/NICEInternationalVietnam.jsp>

Local information and experience from experts will also guide this prioritisation 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. Box 4 shows an excerpt of the local data that were used to inform the topic for the Quality Standard on maternal care in Kerala<sup>19</sup>:

#### **Box 4. Example of local data obtained for the Quality Standard on maternal care in Kerala**

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/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 team supporting the QS Committee and the Working Group will collect and analyse the data, and summarise it in briefing papers that will be presented to the Committee for discussion. This can be conducted through a meeting or workshop to identify one or two key priority areas which are likely to:

- have a high impact on outcomes that are important to patients
- have a high impact on patient safety
- be areas of care where there is evidence or consensus that there is variation in the delivery of, access to or outcomes of care for patients (especially

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<sup>19</sup> 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.

aspects of care that are not widely provided or not considered to be standard practice, but that are feasible)

- have a high cost impact or current high resource use (government, private and out of pocket)

At the meeting/workshop, briefing papers and other summaries of evidence can be supplemented with presentations from experts or relevant policy makers, to help focus the discussions. Table 3 shows an example of such presentations used to inform prioritisation of topic for the QS on improving maternal care in Kerala<sup>20</sup>.

**Table 3. 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>
<b>Maternal death Situation Analysis in Kerala</b>	Director of Health Services, Government of Kerala
<b>Analysis of maternal death audits</b>	Demographer, Directorate of Health Services; Government of Kerala
<b>Developing guides on maternal care</b>	Kerala Federation of Obstetricians & Gynaecologists
<b>Preventable maternal mortality</b>	Head of Dept of Obstetrics & Gynaecology, Medical College Trivandrum
<b>Why mothers continue to die: Confidential review of maternal deaths</b>	Kerala Federation of Obstetricians & Gynaecologists
<p><b>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.</b></p>	

### 5.3 Recruiting a Working Group (Step 3)

A Working Group to develop the QS should be recruited by the MoH (or the independent agency or healthcare insurer) on advice from the QS Committee. The Working Group is likely to be a topic expert group relevant to the selected topic.

<sup>20</sup> 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

However it should also involve input from key relevant interested parties, including practicing healthcare professionals from hospital or primary care settings (doctors, nurses, generalists/family physicians, pharmacists, and other relevant allied health professionals), health insurers, managers, health information specialists and also service users (patients and carers)<sup>21</sup>. Policy makers may also be involved. A workable size for a Working Group is 13–15 people. This balances the opportunity for individuals to contribute effectively with the need for a broad range of experience and knowledge.

The Working Group should have a **Chair** who will lead the discussions. The Chair does not need to be an expert on the selected topic but should have sufficient authority to help the group work collaboratively, ensuring a balanced contribution from all members, and be impartial in order to encourage constructive debate. It would be desirable for all members, including the Chair, to have some experience of guideline development at a national level. Table 4 shows the list of the QS Working Group for Kerala<sup>22</sup>.

In addition, a technical/administrative team should be recruited by the MoH (or health insurer) on advice from the QS Committee, to assist the Working Group in developing the QS. This team would ideally include a range of technical skillsets such as: developing clinical guidelines, health economics (including cost-effectiveness analysis and budget impact analysis), clinical audit, quality improvement and implementation, impact evaluation; as well as project management and logistical support.

The Working Group and the technical team should work to job descriptions specifying their responsibilities and tasks as outlined in Table 4. They should be recruited through open advertisements. Importantly, all recruited members should declare any conflict of interest they may have in becoming involved in the work. Examples of procedures for conflict of interest declarations can be found on the NICE website<sup>23</sup>.

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<sup>21</sup> 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

<sup>22</sup> 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

<sup>23</sup> <http://www.nice.org.uk/getinvolved/joinnwc/advisorybodyrecruitmentpack.jsp>

**Table 4. List of organisations and affiliations in the Working Group for the QS on 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

#### **5.4 Developing the Quality Standard (Step 4)**

This takes 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/administrative team will assist with managing the meeting and preparing briefings/papers for the group.

##### **5.4.1 Selecting source documents**

Relevant documents will 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 WHO guidelines). For international guidelines there are dedicated guidelines databases such as:

- The US National Guidelines clearinghouse: <http://www.guideline.gov/>
- The Guidelines International Network: <http://www.g-i-n.net/library>

Or guidelines produced by governments or professional organisations

- Ministry of Health & Family Welfare of India  
<http://clinicalestablishments.nic.in/En/1068-downloads.aspx>
- The Royal College of Physicians of London:  
<http://www.rcplondon.ac.uk/Pages/Results.aspx?k=guidelines>
- The American College of Chest Physicians  
<http://www.chestnet.org/Guidelines-and-Resources>

A key principle of Quality Standards is that the statements should be based on evidence-informed recommendations. The relevant guidelines or other guidance identified should comply with internationally recognised criteria (for example the AGREE II criteria (<http://www.agreetrust.org/> ) to ensure that they are of sufficient quality and have addressed issues of applicability.

#### **5.4.2 Selecting 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 QS should be developed on the diagnosis of patients with suspected stroke in a hospital emergency department, guidance on palliative care for stroke, or prevention of stroke in primary care will not be relevant. Approximately four or five recommendations from relevant guidelines may be selected for each Quality Statement out of this process.

*Note:* 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.

There is no standard process for selecting recommendations but several criteria can be used as a guide. These refer to recommendations that:

- address specific aspects of the delivery of care
- relate to patient safety
- are likely to have a large impact on patient outcomes
- are likely to have a large cost impact (cost saving) on services
- are likely to have a large impact on the most disadvantaged populations (for example tribal groups).

The searching, assessment and sifting of guidelines and selection of recommendations can be carried out by the technical team with advice from the Working Group.

### 5.4.3 Drafting the Quality Standard

Quality statements are derived from guidance recommendations where there is evidence (from data or collective experience/knowledge) that current practice does not align with the recommendations, or where there is variation in the implementation of the recommendations (See 5.2). The statements therefore cover areas where quality can be improved, and where quality statements and measures could be used to support quality improvement initiatives.

To gain time, the technical 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 statements

Each statement must specify one concept or requirement for high-quality care or service provision (for example, a single intervention, action or event). In some circumstances a statement may contain two concepts or requirements if they are closely linked (for example, treatment or service options that depend on the results of an assessment).

The statements are not a verbatim restatement of the relevant source recommendations. Statements 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 5 shows how a quality statement builds from a guideline recommendation.

**Table 5. Example of NICE recommendation and associated Quality Statement on stroke<sup>24</sup>**

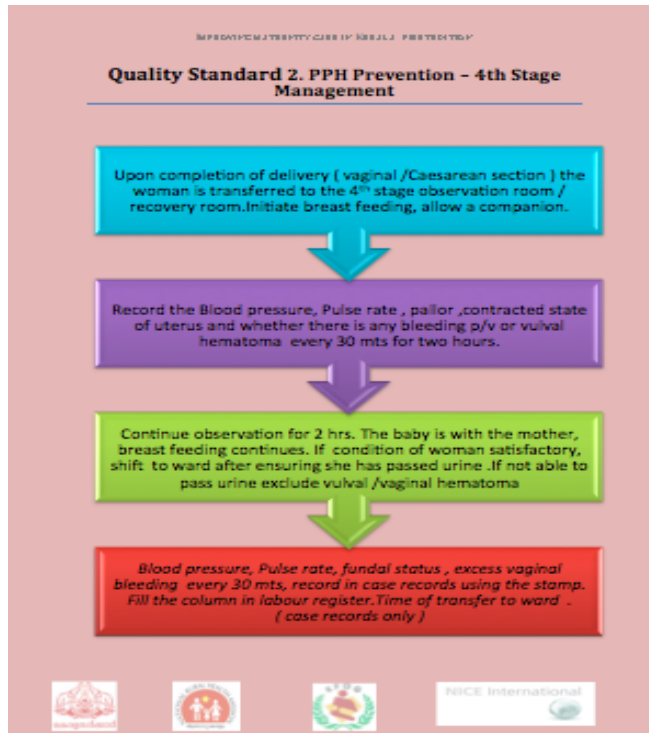
NICE Guideline recommendation	NICE quality standard
Brain imaging should be performed immediately <sup>(1)</sup> for people with acute stroke if any of the following apply: <ul style="list-style-type: none"><li>• indications for thrombolysis or early anticoagulation treatment on anticoagulant treatment</li><li>• a known bleeding tendency</li><li>• a depressed level of consciousness (Glasgow Coma Score below 13)</li><li>• unexplained progressive or fluctuating symptoms</li><li>• papilloedema, neck stiffness or fever</li></ul>	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

<sup>24</sup> <http://publications.nice.org.uk/stroke-quality-standard-qs2>

- severe headache at onset of stroke symptoms
- (1) *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.*

### Developing the quality measures

The **structure** measures list the necessary practical arrangements for implementing the Quality Standard. These arrangements should be visible and measurable (for example display of flow charts on the maternity delivery walls), as shown below.



The **process 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. Using the example of the Quality Standard in Box 4, if the 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** are also specified as a numerator, a denominator, and a proportion in the same format as process measures. Note that not all Quality Standards will include outcome measures (for example, where these are not easily measurable).



**Box 4. Example of a Quality Measure for vaginal deliveries for statement 1. Active Management of Third Stage of Labour (AMTSL)<sup>25</sup>**

**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.

<sup>25</sup> 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

### Other sections

In addition, each statement is accompanied by

- Definitions of the terms used
- Description of the implications of implementing the Quality Standard for different audiences (service providers, health professionals, payers, patients, service users, policy makers)
- The sources of data for measurement (for example registers, databases both national and local)
- The guidance used to underpin the QS (e.g. guideline from which the recommendations were sourced)
- Where relevant, specific considerations for individual groups (for example tribal or ethnic minority groups)

An example of a quality statement for PPH and hypertensive disorders of pregnancy is presented in Appendix 2.

### 5.5 Agreeing the Quality Standard and measures (Step 5)

The QS Working Group discusses the draft Quality Standard at a dedicated workshop. The technical 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 includes assessment of the quality of the guidelines used, and evidence of the relevance of the guidance to the local context. It may also include estimates of the impact of implementing the QS (opportunity costs, likely impact on services).

The technical team presents the quality statement, quality measures and the other components of the QS and each is discussed in turn. The Working Group considers the draft quality statements against the presented evidence. It may refine the wording of the statement and other components of the QS in the 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.*

This stage often leads to passionate debate as the group tackles complex issues of care practice and members express their differing perspectives. The role of the Chair is particularly critical at this stage to ensure that the debate is orderly, and that the discussions are fair and constructive so the group can achieve a consensus.

The Chair should also summarise the key points of the deliberations, and actions required, at regular intervals. These points should be recorded by the technical/administrative team in order to document how the Working Group came to specific decisions, and for future reference (for example, to defend or update the statements when new evidence arises). Excerpts of discussions that took place to agree the Statement on Active Management of Third Stage of Labour (AMTSL)<sup>26</sup> are presented in Box 6.

### **Box 6. Examples of practical issues discussed in developing the QS**

**Draft Quality Standard 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

## 5.6 Consultation with interested parties (Step 6)

Once the Working Group has agreed the QS, interested parties not previously involved in developing QS will be invited to comment on it. Interested parties could include payers, healthcare providers, pharmaceutical and devices companies, relevant professional bodies, patient and carer organisations. The aim of this consultation is twofold:

- Further refine the shortlist of draft quality standards to achieve the best combination of statements and measure
- Obtain feedback on how the quality statements and accompanying measures will work in practice (see Section 6)

This consultation can be carried out through interviews, surveys, or workshops depending on the QS topic and time available. The process needs to be closely managed, and participating parties fully informed so they understand: a) what Quality Standards are, and their objectives, and b) the purpose of their input in the consultation.

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

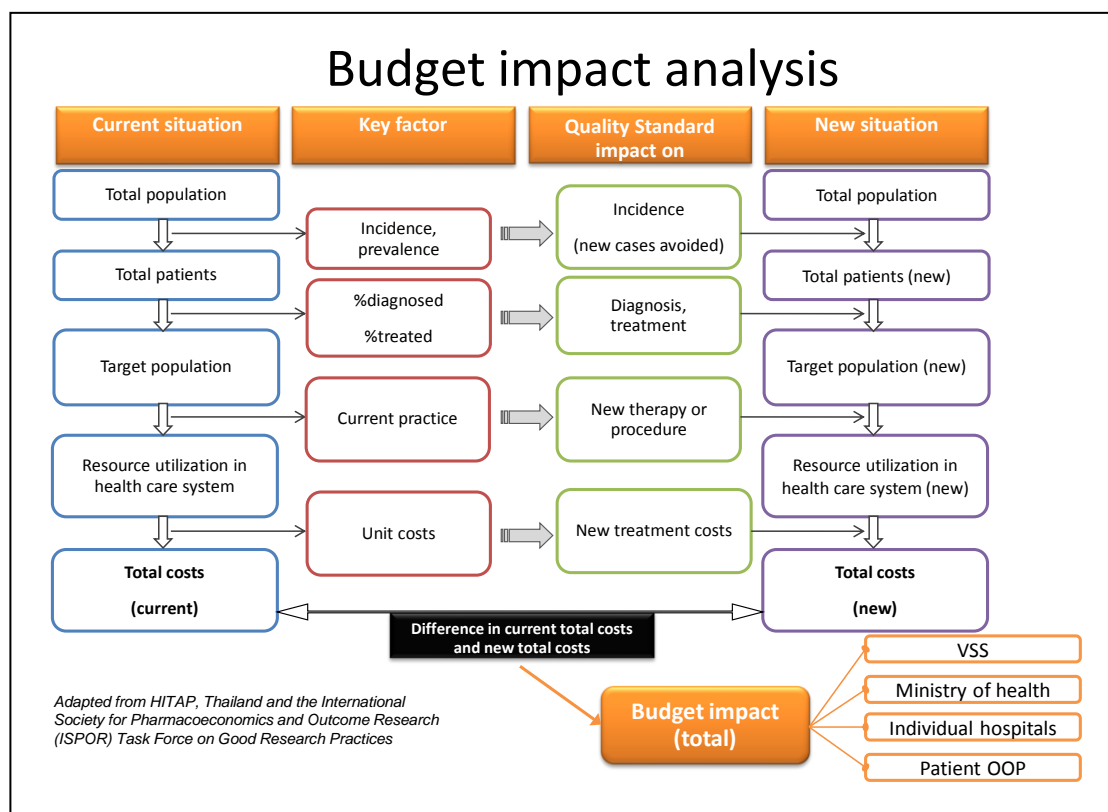
## 5.7 Conducting a budget impact analysis (Step 7)

The technical team undertakes a BIA for implementing the Quality Standard. They will consider a range of local costs related to current practice (services provided, medicines, staffing etc.), together with data on epidemiology, volume of patients, and resource utilisation. The BIA will then consider the cost of implementing the changes required from current practice to achieve the level of practice set by the Quality Standard. Figure 7 shows the different steps and components involved in the BIA. See <sup>27</sup> for an example of a NICE cost impact and commissioning assessment for diabetes in adults in England.

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<sup>27</sup> NICE cost impact and commissioning assessment for diabetes in adults, March 2011.  
<http://www.nice.org.uk/media/109/95/CostingCommissioningImpactAssessmentFinal.pdf>

**Figure 7. Overview of the stages and components of the budget impact analysis for the Quality Standard**



### 5.8 Approving and publishing the Quality Standard (Step 8)

In the final stage the QS is approved by the QS Committee. The committee will ensure that the development process for the quality standards has been followed correctly, including the QS 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 BIA carried out by the technical team.

The technical/administrative team will send for approval:

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

The Chair of the QS Working Group and the technical team should attend the meeting to answer any questions the QS Committee may have. Once the QS Committee has approved the QS, it can be published and disseminated through appropriate channels and portals. To inform the public about the publication, it may be desirable for the press to report on the publication. An example of such newspaper publication is provided in Appendix 3. Ideally, the Committee should

consider a coordinated dissemination and communication plan, working with professional associations, patient groups and the media (see below Section 6).

## **6 Preparing for implementation and piloting**

Implementing the QS will require changes in how practice is structured and delivered. This will need detailed planning and preparation. During QS development, the Working Group will discuss practical issues of implementation, as will the Committee in approving the final version. Consultation with interested parties (5.6) will also highlight potential challenges in applying the QS in practice. Finally, the BIA will highlight resource constraints (see 5.7).

There may be different models for implementing the QS. A phased implementation may be envisaged, starting with a piloting phase (for example, in a small number of hospitals within a locality) before a full roll out. This will depend on the local settings, programmes, existing quality strategy and existing quality initiatives.

The approach described below is based on the experience of implementing pilot testing the QS to improve maternal care in Kerala. The QS is being piloted in eight selected maternity hospitals (6 public and 2 private).

### **6.1 Pre-implementation tasks**

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 6 needed to be put into place for the start of the pilot implementation on 1 April 2013.

**Table 6. Core tasks and description 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 5.
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 6.
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

## **6.2 Piloting the Quality Standard**

Piloting the QS provides valuable information about its applicability in practice, allowing identification of problems not previously recognised. Feedback from pilot sites and regular follow-up are therefore 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. An example agenda of a monthly review meeting is presented in Appendix 7.



## Appendices

### Appendix 1. 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.

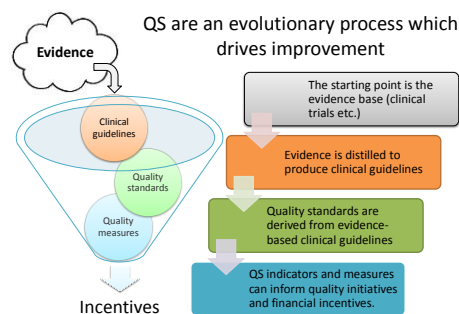
#### Quality Standards aim to improve quality and reduce variation

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

#### QS are an evolutionary process which drives improvement



#### 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

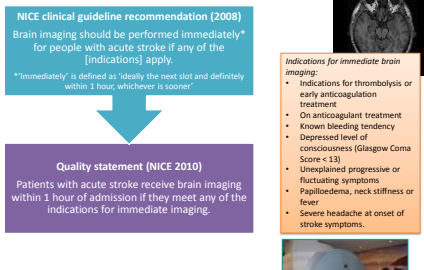
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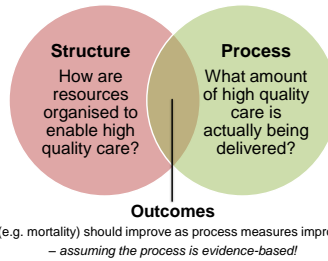
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- **Measurable**: Can be developed into **quality measures**.
- **Timeframe** is usually specified

## 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?*

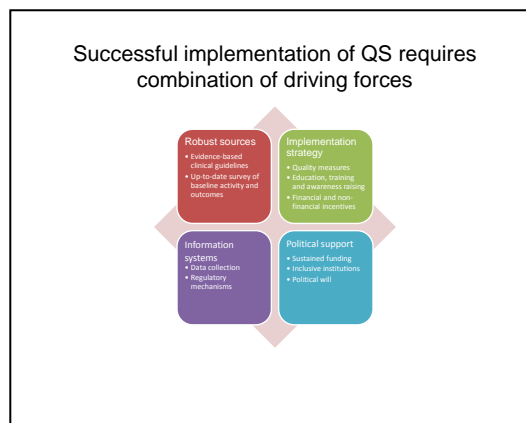
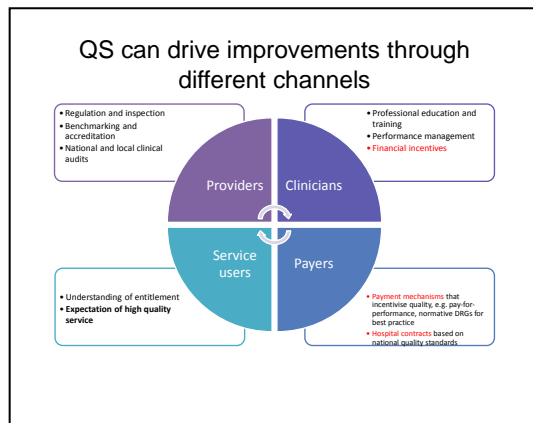
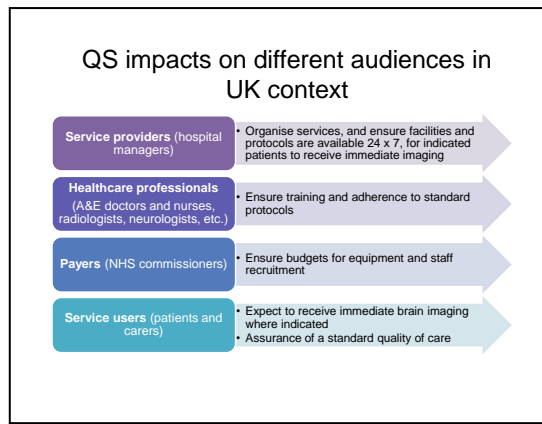
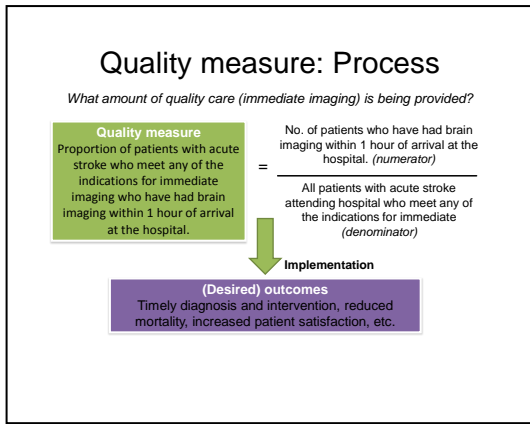
- Are there protocols or clinical pathways in the hospital for managing acute stroke, from admission to A&E onwards?
- Are brain imaging facilities (equipment and personnel) available 24x7, and organised to prioritise acute stroke patients?



## Quality measure: Process

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

$$\frac{\text{Proportion of patients with acute stroke who meet any of the indications for immediate imaging who have had brain imaging within 1 hour of arrival at the hospital. (numerator)}}{\text{All patients with acute stroke attending hospital who meet any of the indications for immediate (denominator)}}$$



## Appendix 2 Example of a Quality statement for post-partum haemorrhage and hypertensive disorders of pregnancy<sup>28</sup>

### Clinical care

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

**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

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<sup>28</sup> 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

- 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 3. Newspaper coverage of the publication of the Quality Standard for post-partum haemorrhage and hypertensive disorders, January 2012

# THE TIMES OF INDIA

## Thiruvananthapuram

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### Health dept releases clinical guidelines for maternal care

TNN Jan 16, 2013, 10:39PM IST

**Tags:** pregnant | Oommen Chandy | Health department | Anna Soubry

**THIRUVANANTHAPURAM:** The health department has set quality standards for maternal care with a focus on improving the care for the pregnant in hospitals. The move is aimed at reducing the maternal mortality.

Health secretary Rajeev Sadanandan said better management of hypertensive disorders and bleeding after delivery, highlighted as leading causes of maternal mortality in a review of maternal deaths, was the need of the hour.

The quality standards, a product of a multi-stakeholder partnership, were released by chief minister **Oommen Chandy** on Tuesday by handing over the first copy to UK parliamentary undersecretary of state for public health **Anna Soubry**. "It has been decided to implement these standards in eight maternity hospitals in the state on a pilot basis this year. These will be extended to the other maternity hospitals later."

The guidelines seek active management of labour in various stages, wherein the new mothers will be monitored for a minimum two hours for evidence of bleeding. The management of haemorrhage after delivery with blood and blood products, anti-hypertensive treatment, clinical care for haemolysis and low platelet count are among the focus areas.

#### RELATED ARTICLES

- [Maternal mortality still high in state](#)  
*July 11, 2011*
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*June 10, 2009*

#### IN-DEPTH COVERAGE

- [Health Guidelines](#)

**Appendix 4. Plan for implementing the Quality Standard for post-partum haemorrhage and hypertensive disorders of in pilot hospitals<sup>29</sup>**

Tasks	Responsibility	Dec 2012	Jan 2013	Feb 2013	Mar 2013
Orientation meeting	NRHM/KFOG	21 Dec			
Inspection of pilot maternities - Needs assessment	NRHM/hospitals				
Baseline data collection forms	NRHM/KFOG				
Reporting form and registers - design	KFOG				
Reporting form and registers - printing	NRHM				
QS editing, final proof	All	22-Dec			
QS launch	Kerala Govt/NRHM		15-Jan		
Flow charts design	KFOG				
Flow charts printing	NRHM				
Training	KFOG				
Data collection and reporting to NRHM	NRHM				
Quality standards document – design	ALL		07-Jan		
Quality standards document – printing	NRHM		12-Jan		
Human Resources	NRHM		30-Jan		
Procurement	NRHM/Kerala Govt				
Roll out to pilot maternities	All				

<sup>29</sup> 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



**Appendix 5. Example of a template for needs assessment in the pilot hospitals for implementing the Quality Standard for postpartum haemorrhage and hypertensive disorders of in pilot hospitals, Kerala, India<sup>30</sup>**

**Template**

<b>Hospital</b>	
<b>Type of institution</b> <ul style="list-style-type: none"> <li>• Medical college</li> <li>• District hospital,</li> <li>• Taluk Hospital,</li> <li>• Community Health Centre</li> </ul>	
<b>Total number of deliveries in the past 3 months</b>	
<b>Human resources</b> <ul style="list-style-type: none"> <li>• Use human resources questionnaire</li> <li>• Sara questionnaire (adapted for local use)</li> </ul>	
<b>Infrastructure</b> <ul style="list-style-type: none"> <li>• Number of labour cots</li> <li>• Space for IV stage observation Y/N</li> <li>• High dependency care Y/N</li> <li>• Fridge Y/N</li> </ul>	
<b>Equipment (functioning)</b>  <i>Specify if each of these is available</i> <ul style="list-style-type: none"> <li>• Delivery Set</li> <li>• Episiotomy kit</li> <li>• Forceps delivery kit</li> <li>• Vacuum extractor metal</li> <li>• Silastic vacuum extractor</li> <li>• Blood pressure apparatus</li> <li>• Sthethoscope</li> <li>• Cardiac monitor adult</li> <li>• Pulse oxymeter</li> <li>• Nebulizer</li> <li>• Weighing scale (adult)</li> <li>• CPAP machine</li> <li>• Head box for oxygen</li> <li>• HP meter</li> </ul>	

<sup>30</sup> 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

<ul style="list-style-type: none"> <li>• Glucometer</li> <li>• Female airway</li> <li>• Electronic Weighing scale for measuring blood loss</li> <li>• Suction apparatus (electrical)</li> <li>• Suction apparatus (foot)</li> <li>• Wall clock</li> <li>• Torch</li> <li>• Emergency call Bell</li> <li>• Oxygen supply (central)</li> <li>• Telephone</li> <li>• Autoclave drums</li> <li>• Railed cot</li> <li>• Gowns for doctors &amp; nurses &amp; mothers</li> <li>• Washable slippers</li> </ul>	
<p><b>Disposables</b></p> <p><i>Specify if each of these is available</i></p> <ul style="list-style-type: none"> <li>• Mat</li> <li>• Cord clamp</li> <li>• Dee Lee's Mucus trap</li> <li>• Neoflon (intravenous catheter) 24 G</li> <li>• Micro drip set with &amp; without burette</li> <li>• Blood transfusion set</li> <li>• 3 way stop cock</li> <li>• Suction catheter size 2.5, 3, 3.5 mm</li> <li>• Sterile gloves and drapes</li> <li>• Chemical disinfectants</li> <li>• Glucostix &amp; Multistix strips (in container)</li> <li>• Cotton, surgical gauze</li> <li>• Normal saline, 10% Dextrose infusion bottle</li> <li>• Sanitary pads</li> </ul> <p><b>Drugs</b></p> <ul style="list-style-type: none"> <li>• Ergometrine</li> <li>• Oxytocin</li> <li>• Prostaglandin F2 alpha</li> <li>• Blood products : packed red blood cells, fresh frozen plasma or cryoprecipitate and platelets</li> <li>• Labetalol (tablets)</li> <li>• Alphadopa and labetalol</li> <li>• Nifedipine</li> <li>• Labetalol (IV)</li> <li>• Hydralizine (IV)</li> <li>• Magnesium sulphate</li> </ul>	
<p><b>Documentation requirements</b></p> <ul style="list-style-type: none"> <li>• Appropriate labour register</li> <li>• Monthly return forms</li> <li>• Case notes</li> </ul>	

**Appendix 6 Data/information required for QS indicators from labour register**  
**Quality Standard for post-partum haemorrhage and hypertensive disorders of in pilot hospitals, Kerala, India**

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	<b>Quality Statement 1</b>
ergometrine Y/N	
PGF2 Alpha Y/N	
Blood loss vaginal	<b>Quality Statement 2</b>
< 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)	<b>Quality Statement 3</b>
For C-Section If more than 1000ml blood loss blood transfusion/blood products (Y/N)	
Transferred/referred to ICU Y/N	<b>Quality statement 4</b>
Acute circulatory failure Y/N	
Organ failure Y/N	
Transfusion Y/N	

Previous CS (Y/N)	<b>Quality statement 5</b>
Myomectomy (Y/N)	
Diagnosed Placenta Pravia (Y/N)	
History of hypertension during pregnancy (Y/N)	<b>Quality statement 6</b>
On hypertensive treatment (Y/N)	<b>Quality Statement 7</b>
History of albuminuria during pregnancy Y/N	
Severe hypertension immediately post-partum (Y/N)	<b>Quality statement 8</b>
CVA (Y/N)	
Eclampsia (Y/N)	
Ocular complications (Y/N)	
neurological complications (Y/N)	
Labetalol (Y/N)	
Hydralize (Y/N)	
Induction of labor	<b>Quality statement 9</b>
Magnesium sulphate Y/N	<b>Quality Statement 10</b>
<b>Observation every 30 minutes for 2 hours</b>	
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	

**Appendix 7. Example of the agenda for a monthly review meeting for the pilot implementation of the QS on maternal care in Kerala**

**Agenda**

**Review meeting on Measures to reduce Maternal Mortality rate in Kerala**

**Date : 18<sup>th</sup> December 2013.**

**Venue : KTDC Mascot Hotel, Trivandrum**

<b>Time</b>	<b>Schedule</b>
9.00 am	Registration
9.30 am	Introduction Secretary, Health and Family Welfare, Government of Kerala.
10.00 am	Activities done so far State Mission Director, NRHM
10.20 am	Presentation by KFOG
10.50 am	Tea break
11.00 am	Presentation and discussion <u>Pilot hospitals</u> 1. WC hospital 2. SAT Hospital 3. DMH Peroorkada 4. THQH Chirayinkeezhu 5. CHC Kanyakulangara 6. GH Ernakulam 7. SUT hospital 8. Mothers hospital, Thrissur
12.00 -1.30 pm	Lunch Break / Accreditation board meeting (for Members)
1.30 to 3.30 pm	Group Discussion on Upscaling of the Project