



REPORT ON NICE INTERNATIONAL'S ENGAGEMENT IN INDIA

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Submitted by Itad
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Report on NICE International's Engagement in India

Table of contents

Acknowledgements

Acronyms 4

1. Introduction 5

1.1. Overview of Theory of Change and Indicator Development 5

1.2. Overview of the Pilot Project in Kerala 5

2. Methodology 8

2.1. Overview 8

2.2. Data collection 8

2.3. Analysis 9

2.4. Limitations 9

3. Findings 11

Indicator 1: % of sampled participants that attend training events on QS held in hospitals, clinics or institutions who found that the training helped them implement the quality standard and improve their practice 11

Indicator 2: The extent to which stakeholders involved in the development of the QS perceive value in the quality standard and reasons why 15

Indicator 3: Number and type of media reports (print and electronic) that reference the pilot 18

Indicator 4: Extent of adoption of similar processes for QS development in other locations 21

Indicator 5: Number and depth of new partnerships developed by NICE International 27

Indicator 6: Publication of legislation/regulatory circular enforcing the uptake of evidence-informed technology and service adoption (or disinvestment) decisions, including evidence-informed quality improvement mechanisms 31

4. Conclusions 33

Bibliography 35

Annex A. List of stakeholders interviewed 37

Annex B. Interview guides 38

Annex C. Media reports reviewed 40

Annex D. Scale for Plotting Extent of Adoption of Similar Processes 44

Annex E: Form for classifying NICE International's partnerships 50

Annex F. Summary of classification of letters 58

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The findings within this document, however, are entirely the responsibility of the Itad team.

Acronyms

AMTSL	Active management of the third stage of labour
CP	Clinical pathway
CRMD	Confidential Review of Maternal Death
DFID	Department for International Development
FGD	Focus group discussion
FIGO	International Federation of Gynecology and Obstetrics
GoK	Government of Kerala
HPS	Health Partnerships Scheme
HTA	Health Technology Assessment
KFOG	Kerala Federation of Obstetrics and Gynaecology
KII	Key informant interview
MoU	Memorandum of Understanding
NDRC	National Development and Reform Commission
NI	NICE International
NICE	National Institute of Health and Care Excellence
N(R)HM	National (Rural) Health Mission
PPH	Postpartum haemorrhage
PS	Principal Secretary
QS	Quality standard
RCOG	Royal College of Obstetricians and Gynaecologists
RSBY	Rashtriya Swasthya Bima Yojana
STG	Standard treatment guideline
ToC	Theory of Change

1. Introduction

1.1. Overview of Theory of Change and Indicator Development

During 2013-2014, NICE International (NI) and Itad have collaborated to develop a Theory of Change for NICE International (see figure 1 below) and then develop a list of linked indicators that could be piloted to report against the Theory of Change (ToC).

The overarching Theory of Change for NI built on the country level Theories of Change that were developed for India and China, but was also designed to capture the other element of NI's work under the heading of "health diplomacy". This overarching ToC brings together the two main streams of NI's engagement and links it to the objectives of its work, unpacking the different levels from activities to longer term impact and beginning to articulate the key assumptions underlying each step.

Following development of the Theory of Change, a long list of indicators were collated which mapped to one or more elements. From this list, NICE International selected six indicators which were refined by Itad (in close consultation with NI):

1. % of sampled participants that attend training events on QS/CP held in hospitals, clinics or institutions who found that the training helped them implement the quality standard/clinical pathway and improve their practice
2. The extent to which stakeholders involved in the development of the QS/CP perceive value in the quality standard/clinical pathway and reasons why
3. Number and type of media reports (print and electronic) that reference the pilot
4. Extent of adoption of similar processes for QS/CP development in other locations
5. Number and depth of new partnerships developed by NICE International
6. Publication of legislation/regulatory circular enforcing the uptake of evidence-informed technology and service adoption (or disinvestment) decisions, including evidence-informed quality improvement mechanisms

To inform reporting on each indicator, data collection protocols were developed to guide the planning of country visits to India and China. The objectives of these visits, and associated document review, were two-fold:

- Reporting on progress of the pilot project based on the six indicators
- Piloting the data collection protocols, to inform refinement of a generic list of indicators and protocols that could be applied to any future NI country pilot project.

This report presents the findings of the India data collection process.

1.2. Overview of the Pilot Project in Kerala

The extent of NICE International's engagement in India has expanded recently, but over the last few years has been centred on a pilot project to develop a Quality Standard (QS) for reducing the maternal mortality rate in the state of Kerala. While NICE International had been engaging in Kerala in 2009, the specific pilot project started in 2012 following a meeting between NI and the Principal Secretary of Health for Kerala¹ and NI's receipt of a multi-country partnership grant from the UK Department for International Development DFID (DFID), as part of the Health Partnerships Scheme (HPS).

The QS pilot is a trilateral partnership between NI, the Government of Kerala (GoK), and the Kerala Federation of Obstetricians and Gynaecologists (KFOG), intended to help reduce maternal mortality in

¹ PMAC Conference, January 2012

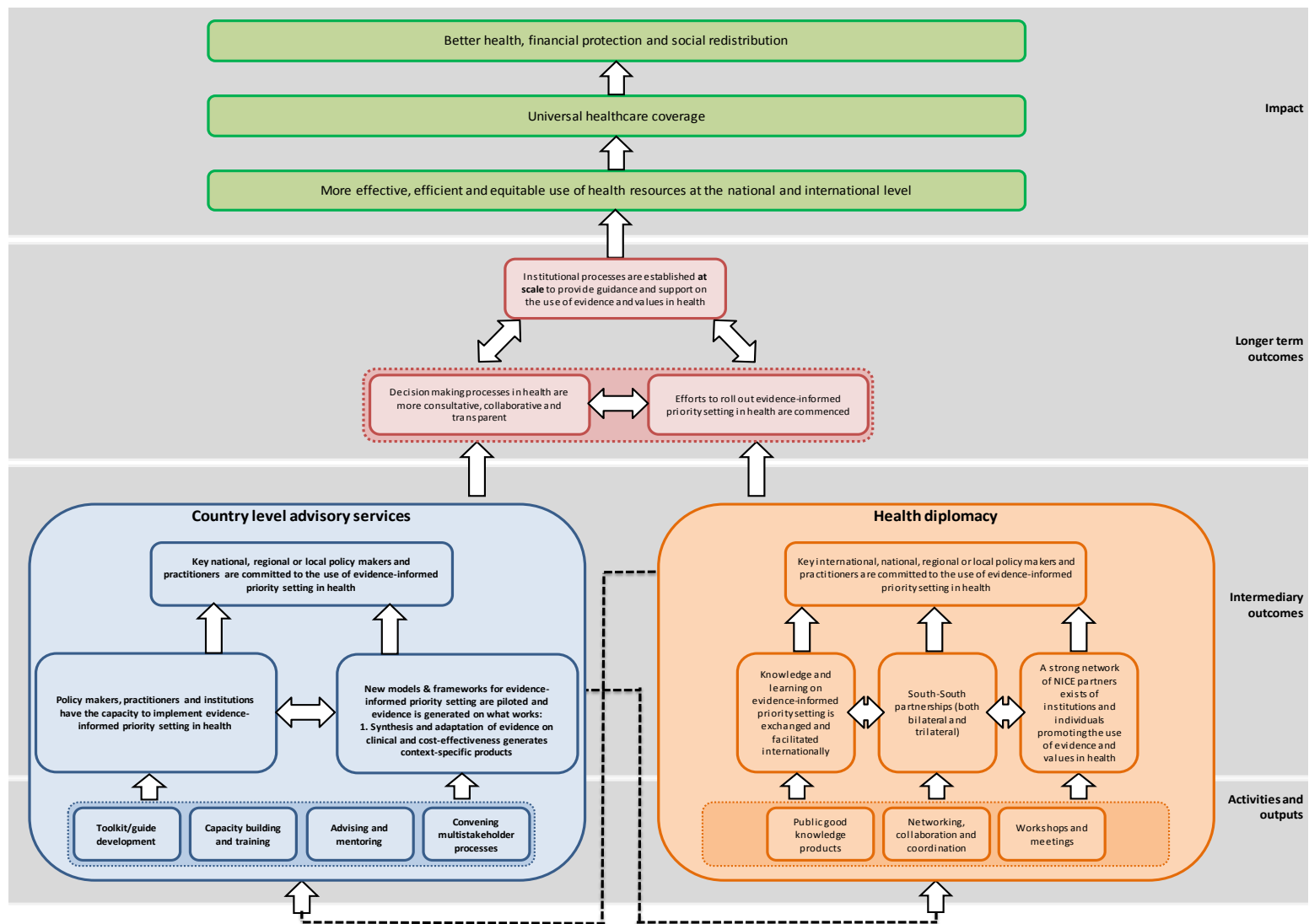
Kerala through the development and implementation of evidence-based quality standards. Although relatively low in comparison to other states in India, the maternal mortality ratio has not reduced in Kerala recently, and through its Confidential Reviews of Maternal Death (CRMD), KFOG identified the leading causes of maternal death in the state as hypertension in pregnancy and postpartum haemorrhage (PPH).²

NICE International was engaged by the state of Kerala to help facilitate the development of quality standards in order to drive improvements in maternal care. During 2012, a number of workshops were held in Kerala to develop the QS – focusing on identifying the problem and developing quality statements to address it. Multiple stakeholders from across Kerala were engaged, under the leadership of the Principle Secretary Health, and NICE International provided technical assistance to support the process. The first edition of the quality standard was launched in January 2013, and it was rolled out to eight pilot hospitals in Kerala during April 2013.³ Following approximately 18 months of implementation of the QS, this data collection process represents an opportune time to reflect on elements of the pilot project, as well other aspects of NICE International's engagement in India.

² Kerala Federation of Obstetrics & Gynaecology. 2012. Second Report of Confidential Review of Maternal Deaths, Kerala 2006 to 2009. Why Mothers Die Kerala 2006-2009, Observations. Recommendations. (Ed VP Paily, K Ambujam Betsy Thomas)

³ Community Health Center, Kanyakulangara; Taluk Head Quarters Hospital Chirayinkezhu; District Hospital Perrorkada; District Hospital Ernakulam; W and C Hospital, Trivandrum; SAT Hospital Trivandrum; SUT Thiruvananthapuram; Mother Hospital, Thrissur

Figure 1: A Theory of Change for NICE International



2. Methodology

2.1. Overview

The design of this review process, in terms of data collection and analysis, was substantively informed by the generic data collection protocol that was developed for the six selected indicators, and the India-specific protocol that was refined by the team in conjunction with NICE International. The review team were provided with documents by NICE International and conducted a preliminary document review to inform the refinement of interview questions and specific issues to be explored at country level. The team then spent ten days in India, conducting interviews in Delhi and in Kerala, as well as visiting four of the pilot facilities⁴ and attending a QS review meeting (known as an MMR meeting). A period of analysis followed the country visit, which included review of additional documentation, write-up and analysis of the qualitative data from interviews, and some liaison with the China team.

2.2. Data collection

Desk review

A process of document review commenced prior to the country visit and continued into the later phases of the assignment. The study drew upon the documents provided by NICE International, and collected further documents from key informants interviewed as well as through systematic internet searches.⁵

The documents reviewed are listed at the end of this document, but broadly consist of:

- Media reports, blogs, and journal articles (to inform findings for indicator 3)
- Letters from NRHM to stakeholders in Kerala (to inform findings for indicator 6)
- Documents related to the different elements of NICE International's work in India, such as study visit reports, Memoranda of Understanding, minutes of meetings, and emails
- Additional documents identified by the review team or provided by key informants (for example, reports on related work ongoing elsewhere in India)

For indicators 3 and 6, the documents were systematically reviewed with the use of two structured checklists; these are incorporated in annex C and annex F.

Key informant interviews

The primary mode of data collection for this phase of work was key informant interviews with stakeholders at the central level and in Kerala. The preliminary list of informants to be interviewed was selected based on consultations with NICE International, ensuring that there was representation from the various stakeholder groups:

- Stakeholders involved in the pilot project in Kerala, either in development or implementation of the quality standard
- NRHM and other government officials in Kerala
- Representatives of Government of India (GoI) and other associated organisations that NICE International is working with at a central level
- Representatives from other states who have been involved in study visits or are engaging in similar quality standard or guideline development processes
- Development partners and other organisations with whom NICE International are engaging (namely, DFID, ACCESS and the World Bank).

The list of stakeholders interviewed is incorporated as annex A. Members of the Itad team visited India for ten days during October 2014, conducting interviews in Delhi (centred on a forum convened by NICE

⁴ W&C Hospital, SAT Hospital, SUT Hospital, and CHC Kanyakulangara

⁵ For indicator 3

International and the World Bank⁶) and in Kerala. Some follow-up interviews were also conducted by Skype. In addition to the list agreed between Itad and NICE International, a degree of snowball sampling occurred during the country visit, as further relevant informants were identified or it became clear that certain informants would not be available (for example, people who had moved facilities or could not be accessed for logistical reasons).

The interviews followed one of several semi-structured interview guides which were based around the indicators (see annex B). The questions were framed according to the indicators; and specific priority issues were highlighted for each stakeholder group, given the anticipated constraints in terms of time available for interviews (particularly for government officials). All interviews were conducted by two members of the review team, and were written up comprehensively by one member.

2.3. Analysis

Following the country visit and desk review, evidence was collated against each of the six indicators – bringing together the findings of the document review with the qualitative data collected during the country visit.

The interviews were analysed according to the principles of framework analysis, which is a qualitative method appropriate to research with “specific questions, a limited time frame, a pre-designed sample (e.g. professional participants) and a priori issues (e.g. organisational and integration issues) that need to be dealt with.”⁷ The interviews were coded thematically against the six indicators. Coding of the interviews in this way allowed collation of qualitative evidence against the relevant indicators – themes could then be drawn out to generate a robust synthesis of views.

During analysis of the evidence, it became clear that reporting against the indicator bluntly, as framed, would result in the exclusion of information that might prove relevant for NICE International’s future work. The data collection process also generated some findings on the indicators themselves, and on the feasibility of the data collection protocols. To capture all of these elements, this report has been structured, by indicator, into the following sections:

- An introduction to the indicator, in terms of the information it was intended to capture, and any reflections on the indicator or process that should be considered when interpreting the findings.
- Findings against the indicator.
- Broader findings around issues related to the indicator.
- Implications of data collection process for refinement of the indicator and/or data collection protocol.

2.4. Limitations

Access to informants

Although the majority of interviews could be conducted as planned, there were some informants who could not be accessed – for example, due to scheduling availability or the fact that they had moved roles. Where feasible, the team conducted follow-up interviews by Skype, but this was not always possible. This particularly presented a challenge for indicator 1 – given the staff turnover, many of the participants in the original training were no longer at the facilities.

⁶ Better Decisions for Better Health: Priority-setting and Health Technology Assessment for Universal Health Coverage in India

⁷ Srivastava, A. & Thomson, S. B. 2009. Framework Analysis: A Qualitative Methodology for Applied Policy Research. Research Note JOAAG, Vol. 4. No. 2.

In addition, in some cases the interviewees had very limited time available and therefore it was not possible to explore all issues in significant depth, and the team had to prioritise.

Conducting focus group discussions

The data collection protocol was defined by the team in advance of the country visit, and planned for focus group discussions (FGDs) to be conducted in the facilities to explore perceptions around training, with a sample of clinicians and nurse/midwives.⁸ The team visited four sites during their visit to Kerala (W&C Hospital, SAT Hospital, SUT Hospital, and CHC Kanyakulangara), and spoke to a number of staff members; however, the methodology originally proposed had to be adapted. The number of staff on duty at any one time, and the facilities for interviews/FGDs, meant that speaking to 12 people was not possible and that taking staff away from their posts for substantial time to do a FGD was not feasible.

Privacy

In a number of cases, the interviews had to be conducted in a reasonably public forum, or in the presence of colleagues or NICE International. It was also not possible to separate clinicians and nurses as in some cases the clinicians were acting as a translator and interviews were taking place in the labour ward. The review team do not feel that this substantively affected the findings in the majority of cases; however, it might have prevented some staff members (particularly in the facilities) speaking freely about the extent to which the quality standards are being followed, or their perceptions of the training.

Further limitations specific to the indicators, and implications for future reporting, are discussed in more detail below.

⁸ The protocol planned that in each hospital, two focus groups would be conducted – one with clinicians and one with nurse/midwives, in order to maximise the likelihood that the participants were able to speak freely. The plan was to split the list of participants in the training by profession, and a random sample of 12 staff members selected from each stratum for the FGD.

3. Findings

Indicator 1: % of sampled participants that attend training events on QS held in hospitals, clinics or institutions who found that the training helped them implement the quality standard and improve their practice

The aim of collecting data on this indicator is to establish firstly the utility of the training in terms of implementation of the quality standard or clinical pathway, and secondly to establish underlying reasons, in order to inform the development of future training events.

Data collection for this indicator was intended to be in the form of focus group discussions; however, this was associated with a number of challenges and in reality, the evidence for this indicator is drawn from a combination of individual interviews with staff and group discussions on the labour ward. Most fundamentally, this meant that the planned quantification of the indicator was not possible because the way that data collection occurred in facilities did not allow for robust separation of individual responses. Secondly, it should be noted that due to staff turnover, the number of staff who actually participated in the original training and were available in the hospital was very limited. In itself, this clearly limits the value in quantification of the indicator given the small sample size, but in addition it means that distinguishing the contribution of the initial training from the ongoing implementation of the QS and capacity development is somewhat challenging. Even among those staff who had received the initial training, many reflected more on the value of *what* they had learned, i.e. the components of the QS, rather than being able to articulate elements of value in the training itself.

Findings on the indicator

The initial training provided by KFOG was universally found to be useful in implementation of the quality standard, and there have been clear changes in practice as a result of the QS and associated training.

Introductory trainings on the content of the quality standard and how to implement its recommendations were carried out by KFOG for staff in the pilot hospitals. The training sessions were interactive and hands-on, and those who attended the initial training found the sessions practical and useful. While to a certain extent, elements of the quality standard reflected care that was already being provided, in other cases the concepts were new, and the general perception was that without the initial training the pilot hospitals could not have rolled out the quality standards. The training seems to have helped to stimulate buy-in among labour room staff, by generating understanding of the changes - the rationale provided for bringing in changes in practice was well accepted by the staff who were spoken to.⁹

Whilst most of the clinicians spoken to stated that the training reiterated the knowledge that they already had or confirmed some of the practices that they were carrying out, all interviewees could identify specific changes in practice that took place following the implementation of the quality standard and all reported that this had been positive in relation to the quality of maternal care. However, it should be noted that many of the changes in practice were reported in relation to the implementation of the QS, rather than specifically as a result of the training itself. Key changes in practice following the introduction of the QS were highlighted by informants as:

- Introduction of management of fourth stage of labour, for example half-hourly measurement of pulse rates and blood pressure and monitoring of vaginal bleeding.
- The use of delivery kits.
- Greater consistency in the management of the third stage of labour and the use of oxytocin.
- The actual measurement of blood loss as opposed to subjective estimation

⁹ However, it should be noted that in some cases, this process has taken time – there has been a need to demonstrate effectiveness and safety to staff to gain buy in.

- Better record keeping – routine use of records developed for the pilot hospitals, which allowed for improved collection of data including clinical parameters.

In CHC Kanyakulangara, staff also reported that training had helped in improving confidence and that there was less tension in the labour room. In addition to changes in practice, some staff also noted specific improvements to women's outcomes. For example, one facility highlighted that there was less need for referral as a result of better management of blood loss and it was more commonly reported that bleeding had reduced as a result of the implementation of the QS, although staff did recognise that this was anecdotal rather than based on objective assessment. In W&C Hospital, the introduction of companionship during the fourth stage of labour was noted as an important development, which had resulted in both increased women's satisfaction and reduced workload for staff (in terms of monitoring the woman). However, not all facilities have the space to be able to implement this component of the standard.

The changes in practice and potential for improved outcomes listed above are broadly in line with the summary of overall pilot experience presented in the October monthly review meeting (see Box 1 for an extract from the presentation by NRHM), suggesting that the reports from those interviewed in the sampled sites are likely to be fairly representative of the wider experience.

Box 1: Excerpt from presentation at Review meeting

Plus points

- AMTSL – great achievement; universally accepted.
- 4th stage – Accepted
- MgSO₄ – More or less used
- Labour register – maintained and entered. Data collected and forwarded
- Blood loss – very low incidence of PPH

Negative points

- 4th stage companion – very seldom
- 4th stage observation – not satisfactory
- Urine protein testing – not uniformly done
- A/N classes – very few
- Not every eclampsia received MgSO₄.

(Source: Quality Standards Review meeting on 16/10/14 at Trivandrum [slides])

There has only been one batch of formal training on the quality standard, and hospital staff report a need for follow-up or refresher training.

Concerns were raised by a number of staff that the initial training was a one-off event, which has not been repeated. There is high turnover of labour room staff, especially nurses, and therefore the perception of interviewees was that there was a need for provision of “retraining, re-orientation or refresher” trainings, ongoing supervision and mentoring visits to consolidate on the implementation of the quality standards. This echoes a discussion from the monthly review meeting held in January – the minutes reflect a view that ‘retraining is required in the selected 8 pilot hospitals’.¹⁰

A training package, for example, consisting of standard training modules, training aids and a cascade plan was not developed for the pilots. The lack of ongoing formal training on the quality standards since the initial round has presented some challenges to implementation of the quality standards within the pilot hospitals, but also presents a limiting factor in terms of plans to scale up the implementation of the quality standards in additional facilities. The clear need for a training plan is widely recognised – at the point of the review team's visit, plans were at a nascent stage but there were encouraging signs of commitment from the Principal Secretary and articulation of next steps in training to facilitate scale up. Key elements of the training plans discussed at the monthly review meeting included:

- The need for both central level sensitisation of administrative staff (in order that implementation is supported) and facility level training of clinicians and nurses
- Collaboration between KFOG and the State Institute of Health and Family Welfare (SIHFW)
- The importance of hands-on training on the labour ward
- The need to minimise staff turnover away from delivery points after training has been provided

¹⁰ Minutes of the Review Meeting on Measures to Reduce Maternal Mortality Ratio in Kerala held on 28th January 2014 at KTDC Mascot Hotel, Trivandrum at 10.00 AM

The plans discussed were incredibly ambitious in terms of timescale for training and implementation; however, were very promising in terms of a shared commitment and cooperation to scale-up implementation of the quality standard from different stakeholders, most notably KFOG and different sections of the Government.¹¹

Although there has been no formalised training since the initial rollout, there are a number of ongoing capacity building processes which are functioning to continue sensitisation of staff and support implementation of the QS.

The Sree Avittom Thirunal Hospital for Women and Children (SAT Hospital), one of the eight pilot hospitals, is a teaching hospital and has taken an institutional approach to introducing the MMR quality standards. Orientation on the quality standards has been integrated into the induction programme for new interns and they are all made aware of the quality standards prior to beginning their internship programme. So far, a few hundred new medical graduates have been trained on the quality standards; however, it was reported that most of these interns will go on to postgraduate study after completing their internship and not immediately to clinical postings, therefore, it is not clear whether this training will be implemented into their clinical practice in the longer term. In contrast, the Women & Children's Hospital had no formal provision for training on the standards for new labour room staff. In this hospital, awareness on MMR standards is built organically during clinical discussions and consultations that take place between doctors and nurses in the labour room. Similarly, in SUT Hospital, new staff are sensitised on the job, through working with experienced clinicians to implement the QS.

Despite the fact that many of the current labour room staff did not attend the initial training organised by KFOG for the pilot hospitals, it was evident that the training, and ongoing implementation, continues to stimulate peer to peer discussion and broader engagement with the quality standards. This has led to labour room staff understanding why the QS interventions and recommended change in practice is necessary.

The ongoing support provided by members of KFOG is highly valued by the senior clinicians who were spoken to. Both Dr. Paily and Dr. Nair are very well regarded in their field – and key informants not only appreciated their expertise at the initial training but also their availability (by phone or at the monthly review meetings) to address queries or challenges in relation to the implementation of the standards. At monthly review meetings, a session is dedicated to discussing progress being made and the challenges faced in the implementation of the quality standards. At these meetings, Dr. Paily and Dr. Nair help identify ways forward and provide guidance to refine elements in the implementation of the standards. In the meeting observed by the review team, the discussions were open and transparent, and were focused on finding solutions to challenges and not attributing blame for non-compliance.

Findings related to the indicator

There is scope for building capacity with regards to analysis and use of data.

Registers specifically developed for the implementation of the standards were in place in all the four pilot facilities visited and are completed by one or more groups of labour room staff. However, it wasn't apparent that data recorded was always being systematically or consistently analysed to help with the compliance of standards. Every month the pilot hospitals report data to the National Health Mission in the state and there is a section in the MMR meeting where hospitals report on the statistics for their facility, but there is clear scope to strengthen the feedback loop between NRHM and facilities. Nor was it evident that clinical discussions taking place in hospitals (other than SAT) comprehensively drew upon the data to help reflect on practice; for example, even in facilities which used internal audit processes, nurses were not engaged in that dialogue. However, although this feedback loop into practice was not always in place, the importance of data seemed to be well-understood across the facilities – for example in SAT Hospital, the register is checked daily and they have an established protocol for quality assurance and ensuring

¹¹ At the time of report drafting, it is unclear what the follow-up has been to action the implementation plan.

completion and in all facilities visited, the staff could show the team the register and explain the process by which it is completed. Future trainings should continue to emphasise the importance of data, to ensure that there is universal understanding at every level of the importance of evidence-gathering and using that data to inform ongoing changes in practice.

Implications of data collection process

When people were discussing the training it was reported as useful, but it was a challenge to draw out the specific elements of value because the majority of staff reflected on the value of what they had learned, rather than the particular characteristics of the training that they found helpful. It was also difficult to separate the contribution of to the formal “training” run by KFOG at the start of the rollout of the QS, because there are also a number of ongoing capacity building processes ongoing in Kerala – most notably, the supervision, sensitisation and discussion around the QS that occurs within facilities and the ad hoc support that members of KFOG provide to pilot hospitals

The findings against this indicator do not reflect NICE International involvement, because NICE International was not significantly involved in the training run by KFOG. However, NI could use the findings to inform similar trainings that they run on their own or through partners, to supplement the huge body of literature available on training methods. The findings against this indicator seem most relevant to the design of the next phase of training in Kerala, and the implementation of any further initiatives, for example, the roll-out of the IMR quality standard.

Recommended refinements to indicator and protocol

The view of the review team is that the ongoing capacity building and diffusion processes are important to capture (given their critical role in ongoing implementation and scale-up) and therefore that the scope of this indicator is expanded to cover these, as well as formal training.

As discussed above, the planned data collection protocol was not feasible and did not allow for robust quantification of the indicator because it was not possible to separate out individual responses. Therefore, for future data collection, the team suggest discontinuing FGDs as a data collection tool and instead focussing on a combination of methods:

1. **Post-training written feedback forms**, administered at the end of the training session. These should include sections for participants to score their perceptions of the utility of the training, highlight any particular elements of value, and make recommendations on what should be altered.
- and
2. **Follow-up key informant interviews** (by phone if required), focusing on firstly, the changes in practice since the training and how training did/did not facilitate implementation, and secondly, the extent to which ongoing capacity building/mentoring is happening in their facilities.

The post-training feedback forms have the benefit of being applied closer to the point of training which will increase the potential sample size (minimising the extent of turnover) and reduce recall bias, but the opportunities for exploring how training has facilitated implementation of the QS are reduced. Conducting KII is more resource intensive but can be applied to a smaller sample, and will elicit more in-depth qualitative evidence as well as the opportunity to explore the wider capacity building and diffusion processes. Therefore, the combination of both methods is recommended.

Indicator 2: The extent to which stakeholders involved in the development of the QS perceive value in the quality standard and reasons why

This indicator aims to explore the extent to which there is perceived value in the QS processes and products, the extent to which they are embedded as a way of thinking and how the process of embedding and promoting acceptance was achieved. The intention was that qualitatively exploring these concepts and identifying the themes that emerged would allow the team to develop and refine the tools for future use and potentially reframe the indicator to allow deeper exploration of different elements of value.

The data collection for this indicator was centred on the use of key informant interviews with stakeholders who were involved in the development process. This list was defined by NI in advance of the country visits; however, what became clear was that a number of informants on that list had a more tangential role in the development process (for example, only attending one meeting or being subsequently involved in the MMR meetings). The core group of people involved in the actual QS development was actually more limited – around eight of the stakeholders spoken to, all of whom were clinicians or representatives of Government of Kerala.

Findings on the indicator

Stakeholders perceive the quality standard as a valuable tool to improve and standardise quality of maternal care, and catalyse reductions in maternal mortality in Kerala.

Improved quality of care and/or clinical outcomes through implementation of quality standards was the key area of value highlighted by almost all interviewees who were involved in the QS development process (and indeed those who were implementing it). The perceived benefits of the NICE-type quality standards, highlighted specifically by a number of the clinicians involved in the development process (although not the government representatives), is that when compared to other sources of guidance the QS is very detailed and explicit. For example, it was noted by one clinician that in contrast to text books, it does not just specify the uterotonic, it also gives the dose and route. While it was acknowledged that there may be some resistance from clinicians to this level of prescription (as opposed to the use of professional judgement), the perception of those involved in the development process was that such direction was necessary to ensure the standardisation of care. For example, a couple of informants noted that the development process had revealed that there was an unexpected variation of practice in the active management of the third stage of labour (AMTSL).

Interviewees held the view that standardisation had improved as a result of the pilots, however, it was also noted that this is not universal and this was confirmed in visits to facilities and in the MMR meeting. For example, in some pilot hospitals there is insufficient space for a companion to be present during the fourth stage of labour and, in addition, there still seems to be variation in practice around the administration of uterotonics. In one hospital visited, staff still expressed a belief in the effectiveness of Methergine over Oxytocin and in another, it was reported specifically that the process of gaining wider buy-in from, for example anaesthetists, for the use of oxytocin had been a lengthy process reliant on demonstrating that a shift in practice did not result in worse outcomes.

The QS development process was perceived as systematic and rigorous; however, much of the focus on value was centred on the end product, rather than the process itself.

When asked about the value of the QS, some of the stakeholders involved in the process were not able to elaborate on the steps of the NICE process or articulate which elements in the process were most valuable. This was a minority, but is a slight concern given their pivotal role in the QS development process. The more universal perceptions of value in the process, from those with both a greater and a lesser role in the development, appear to be linked to the output and reducing maternal mortality, rather than the intrinsic value of an evidence based QS development process. This view was echoed by the interviewees who were not involved in the QS development process (in Kerala and elsewhere) who, when asked about the value of the QS, generally emphasised its clinical value – for example, its contribution to reducing PPH and improving quality of care. They spoke less about the value of the QS as a concept more generally, or of the

development process. Emphasis on clinical benefit has clear value as a tool to promote implementation and to gain buy in among staff. However, this may present a barrier to scale-up, if the QS is perceived as a solution to maternal mortality in Kerala rather than as a process which can be replicated in other geographic locations and for other conditions.

That said, most of the clinicians who were closely involved in the development process (including the three informants who seemed to be most engaged in drafting the quality statements) could clearly articulate the value of the NICE approach, in terms of use of evidence, convening of different stakeholders, and the adoption of a systematic and rigorous process. One informant particularly spoke about personal development, in terms of greater engagement with evidence and the wider literature. Moreover, in comparison to how protocols are commonly developed in India, they recognised that the NICE approach adds value by taking into account beneficiary views and by referencing other internationally accepted guidelines. They highlighted that although the QS development had been long and resource-intensive, this was necessary to ensure rigour. Out of the clinicians interviewed, most either expressed a willingness to be involved in another, similar process or were already.

In terms of the quality standard development process itself, the collaboration between NRHM, KFOG and NICE was highly valued.

The quality standard development process was a joint collaboration between Kerala Federation of Obstetrics and Gynaecology (KFOG), the Government of Kerala/NRHM, and NICE International. Whilst KFOG provided the clinical leadership, NICE provided technical support to the process and played a facilitator role. The link between NRHM and KFOG (i.e. the government and the medical profession) was perceived as vital in terms of promoting implementation, because the process was instigated not as an academic exercise but as something which was planned to be rolled out and implemented. This collaborative aspect of the process was also highlighted as innovative by stakeholders external to the process, in particular those who visited Kerala on study visits.

The brand value and expertise of NICE had a significant contribution. As an independent organisation of international repute NI was well-positioned to facilitate collaboration between KFOG and the Kerala government and to provide technical assistance in relation to the adaptation of guidelines and use of evidence. However, significantly, the development process is viewed to be Kerala owned and KFOG driven. Interviewees identified local commitment and ownership as vital to the process and are appreciative that NICE did not take a prescriptive approach. As articulated by one informant, interviewees perceived the product of the quality standard development process to be very much “made in India”.

Findings related to the indicator

This indicator was specifically framed to explore the perceptions of the people involved in the QS development process. However, a number of other informants interviewed expressed views on the value of the QS and the development group is not particularly well defined. There seems to have been a spectrum of extent of involvement, ranging from members of the core working group who drafted the QS to those who have attended a small number of meetings. While not directly relevant to the indicator as framed, the views of stakeholders not involved, or less involved, in the process do have implications for implementation and scale-up and therefore have been captured here.

Staff who are implementing the QS perceive its value to be in improvements to quality of care and observed reductions in unsatisfactory outcomes.

Although anecdotal, there is a widely-held view among the staff who were interviewed in facilities that the QS has resulted in better outcomes and improved care for women, as a result of changes in practice linked to the QS (as discussed in relation to indicator 1). It was also reported in three of the four facilities visited that they had heard of other hospitals either requesting to join the group of pilot hospitals or beginning to use the QS independently. One informant noted that this could be because association with NICE affirms quality of care, but it was more commonly referenced that the diffusion had been a result of contact between clinicians (for example, presentations by Dr Paily or professional networking) and discussions of

the benefits of using QS. In one case, implementation of the QS in an additional hospital had occurred as a result of transfer of one clinician out of a pilot facility.

As a result of perceived value in the first phase, there are nascent plans for government-led scale-up of QS implementation in Kerala.

Following the initial phase of implementation in eight hospitals, there are now plans to scale-up implementation to a second phase of approximately 25 hospitals, selected on the basis of having willing partners, sharing their data and having a high number of births. Much of the MMR meeting held in October was around planning for this next phase of rollout, including training plans and selection of the next group of facilities. Although it is unclear what the follow-up has been, the stated commitment of the administration to scale-up and making it “part of the government programme” is illustrative of the perceived value of the QS in improving both care and the quality of data available.

There are perceived challenges to ensuring universal acceptance of the value of quality standards, and an evidence-based approach to their development.

Many of the challenges to the robust development and use of QS in India that were identified by stakeholders were linked to external perceptions of value of the product and the evidence-based approach. It was most commonly highlighted that there is likely to be some resistance by the wider medical profession as QS are perceived as replacing professional judgement, and that there is some uncertainty about the need for new evidence-informed QS, given the existence of Government of India and other standards. Linked to the latter point, some stakeholders noted that the process might be considered too long and costly and a minority of people referenced that this could lead to the undermining of some principles of an “evidence-based” approach. The value of the involvement of patients or other stakeholders was referenced by around half of the informants interviewed in Delhi, but it was noted that this is not currently routine, and would require a shift in thinking among some groups, as well as a strengthening of patient associations.

Implications of data collection process

The indicator is framed around the value of the product itself, which results in an emphasis on the clinical aspects of value, particularly when the informants are primarily clinicians. While this may be useful from an implementation point of view, arguably it is less relevant to understanding how to drive scale-up – i.e. how to promote an evidence-informed priority setting process more widely. There is a need to be able to explore explicitly these different elements of value.

Recommended refinements to indicator and protocol

The team suggest reframing of this indicator to explicitly consider the development process, i.e. “the extent to which stakeholders involved in the development of the QS perceive value in the quality standard *and its development process* and reasons why.” Based on this data collection process, questions could be articulated around the following elements:

- Use of evidence
- Rigor/systematic nature of the process
- Collaboration of different stakeholders
- Added value compared to existing products
- Implications for quality of care and maternal outcomes

Indicator 3: Number and type of media reports (print and electronic) that reference the pilot

The aim of this indicator is to establish the extent to which the profile of evidence-based decision making processes is being increased through media exposure.

Reports were identified through ongoing collation by NICE International and additional searches performed by the team (see Annex C), and it is anticipated that the utility of this indicator will increase over time, as the profile of evidence-informed priority setting increases in India and more in-depth analysis of trends and opinions can be done.

Findings on the indicator

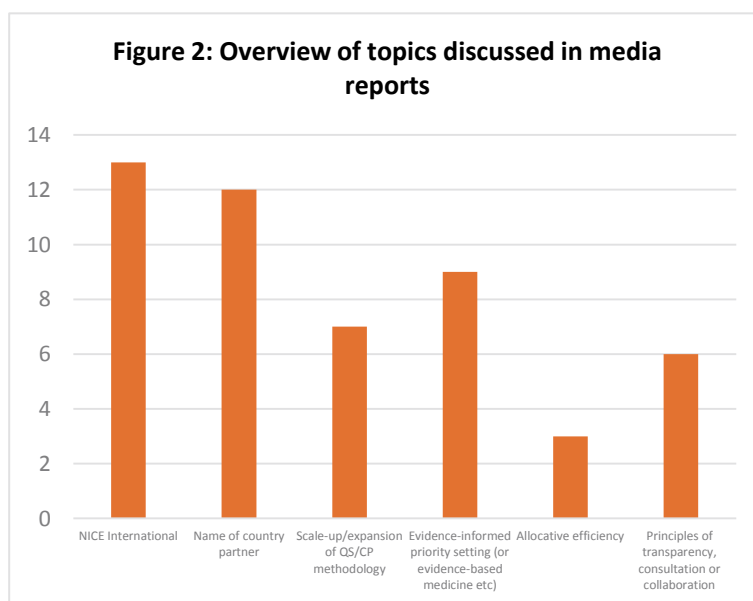
Fourteen reports were identified that referenced the pilot.

The reports identified do not provide evidence of a strong trend in increasing exposure, although there was a clear peak in the number of reports referencing the pilot in the year following its publication. Three reports were published in 2012, seven were published in 2013, and four were published in 2014.

Seven were newspaper articles (print and/or online), three were included in newsletters, and one was a blog. Out of the seven newspaper articles, one was in the Economic Times, one was in the Business Standard and the remaining five were in The Hindu. The Hindu is an English language, daily newspaper which is reported to be fairly influential in India – ‘reportage and editorials are read carefully and taken seriously in the national capital’;¹² however, it is unclear whether the articles appeared in the print edition or whether they were only available online, classified under *Kerala*, which arguably may have affected their profile at national level. It should also be noted that four of these articles were by the same journalist.

Out of the entries in newsletters/comments, one was limited to circulation in Kerala, included in “Quality Kerala” from 2014, but the other two were included on the website of the International Federation of Gynecology and Obstetrics (FIGO) and in the UK Royal College of Obstetricians and Gynaecologists (RCOG) newsletter (2014). The blog, from 2012, was written by a staff member from ACCESS. These set of reports represent some evidence of a potential increased profile, but it should be noted that the circulation of these four is arguably substantively among stakeholders who have an existing link with the pilot or with NICE International’s work – either mediated through professional networks (FIGO/RCOG), geography (the Kerala newsletter) or through the Joint Learning Network (in the case of the ACCESS blog).

In seven out of the fourteen reports, the pilot was the main subject of the report – this included three of the Hindu reports, the blog and the Kerala/RCOG/FIGO entries. All of the seven made reference to NICE International, KFOG and the benefits of the QS in relation to maternal mortality. However, while five out of the seven made reference to the use of evidence, or described the development process (for example, linked to adaptation of NICE guidelines or involvement of different stakeholders), this was generally not explored in substantive detail (with the exception of the blog). This is potentially to be expected given the nature of media reports, however. Some



¹² Encyclopaedia Britannica (<http://www.britannica.com/EBchecked/topic/266283/The-Hindu>)

reference was made to scale-up, for example, linked to contact with Odisha, the development of more maternal standards, or roll-out in more hospitals but again, this was not explored in any detail.

In the remaining seven reports, the pilot was not the main subject of the article. Three of these were newspaper reports that were centred on the visit of a UK health delegation to Kerala as part of the development of ongoing partnerships between UK and Kerala in the move towards universal health care, which also coincided with the launch of the QS. Another newspaper article was focused on the development of the IMR quality standard, but made reference back to the pilot. The remaining three were all journal articles, of which one was focused on the CRMD in Kerala, and two were discussing healthcare effectiveness research in LMIC and HTA in India. In the latter two reports, passing reference was made to the pilot project and links with NICE International in Kerala but this was not explored in detail.

Findings related to the indicator

Stakeholders involved in the QS development process have been involved in a number of the reports, either as authors or providing statements in support of the QS.

Stakeholders from the Kerala QS development process have authored or co-authored three of the reports identified, one of which was published in *BJOG* - a peer-reviewed journal.¹³ In addition to the media reports identified, participants have presented at international conferences¹⁴ or provided supportive quotes for inclusion in the newspaper articles. This is suggestive of a level of commitment to, and a belief in, the evidence-informed priority setting that goes beyond direct involvement in the QS development process.

Additional media reports discussing evidence-informed priority setting were identified, but they do not reference the pilot project and therefore are not captured in this indicator.¹⁵

For example, an additional report in the *Hindu* details the development of the IMR quality standard but does not link it to the related work on the MMR quality standard.¹⁶ A very recent article (published in October 2014) notes that “....in order to ensure patient well-being and value for money, standard treatment protocols and guidelines need to be developed; costing of procedures undertaken....” and references objectives of equity, efficiency and quality in the health system, but does not make the link to the QS work that is ongoing in Kerala and elsewhere in India.¹⁷ Both of these findings may be of concern if the implications is that different pieces of work are not seen as part of an overall movement towards increasing evidence-informed priority setting, and are seen as distinct initiatives.

Implications of data collection process

As framed, this indicator is restricted to reports that reference the pilot, resulting in some articles submitted by NICE International,¹⁸ or identified by the team, being excluded from the pool of reports. While this limits the scope of the indicator to capture scale-up, or wider dialogue around evidence-informed priority setting if the article does not also make the link to the pilot work, this restriction does make data collection substantially more feasible, because search terms can be clearly defined.

NICE International's current system of collecting reported articles does not seem to systematically capture all relevant articles, as revealed by the fact that the searches performed by this team identified additional articles. It should also be noted that, as currently articulated, the data collection protocol is not likely to identify media reports that are not text (for example, video reports). This is a limitation of the current protocol.

¹³ Paily, V.P. et al. 2014. Confidential review of maternal deaths in Kerala: a country case study. *BJOG*, 121 (Suppl 4): 61-68.

¹⁴ For example, the Guidelines International Network (G-I-N) conference on “Measures to Reduce MMR in Kerala”

¹⁵ Note that there are also additional reports produced by NI staff,

¹⁶ Maya, C. State to pilot norms to reduce IMR. *The Hindu*

¹⁷ Rao, S. For public health as political priority. *The Hindu* <http://www.thehindu.com/opinion/lead/for-public-health-as-political-priority/article6493944.ece>

¹⁸ Maya, C. State to pilot norms to reduce IMR. *The Hindu*

Recommended refinements to indicator and protocol

This analysis process revealed the need to refine the classification tool (see annex C) further, to ensure consistent rating of the reports. In particular:

- **Tone:** The criteria for rating is as “positive”, “negative” or “unclear” need to be defined further. In many cases, the reviewer found that the article was more descriptive, rather than falling naturally into any of these categories. In this case, it was marked “unclear.” For the next phase of data collection, it is suggested that the criteria are revised to “positive” (defined as at least one mention of a specific benefit of the QS, for example linked to improved patient care or outcomes), “negative” (mention of risks or downsides to QS development or implementation), “unclear” (both positive and negative points raised), and “descriptive.”
- **Subjects:** In many cases, the subjects were alluded to or described but not explicitly referenced; for example, there might be references to the involvement of stakeholders without explicit consideration of “collaboration.” The approach taken during this process has been more inclusive, based on an understanding of the principles; however, there may be a need to refine this over time. Similarly, once it becomes clear what the “evidence-informed priority setting” process will look like in a country, there may be utility in defining more granular criteria.

Systematic monitoring of this indicator will require resources to be allocated, either to media tracking tools, Google alerts, or regular systematic searching according to defined search terms.

Given the stated rationale for collecting data on the indicator and the evolving nature of NICE International’s engagement in India, the team also recommend that NICE International consider expanding the indicator. For example, rather than a focus solely on reports that reference the pilot, the scope could be expanded to incorporate additional components of NICE International’s engagement at the central level in India, for example, their work on Health Technology Assessment (HTA).


Indicator 4: Extent of adoption of similar processes for QS development in other locations

This indicator aims to capture the extent to which evidence-informed priority setting is taken up more widely following the initial pilot – i.e. the use of adapted NICE methodology to develop quality standards or clinical pathways in other geographical areas. In some cases, this may be in the form of replication of the entire methodology or development process, but more commonly, it may be adoption of specific elements of the approach. In addition to identifying instances where the QS/CP development process is already being adopted, the indicator aims to capture the early stages of wider take-up – for example, interest and engagement from stakeholders in other locations, in order to understand how scale-up happens over the longer term.

Findings on the indicator

The table below presents an overview of the different types of scale-up which are occurring. Further details are presented in the text below, and in annex D.

Figure 3: Overview of adoption of similar processes in India

Phase	Interest	Early engagement	Scoping	Initiation of development	Product finalisation	Product implementation
Type of scale-up	Phase reached and supporting evidence					
Development of new QS/CP for focal condition within focal location					Maternal mortality QS in Kerala	
Development of QS/CP for new condition within focal location	Antenatal care QS in Kerala				Infant mortality QS in Kerala	
Development of QS/CP for focal condition in new location						
Development of QS/CP for new condition in new location	QS in Bihar	QS in Odisha		Development of clinical pathways by RSBY 		Development of standard treatment guidelines in Karnataka

There is evidence of product finalisation of new QS for maternal mortality in Kerala.

In Kerala, following on from the completion of the original MMR quality standard for PPH and hypertension, KFOG have developed additional standards for sepsis and amniotic fluid embolism as an adjunct to the original product.¹⁹ However, the extent of implementation is not clear, because some stakeholders expressed the need for additional standards for these conditions, and in terms of comments on implementation and training, the emphasis was on the original QS. What should be noted is that the work on expanding the QS was very much KFOG-driven, with little or no NI involvement, based on a perceived need and identification of these conditions as additional priorities for quality standards. This is

¹⁹ Minutes of the Review Meeting on Measures to Reduce Maternal Mortality Ratio in Kerala held on 28th January 2014 at KTDC Mascot Hotel, Trivandrum at 10.00 AM

good evidence that there has been an increased capacity to develop evidence-informed products as a result of the pilot.

Product finalisation of a new quality standard for a new condition is underway in Kerala.

In terms of development of quality standards for new conditions in Kerala, the key element of scale-up has been the work on the infant mortality quality standard that is being undertaken by the National Health Mission Kerala in collaboration with the state branch of the Indian Association of Paediatrics and ACCESS.²⁰ At the time of data collection, the process of quality standard development was reported to be near completion, with the publication date set for Children's Day on 14th November.²¹

NICE International have not been involved in the QS, beyond the fact that the representative of ACCESS also collaborates closely with NICE International in other areas. It is evident the process has adopted a similar overall approach to the quality standard development – for example, several working groups and committees of key stakeholders were convened, NICE quality statements were adapted, and where required, evidence has been reviewed to underlie statements. A KFOG representative from the focal QS was also involved in the IMR QS development process; however, the IMR group did not have access to the NICE manual for MMR development until a very late stage in the process and it is therefore unclear the extent to which the robust 'NICE-type' methodology used for the MMR Qs was comprehensively applied. This was echoed by one stakeholder involved, who noted that the main difference to the NICE process was the rigour of the evidence review.

There was also expressed interest from the Principal Health Secretary in Kerala in extending quality standard initiatives in Kerala to include developing a QS for antenatal care. His perception was that a regimen of antenatal care is a fundamental element of maternal and child health (MCH) that is not being implemented effectively in Kerala – four appointments are needed and many women are currently only having one – and that this work could be linked to work on Primary Health that is ongoing in the state.²² While there is no guarantee of any kind of follow-up, this kind of expressed interest by a senior member of the administration is a positive sign of increasing engagement with issues of quality and evidence-informed priority setting.

Overall in Kerala, there does seem to be interest in scaling up the use of QS; however, what is notable to-date is that, while these new initiatives could be considered 'new conditions,' they are all linked to maternal and child health and to a large extent involve obstetricians (with some engagement of paediatricians). On the one hand, this allows the new initiatives to draw on the commitment, expertise and experience of clinicians who have already been involved in development of a QS and should have positive implications for quality of care. However, on the other hand, it arguably provides more limited evidence for wider buy-in, scale-up and prominence given to QS because the new process is being implemented by the same group of stakeholders.

There is some limited evidence of early interest and engagement in QS from other states in India, namely Bihar and Odisha.

In June 2014, delegations from Bihar and Odisha visited Kerala on a study visit coordinated by DFID India. The delegations were formed of representatives from the DFID Bihar Technical Assistance Team²³ (BTAST),

²⁰ ACCESS Health are an organisation that works in India to design and manage programmes to drive improvements in healthcare, for example linked to health finance systems and understanding how these systems can be applied to improve the quality of healthcare services (<http://accessh.org/india/>)

²¹ Conversations with NICE International suggest that this launch did not occur

²² Government of Kerala are working with the University of East London on defining twenty conditions for protocols, of which one is MCH – this includes developing a list of mandatory equipment and services to be provided at facilities.

²³ TASTs are subcontracted by DFID under the Sector Wide Approach to Strengthening Health (SWASTH) programme in Bihar – they provide technical support to various ministries (including health) in a range of areas, one of which is quality assurance mechanisms to improve maternal and child health outcomes.

and ten Odisha representatives from the National Health Mission and Technical & Management Support Team (TMST) among others. Objectives of the visit included “to learn from the Kerala Government, NHM and the Kerala Federation of Obstetricians & Gynaecologists (KFOG) about their experience with developing and implementation of Quality Standards to improve maternal care in maternity hospitals,”²⁴ as well as looking at the CRMD process and reflecting on the lessons for their two states. Representatives attended both a QS Review Meeting and a CRMD meeting, although logistical constraints meant that only Odisha representatives were able to visit a facility to see direct implementation.

There were a number of consistent messages from across the two states, which have implications for future scale-up processes. Firstly, one of key learning points of the study visit was linked to how the CRMD experience in Kerala could be applied in Odisha and Bihar. Follow-up interviews revealed that the CRMD has been restructured in Odisha as a direct result of the visit. Similarly, the perception of the Bihar representatives interviewed was that the main relevance of the Kerala work (and NICE International) was in the strengthening of the maternal death review in Bihar and convening stakeholders, using the strength of NICE, rather than the QS. Interviews with BTAST revealed that another of the key learning points from the study visit had been linked to the engagement of KFOG – it was clearly noted that “*they are very dedicated to what they do.*” FOGI in Bihar are perceived as being less engaged, and it is not clear that this has developed since the visit. Of note is that there were also no representatives from the Bihar government involved in the study visit.²⁵

The Odisha study visit report²⁶ in particular is very focused on the MMR quality standard and CRMD in Kerala, as opposed to more general issues around quality standards and evidence-informed priority setting – this was echoed in an interview with a TMST representative, who highlighted that the focus of the visit was on the rollout of the standard, rather than the process by which it was developed. There is reported openness in Odisha to the use of quality standards, but the perception was that the MMR QS is not directly implementable in Odisha due to differences in context (for example, greater dependency on the public sector in Odisha, and different patterns of healthcare seeking behaviour) and a lack of staff to directly replicate the model. The emphasis appears to be more on the use of NQAS and other GoI standards, and there is not a widely felt need to develop new standards; however, it was reported that Odisha see a potential role for NICE International in development of protocols (e.g. linked to ITU or NCD). Similarly, in interviews with BTAST it was noted that because Bihar are already using the NQAS²⁷ and other standards (FFHI, NABH), there is less of a place for new quality standards.

Overall, the findings from the two states are very consistent – potentially as a result of the joint study visit. Of note is that the experience of the CRMD in Kerala is seen as valuable and transferrable, and indeed there seems to have already been subsequent action to adapt the CRMD in Odisha as a direct results. This is a very positive initial step, which mirrors the early work done in Kerala – starting to consolidate a robust evidence base around the causes of maternal death. Arguably a more concerning finding is that the work on QS in Kerala is not perceived as transferable to other states– implementation of the QS as framed is not seen as appropriate given difference in context, and there is not a perceived need for QS developed according to this kind of methodology, as a result of the other standards that are already in use. This highlights the fact that the term ‘quality standard’ is variously applied in India – many of these may not be a product of a robust ‘evidence-based’ process. The reported emphasis of the study visits on roll-out and implementation of the QS may be a missed opportunity to showcase the process by which it was developed.

²⁴ Report from Bihar Study Visit to Kerala, June 2014

²⁵ The plan was that representatives from Bihar government would attend, but they cancelled at short notice.

²⁶ Report of the Odisha Study Visit to Kerala, June 2014

²⁷ National Quality Assurance System guidelines, developed centrally by the National Health Systems Resource Centre, Government of India

There is evidence that standard treatment guidelines and clinical pathways for new conditions are being developed in new locations.

At national level, Rashtriya Swasthya Bima Yojna (RSBY)²⁸ has commissioned the development of clinical pathways for seven medical conditions, drawing on the quality standards development process for MMR that took place in Kerala, and three more are planned. The objective is to bring reform in the insurance scheme and eliminate the practice of wasteful and expensive medical procedures, which may also be harmful to patients – for example, the overuse of hysterectomy. In Karnataka, as part of Arogyashree²⁹, the Suvarna Arogya Suraksha Trust (SAST) have developed standard treatment guidelines (STGs) for oncology, and plan to development STGs in six more specialties. The intention has been to develop guidelines using an approach similar to that of the NICE model in order to standardise care in participating hospitals, ensuring that patients get the highest quality care and that wasteful medical interventions were minimised.

The RSBY CP development process, while not a scale-up of the QS development, is clearly linked to the pilot project due to the relationship of NICE International with RSBY's CEO and his engagement with the issues of evidence-informed priority setting. NICE International is not directly involved in the development of the clinical pathways, although they have carried out peer review of documentation and supported the process by providing a consultant as a facilitator.³⁰ The CP development process is based on consideration of NICE and other guidelines and where necessary an additional review of evidence; however, wider stakeholder consultation with nursing professionals and patient groups is not evident and views from stakeholders suggested that there is scope for greater examination of evidence.

The development of STGs in Karnataka do not represent a scale-up of the QS development process that can be associated with the pilot, although they are an example of evidence-informed priority setting that appears to have been catalysed by links with NICE International. Early contact with NI at a conference in Chennai³¹ led to senior executives of SAST and leading doctors who are reputed and well respected in the state visiting NICE in the UK on a Joint Learning Network study tour. The strict adherence to clinical pathways and guidelines in facilities was particularly noted, as was the meticulousness taken in the development and the evidence based approach coordinated by NICE. Based on learning from the study tour, SAST decided to develop standard treatment guidelines (STGs) for conditions related to oncology, one of two specialties for which most insurance claims were made.³² More details of the STG development process are included in annex D, but of note is that the process included the formation of expert sub-committees to do background research and review existing guidance, use of a high-level steering committee to validate recommendations from the sub-committees, the linking of reimbursement to use of the guidelines, and gathering of patient feedback through outbound call centres. The guidelines were piloted for two months to address any issues arising in relation to implementation and in February 2014 were rolled out officially in all 42 hospitals – they are now standard practice state-wide in Karnataka. Following nine months of implementation, there are plans to start monitoring outcomes and carry out before and after evaluations. Moreover, SAST has begun a similar process to develop standard treatment guidelines for neurosurgical interventions and has plans to do so for all the six specialties it covers. There is

²⁸ RSBY (Ministry of Labour) is a government health insurance scheme for the poor and is headed by Rajeev Sadanandan, who previously was Principal Health Secretary, Ministry of Health Kerala and instrumental to the engagement of NICE International in QS in Kerala.

²⁹ Arogyashree is a Government of Karnataka health insurance scheme for families living below the poverty line and provides treatment of major ailments that require hospitalization and surgery. Suvarna Arogya Suraksha Trust (SAST) is an autonomous institution that was specifically set up by the ministry to run Arogyashree, which relies on a public private partnership model. SAST has MoUs with 150 hospitals, of which 26 are government.

³⁰ The development of the clinical pathways is being steered by the Federation of Obstetricians and Gynaecologists, India (FOGI) with additional technical support from Federation of the Indian Chamber of Industries.

³¹ 7th forum of government sponsored health insurance schemes in India, a joint World Bank and DFID sponsored event

³² The other area was cardiology; however, at the point of initiation of the development process, the state of AP were developing guidelines in this area, so Karnataka chose oncology.

reported confidence from the two informants spoken to that having had experience, the process will become easier to initiate and manage.

Overall, while neither of these processes represent true 'scale-up' of the pilot, they are examples of the scale-up of components of the evidence-informed priority setting processes – i.e. involving at the very least, use of stakeholder committees, review of some evidence, and adaptation of existing guidance. In the case of Karnataka, there is also promising evidence of explicit consideration of patient views, which was the only example identified the team, although a number of stakeholders referenced its importance.

Findings related to the indicator

External perceptions of the replicability of the Kerala QS development process are mixed, and may represent a barrier to future scale-up.

A number of stakeholders interviewed noted the specifics of the context in Kerala as vital to the success of the QS development and its implementation – particularly, the comparatively better health system in Kerala, the availability of data on causes of maternal death, and the drive and engagement of KFOG and other key stakeholders.

In terms of the Kerala context, there was a perception that it is quite different to that of other states in terms of its health system and progressive history – *“Instead of building monuments, they laid the foundation for the health system”.....“you can't say because it's been successful in Kerala that it will be successful elsewhere.”* It also has a different pattern of healthcare seeking behaviour than some other states, in that the vast majority of women deliver in health facilities.³³ Therefore, while on one hand, Kerala could be considered a model for other states, conversely success in Kerala is not always seen as any kind of signal that a similar process could be applied elsewhere, for example a state like Bihar.

Similarly, it was noted that there are some clearly identified primary causes of maternal death (and good data to support this) in Kerala – some stakeholders expressed concern that the QS development process could not be as easily applied to other conditions where either there was less data (this was highlighted by a number of stakeholders), or there were more diverse causes of death (one informant expressed this as a concern in relation to the IMR QS). However, conversely, some stakeholders perceived the development process as highly replicable – for example, stakeholders from Karnataka noted that processes become more streamlined as more guidelines/QS are developed.

Many interviewees described the engagement of KFOG and other key personalities³⁴ as particularly critical to the success of the QS process in Kerala, and some expressed concern that this would not be replicated elsewhere, for example in states or clinical areas where the professional bodies have less of a presence, or there is less of a commitment from the administration - *“it remains personality driven unless it is institutionalised.”*

To stimulate scale-up, there is a need to generate increased demand and capacity for evidence-informed priority setting at every level.

Although there are a number of activities related to quality, quality standards and use of evidence, ongoing at different levels in India, the overall perception from stakeholders in Delhi that discussed this issue was that evidence-informed priority setting is at a fairly nascent stage in India. There are clear champions, but still a need to generate more widespread demand at every level. For example, from the perspective of clinicians, it was reported that there is not a universal felt need for guidelines or QS to replace individual professional judgement.

³³ Kerala has 99.4% institutional delivery (from SRS 2012) compared to India average of 73.1% (http://www.indiaenvironmentportal.org.in/files/file/mdg_2014%20India%20country%20report.pdf)

³⁴ For example, Shri Rajeev Sadanandam

Most of the interviewees at the central level had been exposed to the NICE approach of quality standard development, either through study visits to Kerala, study visits to NICE, or contact with NICE International. They pointed to the strict adherence to process, its rigor, transparency, the evidence based approach to prioritisation, consideration of cost-effectiveness, and patient involvement as key learnings. At the central level more generally, the issue of quality was reported to have become prominent in wider circles, but there are perceived challenges around the rigour required to generate products and some people noted that there is a lack of capacity that needs to be addressed. Interviewees made various suggestions for stimulating demand, particularly around proof of concept. For example, the utility of hearing experiences from other countries was valued, and by association NICE International were valued for their ability to convene different stakeholders.³⁵ Similarly, some people referenced the need to take both a top-down and a bottom-up approach – i.e. demonstrating proof of concept in states, while also getting central level buy-in.

There are currently various organisations (ICMR, NHSRC) developing guidelines but not a central level coordinating body. The need for a central coordinating body for evidence-informed priority setting is being addressed through the establishment of a Medical Technology Advisory Board (MTAB). Work began 1.5-2 years ago when the importance of identifying cost-effective technologies began to be recognised by government – it has not yet been established, but the target date is June 2015. There is a widespread recognition that the MTAB will need to build its role and capacity, but the intention is that it will become a NICE-type body that can coordinate and commission guidelines. There is an advisory group who are consulting on the development of the MTAB, and Ministry staff commissioned with managing its establishment went on a study visit to NICE³⁶; there is also a bilateral agreement between the Department of Health Research and NICE, but the ongoing role of NICE International in the process of establishing the MTAB is not yet defined.

Implications of data collection process

Data collection for this indicator was unproblematic in terms of methodology; however, it was vital to have oversight of the different activities prior to the country visit, in order to be able to select interviews correctly. It was generally feasible to identify the contribution of NICE International, or understand the process by which the new activity came about; however, what was difficult to draw out conclusively was the extent to which the new processes resemble “NICE-type” methodology, as per the protocol. This is a function of the fact that, as highlighted in at least one interview, there are a lot of people working on standards (and related issues of “quality”) in India, and the definition and understanding of what a quality standard is varies substantially. There is also a potential cross-over in development and implementation – for example, states may be implementing QS, but they are not necessarily standards which have been developed according to principles of use of evidence, collaboration etc. Similarly, what is not captured in this indicator is the scale-up of *implementation* of the QS – so for example, the scale-up to more hospitals in Kerala (which is planned), or the implementation of the Kerala MMR QS in other states (which is not yet occurring).

Recommended refinements to indicator and protocol

The team’s view is that there is utility in expanding the indicator:

- To include scale-up of implementation of the QS (for example, the roll-out to additional hospitals in Kerala) as illustrative of priority being given to QS at the administrative level.
- To explicitly consider other evidence-informed priority setting processes, for example, guideline development or use of HTA, rather than being framed as scale-up or QS/CP development processes.

³⁵ For example, the HTA conference where representatives from countries including China, Afghanistan and Thailand attended

³⁶ Six people went to NICE to understand its functioning

Indicator 5: Number and depth of new partnerships developed by NICE International

The rationale for collecting this indicator is for NICE International to be able to systematically monitor the work that it is doing – i.e. establishing the extent to which its various engagements develop into longer term partnerships. Health diplomacy forms a substantive component of NICE International's activities, and is a key driver of progress towards the longer term outcomes and impacts articulated in the Theory of Change. Given that forming and sustaining different partnerships is an integral part of the process of health diplomacy it is important to be able to track their development. Identifying which partnerships develop may allow NI to learn formative lessons about the factors that promote successful partnership development, in order to apply these in future. It will also allow NICE International to set targets on how they want to see certain partnerships develop over time.

The evidence for this indicator was drawn synthesised from all the key informant interviews (although, primarily those conducted in Delhi and by Skype) and a review of the documentation provided by NICE International. NICE International also provided a brief overview of their perception of the depth of different partnerships; however, this was not based on the final version of the scale and comprehensive supporting evidence was not always provided against the criteria. The result was that the interviews were less of a validation exercise than originally intended, and in some cases the classifications were amended according to the evidence that was gathered. Further details about the rationale for each classification are contained in the completed partnership scale which has been included as annex E to this report. What should be noted is that this report represents a single completion of the scale, the key utility of this indicator is in tracking development of partnerships over time.

Findings on the indicator

NICE International has twelve key partnerships in India, at different geographical scales and at different levels of maturity.

Three of the partnerships are classified as 'nascent', and these are all at state/regional level – namely the early phases of engagement with Bihar, Odisha and Andhra Pradesh. Three of the partnerships are classified as 'emerging', including the work with the Government of Karnataka, and at national level, the engagement with two parts of the Government of India – namely Department of Health Research / ICMR and the National Health Systems Resource Centre. NICE International have two partnerships which are classified as 'established' – with FRICH/FMR at the national level, and with ACCESS Health International at the more global level, given their mutual engagement in the Joint Learning Network. In terms of 'mature' partnerships, NICE International have four key relationships in India – namely with KFOG, and the Government of Kerala at state/regional level, RSBY at national level, and the World Bank at global level.

Figure 4: Overview of NICE International's partnerships in India

Nascent	Emerging	Established	Mature
<ul style="list-style-type: none"> TAST and Government of Bihar Andhra Pradesh Aarogyasri Trust TMST and Government of Odisha 	<ul style="list-style-type: none"> SAST, Government of Karnataka National Health Systems Resource Centre,³⁷ Gol Department of Health Research / ICMR, Gol 	<ul style="list-style-type: none"> FRICH and FMR ACCESS and Joint Learning Network 	<ul style="list-style-type: none"> Government of Kerala KFOG Rashtriya Swasthya Bima Yojna (RSBY), Ministry of Labour, Gol World Bank

	Nascent	Emerging	Established	Mature
State/Regional	3	1	0	2
National	0	2	1	1
Global	0	0	1	1

NICE International has a diverse range of partners in India at different levels, forged through a combination of institutional and individual relationships.

NICE International has paid significant attention to partnerships in India, albeit somewhat opportunistically. The type of partnership has been wide ranging and mixed - with a combination of individuals and institutions. These partnerships span at least five states in the country, as well as some at the centre in Delhi and some that could be considered more 'global' but that are playing out in the India context. Although most of the relationships could be considered informal at this stage, that is, without contracts or MoUs, at least three of these partnerships have been formalised in the form of MoUs.

Many of NI's partnerships in India are personality driven, built on relationships developed with individuals in leadership positions in research institutions and professional organisations, senior administrators and decision makers in state and central government departments and ministries, bilateral and multilateral donor and aid agencies and individual professionals. A critical conduit for NICE International's presence in India is the CEO of RSBY, who was previously the Principal Health Secretary in Kerala. His engagement with the issues of evidence-informed priority setting as a way to reduce MMR led to the initiation of the Kerala project and this was a key factor in the instigation of the clinical pathways for RSBY (although it should be noted that NI are not directly involved in this – they are providing more of an advisory role, for example facilitating use of UK healthcare professionals as peer reviewers).

This approach to partnerships is in line with the context in which NI is operating. The context to partnership building in India is heavily reliant on trust and relationship building, as opposed to legal and contractual frameworks. Both at individual and organisational levels, mutual respect and willingness to provide support in challenging circumstances can be a driver of deeper partnerships. The Associate Director of NI has rightly gauged the context in India and invested in relationship building with key individuals and organisations, which is highly appreciated and valued in the country.

³⁷ National Health Systems Resource Centre (NHSRC) was set up in 2007, under the National Rural Health Mission (NRHM) of Government of India. Its function is to serve as an "apex body for technical assistance". The website states that "the goal of this institution is to improve health outcomes by facilitating governance reform, health systems innovations and improved information sharing among all stake holders at the national, state, district and sub-district levels through specific capacity development and convergence models."

http://nhsrindia.org/index.php?option=com_content&view=article&id=300:organisation&catid=84:about-us&Itemid=730

NICE International's most mature partnership in India is with Kerala Federation of Obstetrics and Gynaecology (KFOG); however, it also has long standing relationships with other institutions that are working in the evidence-informed priority setting 'space' in India.

The partnership with KFOG has seen fruition with the successful development of quality standards related to maternal mortality, the pilot of standards' implementation and current plans for scale up of the standards across the state. The partnership, and in particular the trilateral collaboration with Government of Kerala, has gained significant attention country-wide, and is viewed as an example of good practice that has brought together government, a professional body and an international organisation of repute to collaborate successfully towards a common objective by providing complementary areas of expertise.

NICE International has also had long standing relationship with the World Bank in India especially through the Joint learning Network (JLN). The maturity of the partnership through the JLN led to the joint organisation of the recent Health Technology Assessment Workshop recently in New Delhi. The WB has been key to providing NICE International with leads in the country, acting as an 'on the ground' presence and opening up avenues of collaboration. Significantly, DFID India also views NI as a key UK institution which has significant technical value to offer through collaborations with counterpart Indian institutions in alignment with its strategy post-2015.

Findings related to the indicator

NICE International's engagement at the central level is part of an evolving strategy for their work in India.

NICE International's entry into India began at the state level with the pilot work; however, they have a number of emerging relationships at a more central level. It is not clear that this has been systematically planned or is part of an articulated strategy for engagement, but equally it was recognised by informants spoken to that it is difficult to have a clear strategy in India. The health sector in India is going through big changes with likely restructuring of health departments at the central level and reorganisation of institutions with introduction of new initiatives. The form of NI's future partnerships are likely to be substantively affected by the reforms to the National Health Assurance Mission (NHAM)³⁸ and the ongoing work on the creation of the MTAB, and it is unclear what shape these will take. The informants interviewed certainly saw value in NI's involvement, even if it had not yet been formalised, but relationships and choice of partners is considered important in order to be able influence – for example, one informant noted that NI *"needs to partner with a body the government would respect and draw on when they need advice."*

There are additional opportunities for NI to leverage.

Stakeholders spoken to do see value in NI mapping out its partners, and looking for additional opportunities to act as a convenor in India. For example, it was highlighted by one informant that NI could be lobbying TATA³⁹ for funding, and others highlighted the importance of south-south cooperation and NICE's value in that respect. The use of South-South collaboration and facilitating Indian contact with stakeholders from other low and middle income countries (LMICs) that are implementing evidence-informed priority, such as Thailand, is perceived as a key role and added value of NICE International in India in terms of demonstrating proof of concept and getting buy-in. It was referenced by one informant that using other countries' models is a more effective way to garner support than using examples from within India.

Some stakeholders felt that the capacity and expertise of NICE (UK) could be more effectively drawn upon to mitigate the capacity issues that NI are currently experiencing, and help maximise their ability to capitalise on current and future partnership opportunities in India.

³⁸ The National Health Assurance Mission is currently in the process of being conceptualised. It may subsume NHRM, RSBY, and other programmes; however, plans are not yet publicised

³⁹ TATA Group have trusts that support a number of causes; they were reported by one informant to be under new leadership, and therefore a potential funder (http://www.tata.com/aboutus/sub_index/Tata-trusts)

Implications of data collection process

In terms of the application of the scale tool, completing it as part of this data collection exercise highlighted some potential challenges. Most significantly, although background information was provided, as referenced above, NICE International were not able to comprehensively complete the tool prior to the visit. This was partly a function of the time taken to refine the scale; therefore, should be less of a challenge in future.

Based on a one-off completion of the tool, what this scale currently does not capture is the momentum behind a partnership – i.e. whether things are progressing or stagnant. However, this is a function of the fact that, to be truly valuable, it needs to be completed regularly, so that progression can be mapped. We see the value of this tool as a mapping exercise, allowing NI to plot its multiple different activities, and track them in a systematic fashion over time.

Recommended refinements to indicator and protocol

For future data collection processes, the team see clear value in NICE International comprehensively mapping its partnerships prior to the country visit (going beyond provision of documents which do not always represent the most up-to-date information in a changing context), so that interviews in country are used optimally to elicit the '360 view' of NI's partners and can act as a validation process, as planned.

The key value in this indicator is in plotting trends over time, so the team recommend that this classification process be repeated in 12 months. In order to ensure consistent classification over time and by different people, the tool needs some associated guidance about whether one, some, or all of the criteria need to be met to be classed in a specific category. The team suggest that meeting one of the criteria for a partnership level should be considered sufficient to allow it to be classified.

The scale can currently be applied either partner-wise, or partnership-wise, as NI may have multiple different partnerships with the same organisation. The latter is more complex to apply; however, the former would require some refinements to the tool itself (for example, removal of the categories linked to whether the partnership is bilateral, trilateral etc). The team would welcome dialogue with NI about which classification would be most useful to the organisation in monitoring its work and informing future strategy.

Indicator 6: Publication of legislation/regulatory circular enforcing the uptake of evidence-informed technology and service adoption (or disinvestment) decisions, including evidence-informed quality improvement mechanisms

This indicator is measuring longer term outcomes, aiming to capture the extent to which the institutional context is conducive to, and actively promotes through legislation, the implementation of evidence-informed priority setting in health and the extent to which NICE International and its partners has helped create this context.

What became clear during the data collection for this indicator is that a prior knowledge of the legislative environment is important to maximise the utility of the data collection phase and that many of the informants are not particularly engaged with the issues around legislation. Many of the staff interviewed were not aware of the existence or application of circulars, which made gaining relevant information from the right people a challenge. Therefore, findings for this indicator are based on the meetings with NRHM and the Principal Secretary of Health, observations from the MMR meeting, and document review.

Findings on the indicator

No legislation/regulatory circular enforcing the uptake of evidence-informed technology and service adoption (or disinvestment) decisions, including evidence-informed quality improvement mechanisms, has been published in Kerala linked to the pilot work.

This was specifically noted by representatives of NRHM. However, although no circulars have been published, five letters related to maternal health in Kerala have been circulated, of which three are explicitly linked to the pilot project (see annex F for more details).⁴⁰

These three letters (staff redeployment, training and delivery kits) make reference to implementation of the quality standard to improve quality of care or health indicators – all three were circulated in 2013 by the NRHM Director and were reported to be a result of the Mission Director's visits to the pilot facilities, which demonstrated specific needs in relation to equipment and staffing. The letters effectively provide 'permission' from Kerala NRHM for hospitals to take certain actions, such as procuring items or redeploying staff, but are not reflections of government policy, and are not necessarily associated with extra funding for implementation. It was reported by one informant that they can be hard to implement without back-up, and that there is not always any follow-up.

State-wise implementation of the QS requires a Government Order.

While the letters appear to have facilitated implementation of the quality standard (for example by facilitating procurement of equipment or staff redeployment as described below), they are not reflections of government policy, and it is reported that state-wise scale up really requires a Government Order (GO). This has not yet occurred, but there are promising signals that one might be forthcoming in the shift to scaling up the implementation of the QS and embedding it. In the MMR meeting, it was noted that "...*this is an institutionalised programme of the Department of Health and Family Welfare of Kerala,*" and there seemed to be willingness on the part of the administration to issue circulars, for example in relation to the requirement to complete data in the registers. However, what should be noted is that the GO under discussion is related specifically to the MMR quality standard, rather than any kind of broader mandate or enforcement of evidence-informed priority setting.

Findings related to the indicator

Staff redeployment occurred in some facilities linked to the implementation of the QS, but there are unlikely to be more staff made available during the next phase of scale-up.

⁴⁰ The letters relate to: Staff redeployment, Equipment and infrastructure orders, Delivery kits, Training, Maternal audit

The redeployment letter was focused on the reallocation of staff to delivery points in order to facilitate the implementation of the QS. This need was felt by a number of the facilities visited, who noted that implementation of the QS is associated with increased workload linked to, for example, the measuring of blood loss and the new labour room register. In some facilities (for example, W&C Hospital), additional staff were deployed – including in one hospital, a dedicated JPHN who was appointed specifically for measuring blood loss, weighing placentas and loading oxytocin doses. However, this was not the case across all pilot hospitals and was cited as a barrier.

Staffing levels were reported to have presented a challenge to implementation. However, what was clear is that new staff will not be made available during the next phase of scale-up to additional facilities – in the MMR meeting, when the issue of human resources was raised, it was noted that *“creating jobs is not the answer.”* The Secretary noted that almost 4000 additional posts had recently been created, and that Kerala is well-staffed in relation to other states; therefore, that implementation of the QS (including data collection) needs to be done in the context of the existing staff structure.

The use of delivery kits was highlighted as a key change in practice; however, there have been some issues in relation to supply.

The use of sterile delivery kits was commonly highlighted as a change in practice since the implementation of the QS. Procurement of these kits appears to have been facilitated through the letter, which gave hospitals permission to purchase them; however, it was noted that in one facility, supply of the delivery kits was a problem, leading to the shift to autoclaved kits. Procurement of high quality delivery kits was also raised as an issue for the scale-up process, with the need to prescribe clear specifications to get the right quality.

Implications of data collection process

As described above, the key challenge to data collection for this indicator was that the informants with the most in-depth knowledge on the development of the circulars or legislation are often the most difficult to access. Many of the interviewees (i.e. hospital staff) were not particularly engaged with the policy environment or the process by which legislation is developed, and therefore were not able to speak to various elements of the case study.

Recommended refinements to indicator and protocol

The finding that zero pieces of legislation have been published is not overly informative at this stage in the pilot process – arguably it is more interesting to understand more generally what has occurred in relation to institutionalised support from the administration to evidence-informed priority setting. To maximise the utility of this indicator in the short-medium term, it might be helpful if full scoping of the steps towards publication of legislation could be done prior to data collection – this would allow progress to be plotted, and the case study approach to be applied more comprehensively. However, this does present a challenge to generalisability of the data collection protocol, considering that the variation in legislator mechanisms across countries.

4. Conclusions

This report has substantively presented findings against the six indicators that were selected by NICE International for piloting. The indicators have varying utility for capturing the extent of NICE International's engagement in India. For example, the scale-up and partnership scales are useful tools for systematically classifying the different activities that NI and others are engaged in, but they will be most informative if applied over time, and utilised in conjunction with a situational analysis as a strategic planning tool. Indicator 6 is a blunt instrument for capturing the extent to which the legislative environment is conducive to evidence-informed priority setting – given the early stage of the pilot processes, it will be equally important to capture the stages towards publication and the extent to which there is an appetite among policy makers. While informative in many respects, reporting against the indicators in isolation also does not fully capture the scope of NICE International's engagement in India, and may present only discrete snapshots of its activities. Therefore, this conclusions section represents an attempt to draw together all of the findings, and reflect more broadly on NICE International's engagement within the evolving context of evidence-informed priority setting in India.

NICE has avoided being prescriptive about what evidence-informed priority setting in India should look like, which is welcomed by local stakeholders. Given the value that is attached to products being “made in India”, playing the role of facilitator helps garner buy-in. It is clear that NICE International are valued for their ability to convene, for example providing opportunities for South-South learning, as well as their technical expertise.

Principles of quality and allocative efficiency are clearly gaining prominence, at least in some circles, in India. However, it was evident that the principles and fundamentals of the ‘NICE approach’ are not yet pervasive, and though there might be acknowledgement amongst key stakeholders that the approach is notable, there is also a perception that the approach is not practical to implement in full in the Indian context. There could be a range of reasons for such perception, including a lack of exposure and inexperience, unwillingness to break from tradition and deep rooted practices linked to professional judgement, pressure from interest groups and vested interest, cost, and the complexity of the administrative structure in the public health system including decentralisation to state and districts levels and a myriad of policy making institutions. Breaking through such barriers to promote the use of evidence-informed priority setting processes to guide policy policymakers towards better decision making is a key challenge for both NICE International, and its champions within India (both within Government and outside).

Discussions and dialogue at senior policy making level have a clear contribution to health diplomacy and raising awareness of evidence-informed priority setting. However, to institutionalise the use of processes that rely on evidence (clinical, cost effectiveness, and multistakeholder perception) in making clinical and policy decisions requires “proof of concept” built on affordability, replicability and scalability rather than a reliance on influence through “diffusion.” Providing tools that address questions of feasibility would be a step forward and the NICE International toolkit for quality standards development confirms that direction. Significantly, the current endeavour of the Principal Health Secretary, Government of Kerala to scale up the implementation of the MMR QS across the state would be demonstration of high return on the investments made by the state in having a rigorous process mediated by NICE International, although challenges remain linked to how applicable stakeholders perceive a Kerala experience to be in other states.

It may be an opportune moment for NI to consider having a communication plan to systematically disseminate the learning and success in Kerala at the central level and in other well-resourced states, in order to fully leverage the “proof of concept” of the Kerala QS and other processes that are ongoing (e.g. development of guidelines in Karnataka). While people are aware of the pilot project, perceptions of value are linked more closely to the product and its value for reducing maternal mortality in Kerala, rather than as a demonstration of a process that is scalable and replicable elsewhere. This may partly be as a result of the emphasis in study visits (for example of Odisha and Bihar teams to Kerala) on implementation not development, and seems to be a possible missed opportunity. There could be more focus in future endeavours on communicating about the process itself, and clearly articulating how the process can be replicated in other settings or for other conditions.

It appears that, with plans for the MTAB and National Health Assurance Mission, there will be greater appetite for Health Technology Assessment and NICE International have a 'first-mover' advantage having organised the national workshop on HTA and given its existing partnerships. However, NICE International may need to commit resources to be able to fully capitalise on this, and not just rely on champions to shape future relationships with institutions and ministries, given the need to promote institutionalisation of methods and processes that inform service delivery models, programmatic reforms and health and public policy interventions. Given that NI are constrained by the parameters of the funding they receive, this in turn would require longer term commitment from donors in order to allow resources to be allocated in a more strategic way. It can be challenging to navigate the swarm of interest groups in India including individuals and organisations and ensure that resources invested in partnership building are not wasted. NICE International now has a number of relationships in India, and given the momentum that seems to be building, NI is in a position to be strategic in its outlook and investments in collaborations to contribute to longer term objectives.

There is an obvious need for capacity building on evidence-informed priority setting in India, including processes and methods for development of guidelines, quality standards or clinical pathways. NICE International could encourage its partners to come up with robust capacity building plans in both the development and the implementation of these products in order to capitalise on the early momentum that is evident in different initiatives. For example, implementation of the QS in Kerala would have benefited from a clear and articulated strategy for cascade training and roll-out. As part of the planned scale-up, training is planned for the new hospitals implementing the QS, but this could be usefully expanded to incorporate existing sites and development of a longer term strategy for sustainable capacity building.

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Annex A. List of stakeholders interviewed

Name	Role, Organisation
Delhi	
Dr Dr.Pinnegowda Boregowda	Director General, SUVARNA AROGYA SURAKSHA TRUST
Nell Druce	DFID Senior Health Adviser, Development Partnerships Hub, DFID India
Dr. Ashoo Grover	Scientist D (Medical), ICMR HQ
Dr. Kavitha	Deputy Director, SUVARNA AROGYA SURAKSHA TRUST
Dr Sandeep Kochunarayanan	Senior Consultant, NRHM
Dr Nerges Mistry	Director, FRICH
Dr Somil Nagpal	Senior Health Specialist, Global Practice on Health, Nutrition and Population,
Sireesha Perabathina	ACCESS
Dr Nagesh Prabhu	Joint Secretary, Department of Health Research
Sri Rajeev Sadanandan	CEO, RSBY
Kerala	
Dr Beena	ex Director of Mission, NHM, Kerala
Dr Ellangovan	Principal Health Secretary, Government of Kerala
Dr Jameela	Director, Health Services
Dr.V. Rajasekharan Nair	Professor & HOD Obstetrics & Gynaecology, SUT Academy of Medical Sciences; KFOG
Dr Paily	Professor of Obstetrics & Gynaecology Mother Hospital & Raji Nursing Home, Thrissur; KFOG
Dr Sakeena	
Ms Shobhana (+ 2 colleagues)	Nursing Services
Medical Officer in Charge	CHC Kuyukulangara
Gynaecologist x 2	CHC Kuyukulangara
Nurse x 2	CHC Kuyukulangara
Dr Nirmala Sudhakaran	Former Prof & Head of Department SAT Hospital (now HoD, Aleppi)
Dr Sreekala	Obstetrician, SUT
Dr Lahitha	Obstetrician, SUT
Sandya	Nurse, SUT
Dr Renuka	W&C Maternity Hospital Trivandrum
Dr Ayhsa Beegon	W&C Maternity Hospital Trivandrum
Nurses	W&C Maternity Hospital Trivandrum
Aarthi	Staff Nurse, SAT
Indira	Head Nurse, SAT
Dr Sreelatha	Head of Department, SAT
Skype	
Dr Anita Anasuya	Odisha TMST
Dr Abha Mehndiratta	Consultant, ACCESS, World Bank, NICE International
Dr Kingsuk Misra	BTAST
Dr Arunabh Ray,	BTAST

Annex B. Interview guides

Guide 1: Tool for Focus Group Discussions with training attendees

Date and time of FGD:

Names and job titles of participants:

Focus group discussion questions:

Question to be asked of all participants, and quantitative data recorded:

- To what extent has the training helped you in a.) implementing the quality standard, and b.) improving your practice?

Classification	Number of FGD participants	
	Implementing the QS/CP	Improving practice
Training was very helpful		
Training was somewhat helpful		
Training was not very helpful		
Training was not at all helpful		

Follow-up questions to explore reasons:

- Since you received the training on the quality standard/clinical pathway, what has changed about the way that you work with patients? (Please give examples)
- How has the training helped you in implementing the quality standard/clinical pathway?
- How has the training helped you in improving your practice?
- Would you suggest any changes to the training that might increase its utility?

Guide 2: Semi-structured tool for follow-up interviews with stakeholders involved in development of QS

- Name, Role, Organisation
- How and why did you first become involved in the development of the quality standard/clinical pathway?
- Please can you describe the process by which the quality standard/clinical pathway was developed? How would you describe your role and involvement in the process?
- Where do you see the value in the QS development process that was implemented with NICE? How has your view changed since you first became involved in the process, if at all? Why?
- Have you been involved in any associated processes or follow-up linked to the QS? (e.g. publications, promotional events, speaking at conferences etc)
- Where do you see the value in the final QS for you and your colleagues at _____? Where do you see the value for other stakeholders such as _____?*
- Can you describe an example where you think implementation of the QS has improved patient care?
- Would you be involved in another, similar process in future? Why?
- Would you recommend that your colleagues become involved in a future QS development process? Why?

* tailor to interview (e.g. may be government or medical professionals etc)

Guide 3: Semi-structured interview questions for establishing scale-up of QS/CP processes

Standard question to establish existence of additional similar QS/CP development processes:

Do you know of any instances where there is interest in using a similar process for QS/CP, or where a similar process is ongoing?

Illustrative follow-up questions if similar processes are identified:

- What is the subject of the new process? Where is it being implemented and over what scale?
- What stage has the engagement process reached, and over what time period has it been occurring?
- What was the stimulus for the engagement/development of the new QS/CP?

- How was contact initiated? Who by? What form did the interest take? To what extent was it proactive on the part of the interested stakeholders?
- Was there any interaction/engagement of stakeholders from the pilot process (including NICE International) with stakeholders involved in the new process? Are there plans for any interaction/engagement?
- What stakeholders are engaged in the process to-date?
- Is there any associated documentation? (e.g. MoUs, plans, budgets)
- Have funds been committed to the new process, or are there plans for funds to be committed?
- Was there any pre-existing work on QS ongoing in the location?
- Has development of a product commenced? Have there been development meetings, and what have been the outputs of these meetings to-date?

Guide 4: Data collection tool for case study approach to assessing legislation/regulatory circular

- What was the stimulus for the development/circulation of the document? (for example – was it bottom-up or top-down?)
- Who was involved in the development of the document?
- What facilitated the process of drafting of this circular or piece of legislation? What were the challenges in the process?
- What was the rationale behind the development? What changes do you expect to see as a result?
- Do you have evidence of changes already as a result of publication of this document?
- To what extent does this circular or legislation facilitate the implementation of evidence-informed priority setting? Are there any challenges, or barriers, to implementation that are not addressed by the document?

Annex C. Media reports reviewed

Media reports were sourced from those provided by NI, those cited in the latest HPS report, and additional reports identified through searches. The search terms are listed below – note that the search was expanded in PubMed given the lack of hits:

GOOGLE

(kerala AND [postpartum or PPH] AND “quality standard”)

1170 results; first 4 pages were sifted until it was clear that results were completely irrelevant.

GOOGLE SCHOLAR

(kerala AND [postpartum or PPH] AND “quality standard”)

1 result; not relevant

PUBMED

((kerala) AND quality adj standard) AND postpartum

0 results

((kerala) AND quality adj standard) AND pph

0 results

(kerala) AND postpartum

21 results – none relevant

Kerala AND PPH

1 result – not relevant

(kerala) AND quality adj standard

0 results

NICE AND kerala

11 results – 1 related, but not relevant for inclusion

The following tool was used to categorise the media reports:

What type of media was the report in?	<input type="checkbox"/> Print newspaper/magazine article <input type="checkbox"/> Online newspaper/magazine article <input type="checkbox"/> Journal <input type="checkbox"/> TV coverage <input type="checkbox"/> Online video coverage <input type="checkbox"/> Blog/social media <input type="checkbox"/> Letter/comment <input type="checkbox"/> Press release <input type="checkbox"/> Other (please specify) _____
What was the date that the report was first published/transmitted?	
What is the circulation of the media in which the report was published?	<input type="checkbox"/> Town/City <input type="checkbox"/> State <input type="checkbox"/> National <input type="checkbox"/> International

	<input type="checkbox"/> Internet <input type="checkbox"/> Other (please specify)_____
What was the length of the report?	Numbers of words/minutes (<i>delete as appropriate</i>):
Was the pilot the main subject of the report?	<input type="checkbox"/> Yes <input type="checkbox"/> No
What was the tone of the report towards the pilot?	<input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Unclear
What subjects were discussed in the report?	Please tick all that apply: <input type="checkbox"/> NICE International <input type="checkbox"/> Name of country partner <input type="checkbox"/> Pilot project <input type="checkbox"/> Scale-up/expansion of QS methodology <input type="checkbox"/> Evidence-informed priority setting (or evidence-based medicine etc) <input type="checkbox"/> Allocative efficiency <input type="checkbox"/> Principles of transparency, consultation or collaboration
<u>Please attach a copy of the report, or a link to content, if possible.</u>	

REPORT ON NICE INTERNATIONAL'S ENGAGEMENT IN INDIA

Title	Type of report	Date	Circulation	Length	Tone	Main subject	TOPICS DISCUSSED						
							NICE International	Name of country partner	Pilot project	Scale-up/expansion of QS/CP methodology	Evidence-informed priority setting	Allocative efficiency	Principles of transparency, consultation or collaboration
UK keen to partner Kerala in health care	Online newspaper/magazine article	16.01.2013	Internet	188	Unclear	No	No	Yes	Yes	No	No	No	No
Postpartum haemorrhage drastically reduced in Kerala	Letter/comment	17.10.2013	Internet	185	Positive	Yes	Yes	Yes	Yes	No	No	No	No
Clinical guidelines to achieve IMR reduction	Online newspaper/magazine article	15.07.2013	National	590	Unclear	No	Yes	Yes	Yes	Yes	Yes	No	No
Guidelines bring PPH deaths under control	Online newspaper/magazine article	16.10.2013	National	844	Positive	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Developing quality standards for postpartum haemorrhage to reduce maternal mortality in Kerala	Blog/social media	08.07.2012	Internet	690	Unclear	Yes	Yes	Yes	Yes	No	Yes	No	Yes
Developing Quality Standards in obstetric care and taking appropriate steps to avoid maternal deaths in Kerala	Letter/comment	Mar-14	Internet	500	Positive	Yes	Yes	Yes	Yes	No	Yes	No	Yes
Global comparative healthcare effectiveness research: evaluating sustainable programmes in low and middle resource settings	Journal	Mar-13	Internet	~3700	Unclear	No	Yes	No	Yes	No	Yes	Yes	No
Confidential review of maternal deaths in Kerala: a country case study	Journal	May-14	Internet	~3200	Positive	No	Yes	Yes	Yes	Yes	Yes	No	No
Health Technology Assessment in India: present status and future perspectives	Journal	Jan-Mar 2014	Internet	~3100	Unclear	No	Yes	No	Yes	Yes	Yes	Yes	Yes

REPORT ON NICE INTERNATIONAL'S ENGAGEMENT IN INDIA

Measures to reduce MMR in Kerala meeting at Shoranur; Measures to reduce MMR in Kerala – development of score card;	Letter/comment	Apr-14	State	334	Unclear	Yes	Yes	Yes	Yes	Yes	No	No	No
Guidelines evolved to reduce MMR	Online newspaper/magazine article	19.12.2012	National	860	Unclear	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
UK sees tie-up with State in health sector	Online newspaper/magazine article	16.01.2013	National	538	Unclear	No	Yes	Yes	Yes	Yes	No	No	Yes
UK Health ministers for health sector partnership with Kerala	Online newspaper/magazine article	Jan-13	National	354	Positive	No	Yes	Yes	Yes	No	No	No	No
NICE of UK to help mother and baby care	Online newspaper/magazine article	29.06.2012	National	526	Positive	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes

Annex D. Scale for Plotting Extent of Adoption of Similar Processes

Phase	Interest	Early engagement	Scoping	Initiation of development	Product finalisation	Product implementation
Description	<p>This is an early phase of the process, characterised by some level of expressed interest by stakeholders in other locations:</p> <ul style="list-style-type: none"> • Interest is expressed casually/informally • Likely to result from ad hoc contact (for example, at meetings or social events) or engagement with publications/presentations by stakeholders from focal project. • Interest may be superficial or genuine, and may or may not be followed up 	<p>Following an initial expression of interest, this phase is characterised by proactive learning on the part of the stakeholder(s), indicative of genuine interest; for example:</p> <ul style="list-style-type: none"> • Study visit to location of focal product implementation • Attendance at meeting convened by stakeholders from focal project • Request to NI or stakeholders engaged with focal product for more information • Sustained contact between stakeholders in new location and those engaged with focal product (or NICE International) 	<p>The planning phase is characterised by actions that illustrate an intention to implement a process of QS/CP development, such as:</p> <ul style="list-style-type: none"> • Plans for development of QS/CP approved • Funds for development process secured • Local human resources committed • Key stakeholders identified 	<p>This phase represents the start of the development process:</p> <ul style="list-style-type: none"> • Working group (or other committee of key stakeholders) convened • Review of existing guidance and background research conducted • First meeting of QS/CP development group held 	<p>This phase is characterised by the completion of the QS/CP product:</p> <ul style="list-style-type: none"> • Development process completed • Consultation with wider group of stakeholders may be conducted • QS/CP published • Associated publicity, for example media reports, and government statements, letters or circulars 	<p>This phase is focused specifically on the implementation of the product:</p> <ul style="list-style-type: none"> • QS/CP implemented in at least one healthcare facility • Instigation of reforms/management systems associated with QS/CP

Type of scale-up ⁴¹	Phase reached and supporting evidence					
Development of new QS/CP for focal condition within focal location ⁴²	Interest <input type="checkbox"/> Evidence:	Early engagement <input type="checkbox"/> Evidence:	Scoping <input type="checkbox"/> Evidence:	Initiation development <input type="checkbox"/> Evidence:	of Product finalisation <input type="checkbox"/> Evidence:	Product implementation <input type="checkbox"/> Evidence:
Development of QS/CP for new condition within focal location ⁴³	Interest <input type="checkbox"/> Evidence:	Early engagement <input type="checkbox"/> Evidence:	Scoping <input type="checkbox"/> Evidence:	Initiation development <input type="checkbox"/> Evidence:	of Product finalisation <input type="checkbox"/> Evidence:	Product implementation <input type="checkbox"/> Evidence:
Development of QS/CP for focal condition in new location ⁴⁴	Interest <input type="checkbox"/> Evidence:	Early engagement <input type="checkbox"/> Evidence:	Scoping <input type="checkbox"/> Evidence:	Initiation development <input type="checkbox"/> Evidence:	of Product finalisation <input type="checkbox"/> Evidence:	Product implementation <input type="checkbox"/> Evidence:
Development of QS/CP for new condition in new location ⁴⁵	Interest <input type="checkbox"/> Evidence:	Early engagement <input type="checkbox"/> Evidence:	Scoping <input type="checkbox"/> Evidence:	Initiation development <input type="checkbox"/> Evidence:	of Product finalisation <input type="checkbox"/> Evidence:	Product implementation <input type="checkbox"/> Evidence:

⁴¹ **Bold indicates generic types of scale-up; footnotes indicate the specific illustrative examples for the PPH pilot**

⁴² For example, QS linked to maternity care/PPH, in Kerala

⁴³ For example a QS for a condition other than PPH, in Kerala

⁴⁴ For example, QS linked to maternity care/PPH in a new location

⁴⁵ For example a QS for a condition other than PPH, in a new location

Overview of scale-up activities

Development of new quality standard for focal condition within focal location

- **PRODUCT FINALISATION of additional Maternal Mortality quality standard in Kerala**

Following on from the completion of the MMR quality standard for PPH and hypertension, KFOG have developed additional standards for sepsis and amniotic fluid embolism.⁴⁶ The extent of implementation is not clear though, because some stakeholders expressed the need for additional standards, and in terms of comments on implementation and training, the emphasis was on the original QS.

Development of new quality standard for new condition within focal location

- **INTEREST in developing an Antenatal Care quality standard in Kerala**

There was expressed interest from the PS in Kerala in extending quality standard initiatives in Kerala – for example, developing a QS for antenatal care. His perception was that a regimen of antenatal care is a fundamental element of maternal and child health (MCH) – four appointments are needed and many women are currently only having one – and that this work could be linked to work on Primary Health that is ongoing in Kerala.⁴⁷

- **PRODUCT FINALISATION of a Quality standards for reducing infant mortality in Kerala**

The National Health Mission Kerala has collaborated with the state branch of the Indian Association of Paediatrics and ACCESS⁴⁸ on the development of an infant mortality QS, with no direct involvement from NICE International beyond the fact that the representative of ACCESS also collaborates closely with NICE International in other areas.

At the time of data collection, the process of quality standard development was reported to be near completion, with the publication date set for Children's Day on 14th November.⁴⁹ In terms of implementation, perceptions were that the product was on the verge of being finalised and would be rolled out to a number of hospitals in the first instance.

It is evident the process has adopted methodology from the MMR initiative – for example, several working groups and committees of key stakeholders were convened, NICE quality statements were adapted, and where required, evidence has been reviewed to underlie statements. The main difference to the NICE process was reported to be the rigour of the evidence review. A KFOG representative from the MMR QS (Dr Nair) was involved in the IMR QS development process, and invited to make a presentation on the MMR quality standard development process to provide guidance, share experiences and inform the process. However, the IMR group did not have access to the NICE manual for MMR development until a very late stage in the process.

Development of QS/CP for focal condition in new location

No specific examples identified.

Development of QS/CP for new condition in new location

- **INTEREST-EARLY ENGAGEMENT in Bihar**

⁴⁶ Minutes of the Review Meeting on Measures to Reduce Maternal Mortality Ratio in Kerala held on 28th January 2014 at KTDC Mascot Hotel, Trivandrum at 10.00 AM

⁴⁷ Government of Kerala are working with the University of East London on defining twenty conditions for protocols, of which one is MCH – this includes developing a list of mandatory equipment and services to be provided at facilities.

⁴⁸ ACCESS Health are an organisation that works in India to design and manage programmes to drive improvements in healthcare, for example linked to health finance systems and understanding how these systems can be applied to improve the quality of healthcare services (<http://accessh.org/india/>)

⁴⁹ Conversations with NICE International suggest that this launch did not occur

In June 2014, a delegation from Bihar (consisting of representatives from the DFID Technical Assistance Team⁵⁰ [TAST]) visited Kerala on a study visit coordinated by DFID India. Objectives of the visit included “to learn from the Kerala Government, NHM and the Kerala Federation of Obstetricians & Gynaecologists (KFOG) about their experience with developing and implementation of Quality Standards to improve maternal care in maternity hospitals,”⁵¹ as well as looking at the CRMD process and reflecting on the lessons for Bihar. Representatives attended both a QS Review Meeting and a CRMD meeting, although logistical constraints meant that they were not able to visit a facility to see direct implementation.

There were a number of next steps and action points described in the study visit report; for example, strengthening the role of professional bodies in Bihar through a meeting with Dr Paily, rolling out Delivery Point Mentoring and the Safe Birthing Checklist, and strengthening the MDR committee at District Level. Interviews with BTAST revealed that one of the key learning points from the study visit had been linked to the engagement of KFOG – it was clearly noted that “*they are very dedicated to what they do.*” FOGI in Bihar are perceived as being less engaged, and it is not clear that this has developed since the visit – similarly, the invite to Dr Paily has not yet materialised, although this does still seem to be planned.

The perception of the Bihar representatives interviewed was that the main relevance of the Kerala work (and NICE International) was in the strengthening of the maternal death review in Bihar and convening stakeholders, using the strength of NICE, rather than the QS. In general, it was felt that because Bihar are already using the NQAS⁵² and other standards (FFHI, NABH), there is less of a place for new quality standards – instead the focus should be on the MDR. The representatives seemed very positive about potential future involvement of NICE International; however, there are no direct plans in place and it was noted that the Bihar government were not involved in the study visit.⁵³

- **EARLY ENGAGEMENT in Odisha**

In June 2014, a delegation from Odisha, consisting of ten delegates from the National Health Mission, Technical & Management Support Team (TMST) and others, visited Kerala on a study visit coordinated by DFID India. The visit was joint with the Bihar team (as described above), with similar stated objectives in relation to learning and sharing experience with regards to maternal mortality; however, the Odisha delegation were additionally able to visit facilities to see implementation.

Of note is that the study visit report⁵⁴ is very focused on the MMR quality standard and CRMD in Kerala, rather than more general issues around quality standards and evidence-informed priority setting – this was echoed in an interview with a TMST representative, who highlighted that the focus of the visit was on the rollout of the standard, rather than the process by which it was developed. Next steps articulated in the study visit report include reference to increasing dissemination of CRMD among professionals, intensifying involvement of obstetricians and gynaecologists in the CRMD through the development of a technical group of FOGSI members, proceeding with the implementation of NQAS, and providing disposable delivery kits at health facilities.

Follow-up interviews revealed that the CRMD has been restructured in Odisha as a direct result of the visit. There is also a reported openness in Odisha to the use of quality standards, although not implementation of the MMR quality standard as articulated in Kerala. The perception was that the MMR QS was not directly implementable in Kerala, due to differences in context (for example, greater dependency on the public sector in Odisha, and different patterns of healthcare seeking behaviour) and a lack of staff to directly

⁵⁰ TASTs are subcontracted by DFID under the Sector Wide Approach to Strengthening Health (SWASTH) programme in Bihar – they provide technical support to various ministries (including health) in a range of areas, one of which is quality assurance mechanisms to improve maternal and child health outcomes.

⁵¹ Report from Bihar Study Visit to Kerala, June 2014

⁵² National Quality Assurance System guidelines, developed centrally by the National Health Systems Resource Centre, Government of India

⁵³ The plan was that representatives from Bihar government would attend, but they cancelled at short notice.

⁵⁴ Report of the Odisha Study Visit to Kerala, June 2014

replicate the model. The emphasis appears to be more on the use of NQAS and other GoI standards, and there is not a widely felt need to develop new standards; however, it was reported that Odisha see a potential role for NICE International in development of protocols (e.g. linked to ITU or NCD). Funding is a limitation, as GoO will not be able to directly finance NI's work.

- **INITIATION OF DEVELOPMENT of Clinical pathways for Rashtriya Swasthya Bima Yojna (RSBY), Ministry of Labour, Government of India**

RSBY⁵⁵ has commissioned the development of clinical pathways for seven medical conditions based on the quality standards development process for MMR that took place in Kerala. Three more are planned. The objective for the development of clinical pathways is to bring reform in the insurance scheme and eliminate the practice of wasteful and expensive medical procedures, which may also be harmful to patients – for example, the overuse of hysterectomy. The development of the clinical pathways is being steered by the Federation of Obstetricians and Gynaecologists, India (FOGI) with additional technical support from Federation of the Indian Chamber of Industries. The development process is based on consideration of NICE and other guidelines and where necessary an additional review of evidence. NICE International is not directly involved in the development of the clinical pathways, but has carried out peer review of documentation and supported the process by providing a consultant as a facilitator. In addition, Dr. Paily from KFOG was invited by the Government of India to provide his expertise on the development of quality standards processes. Various sub-groups of experts representing professional bodies were formed to help with the development of clinical pathways which are to be published soon. Wider stakeholder consultation with nursing professionals and patient groups is not evident.

- **PRODUCT IMPLEMENTATION of Standard Treatment Guidelines by Arogyashree, Ministry of Health and Family Welfare, Government of Karnataka**

Arogyashree is a Government of Karnataka health insurance scheme for families living below the poverty line and provides treatment of major ailments that require hospitalization and surgery. Suvarna Arogya Suraksha Trust (SAST) is an autonomous institution that was specifically set up by the ministry to run Arogyashree, which relies on a public private partnership model. SAST has MoUs with 150 hospitals, of which 26 are government.

SAST first came into contact with NICE International at the 7th forum of government sponsored health insurance schemes in India, a joint World Bank and DFID sponsored event, at Chennai. The presentation by NICE International at the event led to interest in evidence informed priority setting and its application and importance for the effective functioning of the scheme. This early contact led to senior executives of SAST and leading doctors who are reputed and well respected in the state visiting NICE in the UK on a Joint Learning Network study tour. NICE International provided an understanding of the NHS in the UK by organising visits to facilities and to learn how evidence-based guidelines are developed and implemented, including the steps and methodology, the time taken and the process of stakeholder consultation. The strict adherence to clinical pathways and guidelines in facilities was particularly noted, as was the meticulousness taken in the development and the evidence based approach coordinated by NICE.

Based on learning from the study tour, SAST decided to develop standard treatment guidelines (STGs) for conditions related to oncology, one of two specialties for which most insurance claims were made.⁵⁶ The intention to develop guidelines using an approach similar to that of the NICE model was intended to standardise care in participating hospitals, ensuring that patients get the highest quality care and that wasteful medical interventions were minimised. A roadmap was developed; all 42 hospitals that provide oncology related hospitals and participate in the scheme were co-opted to participate in the development,

⁵⁵ RSBY is a government health insurance scheme for the poor and is headed by Rajeev Sadanandan, who previously was Principal Health Secretary, Ministry of Health Kerala and instrumental to the engagement of NICE International in QS in Kerala.


⁵⁶ The other area was cardiology; however, at the point of initiation of the development process, the state of AP were developing guidelines in this area, so Karnataka chose oncology.

and expert sub-committees led by senior doctors who attended the study tour were formed. The development process was coordinated and financed by SAST without external support. The expert sub-committees held several meetings, conducted background research and reviewed existing guidance to develop guidelines that covered medical, radiological and surgical aspects of cancer treatment that were suited to Karnataka. A high-level steering committee for the development process validated recommendations from the sub-committees and the draft guidelines which were finally approved by the board of SAST.

A series of trainings to doctors and other administrative staff from member hospitals were organised and the guidelines were piloted for two months to address any issues arising in relation to implementation and in February 2014 were rolled out officially in all 42 hospitals. SAST has revised its MoU with participating hospitals to incorporate the standard treatment guidelines and all hospitals are mandated to use the standard treatment guidelines. An illustration of learning from the study tour in addition to the development process is the need for setting up of a “tumour board” in the treatment guidelines. The approach requires medical, surgical and radiology to come together to take a collective decision, regardless of what type of intervention may be needed – prior to the treatment guidelines, there was no common approach and there were reported to be subjective or ad hoc decisions made in relation to treatment of cancer. The STGs are linked to the claim processes and claims are denied that are not in line with STGs. Outbound call centres are used to elicit patient feedback.

As all hospitals in the state that provide cancer treatment participate in Arogyashree, the STGs have become standard practice state-wide in Karnataka. Following nine months of implementation, there are plans to start monitoring outcomes and carry out before and after evaluations. Moreover, SAST has begun a similar process to develop standard treatment guidelines for neurosurgical interventions and has plans to do so for all the six specialties it covers. There is confidence that having had experience, the process will become easier to initiate and manage.

Annex E: Form for classifying NICE International's partnerships

Date completed				
Name and type of partner(s)				
Scale of implementation	<input type="checkbox"/> State/Regional <input type="checkbox"/> National <input type="checkbox"/> Global			
Type of partnership	<input type="checkbox"/> Bilateral <input type="checkbox"/> Trilateral <input type="checkbox"/> Other (please specify) _____			
				
Phase reached	Nascent <input type="checkbox"/>	Emerging <input type="checkbox"/>	Established <input type="checkbox"/>	Mature <input type="checkbox"/>
Description	<p>This is an early phase of engagement, characterised by a period of scoping and exploration. For example, activities may include:</p> <ul style="list-style-type: none"> • Networking and initial contact with a potential partner, for example at conferences • An initial scoping meeting between NICE International and partner(s) to discuss ideas for possible engagement 	<p>Following initial engagement activities, an emerging partnership may be characterised by:</p> <ul style="list-style-type: none"> • Signed Memorandum of Understanding • Multiple meetings between partner and NICE International with the specific aim of discussing possible engagement • Two-way, mutual communication, with both partners proactive in driving partnership forward • Identification and agreement on focus of collaboration – i.e. shared vision • Joint output(s), for example a concept note, draft MoU or joint funding application 	<p>An established partnership is defined by formalisation of the partnership, and the beginning of implementation on joint projects, for example:</p> <ul style="list-style-type: none"> • Successful application for joint funding • Governance and working arrangements for partnership defined • Commencement of implementation of a joint project • Good working relationship, with regular communication 	<p>A mature partnership may be characterised by the following features:</p> <ul style="list-style-type: none"> • Long standing partnership, with at least one project or phase completed • Reviews and assessment of partnership of done, to improve joint working • New collaborations, or renewal or expansion of existing collaboration • High levels of institutional trust between NICE International and partner, for example, sharing of financial data
Name and type of partner(s)	Technical Assistance Support Team and Government of Bihar			
Scale of	<input checked="" type="checkbox"/> State/Regional <input type="checkbox"/> National <input type="checkbox"/> Global			

implementation				
Type of partnership	<input checked="" type="checkbox"/> Bilateral <input type="checkbox"/> Trilateral <input type="checkbox"/> Other (please specify) _____			
Phase reached	Nascent <input checked="" type="checkbox"/>	Emerging <input type="checkbox"/>	Established <input type="checkbox"/>	Mature <input type="checkbox"/>
Evidence (record which activities are being done)	NI had one field visit with DFID, and met with MoH and other agencies (2012). ⁵⁷ BTAST participated in a study tour to Kerala (2014), with an output of a study report which details action points; however, no representatives of the Government of Bihar or NHM Bihar attended and it is therefore unclear what the mandate for follow up is.			
Name and type of partner(s)	Andhra Pradesh Aarogyasri Trust			
Scale of implementation	<input checked="" type="checkbox"/> State/Regional <input type="checkbox"/> National <input type="checkbox"/> Global			
Type of partnership	<input type="checkbox"/> Bilateral <input checked="" type="checkbox"/> Trilateral <input type="checkbox"/> Other (please specify) _____			
Phase reached	Nascent <input checked="" type="checkbox"/>	Emerging <input type="checkbox"/>	Established <input type="checkbox"/>	Mature <input type="checkbox"/>
Evidence (record which activities are being done)	It is reported by NI that there was a Joint workshop on “Collaborative on Case Selection and Clinical Audit Guidelines and Implementation in the Aarogyasri Perspective with NICE International, UK”. There was subsequently a follow-up meeting, which was intended “To outline a plan for future work of NICE International, UK supporting the clinical audit activity of Aarogyasri Healthcare Trust under the Joint Learning Network” and articulated plans for a scoping workshop (also involving ACCESS);			

⁵⁷ Referenced in an email from Billy Stewart (then Senior Health and AIDS Advisor, DFID India) on 28th November 2012

	however, progress on this work is reported to have stalled.			
Name and type of partner(s)	Technical and Management Support Team and Government of Odisha			
Scale of implementation	<input checked="" type="checkbox"/> State/Regional <input type="checkbox"/> National <input type="checkbox"/> Global			
Type of partnership	<input checked="" type="checkbox"/> Bilateral <input type="checkbox"/> Trilateral <input type="checkbox"/> Other (please specify) _____			
Phase reached	Nascent <input checked="" type="checkbox"/>	Emerging <input type="checkbox"/>	Established <input type="checkbox"/>	Mature <input type="checkbox"/>
Evidence (record which activities are being done)	<p>NI visited Odisha in late 2013, and submitted a proposal for QS; however, the work did not go ahead.</p> <p>In 2014, Odisha TMST and Representatives from NHM visited Kerala. There is registered interest in moving forward with collaboration, but does not appear to be any formal planning or understanding based on the interviews conducted.⁵⁸</p>			
Name and type of partner(s)	SAST, Government of Karnataka			
Scale of implementation	<input checked="" type="checkbox"/> State/Regional <input type="checkbox"/> National <input type="checkbox"/> Global			
Type of partnership	<input checked="" type="checkbox"/> Bilateral <input type="checkbox"/> Trilateral <input type="checkbox"/> Other (please specify) _____			
Phase reached	Nascent <input type="checkbox"/>	Emerging <input checked="" type="checkbox"/>	Established <input type="checkbox"/>	Mature <input type="checkbox"/>
Evidence (record which activities are being done)	<p>Representatives visited NICE for a study tour, and subsequently they generated STGs in oncology (see indicator 4 for more details).</p> <p>Stakeholders reported being in regular communication with NI;</p>			

⁵⁸ NI classify this partnership as “Emerging.” It would be useful to explore evidence – given the criteria for Emerging defined by the scale.

		however, this seems to be on an ad-hoc, informal basis. Plans for expanding the partnership are unclear– while SAST were going to visit China to present experience, their permission was denied.		
Name and type of partner(s)	National Health Systems Resource Centre⁵⁹ Government of India			
Scale of implementation	<input type="checkbox"/> State/Regional <input checked="" type="checkbox"/> National <input type="checkbox"/> Global			
Type of partnership	<input checked="" type="checkbox"/> Bilateral <input type="checkbox"/> Trilateral <input type="checkbox"/> Other (please specify) _____			
Phase reached	Nascent <input type="checkbox"/>	Emerging <input checked="" type="checkbox"/>	Established <input type="checkbox"/>	Mature <input type="checkbox"/>
Evidence (record which activities are being done)		Staff went on a study visit to NICE A report has been prepared and submitted, with recommendations around an independent HTA board		
Name and type of partner(s)	Department of Health Research / ICMR, Government of India			
Scale of implementation	<input type="checkbox"/> State/Regional <input checked="" type="checkbox"/> National <input type="checkbox"/> Global			
Type of partnership	<input checked="" type="checkbox"/> Bilateral <input type="checkbox"/> Trilateral <input type="checkbox"/> Other (please specify) _____			
Phase reached	Nascent <input type="checkbox"/>	Emerging <input checked="" type="checkbox"/>	Established <input type="checkbox"/>	Mature <input type="checkbox"/>
Evidence (record which activities are being done)		Staff from DHR attended a study visit in NICE this year, and there is a bilateral agreement (including MoU) between NICE and DHR. The objectives were 1.) generate an		

⁵⁹ National Health Systems Resource Centre (NHSRC) was set up in 2007, under the National Rural Health Mission (NRHM) of Government of India. Its function is to serve as an “apex body for technical assistance”. The website states that “the goal of this institution is to improve health outcomes by facilitating governance reform, health systems innovations and improved information sharing among all stake holders at the national, state, district and sub-district levels through specific capacity development and convergence models.” http://nhsrindia.org/index.php?option=com_content&view=article&id=300:organisation&catid=84:about-us&Itemid=730

REPORT ON NICE INTERNATIONAL'S ENGAGEMENT IN INDIA

		understanding of NICE methodology for conducting health technology assessments; 2.) get samples of SOPs used at NICE for various thematic areas within HTA; 3.) define ToRs and expected roles of members/constitution of appraisal board. NI and members of DHR have had multiple meetings; however, the role of NICE International in the MTAB and ongoing work is yet to be decided.		
Name and type of partner(s)	FRICH and FMR			
Scale of implementation	<input type="checkbox"/> State/Regional <input checked="" type="checkbox"/> National <input type="checkbox"/> Global			
Type of partnership	<input type="checkbox"/> Bilateral <input type="checkbox"/> Trilateral <input checked="" type="checkbox"/> Other (please specify) Variable_			
Phase reached	Nascent <input type="checkbox"/>	Emerging <input type="checkbox"/>	Established <input checked="" type="checkbox"/>	Mature <input type="checkbox"/>
Evidence (record which activities are being done)			<p>Several national workshops on a) appraising maternity management and family planning guidelines with representatives from several states and FOGI.</p> <p>NICE and Nerges Mistry have worked together on the AGREE work, which was presented at the 2014 Guidelines International Network (G-I-N) conference.⁶⁰</p> <p>NICE International have also facilitated a link with the RCOG – FRICH are now working with the College on training (NICE less</p>	-

⁶⁰ Appraisal of maternity management and family planning guidelines using AGREE-II instrument in India

REPORT ON NICE INTERNATIONAL'S ENGAGEMENT IN INDIA

			involved). Currently in discussions about how to take work forward, for example in states that may be able to take on lessons from Kerala.	
Name and type of partner(s)	ACCESS and Joint Learning Network			
Scale of implementation	<input type="checkbox"/> State/Regional <input type="checkbox"/> National <input checked="" type="checkbox"/> Global			
Type of partnership	<input type="checkbox"/> Bilateral <input type="checkbox"/> Trilateral <input checked="" type="checkbox"/> Other (please specify) variable depending on the piece of work			
Phase reached	Nascent <input type="checkbox"/>	Emerging <input type="checkbox"/>	Established <input checked="" type="checkbox"/>	Mature <input type="checkbox"/>
Evidence (record which activities are being done)			ACCESS and NI were partners for quality initiatives as part of the Joint Learning Network (JLN). ACCESS have funded various study visits to NICE for countries/states. ACCESS are engaged in a number of different pieces of work in India – for example, they are currently preparing for a Primary Care Capacitation Pilot in Uttar Pradesh, and see utility in the use of QS as part of this.	
Name and type of partner(s)	Government of Kerala [including Department of Health, Department of Medical Education] and NRHM Kerala			
Scale of implementation	<input checked="" type="checkbox"/> State/Regional <input type="checkbox"/> National <input type="checkbox"/> Global			
Type of partnership	<input type="checkbox"/> Bilateral <input checked="" type="checkbox"/> Trilateral <input type="checkbox"/> Other (please specify) _____			
Phase reached	Nascent <input type="checkbox"/>	Emerging <input type="checkbox"/>	Established <input type="checkbox"/>	Mature <input checked="" type="checkbox"/>
Evidence (record which activities are being done)				The MMR QS project has been completed, and NI continue to be involved in discussions around scale-

being done)				up and development. There is clearly a high level of value placed on NI involvement, although a desire for the QS to become part of the programme of the GoK.
Name and type of partner(s)	Kerala Federation of Obstetricians and Gynaecologists (KFOG)			
Scale of implementation	<input checked="" type="checkbox"/> State/Regional <input type="checkbox"/> National <input type="checkbox"/> Global			
Type of partnership	<input type="checkbox"/> Bilateral <input checked="" type="checkbox"/> Trilateral <input type="checkbox"/> Other (please specify) _____			
Phase reached	Nascent <input type="checkbox"/>	Emerging <input type="checkbox"/>	Established <input type="checkbox"/>	Mature <input checked="" type="checkbox"/>
Evidence (record which activities are being done)				The MMR QS project has been completed, and NI continue to be involved in discussions around scale-up and development. NI and members of KFOG clearly have a strong personal relationship, and keep in close contact.
Name and type of partner(s)	Rashtriya Swasthya Bima Yojna (RSBY), Ministry of Labour, Government of India			
Scale of implementation	<input type="checkbox"/> State/Regional <input checked="" type="checkbox"/> National <input type="checkbox"/> Global			
Type of partnership	<input type="checkbox"/> Bilateral <input checked="" type="checkbox"/> Trilateral <input type="checkbox"/> Other (please specify) _____			
Phase reached	Nascent <input type="checkbox"/>	Emerging <input type="checkbox"/>	Established <input type="checkbox"/>	Mature <input checked="" type="checkbox"/>
Evidence (record which activities are being done)				NICE is supporting the development of clinical pathways in conjunction with RSBY (building on a strong link with Shri Rajeev Sandanam from the Kerala work). They are facilitating the peer review process, as well as providing technical assistance, although the NICE brand will not be associated with the CP. A number of

				the CP (e.g. hysterectomy) have been drafted.
Name and type of partner(s)	World Bank			
Scale of implementation	<input type="checkbox"/> State/Regional <input type="checkbox"/> National <input checked="" type="checkbox"/> Global			
Type of partnership	<input type="checkbox"/> Bilateral <input type="checkbox"/> Trilateral <input checked="" type="checkbox"/> Other (please specify) variable			
Phase reached	Nascent <input type="checkbox"/>	Emerging <input type="checkbox"/>	Established <input type="checkbox"/>	Mature <input checked="" type="checkbox"/>
Evidence (record which activities are being done)				<p>WB in India have had a relationship with NI since the Chennai WB Forum, and they recently convened a joint HTA conference. WB are also associated with the JLN, which NI are involved in.</p> <p>WB are funding RSBY work (with DFID), and NI are providing technical support in terms of peer review.</p> <p>WB provides an Indian presence and acts as a convenor, to bring NI's technical expertise.</p> <p>Planning for future depends on the government plans.</p>

Annex F. Summary of classification of letters

Documents reviewed:

- Staff redeployment (10/04/2013)
- Equipment and infrastructure orders (01/05/2013)
- Delivery kits (09/04/2013)
- Training (07/03/2013)
- Maternal audit (02/04/2013)

Staff redeployment

Title of legislation/regulatory circular	Measures to Reduce Maternal Mortality in Kerala – Additional Human Resource for the delivery points in the selected pilot hospitals on contract basis - permission granted to re deployment of staff to delivery points- reg
Date published	10/04/2013
Source of circular	Dr M. Beena, State Mission Director, NRHM, Government of Kerala
Target of circular	District Programme Manager, Trivandum
Scale of application	<input type="checkbox"/> Local <input checked="" type="checkbox"/> Region/state <input type="checkbox"/> National <input type="checkbox"/> Multinational
What aspects of evidence-informed priority setting are the subject of the circular? (tick all that apply)	<input checked="" type="checkbox"/> Implementation of QS/CP to improve quality of care or health indicators <input type="checkbox"/> Use of clinical evidence <input type="checkbox"/> Use of cost-effectiveness data <input type="checkbox"/> Transparency in decision-making <input type="checkbox"/> Establishment of regulatory body <input checked="" type="checkbox"/> Staff redeployment linked to implementation of QS/CP <input type="checkbox"/> Training linked to implementation of QS/CP <input type="checkbox"/> Allocation of funds / budget revisions linked to implementation of QS/CP <input type="checkbox"/> Procurement (e.g. of infrastructure or equipment) linked to implementation of QS/CP
Notes	This letter deals with the redeployment of existing staff to meet the needs of implementation of the QS in the pilot hospitals.

Equipment and infrastructure orders

Title of legislation/regulatory circular	Health & Family Welfare Department – Annual Plan 2012-13 - Implementation of the scheme 'Women & Children Hospitals' – Infrastructure modification and procurement of quality equipments for Women & Children Hospitals at Thiruvananthapuram and Ponnani and Women & Children wing of 4 other Government Hospitals – Administrative Sanction accorded – Orders issued
Date published	25/03/2014
Source of circular	Rajeev Sadanandan, Principal Secretary (Health), Health and Family Welfare Department
Target of circular	Director of Health Services, Thiruvananthapuram Member Secretary, State Planning Board, Pattom,

	Thiruvananthapuram Accountant General (A&E), Kerala, Thiruvananthapuram Planning & Economic Affairs (A) Department Finance (H&L-A)/(Planning-B) Department
Scale of application	<input checked="" type="checkbox"/> Local <input type="checkbox"/> Region/state <input type="checkbox"/> National <input type="checkbox"/> Multinational
What aspects of evidence-informed priority setting are the subject of the circular? (tick all that apply)	<input type="checkbox"/> Implementation of QS/CP to improve quality of care or health indicators <input type="checkbox"/> Use of clinical evidence <input type="checkbox"/> Use of cost-effectiveness data <input type="checkbox"/> Transparency in decision-making <input type="checkbox"/> Establishment of regulatory body <input type="checkbox"/> Staff redeployment linked to implementation of QS/CP <input type="checkbox"/> Training linked to implementation of QS/CP <input checked="" type="checkbox"/> Allocation of funds / budget revisions linked to implementation of QS/CP <input checked="" type="checkbox"/> Procurement (e.g. of infrastructure or equipment) linked to implementation of QS/CP
Notes	This order relates to 6 hospitals specifically, linked to the “Women & Children’s Hospitals” scheme. It does not relate to the QS specifically.

Delivery kits

Title of legislation/regulatory circular	Measures to Reduce Maternal Mortality in Kerala – Disposable delivery kits and Urine Albumin examination strips – permission granted to purchase using JSSK funds
Date published	09/04/2013
Source of circular	Dr M. Beena, State Mission Director, NRHM, Government of Kerala
Target of circular	Superintendent, W and C Hospital, Trivandrum Superintendent, SAT Hospital, Trivandrum Superintendent, General Hospital, Ernakulam Superintendent, District Hospital, Peroorkada Superintendent, THQH Chirayinkezhu Medical Officer In Charge, CHC Kanyakulangara
Scale of application	<input checked="" type="checkbox"/> Local <input type="checkbox"/> Region/state <input type="checkbox"/> National <input type="checkbox"/> Multinational
What aspects of evidence-informed priority setting are the subject of the circular? (tick all that apply)	<input checked="" type="checkbox"/> Implementation of QS/CP to improve quality of care or health indicators <input type="checkbox"/> Use of clinical evidence <input type="checkbox"/> Use of cost-effectiveness data <input type="checkbox"/> Transparency in decision-making <input type="checkbox"/> Establishment of regulatory body <input type="checkbox"/> Staff redeployment linked to implementation of QS/CP <input type="checkbox"/> Training linked to implementation of QS/CP

	<input type="checkbox"/> Allocation of funds / budget revisions linked to implementation of QS/CP <input checked="" type="checkbox"/> Procurement (e.g. of infrastructure or equipment) linked to implementation of QS/CP
Notes	This circular grants permission for the hospitals to purchase disposable delivery kits and urine albumin examination strips using JSSK funds

Training circular

Title of legislation/regulatory circular	(1) email from V P Paily, Kerala Federation of Obstetrics and Gynecology dated 25 February 2013 (2) Pre launch staff training – proposal submitted by V P Paily, Kerala Federation of Obstetrics and Gynecology
Date published	07/03/2013
Source of circular	Dr M. Beena, State Mission Director, NRHM, Government of Kerala
Target of circular	Superintendent, W and C Hospital, Trivandrum Superintendent, District Hospital, Perrorkada Superintendent, THQH Chirayinkezhu Medical Officer in charge, CHC Kanyakulangara Superintendent, SAT Hospital
Scale of application	<input checked="" type="checkbox"/> Local <input type="checkbox"/> Region/state <input type="checkbox"/> National <input type="checkbox"/> Multinational
What aspects of evidence-informed priority setting are the subject of the circular? (tick all that apply)	<input checked="" type="checkbox"/> Implementation of QS/CP to improve quality of care or health indicators <input type="checkbox"/> Use of clinical evidence <input type="checkbox"/> Use of cost-effectiveness data <input type="checkbox"/> Transparency in decision-making <input type="checkbox"/> Establishment of regulatory body <input type="checkbox"/> Staff redeployment linked to implementation of QS/CP <input checked="" type="checkbox"/> Training linked to implementation of QS/CP <input type="checkbox"/> Allocation of funds / budget revisions linked to implementation of QS/CP <input type="checkbox"/> Procurement (e.g. of infrastructure or equipment) linked to implementation of QS/CP
Notes	Relates to the deployment of staff for training sessions on the implementation of the QS

Maternal audit circular

Title of legislation/regulatory circular	Health & Family Welfare Department – To reduce the maternal mortality rate – maternal death audit – Guidelines – Orders issued
Date published	02/04/2013
Source of circular	Rajeev Sadanandan, Principal Secretary (Health), Health and Family

	Welfare Department
Target of circular	<p>Director of Medical Education, Thiruvananthapuram Direct of Health Services, Thiruvananthapuram All District Collectors State Mission Director, National Rural Health Mission, Thiruvananthapuram Director, Clinical Epidemiology Resource and Training Centre, Thiruvananthapuram All District Medical Officers All Principals, Medical Colleges All Head of Departments of Obstetrics & Gynaecology, Medical Colleges All Reproductive Child Offices, O/o the District Medical Office All Superintendents of District and Taluk Hospitals (Through DMO) All Medical Officers of Community Health Centres and Primary Health Centres (Through</p>
Scale of application	<p><input type="checkbox"/> Local <input checked="" type="checkbox"/> Region/state <input type="checkbox"/> National <input type="checkbox"/> Multinational</p>
What aspects of evidence-informed priority setting are the subject of the circular? (tick all that apply)	<p><input type="checkbox"/> Implementation of QS/CP to improve quality of care or health indicators <input checked="" type="checkbox"/> Use of clinical evidence <input type="checkbox"/> Use of cost-effectiveness data <input type="checkbox"/> Transparency in decision-making <input type="checkbox"/> Establishment of regulatory body <input type="checkbox"/> Staff redeployment linked to implementation of QS/CP <input type="checkbox"/> Training linked to implementation of QS/CP <input type="checkbox"/> Allocation of funds / budget revisions linked to implementation of QS/CP <input type="checkbox"/> Procurement (e.g. of infrastructure or equipment) linked to implementation of QS/CP</p>
Notes	This relates to the submission of documents for the maternal death audit, functioning to identify cause of death