10

Developing quality standards for hypertensive disorders in pregnancy at primary care level in South Africa

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Development of Quality Standards may enhance the implementation of clinical practice guidelines in South Africa, which should result in high-quality, evidence-based, and cost-effective care in the country.

South Africa is committed to reducing its maternal mortality ratio to below 70 per 100 000 live births by 2030 (from 138 per 100 000 live births in 2015). The National Department of Health developed maternity care guidelines for primary care and district hospitals in 2016, but implementation needs to be reviewed and improved.

Quality Standards (QS) are an innovative implementation tool that can bridge the gap between clinical guideline development and successful implementation thereof. QS are evidence-based, clinical statements designed to maximise impact on clinical outcomes in areas of poor or highly variable clinical practice. The National Institute for Health and Care Excellence in London has been developing QS since 2010 for use in England's National Health Service, as well as assisting countries like Vietnam and India to develop and implement QS.

This review documents the recent development of South Africa's maternal QS for hypertensive disorders in pregnancy at primary care level. These QS were developed to contribute to the Gauteng province goal of reducing hypertensive disorders in pregnancy by 20% by 2020. A multi-disciplinary working group was established that reviewed recommendations derived from the national clinical practice guideline for maternity care and other local and international evidence, and seven quality statements were developed by October 2018. These QS have been aligned with existing initiatives to address hypertension-related morbidity and mortality.

Development of QS may enhance the implementation of clinical practice guidelines in South Africa, which should result in high-quality, evidence-based, and cost-effective care in the country. Evidence of successful implementation in other low- and middle-income settings suggests that QS complement and strengthen existing health-system-wide quality-improvement initiatives, which are essential for South African National Health Insurance to succeed. For QS to guide quality improvement efforts effectively in South Africa, they must be pilot tested, evaluated, maintained and implemented in different healthcare settings.

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Introduction

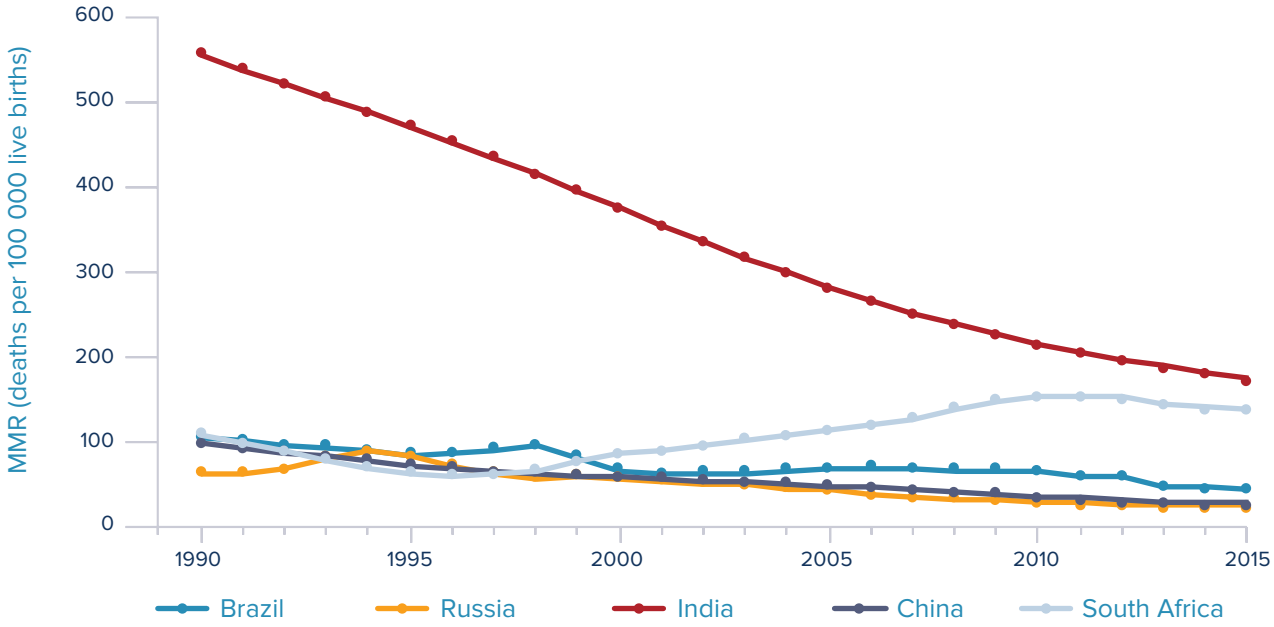
South Africa has high levels of maternal mortality. From 2003, more than 1 100 mothers have died annually from complications during childbirth.[1] This figure represents more maternal deaths per live births than in 1998.[2] While South Africa's national spending on health ranks high among emerging economies, maternal health outcomes are lagging,[3] as shown in Figure 1.

South Africa is committed to achieving Sustainable Development Goal (SDG) target 3.1 by reducing the maternal mortality ratio from 138 per 100 000 live births in 2015 to below 70 deaths per 100 000 live births by 2030.[5] While the number of maternal deaths related to HIV and obstetric haemorrhage decreased from 2011 to 2016, deaths due to hypertensive disorders of pregnancy increased by 14% over this time period.[1] Hypertensive disorders were the main underlying direct cause of maternal deaths (n=661) in South Africa between 2014 and 2016, accounting for up to one-third of the direct causes of deaths (Table 1). Between 2014 and 2016, Gauteng province (GP) had the highest number of maternal deaths (n=792) in the country, in part due to the large number of births taking place in the province and in part due to having the highest number of deaths due to hypertensive disorder in pregnancy (n=116).[1] Table 1 shows the distribution of causes of maternal deaths in South Africa from 2014 to 2016.

While achieving desired clinical outcomes in hypertensive disorders in pregnancy requires experienced and skilled staff able to make appropriate clinical decisions, this needs to be complemented by a strong health system where facilities are appropriately equipped and stocked, and referral and transport systems are highly functional. A key finding of the Saving Mothers Report 2014 - 2016 was that referral problems, including inter-facility transport issues, were a major contributor to maternal deaths. In the case of hypertension-related maternal deaths in pregnancy, transport problems were identified as an avoidable factor in 18.5% of deaths, and at community-health-centre level, delays in referring patients accounted for 19.4% of deaths.[1] Lack of skilled personnel to screen and manage hypertension in pregnancy is a persistent concern; 30.7% of avoidable factors for hypertension-related maternal deaths are due to a lack of appropriately trained doctors or nurses.[1] Poor initial assessment, problems with recognition/diagnosis, referral delays and sub-standard management have been found to be important avoidable factors for deaths at community-health-centre level.[1]

Identifying and managing hypertensive disorders and complications thereof in pregnancy constitutes one of the top 10 priority targets for improving maternal, neonatal and child health.[6] Moreover, the Minister of Health has called for renewed focus on patient safety and implementation of the National Core Standards[7] to help address the explosion in medical malpractice litigation.[8] The National Department of Health (NDoH) developed and distributed comprehensive Clinical Practice Guidelines (CPGs) for maternity care in primary care settings and district hospitals.[9] Despite clear commitment to quality health care, implementation of policies and guidelines has not been optimal: initiatives

Figure 1: Maternal mortality ratios in BRICS countries, 1990 - 2015



Source: World Bank, 2017.[4]
BRICS = Brazil, Russia, India, China, South Africa.

have been fragmented and uncoordinated; there has been insufficient focus on quality improvement through implementing evidence-based care; and there has been insufficient training of relevant healthcare personnel in quality improvement.[10]

In response to this situation, a partnership was formed between the Gauteng Department of Health (GDoH), the University of the Witwatersrand Obstetrics and Gynaecology Department, and the South African Medical Research Council (SAMRC)/Wits Centre for Health Economics and Decision Science (PRICELESS SA), and maternal Quality Standards (QS) were developed for the management of hypertensive disorders in pregnancy at primary care level in GP.

This chapter describes the process of developing these QS for maternal health in GP, outlines lessons learnt, and provides recommendations. In particular, the chapter addresses the following questions: what are QS; how are they used; how are QS different from clinical guidelines; what are the necessary steps in the process of QS development; and what is needed going forward?

Quality standards and their application

QS are concise sets of evidence-informed statements that describe optimal clinical care, and that can be used in combination with the associated quality measures to stimulate and evaluate clinical quality improvement over time in a particular area of care.[11]

QS are practical, clear and measurable, and focus on areas where sub-optimal care and variation in clinical practice are common. A guiding principle of QS is that they are based on evidence-informed clinical recommendations; as such, high-quality clinical practice guidelines (developed through a systematic review of the best available evidence) are good evidence sources for QS development. QS are not clinical guidelines in themselves, but instead prioritise and focus on a carefully selected set of clinical recommendations that will have the highest potential impact on outcomes if implemented. Therefore, QS can bridge the gap between clinical guidelines and their successful implementation.

QS can be used by different audiences and enable:

- Patients and carers to gain information on the quality of care they can expect;
- Health professionals to provide evidence-informed clinical care that can be audited and drive continuous quality improvement;
- Facility and district managers to track the availability of drugs and equipment, as well as training requirements;
- Service providers to examine the performance of their organisation and drive quality improvement;
- Policy makers and health service managers to ensure that high-quality care is commissioned, and help them to budget and plan accordingly; and
- Medico-legal processes to refer to documented standards of care for a particular setting when sub-standard care leads to litigation.

Quality standards have been used successfully in the National Health Service (NHS) in England and Wales since 2010, applied in more than 90 therapeutic areas and care pathways.[12] This work occurs within the context of a public body, the National Institute for Health and Care Excellence

Table 1: Number of maternal deaths per direct underlying cause per year in South Africa, 2014 - 2016

Underlying cause	2014	2015	2016
Direct	689	702	648
Hypertensive disorders	221	222	218
Obstetric haemorrhage	226	217	181
Ectopic pregnancy	23	36	36
Miscarriage	48	61	56
Pregnancy-related sepsis	65	65	71
Anaesthetic complications	34	28	25
Embolism	38	37	36
Acute collapse	26	31	20
Miscellaneous	8	5	5

Source: NDoH, 2018.[1]

(NICE), which also sets priorities and looks at the impact of these interventions through a lens that includes economic evaluation. A small number of QS have also been initiated and adapted successfully in resource-constrained settings, where conditions are similar to those in South Africa. In India, the State Government of Kerala (with technical assistance from NICE International) developed and implemented QS for postpartum haemorrhage.[13] The initial successes led to the expansion of QS to other areas of care, notably to improve detection and management of hypertension in pregnancy.[14] A recent evaluation of the QS programme in Kerala found that hospitals participating in the intervention saw improvements in several preventive care measures.[15] A similar process supported the development and implementation of diabetic foot QS within primary care in Mumbai,[16] and the Ministry of Health in Vietnam developed a QS for hospital management of acute stroke.[17]

In South Africa, different strategies have been developed across primary health care (PHC) and hospital settings to improve quality of care for mothers. These initiatives include organisation-wide quality-improvement programmes such as the National Core Standards for Health Establishments in South Africa issued by the Office of Health Standards Compliance (OHSC),[7] and programme- or service-specific quality improvements like the Basic Antenatal Care (BANC)[18] and the Adult Primary Care (APC) by the NDoH, which is the new name for the Primary Care 101 initiative developed by the Knowledge Translation Unit at the University of Cape Town Lung Institute.[19] Similar to existing quality-improvement initiatives, QS are evidence-based, developed through a consultative process, and designed to be locally relevant. QS add additional value by focusing on specific areas of clinical care that have been shown to drive morbidity and/or mortality, and they include implementation steps that strengthen clinical care and health services. Measures should be put in place to track quality-improvement for each quality statement, and to estimate the costs and savings of implementing the changes.

Developing quality standards in South Africa

Initial discussions on applying QS to the South African context started in 2016 when PRICELESS SA convened a workshop with key stakeholders, including the national and provincial Departments of Health, District Clinical Specialist Teams (DCSTs),[a] NICE International, and the Kerala Federation of Obstetrics and Gynaecology. The workshop, 'Maternal Care Quality Standards in the South African Context', was designed to review existing guidelines and quality-improvement initiatives in maternal care, to learn about the experience of adapting NICE QS to developing country settings, and to explore the applicability of the QS approach to the South African context. What followed was the proposal of a five-step QS development framework by PRICELESS SA for developing QS in South Africa (available on the PRICELESS SA website).[20]

At the outset of the project, a multi-disciplinary working group was set up to develop QS for hypertensive disorders in pregnancy for Gauteng province. The working group included a chairperson and obstetricians, public health specialists, nurses, health service managers, provincial representatives, Gauteng representative of the National Committee on Confidential Enquiries into Maternal Deaths, PRICELESS SA, and a representative from the International Decision Support Initiative (iDSI) (a global network working to achieve universal health coverage and SDG3).

Developing the QS involved several stages. The first step was defining the scope and determining the clinical focus area of the QS. The priority area for the project was identified as hypertensive disorders in pregnancy at primary care level. A selection of simple and implementable quality statements were drafted for hypertensive disorders in pregnancy at primary care level, based on the recommendations in the Guidelines for Maternity Care: A Manual for Clinics, Community Health Centres and District Hospitals[9] and a review of the published literature on hypertension in pregnancy, including the International Society for the Study of Hypertension in Pregnancy Guidelines.[21] Through close collaboration and multiple inputs from the working group and DCSTs from all five districts in GP, the quality statements were developed further to include measurable performance indicators, following the NICE QS format.[11] The DCSTs were identified as being central given their role in providing supportive supervision and clinical governance, ensuring quality of clinical services, supporting health systems and logistics, and their role in teaching and research activities. The DCSTs include a specific focus on maternal and child health.[22]

The draft QS for screening and management of hypertension in pregnancy at primary care level: clinics and community health centres (see Table 2) is a set of seven statements that the working group prioritised to drive quality improvement in the management of hypertension in pregnancy at primary care level in GP. QS 1 - 4 aim to strengthen detection and timeous management by clinical staff, while QS 5 - 7 focus on health system support of desired clinical outcomes, spanning the care continuum from community to primary care clinics/health centres to hospital levels for severe cases.

In addition to the seven quality statements, the full QS includes the following information:

- Definitions of key terms;
- Quality measures (structural/infrastructure, process and outcome measures);
- Implications for midwives and professional nurses, health facility managers, provincial department, patients and the public;
- Data sources; and
- Relevant guidelines and audit tools.

a The DCST includes medical and nursing specialists from Obstetrics and Gynaecology, Paediatrics, Family Medicine/PHC and an Anaesthetist.

Active guidance of working group members, including the Gauteng Department of Health's Quality Assurance Unit, was key in developing the QS and in aligning the QS with existing initiatives addressing hypertension-related morbidity and mortality in South Africa. Further presentation and feedback from the National Maternal Neonatal Child Health Women and Nutrition Think Tank has formed an important part of the process.

Lessons learnt

Local context

An important lesson learnt in the development process is that while QS principles are relevant to health systems globally, there is no one-size-fits-all approach.[13] While scientific evidence and guidelines are frequently provided

Table 2: Summary of quality standards and statements for Gauteng, 2018

Quality standard	Quality statement
Screening for hypertension in pregnancy at primary care level (clinics /community health centres (CHCs))	In the case of all pregnant women, blood pressure is taken, recorded, and abnormalities reported, and urine is tested for protein (using reagent strips/ dipstick) at the first antenatal visit and every subsequent antenatal visit.
Management of hypertension in pregnancy at primary care level	Any pregnant woman who has a diastolic blood pressure (DBP) ≥90 mmHg or a systolic blood pressure (SBP) ≥140 mmHg four hours apart at first or subsequent antenatal visits with or without proteinuria is referred to a district or regional hospital. Any pregnant woman who has a progressively increasing blood pressure, even if below 140/90 mmHg, is referred to a district or regional hospital.[a]
Management of severe hypertension at primary care level before 20 weeks of gestation	Any pregnant woman <20 weeks who has a DBP ≥110 mmHg and/or a SBP ≥160 mmHg at first or subsequent antenatal visits with or without proteinuria receives Adalat (nifedipine) 10 mg immediately and Aldomet (methyldopa) 1 g stat and is referred to a regional or tertiary hospital on the same day.
Management of severe hypertension at primary care level after 20 weeks of pregnancy	Any pregnant woman who is at gestational age 20 weeks or more and who has a DBP ≥110 mmHg and/or a SBP ≥160 mmHg at first or subsequent antenatal visits with or without proteinuria receives Adalat 10 mg immediately, Aldomet 1 g stat, a loading/initial dose of magnesium sulphate immediately (4 g in 200 ml saline to run over 20 minutes), 10 g by intramuscular injection (5 g in each buttock), and is referred to a regional or tertiary hospital as an emergency.
Ensuring availability of appropriate equipment for the diagnosis of hypertension in pregnancy at clinics and CHCs	Adequate numbers of working BP machines available, i.e. one per consultation room, with the correct cuff sizes, and calibrated regularly as per manufacturer requirements.
Effective referral processes for hypertension in pregnancy at primary care level	An effective referral is achieved in all cases of hypertension (SBP <160 mmHg and/or DBP <110 mmHg) through a standard referral letter, clear patient information and a receiving facility. The patient is able to travel to the hospital independently on the same day. Facility contacts patient through community health worker to check if she has gone to the referred facility.[2]
Effective referral processes for severe hypertension in pregnancy at primary care level	An effective referral is achieved in all cases of severe hypertension through direct telephonic contact with the obstetric doctor on call, transport in an obstetric ambulance with a response time of 15 minutes, and direct admission to the maternity section of the hospital.

[a] These are Gauteng-specific quality standards and statements in response to local experience.

at global level by organisations such as the World Health Organization, decisions must be made locally and with consideration given to the relevance of source guidelines (e.g. cost-effectiveness), and contextualisation. Given that QS are highly context-specific, provinces, and possibly districts, may have specific requirements and procedures and therefore may need to adjust the QS-development process to fit their local setting. Practically, QS will need to be adapted to local conditions such as the available skills at facility and district levels, e.g. the number and distribution of advanced midwives, which will likely vary across districts, as well as the training and referral processes in place. Increasingly, the practice of referral to the next level of expertise is being adopted, which takes account of this variation. Catchment areas and/or districts need to identify where the next level of expertise is after the PHC clinic or CHC. Given that DCSTs are engaged in several primary care level trainings, piloting of the QS will also need to explore how best to synergise and if possible integrate QS training so that existing efforts are strengthened. Despite local variation, it is anticipated that the QS development process described in this chapter will be useful in providing health professionals with a starting point from which they can initiate the development/adaptation of their own QS to drive quality improvements locally.

Process of quality standard development

The development process can take up to six months and it builds heavily on CPGs. Imperative to the process is the engagement of all key role-players such as government entities, regulatory bodies, clinicians and the public health sector. Continuous stakeholder involvement through regular meetings and follow-up consultations throughout the QS development process will ensure commitment and buy-in at appropriate levels. To this end, a lead organisation is needed, with administrative, co-ordination and documentation capacity. This role was fulfilled by PRICELESS SA.

Identifying the focus area

Prior to developing QS, it is important that stakeholders/QS working groups consider:

- What are the local priorities for improvement?
- Which QS will have the most impact in the local context?
- How can local health system structures, processes and resources drive implementation of QS?[23]

Continuity

The enthusiasm and time invested in QS development need to be matched by investment in testing the implementation at identified sites. Due to lack of funding, implementation and testing have been challenging. Future efforts to develop QS need to ensure that there is continuity from development to pilot testing of implementation, and related evaluation.

Conclusions

As South Africa moves towards Universal Health Coverage through the implementation of National Health Insurance, ensuring access to good-quality health care is essential. In light of resource constraints, policymakers have to consider how available resources can be used to achieve good-quality care.[24] Strengthened implementation of existing national CPGs would lead to greater progress in reaching national and international health targets; however, the cost of such improvements is currently unknown. It is imperative to understand the costs of quality improvement through conducting economic evaluations of the proposed interventions. Evidence from Niger showed improved health and reduced healthcare resources when a quality-improvement initiative was conducted in childbirth facilities. Improved quality led to reduced delivery cost by an average of 20%, from $35 to $28.[25] Importantly, systematic economic assessment of the costs and effects of quality-improvement interventions is essential for prioritising decision making and could be embedded in a more systematic mechanism ideally driven by a priority-setting entity. Such an institution could provide technical and consultative support in economic evaluation of interventions and lead to transparent and evidence-based health spending.[26] In South Africa, options for locating such an entity within an existing structure such as the OHSC, or creating a new institution, need to be carefully appraised.

Adapting the NICE Quality Standard framework or a similar tool to the South African context should be tested to encourage implementation of high-quality, evidence-based, and cost-effective care. For the first time in South Africa, the GP maternal quality standards initiative has demonstrated that QS can be developed relatively quickly through a stakeholder engagement process. This allows healthcare providers to initiate appropriate quality-improvement initiatives based on accessible and reliable indicators of quality.

Recommendations

Since work to date has not examined processes of implementation or the impact of QS in practice, an evaluative study is recommended to explore the effectiveness of QS in improving the quality of maternal health care. To this end, a pilot study within one district of Gauteng is recommended as the next step.

From the NICE experience, successful implementation of QS requires a combination of driving forces, as shown in Figure 2.

These principles will apply similarly to pilot testing of the QS, and specific elements are recommended below:

Partnerships and political support

One of the most important success factors in QS implementation is involvement and commitment from all relevant stakeholder groups (e.g. provincial and district programme managers, midwives, clinicians, training institutions and research groups) from the start of the QS development process. Continuous engagement will allow for sustained political will and commitment to using QS to drive quality improvement and ensure that frontline staff are supported and that the required activities/changes are funded adequately.

Baseline data

A survey of baseline activities and infrastructure within the facilities of the identified pilot site will be important to document in advance of implementation. This will add additional focus to aspects requiring quality improvement. In the context of these QS, baseline data will include:

- BP machines with pregnancy cuffs and service records;
- Reagent strips;
- Drug availability;
- Written referral processes;
- Emergency transport;
- Trainings currently underway;
- Role and training of community health workers; and
- Quality measures and data sources for quality statements.

The QS include proposed quality measures for infrastructure, processes and outcomes. Prior to training in QS, routine data need to be identified that can be used to generate the quality measures. Where data are lacking in current systems, adaptations to data collection will need to be explored. As far as possible, quality measures need to be tracked using existing information systems.

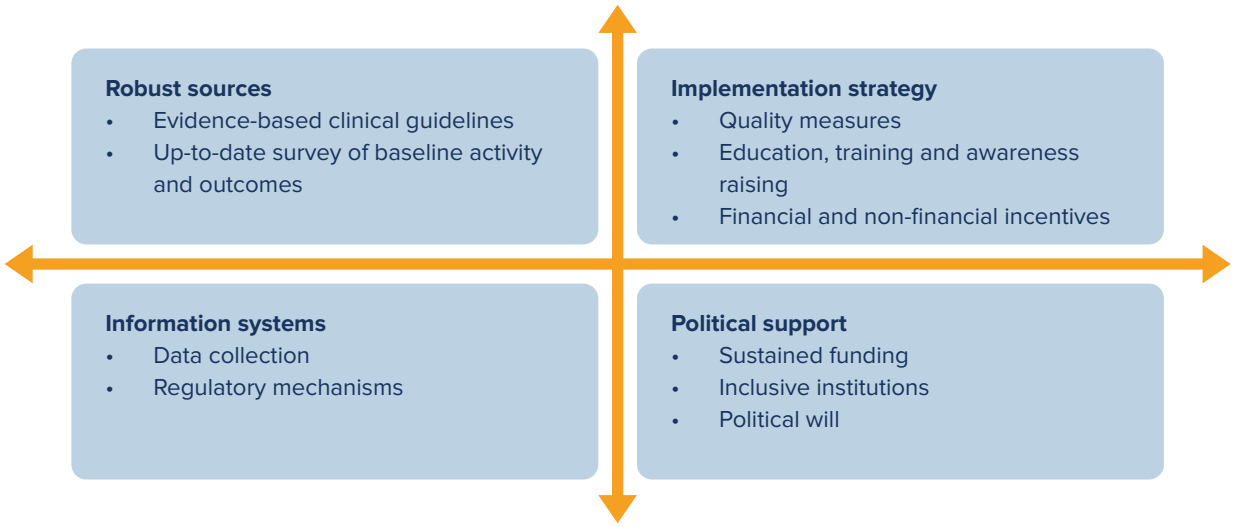
Training

The DCSTs have been identified as vital partners that can drive implementation of maternal health QS. Several initiatives are underway in all GP districts, but challenges remain, including ongoing gaps in staff knowledge and skills in identifying and managing hypertension in pregnancy at PHC level, and challenges with adherence to existing protocols.[b] QS training needs to harmonise, align and strengthen existing quality of care training underway at PHC level, and provision should be made to train community health workers in ward-based outreach teams to QS 6 and 7 level (Table 2).

Documentation

In order to determine the applicability and acceptability of maternal QS in South Africa, specific attention must be paid to the appropriateness and effectiveness of implementation through the DCSTs. The pilot needs to test the value of the quality statements and related measures at primary care level, as well as provide data on factors that enable or hinder implementation, the processes of implementation, and an early indication of the impact of maternal health QS in shifting maternal outcomes. Evaluation will also allow identification and tackling of additional issues previously not recognised and inform up-scaling of the approach.

Figure 2: Driving forces in quality standard implementation



Source: Cluzeau, 2016.[23]

b DCST consultation meeting, PRICELESS, 15 October 2018 attended by Gauteng Department of Health and representatives from all five districts in the province.

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