Quality Improvement Structures in Nepal – Options for Reform

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This report has been developed as an effort to understand the existing policy, governance and
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Message

The Government of Nepal, over the last few decades, has invested significantly in the expansion and strengthening of public sector health institutions which has paid the dividends in terms of improved health outcomes of the citizens. However, we still have numerous existing and emerging public health challenges to tackle and this would require, as compared to the past, much more coherent and comprehensive efforts to drastically improve the quality of care across both public as well as private health institutions. This, in turn, requires appropriate legal and policy instruments as well as suitable structures to empower the government in its regulatory and health governance capacities.

This report comes at an opportune time as the government begins to operationalize its constitutional mandate to protect and advance people’s right to quality health care services. The report provides a roadmap and a basis for establishing autonomous structures responsible for defining health care standards to ultimately ensure that all citizens – regardless of their ability to pay and irrespective of their socio-cultural background – are able to obtain the same quality of healthcare.

A particular innovation proposed by this report – the establishment of an autonomous entity to certify and accredit health care institutions – is a means for providers to demonstrate high quality of care and to compete in the market on that basis. As shown by experiences in the region, the introduction of these voluntary measures should be coupled with strong regulatory measures to make the sector more accountable as well as robust financing mechanisms that pay for high quality care, supported by strong partnerships among federal, provincial and local governments, and across public and private providers.

I appreciate the efforts made by the Ministry team and its supporting partners to make this report possible. It represents an important milestone towards our ongoing effort to establish comprehensive governance framework for improving the quality of health care. I offer my full commitment and support to propel this reform forward.

Gagan Kumar Thapa
Minister
Preface

It is the prime responsibility of the Government to ensure the provision of quality health services to people across both the public and private sectors. This task is of particular importance as Nepal transitions into a federal system where different layers of Government are responsible for providing health care services and as the private health care sector continues to expand rapidly.

Over the last decade major improvements have been achieved in areas such as maternal and child health, but findings from recent surveys, including Nepal’s Health Facility Survey 2015, also show that major efforts are still required to provide facility-based care that is efficient, safe for the patient, and respectful of people’s dignity. In resource-constrained countries like Nepal, the sentiment often prevails that certain preconditions, such as sufficient finances, human resources or better equipment, must be in place before one can talk about improving service quality. However, Nepal has proudly embraced quality health care as a human right and not as a privilege reserved for people who can afford to buy health services of an acceptable quality.

Over the period of Nepal’s Health Sector Strategy 2015 – 2020, the Ministry of Health is committed not only to investing in a better healthcare infrastructure and additional human resources, but also to pursuing a more strategic and comprehensive approach to quality improvement.

There is an urgent need to establish a culture of continuous quality improvement in both public and private health care institutions. This culture should value evidence-based medical practice, patient centeredness, teamwork, and accountability at all levels. It is the responsibility of the Ministry of Health to provide the framework that lays the foundation and provides benchmarks for this culture.

I therefore welcome the report “Quality Improvement Structures in Nepal – Options for Reform” which summarises current approaches to quality improvement and outlines the different options for the sector to institutionalise these efforts.

Dr. Senendra Raj Upreti
Secretary, Ministry of Health
ACKNOWLEDGEMENTS

This report aims to provide a picture of the current structures for quality improvement in Nepal and to further explore the role an envisioned “accreditation body” might play. This report is the result of extensive inputs from various stakeholders ranging from policymakers and regulators to evaluators and development partners. The desk reviews, interviews and consultations which form the basis of this report were conducted in Kathmandu during October and November 2016.

I express my sincere appreciation to everyone who has contributed to this report. I would like to acknowledge the crucial role of the staff of the Support to the Health Sector Programme (S2HSP), GIZ Nepal, for their facilitation and technical assistance in the process. I would also like to thank authors of this report, Dr. Eva Tezcan and Amit Aryal as well as the legal advisor Ramesh Badal. Finally, I extend my appreciation to the following experts who provided their time for interviews, discussions and clarifications:

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I am hopeful that this report will be a valuable resource for stakeholders as they guide the process of institutionalizing comprehensive quality improvement measures in Nepal’s health system.

Dr. Hemant Ojha
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Abbreviations

AFS  Adolescent friendly service
APHIN  Association of Private Health Institutions of Nepal
BMZ  Federal Ministry for Economic Cooperation and Development (Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung)
DALY  Disability-adjusted Life Year
DDA  Department of Drug Administration
DoHS  Department of Health Services
GIZ  Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH
GoN  Government of Nepal
HPEC  Health Profession Education Commission
IMIS  Insurance Management Information System
ISQua  International Society for Quality in Healthcare
MoH  Ministry of Health
MPDR  Maternal and Perinatal Death Reviews
MPDSR  Maternal and Perinatal Death Surveillance and Response
NCD  Non-communicable disease
NHSS  Nepal Health Sector Strategy
NPHL  National Public Health Laboratory
PBMS  Performance-Based Management System
S2HSP  Support to the Health Sector Programme
SBA  Skilled Birth Attendant
SHSP  Social Health Security Program
WHO  World Health Organization
Executive Summary

Over the past two decades, the Government of Nepal has improved people’s access to health care by expanding health services and strengthening community-based interventions (e.g. Female Community Health Volunteers). Efforts have also been made to reduce financial barriers to accessing care, including the introduction of free health services, the promotion of the Safe Motherhood programme and, recently, the establishment of National Health Insurance. In many cases, however, the expansion of health services has not been accompanied by improved quality at the point of care. People lack trust in health care providers and, as a consequence, either do not use health services or delay utilisation. Sometimes they turn to private providers with the expectation of receiving adequate care, however this may often not be the case.

Health care providers in Nepal face significant challenges in providing adequate care, including understaffing and a lack of equipment and supplies. Health care management does not yet have the orientation needed to create a health service focused on efficiency and quality. Managers of health institutions often feel poorly prepared and inadequately supported to fulfil their roles successfully.

These challenges limit the effectiveness of preventive and curative health care and the efficiency of health budget allocations. At the same time, deficits in quality of care have only been substantiated through a limited number of surveys. The recently completed 2015 Nepal Health Facility Survey, for example, applied nine tracer standards\(^1\) to assess the minimum standards of quality of care at the point of delivery – and generated sobering results. Critically, there are no routinely collected data which can be used to measure the quality of care and to make evidence-based policy decisions to improve quality. The lack of information on quality is also a serious limitation for rational purchasing decisions, which will become even more relevant with the expansion of National Health Insurance.

At the strategic and policy level, the issue of “quality at the point of service delivery” has gained enormous visibility through the emphasis placed on universal coverage of basic health services in the Constitution of Nepal 2015. Quality of care is one of the four strategic principles of the Nepal Health Sector Strategy 2015-20 (NHSS). National stakeholders – including health care administrators, clinicians, consumer representatives and international development partners – are paying increasing attention to the need for an objective measurement of the performance of health care institutions in order to steer quality improvement efforts more effectively, on the one hand, and to increase transparency and accountability, on the other. The NHSS envisions the establishment of an “accreditation body for quality assurance” which could potentially address this gap, however the purpose, structure and role of this proposed entity are still undefined.

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\(^1\) The nine tracer standards are: soap and running water or alcohol-based hand disinfectant, safe final disposal of infectious waste, equipment and knowledge of processing time, trained staff, quality assurance guideline, clinical protocols observed, availability of all four tracer amenities, waiting room, tracer medicine.
A review of mechanisms for improving the quality of care

In 2016 the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, commissioned by Germany’s Federal Ministry for Economic Cooperation and Development (BMZ), initiated a review to inform the current debate on quality improvement in the health sector in Nepal and to further explore the role an “accreditation body” might play. This report summarises the findings of the exercise, which was conducted in Kathmandu in October-November 2016. The report takes as its starting point the belief that some form of measurement of the performance of health institutions is an indispensable element of a functioning health system, and that performance measurement complements other elements such as regulation, internal quality improvement, complaints management, incentives, regulated and not-regulated standards, clinical protocols and guidelines. In this report, the authors aim to provide an accurate picture of the current framework conditions for establishing an appropriate performance measurement system in Nepal and to provide some recommendations for the institutionalisation of such a system.

Chapter 1 sets out the background to the assignment and provides operational definitions for key terms and concepts. It also explains how the term “accreditation body” is used in the text and discusses issues related to the phrase “quality assurance.” Chapter 2 describes the strategic framework conditions for a quality improvement system, the regulatory framework, and the relevant governance structures which presently exist in Nepal. Chapter 3 summarises the country’s experience to date with different quality improvement approaches. Chapter 4 discusses the implications of the findings in light of the envisioned reforms and offers technical recommendations.

Key findings

Strategic framework

At present there is not a coherent strategic framework for improving the quality of care in Nepal. The existing framework, which is shaped by different actors, is characterised by overlaps and duplicated efforts.

• The current strategic framework for addressing quality of care is largely shaped by three policies and strategies: the Policy on Quality Assurance in Health Care Services 2007, the National Health Policy 2014, and the Nepal Health Sector Strategy 2015-2020. Terminology is not used consistently across these three key documents.

• Projects and programmes under the Ministry of Health (MoH) have their own strategies and implementation frameworks which touch on quality of care.

• The newly introduced National Health Insurance has specific interests in quality of care, but these have not yet been operationalised as part of an overall quality improvement strategy for the health sector.

• There is broad consensus over the importance of performance monitoring across the health sector and, in particular, at the point of service delivery, but it is unclear how performance monitoring will be linked to quality improvement interventions employed by MoH. The role and functioning of the “accreditation body” envisioned in the NHSS is unclear.

• There is a lack of clear strategic orientation regarding the envisioned roles and responsibilities of, and interplay between, the different stakeholders involved in a coherent quality improvement system.
The current strategic framework does not provide sufficient orientation for implementing a stepwise quality improvement process.

- The existing strategic framework provides sufficient orientation to determine maximum standards for the performance of health institutions, but it lacks prioritisation.
- National quality improvement goals are not yet explicitly formulated and agreed (they are implicit in the objectives and indicators of the NHSS).

**Regulatory framework**

The regulatory framework for health institutions is patchy and the actual regulation of health care services is of limited effectiveness.

- The Constitution mandates the establishment, by 2018, of an adequate regulatory framework to improve the quality of health care.
- An overarching Public Health Act is currently being prepared and several laws related to the quality of health care are currently under review.
- The regulation of health institutions lacks a firm legal basis.
- The effectiveness of regulation is limited due to low levels of enforcement and insufficient resources.

**Governance framework**

The absence of clearly defined and commonly agreed quality improvement goals, along with insufficient coordination among actors, contributes to a fragmented approach to quality improvement.

- The current governance structure for quality improvement reflects the orientations and shortcomings of the Policy on Quality Assurance in Health Care Services 2007.
- The governance structures for quality improvement are not sufficiently institutionalised. Instead, governance depends to a large degree on different committees across all levels of the health system.
- The capacity of the MoH to oversee the quality of health care and to steer quality improvement is limited.
- A proposed National Quality Improvement Structure makes no reference to either the “accreditation body” or the new National Health Insurance.
- Several different approaches are used to collect patient and community feedback. Bodies referred to as “compensation committees” award compensation to patients for losses and damages caused by unsafe health services. However, the fact that there are no functional health-specific structures to deal with patient grievances and complaints leads to a high degree of uncertainty for patients and health care providers alike.
Rich experiences with different quality improvement approaches have not been drawn together into a coherent quality improvement system.

- Many different quality improvement approaches have been implemented in Nepal in recent decades, including Standards-Based Management and Recognition, Quality and Service Improvement of District Hospitals, and Maternal and Perinatal Death Surveillance and Response.

- Most of these approaches require considerable external support to initiate and to implement on a sustained basis. Apart from the Minimum Service Standards (MSS) approach, which is aimed at embedding internal quality improvement as a central task for managers of health institutions, the other reviewed approaches all rely heavily on committees and project staff.

- Although valuable and valid performance measurement tools have been developed and introduced in Nepal, these have not been systematically linked to regulatory measures in the form of incentives or punitive actions.

- Quality improvement efforts have not been oriented toward providing the MoH or the general public with a continuous stream of data on the performance of health institutions.

**Key recommendations**

The Ministry of Health should establish a national framework for measuring the performance of health institutions.

A national framework for measuring the performance of health institutions could serve as the basis for aligning stakeholders to a common reference for quality of care. A system-wide approach would enable the sector to track the progress of health institutions towards the achievement of national quality improvement priorities. It is therefore recommended to develop and agree on such a system. The “accreditation body” envisioned in the NHSS could implement and oversee regular performance assessments.

- As a first step, the MoH should explicitly state the main quality improvement goals for health institutions. In doing this, it is important to be realistic, to limit the priorities to a manageable number, and to envisage a stepwise improvement process.

- On the basis of explicit quality improvement goals, the MoH should then determine the scope and specific objectives of the future performance assessment in consultation with stakeholders.

- It is important to be specific regarding the desired regulatory functions of the “accreditation body,” if any, and to avoid confounding these with other objectives. If the “accreditation body” is to act as a regulator, it needs to be authorised by law to assess health institutions against pre-determined requirements (which must be derived from legislation) and to take action in the event of non-compliance. The requirement for legal backing limits the range and scope of the assessment and leaves less room for encouragement towards continuous quality improvement.
• When designing the performance assessment framework, it is crucial to assess which type of assessment (content, frequency, specific objectives, type of information sharing on level of performance) will help the National Health Insurance to meet its objective to ensure Universal Health Coverage and to improve the effectiveness, efficiency, accountability, and quality of care. In the long term, health insurance will be essential for establishing a sound incentive system to encourage acceptance of performance assessments and compliance with the standards.

• Once the scope of performance assessment (or different performance assessments for different purposes) is clear, a task force nominated by the MoH or staff of the new “accreditation body” should assess existing measurement frameworks for licensing, minimum standards (district hospitals), and Standard-Based Management and Recognition (Comprehensive Emergency Obstetric and Neonatal Care) in light of the strategic improvement priorities for health institutions. The experience generated through these (past) experiences should inform both the methodology and the regular performance assessment structures for health institutions. Existing measurement frameworks can be used in their current forms, or broadened to include additional standards.

• Finally, it is important to ensure that selected data from regular performance assessments are linked to the District Health Information System, fed into routine data analysis and utilised for monitoring and steering of the overall health system.

The Ministry of Health should revise the Policy on Quality Assurance in Health Care Services 2007.

A revision of the Policy on Quality Assurance in Health Care Services 2007 would present an opportunity to provide better guidance for an integrated quality improvement system.

• The MoH should ensure that sufficient quality improvement expertise is drawn upon in this process and that the potentially differing interests of public and private sector stakeholders, purchasers, providers and consumers are balanced.

• The revision should be used to streamline the use of terminology where necessary.

• The revised policy should clearly describe the interplay between different activities, processes, and institutional levels in an integrated quality improvement system.

• Ideally, the policy should represent a coherent roadmap for the journey towards quality of care.

The Ministry of Health should lay the foundation for meaningful quality improvement legislation.

The planned Public Health Act could be used as an opportunity to set out the foundations for meaningful quality improvement legislation. In order to leave enough room for strategic decisions, detailed legislation should be planned at a later stage.

Key stakeholders should institutionalise and professionalise governance structures for quality improvement.

Quality improvement is, by definition, a continuous process. It requires reliable and
permanent support which is itself of high quality. Performance assessment is not a panacea for all quality issues, but it does represent a systematic way to identify areas where improvement is needed. It can be a powerful instrument for healthcare reform if it is implemented with adequate resources and support. Doing this will require some structural adjustment across the health system, including:

- Adequately-staffed entities within the MoH.
- One or two new independent structures (regulation and support for continued quality improvement may or may not be combined, and regulation may or may not continue to be an internal MoH function).
- Sustained capacity development interventions (including delegation of powers and responsibility) to strengthen health institution management.
- A well-established system to collect feedback, complaints and grievances from all levels of care. This system should inform quality improvement processes and receive, investigate, and resolve grievances related to health care in a transparent manner which is fair to both the patient and the provider.

**The Ministry of Health should ensure the relevance, effectiveness, efficiency and sustainability of a future “accreditation body.”**

Internationally there is now rich experience in setting up different types of external assessment organisations and programmes. To ensure that the “accreditation body” envisioned for Nepal becomes a healthy organisation, it is important to avoid common pitfalls and to apply lessons learned from other contexts. These include:

- Taking enough time to clarify the fundamentals (e.g. scope and purpose, role of government, incentives).
- Setting up the organisation with secure funding and solid management systems.
- Developing a measurement framework appropriate for the scope and purpose.
- Selecting and training assessors; developing mechanisms to ensure reliability, integrity and reliability; and designing and managing assessment processes to meet expectations.
- Planning for operational research and for an institutional evaluation of the accreditation body.
Introduction

1.1 The challenge of quality improvement in Nepal’s health sector

Over the past two decades, Nepal has improved people’s access to health care by expanding health services and strengthening community-based interventions. There have also been efforts to improve financial access to health care, including the introduction of free health services, the promotion of the Safe Motherhood programme and, recently, the establishment of National Health Insurance.1

Despite impressive declines between 1990 and 2014, child, infant, neonatal and maternal mortality rates remain high and need to be reduced further. The Nepal Health Sector Strategy 2015-2020 states that the expansion of public health services has “in many instances not been accompanied by improved quality at the point-of-care.” 2 Curative services have been particularly affected by these quality challenges.

Studies3 have indicated that irrational practice, primarily in relation to non-generic prescribing and the use of antibiotics, is common and that the standard of patient care provided by health facilities is insufficient. An assessment of birthing centres,4 for example, has shown severe limitations in both hygiene and clinical practice. Despite improvements, health service utilisation remains low: less than half of all deliveries are attended by skilled birth attendants. 5 The population lacks trust in public health care providers and, as a result, may avoid or delay treatment. Sometimes they turn to private health care providers with the expectation of receiving adequate care, however this may often not be the case. According to the NHSS, “citizens face inappropriate, inadequate, and unnecessary care

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1 Launched in May 2016, a national health insurance scheme is being gradually introduced throughout the country. The voluntary scheme covers services in public and private facilities, with subsidies from government for poor households.
2 p. 11.
4 MoH 2014: Results from Assessing Birthing Centers in Nepal
5 WHO Country Profile
due to weak regulation of the private sector.”

The perceived lack of quality in the health sector has only been substantiated through a limited number of surveys. The annual Nepal Health Facility Survey (NHFS) only recently included an assessment of the quality of care at the point of delivery. The 2015 NHFS revealed that less than 1% of the 940 public and private facilities fulfilled all nice tracer standards. Only 19.9% had regular documented quality assurance activities and only 2.5% had a client feedback system in place.

There are no routinely collected data on the quality of health care which could be used for measuring the quality of care, communicating results to health care consumers, or making evidence-based policy and management decisions to improve quality. The lack of information on quality is also a serious limitation for rational purchasing decisions which will gain relevance with the expansion of the new National Health Insurance. Health care management lacks the orientation needed to create a health service focused on efficiency and quality. Managers of health institutions often feel poorly prepared and supported to fulfil their roles successfully.

The “triple burden” facing Nepal’s health sector has an enormous impact on both people’s expectations towards health services and on the technical requirements for health service delivery. While communicable diseases continue to account for a large proportion of deaths and disability, an increasing number of non-communicable diseases require new approaches to treatment and care. In addition, adequate responses to threats from natural disasters, the adverse effect of climate change, accidents, violence, and injuries are required. The leading causes of Years of Life Lost (YLL) are now lower respiratory infections, ischaemic heart disease and neonatal encephalopathy. Addressing these requires complex health care interventions – including effective emergency and specialised care – which go beyond basic health services.

1.2 Quality of care emerges as a priority issue

With a focus on better outcomes, quality of care has become a major concern for the Government of Nepal (GoN). “Quality” can be understood as the result of improvements across all the components of a health system (Figure 1). The health systems model, however, fails to illustrate why improvements across the health system components (or “building blocks”) do not automatically lead to improved quality at the point of service delivery and to better health outcomes. In other words, quality seems to be more than the simple addition of improvements to each health system component. As a result, there is a growing interest in steering interventions across those components more strategically towards better quality of care.

The MoH also faces increasing pressure from citizens, the GoN and international partners to be accountable for the appropriate use of limited public funds to provide universal access to quality health care. Finally, patients have the right to be informed which health

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6 p. 16.
7 The nine tracer items are: soap and running water or alcohol-based hand disinfectant, safe final disposal of infectious waste, equipment and knowledge of processing time, trained staff, quality assurance guideline, clinical protocols observed, availability of all four tracer amenities, waiting room, tracer medicine.
services have systems and processes in place to ensure that they receive effective, safe, client-centred, timely, equitable, culturally appropriate, efficient, and reliable care. All three aspects – quality, accountability, and transparency – require a focus on the performance of health care institutions, objective measurement, and communication about levels of performance.

This report takes as its starting point the belief that some form of measurement of the performance of health institutions is an indispensable element of a functioning health system, and that performance measurement complements other elements, such as regulation, internal quality improvement, complaints management, incentives, regulated and not-regulated standards, clinical protocols and guidelines. The authors aim to provide an accurate picture of the current framework conditions for establishing a suitable performance measurement system in Nepal and to provide some recommendations for the institutionalisation of such a system.

This document is the result of a review undertaken on behalf of the Support to the Health Sector Programme (S2HSP), which is implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH on behalf of Germany’s Federal Ministry for Economic Cooperation and Development (BMZ), to inform the current debate on quality improvement in Nepal. It is based on an extensive document review and discussions with a range of stakeholders in Kathmandu during October and November 2016 (see list in Appendix 1). Preliminary findings were presented and discussed at a consultative meeting, held in Kathmandu on November 7, 2016, with representatives of the MoH and the National Health Insurance, health care providers from both the public and private sectors, and international development partners.

1.3 Definition of key terms and concepts

Quality of care is a multi-faceted concept and the terms associated with it can mean different things to different people. In the following we clarify how different terms are used in this document:
Health care is of good quality when it is effective, safe, client-centred, timely, equitable, culturally appropriate, efficient, and reliable.\(^\text{11}\)

Quality improvement is an ongoing response to quality assessment data about a service, in ways that improve the processes by which services are provided to clients.\(^\text{12}\)

Regulation is a form of external evaluation by which a body, authorised by law, assesses an organisation or person against pre-determined requirements. As these requirements are derived from legislation, the regulator may take action in the event of non-compliance.\(^\text{13}\)

A system is a set of interacting or interdependent processes forming an integrated whole function.\(^\text{14}\)

Performance is the level of achievement in relation to specified targets, either clinical or administrative/managerial.

Standards are “a desired and achievable level of performance against which actual performance is measured.”\(^\text{15}\) They are short derivatives of guidelines, protocols, or standard operating procedures.

“Accreditation body,” in this text, is used in quotation marks to refer to a new and independent structure related to quality improvement, as envisioned in the NHSS.

Quality assurance is only used in this report in the context of direct quotations from various national texts, which make inconsistent use of the term. The authors refrain from using the term for three reasons: a) the term is not necessary (the relevant issues can be more clearly discussed using the terms defined above); b) the term is less and less used in the international discourse on quality of health care; and c) the term may contribute to the misconception that a single intervention or package of interventions can ensure quality, which is definitely not the case.

\(^{11}\) Nepal Health Sector Strategy 2015–2020, p. 22.
\(^{13}\) Ibid.
\(^{14}\) Ibid.
\(^{15}\) ISQua 2015: Guidelines and Principles for the Development of Health and Social Care Standards.
Framework conditions

2.1. Strategic framework

Quality of health care features prominently in the current debate over the operationalisation of the NHSS which is taking place among politicians, health administrators, consumer representatives and health care providers in Nepal. Relevant strategic documents all point to the importance of performance monitoring across the health sector and, in particular, at the point of service delivery. However, there is not yet a clear strategic orientation regarding the envisioned roles and responsibilities of, and interplay between, the different stakeholders involved. This applies in particular to the division of roles between the GoN and the “independent accreditation body” envisioned in the NHSS. Furthermore, quality improvement goals⁴ are still insufficiently prioritised, which may be an important reason for the frequently observed fragmentation of quality improvement approaches. A lack of prioritisation is also likely to present a major challenge when moving from the strategic level to operationalisation in the context of resource shortages.

2.1.1. Policy on Quality Assurance in Health Care Services

The Policy on Quality Assurance in Health Care Services 2064 (2007) aims to integrate activities related to the development and improvement of quality health services with all types of health programmes and to ensure that a “quality assurance system” is in place in all health facilities. “Quality assurance” is defined as “a continuous process which includes a series of activities for improving and maintaining an optimum level of quality health services.” These activities include “setting standards and protocols, communicating standards, developing indicators, monitoring compliance with standards and solving problems by a team approach.” The Policy lists a range of elements (Figure 2) which may be seen as part of the envisaged “quality assurance system,” but provides no guidance as to how the different elements should interact, i.e. how the system should function. It states that a “hospital accreditation system will be established and gradually extended,” but does not provide any guidance as to how this should be done. The Policy does not make reference to regulation.

1 Quality improvement goals are different from broader health goals in that they are more specific about what needs to change in relation to particular domains of quality. In Quality of Care: A process for making strategic choices in Health Systems, WHO provides examples, e.g. the health goal “reduce avoidable mortality” may be translated in the quality improvement goals to “reduce medication errors by 50%.” Only explicit quality improvement goals provide a basis for measuring progress and impact in the change process.

2 Chapter 5, Article 17.
2.1.2. National Health Policy

The National Health Policy 2071 (2014) makes no specific reference to the Policy on Quality Assurance in Health Care Services, but embodies a rights-based approach to access to quality health services (universal health coverage). Good governance and the right to information feature prominently throughout the policy. The document further notes that professional councils shall be strengthened to ensure “professional standards and quality of health services.”

Policy Orientation 8 in the National Health Policy – ensuring the provision of quality health services through an efficient and accountable mechanism and process of coordination, monitoring and regulation – is supported through the following strategies:

- A regulatory authority for “quality assurance” to regulate all services delivered by public and private providers;
- Regulation of drugs;
- National (treatment) guidelines and protocols;
- Regular monitoring of health care quality;
- Standardisation and regulation of laboratories and blood banks;
- A system of awards and punishment for health care providers on the basis of their performance;
- An appropriate institutional mechanism to hear and deal with complaints and grievances from patients and service providers;
- Regulation of the private sector;
- Early warning for epidemic threats; and
- Prescription of generic drugs.

3 N.B. In Nepal “health services” apparently refer to the structural functioning of different categories of health care workers and not to the performance of health institutions (compare Health Services Act and Rules).

4 This is a direct translation of the original Nepali version. The unofficial English translation available on the internet speaks of a “legal system,” rather than an authority.
The Policy does not provide further direction as to how (a) and (d) should be operationalised. Moreover, the “hospital accreditation system” as envisioned in the Policy on Quality Assurance in Health Care Services is not mentioned; it is unclear whether the regulatory authority referred to in (a) is the same as the “hospital accreditation system.”

2.1.3. Nepal Health Sector Strategy

The Nepal Health Sector Strategy 2015-2020, the most recent strategic document published by the MoH, sets as its goal to “improve [the] health status of all people through an accountable and equitable health service delivery System” (p. ii). The Strategy aims to strengthen the institutional capacity of the MoH to ensure that healthcare institutions become “more accountable to people and patient outcomes rather than simply quantities of services” (p. 24). Service delivery targets are specified in the Strategy’s results framework (pp. 48-70) and could be used to establish a performance measurement framework for health facilities, i.e. by breaking down the aggregate targets into specific targets for different types of health institutions.5 Quality improvement goals for health institutions6 can be derived from the goals and the indicators, as shown by the following examples:

- Health institutions’ accountability to purchasers, clients and the general public is increased (Goal)
- Access to the health institution is improved (Goal)
- Maternal, newborn and child health services are improved (Indicators: maternal, neonatal and child mortality rates)
- Health institutions provide family planning services according to standards (Indicator: Total Fertility Rate)
- Health institutions provide psychosocial services according to standards (Indicator: suicide rate)
- Health institutions provide prevention and care of non-communicable diseases according to standards (Indicator: Disability-Adjusted Life Years non-communicable diseases)
- Health institutions provide emergency care and rehabilitation of injuries according to standards (Indicator: Disability-Adjusted Life Years injuries)

The NHSS emphasises that “cumulative improvements in the health system actually result in improved quality of care at the point of service delivery” and that this “can be measured through explicitly defined quality standards.” According to the NHSS, care is of quality when it is effective, safe, client-centred, timely, equitable, culturally appropriate, efficient, and reliable. Key interventions to achieve “improved quality at the point of delivery” (outcome 2 of the strategy) include the development of a “comprehensive regulatory framework and an independent body for quality assurance and accreditation.” However, the terms “quality assurance” and “accreditation” are not clearly defined. Their use in the document is not consistent and leaves ample room for interpretation.

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5 Some outputs are more related to functions of MoH, the National Health Insurance or other entities, while most inputs could be easily translated into relevant standards for health institutions.

6 To be measurable they would need to be made more specific, however the strategy does not provide sufficient information to do so.

7 p. 12.
In different parts of the NHSS, the following functions (purposes) of the “accreditation body” are mentioned:

- “Quality assurance” of health services in public and private sectors (p. ii; p. 22);
- Ensuring quality standards are developed, introduced and employed across all types of public and private sector providers (p. 22);
- Ensuring high standards of health services (p. 23);
- Promoting safe and good medical practices (ibid);
- Regulating quality (ibid); and
- Investigating non-compliance of service providers (ibid).

2.1.4. Other strategic documents

With the establishment of National Health Insurance, an important new strategic player has entered the scene. The objective of the National Health Insurance Policy is to “ensure Universal Health Coverage by increasing access to, and utilization of necessary quality health services.” It aims to “improve the effectiveness, efficiency, accountability, and quality of care in the delivery of health care services.” Once the National Health Insurance achieves significant coverage, its purchasing power will create substantial leverage to reward good performance and sanction poor performance. Specific contractual arrangements between the Insurance and health care institutions may provide additional opportunities to promote quality of care.

Different projects and programmes under the MoH have their own strategic plans, each of which also reflects notions of quality improvement. While some of the strategies speak of integration and coordination with other programmes and divisions, they do not indicate how this integration should be achieved. For example, the National Safe Motherhood and Newborn Health Long-Term Plan 2016-2017 seeks to “improve the quality of services through [the] development of quality assurance and monitoring systems with on-site coaching and logistic support, in coordination with appropriate divisions” (p. 23), but does not specify the institutional set-up for the “systems” or the “coordination.”

The National HIV/AIDS Strategy 2011-2016 aims to “establish external and internal quality management systems to address clinical care, laboratory testing, and workplace improvement for ensuring and improving the quality of care.” Furthermore, it seeks to “establish standardized procedures to accredit health facilities and to certify health care providers in the delivery of HIV prevention, treatment and care” (p. 46), but makes no reference to the required institutional set-up.

The Urban Health Policy 2072 foresees establishing “certain criteria and standards for assessing the quality of the basic health services” and developing “implementation guidelines to assess the quality of basic health services delivered and [to] monitor the activities regularly” (p. 7). The establishment of mechanisms for monitoring and evaluation depend upon an unspecified “coordination committee” (p 10).

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8 Social Health Security Programme: Structure and Core Standard Operating Procedures, 2016, p. 3.
2.1.5. Assessment of the strategic framework

This section has illustrated how the strategic framework for improving the quality of care in Nepal is shaped by different actors, resulting in a context characterised by inconsistencies, overlaps and duplicated efforts. At present, the country does not have a coherent roadmap for the journey towards better quality of care. In particular, the roles and functioning of the envisioned “accreditation body” and the National Health Insurance are not developed. The roles and responsibilities of different actors, and the way in which they should communicate and complement one another, are not described in sufficient detail to serve as guidance for strengthening quality improvement efforts in the country.

2.2 Regulatory framework

This section reviews the existing and planned legislative basis for quality improvement and the introduction of an “accreditation body.” It begins by considering the relevant provisions in the new Constitution of Nepal and the envisioned Public Health Act, and then addresses the regulation of health institutions and related topics such as the registration and licensing of the health workforce and educational institutions, the regulation of medicines, related products and pharmacies, and the regulation of laboratories. Finally, it explores existing legal provisions which are relevant for the creation of an “accreditation body.”

2.2.1 Constitutional and legal basis for quality improvement in health institutions

Before considering existing regulations for health care institutions, this sub-section looks at the highest-level legal framework: the Constitution and the pending Public Health Act.

The Constitution of Nepal 2015 recognises health as a fundamental human right. Article 35 sets forth the right to health care:

(1) Every citizen shall have the right to seek basic health care services free of cost from the state and no citizen shall be deprived of emergency health care. (2) Each person shall have the right to be informed about his/her health condition with regard to health care services. (3) Each person shall have equal access to health care. (4) Each citizen shall have the right to access to clean water and hygiene.

Article 44, the right of consumers, states that each consumer shall have the right to quality foodstuffs and services. A “person who has suffered from sub-standard object or service shall have the right to be compensated as provided for by law.” Finally, Part 4 of the Constitution declares that the State shall enact policies which ensure easy and equal access to high-quality health care for all (Article 51 h (6)). Framing the establishment of a performance measurement system as (part of) one of these policies would provide a strong regulatory basis for such a system.

The immediate mandate to adjust existing legislation and/or to develop new legislation to promote the quality of health care can be found in Article 47, which states that the State shall make legal provisions, as required, within three years of the commencement of the Constitution for the enforcement of the rights conferred. This means that legislation to ensure “access to high quality care” should be developed by 2018.
A number of other fundamental rights need to be taken into consideration when designing a performance management system for the health sector. Some examples include:

- Article 27: The right to seek information on any matter of concern to a citizen
- Article 28: The right to privacy
- Article 30: The right to a healthy and clean environment
- Article 42: The right of equal access for poor people and persons with physical impairment

Despite the statement of intent in the Health Policy to develop a Public Health Act, Nepal does not currently have an overarching health act specifying the functions of, and interplay between, different stakeholders. Such an act is currently under development, but has not been studied in this assignment.

Ideally this act should, inter alia, outline the entire quality improvement system in general terms. To allow sufficient space and time for the technical processes needed for setting up the relevant institutions and regulations, it may be beneficial to defer further regulation to a specific act or rules and to indicate a realistic timeframe for this to be completed.

### 2.2.2 Regulation of health institutions

Efforts to better regulate health care provision date back to 2002, when a Health Institution Operation Act was submitted to the upper house of parliament for discussion. The GoN committed to passing the Act by 2013 as a condition of the country’s membership in the World Trade Organization. In 2012 GIZ supported the MoH to develop a Health Institution Regulation and Operations Bill. Despite provisions in the Nepal Health Policy 2014 for a legal system to regulate all health services provided by the government and by non-governmental organisations, the process came to a halt and, to date, no such law has been passed. A detailed report describes the process and important discussions related to the establishment of the Bill.9

Currently, the MoH regulates health institutions on the basis of the Guidelines relating to Standards for Establishment, Operation, and Upgrading of Health Institutions (2014). Chapter 3 of these guidelines stipulates that “nobody should operate/run health services without acquiring license for the same.” While the Guidelines are intended for both state and non-state health institutions, the government’s sole focus when implementing the Guidelines has been on the for-profit sector. According to the Guidelines, the responsible licensing authority is determined by the number of beds at an institution, not by the type or level of the institution (Table 1). A similar system is foreseen for Ayurveda clinics and hospitals.

According to the Guidelines, a license (i.e. permission to operate) can be granted or refused on the basis of compliance with a set of formal requirements (e.g. application, fees, etc.) and compliance with standards is documented in a report based on self-assessment. Temporary licenses can be given for a period of up to three years to fulfil infrastructure requirements and standards. Despite this, the licensing authority may send

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inspection teams to carry out surprise monitoring visits (Chapter 4). If a health institution fails to cooperate during an inspection, does not meet the standards and infrastructure requirements, and/or does not submit its annual quality assessment report, the licensing authority may issue an order for the institution to immediately cease the provision of services (either completely or partially). There is growing anecdotal evidence that health facilities have indeed been closed following such inspections. However, the legal basis for such actions is incomplete. While the preamble to the Guidelines refers to the authority granted in Clause 45 of the Good Governance Act, 2064, this clause only allows the GoN to frame and implement necessary directives or manuals “for the purpose of carrying out the activities of government offices or work performance in a manageable, speedy, and economical manner in terms of process.”

The Guidelines are not a regulatory document per se – as acts, laws, bylaws and rules are – and can therefore only be enforced with reference to laws that are not specific to the health sector, such as the Consumer Protection Act. This Act clearly prohibits the supply of services which may cause harm to the health of consumers. Its provisions aim to protect consumers from, inter alia, irregularities in the quality of services, including paid health care services. The standards set out in the Guidelines Relating to Standards for Establishment, Operation, and Upgrading of Health Institutions can be enforced under the Consumer Protection Act once it has been officially published in the Nepal Gazette.

The Consumer Protection Act contains three other provisions which are significant for the regulation of health services:

- Clause 28 states that GoN or the Consumer Protection Council may delegate some of the powers vested in it under the Act to any Sub-Committee or to any officer as required. Clause 27 allows for the formation of necessary Sub-Committees in order to fulfil the objectives of the Act. The Council may form a Sub-Committee relating to health in combination with representatives of the MoH and other stakeholders. It is, however, important to keep in mind that, until this point, the Consumer Protection Council has not met regularly and it is unclear how effective structures operating under it would be.

- The notion of “unfair trade practices” is of relevance in the context of any form of endorsement of health services by the MoH. “Unfair trade practices,” which are a punishable offense, include making false or misleading claims about the actual quality

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of services. This provision places (indirect) liability on the MoH for the provision of licenses.

- Clauses 22 and 23 cover the establishment of Compensation Committees in every district to conduct inquiries into complaints filed and to award compensation for losses or damages suffered by the consumer as a result of services rendered.

In addition to the Consumer Protection Act, a number of other laws regulate selected aspects of health care institutions. Such laws include:

- **Infrastructure Construction and Operation of Private Investment Rules** regulate the construction of private health institutions;
- The **Environment Act**, which requires an environmental impact assessment for the operation of hospitals or nursing homes with more than 25 beds;
- The **Good Governance Act**, which contains some provisions relevant for the management of health institutions. For example, Chapter 5 stipulates that a “complaint box shall be maintained at the visible place of every ministry, department, and government agency and office for the management of grievance relating to quality, effectiveness of the work carried out by such ministry, department and agency or office and possible irregularities in them;” and
- The **Labour Law** (currently under revision), which contains provisions regarding staff safety and fire prevention.

### 2.2.3 Registration and licensing of the health workforce and educational institutions

All health professionals receive certification from their training institute after finishing their education, but need to register and be licensed by their respective professional council in order to practice. The councils are autonomous bodies regulated on the basis of four Acts: the Nepal Medical Council Act, 2020 (1964), Nepal Nursing Council Act, 2052 (1996), Nepal Health Professional Council Act, 2053 (1997), and Nepal Pharmacy Council Act, 2057 (2000). The councils may revise their decisions and cancel registration or recognition.

Unlike the other acts, the Medical Council Act requires the development of a code of conduct for its members. The Nursing Council Act foresees renewal of registrations (as an administrate procedure) and, in contrast to the other acts, explicitly introduces the possibility of re-examination of its professional members at the stage of renewal. The GoN may frame rules needed to implement the acts, based on advice by the respective councils.

The aforementioned acts allow, in principle, for the councils to formally recognise educational institutions in their respective fields, as well as the certificates and degrees awarded by these institutions, based on standards to be set by the councils themselves.

Responding to public pressure to make health education more scientific, credible, equitable and socially accountable, the GoN tabled the Health Profession Education Bill on September 14, 2016. The Bill proposes a 10-year moratorium on the establishment of new medical, dental and nursing colleges in Kathmandu Valley. It also proposes the creation of
a Health Profession Education Commission (HPEC) which would centralise the regulation of academic institutions which is currently carried out by the respective professional councils. HPEC will be tasked with issuing licenses for new academic institutions and made responsible for the quality of education provided by these institutions. Beyond this, a key function of HPEC will be to formulate national policies on education for health professionals.

2.2.4 Regulation of medicines, related products and pharmacies

The Department of Drug Administration (DDA) was established in 1979 as the Medicines Regulatory Authority under the auspices of the Drug Act 2035 (1978). The regulation of medicines and related products under the Drug Act and the Drugs Registration Rules 2038 (1981) are rather out-of-date. According to a previous analysis, key issues include:

- A narrow definition of “drug” which excludes homeopathic drugs, medicinal herbs and ayurvedic substances;
- A lack of efficiency and flexibility in the registration processes for medicines and related products;
- A weak and insufficiently independent regulatory mechanism (DDA);
- Provisions relating to the licensing of medicine manufacturers and wholesalers, pharmacies and other medicine retailers are outdated, lack clarity, and/or do not adequately safeguard consumers; and
- A lack of regulation-making powers to enable flexibility for new standards and innovations in medicine, such as electronic prescribing.

Initiatives to establish a National Drug Administration Bill had come to a halt, but, according to the Director of the DDA, have recently been taken up again.

The DDA is also responsible for the registration and inspection of pharmacies (Drug Act (2035) Section 34, and Drug Investigation and Inspection Rules, 1983). Punitive measures may be applied when licensing requirements are not met. While some pharmacies have been closed, the overall system is not yet sufficiently functional. The reasons for this, according to interview respondents, include incomplete registration of pharmacies in the electronic registration system, lack of manpower to conduct inspections and, occasionally, fear of being attacked when closing pharmacies. A set of standards for pharmacies has been drafted (the Nepal Pharmacy Council’s National Good Pharmacy Practice Guidelines), but has not been endorsed by the GoN.

2.2.5 Regulation of laboratories

In accordance with the National Health Policy 2014 and National Health Laboratory Policy 2069, the National Public Health Laboratory (NPHL) is the country’s central and specialised national referral public health laboratory. It is also the regulatory body for licensing both public and private labs. As the focal point for blood safety in the country, the
NPHL also hosts the National Bureau of Blood Transfusion Service. While the National Health Policy states that “necessary laws will be prepared that will allow laboratories to operate only after accreditation,” no such laws exist. The NPHL conducts supervisory visits, but there does not seem to be any systematic evaluation of public and private labs against standards. The major challenge facing the NPHL is a shortage of human resources.

2.2.6 Existing legal provisions with relevance for the creation of an “accreditation body”

As the NHSS envisions the establishment of an “accreditation body,” the consultant team reviewed existing legislation to find possible implications for such a body in Nepal’s current laws.

According to the Constitution of Nepal – which outlines the distribution of state power to three main levels: federal, provincial and local – health standards, quality and monitoring are federal powers. This constitutes the basis for the creation of a national “accreditation body” which may or may not have some administrative units within the country.

In principle, publication in the Nepal Gazette of the standards against which health institutions will be assessed may provide a sufficient legal basis to regulate paid services under Clause 11.2 of the Consumer Protection Act. However, this Act only provides coverage for punitive action in cases of non-compliance with standards and is insufficient to grant regulatory power in terms of incentives and/or other possible mandates of the “accreditation body.”

The future Public Health Act may provide a more adequate legal basis for the establishment of an accreditation body. Details could then be further developed in subsequent legislation (e.g. bylaws, rules).

In addition, the Good Governance Act may be used as a legal basis for creating a preliminary structure that could be tasked with setting up the organisation. Enshrined in this Act is the opportunity to set up essential bodies. In addition to ministries, departments, and offices, the GoN may constitute secretariats, commissions, boards, centres, committees or other such bodies as needed to carry out administrative functions. The functions, duties, powers and terms of reference of such entities shall be determined by the GoN.

Whether and how the task of setting up the “accreditation body” may be contracted out could not be fully clarified within the scope of this assignment. Under the Good Governance Act, an “accreditation body” can be set up in terms of a “project or programme of national priority” by entering into a performance contract with any official, assigning him/her the responsibility of executing such work (Clause 19). However, Clause 3 of the Public Procurement Act 2007 seems to limit the freedom to conclude such a performance contract by stating that any public entity shall have to make such procurement in compliance with the procedures set out in this Act and that any procurement made in such a manner as to be contrary to the Act shall be void and invalid.

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14 Ibid and verbal communication during the mission.
Under the Development Board Act, the GoN can form a Board by a Notified Order in order to execute any development plan or development work as mentioned in that Order. An “accreditation body” could therefore be formed by a Notified Order, however it might need additional legal backing in the event that its role involved enforcing sanctions.

2.2.7 Assessment of the regulatory framework

This section has explored the existing and planned legislative basis for quality improvement and the introduction of an “accreditation body.” The Constitution of Nepal enshrines the mandate to improve the quality of health care and to establish necessary policies and laws by 2018. At present, the regulatory framework for health institutions and for regulating the quality of health care is patchy. Some laws related to quality of care, such as the Labour Act, are currently under review. The effectiveness of regulation is limited due to low levels of enforcement and insufficient resources. The pending Public Health Act provides an opportunity to set out the foundations for meaningful quality improvement legislation. The regulatory framework for the future “accreditation body” can be connected to some existing laws, but will most likely require additional legal backing depending on the concrete functions the body will perform.

2.3 Governance structures

A quality improvement governance structure should ideally include all relevant stakeholders at various governance levels: technical, strategic, and political steering/oversight. (A list of the most relevant stakeholders in Nepal is provided in Appendix 1.) This section looks into the interactions between different stakeholders and current practices at different levels of governance.

The current governance situation reflects the orientations and shortcomings of the Policy on Quality Assurance in Health Care Services 2007, which relies heavily on oversight and steering through committees and fails to clearly demark the interdependent, yet distinct domains of regulation and continuous quality improvement.

The lack of linkages between the current governance entities – the various committees and the Health Facility Development and Quality Section in the Management Division – and newer structures, such as the licensing authorities and the Social Health Security Development Committee, indicate that the current governance structure may be outdated. Furthermore, the current governance structure does not make use of the institutional opportunities enshrined in the Consumer Protection Act (see Chapter 2.2.2). The MoH is not a member of the Consumer Protection Council and no health-specific sub-committee or working group has been established.

The MoH is responsible for making the necessary arrangements and for formulating policies for the effective delivery of curative services, disease prevention, health promotion activities, and the establishment of a primary health care system. It is currently a provider, a regulator and, in some instances, a purchaser16 of health care services. However, it faces challenges in terms of provision and regulation and may need to redefine its roles and

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16 Under contractual arrangements with government health care providers, hospitals hire private providers for C-sections and also pay for uterine prolapse (among others).
functions, particularly in the area of quality improvement. The NHSS notes that the current structure, “which is more than 25 years old, may not be prepared enough to address the contemporary and emerging health challenges” (pp. i-ii).

The main quality structures within the MoH at central level include the licensing authorities (see Chapter 2.2.2) and the Health Facility Development and Quality Section in the Management Division. According to the National Policy on Quality Assurance in Health Care Services, the Health Facility Development and Quality Section “will be developed as a focal point for overall quality improvement” and “will be responsible for implementation, monitoring and evaluation of quality assurance17 activities carried out by the government and non-government sectors throughout the country” (Chapter 5).

In practice, the Quality Section has never been adequately staffed to perform this large responsibility. Most of the activities that fall under the policy’s definition of “quality assurance” – such as setting protocols and standards, compiling data or supporting quality improvement within health institutions – are conducted by a range of entities under the MoH or, in certain cases, outside of it (e.g. the rare cases of ISO certification). Often, activities are driven by external development partners who have no working relationship with the Management Division. Structurally there are no platforms which would enable the Quality Section to oversee and steer these various activities and it is therefore unclear how “being responsible” should be operationalised. A view expressed by many interview partners (and shared by the authors) is that the positioning of the Quality Section within the MoH hierarchy represents an obstacle to the Section’s ability to carry out its designated functions.

Currently the Health Facility Development and Quality Section also acts as the licensing authority for hospitals with 51 to 200 beds. (As described in Chapter 2.2.2, the MoH has set up licensing authorities at all levels. However, these are insufficiently backed by legislation and suffer from human resource constraints.18)

Apart from these institutional arrangements, coordination structures in the form of “quality assurance” committees throughout the health system are envisioned by the Policy on Quality Assurance in Health Care Services 2007. In practice, however, “quality assurance mechanisms are weak” and there is “no resource backup for the intended mechanisms.”19 Interviews revealed that the quality assurance steering committee has met only twice since 2007; committees at district and hospital level depend to a large degree on material and motivational support from externally-financed projects. There is also a large range of fragmented quality improvement initiatives which require separate committees with partly overlapping functions. Such committees include, for example, the “operation committees” under the Quality and Service Improvement of District Hospitals Programme, or the “maternal perinatal death review committees” required by the Maternal and Perinatal Death Surveillance and Response Guideline.

17 See Chapter 2.1 for the definition of “quality assurance” in the National Policy on Quality Assurance in Health Care Services.

18 Verbal communications during the review. The MoH does not maintain a database of the number of hospitals (licensed and unlicensed) which exist in this category, but we estimate that this category must number in the hundreds. There are limited staff in the Management Division to plan and execute licensing visits.

19 Health & Education Advice and Resource Team (HEART) 2013: Nepal Health Sector Programme II (NHSP II) Mid-Term Review, p. 49.
With a view to relaunching national quality improvement efforts, some stakeholders, with support from the Health4Life project, held an initial meeting of a Quality Improvement Technical Advisory Committee (QI TAC) on January 21, 2014. The meeting participants agreed to draft a framework for a National Quality Improvement System, as well as TORs for different committees. The proposed entities were approved by the Director General of the Department of Health Services (DoHS) in February 2014. A technical working group under the technical advisory committee proposed a National Quality Improvement Structure, as visualised in Figure 3. In a presentation during the External Development Partner Meeting on October 26, 2016 in Kathmandu, the chief of the quality assurance section said that, while committees are still “unable to adequately steer quality improvement,” there is currently a process underway to make the committees more functional. The proposed National Quality Improvement Structure makes no reference to the planned “accreditation body” – its placement within the quality improvement structures remains unclear – nor does it refer to the National Health Insurance.

When discussing the National Quality Improvement Structure, practitioners highlighted the lack of adequate governance structures to deal with patient complaints and grievances in a structured, predictable manner. This may lead to unrealistic and exaggerated claims, which can pose a considerable risk to both health institutions and individual practitioners. From the consumer perspective, however, the result of this situation is a lack of clarity on how, where and when to file complaints and a perception that one is “at risk” when seeking health care. The Nepal Medical Council accepts complaints and grievances against physicians and is able to follow them up as resources permit, however this approach remains far from a well-structured, universally acceptable complaints system.

21 Ibid.
2.3.1 Assessment of governance structures

The section on governance has looked at the technical, strategic, and political management of quality improvement activities in Nepal, as well as interactions between key stakeholders. As it currently stands, the governance framework for quality improvement is not sufficiently institutionalised and depends to a large degree on the work of different committees at all levels of the health system. The National Quality Improvement Structure which has been proposed makes no reference to National Health Insurance as a new key player in quality improvement. Neither does it refer to the “accreditation body” envisioned in the NHSS.

The capacity of the Health Facility Development and Quality Section in the Management Division of the DoHS lacks both the resources and the structural power to fulfil its mandate as a focal point for quality improvement, as stipulated in the Policy on Quality Assurance in Health Care Services 2007. The resulting deficiencies in stewardship for quality improvement activities and in coordination among different actors contribute to the fragmented approach to quality improvement.
Experiences with quality improvement approaches in health institutions in Nepal

Nepal has more than two decades of experience with different quality improvement approaches, all of which have been initiated by or strongly associated with externally-funded projects and have yet to be institutionalised. This chapter describes a selection of current and past (documented) quality improvement approaches in health institutions. These examples were identified through stakeholder interviews and internet research and should not be taken as comprehensive overview.

3.1. Standard-based approaches

3.1.1 Temporary licensing of private health institutions

As described in Chapter 2.2, the MoH has recently started to inspect private health institutions on the basis of the Guidelines relating to Standards for Establishment, Operation, and Upgrading of Health Institutions. Discussions during the review indicate that, while the closure of health institutions is the last resort in cases of non-compliance with required standards, the primary intention is to lift health institutions to the level of the standards. For this purpose, non-compliant health facilities receive recommendations and are issued temporary licenses which allow them to continue operating while working to meet the requirements. However, this approach to inspections cannot be systematically applied because of a lack of human resources. Inspection and feedback are not yet standardised and are not perceived as fair and transparent by respondents interviewed during this review. Self-assessment and inspection data are not available electronically, which makes comparison, aggregation, and follow-up extremely difficult. Some private health care providers indicated that they would appreciate more constructive support to meet the standards. This might mean, for example, guidance on realistic ways to measure and improve the quality of care, rather than a focus on standards that are perceived to overrate infrastructure characteristics. Benchmarking with other facilities, learning opportunities and incentives for good quality would also be appreciated.
3.1.2 Standard-based assessment of clinical and managerial performance to stimulate quality improvement

With support from different development partners, the National Health Training Centre (NHTC) has developed a set of quality improvement tools\(^1\), which set forth rather sophisticated measurable performance standards for sexual and reproductive health services, particularly maternal and newborn emergency care and family planning.\(^2\) The standards have been used in the context of different projects as a basis for gap identification, action planning and mentoring to enhance the quality of care. Owing to the complexity and specificity of the standards, assessment can only be done by well-skilled and experienced professionals.

A well-documented example stems from the Improving Emergency Maternal and Newborn Care Project, which implemented a comprehensive quality improvement mechanism – the Standards-based Management and Recognition approach\(^3\) – as a pilot in several districts\(^4\) between July 2014 and July 2016\(^5\) under the leadership of the MoH’s Family Health Division with support from GIZ/S2SHP. The approach included assessment of maternal and newborn care and management against standards, as well as training and regular mentoring support, to improve areas of weakness and to address underlying circumstances and processes. Operational research\(^6\) indicated that combined clinical and management mentoring led to improved clinical competence and facility management performance. However, many district supervisors reported that the work environment was largely unchanged and stressed the need for more equipment and infrastructure support.

3.1.3 Standard-based self-assessment of minimum standards for district hospitals

On the basis of standards developed by the MoH’s Curative Services Division, and with support from Nick Simons Institute (NSI), a self-assessment tool focused on monitoring the performance of hospital management practices has been developed for quantifying compliance with standards.\(^7\) The tool is embedded in the Quality and Service Improvement of District Hospitals Program, supported by NSI, which aims to strengthen hospital management functions to ensure the provision of basic health services. In this context, self-assessment serves as a key element in the classic Plan-Do-Check-Act (PDCA) – or Deming

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2. The quality improvement tools should not be confused with the tool for the Skilled Birth Attendant Follow-up Enhancement Program (SBA-FEP), which is a mixture of knowledge and skills assessment. The SBA-FEP tool is designed to enhance skills of individual providers, but does not measure the performance of the health institution. It is not a quality improvement tool.
3. Developed and implemented worldwide by the international non-governmental organisation Jhpiego.
4. Far Western Region (Achham, Baitadi, Dadeldhura, Doti, Kailali), Mid-Western Region (Bardiya, Dailekh, Jumla, Surkhet) and Central Region (Dhading).
5. MoH/GIZ/GFA/Jhpiego: Standards-Based Management and Recognition: Improving the Quality of Maternal and Newborn Care through Structured On-site Mentoring.
7. MoH Curative Services Division 2015: Checklist to Identify the Gaps in Minimum Service Standards (MSS) of District Hospitals.
– Cycle to identify gaps and to measure the success of quality improvement activities. Through the programme, financial resources for improvement are made available and the self-assessment is supposed to be combined with community feedback through social audits (see below). Presentations made by district hospitals during the annual regional reviews in 2016 indicate that the tool has been successful in facilitating improvements in management practices and in encouraging competition among hospitals for the highest score.

The minimum standards have already been implemented in over 40 district hospitals and will be extended to the rest of them. Similar minimum standards for other levels of care are also being prepared. Critics note that performance measurement against the minimum standards has only limited value to predict the level of quality of care achieved (although thus far there is no research which has correlated compliance with the minimum standards with process and outcome indicators).

3.1.4 Certification based on ISO standards

ISO develops international standards, but is not involved in their certification or in the issuing of certificates. This function is performed by external certification bodies which may or may not have to be “accredited” (here: acknowledged) by the International Accreditation Forum as operating in accordance with international standards.

It is important to point out that having a certificate is only loosely associated with the quality of health care services. No institution can be “ISO-certified.” Institutions can, however, receive a certificate of conformity with ISO standards for a specific purpose, for example:

- ISO 9001:2015 specifies the requirements for a quality management system when an organisation a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements; and b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

- ISO 13485:2016 specifies the requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

- ISO 30302:2015 gives guidance for the implementation of a management system for records and describes the activities to be undertaken when designing and implementing such a system.

ISO is a network of national standards bodies from around the world. There is only one member per country, and each member represents ISO in its country. The Nepal Bureau of Standards & Metrology, the national standard body in Nepal, is a government organisation under the Ministry of Industry. It is also the national enquiry point (nodal point) for the World Trade Organization. As a full ISO member, it can influence ISO standards
development and strategy by participating and voting in ISO technical and policy meetings. It sells and adopts ISO international standards nationally.

In Nepal’s health sector, there is only very limited experience with certification for compliance with ISO standards. The NPHL is currently preparing for certification. Norvic International Hospital is certified in accordance with ISO 15189:2012, which specifies requirements for quality and competence in medical laboratories. In 2015, Samyak Diagnostic Pvt Ltd received the certificate for conformity with the same standard.

### 3.1.5 Adolescent-friendly service (AFS) centres

The Family Health Division of the MoH, with support from UNFPA, has developed a process which aims at certification of AFS centres using a quality improvement and certification tool. The process includes whole site orientation, establishment of adolescent-friendly centres, onsite training, training for service providers from AFS centres and, finally, the certification of AFS centres. This particular certification is yet to be rolled out nationwide. However, there have been past attempts at certification for the same services by the Family Health Division, with support from GIZ, with little evidence to link improved quality of AFS services with the implemented certification process.

### 3.2 Community-based approaches

#### 3.2.1 Social audits

Social audits have been introduced to increase citizens’ participation in decision making about local health facilities. Results of the different information-gathering activities (e.g. records, exit interviews) are presented at a public meeting where community members air concerns, ask questions of care providers and decision makers, and participate in forming an action plan. The report and action plan provide a road map for the following year, identifying problems that need to be solved and ways to improve the quality of services.8

While social audits can, in theory, increase understanding between health service providers and clients, thereby leading to direct improvements in services, research in Nepal has not documented these results. Anecdotal evidence points to improved performance of facilities, including longer and more regular service hours; more polite and caring treatment of clients, especially those from lower castes and economic groups; recruitment of additional staff by facility management committees; and improved cleanliness and infrastructure (e.g. water supply, waiting rooms).9

According to a presentation during the Joint Annual Review, social audits were conducted in 1,252 facilities across 55 districts in 2015-16. According to the current Policy on Quality Assurance in Health Care Services, they are part of the national quality improvement system.

8 GIZ 2015: Making local health services accountable: Social auditing in Nepal’s health sector.
3.2.2 COPE/PLA

Taking inspiration from the Client Oriented Provider Efficient (COPE®) process, which has been proven to be an effective tool for improving the quality of service delivery in reproductive health services, a new model – COPE/PLA – has been developed based on work done by Kate Butcher and Pitambar Dunghana in Nepal in early 1999. COPE/PLA combines key components of COPE with Participatory Learning and Action (PLA) methods.

The COPE/PLA approach was implemented for 2.5 years at health posts in Dhading and Siraha districts by GTZ’s Primary Health Care Project, starting in 1999. The main results included: improvements in drug management and the rational prescription of drugs, service provider–patient communication, infection prevention and waste disposal, management of human resources, and facility maintenance of facilities. Participation of the community in planning and management, gender sensitivity and resource mobilisation also showed improvements. The most relevant proven impact has been the dramatic increase in the number of patients.

An evaluation highlighted two lessons learned:

- Health posts are not fully staffed, especially in the remoter regions of the districts, and in such facilities it is not possible to use COPE/PLA.
- Regular follow-up is essential to ensure success with COPE/PLA, but this is time consuming for all parties (the health post staff, Health Management Committee members, and facilitators). Also, the follow-up requires 2-3 experienced facilitators, but only a limited pool of facilitators is available and affordable.

3.3 Approaches using critical incidents

Maternal and Perinatal Death Reviews (MPDR) have been conducted in Nepal for a long time, but have made little progress in addressing the underlying causes of maternal and perinatal mortality. Maternal and Perinatal Death Surveillance and Response (MPDSR), an approach which has recently been introduced to address the shortcomings in dealing with maternal and perinatal deaths, combines continuous surveillance/routine identification and notification of maternal and perinatal deaths. The ultimate goal is to reduce the maternal and neonatal death rate. MPDSR is based on a classical PDSA-cycle of continuous quality improvement and involves the following steps:

1. Identification and notification on a continuous basis.
2. Review of maternal deaths by maternal perinatal death review committees in the local health facility, who develop and implement recommendations immediately.
3. Analysis and interpretation of aggregated findings from review at district, regional and

10 Now GIZ.
national level, development of recommendations, implementation, and monitoring implementation.

These activities are to be conducted through a structure of committees throughout the health system. It is too early to understand whether or not the system will work and which factors influence the system.

3.4 Performance-based management

3.4.1 Performance-based grant agreements

In 2012-2013, the MoH finalised the first performance-based grant agreements with seven health institutions and applied a standard monitoring framework. Under the agreement, the Ministry transfers money to a hospital under the budget heading 'Social Service Grant,' with the transfer conditional on the hospital achieving predetermined measurable performance targets. This incentivises the hospital to attain the targets or results. Verification of achievement of the performance indicators is based on self-assessment/reporting inspection and on supervision visits by the Ministry as per the grant agreement. The performance indicators are defined individually per contract and are not based on defined system-wide standards of “good performance.” The implementation of these grants remains to be assessed and rolled out to more hospitals, as initially planned.

3.4.2 Performance-based management system

In 2009 the MoH initiated a Performance-Based Management System (PBMS) which aims to improve the performance of public sector health workers and, ultimately, the public health care system as a whole. PBMS aims to:

- Encourage health institutions and staff with excellent performance and remarkable achievement;
- Support the continuous learning, growth, and development of staff; and
- Strengthen the basis for and develop a culture of result-oriented actions at district level.

Under this approach, high-performing health institutions are to be encouraged, while low-performing facilities should be provided with greater support using facility improvement plans that include specific targets. However, research has indicated that low-performing facilities remained low performing due to a lack of adequate support. Performance management is supposed to be handled by a district-level performance management committee, under the leadership of the District Health Officer, at regular intervals. The complex system depends on the functionality of the committees and other elements, such as good quality supportive supervision, data collection, and management. Research indicated that an innovation like the PBMS needs a dedicated person to work on the process in a focused manner. Extra staff are needed for several years as processes are

13 HERD 2014: Empowering District Level Managers to Improve Health Worker Performance in Nepal.
time consuming. Regional and central backup and monitoring are not sufficient to execute the PBMS effectively or thoroughly; central-level support and monitoring visits would be needed (ibid).

3.4.3 The Community-Based Newborn Care Package

The Community-Based Newborn Care Package, a set of complementary strategies and interventions that aim to reduce neonatal mortality in Nepal, has been designed and implemented by the DoHS with the support of a wide range of partner agencies. One element of the package involves providing Female Community Health Volunteers with an incentive based on their performance of selected key services. This example is mentioned here because of a specific finding during an evaluation of the approach\(^{14}\) which is relevant when designing quality improvement systems. The evaluation found that the calculation of incentive payments based on data induced over-reporting and therefore limited the usefulness of the data for monitoring.

3.4.4 Claim evaluation on the basis of patient feedback and medical review

A specific form of performance-based management is currently being introduced in the pilot districts for the National Health Insurance. Standard Operating Procedures for the Social Health Security Programme (SHSP) foresee that enrolment assistants go to the house of the SHSP member whose claim was selected for feedback and fill out the form in the feedback app according to the process described in the Insurance Management Information System (IMIS) Mobile Phone Application User Manual. Once the form has been completed, it is sent via the internet, or via the enrolment assistants if there is no internet connectivity, to the IMIS. The medical review team then evaluates the particular claim based on the feedback received from the SHSP member.\(^{15}\) Hospitals shall receive feedback and may use the feedback to address processes that led to the complaint from patients. Data collection on the quality of services may include other sources, such as the complaint hotline (Ibid). A medical review of samples of claims through the SHSP medical review team provides feedback to the health facilities.\(^{16}\) Adjustment is supported by District Social Health Security Coordination Committees which “assist health facilities to improve their infrastructure” (Ibid, p. 6). The imposed fee (50% co-payment) for bypassing the first service point may or may not have some leverage on quality of care.

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14 Assessment of the Community-Based Newborn Care Package in Nepal. (The report is a simple Word document without author and date. It has been based on the Terms of Reference of an “Assessment Reference Group” which was formed in early 2011 and included representatives from organisations and agencies that support the CB–NCP).


16 Rejection/Valuation variation criteria related to 'Service Provision' area. Over-prescription of drugs (manually done in IMIS by claim reviewers). Unrelated services (ICD Codes vs. Services) also done manually in IMIS by claim reviewers.
4.1. Strategic level

1. The review of the strategic framework reveals that there is now a clear focus on quality of care and an orientation towards the establishment of some form of regular, well-documented and system-wide assessment of performance against standards.

   This will require the development of, and agreement on, a measurement framework.

2. Quality improvement goals for health institutions can be derived from the NHSS, but achieving all of these, at all levels of care, is ambitious and may not be commensurate with available resources. This implies that it may be necessary to prioritise and further specify goals for different types of health facilities.

   A joint measurement framework would enhance consistency and synergy across different quality improvement interventions, reduce duplication, and ease the burden on health managers and health workers who are currently called upon to implement strategies for all the MoH’s different projects and programmes. Once the quality improvement priorities for the different types of health institutions are determined, it will be easier to decide the specific content and focus of a measurement framework for tracking progress on these priorities. It is therefore recommended to set prioritisation criteria, to focus on the highest priorities, and to get started. It is always possible to broaden the scope of the measurement framework at a later stage.

3. The current strategic framework is somewhat ambiguous about the specific objectives of performance assessment, and the functions of the envisioned “accreditation body” are not yet sufficiently defined. Interviews conducted in the context of this review revealed views, concerns, and expectations regarding the “accreditation body” which go beyond or differ from those mentioned in the NHSS. Expectations of interviewees towards the “accreditation body” include the following:
   • Providing benchmarks for comparison
   • Providing certificates that can be displayed to inform clients/population
   • Stimulating continuous quality improvement
   • Providing data for national planning and steering of health service delivery
   • Providing a basis for empanelment with health insurance
   • Regulation to prevent sub-standard service delivery
It will be easier to determine the approach to regular performance assessments, as well as the organisational and governance structure of the envisioned “accreditation body,” once the specific objectives of these assessments are spelled out. It is particularly important that the desired regulatory functions are clearly identified and that these not be confounded with other objectives. It is necessary to keep in mind that the future “accreditation body” may or may not be a regulatory authority.

4. National Health Insurance depends on health services of adequate quality to attract and sustain members and to use its resources effectively (for services that indeed improve the health of the insured). At the same time, proportionate to the membership and the purchasing power of the Insurer, claims payments can have significant leverage on the behaviour of health institutions.

It is necessary to clearly assess the needs of health insurance and to consider these when setting up a system of regular performance assessments. The implementation of health insurance should go hand in hand with operational research aimed at better understanding health care provider behaviour in the Nepali context. (In the long term this will be essential for establishing a sound incentive system which encourages acceptance of the assessment and compliance with standards).

5. The strategic framework is characterised by inconsistent use of terminology and a lack of orientation to the institutionalisation of a quality improvement system.

Revising the Policy on Quality Assurance in Health Care Services would provide an opportunity to streamline the use of terminology, where necessary, and to describe the interplay between the different activities, processes and institutional levels of an integrated quality improvement system.

4.2 Regulatory level

6. At present there is insufficient legal backing for regulation of quality improvement. This applies to a) regulatory backing of standards; and b) a legal assignment of authority for punitive or incentive-based regulatory action.

The planned Public Health Act provides an opportunity to set the foundation for meaningful legislation on quality improvement. In order to leave enough room for the strategic decisions that need to be made (e.g. defining specific objectives, appropriate set-up), detailed legislation should be planned at a later stage.

7. The Consumer Protection Act has thus far not been used proactively by the MoH to foster accountability across the health system. The Act, for example, provides for the creation of sub-committees to fulfil its objectives, including to protect consumers from sub-standard services.

A health sub-committee under the Consumer Protection Act could be an appropriate platform for facilitating the necessary stakeholder consultations for the reform of regulatory elements and communication mechanisms. In the event that the MoH plans to set up a certification or reporting system that informs consumers about the quality of care, it could play a special role. This recommendation should be considered with caution, however, because it is currently unclear whether structures foreseen under the Act will be able to exercise sufficient leverage.
4.3 Governance level

8. Currently, the focal point for quality improvement is the Health Facility Development and Quality Section in the Management Division of the DoHS. This may not be the appropriate place for a structure that, in a federal system, has to assume the federal power for quality monitoring and steering. This organisational arrangement may be a major obstacle to federating efforts across the various health system building blocks, and under the purview of different entities, towards the joint outcome “quality.” Due to the lack of strategic orientation and regulatory provisions, the role of the GoN in relation to the envisioned independent “accreditation body” is unclear.

The placement of the focal point for quality improvement should be reviewed once the GoN’s role in quality improvement in the public and private sector is clearly defined.

9. Coordination and implementation of the quality improvement system relies heavily on committees whose boundaries vis-à-vis other committees are undefined (or poorly defined) and whose mandates overlap with the regular management functions of health institution management teams.

It is recommended to institutionalise and professionalise quality improvement governance structures. This can be done through adequately staffed entities within the MoH, one or two new independent structures, and sustained capacity development (including delegation of powers and responsibility) for health institution management teams.

10. At present, patient grievances and complaints are not adequately invited or addressed. Compensation committees may lack medical expertise to make appropriate decisions and it is not their role to foster a climate in which critical incidents are dealt with in a constructive manner, rather than apportioning blame, thereby promoting learning and continuous quality improvement. Structures for institutionalising a quality-oriented approach to grievances and complaints are missing.

It is recommended to design and institutionalise a system to welcome feedback, complaints, and grievances from all levels of care. This could be a department or section within the future “accreditation body,” or attached to another structure (e.g. the National Health Insurance, the Nepal Medical Council or other). The system should serve two purposes: a) to analyse data and feed these into quality improvement processes; and b) to receive, investigate, and resolve all grievances related to health care in a transparent manner which is fair to both patients and providers. It is therefore essential that the structure is seen as impartial.

4.4 Implementation level

11. Quality improvement approaches which have been implemented in Nepal have enjoyed varying degrees of success. While it is impossible to systematically compare the different approaches because of the lack of a joint measurement framework, three

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1 Regulation and support for continued quality improvement may or may not be combined; regulation may or may not continue to be an internal function of MoH.
experiences stand out because they already have a measurement framework that has been tested and can be applied system-wide. These are: a) licensing (all hospitals in the private sector); b) Minimum Standards (district hospitals); and c) Standard-Based Management and Recognition (Comprehensive Emergency Obstetric and Neonatal Care services). While the first has a regulatory function, the second and third are oriented on capacity development.

The three measurement frameworks should be assessed in light of the strategic priorities for quality improvement in health institutions which will be set by MoH and its partners, and built upon the creation of a regular performance assessment system for health institutions. (The existing measurement frameworks can be used as they are, or broadened on the basis of additional standards).

12. More data on the actual quality of care are needed for monitoring and steering the overall health system. Quality improvements – the results of the different quality improvement interventions – cannot be captured in the national health information

<table>
<thead>
<tr>
<th>Indicator</th>
<th>A mechanism for clear identification of the newborns is implemented in the HCI according to the regulatory documents of the Ministry of Health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Items</td>
<td>1. Are 2 identification bracelets/Medallions fixed on the newborn’s both wrists?</td>
</tr>
<tr>
<td></td>
<td>2. Is this procedure done in the presence of the mother and/or the partner?</td>
</tr>
<tr>
<td></td>
<td>3. Do they indicate:</td>
</tr>
<tr>
<td></td>
<td>- date and time of birth,</td>
</tr>
<tr>
<td></td>
<td>- child’s sex,</td>
</tr>
<tr>
<td></td>
<td>- weight,</td>
</tr>
<tr>
<td></td>
<td>- height,</td>
</tr>
<tr>
<td></td>
<td>- mother’s surname?</td>
</tr>
<tr>
<td>Instrument</td>
<td>FC</td>
</tr>
<tr>
<td>Standard</td>
<td>The procedure of clear identification of the newborn is being implemented</td>
</tr>
<tr>
<td>Document &amp; page(s)</td>
<td>Standards for Accrediation of Hospitals; Block III. “The quantity of medical care for patients” Standard 3.37</td>
</tr>
<tr>
<td>Comment</td>
<td>Process</td>
</tr>
</tbody>
</table>

Source: AQUA/evaplan 2016

Table 2: An example for standard- versus indicator-based assessment

<table>
<thead>
<tr>
<th>Indicator in this dimension</th>
<th>target achievement in % from the best value</th>
<th>Number of items in this indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicators</td>
<td>your hospital</td>
<td>average</td>
</tr>
<tr>
<td>1</td>
<td>Fee schedules are prominently displayed at all payment points</td>
<td>73.9</td>
</tr>
<tr>
<td>2</td>
<td>Patients were not asked to pay for any of the services</td>
<td>54.3</td>
</tr>
<tr>
<td>3</td>
<td>The patients consider that those who should be exempted receive services at the hospital without having to pay</td>
<td>62.5</td>
</tr>
<tr>
<td>Total</td>
<td>63.6</td>
<td>63.6</td>
</tr>
</tbody>
</table>

Source: AQUA/evaplan 2016

Figure 4: Software-based visualisation of assessment results
system. Most quality improvement approaches do not utilise IT-based collection of assessment data.

The measurability of standards can be enhanced by translating all standards into indicators with a clear nominator and denominator. Table 2 shows how a standard can be transformed into an indicator; Figure 4 shows how software can visualise assessment data for feedback and benchmarking.

13. The standards and procedures for assessing health institution performance – and therefore the required institutional arrangements, including the functioning of the envisioned “accreditation body” – differ depending on the objectives of the assessment.

The purpose of assessing health institutions needs to be clearly defined. Is it regulatory or developmental? Regulation refers to control of service delivery through registration, licensing and restrictions on unsafe care (minimum patient safety requirements). If the purpose of assessment is regulatory, the “accreditation body” would set minimum requirements for health institutions to operate. These requirements must not be confused with the Minimum Service Standards for District Hospitals. Rather, they would build on the Guidelines relating to Standards for Establishment, Operation and Upgrading of Health Institutions and the Draft Health Institution Regulation and Operations Bill 2012. However, it is strongly recommended to review these standards in light of the well-defined regulatory assessment purpose2 before seeking to enforce them.

If the purpose of assessment is developmental, “the “accreditation body” would contribute to the organisational development of health institutions. It would aim to improve the quality of health care and the safety of patients (and staff). By focusing on continuous improvements, it would gradually lead to high-quality health care and improved patient outcomes. Some countries are trying to create organisations that meet both purposes. However, as far as the consultant team is aware, no scientific research has been undertaken into the feasibility of such an approach. Despite this, it is obvious that a mixed (dual) purpose would entail conflicts of interest and could lead to the confusion of roles. It would therefore be important to clearly separate the regulatory and developmental functions if they are to be housed in the same body. Table 3 further elaborates the implications of different purposes.

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2 For example, should they rather ensure patient safety or equity in terms of distribution? Should the minimum requirements ensure cost containment and efficiency, or should they have a strong focus on ensuring that health institutions have continuous quality improvement structures in place? Or should health institutions meet several of these – as well as other – requirements?
### Quality Improvement Structures in Nepal – Options for Reform

<table>
<thead>
<tr>
<th>Specific objective</th>
<th>Recommended types of assessment</th>
<th>Type of standard</th>
<th>Assessment body</th>
<th>Suggested entry points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid sub-standard practice</td>
<td>Mandatory. Assessment by external body with regulatory function</td>
<td>Minimum standards, focused on patient safety, with legal backing</td>
<td>Regulatory authority</td>
<td>Improve the current licensing practice</td>
</tr>
<tr>
<td>Ensuring that quality standards are employed across all facilities</td>
<td>Mandatory. Assessment by external body with regulatory function</td>
<td>Minimum management and clinical standards with regulatory backing</td>
<td>Regulatory authority</td>
<td>Institutionalise application of the measurement framework for systematic application of Minimum Standards and a sub-set of Skilled Birth Attendant (SBA) standards (Family Health Division/National Health Training Centre)</td>
</tr>
<tr>
<td>Ensuring high standards of service</td>
<td>Mandatory. Assessment by external body with regulatory function</td>
<td>Maximum management and clinical standards, with regulatory backing</td>
<td>Regulatory authority</td>
<td>New approach</td>
</tr>
<tr>
<td>Promoting safe and good medical practice</td>
<td>Voluntary or mandatory. Self-assessment and peer review</td>
<td>Safety standards and clinical standards (possibly evolving level of complexity)</td>
<td>Authorised body</td>
<td>Planned WHO mission on patient safety. Building on current licensing, SBA and other standards, develop measurement framework</td>
</tr>
<tr>
<td>Regulating quality (investigation of non-compliance)</td>
<td>Mandatory. Assessment by external body with regulatory function</td>
<td>Defined quality standards (possibly evolving level of quality)</td>
<td>Regulatory authority</td>
<td>Health Act. Design punitive and incentive mechanisms for regulation (cooperation with NHI)</td>
</tr>
<tr>
<td>Providing benchmarks for comparison</td>
<td>Voluntary or mandatory. Any form of assessment</td>
<td>Any standard</td>
<td>Authorised body</td>
<td>Creating an IT-base for the selected measurement framework. Improved specificity and validity of measurement</td>
</tr>
<tr>
<td>Stimulating continuous quality improvement</td>
<td>Voluntary. Self- or peer-assessment or external assessment with detailed feedback</td>
<td>Progressively evolving standards (must be achievable and relevant)</td>
<td>Authorised body</td>
<td>Training and capacity development interventions. Health insurance (incentives)</td>
</tr>
<tr>
<td>Providing data for national planning and steering of health service delivery</td>
<td>Mandatory. Standardised external assessment</td>
<td>Standards-based on national quality improvement goals</td>
<td>Authorised body</td>
<td>HMIS, e-health strategy</td>
</tr>
<tr>
<td>Providing a basis for empanelment with health insurance</td>
<td>Voluntary. Standardised external assessment</td>
<td>Standards-based on NHI needs</td>
<td>Authorised body</td>
<td>NHI</td>
</tr>
<tr>
<td>Providing certificates for display or reports to inform clients/population</td>
<td>Voluntary or mandatory. Standardised external assessment</td>
<td>Standards-based on expectations of clients</td>
<td>Authorised body</td>
<td>Sub-committee under Consumer Protection</td>
</tr>
</tbody>
</table>

Table 3: Set-up and entry points to institutionalise regular performance measurement in health institutions
14. The various quality improvement approaches implemented in Nepal have shown a weak level of sustainability. A major bottleneck has been the additional amount of work required to implement the approaches. In most cases, this has been paid for, or otherwise compensated by, projects and programmes, not by the health system itself. The current ambition to introduce an “accreditation body” is seen by many interviewees as an opportunity to foster institutionalisation of system-wide quality improvement approaches.

It is important that the process of setting up the “accreditation body” as a new element in Nepal’s quality improvement system focuses, from the very start, on creating a healthy institution. International Society for Quality in Healthcare (ISQua) has summarised international experience to provide guidance on the important elements and steps of this process, and the consultant team has drawn upon this guidance in proposing concrete steps towards the establishment of an “accreditation body,” based on the findings of this review (for a summary, see Figure 5).

The establishment of a fully functioning “accreditation body” is likely to take at least two years, but could take considerably longer depending on factors largely outside the control of the body itself. Typical stages of the process (which may overlap) are the following:

- **Step One:** Policy decision to develop the “accreditation body.”
- **Step Two:** Defining the scope of the assessment programme; optional appraisal of different models.
- **Step Three:** Setting up the organisational structure and funding.
- **Step Four:** Development of standards and assessment methodologies.
- **Step Five:** Assessor selection and training.
- **Step Six:** Piloting, education and marketing campaigns. Revision of standard and methods based on feedback from piloting.
- **Step Seven:** First “real assessments” and related decision making.

It is very important to allow adequate time for each step of the process. Short-term political gains can come at the expense of the quality and sustainability of the programme.

The first step is to establish the fundamentals. This could be done by an informal group of experts or by an officially-appointed body, such as a task force, a preliminary board or a commission. Such a task force should be different from existing committees in terms of its distinct deliverables, its clear accountability to the Minister of Health, and the designation of a realistic time frame to achieve the deliverables.

Deliverables should include:

- **A clear definition of the purpose of the “accreditation body”** (see 13 above).
- **A clear definition of the scope of the assessment programme:** Should the public

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3 ISQua 2015: Guidance on Designing Health Care External Evaluation Programmes including Accreditation (Fortune T. et al.).
and private sectors be assessed in the same manner? Which level of care should be addressed first? Guidance can be derived from the legal and strategic framework described in this report. In Nepal, the Constitution emphasises basic health services and emergency health care. NHSS provides a framework to address all levels of care. For example, as the quality of emergency care is typically the result of a functioning network of health care institutions and ambulance services, one option would be to assess the performance of such networks. On the other hand, these networks barely exist at present and it may therefore be more appropriate at the outset to assess the performance of individual health care institutions. Feasibility may be another factor to consider when defining the scope of the programme. For example, a focus on a large number of smaller units (primary health care) may lead to higher unit costs for each assessment and have implications for the number of assessors to be trained and managed.

• **A clear description of the role of government:** Government departments (in particular, but not only, those under the MoH) have a major impact on quality of care, yet the relationships between these departments are unclear. The role of the Health Facility Development and Quality Section, DDA, NPHL, the National Bureau of Standards and Metrology, and other ministries need to be clarified as part of an overall quality improvement policy. Furthermore, it is essential that a specific agreement be reached as to whether or not the “accreditation body” should be government controlled. While government support for the functioning of the “accreditation body” is indispensable, strong government involvement presents a number of risks (Box 1). The task force should prepare a clear plan for how these risks should be mitigated.

• **A clearly-defined incentive structure:** If participation is not mandatory, incentives are useful for promoting and sustaining it. If participation *is* mandatory, incentives may increase acceptability. This can, in turn, make the difference between health institutions regarding assessment as a formalistic exercise (which can, in the worst cases, express itself as “purchasing good assessment results”) rather than as a developmental approach. Incentives may include increased public funding, additional subsidies, exchange of data with the health insurance (and private purchasers) to inform purchasing and payment decisions, public recognition, exemption from regulatory inspection and others. Past experiences with performance-based quality approaches (described in Chapter 3.4) should be considered, as should new opportunities arising from the introduction of National Health Insurance.

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**Typical risks of strong government involvement with quality assessment programmes**

- Inconsistency in policy and management with changes of government
- Failure to review and update measurement framework in a consistent and timely manner
- Public perception of government may impinge on the credibility of measurement
- Conflict of interest between government as purchaser, regulator and provider
- In the context of Federalism, establishment of decentralised organisations to implement the programme may lead to cost duplications and inconsistencies in programme implementation

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*Box 1: Risks of strong government involvement*
• **A plan for stakeholder management:** The “accreditation body” needs to have adequate relations with a range of stakeholders (see Appendix 1).

The **second step** is to establish the governance board and framework for the “accreditation body.” If the fundamentals have been developed by an informal think tank, it is now very important to formally create the preliminary board or commission. Depending on the role of government defined under Step One, the governance body should represent, in a balanced manner, the different interests in quality of care.

ISQua suggests that the governance framework should include the following elements (ibid):

- The composition of the governing body;
- The process for appointing its members;
- Lines of accountability between the “accreditation body” and other structures, for example, the Ministry of Finance;
- The terms of reference of the governing body and its working groups; and
- Responsibility and rules for making decisions.

At this stage it is also important to think about how conflicts of interest will be avoided. A fair system for complaints and appeals regarding decisions of the “accreditation body” should be designed.

During this step of the process, the funding sources from government, health insurance and external development partners for a reasonable period (at least two years) also need to be established.

The **third step**, once the permanent governing body is established, is to staff the “accreditation body.” This includes the appointment of a capable chief executive and the selection, training and payment of staff. Staff may be employed on a permanent or temporary basis, or sub-contracted. Depending on the scope of the assessment programme defined under Step One, the “accreditation body” may rely on a few core staff and sub-contract/cooperate with implementers, or may develop its own departments for survey planning and management, surveyor recruitment and development, standards development and revision, user education, technical support, and administration.

The “accreditation body” needs to set up its own systems for human resource management, financial management and internal information systems, as well as the bridges to other information systems (e.g. National Health Insurance, District Health Information System). ISQua (ibid) suggests that the “accreditation body” needs to model the safety and quality approach it expects from its client organisation. A robust approach to risk management would therefore be another important task of the body.

Finally, the accreditation body will need to develop a sound business plan to ensure financial sustainability beyond the initial funding.
The **fourth step** consists of the development of standards and assessment methodologies. These steps can draw on the existing experiences with standard-based approaches described in Chapter 3.1. Existing standards can be quickly revised and adapted to the purpose and scope of the programme. The assessment methodology should be matched to the configuration of management and information systems determined in Step Three. It may be useful to prioritise standards in order to reduce the complexity of the assessment and to consider translating all standards into indicators with a clear nominator and denominator, as illustrated in Table 2.

The **fifth step** depends on the methodology selected (i.e. inspection, external assessment or facilitation of self-assessment). Inspectors, assessors, or facilitators should be recruited, selected, employed or contracted, and trained. It is very important that the skills level of the inspectors, assessors or facilitators is standardised and that it supports the credibility of the programme. Based on the decisions made in Step Three, this process can also be contracted out or delegated to a selected partner organisation.

The **sixth step** consists of piloting the adjusted measurement tools/standards and methodologies. Thanks to the evidence base generated during earlier implementation, this phase can be fairly short and targeted. However, it should not be omitted, as it is important to verify the validity and reliability of measurement. The standards and methods may or may not require amendment to further enhance validity, reliability and user-friendliness.

The **seventh step** is to conduct the first official assessments under full authority of the “accreditation body.” Decisions based on the results of the assessments should be made according to the responsibilities and rules defined in Step Two.

**Figure 5: Steps towards establishing an “accreditation body” for healthcare institutions in Nepal**

* In this context “commission” refers to a defined entity (e.g. task force) with a clear terms of reference, a mandate from government, a budget, and a time frame
### Appendix 1

**Key Stakeholders: Quality Improvement in Health Care**

<table>
<thead>
<tr>
<th>Organisation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ministry of Health</strong></td>
<td></td>
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<tr>
<td>Department of Drug Administration</td>
<td>The DDA is a regulatory authority for licensing of drugs, manufacturers of drugs, and pharmacies.</td>
</tr>
<tr>
<td>Department of Health Services</td>
<td>The DoHS accounts for almost 70 percent of the Ministry’s budget. It manages the Quality Assurance Section, which is housed within the Management Division.</td>
</tr>
<tr>
<td>National Public Health Laboratories</td>
<td>The NPHL is a national reference lab and also regulates private laboratories. It has started a certification process based on self-assessment.</td>
</tr>
<tr>
<td>Public Health Administration and M&amp;E Division</td>
<td>PHAMED is the focal point for the Quality Assurance Steering Committee created by the QA Policy (2007). They are also responsible for the M&amp;E of the sector and, as such, the Results Framework for NHSS.</td>
</tr>
<tr>
<td>Curative Services Division</td>
<td>CSD is responsible for the overall management of public hospitals above the district level.</td>
</tr>
<tr>
<td>Legal Section</td>
<td>The Legal Section drafts all legal provisions related to the Ministry of Health.</td>
</tr>
<tr>
<td>National Health Training Centre</td>
<td>The NHTC is a training provider and coordinator. It “owns” the measurement frameworks for maternal and newborn care and family planning (part of the so-called QI Tools).</td>
</tr>
<tr>
<td><strong>Semi-Autonomous Institutions</strong></td>
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<tr>
<td>Councils (Medical, Pharmacy, Health Professional, Nursing, Ayurveda)</td>
<td>The Councils are responsible for issuing licenses to health professionals based on an exam and for licensing academic institutions based on inspections against pre-determined standards.</td>
</tr>
<tr>
<td><strong>Ministry of Industry</strong></td>
<td></td>
</tr>
<tr>
<td>National Bureau of Standards and Metrology</td>
<td>NBSM is Nepal’s apex standards body, located under the Ministry of Industry, and is responsible for implementation of Nepal’s standards certification. It is a full member of ISO, which means that it can influence ISO standards development and strategy by participating and voting in ISO technical and policy meetings. It also sells and adopts ISO International Standards nationally.</td>
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<tr>
<td>Organisation</td>
<td>Description</td>
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<tr>
<td><strong>Associations</strong></td>
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<tr>
<td>Association of Private Health Institutions of Nepal</td>
<td>APHIN represents a majority of the privately-owned hospitals in the country.</td>
</tr>
<tr>
<td>Professional Associations</td>
<td>Many professional associations operate in the health sector, with roles ranging from advocacy on specific issues to working with the MoH and other Development Partners to develop policies and related documents.</td>
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<tr>
<td><strong>Non-Governmental Organisations</strong></td>
<td></td>
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<tr>
<td>Nick Simons Institution</td>
<td>NSI has been working with the government to strengthen the district health system, including by placing Medical Doctor in General Practice (MDGPs) in district hospitals in remote areas. More importantly, it has developed and implemented Minimum Service Standards (MSS), a checklist of minimum management functions required for the operation of district hospitals.</td>
</tr>
<tr>
<td>Forum for Protection of Consumer Rights</td>
<td>FPCR advocates with the government to realise consumer rights through legal and other means. It represents consumers in cases where their rights have been violated and often also mediates conflicts between consumers and service providers. It also carries out market monitoring when there are reported cases of unscrupulous business practices.</td>
</tr>
<tr>
<td><strong>Multilateral Organisations</strong></td>
<td></td>
</tr>
<tr>
<td>World Health Organization – Nepal</td>
<td>WHO works in Nepal in multiple areas. Along with support in core areas such as maternal &amp; newborn health, immunisation, surveillance, outbreak preparedness and response, it has also championed the cause of Universal Health Coverage and, more recently, the roll out of the PEN package (Package of Essential NCD Interventions). WHO works closely with the MoH on policies relevant in these areas. WHO is preparing an initiative on patient safety starting in November 2016.</td>
</tr>
<tr>
<td>UNICEF</td>
<td>UNICEF works closely with the MoH to improve maternal and newborn health. It works at the policy level through consistent engagement with MoH and clinical divisions, and also works on the ground at tertiary and primary health facilities.</td>
</tr>
<tr>
<td>UNFPA</td>
<td>UNFPA works closely with the Family Health Division on family planning. Recently the Family Health Division has developed a certification system for adolescent friendly services.</td>
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### Organisation Description

<table>
<thead>
<tr>
<th>Organisation</th>
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<tbody>
<tr>
<td><strong>Bilateral Organisations</strong></td>
<td></td>
</tr>
<tr>
<td>United States Agency for International Development</td>
<td>USAID has long history of working with the MoH in the areas of maternal and newborn health, family planning, HIV, health-related surveys and, more recently, nutrition. USAID-funded technical assistance to the MoH has focused on improving the functioning of district health systems in selected districts.</td>
</tr>
<tr>
<td>Health 4 Life</td>
<td>Health 4 Life is a USAID-funded technical assistance project to enhance the MoH’s capacity to plan, manage, and deliver high-quality family planning and maternal, newborn and child health services. An objective of this project is to establish a national quality improvement system. The Chief of Party of Health 4 Life is the chair of a newly-established working group of external Development Partners on quality improvement.</td>
</tr>
<tr>
<td>GIZ/Support to the Health Sector Programme (S2HSP)</td>
<td>Support to the Health Sector Programme (S2HSP) is a technical assistance programme executed by Ministry of Health (MoH) and supported by GIZ, on behalf of German Federal Ministry for Economic Cooperation and Development (BMZ). The programme is working on diverse issues including maternal and newborn health, health insurance, health information systems, governance and urban health.</td>
</tr>
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Appendix 2

List of Laws Reviewed

Constitution of Nepal
Consumer Protection Act, 2054 (1998)
Development Board Act 2013 (1956)
Good Governance (Management and Operation) Act, 2064 (2008)
Nepal Health Professional Council Act, 2053 (1997)
Nepal Health Service Act
Nepal Health Service Regulation
Nepal Medical Council Act, 2020 (1964)
Nepal Nursing Council Act, 2052 (1996)
Public Procurement Act 2007