REGULATION AND STANDARDS
AND THEIR IMPACT ON
GOVERNANCE IN HEALTH CARE

SUPERINTENDENCE OF PUBLIC HEALTH

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FOREWORD

Quality of care is an established Government priority which over the past years has been given heightened consideration. Quality, together with affordability and sustainability, is one of the three pillars on which all Government policies are based.

In order to ensure that an optimal standard is maintained throughout the health care sector, four years ago, the Ministry functionally split the roles of the Chief Medical Officer and Superintendent of Public Health. Last year the relevant legislation was published. The Superintendence of Public Health now holds a distinct separate role.

Together with safeguarding the country’s public health, by ensuring the enforcement of all existent public health legislation, the Superintendence of Public Health also seeks to establish and maintain optimal standards of quality in the services and care provided to our people.

It is a great pleasure for me to endorse the professional and scientific approach being adopted by the Superintendence in formulating and launching national standards across the health care system.

This document provides an understanding of the role and function of the Superintendence, and of all stakeholders, in ensuring high quality standards across the health care system and its processes.

I appeal to all stakeholders to support the development, implementation and maintenance of optimal standards determined by the Superintendence of Public Health.

Drawing on the contention that we are all, individually and collectively, responsible for ensuring optimal care for our people, I trust we will all seek to participate, co-operate and contribute accordingly.

Dr. Joe Cassar
Minister of Health, the Elderly and Community Care
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1. Regulation

Regulation aims to achieve and safeguard public health standards. The Superintendence for Public Health (SPH) is responsible for regulation of health care services and health care delivery by professionals mainly through legislation and standards. The SPH regulates in the public interest to protect public health, and to provide safety for the patients / citizens. In designing legislation and standards, the SPH aims to achieve excellence in health care by making sure that health service providers are using the right tools for the delivery of care within the resources available to the country, that benefits are maximised, while negative effects are minimised. In an era of globalisation, citizens expect their governments to ensure their safety and welfare and businesses expect public authorities to ensure a level playing field and boost competitiveness. Regulation is key to meeting these challenges. Regulation is a necessary and accepted aspect of modern society.

2. Introduction

This document provides an overall framework of standards required for the operation of health care settings. It links with other specific standards and criteria that will be developed by the Superintendence of Public Health. Health care standards are requirements that help to ensure public health protection. They inform health care professionals and managers of health care establishments of their accountabilities and responsibilities and the public of what to expect of health care professionals and health care establishments.

Standards support the scope of practice and relevant educational preparation. Standards outline the minimum requirements for safe practices. Meeting the standards helps to ensure that performance is at the required level.

3. Definitions

3.1 Health care professionals – all health care professionals who are registered with their respective professional regulatory council as established under the Health Care Professions Act (CAP 464 of 2003).
3.2 Health care service – the delivery of health care to the patient in any health care setting.
3.3 Health care setting – a place where a health care service is provided to patients and may include a licensed health care establishment or a domiciliary setting.
3.4 Health care establishment – A health care setting that is licensed by the relevant Competent Authority to provide a healthcare service such as hospitals, clinics or homes for the elderly.
3.5 Domiciliary setting – in the patient’s residence.

4. Applicability

National standards are applicable to:
4.1 All service providers irrespective of whether they are public, private or both,
4.2 All health care establishments,
4.3 All health care professionals and relevant support workers, irrespective of:
   - Their role, job description or area of practice
   - The way they are engaged to work (full time, part time, secondment, detailed, contractual)
   - Where they are practising, including in domiciliary settings

These standards also apply to:
   - Health care students under direct supervision of qualified health care professionals and following appropriate training.

The standards and criteria are intended to ensure that the safety and wellbeing of the patient is secured through:
   - Practices that reflect current knowledge
   - Establishing minimum criteria through the application of legislation and standards
   - Maintenance of codes of professional practice
   - Documented organisational policies and procedures

National standards and local policies are to be in line with other national legislation as applicable (e.g. Freedom of Information Act, Data Protection Act).
5. Patients as the focus

The patient as the client of health care services and care should be the focus of all related activities and decisions. Standards are primarily aimed at ensuring patient safety and optimisation of patient care. There should be transparency and communication with patients, and patients are to be empowered to participate in decision making which concerns their care and well being and also to take an active role in their care.

Every health care establishment shall have a well established customer care service which caters for patient complains and suggestions in an efficient and transparent manner. Moreover, health care establishments shall actively get feedback from customers and should utilise this information in their strategies, policies and also for total quality management.

6. Standards

National standards and criteria issued by the Superintendence of Public Health provide the necessary framework for health care establishments and those providing a health care service to draft their own internal policies, guidelines and standard operating procedures and develop their own internal governance to support the determinants of quality care.

These standards should be translated into practices which specify indicators (such as key performance indicators) for practice within health care settings. Indicators are to be implemented and should be monitored routinely. These practices and the criteria for monitoring should be documented.

Monitoring and evaluation related to standards of practice ensure consistency and quality of care provision. Monitoring involves measuring actual practice against set standards, guidelines and standard operating procedures and consequently identifying areas that require improvement.

National standards support health care professionals to understand their responsibilities and enable them to make decisions and guide their thinking. Every situation is unique and health care professionals are required to exert their clinical judgement.
7. Governance

Health care establishments are responsible to set up a governance framework within their organisation. Clinical governance has been formally defined as:

“...A framework through which health care service organizations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.” (Donaldson and Gray, 1998).

The components necessary for successful clinical governance is illustrated in a temple model with seven “pillars” which provide the support for the patient-professional partnership at the heart of clinical governance (see Figure 1). What clinical governance brings is a co-ordination of these activities (pillars), as illustrated in the temple paradigm below. Underpinning the successful implementation of clinical governance is an awareness of the need for solid foundations to establish an enabling culture. The five cultural components are:

- Systems awareness
- Teamwork
- Communication
- Ownership
- Leadership

These represent the areas needed to share “beliefs, attitudes, values and norms of behaviour” (Davies et al., 2000) in order to deliver sustainable quality improvement in health care.
Figure 1: The Temple Paradigm

8. The Responsibilities and Role of the Superintendent of Public Health

The Superintendent of Public Health is the chief advisor to government on public health matters and among others is responsible for:

8.1 Fulfilling all the duties and responsibilities emanating from law
8.2 Developing and leading programmes that promote the highest standards of public health and hygiene
8.3 Safeguarding the health and wellbeing of the public through the enforcing of all national and international regulations and public health legislation
8.4 Drawing up policies in the area of public health, formulating regulations and standards in line with Government direction and ensure their enforcement
8.5 Promoting health, preventing communicable and non-communicable diseases and carrying
out surveillance in order to protect the general public from such diseases
8.6 Maintaining national and international networking in the field of public health and representing government in international public health related issues
8.7 Receiving and processing applications for and issuing of licenses for operating health care establishments, and other services in line with existing legislation
8.8 Fostering the development and maintenance of a patient safety culture within health care establishments

9. The Responsibilities of the Health Care Establishments

9.1 Abiding with legislation, policies and standards issued by the SPH
9.2 Identifying and agreeing on internal policies and standard operating procedures which reflect and cover the national standards
9.3 Documenting these policies and practices
9.4 Monitoring and evaluating the achievement of these standards
9.5 Reporting and documenting incidents
9.6 Evaluating health care practices for risk points, and that the health care practice is carrying out a risk assessment and a risk management programme
9.7 Identifying health care practices which need to be improved in terms of safety
9.8 Identifying opportunities for improvement by routinely evaluating literature for new and successful practices that have been proved to enhance safety
9.9 Conducting a regular process of self-monitoring (including internal audit) at least annually as well as ad hoc evaluations as required
9.10 Taking corrective and preventive actions wherever indicated
9.11 Reviewing internally generated reports, audit results and other information (including benchmarking) to identify trends or issues related to practices; there should be management review of operations and processes periodically, at least once every three years
9.12 Using information from data analysis to identify changes needed to improve health care practices
9.13 All documentation, including documentation of the internal audits and reviews, shall be kept and made available upon request to the inspectorate team for the purpose of licensing
9.14 Following the inspection, the health care establishment is to implement the recommendations of the inspection team within set time frames
Health care staff needs to prioritise and do their best with the resources available. When health care staff is faced with inability to implement standards due to limited resources, they should approach management to inform them of the situation and request additional resources, and raise concern. This communication should be further consolidated in writing. The health care establishment and its management are responsible to provide a framework for communicating with staff, and to address the concerns and improve, advise, educate and find alternative solutions.

10. The Responsibilities of the Health Care Professionals

Each health care professional is accountable and responsible to practice according to the standards. Health care professionals should ensure that they:

10.1 Abide by standards while using professional judgement
10.2 Ensure the well being of the patient while implementing standards
10.3 Understand and be knowledgeable in the areas of care delivery
10.4 Provide person-centred care while implementing standards
10.5 Understand the legal and ethical frameworks relevant to their practice
10.6 Know what to do if they suspect inappropriate or abusive practice
10.7 Understand and seek to minimise the risks for patients and promote safety

11. Bibliography


