

Health Care Standards Directorate

Annual Report 2012

Inspiring Excellence in Health Care

Overall Purpose of the Health Care Standards Directorate

The Mission Statement for the Health Care Standards Directorate is “To Promote and Safeguard Public Health by ensuring that the Health Care provided is of good quality and safe”

The vision for the Health Care Standards Directorate is to be an organisation that “Inspires Excellence in Health Care”

Patient Safety is of paramount priority as there cannot be Quality of Care without Patient Safety and this principle will be foremost in view when planning all the Directorate’s activities.

Remit

The remit of the Directorate’s regulatory jurisdiction includes:

- Quality Care, Quality Assurance, Medical audit/Clinical Performance and Patient Safety
- Licensing of Health Care Establishments and services and Homes for Older Persons
- Formulation of National Standards for Health Care, Health Care establishments and Health Services including Primary Care and Mental Care Services
- Regulatory aspects related to Blood, Tissues and Cells and Organs, Surveillance and Vigilance of Substances of Human Origin and Licensing of tissue & cell establishments

The above mentioned areas are represented in Figure 1.

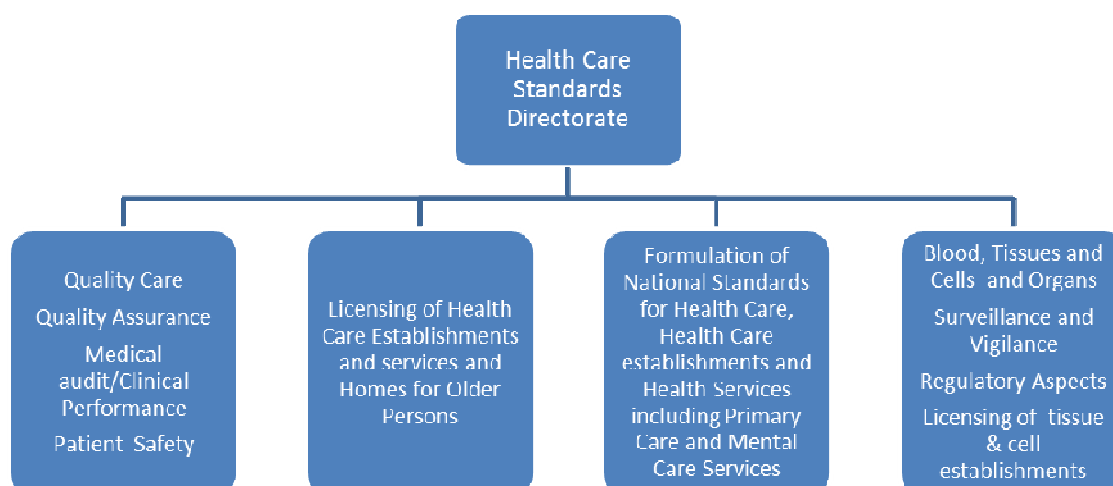


Figure 1: The regulatory remit of the Health Care Standards Directorate.

The Directorate for Health Care Services Standards embraces the following mission, vision and values:

MISSION: “To Promote and Safeguard Public Health by ensuring that the Health Care provided is of good quality and safe”

VISION: ensure that care services should, improve people’s lives, be accessible and timely, support independence and offer choice

VALUES: being people centred, transparent and accessible and finally be rigorous and fair, and actively involved to change for the better.

Functions of the Health Care Standards Directorate

1. To formulate, monitor and support the introduction and maintenance of high quality national standards for health care establishments and professional services;
2. To support policy formulation and promote the development of methodologies that address evolving public health challenges and existent and potential shortcomings in medical care and hospital, community and primary care services;
3. To promote a quality culture within public and private service providers and the development of appropriate quality assurance and medical audit programmes;
4. To monitor medical service provision and clinical performance, identify where improvements should occur and advise on how they can be achieved while supporting policy formulation and promoting the development of methodologies that address evolving service delivery and health care provider challenges.;
5. To take necessary measures to remove, control or reduce threats to public health and patient safety, and identify risk factors so as to minimise disease and ill-health impacts on people using health services;
6. To regulate the use of human blood, tissues and cells and organs in terms of the relevant legislation;
8. To inspect and license hospital services, clinics, community and primary care services.
9. To manage representations from members of the public and co-ordinate and monitor the outcome of complaints investigated;
10. To assist the Superintendent of Public Health in regulatory functions related to standards of health care.

Achievements During 2012

The most important achievements of the Directorate during 2012 were:

a) The licensing of Public and Private Clinics and Hospitals

There are currently 9 private clinics/hospitals in Malta and scheduled inspections took place to ensure that standards of care are being upheld. All clinics are licensed up to end 2013. These inspections could not be carried out single handed without an inspectorate team. External professional services to augment the department’s Inspectorate Team were engaged by obtaining the services of consultant specialised in anaesthesia. DHCS also collaborated with the St. Luke’s’ Hospital Engineering Division, various staff from Mater Dei Hospital and the Environmental Health Department to augment its Inspection Team to visit clinics/hospitals for licensing purposes. For each Private Clinic inspected, the yearly license was

issued by the Minister for Health, after the Directorate had presented the inspection report for each of these entities, with specific recommendations for the amelioration of service provision.

For the first time, during 2012, the Health Care Standards Directorate has started inspecting also Public Hospitals. The process of inspection of Mater Dei Hospital was also started during the last quarter of 2012 with a view to licensing it, by end of 1st Quarter 2013. Mount Carmel Hospital has also been recommended for licensing following a number of inspections

b) The licensing of Homes for Older Persons and Long Term Care Wards

The homes for older people which are run by the private sector, the Church and the public sector total 39 and inspections continued during 2012 to ensure standards of care are being upheld. All 39 homes are now licensed up to the end of 2013. Zammit Clapp was licensed for the first time this year both as a home for the elderly and part of its ground floor as a mental nursing home.

There are also 5 Long Term Care premises/wards which house older people. These include St. Jean Antide Ward, San Gorg Preca and Santa Bernadetta Ward within the Mount Carmel Hospital premises and the Male Geriatric Ward and St. Anna within Gozo General Hospital. The total number of licensed beds in these long term care wards is 281 beds. These are now licensed up to the end of 2013.

<i>Homes for Older Persons</i>	<i>Number of Homes</i>	<i>Number of Licensed Beds</i>
Church Homes	16	728
Private Homes	14	1233
TOTAL	30	1961

Table 1: The licensing of Church and Private Homes for Elderly residents during 2012.

<i>Homes for Older Persons</i>	<i>Number of Homes</i>	<i>Number of Licensed Beds</i>
Government Homes	8	782
Zammit Clapp Hospital Residential Floors	1	84
Government Long Term Care facilities including St Vincent de Paule Residence	6	1718
TOTAL	15	2584

Table 2: The licensing of Government Homes and Government Long Term Care Facilities during 2012

The Health Care Standards Directorate was also involved in assessing requests by a number of Homes for Older Persons to increase the number of beds. An increase in number of 61 new beds in the private sector was approved.

c) The licensing of Rehabilitation Centres

The Rehabilitation hospital, Karen Grech has also been recommended for licensing. A private rehabilitation Centre in Sliema has also been licensed this year. The total number of beds licensed in these rehabilitation centres is 294 beds.

d) The Licensing of Mental Nursing Homes

The Health Care Standards Directorate also inspects mental nursing homes in order to ensure that standards of care are upheld. During 2012, the Directorate inspected three public and one private wards and issued a recommendation for their licensing as mental nursing homes. The number of beds licensed as mental nursing beds is 91beds.

e) Expansion of the Licensing Remit of the Health Care Standards Directorate

During the last quarter of 2012, the Directorate assumed responsibility for the administrative issues related to the licensing of various clinics related to the provision of health services and services that affect health. These include dental, podology, physiotherapy, acupuncture and radiology clinics, medical diagnostic labs and tattoo/body piercing studios. The current number of licenced establishments and service providers is found in Table 3.

<i>Category of Establishment or Service Provider</i>	<i>Number of Licensed Establishments or Service Providers</i>
Dental clinics	99
Podology clinics	4
Medical diagnostic laboratories	6
Acupuncture clinics	2
Physiotherapy clinics	9
Radiology clinics	14
Tattooists	76
Body Piercing	18

Table 3: Category and total Number of Licenced Establishments and Service Providers

f) The Investigation of Service Users Complaints

DHCS continues to investigate and act in a timely manner to service users' complaints. These investigations amounted to 40 in total during 2012. DHCS intention is not to substitute or replicate the customer care services that each entity needs to have in place as part of good governance. These filtered reports necessitate to be subject to a structured analysis which takes into account the wider factors within the organization which may have given rise to the complaint. This is 'root cause analysis' – a term borrowed from the world of engineering and this process allows all of the factors which might have contributed to an event to be identified, analysed with remedial action recommendations not to have recurrence.

d) The Formulation, Monitoring and Introduction of Standards for Health Care

As part of a Working Group we are finalising national standards for the use of medicines and finalised the drafting of National standards for 'professional care'.

The Directorate also formed part of a Working Group for the development of National Standards for the Administration of Blood and Blood Components, which standards were launched during July 2013.

The Directorate continues to be actively involved in the formulation of standards and has done extensive literature reviews and formulated the first drafts of standards related to decontamination of dental instruments and validation of the associated processes, standards related to medical equipment within ambulances and vehicles used in the transportation of patients and standards on Practices of Mild/moderate sedation in Dental Practices.

e) Regulatory Aspects related to Substances of Human Origin.

One of the functions of the Health Care Standards Directorate is to see that the standards set for the Quality and Safety of Blood and Blood components and of Tissues and Cells Intended for Human Transplantation are reached. The Health Care Standards Directorate is responsible for monitoring that the EU legal obligations emergent from the transposition into Maltese legal framework of the EU Blood and Blood Components Directive as well as the Tissues and Cells Directive are satisfied.

The year 2012 showed that the haemovigilance system for the reporting and investigation of serious adverse events and reactions related to blood transfusion is now well established following the re-engineering of the system in the previous years. The collection of reports on Adverse Reactions and Events related to blood transfusion by the Haemovigilance Unit within the Directorate continued throughout 2012. The number of reports received by the Haemovigilance Unit during 2012 has stabilised to a level of approximately 55 reports per annum. The fifth Maltese National Haemovigilance Report with data pertaining to 2011 was submitted to the European Commission as stipulated by the EU Directives on Blood and Blood Components.

In a similar fashion, the directorate also continued refining the system for reporting of Adverse Reactions and Events related to Tissue/Cell Transplantation. The fourth report on Adverse Reactions and Events related to Tissue/Cell Transplantation pertaining to 2011 was submitted to the European Commission.

The Health Care Standards Directorate also fulfilled several other EU reporting obligations, including a report on the transposition of the Directive on Quality and Safety of Tissues and Cells for Human Transplantation.

During 2012, the Directorate continued strengthening the Rapid Alert System for the dissemination of alerts related to Substances of Human Origin. This included involvement in an EU-wide network, communication at EU level through the CIRCA (Communication and Information Resource Centre Administrator) platform and the distribution locally of alerts to the interested stakeholders. The Directorate also participated in the reengineering of the system of alerts which will be replaced at an EU level by the RATC (Rapid Alert on Tissues and Cells) System. This included attendance for training on the use of the system and development of a protocol for the creation and dissemination of alerts.

During 2012, the Directorate has finalized the setting up of the mechanisms and structures to have the stem cell collection service providers assessed with an intention to regulate and license according to national legislation.

The Directorate also attended various EU level meetings on behalf of the Competent Authority on Blood, Tissues and Cells and Organs. The Health Care Standards Directorate continued with its networking with other European partners with the aim of sharing best practices and developing competencies and skills for the inspection, regulation and licensing of tissue and cell establishments in line with the EU Tissue and Cells Directives.

A novel area that Directorate has worked on during 2012 was that of the Quality and Safety of Organ Transplantation. The Directorate has been very active in providing recommendations during the

drafting phase of the EU Directive on the Quality and Safety of Organ Transplantation. The Directorate has assisted the Superintendent of Public Health in the drafting of the transposition of the Directive on the Quality and Safety of Organ Transplantation and in the consultation stage. The transposition was published as Legal Notice 345 of 2012.

It is also assisting in setting up the appropriate regulatory mechanisms. The Directorate has actively contributed to the ACCORD Joint Action (the Joint Action between Member States and the European Commission on Achieving Comprehensive Coordination in Organ Donation throughout the European Union).

f) Other Miscellaneous Activities/Initiatives Carried Out by the Health Care Standards Directorate during 2012

Involvement in Malta Environment and Planning Authority's Consultation Processes

During 2012, the Directorate continued to offer recommendations in view of MEPA's consultation process in respect of proposals of building/converting into homes for older persons and private clinics/hospitals and other premises. The replies sent to MEPA amounted to 19.

Assistance to Entrepreneurs Interested in Opening Homes for Older Persons and Private Clinics/Hospitals

Furthermore the directorate carried out pre-consultation discussions with a number entrepreneurs interested in considering proposals to build/convert buildings to new homes for older persons and private clinics/hospitals.

Preventive Programmes for the Mitigation of the Ill-Effects of Extreme Weather Temperatures on Vulnerable Persons.

During 2012, The Health Care Standards Directorate continued working on the preventive programmes to mitigate the ill effects of extreme weather temperatures - namely heat waves in summer and extreme cold in winter – on vulnerable residents in Homes for Older Persons licensed by the Directorate. Actions in the field were:

1. The conduction of a literature research to update the draft guidelines targeting managers and carers in nursing Homes to take preventive action to increase resilience and mitigate the ill effects of summer heat waves and winter cold temperatures on vulnerable older persons.
2. Widening consultations for consensus building including geriatricians, policy makers and administrators of institutional entities.
3. Circulating both updated guidelines to prevent hyperthermia in summer and hypothermia in winter, in good time for Homes to implement the recommendations and posting them on the Directorate's website at www.healthstandards.gov.mt
4. Liaising with the Parliamentary Secretariat for the Elderly to monitor, by active scrutiny during the summer and winter months that the recommendations have actually been implemented.

A number of surprise inspections were carried out to ensure Departmental recommendations were being followed and that all Homes for older persons took measures to guarantee that residents did not suffer from any ill effects, such as those due to hypothermia and the heat wave effects.

During the cold season, the directorate inspected and audited 8 Government Homes, 14 Private Homes and 16 Church Homes. Also 2 wards at Gozo General Hospital and 3 wards at Mount Carmel Hospital to assess the preparedness of the Homes for protecting older persons from the cold weather. During the

summer months, the Directorate inspected 5 Government Homes, 7 Private Homes, 6 Church Homes, 4 wards at St.Vincent de Paule Residence, 3 wards at Mount Carmel Hospital, 2 wards at Karen Grech Rehabilitation Hospital, and Zammit Clapp Hospital to assess their preparedness for heat waves.

Collaboration with other Directorates

Collaboration with the Director for Elderly Care also continued as part of the screening process in the Private Public Partnership (PPP) scheme. The Directorate screens and actively engages in a propitious process to ameliorate the conditions of care in the Homes from which Government considers buying beds for Older Persons under the PPP scheme. The Directorate worked on the production of an Environmental Grading tool for assessing the environment within Homes for Older Persons.

Work and collaboration continues with the Director of Health Information and Research, to ensure that the granularity and content of the data collection especially at Mater Dei as in the Hospital Activity Analysis, will enable effective monitoring and auditing by the development of clinical performance indicators. One of the main purposes of this collaborative initiative is to increase the scope of the data being collected to meet national and international health care reporting obligations. Furthermore the active participation of the Health Care Standards Directorate is to ensure that such data could be transformed into information for quality monitoring as well as comparative analysis of key performance indicators. This inter-Directorate collaboration upholds relevant European initiatives such as the Minimum Hospital Data Set, and System of Health Accounts and Health Labour Accounts.

This initiative aims at starting to address the need for improved effectiveness and efficiency of performance indicators and their linkage to other governance policies. The Directorate actively participates in inter-Directorate initiatives of having a standardized system for data collection to be able to uniformly code, validate and analyse clinical information.

Service Users' Satisfaction Surveys

One of the main remits of DHCS is to ensure quality of care by monitoring standards of the service deliverance and it is of paramount importance that the service users' perspectives are considered actively not only in the standard setting process but also as part of the monitoring process. In this respect DHCS is carrying out for the fourth year running a project entitled: 'Measuring the Quality of Care in Homes for Older Persons - the service user perspective'. As part of the project more than 600 randomly selected residents were interviewed in the various Homes using a well- tested tool to measure their satisfaction with the quality of care in the home.

Medical Devices Alert cascade.

DHCS continues to be actively engaged in the Medical Devices Alert cascade. It is subsequent to the close collaborative networking between DHCS, the Director of Procurement at Mater Dei Hospital and the Malta Standards Authority, that we could contribute jointly to this 'engineered safety devices' structured approach as per EU Directives. During 2012, all the Public and Private Clinics/Hospitals continued to be included in this Medical Devices Alert cascade.

Data on Homes for Older Persons

The Health Care Standards Directorate regularly collects data on the distribution and the level of dependency of residents in Homes for Older Persons in the Church, the Private and the Public sector. In addition, it also collects data on the staffing levels within these homes. In determining appropriate staffing levels in all care homes, and in nursing care homes in particular, the regulatory requirement that staffing levels and skills mix are adequate to meet the assessed and recorded needs of the residents at all times in the particular home in question must be met.

Attendance to Seminars

During 2012, the Health Care Standards Directorate continued to be actively engaged in a number of seminars which included those on Data Protection, Freedom Of Information and the Common Assessment Framework.

Screening of Adverts Related to Health Care Services

During 2012, the Directorate, on behalf of the Superintendence of Public Health, screened a number of adverts related to Health Care Services. It also produced a first draft of a document consisting of guidelines on the Advertisement of Health Services. The Directorate routinely collaborates with the Malta Broadcasting Authority on issues related to advertisements about health care services.

Quality Initiatives

The Directorate, during 2012 formed part of a drafting group that worked on the Ministry's Total Quality Management System. The directorate also attended training on the Common Assessment Framework.

Facilitating the interface with service users

Website update

As one of the Directorate's key communications channels, the website has been continually updated to reflect stakeholder needs.

The services offered through the website are diverse and include information about the Directorate's remit, updated contact information, a series of electronic forms for use by various stakeholders (e.g.: forms used by health care professionals for the reporting of adverse reactions and events related to blood transfusion or transplantation of tissues and cells and forms to be used by persons wishing to open a Home for Older Persons) and links to legislation relevant to the Directorate's remit areas.

As in previous years guidance and advice especially to Homes for Older Persons with regards to Hypothermia and Hyperthermia prevention are updated.

The complete list of licensed Homes for Older Persons, Long Term Care facilities and Night Shelters as well as the list of licensed Private Clinics is also regularly updated.

Additional a more user friendly URL was created: www.healthstandards.gov.mt together with the availability of a generic email.

Dr Miriam Vella
Director
Health Care Standards

January 2013