



Ministry for Social Policy

DEPARTMENT OF HEALTH CARE SERVICES STANDARDS

OVERALL PURPOSE

The principal purpose for the Department for Health Care Services Standards is to achieve improvement in the quality of care and ensure patient safety through regulation. 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 Department's activities in the years to come.

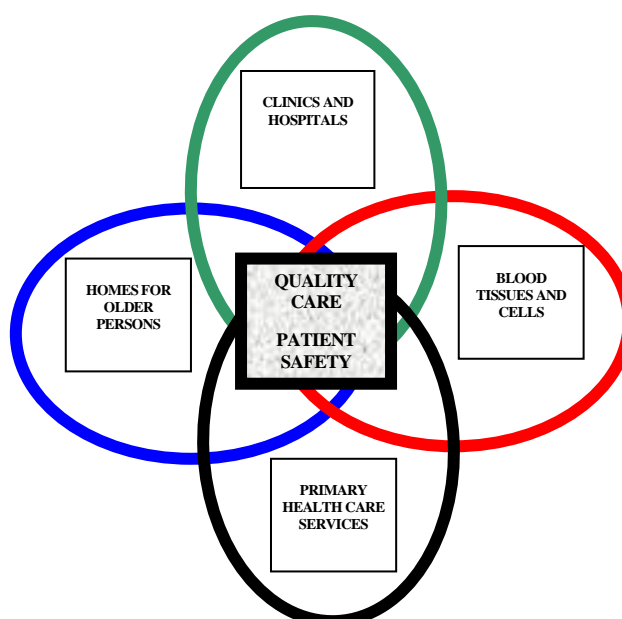
REMIT

The remit of the Department's regulatory jurisdiction can be classified into the following four main sectors where health care services are delivered:

- Clinics and hospitals including public hospitals;
- Homes for older persons including government homes;
- Primary health care including all service providers in this sector – public and private and also mental health services;
- Blood transfusion services – including the National Blood Establishment and blood banks (public and private), and services involving tissues and cells.

The above-mentioned four main health care services sectors are regulated by DHCSS with an overlapping central area representing quality of care improvement and guaranteeing patient safety as the main focus.

Consequent to the extensiveness of this territory to be regulated, DHCSS has submitted formal requests for a proportionate and proper investment in capacity building to enable the Department to discharge its functions in a proper and timely manner.



STRATEGIC DEVELOPMENT AREAS

This Department's strategic objectives and the most important achievements during 2008 have been in:

Consolidation of the Core Regulatory Functions

There are 29 church and private homes for older persons in Malta and Gozo, and their scheduled inspections have continued during 2008 to ensure standards of care are being upheld. For each home, the

yearly licence was issued by the Minister for Social Policy, after DHCSS had presented the inspection report for each of these homes, with specific recommendations for the amelioration of service provision. During 2008, two applications for the opening of new homes have been processed and key inspections carried out with a view to license.

Homes for Older Persons	Number of Homes	Number of Beds
Church Homes	18	738
Private Homes	11	917
Total	29	1,655

- *Participation in the Leonardo IV, European programme involving mobility of professionals – to increase staff competences in the regulation of health care services:* During 2008, DHCSS has continued participating in a collaborative project led by the *Centre Hospitalier Intercommunal du Pays des Hautes Falaises de Fécamp*, Normandy France, on the theme of prevention of back pain. A delegation from Normandy came over to Malta in October and demonstrated appropriate techniques in handling patients and elderly alike in a number of seminars including at Mater Dei Hospital. Their visit to Malta was jointly co-ordinated by DHCSS and the DNSS so as to maximise effective benefits to a wider audience of local participants in the workshops that took place during their one week's visit. This project has now been transferred for co-ordination by the DNSS.
- During 2008, work continued in close collaboration with the DNSS and the Director General for Public Health Regulation to refine the standards for long term care with the ultimate aim to enshrine them in a legal framework. The National Standards to Open a New Home for Older Persons which will mainly focus on the physical aspects of the health care service provision will be part of the above referred to standards.
- *Continued to engage in ongoing research such as action research studies on special themes for each year's inspections:* During 2008, the very pertinent theme of Fire Safety in Homes for Older Persons was revisited. A purposely-designed questionnaire was distributed to all the homes and the preliminary findings of the trends indicated the imminent importance of this safety issue in homes for older persons.

As a follow-up to the fire safety survey, a collaborative initiative between DHCSS and Civil Protection was launched to address the concerns and preoccupations regarding this important safety issue that concerns elderly residents in Homes. This collaboration culminated in a Fire Safety Awareness Seminar in April 2008, for managers of all the homes for older persons – government, church, and private. Certificates of participation were presented by the Hon Parliamentary Secretary for the Elderly. It is envisaged that for licensing purposes, all Homes would be equipped with an emergency evacuation plan to ensure safety of vulnerable residents in such cases of emergencies.

Furtherance of the licensing process of Private Clinics and Private Hospitals

There are 12 private clinics/hospitals with a total of 208 beds, and their scheduled inspections have continued during 2008 to ensure that standards of care are being upheld. For each clinic/hospital, the yearly licence was issued by the Minister for Social Policy, after DHCSS had presented the inspection report for each of these entities, with specific recommendations for the amelioration of service provision. During 2008, a new application for a private clinic was processed and a key inspection carried out and the licence issued.

During 2008, the external professional services of a retired anaesthetist were engaged to augment DHCSS's Inspectorate Team. It is planned that more external professionals will be contracted in future to develop an independent core Inspection Team that will eventually be utilised to inspect government entities such as public hospitals and government homes for older persons. The services of this same professional were engaged to draw up Guidelines for the Terms of Obsolescence of Anaesthetic machines in use in Clinics and Hospitals. The discussions also included a panel of experts chaired by the President of the Malta College of Anaesthetists and in consultation with the Chairperson of Anaesthesia. This model of

participatory regulation has achieved the intended outcomes and it is hoped that this structured approach will be used in other sectors to be regulated.

During 2008, DHCSS collaborated with the DNSS to augment its Inspection Team to visit the Homes and clinics/hospitals for licensing purposes. This inter-directorate synergy is a step towards more transverse collaboration and adds inter-disciplinary value to the inspection process.

One of the first initiatives of DHCSS was to organise a meeting with MEPA representatives to streamline the MEPA consultation process in proposals concerning homes for older persons and clinics/hospitals, to safeguard the interest of service users, especially of older persons, by guaranteeing standards even at this planning phase. A standard operation procedure was agreed to and DHCSS plans to monitor the MEPA website in order to follow up effectively the consultation process in applications that fall within DHCSS regulatory remit. During 2008, DHCSS continued to proffer its recommendations to MEPA in respect of proposals of building new homes for older persons and private clinics/hospitals.

In addition, DHCSS in collaboration with the Parliamentary Secretariat for the Elderly continued to participate in the pre-consultation discussions with private entrepreneurs interested in submitting proposals to build new homes for older persons and private clinics/hospitals.

Collaboration with the Director for Elderly Care also continued as part of the screening process in the Private Public Partnership (PPP) scheme. DHCSS 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.

As part of DHCSS's responsibility to facilitate communication and ensure ongoing consultation with all stakeholders, especially external ones, the Department remains in active discussions with the umbrella organisation of non-government organisations, namely Malta Health Network. DHCSS will be building on previous consultation initiatives such as the healthy links which already exist with Kunsill Nazzjonali Anzjani to be receptive to these well articulated expectations of all health care service users. Also, during 2008 very useful links were made with the newly established Maltese Association of Psychiatric Nurses.

DHCSS continues to be actively engaged in the focus groups set up for feedback and consultation for the improvements of the primary health care sector and community care. DHCSS has the remit to license these services and furthermore ensure a seamless transition of the service user's pathway from community/primary health care to institutional/hospital care.

DHCSS continues to investigate and act on service users' complaints. DHCSS 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 subjected to a structured analysis which takes into account the wider factors within the organization which may have given rise to the complaint.

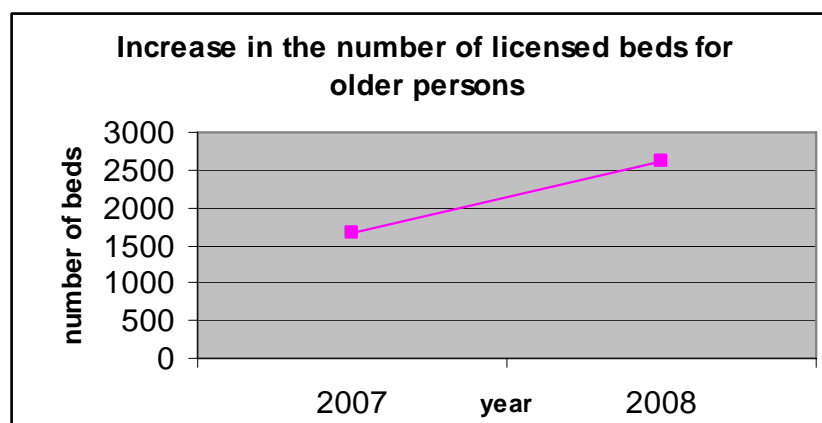
DHCSS continues to be actively engaged in the Medical Devices Alert cascade. It is subsequent to the close collaborative networking between DHCSS, the Director of Procurement and the Malta Standards Authority, that we could contribute jointly to this 'engineered safety devices' structured approach as per EU directives. During 2008, the two main private hospitals were also included in the alert cascade.

Expansion of the Existing Core Functions into areas of Health Care not yet regulated

There are to date eight government homes for older persons in Malta, and in close collaboration with the Director for Elderly Care, for the first time these homes were inspected during 2008 with the intention to license, to ensure standards of care are being upheld. For each home, the licence to be renewed on a yearly basis was issued for the first time by the Minister for Social Policy, after DHCSS presented the inspection report for each of these homes, with specific recommendations for the amelioration of service provision.

Homes for Older Persons	Number of Homes	Number of Beds
Government Homes	8	782
Long-term Care	4	175
Total	12	957

In accordance with the departmental remit to include within its regulated remit all the residential care services for older persons, for the first time the long-term facilities of St JeanneAntide Ward in Mount Carmel Hospital, St Anna's Residence in Gozo General Hospital and Capua Long-term Care Residence at Capua Hospital, Sliema were inspected during 2008 with the intention to license to ensure standards of care are being upheld. The licence for each was issued for the first time.



Depicting a registered 58% increase in the number of beds licensed by DHCSS

In close collaboration with the DNSS, DHCSS has initiated the process to have a set of standards to license nursing services agencies.

DHCSS has continued to invest in close collaborative links with the geriatricians and discussions took place during 2008 to address the sensitive issue of dementia care and how standards will need to be applied, keeping in mind the demographic shift in the population and the ever-increasing cohort of this group of older persons requiring extra attention by carers.

A series of discussions were held during 2008 with the management of St Vincent de Paule (SVPR) as regards the licensing of the Residence. During 2008, an innovative method of using a pre-inspection self-assessment questionnaire has been piloted in all the wards and sections of SVPR. On the basis of this information gathering exercise, it is planned that during 2009 the inspections with a view to license SVPR will be carried out.

A series of discussions with a number of stakeholders including top management of Mt Carmel Hospital were held during 2008 and are planned to continue during 2009, with a view to collate a set of standards to be used for licensing mental health services.

A standard format for reporting the key inspection findings has been drawn up to have a transparent and clear reporting vehicle. This format will include, in a standard manner, the demographic data pertinent for each Home, the inspectorate process and the strengths and areas identified for improvement within an agreed upon timeline. It is planned that a list of licensed homes and clinics/hospitals will be made available on the Department's website (<http://www.gov.mt/frame.asp?l=1&url=http://www.sahha.gov.mt>), together with a specially designed departmental logo developed in 2008.

Development on the Existing Regulatory Competencies and Embark into New Regulatory Services

With the steering initiative of DHCSS, a number of inter-departmental working committees have been set up - involving the Director of Health Information and Research, to enable effective monitoring and auditing by the development of clinical performance indicators for MDH, involving clinical consultants and CEO Mt Carmel Hospital with a view to license, and with Superintendent SVPR with a view also to license. A quality rating framework for Homes of Older Persons has been designed and is already being piloted.

Work continues within the inter-departmental working committee - involving the Director of Health Information and Research, the Director of Implementation and Monitoring and the Head Financial Monitoring and Control to ensure that the granularity and content of the data collection especially at MDH as in the hospital activity analysis, will enable effective monitoring and auditing by the development of clinical performance indicators.

One of the main remits of this Working Committee is to increase the scope of the data being collected to meet national and international health care reporting obligations. Furthermore, the active participation of DHCSS 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-departmental collaboration upholds relevant European initiatives such as the Minimum Hospital Data Set and Systems Health Accounts. It is envisaged that for outcomes that could be quantifiable, Statistical Process Control (SPC) technique is used to monitor and control the process of care. SPC will be used to ensure that the process meets specific standards by measuring its performance.

By the active participation in this inter-departmental initiative, of having a standardised system for data collection to be able to uniformly code, validate and analyse clinical information, DHCSS has effectively taken the first step of many that will necessitate to be implemented in the plan for the accreditation/licensing of MDH.

Diversification into New Territory and Regulating Novel Sectors of Health Care Services

This strategic developmental area of diversification for DHCSS is essential to satisfy 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.

During 2008, DHCSS participated in the EU Training Programme of EUSTITE (EU Standards and Training for the Inspection of Tissue Establishments) that offers invaluable learning opportunities through collaboration with other European partners in the training of competencies and skills for the inspections and licensing of tissue establishments.

Service users' satisfaction is the key measurement of any service provision and during 2008, the residents' perception of the quality of care in the homes for older persons was surveyed in a 500 residents' sample from all homes including private, church and government homes.

DHCSS also believes that a concern for the safety of patients must be both constant and proactive and has set this issue as a key target on its agenda. During 2008, for the first time the patient safety culture of Mater Dei has been surveyed for benchmarking purposes. Also, in collaboration with the Civil Protection Department, a fire safety awareness seminar was organised for managers of all homes of older persons. During the summer months, monitoring was undertaken to ensure that recommendations to mitigate the ill effects of the heat wave were being implemented.

During 2008, DHCSS followed up the previous year's planned roadmap in collaboration with the Medicines Authority for the setting up of the necessary mechanisms and structures to license the National

Blood Transfusion Services as a Blood Establishment according to the recommendations of the EU Directives.

Subsequent to the achievement of the aforementioned milestone, DHCSS developed a plan to build the appropriate mechanisms and structures to have the various blood banks assessed with an intention to regulate. Both private and public blood banks will be included in this regulatory framework.

In the first half of 2008, DHCSS submitted to the EU Commission the first Maltese National Haemovigilance Reporting system as stipulated by the same EU Directives on Blood and Blood Components.

Also during 2008, in collaboration with Medicines Authority, DHCSS reengineered the haemovigilance system for the reporting and investigation of serious adverse events and reactions according to the specified EU Directives. The EU Twinning programme with the Dutch haemovigilance TRIP organisation was instrumental to the success of this business process reengineering (BPR) exercise.

DHCSS has also made key links with UK foreign expert to initiate the setting up of the mechanisms and structures to have the tissue banks assessed as regards the Tissues and Cells EU Directive. In September 2008, DHCSS organised a visit by a UK expert to the Eye Bank at MDH with the intention to advise and proffer recommendations for improvements.

During 2008, DHCSS has continued with the essential networking with the same foreign expert to initiate the setting up of the mechanisms and structures to have the stem cell collection service providers assessed with an intention to inspect, regulate and license according to national legislation.

DHCSS has become a member of the European Haemovigilance Network, and by directing a grant from the latter, was instrumental to encourage participation in a short training course on Haemovigilance in Dublin Ireland, by a member of staff from MDH Blood Bank.

Knowledge Management

Knowledge management is an essential constituent of health intelligence which is of paramount importance to support evidence-based decision making. During 2008, aware of the centrality of patient safety and quality of care in the very existential ethos of this regulatory Department, DHCSS engaged in three main research initiatives:

- Measuring and benchmarking the culture of patient safety in Mater Dei Hospital.
- Situational analysis of the measures being implemented in homes for older persons to mitigate the negative effects of the summer heat wave.
- Analysing the service users' perception of the quality of care in homes for older persons.

Culture of Safety

Cognisant that local research is needed in this sector, DHCSS during 2008 conducted for the first time a survey to measure and benchmark patient safety culture in Mater Dei. The term culture of safety refers specifically to the contextualisation of the concern for patients' safety which needs to be embedded at every level of the organisation. A culture of safety is one that seeks to analyse and thereby anticipate adverse events including errors and, in the light of that analysis, to organise systems and practices which, as far as possible, prevent them. Barriers or defences can be built into systems so as to help avert them, or to contain and mitigate their potential for harm.

Approximately 400 face-to-face interviews with staff at all levels from Mater Dei were conducted using an internationally standardised questionnaire specifically addressing 12 patient safety culture composites.

Whilst the gathered data via this survey is still being analysed, there are emergent trends of strengths and key performance indicators that differentiate Mater Dei as best in class amongst other hospitals, when the local data is benchmarked with the comparative databases of international hospitals.

These are all positive indicators of a good platform to transform Mater Dei into a learning organisation and a centre of excellence as regards patient safety. The main challenge, as the results indicate, is an element of under-reporting which needs to be addressed. An open and non-punitive environment in which it is safe for health care professionals to report adverse events, safe to admit error, is essential to explore the root cause analysis and transform such events into an organisational learning opportunity.

Measures to Mitigate the Heat Wave in Homes for the Elderly

DHCSS has felt the need of surveying Community Homes for the Elderly with the intention of finding what heat wave measures are currently being implemented to mitigate the ill effects of high ambient temperature on the elderly residents. To accomplish this, the Department prepared a detailed questionnaire and the homes chosen for the survey were randomly selected and included state, private and church community homes for the elderly. The survey was conducted over a period of one month, between 27 July and 27 August. The 13 homes were visited at random and with no prior notice.

Strengths were identified that need to be encouraged such as the positive key finding that 92.3% of the homes participating in the survey monitor and observe the residents for signs of dehydration in a heat wave.

Another positive finding is that most of the homes (92.3%) alter their menu to include meals with a higher water content during high ambient temperatures.

These identified strengths should encourage the various service providers to do more such as documenting their monitoring and to draw up written protocols to ensure that all care givers know the standard operating procedures how to deal with heatstroke, amongst the most salient precautionary measures. DHCSS will be actively considering these findings for licensing purposes to ensure the implementation of appropriate measure to mitigate the ill effects of excessive heat on elderly residents in homes for older persons.

Service Users' Perception of Quality of Service

A representative sample of approximately 500 service users from all the homes for older persons was interviewed using a specially designed Quality of Care Evaluation questionnaire. As part of the summer work opportunities for university students, three students conducted this survey for DHCSS. Whilst the Department is still analysing the results, it is gratifying to note that for the question: *Do you consider yourself happy/content?* 92% of residents in Homes for Older Persons answered in the affirmative. Whilst there is no place for complacency, these findings are encouraging. The yearly inspections co-ordinated by DHCSS and which form the backbone of the regulatory framework for this particular health care sector, are surely contributing in the achieving of such positive results.

The representative sample size and the inclusion in this cross sectional survey of all homes, namely government, private and church homes, will surely provide a robust scientific platform for evidence based policy planning purposes to ensure quality of care in this sector of health care.

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