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CONSOLIDATION OF PUBLIC POLICIES FOR QUALITY AND PATIENT SAFETY IN HEALTH (2015–2019)

CONSOLIDAÇÃO DAS POLÍTICAS PÚBLICAS PARA A QUALIDADE E SEGURANÇA EM SAÚDE (2015-2019)

CONSOLIDACIÓN DE LAS POLÍTICAS PÚBLICAS PARA LA CALIDAD Y LA SEGURIDAD EN SALUD (2015–2019)

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ABSTRACT

The objective of this article is to share a critical analysis of public policies for healthcare quality and safety from 2015 to 2019. Bibliographic sources were used to search for evidence to assess the evolution of public policies during that period, as well as selected legislative sources and content analysis of available documentation. The consolidation of the National Healthcare Quality Strategy 2015-2020, which includes the National Patient Safety Plan and the List of Indicators for Quality Monitoring, stood out. Between 2015 and 2018, the highlights included political initiatives and legislation aimed at promoting public health, improving NHS governance, hospital management, and expanding the primary healthcare network, improving healthcare quality, creating referral networks, recognizing and establishing referral centers, strengthening citizen empowerment in the NHS, and reducing inequalities in access to healthcare. In the period following the ministerial change, notable highlights included the approval of the Health Guidelines and Bases Law, the approval of the transition from Model A to Model B for 20 family health units, and the consolidation and development of Home Care Units in SUS hospitals. Until 2019, there was no evaluation policy for the National Strategy for Quality in Healthcare 2015-2020, enshrined in program contracts. This policy was based on the establishment of a network of hospitals and other healthcare units, coupled with benchmarking and incentives at the national level.

Keywords: Health Policies. Public Health Policies. Public Policies. Quality and Safety in Healthcare.

RESUMO

O objetivo do presente artigo é partilhar a análise crítica das políticas públicas para a qualidade e segurança em saúde, no período 2015-2019. Recorreu-se a fontes bibliográficas na procura de evidências para avaliar a evolução das políticas públicas nesse período, bem como às fontes legislativas selecionadas e análise de conteúdo da documentação disponível. No período 2015-2019, destacou-se a consolidação da Estratégia Nacional para

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a Qualidade na Saúde 2015-2020, que inclui o Plano Nacional para a Segurança do Doente e a Lista de Indicadores para Monitorização da Qualidade. Entre 2015 e 2018, destacaram-se, designadamente as iniciativas políticas e legislação que visam a promoção da saúde pública, a melhoria da governação do SNS, da gestão hospitalar e da expansão da rede cuidados de saúde primários, a melhoria da qualidade dos cuidados de saúde, a criação de redes de referenciação, o reconhecimento e a determinação de centros de referência, o reforço do poder do cidadão no SNS e a redução das desigualdades no acesso aos cuidados de saúde. No período após a mudança ministerial, destacaram-se a aprovação da Lei de Bases da Saúde, a aprovação da transição do modelo A para o modelo B para 20 unidades de saúde familiar e a consolidação e desenvolvimento de Unidades de Hospitalização Domiciliária nos estabelecimentos hospitalares do SNS. Até 2019, não existe uma política de avaliação da Estratégia Nacional para a Qualidade na Saúde 2015-2020, inscrita nos contratos-programa, baseada no estabelecimento de uma rede de hospitais e das outras unidades de saúde, associada a um benchmarking e a incentivos, a nível nacional.

Palavras-chave: Políticas de Saúde. Políticas de Saúde Pública. Políticas Públicas. Qualidade e Segurança em Saúde.

RESUMEN

El objetivo del presente artículo es compartir el análisis crítico de las políticas públicas para la calidad y la seguridad en salud durante el período 2015-2019. Se recurrió a fuentes bibliográficas en la búsqueda de evidencias para evaluar la evolución de las políticas públicas en ese período, así como a fuentes legislativas seleccionadas y al análisis de contenido de la documentación disponible. En el período 2015-2019, se destacó la consolidación de la Estrategia Nacional para la Calidad en Salud 2015-2020, que incluye el Plan Nacional de Seguridad del Paciente y la Lista de Indicadores para el Monitoreo de la Calidad. Entre 2015 y 2018, sobresalieron, en particular, las iniciativas políticas y la legislación orientadas a la promoción de la salud pública, la mejora de la gobernanza del SNS, de la gestión hospitalaria y de la expansión de la red de atención primaria, la mejora de la calidad de la atención sanitaria, la creación de redes de referencia, el reconocimiento y la designación de centros de referencia, el fortalecimiento del poder del ciudadano en el SNS y la reducción de las desigualdades en el acceso a la atención sanitaria. En el período posterior al cambio ministerial, se destacaron la aprobación de la Ley General de Salud, la aprobación de la transición del modelo A al modelo B para 20 unidades de salud familiar y la consolidación y desarrollo de Unidades de Hospitalización Domiciliaria en los establecimientos hospitalarios del SNS. Hasta 2019, no existe una política de evaluación de la Estrategia Nacional para la Calidad en Salud 2015-2020 incluida en los contratos-programa, basada en el establecimiento de una red de hospitales y otras unidades de salud, asociada a procesos de benchmarking e incentivos a nivel nacional.

Palabras clave: Políticas de Salud. Políticas de Salud Pública. Políticas Públicas. Calidad y Seguridad en Salud.

1 INTRODUCTION

Quality and safety in health represent fundamental pillars for building accessible, safe and equitable care systems. In the context of Portugal, between 2015 and 2019, the consolidation of public policies in this area has been aimed at ensuring that the care provided can meet the needs and expectations of citizens, promoting their adherence and satisfaction. Achieving these objectives requires efficient management of available resources, as well as the implementation of practices that ensure patient safety at all levels and stages of healthcare. In addition, any economic and financial scenario at a global level imposes the need to improve the efficiency and effectiveness of health care provision, considering these aspects as essential foundations of quality in health. Thus, the close link between quality and safety of health care is a guarantee of the sustainability of the National Health System and the health system in Portugal, contributing to its resilience and ability to respond to the demands of the population.

The creation of the Department of Quality in Health (DQS), based in the Directorate-General for Health (DGS) in 2009, was an important milestone for the definition of a national strategy for Quality and Safety in Health (Martins d'Arrábida C. (2013). This established leadership has made it possible to accompany the European Union in strengthening the competences of the governments of the Member States, which had not occurred until then, except for the recommendations on the prevention and control of healthcare-associated infection.

In the *top-down* approach to the implementation of the ENQS 2009-2014, competencies had been defined according to the entities involved, namely the Directorate-General for Health, the Department of Quality in Health, the Regional Health Administrations and the Health Units (Order No. 3635/2013, of 7 March[i], cited by Martins d'Arrábida, 2013). The objectives of the action plan of the health units should be included in the program contracts agreed with each type of health unit (Hospital, Hospital Center, Local Health Unit and Group of Health Centers), and it was observed that only some health units integrated political measures of the National Strategy in their respective program contracts.

In 2013, the creation of the Quality and Safety Commissions (CQS) initiated the implementation of the National Strategy for Quality in Health – ENQS 2009-2014 (Order No. 3635/2013, of March 7). Despite the institution of the CQS, at the national level, several health units have maintained the Humanization Commission to this day, integrated or not in the respective CQS.

As a result of Council Recommendation 2009/C 151/01 of 9 June on patient safety, the Commission's second report to the Council in 2014 stated that, among the 13 measures

applied based on each country's self-assessment, Portugal indicated that 8 of these measures were implemented.

Also in 2014, the publication of the European Union's Health Action Programme for 2014-2020[ii], together with the report "A Future for Health – We all have a role", by the Calouste Gulbenkian Foundation (2014), were important references for the consolidation of the National Strategy for Quality in Health, in 2015, one year after the intervention of the Troika (Martins d'Arrábida, 2023).

A new political cycle in coalition took place between 11 June 2011 and 26 November 2015 with a ministerial change on 30 October 2015.

In 2014, the publication of the European Union Health Action Programme for 2014-2020 [iii], together with the Report "A Future for Health – We all have a role of the Calouste Gulbenkian Foundation (2014), became a reference for the consolidation of the National Strategy for Quality in Health.

At the national level, a new policy cycle began on 26 November 2015 with a ministerial change on 15 October 2018. The ministerial change that took place on October 15, 2018, was maintained in the second legislature that began on October 26, 2019.

The objective of this article is to share the critical analysis of public policies for quality and safety in health in the period 2015-2019.

2 METHODOLOGICAL PROCEDURE

In the preparation of this article, bibliographic sources were used in the search for evidence to evaluate the evolution of public policies in the period between 2015 and 2019. The comparative analysis of the selected legislative sources and other documentary analysis led to the set of bibliographic references presented, based on the evaluation and analysis of the respective contents to be included in this article.

3 NATIONAL STRATEGY FOR QUALITY IN HEALTH 2015-2020

One year after the intervention of the *Troika*, the Directorate-General for Health (DGS), on the proposal of the Department of Quality in Health, (DQS) proposed to the member of the Government responsible for the health area, the scheduling of the public health policy, the National Plan for Patient Safety (PNSD) 2015-2020 and, in the same year, the National Strategy for Quality in Health (ENQS) 2015-2020.[iv,v]

It was necessary, on the path to improvement, to increase accountability for the quality of all levels of the system and the involvement of professionals and leaders, through ENQS 2015-2020 (Order No. 5613/2015 of 27 May).[vi] The consolidation of public policies for quality

and safety in health, expressed in ENQS 2015-2020, is aimed at: a) the citizen, as the protagonist of the services that make up the health system, as a client, as a user and as the owner of the National Health Service; b) health professionals, regardless of their level of responsibility, from the management, coordination and operationalization of health care.

This National Strategy for Quality in Health respects the National Health Plan 2012-2016, intersecting the national priority health programmes and articulates with the complementary and concerted actions of central, regional and local institutions, under the supervision of the Ministry of Health (Order No. 5613/2015 of 27 May).

The following strategic priorities were adopted:

a) Focus on local interventions, services, provider units and institutions;
b) Improvement of clinical and organizational quality;
c) Increased adherence to clinical guidance standards;
d) Strengthening patient safety;
e) Strengthening clinical research;
f) Permanent monitoring of quality and safety;
g) Disclosure of comparable performance data;
h) Recognition of the quality of health units;
i) Transparent information to citizens and increase their training.

The National Plan for Patient Safety (PNSD) 2015-2020, addressed to the National Health Service (Order no. 1400-A/2015 of 10 February), is part of ENQS 2015-2020 and, in this context, is coordinated, at national level, by the Department of Quality in Health in the Directorate-General for Health.[vii] The PNSD 2015-2020 focuses on the evaluation of safety culture, the safety of communication in times of care transitions, the increase of surgical safety and the safety of the use of medicines, on ensuring the unequivocal identification of patients and the systematic practice of incident reporting and on the prevention of falls, pressure ulcers and healthcare-associated infections (HAIs).

It is the responsibility of the highest management bodies of public services and entities providing health care, namely groups of health centres, hospitals and local health units, to allocate resources, validate the programmed actions and monitor the results of the management of risks associated with health care (Order No. 1400-A/2015 of 10 February).

3.1 POLICY FOR THE EVALUATION OF PUBLIC POLICIES

In 2013, it had been determined that the objectives of the annual action plans should be included in the programme contracts agreed with each NHS health unit (Order No. 3635/2013, of 7 March).[viii] However, the formulation of public policies for quality in patient

health and safety and its ongoing implementation process is not associated with an evaluation policy, based on the establishment of a network of hospitals and other health units, on *benchmarking* and the creation of incentives.

Within the scope of ENQS 2015-2020, a List of Indicators for Quality Monitoring was defined for ACES, Hospitals, Hospital Centers and Local Health Units (ULS), as applicable, identifying the obligation of health institutions and professionals to ensure that the health care they provide to citizens responds to quality criteria. It was intended to provide information to the public on the performance of hospitals, local health units, regional health administrations and their groupings of health centres and other services of the National Health Service and to improve the transparency of health information. It is up to the ACSS to disclose it quarterly and, together with the DGS, to assess the need to review the indicators disclosed every six months (Order 5739/2015 of 29 May). [ix]

3.2 COMPETENT AUTHORITY

As of 2015, the Directorate-General for Health (DGS) became the competent authority, responsible for verifying compliance with the requirements set out in this law throughout the national territory, without prejudice to the articulation with the General Inspection of Health Activities (IGAS), in matters of supervision and inspection, and the competences of the Portuguese Institute of Blood and Transplantation, I.P. (IPST, IP), in terms of coordination of the harvesting and transplantation activity, strategic planning to respond to national needs and authorisation of the import and export of organs (Law No. 2/2015 of 8 January).[x]

Decree-Law No. 185/2015 of 2 September also made the second amendment to Decree-Law No. 267/2007 of 24 July, identifying the competences of the DGS and IPST, IP.[xi] Internally, there were no changes regarding the specific competences of the Department of Quality in Health (DQS).

Also in 2017, the European Commission's Directive EU 2016/1214 on the specifications of the quality system for blood services was transposed, through an Organizational Standard of the Directorate-General for Health, by joint proposal of the Department of Quality in Health and the Portuguese Institute of Blood and Transplantation IP (Decree-Law No. 86/2017 of 27 July).[xii] Accordingly, the DQS prepared Standard No. 021/2017 DGS of 17/10/2017 "Specifications of the Quality System of Blood Services and Transfusion Medicine Services".[xiii]

Law no. 99/2017 of 25 August makes the second amendment to Law no. 12/2009, of 26 March, which establishes the legal regime of quality and safety relating to the donation, collection, analysis, processing, preservation, storage, distribution and application of tissues

and cells of human origin, amended by Law no. 1/2015, of 8 January, in order to transpose into the national legal order Commission Directive 2015/565/EU of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of tissues and cells of human origin. It was determined that the competent authorities, responsible for verifying compliance with the technical requirements are the DGS, the IPST, I. P., and the National Council for Medically Assisted Procreation (CNPMA).[xiv]

3.3 INTEGRATED STRATEGY FOR RARE DISEASES 2015-2020

At the national level, in 2015, the Integrated Strategy for Rare Diseases 2015-2020 was approved, coordinated by an interministerial committee and chaired by the Director-General of Health (Order No. 2129-B/2015, of 27 February).[xv] The European Union designation of rare disease was adopted - prevalence not exceeding 5 cases per ten thousand people. The National Programme for Rare Diseases, approved in 2008, has been revoked.

It is part of Ordinance No. 194/2014, of 30 September, which established the process of identification, approval and recognition of National Reference Centres, with regard to the identification and proposal for recognition of Reference Centres for Rare Diseases. [xvi]

The implementation of the Rare Disease Person Card is part of the Integrated Strategy for Rare Diseases 2015-2020.

3.4 REFERENCE CENTERS

The Department of Quality in Health (DQS), in conjunction with the Director-General of Health and member of the Government responsible for the health area, participated in the identification of priority areas in which reference centers should be recognized.

Order No. 235-A/2015 of 8 January and Order No. 2999/2015 of 24 March defined the priority areas of intervention for the recognition of Reference Centres.[xvii]The[xviii] DQS coordinated the definition of application criteria and the first phase of the organization of the selection of applications for the respective reference centers, and the first reference centers were recognized in 2015 for the areas of Refractory Epilepsy, Onco-Ophthalmology, Familial Paramyloidosis, Lung Transplantation, Pancreas Transplantation and Liver Transplantation (Order No. 11297/2015 of 8 October).[xix]

Subsequently, a set of Reference Centres was recognised in the areas identified as priorities, for the provision of quality health care and for the prestige and competitiveness of the Portuguese health system in relation to the health systems in the European Union, in

order to enable and enhance applications to European Reference Networks that may be created (Order No. 3653/2016 of 11 March).[xx]

The Department of Quality in Health is part of the National Commission for Reference Centres, through the appointment of its director, as a representative of the Directorate-General for Health (Order 11648-A/2016 of 29 September), [xxi]a designation that remains (Order No. 29/2019 of 20 January).[xxii]

Order No. 6669/2017 of 2 August determined the Reference Centres recognised by the Ministry of Health, for the areas of cystic fibrosis, interventional neuroradiology, cerebrovascular disease, congenital coagulopathies, cochlear implants and ECMO (extracorporeal membrane oxygenation) (Order 6669/2017 of 2 August)[xxiii] and the Declaration of Rectification No. 530/2017 of 8 August.[xxiv]

3.5 CONTINUING AND PALLIATIVE CARE

The installation and operating conditions for the level 1 paediatric integrated care inpatient units and the operating conditions of the teams of these units and the discharge management teams were defined (Ordinance 345/2015 of 12 October).[xxv]

The expansion and improvement of the integration of the Continued Care Network and other support services for people in situations of dependence was defined, and the National Coordination Commission of the National Network of Integrated Continued Care was established under the Secretaries of State for Social Security and Deputy Health (Order 4663/2016 of 5 April).[xxvi]

Of note is the progressive implementation of the paediatric long-term care inpatient units and paediatric outpatient clinics, which is carried out, in a first phase, through pilot experiences focusing on clinical rehabilitation care, taking place over a period of one year, whose care and services are the responsibility of the Ministry of Health (Ordinance no. 153/2016 of 27 May).[xxvii]

Orders the Government, through the Assistant Secretary of State for Health, to implement a regional coordination of the National Palliative Care Network (RNCP), with the aim of promoting the creation of palliative care services that support the three levels of care (primary, hospital and integrated continuing health care) and the continuous improvement of their quality in accordance with the provisions of Law No. 52/2012, of September 5 (Basic Law on Palliative Care). In this way, the first amendment to Ordinance No. 340/2015, of October 8, which regulates, within the scope of the National Palliative Care Network (RNCP), the characterization of services and admission to local teams and the conditions and

requirements for the construction and safety of palliative care facilities (Ordinance No. 165/2016 of June 14) was made.[xxviii]

Ordinance No. 249/2018 of 6 September defines, in particular, the conditions for the installation and operation of inpatient and outpatient units, the operating conditions of the discharge management teams and the RNCCI's integrated long-term care teams. Makes the third amendment to Ordinance No. 174/2014, of 10 September (amended by Ordinance No. 289-A/2015, of 17 September, and by Ordinance No. 50/2017, of 2 February).[xxix]

The Health Strategy in the Area of Dementias was approved and the constitution and composition of the Coordination of the National Health Plan for Dementias was determined, with the mission of monitoring the preparation of the Regional Plans for Dementia. The mandate of the Coordination was extinguished with the presentation of the reports to the Assistant Secretary of State for Health, Fernando Araújo (Order No. 5988/2018 of 19 June).[xxx]

4 CENTRALIZATION OF THE ACQUISITION OF SPECIFIC GOODS AND SERVICES IN THE HEALTH AREA

In order to consolidate the rational use of resources and ensure their greater effectiveness and efficiency in public procurement in the health area, the centralization of the acquisition of specific goods and services in the health area was established, for the entities of the NHS and the bodies and services of the Ministry of Health, to be ensured by the SPMS, EPE (Shared Services of the Ministry of Health, E. P. E.) (Order 1571/2016 of 10 February).[xxxi]

4.1 NATIONAL HEALTH PROGRAMS

The creation of the National Program for Health Education, Literacy and Self-Care was determined. The coordination of this Programme includes the Directorate-General for Health, at national level, the Regional Departments of Public Health, at regional level, and the Public Health Units, at local level (Order No. 3618-A/2016 of 10 March).[xxxii]

The objective "To contribute to the improvement of health education, literacy and self-care of the population, promoting citizenship in health, making people more autonomous and responsible in relation to their health, the health of those who depend on them and that of their community" Several projects were determined in the 2016-2017 biennium, including navigability, in the NHS in and in the health system on three topics: reproductive health; oncological disease and living will (Order No. 3618-A/2016 of 10 March).

It was also planned to create a National Program for Health Education, Literacy and Self-Care and the reinforcement and deepening of actions, such as epidemiological surveillance, health promotion, primary prevention and secondary prevention, the

Communicable Disease Control Program, smoking prevention measures (expanding access to smoking cessation consultations), healthy eating (collective food in schools and workplaces), prevention of alcohol consumption and other addictive products, and the National Vaccination Program (Order No. 4027-A/2016 of 18 March).

The creation of a Programme for the Prevention and Management of Chronic Disease and health promotion was established as a priority, determining in a first phase the establishment of a strategic coordination for the prevention and management of chronic disease and its elaboration (Order No. 4027-A/2016 of 18 March).[xxxiii]

The priority national health programmes (diabetes, HIV/AIDS infection, smoking, healthy eating, mental health, oncological, respiratory and cerebro-cardiovascular diseases and the prevention and control of infections and antimicrobial resistance) include communicable and non-communicable diseases, long-term diseases and their exacerbations (Order no. 4027-A/2016 of 18 March).

The following instruments were also foreseen, among others, for the dissemination of the objectives: a) Contracting the performance of the NHS units; b) Monitoring progress in the prevention and management of the disease; c) Sharing information and literacy in prevention and management of the disease as a whole; d) Health planning (Order no. 4027-A/2016 of 18 March).

Sakellarides was appointed consultant to a Strategic Support Center (NAE), whose function is to support the government team of the Ministry of Health within the scope of strategic coordination and periodic evaluation of the new horizontal programs - "Education for Health, Literacy and Self-Care" and "Prevention and Management of Chronic Disease", without prejudice to the competences of the Directorate-General for Health (Order No. 5372/2016 of 20 April).[xxxiv]

Within the scope of user referral, for the first hospital consultation in the NHS, provisions were established (Order no. 5911-B/2016 of 3 May).[xxxv]

The PNS 2012-2016 revision and extension to 2020 defines, as one of its priority axes, equity and adequate access to health care, and quality in health. As proposals for strategic guidelines, they are, in particular, the strengthening of the articulation of health services, through the reorganization of integrated primary, hospital and continuing health care, thus consolidating an integrated and efficient care delivery network (Ordinance No. 147/2016 of 19 May).[xxxvi]

It was determined the development, within the scope of the National Health Plan, of priority health programs in the areas of Tobacco Prevention and Control, Promotion of Healthy Eating, Promotion of Physical Activity, Diabetes, Cerebro-cardiovascular Diseases,

Oncological Diseases, Respiratory Diseases, Viral Hepatitis, HIV/AIDS and Tuberculosis Infection, Prevention and Control of Infections and Antimicrobial Resistance and Mental Health (Order No. 6401/2016 of 16 May).[xxxvii]

In 2016, four years after the creation of the priority health programmes, the DGS continued with the development of a set of eleven Priority Health Programmes (Order No. 6401/2016 of 16 May).[xxxviii]

In the governance model for 2020 (2016) that involves the PNS and the Priority Programs, the various areas of the Priority Health Programs collaborate with the different Departments, Functional Units, Programs and Projects promoted by the DGS. They are part of the Pataformas for the Prevention and Management of Chronic Diseases, for the Prevention and Management of Communicable Diseases and for Mental Health, under the coordination of the Director-General of Health, assisted by the Executive Director of the National Health Plan. The various areas are part of the platforms, intending to harmonize and enhance the strategies of health interventions, with a view to contributing, together, to achieving the goals recommended in the National Health Plan for 2020. The areas collaborate with the different Departments, Functional Units, Programs and Projects promoted by the DGS.[xxxix]

Likewise, the need and relevance of direct articulation of the Department of Quality in Health with the Programs and the National Health Plan for 2020 and reporting the DQS, directly to the Director-General of Health, which, in fact, was not ensured by Order No. 3049/2019 of March 20, as will be seen below. Collaborating is everyone's duty, not exactly a specific competence or attribution.

In the context of Patient Safety and the prevention of HAIs and AMR, the main objectives of the Programme for the Prevention and Control of Infections and Antimicrobial Resistance (PPCIRA) were defined as a national priority programme until 2020; a) Improve the prevention and control of infections in health units, reducing HAIs; (b) Improve the quality of antimicrobial prescribing; c) Reduce resistance to antimicrobials (Order No. 6401/2016 of 16 May):

In the same year, the articulation of the PPCIRA with the Department of Quality in Health was consolidated, replacing the previous attribution of the specific competence of this department, in terms of coordination of the national strategy, since the PPCIRA started to report directly to the Director-General of Health, as of 2016.

As part of the strengthening of the citizen's power in the NHS and the improvement of the relationship of citizens with the Administration and the quality of health care provided, ensuring patient safety, an administrative simplification program was created, within the

scope of the National Child and Youth Health Program and the National Vaccination Program, which aims to bring the Health System closer to the Citizen, benefiting from the advancement of information technologies, in the issuance of "Nascer Utente", "Birth News", "eChild and Youth Health Bulletin", "eVaccine Bulletin" (Order No. 6744/2016 of 23 May).[xl]

4.2 GOVERNANCE MODEL OF THE PNS AND THE ENROLLED PROGRAMS

In 2018, the governance model applicable to the PNS and the Priority Health Programmes included in it was established. The National Health Plan (PNS) is coordinated by the Director-General of Health and guided by the Executive Director of the PNS (Order No. 728/2014, of 6 January, amended by Order No. 1695/2018, of 7 February)[xli] (Order No. 4429/2018 of 7 May). [xlii]

The articulation of the directors of each Priority Health Programme with the Executive Director of the PNS and with the organic structure of the DGS stands out, whether at the level of service directorates, divisions, support units or other national health programmes. The directors of each Priority Health Programme integrate Platforms according to their area of specialty, namely: a) Prevention and Management of Chronic Diseases; b) Prevention and Management of Communicable Diseases; c) Mental Health (Order No. 4429/2018 of 7 May).

The Government mandates that each Priority Health Programme be endowed with a Scientific Council, with the competences, in addition to analysis and discussion of proposals, "to ensure criteria of evidence, quality and transparency of action, made up of specialists with recognised scientific merit, appointed by order of the Director-General of Health (Order no. 4429/2018 of 7 May).

"The representation of the PNS and the Priority Health Programmes, unless expressly delegated, is the responsibility of the Director-General of Health, particularly for acts that may externally bind the institution" (Order no. 4429/2018 of 7 May).

As will be seen below, the governance model applied to the PNS and the Priority Health Programmes implies the clarification of the articulation of the DQS with the Programmes, the specific competences relating to National Strategies and Commissions and the direct articulation with the Director-General of Health.

Within the scope of the process of conducting Clinical and Organizational Standards, carried out within a division of the DQS, in terms of streamlining the preparation and updating of Standards, the type of direct articulation with the Programs and with the Executive Director of the PNS is not clarified. Further on, Order No. 3049/2019 of 20 March recalls the issues of the articulation of the DQS internally within the DGS and with other bodies. The duties of the Department of Quality in Health are delegated to the Deputy Director-General of Health.

4.3 GOVERNANCE MODEL OF THE DEPARTMENT OF QUALITY IN HEALTH

At the level of the DQS, the competences related to the attributions of the Department of Quality in Health were delegated to the Deputy Director-General of Health, which may raise questions regarding the direct articulation of the DQS with the Priority Health Programs and the National Health Plan, under the coordination of the Director-General of Health (Order No. 3049/2019 of 20 March).[xliii] The process of elaboration and updating of Clinical and Organizational Standards is one area, among others, that can be achieved, in terms of agility and opportunity, with regard to the clarification of the specific competences of the DQS to the governance model at the level of the DGS.

4.4 ELABORATION AND UPDATE OF STANDARDS

As part of the preparation and updating of Clinical and Organizational Standards, in 2016, it was determined that the Directorate-General for Health should promote involvement and collaboration with the different professional orders in the health sector, within the scope of Quality in Health, namely, in the process of preparing Guidelines for Health, as well as the signing of protocols (Order No. 9416/2016 of the Office of the Assistant Secretary of State and Health of 22 July).[xliv]

The report "*OECD Reviews of Health Care Quality: Portugal 2015*" recommended that Portugal should encourage adherence to agreed health care standards and the use of clinical guidelines, which are basic in the hospital system, to optimize clinical outcome, use of resources and reduce variability in clinical practice.

External audits should be supported by *feedback* to health professionals at the local level and also linked to well-designed financial incentives or sanctions, also mentioning that the Directorate-General for Health planned to introduce economic incentives and sanctions, for good or bad adherence, to clinical practice guidelines (OECD, 2015).

The issuance of Standards is closely related to the objectives of reducing the heterogeneity of action, the definition of the guarantee of access to the different levels of care, the definition of the conditions to ensure the financing of health units, included in the contract, in conjunction with the ACSS, as well as access to pharmacological therapy, in conjunction with INFARMED.

At the national level, Professional Orders and Scientific Societies have all the legitimacy to develop and publish Recommendations and Clinical Guidelines. However, it is up to the DQS in the DGS and the DGS, to issue Clinical and Organizational Standards.

The elaboration and updating of Clinical and Organizational Standards in the Quality Management Division of the DQS has revealed the expansion of its sphere of intervention in the Directorate-General for Health (DGS).

In this context, it can be questioned to what extent the entire Standards process should be reported to a Division within the DQS, in terms of organizational structure, considering that this process implies a direct articulation, namely, with the Priority Programs. On the other hand, the DGS pursues the attributions of the process of issuing standards and guidelines, both clinical and organisational within the scope of its organic structure (Regulatory Decree No. 14/2012 of 26 January).

it will be up to the DGS and the DQS to prepare and review Clinical and Organizational Standards in conjunction with the Priority Programs and other National Programs and Strategies that can contribute to reducing variability in practice, and for people to receive high quality and safe health care, supporting the model of integrated and person-centered care, defined by the Ministry of Health.

In the context of the safety of health professionals, the notification of violence against health professionals in the workplace has had the participation of health professionals on a national *online platform* started in the DGS since 2007 and in the DQS, from 2009. [xlv] Encompassing the safety of patients and health professionals, the variables that integrate the notification of violence in health care contexts, and which can affect professionals and people who receive health care, were updated and integrated into the NOTIFIC@ in 2016.

4.5 NATIONAL HEALTH COUNCIL (CNS)

As part of the strengthening of citizen power, Decree-Law No. 49/2016 of 23 August established that the National Health Council (CNS) is an independent body, consulting the Government in the definition of health policies, its specific competences and its composition.[xlvi]

4.6 RESPONSES IN PUBLIC HEALTH EMERGENCIES

The first amendment to Ordinance No. 248/2013, of 5 August, which approves the Regulation on Mandatory Notification of Communicable Diseases and Other Public Health Risks (Ordinance No. 22/2016, of 10 February) was approved.[xlvii]

Within the scope of the recommendations of the European Commission and the WHO, the lessons arising from the outbreak of Legionnaires' Disease in the last quarter of 2014 and the situations that constitute public health emergencies of international scope, in the context of the International Health Regulations, namely Ebola and Zika, the Public Health Emergency

Centre (CESP) was created within the scope of the Directorate-General for Health. On the one hand, it is intended to "strengthen the systems for early detection of these threats, anticipating them, increasing the capacity to monitor indicators and warning signs, promoting communication in terms of response and intensifying the respective coordination capacity" (Order no. 11035-A/2016 of 13 September). [xlviii]

On the other hand, it was established "to develop the current risk analysis and management instruments, always in conjunction with other national and international institutions, as well as to enhance the use of electronic platforms for analysis and issuance of notifications and alert systems, in a collaborative environment, in order to ensure quick and appropriate responses" (Order No. 11035-A/2016 of 13 September).

4.7 NATIONAL STRATEGY FOR MEDICINES AND HEALTH PRODUCTS

The National Strategy for Medicines and Health Products was also approved, aiming to improve governance, promote a sustainable policy in the area of medicines in order to reconcile budgetary rigor and access to therapeutic innovation, increase the use of generic medicines and the use of biosimilars. In addition, there is the stimulus to research and national production of the medicine (Resolution of the Council of Ministers no. 56/2016 of 13 October).[xlix]

In terms of quality, it was assumed that specific policies and programmes should be strengthened to develop health technology assessment models that can assess new medicines, medical devices and non-pharmacological interventions. One of the vectors is also the reduction of situations of conflicts of interest between the public and private sectors, including the relationship with the health industry (Resolution of the Council of Ministers no. 56/2016 of 13 October).

4.8 LEGAL REGIME AND STATUTES OF HEALTH UNITS

The regulation of the Legal Regime and the Statutes applicable to the health units of the National Health Service with the nature of Public Business Entities, as well as those integrated in the Public Administrative Sector (Decree-Law No. 18/2017 of 10 February) was published.[l]

Ordinance no. 71/2018 of 8 March makes the first amendment to Ordinance no. 330/2017, of 31 October, which defines the model of the internal regulation of the services or functional units of the NHS Health Units, with the nature of public business entities, endowed with legal personality, administrative, financial and patrimonial autonomy, which are

organized in Integrated Responsibility Centers (CRI).[li] With the publication of these diplomas, the ACSS states that the conditions for the implementation of CRI in the NHS are created.[lii]

4.9 ACCESS TO HEALTH AND CARE IN THE NHS

With the aim of reducing inequalities, by improving access to health and care in the NHS, and improving the management of hospitals, the circulation of clinical information and the articulation with other levels of care and other agents in the sector, the Integrated Access Management System for users of health services was amended.

This amendment is the first to Law No. 15/2014 of 21 March, which aims to consolidate the rights and duties of the user of health services, defining the terms to which the Charter of Rights of Access to Health Care by Users of the National Health Service must comply, and creates the Integrated Access Management System (Decree-Law No. 44/2017 of 20 April).[liii]

In Order No. 8254/2017 of 21 September, of the Office of the Assistant Secretary of State for Health, it was established that, in addition to equity and adequate access to health care, through population-based screenings, the development and implementation of diagnostic and treatment care processes so that the citizen receives adequate and timely health care. [liv] In 2016, provisions had been established on the implementation of population-based screenings in several areas to ensure equity and access to healthcare in the areas of breast cancer, cervical cancer, colon and rectal cancer and diabetic retinopathy (Order No. 4771-A/2016 of 7 April).[lv]

With the diploma on the development and implementation of integrated care processes and, in conjunction with the PNS revision and extension to 2020, Fernando Araújo initiated a government leadership strategy, through the development and implementation of integrated care processes in order to ensure coordination between the different levels of care, centered on the citizen and guaranteeing equity and access and quality in health with the involvement of health professionals and of citizens.

The strategy for the implementation of Home Hospitalization Units in the NHS was determined by Order No. 9323-A/2018 of 3 October.[lvi] Conducted by the DQS, a Standard on Home Hospitalization was approved by the DGS.[lvii]

It was determined that the Ministry of Health promotes the consolidation and development of Home Hospitalization Units in NHS hospital establishments, with a view to extending this model of health care provision to all NHS hospital establishments (Order No. 12333/2019 of 23 December).[lviii]

With a view to expanding the USF, the transition from model A to model B was approved for 20 family health units (Order No. 11307-A/2019 of 29 November).[lix]

4.10 CONTACT CENTRE OF THE NATIONAL HEALTH SERVICE (SNS24)

On July 24, 2017, the Contact Center of the National Health Service (SNS24) was inaugurated, which was part of Saúde 24, in a ceremony presided over by the Minister of Health Adalberto Campos Fernandes, maintaining the number 808 24 24 24 and continuing the Screening, Counseling and Referral Services by nurses.

In the SNS24, the nurse assesses the level of risk on signs and symptoms reported by the citizen, and whenever necessary, refers him to the NHS health care structure most appropriate to his condition (INEM, CIAV, CSP, SU) or recommends self-care, and may make contacts for follow-up. [lx]

The mission of SNS24 is, in an integrated way, to provide the User, through a single, omnichannel point of contact (telephone channel; email; web), information and services that facilitate access, ensure equity and simplify the use of the SNS (Decree-Law No. 69/2017 of 16 June).[lxi]

4.11 DIFFERENTIATED INTERVENTION MODEL IN PROLONGED GRIEF

As part of the improvement of the governance of the NHS and the improvement of the quality of health care, a committee was created to monitor the implementation of the differentiated intervention model in prolonged grief and which will be extinguished on December 31, 2019, with the presentation of an evaluation report on the implementation of the differentiated intervention model in prolonged grief, namely, of the pilot experiments, "without prejudice to any extension, if necessary". The needs of people grieving significant losses require specific attention from the NHS to bereaved people, who constitute risk groups for the development, in about 10 to 30% of cases, of physical and mental complications (Order No. 3254/2018 of 29 March).[lxii] Following this order, the Standard on "Model of Differentiated Intervention in Prolonged Grief in Adults" was published.[lxiii]

4.12 APPLICATION OF THE NATIONAL TABLE OF FUNCTIONALITY

After the experimental phase of the application of the National Table of Functionality that had been taking place since 2014, it was determined, in 2018, the expansion of its implementation aimed at NHS users over the age of 18, with specific conditions and the improvement of its applicability, namely, streamlining and dematerializing itIt was also determined the creation of a commission under the coordination of the DGS for the follow-up, monitoring and evaluation of the implementation of the National Table of Functionality, aiming to ensure an effective evolution of its application. (Order 4306/2018 of 30 April).[lxiv]

Norm No. 001/2019 of 25/01/2019 "Implementation of the National Table of Functionality in Adults and Elderly" was published.[lxv]

4.13 NEW BASIC HEALTH LAW

The approved Basic Law on Health (Law No. 95/2019 of 9 April) repeals Law No. 48/90, of 24 August, and Decree-Law No. 185/2002, of 20 August. It determines that the National Health Service must guide its performance, among others, by the principle of integration of care, safeguarding that the delivery model guaranteed by the NHS is organized and works in an articulated and networked way. It is up to the member of the Government responsible for the health area to propose the health policy to be defined by the Government, to promote its implementation and supervision and to coordinate its action. [lxvi]

Base 34 of the Basic Law on Health establishes the competences of the health authority.

Law no. 81/2009 of 21 August remains unregulated, with the Basic Law on Health (Law no. 95/2019 of 4 September, which approved the Basic Law on Health and repealed Law no. 48/90 of 24 August, and Decree-Law no. 185/2002, of 20 August).

5 FINAL NOTES

In the period between 2015 and 2019, public policies for Quality in Health and Patient Safety were consolidated, through the National Strategy for Quality in Health 2015-2020 and the National Plan for Patient Safety (PNSD) 2015-2020, an integral part of the Strategy. The National Health Plan, in its revision and extension to 2020, proposed to strengthen the implementation of the National Quality Strategy.

The development of the Integrated Strategy for Rare Diseases 2015-2020 was carried out at the level of the Department of Quality in Health, and the "Rare Disease Person Card" was implemented. In 2016, the legal regime of the National Health Council (CNS) was established.

In the "Strategic Axis 3.3 Quality in Health", the PNS proposes "The reinforcement of the impact of quality in the evaluation of professional and institutional performance and in the financing of care institutions" (PNS revision and extension to 2020).

Although the implementation of the national public policy implies that the objectives of the action plans of each health unit must be integrated into the program contracts, the inclusion of the political measures of the ENQS 2015-2020, including the PNSD 2015-2020, as well as the List of Indicators for Quality Monitoring, in the contracting with the health units, has not been understood.

The formulation and consolidation of public policies, expressed in the National Strategy for Quality in Health, and the process of its implementation underway at the national level, has become a reality.

However, there is no policy for evaluating the National Strategy for Quality in Health 2015-2020, included in the program contracts, based on the establishment of a network of hospitals and other health units, associated with *benchmarking* and incentives at national level.

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[v] Portugal (2015). Ministry of Health. Order No. 1400-A/2015 of the Office of the Assistant Secretary of State to the Minister of Health. Official Gazette No. 28/2015, 1st Supplement, Series II of 2015-02-10. Approves the National Plan for Patient Safety 2015-2020.

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[xv] Portugal (2015). Ministries of Health, Education and Science and Solidarity, Employment and Social Security - Offices of the Ministers of Health, Education and Science and Solidarity, Employment and Social Security. Order no. 2129-B/2015, of 27 February of the Cabinets of the Ministers of Health, Education and Science and of Solidarity, Employment and Social Security. Approves the Integrated Strategy for Rare Diseases 2015-2020 and repeals the National Programme for Rare Diseases, approved in 2008, and the creation of a National Network of Reference Centres for Rare Diseases, approved in 2011 by the Ministry of Health. Official Gazette No. 41/2015, 2nd Supplement, Series II of 2015-02-27.

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[xvii] Portugal (2015) Ministry of Health. Office of the Assistant Secretary of State to the Minister of Health. Order No. 235-A/2015. It defines the priority intervention areas in which Reference Centres should be recognised in 2015. Official Gazette No. 5/2015, 1st Supplement, Series II of 2015-01-08.

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[xxiv] Portugal (2017). Ministry of Health. Office of the Assistant Secretary of State for Health. Declaration of Rectification No. 530/2017. Diário da República, No. 152/2017, Series II of 2017-08-08.

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[xxvi] Portugal (2016). Ministries of Labour, Solidarity and Social Security and Health. Cabinets of the Ministers of Labour, Solidarity and Social Security and Health. Order No. 4663/2016. Creates, under the Secretaries of State for Social Security and Deputy Secretary of State for Health, the National Coordination Commission of the National Network of Integrated Continued Care. Official Gazette No. 66/2016, Series II of 2016-04-05.

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the characterization of services and admission to local teams and the conditions and requirements for the construction and safety of palliative care facilities. Official Gazette No. 112/2016, Series I of 2016-06-14.

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[xxx] Portugal (2018). Office of the Assistant Secretary of State for Health. Order No. 5988/2018. Approves the Health Strategy in the Area of Dementia and determines the constitution and composition of the Coordination of the National Health Plan for Dementia. Official Gazette No. 116/2018, Series II of 2018-06-19.

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[xxxiii] Portugal (2016). Ministry of Health. Office of the Assistant Secretary of State for Health. Order No. 4027-A/2016. It determines the establishment of a strategic coordination for the prevention and management of chronic disease. Official Gazette No. 55/2016, 1st Supplement, Series II of 2016-03-18.

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[xxxvi] Portugal (2016). Ministry of Health. Ordinance No. 147/2016. Establishes the classification process of hospitals, hospital centres and local health units of the National Health Service and defines the process of creation and revision of Hospital Referral Networks. Official Gazette No. 97/2016, Series I of 2016-05-19.

[xxxvii] Portugal (2016). Ministry of Health. Office of the Assistant Secretary of State for Health. Order No. 6401/2016. Determines the development, within the scope of the National Health Plan, of priority health programmes in the areas of Tobacco Prevention and Control, Promotion of Healthy Eating, Promotion of Physical Activity, Diabetes, Cerebro-cardiovascular Diseases, Oncological Diseases, Respiratory Diseases, Viral Hepatitis, HIV/AIDS Infection and Tuberculosis, Prevention and Control of Infections and Antimicrobial Resistance and Mental Health. Repeals Orders no. 404/2012, published in the Official Gazette, 2nd series, no. 10, of 13 January, and no. 2902/2013, published in the Official Gazette, 2nd series, no. 38, of 22 February. Official Gazette No. 94/2016, Series II of 2016-05-16.

[xxxviii] Portugal (2016). Ministry of Health. Order No. 6401/2016 of the Office of the Assistant Secretary of State for Health. Determines the development, within the scope of the National Health Plan, of priority health programmes in the areas of Tobacco Prevention and Control, Promotion of Healthy Eating, Promotion of Physical Activity, Diabetes, Cerebro-cardiovascular Diseases, Oncological Diseases, Respiratory Diseases, Viral Hepatitis, HIV/AIDS Infection and Tuberculosis, Prevention and Control of Infections and Antimicrobial Resistance and Mental Health. Repeals Orders no. 404/2012, published in the Official Gazette, 2nd series, no. 10, of 13 January, and no. 2902/2013, published in the Official Gazette, 2nd series, no. 38, of 22 February. Official Gazette No. 94/2016, Series II of 2016-05-16.

[xxxix] Portugal (2016). Ministry of Health. Directorate-General for Health. Governance Model for 2020 – National Health Plan and Priority Health Programs. Lisbon: Directorate-General for Health, 2nd EDITION 2016. ISBN: 978-972-675-266-0.

[xl] Portugal (2016). Presidency of the Council of Ministers and Health. Offices of the Assistant Secretary of State for Administrative Modernization and the Assistant Secretary of State for Health. Order No. 6744/2016. Establishes provisions on the administrative simplification program, within the scope of the National Child and Youth Health Program and the National Vaccination Program, which includes the following projects: "Nascer Utente", "Birth News", "eChild and Youth Health Bulletin" and "eVaccination Bulletin". Official Gazette No. 99/2016, Series II of 2016-05-23.

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[xlii] Portugal (2018). Office of the Assistant Secretary of State for Health. Order No. 4429/2018. Establishes the governance model applicable to the National Health Plan (PNS) and the Priority Health Programmes integrated in this Plan. Official Gazette No. 87/2018, Series II of 2018-05-07.

[xliii] Portugal (2019). Ministry of Health. Directorate-General for Health. Order No. 3049/2019. Delegation of powers to the Deputy Director-General of Health, Dr. Catarina Sena; the Deputy Director-General of Health, Dr. Diogo Cruz; the service directors and the head of the Management Support division. Official Gazette No. 56/2019, Series II of 2019-03-20.

[xliv] Portugal (2016). Ministry of Health. Order No. 9416/2016 of the Office of the Assistant Secretary of State and Health of 22 July. Determines that the Directorate-General for Health must promote involvement and collaboration with the different professional associations in the health sector, within the scope of Quality in Health, namely in the process of drafting Health Guidance Standards, as well as celebrate, until September 30, 2016, collaboration protocols, within the scope of Quality in the Health System, with the Order of Biologists, the Order of Pharmacists, the Order of Nutritionists and the Order of Psychologists. Official Gazette No. 140/2016, Series II of 2016-07-22.

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[l] Portugal (2017). Ministry of Health. Decree-Law No. 18/2017. Regulates the Legal Regime and the Statutes applicable to the health units of the National Health Service with the nature of Public Business Entities, as well as those integrated in the Public Administrative Sector. Official Gazette No. 30/2017, Series I of 2017-02-10.

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[lv] Portugal (2016). Ministry of Health. Office of the Assistant Secretary of State for Health. Order No. 4771-A/2016. It establishes provisions on the implementation of population-based screenings in the areas of breast cancer, cervical cancer, colon and rectal cancer and diabetic retinopathy. Official Gazette No. 68/2016, 1st Supplement, Series II of 2016-04-07.

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[lxvi] Paragraph d) of Base 20 of the Basic Law on Health.