IMPACTO CIENTÍFICO EDITORA

HEALTH AND PUBLIC HEALTH POLICIES IN PORTUGAL: FOCUS ON QUALITY AND SAFETY IN HEALTH IN THE NEW MILLENNIUM (2000-2014)

POLÍTICAS DE SAÚDE E DE SAÚDE PÚBLICA EM PORTUGAL: FOCO NA QUALIDADE E SEGURANÇA EM SAÚDE NO NOVO MILÉNIO (2000-2014)

POLÍTICAS DE SALUD Y SALUD PÚBLICA EN PORTUGAL: ENFOQUE EN LA CALIDAD Y SEGURIDAD EN SALUD EN EL NUEVO MILENIO (2000-2014)

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Cristina Maria Antunes Martins d´Arrábida[1], Adalberto Campos Fernandes[2]

ABSTRACT

Between 2000 and 2005, there was a focus on public health policies based on the complementarity of the private and social sectors, on the articulation between care networks and on the corporate transformation of hospitals. The definition of a national network of continuing care was reflected in the National Health Plan 2004-2010 and a new legal framework for hospital management was approved. The Health Regulatory Authority was created. In the new millennium, there were setbacks and advances in the definition of public policies, some isolated measures and a lack of continuity in implementation, monitoring and evaluation: the attribution of competences in the area of quality in healthcare to various entities, the attributions of Quality to the Institute of Quality in Healthcare and its extinction in 2006, leading to the compartmentalization of clinical quality in the Directorate-General for Health and of organizational quality in the Central Administration of the Health System I.P. and the creation and extinction of the Agency of Quality in Healthcare, with the transfer of organizational quality to the Directorate-General for Health in 2008. Up until 2014, the highlights were the creation of the Department of Quality in Healthcare based in the Directorate-General for Health in 2009 and the formulation for the first time of public policies for quality and safety in healthcare, expressed in the National Strategy for Quality in Healthcare 2009-2014. The creation of the department and the National Strategy constitute pillars that underpin public policies on quality and safety in health. Based on these initiatives, future actions and decisions regarding public health must consider the established political measures, in the search for continuous improvement in the quality and health safety of the population.

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

[1] Doctorate student in Public Policy. Instituto Universitário de Lisboa (ISCTE). E-mail: cristinr2001@gmail.com Orcid: https://orcid.org/0000-0002-2794-9887

[2] Professor at the National School of Public Health. Universidade Nova de Lisboa .
E-mail: adalberto.fernandes@ensp.unl.pt Orcid: https://orcid.org/0000-0003-3784-8198

RESUMO

Entre 2000 e 2005, houve um foco em políticas públicas de saúde assentes na complementaridade do setor privado e social, na articulação entre as redes de cuidados e na empresarialização de hospitais. A definição de uma rede nacional de cuidados continuados estava refletida no Plano Nacional de Saúde 2004-2010 e foi aprovado um novo regime jurídico da gestão hospitalar. A Entidade Reguladora da Saúde foi criada. No novo milénio, houve retrocessos e avanços na definição de políticas públicas, algumas medidas avulsas e uma ausência de continuidade na implementação, monitorização e avaliação: a atribuição de competências em matéria de qualidade na saúde a várias entidades, as atribuições da Qualidade ao Instituto da Qualidade em Saúde e a sua extinção em 2006, levando à compartimentação da qualidade clínica na Direção-Geral da Saúde e da qualidade organizacional na Administração Central do Sistema de Saúde I.P. e a criação e extinção da Agência de Qualidade na Saúde, com a transferência da qualidade organizacional para a Direção-Geral da Saúde em 2008. Até 2014, destacaram-se a criação do Departamento da Qualidade na Saúde sediado na Direção-Geral da Saúde em 2009 e a formulação pela primeira vez das políticas públicas para a qualidade e segurança em saúde, expressa na Estratégia Nacional para a Qualidade na Saúde 2009-2014. A criação do departamento e a Estratégia Nacional constituem pilares que fundamentam as políticas públicas de qualidade e segurança em saúde. A partir dessas iniciativas, as ações e decisões futuras em relação à saúde pública devem considerar as medidas políticas estabelecidas, na procura da melhoria contínua da qualidade e a segurança em saúde da população.

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

RESUMEN

Entre 2000 y 2005, las políticas de salud pública se centraron en la complementariedad de los sectores privado y social, la articulación de las redes de atención y la corporación de los hospitales. La definición de una red nacional de atención continuada se reflejó en el Plan Nacional de Salud 2004-2010, y se aprobó un nuevo marco legal para la gestión hospitalaria. Se creó la Autoridad Reguladora de la Salud. En el nuevo milenio, hubo retrocesos y avances en la definición de políticas públicas, algunas medidas aisladas y una falta de continuidad en la implementación, el monitoreo y la evaluación: la asignación de responsabilidades de calidad de la atención médica a varias entidades, la asignación de Calidad al Instituto de Calidad en Salud y su disolución en 2006, lo que llevó a la compartimentación de la calidad clínica dentro de la Dirección General de Salud y la calidad organizacional dentro de la Administración Central del Sistema de Salud (IP). y la creación y disolución de la Agencia de Calidad Sanitaria, con la transferencia de la calidad organizativa a la Dirección General de Salud en 2008. Hasta 2014, los hitos incluyeron la creación del Departamento de Calidad Sanitaria, con sede en la Dirección General de Salud, en 2009, y la formulación de políticas públicas de calidad y seguridad sanitaria, expresadas en la Estrategia Nacional de Calidad en Salud 2009-2014. La creación del departamento y la Estrategia Nacional constituyen los pilares que sustentan las políticas públicas de calidad y seguridad sanitaria. Con base en estas iniciativas, las futuras acciones y decisiones en materia de salud pública deben considerar las medidas políticas establecidas, buscando la mejora continua de la calidad y la seguridad sanitaria de la población.

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

1 INTRODUCTION

The area of quality and safety in health continues to be prominent in the formulation of public health policies. "Quality in Health is one of the most frequently cited principles in health policy, and is currently at the top of the agenda of policymakers at various international levels" (EC, 2016, OECD, 2017, WHO, 2018, WHO/OECD/World Bank, 2018, according to Buses *te al*., 2019, cited by Martins d'Arrábida C., 2023).[i,ii]

How have health policies and public health policies evolved in the new millennium in Portugal?

At the end of the first decade of the new millennium, the Department of Quality in Health (DQS) was created, based in the Directorate-General for Health (DGS), at national level. The formulation of public policies for quality and safety in health is expressed for the first time in the National Strategy for Quality in Health (2009-2014).

In the period between 17 May 2011 and 4 May 2014, the country was subject to an adjustment programme, commonly known as the Troika, through a memorandum of understanding with the European Commission, the European Central Bank and the International Monetary Fund.

These two conditions influenced the focus of the analysis period of this article.

The attributes of quality (efficacy, effectiveness, efficiency, optimization, acceptability, legitimacy and equity), the legacy of Donabedian (1980[iii], 1990[iv]) continue to be a reference in the implementation of Quality and Safety in Health policy measures. Kohn *et al.* (2000) disseminated the concept of Patient Safety - "It is the reduction, to an acceptable minimum, of the risk of harm associated with health care.".[v] The *Institute of Medicine* (IOM) (2001) saw safety as a critical component of good quality care in the To *Err is Human report*. The *Agency for Healthcare Research & Quality* (AHRQ) and the IOM reported that while all dimensions of quality (safe, effective, person/patient/family-centered, timely, efficient, and equitable) are important, patient safety is the most critical, as it underpins the effectiveness, efficiency, and overall quality of health care delivery. The safety of the person/patient is the basis because it directly impacts the well-being and overall outcomes of the person/patient.[vi,vii] AHRQ (2005) states that Donabedian "... developed the way to measure quality, evaluating elements of structure or process with proven connections with the main results to be noted".[viii] This approach has become the paradigm for measuring quality in health care. Donabedian drew on the concept of "input-process-output" used in the industry to propose the triad of structure, process, and outcome for quality assessment.

The Council of Europe (1997)[3] states that "The quality of care is the degree to which the treatment provided increases the patient's chances of achieving the desired results and decreases the chances of undesirable results, taking into account the current state of knowledge" (Martins d'Arrábida C., 2023). The WHO (2009) publishes the international classification.[ix]

The European Commission (2010) [4] publishes "[*Good quality care is]* effective, safe healthcare that responds to patients' needs and preferences. The document also notes that "other dimensions of quality of care, such as efficiency, access and equity, are seen as part of a broader debate and are being addressed in other forums".

The European Patients Forum (EPF) 2014)[5] participated in the work of the Expert *Panel on Effective Ways of Investing in Health on Future EU Agenda*. The focus was on the quality of health care, with special emphasis on patient safety, highlighting patient-centricity as a fundamental dimension of health care quality.

The attributes of quality in health, which include safety, defined at national, regional and local levels, reflect the level of quality that adds value to the adequacy of health care (Martins d'Arrábida C., 2013).[6] Thus, these attributes become linked to the fundamental rights of people/patients, implying the formulation and implementation of public health policies.

In this article, the terms quality and safety in health, as an instrument for disseminating safety, as a critical dimension of quality, are inseparable. According to Liam, patient safety is a global imperative, with far-reaching implications for all WHO Member States, for all health professionals, and for all people in their health/disease experience (cf., Donaldson L. J., 2005).[x]

At the national level, the new millennium (2000-2014) was marked by several legislatures, at the national level. The second legislature of the political cycle that took place between October 25, 1999 and April 6, 2002, had a ministerial change in health on October 25, 1999 and the other that took place between July 3, 2001 and April 6, 2002.

A period of new coalition political governance took place between 6 April 2002 and 12 March 2005, with the change of prime minister on 17 July 2004.

A new political cycle took place between 12 March 2005 and 21 June 2011, with a second parliamentary term beginning on 30 January 2008 and ending on 21 June 2011.

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[3] In: *"The development and implementation of quality improvement systems (QIS) in health care. Recommendation No. R (97) 17".*
[4] In: *"Quilite the Heth carre: police actinos until I lead. Reflected pape forte European Coucil".*
[5] https://www.eu-patient.eu/policy/Policy/Patients-Safety/
[6] The term adequacy is used in the sense of the act of adapting – adjusting, adapting.

A new coalition political cycle ran from 11 June 2011 to 26 November 2015, with a ministerial change on 30 October 2015.

In a context of political alternation between 2009 and 2014, this article aims to share the analysis of health policies and public health policies for quality and safety in health, at the national level.

The methodology used was documentary analysis as an instrument of public policies, based on the analysis and comparison of the literature review, which deals with health and public health policies.

Whenever possible, primary sources were used, and international and national sources were considered. The selected references represent the systematization of specific contents, which can contribute to the reflection of the present theme, in this specific period.

The wording of this article complies with the rules of the Orthographic Agreement of the Portuguese Language (1990) which has been in force since the beginning of 2009. However, in some transcriptions, it was possible to preserve the written language of the time.

In the first part, the National Health Plans are presented. Then, health policies, public health policies are addressed and in this area public policies for quality and safety in health stand out. Finally, some final notes are presented.

2 NATIONAL HEALTH PLAN 2004-2010

The National Health Plan 2004-2010 emerged under the leadership of Pereira Miguel, as "High Commissioner of Health" and Director-General of Health, as a guiding guide for change (Martins d'Arrábida C, 2023).[xi] The guiding values were universality, equity and solidarity, and sustainability and continuity were highlighted as principles. Targets and indicators were defined for the defined programmes, initiating a new approach to monitoring and evaluation (National Health Plan 2004-2010).[xii]

In the report on the evaluation of the National Health Plan (2004-2010), the WHO (2010) noted that the plan included numerous policy gaps, including, among others, in addressing health inequalities, in the sustainability of the health system, and in the quality and safety of health care, which poses challenges for, based on robust evidence, address the identified gaps (WHO, 2010, cited by Martins d'Arrábida C., 2023).[xiii]

The WHO evaluated the PNS 2004-2010, the second technical cycle of national strategic health planning, constituting a broad and guiding reference for the activities of the health system, and there was an improvement in health indicators, bringing them closer to the European average. However, he referred to a limited articulation between the PNS and the governance instruments (contracting, regulation, performance indicators) and also a lack

of definition of several areas of responsibility (cf., Ferrinho P. Guerreiro C. S. Portugal R., 2018, WHO, 2010, cited by Martins d´Arrábida C., 2023).[xiv]

3 NATIONAL HEALTH PLAN 2012-2016

In 2011, the Organic Law of the Ministry of Health reinforces the specific competences of the Directorate-General for Health (DGS), which now includes "coordination in the areas of strategic planning, monitoring and evaluation of the quality and accessibility of health care provided and international relations, thus accepting the attributions, until then, entrusted to the High Commission for Health" (Decree-Law No. 124/2011 of 29 December).[xv]

The High Commission for Health was extinguished, and the National Health Plan 2012-2016 was concluded at the DGS, under the coordination of the Director-General for Health. The Advisory and Monitoring Council of the Plan was also established, appointed by order of the member of the Government responsible for the health area, on the proposal of the Director-General of Health (Order No. 728/2014 of the Assistant Secretary of State to the Minister of Health of 16 January).

The National Health Plan 2012-2016 aimed, among others, at obtaining additional health outcomes that should include the most vulnerable population, through the integration of efforts from various sectors of society. Policies for quality and safety in health should, among others (i) strengthen the responsibility for the integrated governance of the Health System, in line with the National Strategy for Quality in Health, (ii) evaluate the quality policy, (iii) develop standardization instruments (standards) for the promotion of quality in clinical procedures, information, quality indicators, monitoring and evaluation, training and management of services and institutions, (iv) promote the accreditation of health care services, (v) promote the adoption of interventions with better cost-effectiveness and fight against waste, (vi) develop mechanisms that promote *benchmarking*, the identification of good practices and the increase of the value chain (National Health Plan, 2012-2016).[xvi]

Quality was considered, for the first time, as one of the four strategic axes (cf., Ferrinho P., Guerreiro C.S., Portugal R., 2018), [xvii]placing the Department of Quality in Health (DQS) in direct articulation with the Health Programs and National Strategies, reporting directly to the Director-General of Health (Martins d'Arrábida C., 2023).

4 HEALTH POLICIES

Health policies refer to a set of decisions, guidelines and actions aimed at organizing, planning and administering health services, especially with a focus on (i) organizing and financing health services (e.g., hospitals, health programs), (ii) ensuring that all citizens have

access to adequate health care, (iii) improving and controlling the quality of health services provided, and (iv) training and education of health workers.

The Declaration of Alma-Ata (1978), which talks about the importance of health for all and the role of health policies in promoting the well-being of the population, expresses "the right and duty of populations to participate individually and collectively in the planning and delivery of health care". At this International Conference on Primary Health Care in Alma-Ata, "Health for All", the foundations of the Primary Health Care strategy were laid, a key element for the goal to be achieved - Health for All. The commitment of the governments obtained was expressed in the recognition that health is a fundamental human right and that inequalities in the state of health are politically, socially and economically unacceptable (Martins d'Arrábida C., 2023).[xviii]

The national health policy emanating from Base II of the Basic Law on Health obeys the following guidelines, namely (i) health promotion and disease prevention are part of the priorities in the planning of State activities, (ii) to achieve equal access to health care, whatever their economic condition and wherever they live, as well as ensuring equity in the distribution of resources and in the use of services, (iii) special measures in relation to groups subject to greater risks, ..., (iv) health services are structured and operate in accordance with the interests of users and are articulated with each other and with social security and welfare services, (vi) management of available resources must be conducted in such a way as to obtain the greatest socially useful benefit from them and to avoid the waste and misuse of services, (vii) support for the development of the private health sector and, in particular, the initiatives of private institutions of social solidarity, in competition with the public sector, (viii) the participation of individuals and the organised community in the definition of health policy and planning and in the control of the functioning of services is promoted (Law no. 48/90 of 28 April).[xix]

4.1 NATIONAL NETWORK OF LONG-TERM CARE

In 2002, a national network of long-term care was defined (Resolution of the Council of Ministers no. 59/2002 of 22 March).[xx] "The following year, the long-term health care network was created, consisting of services integrated in the National Health Service (SNS), private institutions of social solidarity (IPSS), misericórdias, legal persons of public utility and private entities that provide complementary health care to users of the SNS, under the terms of contracts entered into under the legislation in force, or other entities with which contracts or cooperation agreements are signed, which can be translated into protocols" (Decree-Law No. 281/2003, of 8 November, cited by Martins d'Arrábida C., 2023).[xxi]

The Resolution of the Council of Ministers no. 59/2002, of 22 March and Decree-Law no. 281/2003, of 8 November, in 2006, were revoked and the National Network of Integrated Continued Care was created, within the scope of the Ministries of Health and Labour and Social Solidarity (Decree-Law no. 101/2006 of 6 June).[xxii]

4.2 CORPORATIZATION OF HOSPITALS

The corporatisation of hospitals, an option expressly admitted in the Basic Law on Health (Law no. 48/90, of 24 August), was considered an essential vector of the ongoing reform of hospital management and an indispensable factor to improve the overall level of performance of the National Health Service. Thus, it was established that the management of health units would obey, as far as possible, business management rules and allow innovative management experiences (Resolution of the Council of Ministers no. 41/2002 of 7 March, cited by Martins d'Arrábida C., 2023).[xxiii]

Public-private partnerships were also one of the government's priorities. The legal regime was defined within the scope of the establishment of formal cooperation between public and private entities, with the private sector being responsible for financing and management and the public sector ensuring the amortization of the investment made and financed the exploration (Decree-Law No. 185/2002 of 20 August, cited by Martins d'Arrábida C., 2023).[xxiv]

The mission unit "Hospitais SA" was created for the process of corporatisation of hospitals with the legal nature of public limited companies with exclusively public capital (Resolution of the Council of Ministers no. 15/2003, of 5 February).[xxv] As part of the new political cycle, after the transformation of 36 hospitals into 31 public limited companies, public limited company hospitals were transformed into public business entities in 2005 (Decree-Law No. 93/2005 of 7 June, cited by Martins d'Arrábida C., 2023).[xxvi]

4.3 HOSPITAL MANAGEMENT REGIME

The first amendment to Law No. 48/90 of 24 August was made, leading to the approval of a new legal regime for hospital management (Law No. 27/2002 of 8 November).[xxvii]

The Assembly of the Republic decreed, among others, the submission of health professionals in the NHS to the rules of the Public Administration, which may constitute special bodies; the NHS, financed by the State Budget, through the payment of the acts and activities actually carried out, were according to a price list with classification of the same acts, techniques and health services; the exercise of any profession under a liberal regime was regulated and supervised by the Ministry of Health, without prejudice to the functions

entrusted to the Order of Doctors, the Order of Nurses and the Order of Pharmacists; the law could provide for the creation of health units in the nature of public limited companies (Law no. 27/2002 of 8 November, cited by Martins d'Arrábida C., 2023).

4.4 UNITS OF THE HEALTH CENTER GROUPS

The typologies of the Health Center Groups (ACES) were established (i) family health unit (USF), (ii) personalized health care unit (UCSP), (iii) community care unit (UCC), (iv) public health unit (USP), (v) shared care resources unit (URAP), (vi) other units or services, proposed by the respective ARS, I. P., and approved by order of the Minister of Health, and which may be considered necessary (Decree-Law no. 28/2008 of 22 February, cited by Martins d'Arrábida C., 2023).

4.5 NATIONAL PROGRAMME FOR RARE DISEASES

The National Programme for Rare Diseases, which was part of the National Health Plan 2004-2010, was approved in 2008 (Order of 12 November of the Minister of Health).[xxviii]

The 2004-2010 PNS recognized that rare diseases contribute significantly to morbidity and mortality during the first 18 years of life. The PNS also provided for the National Program for the Control of Hemoglobinopathies, started in 1987 at the National Institute of Health Ricardo Jorge (INSA) and the National Program for Early Diagnosis (PNDP) for hereditary diseases of metabolism and congenital hypothyroidism, started in 1979 by the Jacinto Magalhães Institute of Medical Genetics[7].

4.6 RARE DISEASE PERSON CARD

Following the recommendation to the Government made by the Assembly of the Republic, efforts were made to create the "card for special protection of rare disease carriers", with the beginning of its implementation, at the beginning of 2014, at national level (Resolution of the Assembly of the Republic no. 34/2009).[xxix]

In the first fifteen years of the new millennium, the implementation of the "Rare Disease Person Card (RDPC)" was conducted at the level of the Department of Quality in Health, in pursuit of the following objectives (i) to ensure that, in urgent and/or emergency situations, health professionals have access to relevant information on the person with a rare disease, (ii) improve continuity of care and (iii) facilitate appropriate and rapid referral (Norm No. 008/2014 of 21/07/2014).[xxx]

[7] https://www.sns.gov.pt/noticias/2019/02/28/doencas-raras/

4.7 NATIONAL TABLE OF FUNCTIONALITY

Following the Assembly of the Republic recommending to the Government, in 2010, the elaboration, based on the International Classification of Functioning, Disability and Health (ICF), a structure composed of interministerial and multidisciplinary experts was created for the preparation of a table of disabilities resulting from chronic diseases and a table of functionality (Resolution of the Assembly of the Republic No. 90/2010 of 10 August).[xxxi]

In 2012, a new recommendation to the Government was the creation of the statute of the chronically ill and the national table of disability and health functionality (Resolution of the Assembly of the Republic no. 102/2012).[xxxii] The study, coordinated by the DQS, was completed in 2013 (Diniz A. *et al.*, 2013, cited by Martins d'Arrábida C., 2023).[xxxiii] The National Table of Functionality was intended, among others, to support the adoption of political and social measures, according to the functionality of the person with chronic illness and not only according to their disability (Martins d'Arrábida C., 2023). In the period between 1993 and 2003, national regulations had been published for chronic diseases eligible for benefits, under special social protection.[8] It was observed that a list of chronic diseases could not predict, among others, all the diseases that exist and the specific degrees of disability. On the other hand, the fact that a disease was not provided for in national legislation prevented the person's access to social protection. It was questioned over time whether a list of diseases determined who would effectively benefit from state protection and whether it should be the consequences of the disease on each person that established who should have social protection. Instead of the list of diseases, the degree of disability began to define the specific conditions of disability of each person, and a new complementary instrument emerged, the assessment of functionality, within the scope of a comprehensive approach to the need for appropriate responses to each person with health/disease processes of evolution throughout life (Martins d'Arrábida C., 2023).

4.8 CHARTER OF PATIENTS' RIGHTS IN ACCESS TO HEALTH CARE

The Oviedo Convention for the Protection of Human Rights and the Dignity of the Human Being: Convention on Human Rights and Biomedicine had been opened for signature by the Member States of the Council of Europe in Oviedo on April 4, 1997 and implemented by thirty-five countries. Approved for ratification by Resolution of the Assembly of the Republic on 19 October 2000, it was ratified by Decree of the President of the Republic No. 1/2001, of 3 January.

[8] https://www.dgs.pt/ficheiros-de-upload-1/beneficios-doencas-cronicas-htm.aspx

The Charter of Patients' Rights in access to health care was published in 2007. The Charter of Access Rights defines the maximum guaranteed response times (TMRG) and the right of users to information about these times (Law No. 41/2007 of 24 August).[xxxiv]

2014 was a remarkable year in terms of legislation on the rights and duties of health service users and determination on the adequacy of health care provision (Law No. 15/2014 of 21 March). [xxxv]

The transposition into the legal order of the Directives of the Parliament, the Council and the Commission, respectively, on cross-border healthcare, determined, in addition to the right to reimbursement, the guarantee of access to quality and safe healthcare in the countries of the European Union (Law no. 52/2014 of 25 August, cited by Martins d'Arrábida C., 2023).

4.9 REFERENCE CENTERS

The transposition into the national legal order of Directive No. 2011/24/EU, of the European Parliament and of the Council, of 9 March 2011, on the application of patients' rights in cross-border healthcare, establishes that it is the responsibility of the Ministry of Health to identify, approve and recognise national reference centres, namely for the diagnosis and treatment of rare diseases and to promote the participation and integration of national reference centres within the scope voluntary integration into European Reference Networks (Law No. 52/2014, of 25 August, cited by Martins d'Arrábida C., 2023).[xxxvi]

The process of identification, approval and recognition of National Reference Centres for the provision of health care, namely for the diagnosis and treatment of rare diseases, was established by Ordinance No. 194/2014, of 30 September.[xxxvii]

The National Commission for Reference Centers (CNCR) was constituted and works with the ACSS (Order of the Minister of Health No. 13163-C/2014, of October 29, cited by Martins d'Arrábida C., 2023).[xxxviii]

5 PUBLIC HEALTH POLICIES

Public health policies have a broader and population-oriented focus, emphasizing (i) health promotion with initiatives aimed at improving the well-being and health of the population (e.g., vaccination campaigns, nutrition programs, physical activity, etc.)[9], (ii) disease prevention, with actions for disease prevention, outbreak monitoring (e.g. epidemic control) and contingency plans for responses to public health emergencies, (iii) social determinants of health, approaches that consider socioeconomic and environmental factors

[9]Health Programs in https://www.dgs.pt/pns-e-programas/programas-de-saude.aspx and Priority Health Programs in https://www.dgs.pt/.

that affect population health, and (iv) equity policies focusing on reducing health inequalities between different population groups.

Public policies must prioritize health as a social good, and quality and safety are fundamental pillars to guarantee this right, intervening in a transversal way to all areas.

5.1 HEALTH 24 PEDIATRICS

In 1999, Maria de Belém Roseira, launched SAÚDE 24 Pediatria "Dói-Dói-Trim-Trim", a national service line aimed at parents and children up to 14 years old. This national service line, carried out by nurses, based on a system of clinical algorithms, became the Health Line 24 in 2007, ensuring care for all age groups, resulting from the merger with the Public Health line. Created in 2002, it was based in the Directorate-General for Health (DGS) (Martins d'Arrábida C., 2023).

5.2 CREATION OF THE HEALTH REGULATORY AUTHORITY

Created in 2003, the Health Regulatory Authority (ERS) had as its object the regulation, supervision and monitoring of the provision of health care and some attributions in the area of quality.[10] In a political context of promoting complementarity, of the various health sectors, to be regulated by the ERS, an independent and autonomous entity, however, there was an overlap of competences with the DGS (Decree-Law No. 309/2003 of 10 December, cited by Martins d'Arrábida C., 2023).[xxxix]

In 2009, at national level, the ERS was restructured, with the definition of its attributions, organisation and operation, adapting it to the performance of competition regulation functions in health and providing it with the necessary means and competences (Decree-Law No. 127/2009 of 27 May).[xl] In 2014, the Health Regulatory Authority (ERS) was also restructured, defining its attributions, organization and operation (Statutes of the Health Regulatory Authority), by Decree-Law No. 126/2014 of 22 August.[xli] It became up to the ERS to assess the complaints and claims of NHS users and to monitor the follow-up carried out by the health care establishments, assuming the powers assigned to the then SIM-Citizen System defined by Order No. 8958/2013 of 27 July.[xlii]

5.3 EXTINCTION OF THE INSTITUTE OF QUALITY IN HEALTH (IQS)

The Institute for Quality in Health (IQS) was extinguished in 2006, by the Organic Law of the Ministry of Health, which determined the integration of the attributions related to clinical quality in the Directorate-General for Health and those of organizational quality in the Central

[10] Article 25(3)(a) of Decree-Law 309/2003 of 10 December.

Administration of the Health System (ACSS) I.P) (Decree-Law No. 212/2006 of 27 October). The organic law of the Central Administration of the Health System, I. P. (ACSS) and the organic law of the Directorate-General for Health, were approved, resulting in the separation of competences in the area of quality (Decree-Law No. 219/2007, of 29 May, Regulatory Decree No. 66/2007, of 29 May).[xliii]Thus,[xliv] this compartmentalization of the area of quality in health was determined (Martins d'Arrábida C., 2023).

5.4 CREATION AND EXTINCTION OF THE HEALTH QUALITY AGENCY

The organic structure of the Central Administration of the Health System, I. P. (ACSS) was approved. In this context, the Health Quality Agency was created, endowed with scientific and technical autonomy and aiming to pursue the attributions of the ACSS, in the field of quality in health, namely with regard to certification (Decree-Law No. 219/2007 of 29 May, cited by Martins d'Arrábida C., 2023).[xlv]

The competences of organizational quality entrusted to the ACSS were transferred to the area of quality in health, in the Directorate-General for Health (DGS). The mission of this is now to regulate, guide and coordinate health promotion activities, disease prevention, define the technical conditions for adequate health care provision and plan and program the national policy for quality in the health system. In this way, the Health Quality Agency was extinguished (Decree-Law No. 234/2008 of 2 December).[xlvi]

5.5 COMPETENT AUTHORITY

At national level, the legal framework for the quality and safety of human blood and blood components has been established, which covers technical requirements, traceability and reporting requirements for serious adverse reactions and incidents, as well as standards and specifications relating to the quality system of blood services. The aim is to ensure a high level of protection of public health. The Competent Authority, assigned to the Authority for Blood and Transplantation Services (ASST), was responsible for articulating its activities with the General Inspection of Health Activities (IGAS), especially in the areas of inspection and inspection, in addition to regulating and controlling compliance with quality and safety standards in the activities of donation, collection, analysis, processing, preservation, storage and distribution of human blood, blood components, organs, tissues and cells of human origin (Decree-Law No. 267/2007 of 24 July).

In 2011, the Organic Law of the Ministry of Health strengthened the competences of the Directorate-General for Health (DGS), including the monitoring and control of quality and safety in the activities of blood services, collection, analysis and manipulation of tissues and

cells of human origin, resulting in the extinction of ASST (Decree-Law No. 124/2011 of 29 December). The following year, with the approval of its organic structure, the DGS began to exercise the functions of Competent Authority, authorizing units, services and processes in the control of the quality and safety of the aforementioned activities, in collaboration with the General Inspection of Health Activities (Regulatory Decree No. 14/2012 of 26 January).

As of May 22, 2012, ASST's competences were transferred to the Department of Quality in Health (DQS), located in the Directorate-General for Health. Among its attributions, the following stand out: (i) authorize units, services and processes related to the donation, collection, analysis, processing, preservation, storage and distribution of human blood, blood components, organs, tissues and cells of human origin; (ii) exercise the functions of competent authority as established in Law No. 12/2009, of 26 March, and in Decree-Law No. 267/2007; (iii) regulate and control compliance with quality and safety standards for the aforementioned activities (Ordinance No. 159/2012, of 22 May). The DQS, due to the nature of its functions, ensured the independence, impartiality and objectivity of the Competent Authority at the national level, reporting directly to the director of the department (Martins d'Arrábida C., 2023).

5.6 PUBLIC HEALTH SURVEILLANCE SYSTEM

Promoted by Ana Jorge, the publication of Law No. 81/2009 of 21 August on the public health surveillance system, once again came to frame, once again, Public Health. In this context, Law No. 2036, of 9 August 1949, and the respective regulatory provisions, namely on the declaration of mandatory diseases, were repealed. For the first time, issues related to Public Health, provided for but not regulated in Base XX of Law No. 48/90 of 24 August, cited by Martins d'Arrábida C. (2023), were addressed.[xlvii] The organic structure of the Directorate-General for Health (DGS) was approved by Regulatory Decree No. 14/2012 of 26 January. In the development of its mission, the DGS also continued to collaborate, within the scope of health emergency planning, with the National Institute of Medical Emergency, I. P., under the terms of Law No. 81/2009, of 21 August.

The Regulation on Mandatory Notification of Communicable Diseases and Other Public Health Risks, applying to all health services in the public, private or social sector, was published in 2013, by Ordinance No. 248/2013 of 5 August.[xlviii]

5.7 INFARMED ORGANIC

In 2012, the organic structure of INFARMED - National Authority for Medicines and Health Products, I. P. was approved. (Decree-Law No. 46/2012, of 24 February).[xlix] The

following year, the National Commission for Pharmacy and Therapeutics was created under the terms and under paragraph 7 of article 8 of Decree-Law no. 46/2012, of 24 February 2012 to prepare a national formulary of medicines and guidelines on the prescription of medicines.[l]

5.8 INSA'S COMPETENCIES

Decree-Law No. 27/2012, of 8 February, qualified INSA (National Institute of Health Doutor Ricardo Jorge, I. P.), as a State laboratory in the health sector, a national reference laboratory and a national health observatory.[li]

The competences of the Department of Public Health of the Regional Health Administration of Lisbon and Tagus Valley, I. P. (ARSLVT, I. P.), in the part relating to the Public Health Laboratory (Mycobacteriology/Tuberculosis) were transferred to the National Institute of Health Doutor Ricardo Jorge, I. P. (INSA, I. P.), in 2012 (Ordinance No. 279/2012 of 19 April). [lii]

6 PUBLIC POLICIES FOR QUALITY AND SAFETY IN HEALTH

Public policies for quality and safety in health are part of public health policies, reaffirming the need for their centrality in public policies. In this area, we highlight (i) quality and safety in health outcomes: directly linked to the reduction of mortality, increased person/patient satisfaction and the effectiveness of health care, and (ii) as an instrument of evaluation and continuous improvement: quality and safety as performance indicators of the health system, enabling the identification of areas that need improvement and the implementation of necessary adjustments, within the scope of promoting a cycle of evaluation and continuous improvement.

Health systems with high quality and safety can reduce costs, improve health outcomes, and increase person/patient satisfaction and improve their health/disease experience. The question arises of the ethical responsibility of the State to provide safe and high-quality care to the citizen.

In 2001, the Program "Humanization, access and care in the National Health Service" was created, and the National Commission for the Humanization and Quality of Services (CNH) was established as an advisory body to the Assistant Secretary of State to the Minister of Health for the implementation of the program (Order No. 19204/2001 of 13 September).

In the previous year, the PNCI (National Infection Control Plan) was transferred to INSA (National Institute of Health Dr. Ricardo Jorge) by order of the Assistant Secretary of State for Health, on September 13th.[liii] The prevention of healthcare-associated infection (HAIs) has been integrated into the strategic guidelines of the National Health Plan 2004-

2010, according to the report of the Commission for the Formulation of the National Programme for the Prevention of Nosocomial Infections, established by the High Commissioner for Health (Order of the High Commissioner of 30 September 2005).

Correia de Campos ordered the transfer of the Infection Control Program again to the Directorate-General for Health in 2006 (Order No. 256/2006 of 10 October, cited by Martins d'Arrábida C., 2023). [11][liv]

The core structure of the DGS became part of the Directorate of Clinical Quality Services (DSQC), determined by Ordinance No. 644/2007 of 30 May, cited by Martins d'Arrábida C. (2023).[lv]

In 2007, the "National Program for the Prevention and Control of Healthcare-Associated Infection" (PNCI) and the creation of infection control committees (CCI) were approved in public health care units integrated in the national network of hospital health care, long-term care and primary health care and in private units, under the direct responsibility of the Directorate-General for Health (DGS) (Order No. 14 178/2007 of 4 July of the Secretary of State for Health).[lvi] Underlying the policy measures approved by Francisco Ramos, it was considered that healthcare-associated infection (HAIs) was a problem of great relevance at the national level and that HAIs include, among others, a considerable increase in morbidity and mortality, the use of more aggressive therapies and an increase in hospitalization time, which negatively interferes with quality and productivity indicators (Martins d'Arrábida C., 2023).

In 2007, the DGS determined the restructuring of the infection control committees (CCI), defining the organizational model (Order No. 18 052/2007 of 14 August) and its amendment, in relation to the previous model of 1996 (Order of the Director-General of Health of 23/10/1996).[lvii]

Regulatory Decree No. 66/2007, of 29 May, which approved the organic structure of the Directorate-General for Health, was amended and, in this way, the DGS succeeded in the attributions related to the organisational quality of the Central Administration of the Health System, I. P. (Regulatory Decree no. 21/2008, of 2 December, cited by Martins d'Arrábida C., 2023).[lviii]

In 2008, the National Program for the Prevention of Antimicrobial Resistance (PNPRA) was approved (Order No. 20729/2008 of the Minister of Health of August 7)[lix] and the Technical Commission for the Prevention of Antimicrobial Resistance (CTPRA) was created, under the direct responsibility of the Director-General of Health, cited by Martins d'Arrábida C. (2023), This Commission aimed to conceive, implement, monitor and evaluate the

[11] https://www.dgs.pt/?ci=362&ur=1&newsletter=63

PNPRA. Thus, its operation was determined within the scope of the Directorate of Clinical Quality Services/Clinical Safety Division of the Directorate-General for Health, to support the work to be carried out (Martins d'Arrábida C., 2023).

Within the scope of the organic structure of the Directorate-General for Health, in 1997, the Quality Division in the Directorate of Care Services (DSPCS) had been created. However, the Institute for Quality in Health, created in 1999, was extinguished in 2006 and its attributions transferred to the Directorate-General for Health, with the exception of the organizational quality attributed to the ACSS. In 2007, the Directorate of Clinical Quality Services was created, which integrated the Quality Division into the Directorate-General for Health, and the Clinical Safety Division was created.

The Health Quality Agency created in 2007 in the ACSS was extinguished in 2008, with the transfer of organizational quality to the quality area in the DGS (Decree-Law No. 234/2008 of 2 December).[lx]

In this context, after the extinction of the Institute of Quality in Health and the Agency for Quality in Health, it was created in 2009, the Department of Quality in Health (DQS) in the Directorate-General for Health was inaugurated by Ana Jorge on 31 May 2009 (Ordinance No. 155/2009 of 10 February). [lxi]

The DQS was responsible, in particular, for coordinating and evaluating the activities and programs for continuous improvement of clinical and organizational quality and coordinating the qualification system of health units. It was also responsible for creating and coordinating activities and programmes to promote patient safety; developing and maintaining the surveillance of diseases covered by the integrated disease management system and coordinating the mobility flows of Portuguese patients abroad and foreign patients in Portugal and assessing their impact on the health system (Ordinance No. 155/2009 of 10 February). The competences of the DQS did not include the issuance of Clinical and Organizational Standards, attributed to the Directorate-General for Health.

Within the scope of its technical autonomy determined by Ordinance No. 155/2009 of 10 February, the DQS also had competences in the areas of planning and programming of the national policy for quality in the health system.

The formulation of public policies for quality and safety in Health emerged for the first time at the national level in 2009, expressed in the National Strategy for Quality in Health (ENQS 2009-2014). The scheduling may have occurred through the work of a political entrepreneur, Alexandre Diniz, in which the three independent flows were articulated, forming a window of opportunity for the formulation of policies and subsequent dissemination of the idea in formal and informal networks of the political system (Kingdon J., 1984).[lxii] The relevant

actors of a public policy are the *staff* of the executive branch (government officials, central administration collaborators). The actors, who exert influence on the integration of the three flows, are the entrepreneurs of public policies (i) make themselves heard, (ii) articulate politically through the positions they occupy, (iii) have direct access to the rulers, (iv) have skills to negotiate and some persistence. The scheduling took place in the convergent presence of public perception of problems (flow of problems), knowledge of political solutions (flow of policies) and governance conditions (flow of policies), according to Martins d'Arrábida C. (2023).

The ENQS 2009-2014 established was addressed to the health system, in the legal understanding that the Ministry of Health is the coordinator of the Portuguese health system (Order No. 14223/2009 of 24 June). [lxiii] One of its missions was to enhance its cohesion and the quality of health care provision, to guarantee the rights of citizens in their relationship with the health system. In this context, the following strategic priorities for action were adopted, as defined in the ENQS 2009-2014: (i) clinical and organizational quality, (ii) transparent information to the citizen, (iii) patient safety, (iv) qualification and national accreditation of health units, (v) integrated disease management and innovation, (vi) management of international patient mobility, (vii) evaluation and guidance of complaints and suggestions from citizens using the National Service of Health (Order No. 14223/2009 of 24 June).

The strategic priority of patient safety was part of a public policy to combat safety incidents associated with the provision of health care within the scope of the National Health Service (SNS), which was not unrelated to the perception of the need to integrate the Recommendation of the Council of the European Union, of 9 June 2009 into ENQS 2009-2014, including the prevention and control of healthcare-associated infections.[lxiv]

The policy measures developed in the area of control of healthcare-associated infections (IACS) by the Directorate-General for Health (DGS), between 2006 and 2008, began to be ensured by national coordination based in the then Patient Safety Division at DQS and later by the Quality Management Division created in 2012 until its autonomy in 2016.

Based on the analysis that allowed it to be stated that the accreditation model of the Andalusian Quality Agency gave more guarantees of financial sustainability and allowed the accreditation of all health services of the NHS, the DGS proposed the adoption of the Andalusian model (ACSA), approved by Ana Jorge (Order No. 69/2009 of 31 August).[lxv] Private health units could adopt the model they wanted. In the study coordinated by Vaz Carneiro on the Quality of Care and Services, within the scope of the "National Health Plan 2011-20162, quoting Saturno, it was mentioned that accreditation programs, when

supervised by the Government, lose independence, which is the essence of their nature. On the other hand, when patients do not have freedom of choice, it can become problematic when a health unit is not certified (cf. Campos, Saturno and Vaz Carneiro, 2010, cited by Martins d'Arrábida C., 2023).

For the strategies in the area of attributions of the Department of Quality in Health (DQS), the National Council for Quality in Health was appointed in 2009 (Order 13793/2009 of 16 June), an advisory body with competence to pronounce on issues inherent to the execution of the DQS mission, through the operationalization of ENQS 2009-2014. [lxvi]

In the period between 2010 and 2014, the Department of Quality in Health (DQS), based in the Directorate-General for Health, put in place several political measures for quality in health and patient safety, highlighting the beginning and development of Certification, the creation of antimicrobial commissions, the creation of the National Incident Notification System, subsequently referred to as NOTIFICA, the publication of Guidelines for the prevention of pressure ulcers and unambiguous identification of patients and the issuance of Standards on (i) Hand hygiene, (ii) Safe surgery saves lives, (iii) Epidemiological surveillance of antimicrobial resistance, and (iv) Informed, informed and free written consent.

The publication of Ordinance No. 159/2012, of 22 May, had determined the core structure of the Directorate-General for Health (DGS) and established the maximum number of flexible and matrix organic units of the service and the competences of the respective core organic units. The DQS is now responsible, among others, for "Issuing standards and guidelines, both clinical and organizational, including programs in the area of promoting patient safety, in terms of public health and for improving the provision of care in relevant areas of health, namely primary, hospital, continuing and palliative health care".

In the Department of Quality in Health (DQS), the Division of Integrated Disease Management, the Division of Patient Safety and the Division of Clinical and Organizational Quality were extinguished in 2012. In terms of organizational structure, there are now two divisions (i) Quality Management Division and (ii) Patient Mobility Division. The DQS Quality Management Division, created in 2012, is also responsible for "Proposing the issuance of guidelines and technical standards based on the best available scientific evidence and monitoring their application" and among others "Coordinating measures for the prevention and control of healthcare-associated infections and antimicrobial resistance" (Order No. 7763/2012 of 5 June), [lxvii] placing the two national programs of the Directorate-General for Health under the purview of this division.

In 2013, within the scope of eight priority health programmes to be developed by the DGS, established in the previous year (Order No. 404/2012 of 13 January of the Assistant

Secretary of State to the Minister of Health),[lxviii] Fernando Leal da Costa determined that the Directorate-General for Health should also develop, as a priority health programme, the Programme for the Prevention and Control of Infections and Antimicrobial Resistance (PPCIRA). This program resulted from the merger of the National Program and Control of Infection Associated with Health Care (PNCI) and the National Program for the Prevention of Antimicrobial Resistance (PNPRA) (Order No. 2902 of February 22, 2013 of the Assistant Secretary of State to the Minister of Health).[lxix]

PPCIRA is now responsible for establishing the appropriate articulation between Hospitals, Primary Health Care, Integrated Continued Care and other care providers, in order to promote greater collaboration and inter-institutional communication, in order to aggregate efforts, resources and knowledge in this area. Along with these skills, the sharing of responsibility for clinical safety and improvement of the quality of health care, he was part of this priority program as an active participant in the leadership of one of the areas of patient safety.

In addition to the determination of the PPCIRA, as a priority program, quality, one of the four strategic axes of the National Health Plan 2012-2016, placed the DQS in direct articulation with the Health Programs, namely the Priority Programs and National Strategies, reporting directly to the Director-General of Health. However, the organizational structure, which kept PPCIRA in the Quality Management Division, remained the same in this period (2000-2014).

There was evidence that Portugal was one of the countries in the European Union with the highest prevalence rate of nosocomial infections, around 9.8%, which showed an upward trend over the first decade of the century (Order No. 2902/2013 of 22 February).[lxx]

In the same year, the creation of PPCIRA Regional Coordination Groups and Local Coordination Groups at the different levels of care of the health units integrated in the National Health Service (SNS) was also determined and action plans were launched to regulate the consumption of antibiotics in human medicine (Order No. 15423/2013 of 26 November) and reduce the use of antibiotics in animals (DGAV, 2013 cited by OECD, 2017).[lxxi,lxxii]

José Artur Paiva led this new cycle of development and implementation of strategies for the prevention and control of infections and antimicrobial resistance at national level.

In 2013, the National Incident and Adverse Event Notification System (SNNIEA) had been made available to citizens and health professionals. Reconfigured in 2014, it was renamed the National Incident Notification System – NOTIFIC@, being managed by the DQS in the DGS. The NOTIFIC@ that aims to guarantee the anonymity and confidentiality of notifications (Norm No. 015/2014 of 25 September), referred to by Martins d'Arrábida C.

(2023).[lxxiii] The National Incident Notification System (NOTIFIC@) also made it possible to register notifications of incidents with sharp devices since 2014.

Aimed at health professionals, the NOTIFIC@, as it is a computerized system, may present more advantages in the description of the incident, eventually enabling greater participation. The NOTIFIC@ also allows effective citizen participation in the *online platform*, at the national level (Martins d'Arrábida C., 2023).

Within the scope of the mission of the Department of Quality in Health (DQS), continuing the previous one, the National Council for Quality in Health was defined with a duration of three years, and it is responsible for pronouncing generically on issues inherent to the execution of the mission of the Department of Quality in Health (Order No. 15883/2013 of 5 February).[lxxiv]

In 2013, the creation of the Quality and Safety Commissions (CQS) set in motion the implementation of the National Strategy for Quality in Health – ENQS2009-2014 (Order No. 3635/2013, of March 7).[lxxv] Despite the creation of the CQS, at the national level, several health units have maintained the Humanization Commission until today, integrated or not in the respective CQS.

In the *top-down* approach to the implementation of ENQS2009-2014, competencies were defined according to the entities involved (DGS, DQS, Regional Health Administrations (ARS) and Health Units (Order No. 3635/2013, of March 7, cited by Martins d'Arrábida C., 2013). The objectives of the health units' action plan should be included in the program contracts agreed with each Hospital, Hospital Center, Local Health Unit (ULS) and Health Center Group (ACES), noting that only some health units started to include some political measures of the National Strategy in their respective program contracts.

The creation of the DQS, based in the Directorate-General for Health (DGS), whose technical autonomy promoted by Francisco George, as Director-General of Health and the leadership assumed by Alexandre Diniz, as Director of the Department of Quality in Health, were decisive for the definition of a national strategy, referred to by Martins d'Arrábida C. (2013).

This leadership has made it possible to accompany the European Union in strengthening the competences of Member State governments, which had not happened until then, with the exception of the recommendations on the prevention and control of healthcare-associated infection.

However, since the creation of the Department of Quality in Health (DQS) it has been observed that the development of the competences of the DQS contrasted with the reinforcement of the competences of the Directorate-General for Health (DGS) in the area of

quality and safety in health attributed to the DQS, raising questions related to the reduction of scientific and technical autonomy, under the responsibility of the Director-General of Health. The situation easily compared with the scientific, technical and administrative autonomy of the Institute of Quality in Health (IQS), created in 1999 and which was extinguished in 2006.

Following 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 implemented, based on each country's self-assessment, Portugal reported that 8 measures had been implemented.[lxxvi,lxxvii]

In 2014, the publication of the European Union Health Action Programme for 2014-2020 [lxxviii], 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 in 2015, one year after the intervention of *the Troika* (Martins d'Arrábida C., 2023).

7 FINAL NOTES

In the period of the second legislature of the political cycle that took place between October 25, 1999 and April 6, 2002, the creation of the National Infection Control Program (PNCI), the creation of the Institute for Quality in Health (IQS), the family health units (USF), the approval of the Oviedo Convention for ratification by Resolution of the Assembly of the Republic and ratified by the Decree of the President of the Republic, the creation of SAÚDE 24 Pediatrics and the creation of the "Program for Humanization, access and care in the National Health Service".

In the period of new political governance in coalition that took place between April 6, 2002 and March 12, 2005, there was a focus on public health policies based on the complementarity of the private and social sectors, on the articulation between care networks, on the corporatization of hospitals reflected in the National Health Plan 2004-2010, the definition of a national network of long-term care and the approval of a new legal regime for hospital management. The Health Regulatory Authority (ERS) was also created.

In the new political cycle that took place between March 12, 2005 and June 21, 2011, the creation of public business entities, the creation of the National Network of Integrated Continued Care, the extinction of the Institute of Quality in Health (IQS), the transfer of Clinical Quality to the Directorate-General for Health and Organizational Quality to the Central Administration of the Health System (ACSS) I.P), the creation and extinction of the Health Quality Agency in the ACSS, the creation of the "National Program for the Prevention and

Control of Infection Associated with Health Care" (PNCI) and the National Program for the Prevention of Antimicrobial Resistance (PNPRA). The Charter of Patients' Rights in access to health care was published and the legal regime for the quality and safety of human blood and blood components was established, with a view to ensuring a high level of public health protection. In the DGS, the Directorate of Clinical Services for Clinical Quality was created, as part of the approval of the organic structure of the Directorate-General for Health (DGS) and the restructuring of the infection control committees (CCI) in the Portuguese health system was determined.

The creation of the Department of Quality in Health (DQS) in 2009 and the formulation of public policies for quality and safety in health, expressed in the National Strategy for Quality and Safety in Health 2009-2014, constitute the national framework of public policies for quality and safety in health. Based on this initiative, future actions and decisions in relation to public health must consider the established principles, in the search for continuous improvement of quality and safety, playing an essential role that adds value to the health of the population.

Between 2011 and 2014, during the Troika period, the Minister of Health's order for the process of issuing Standards, the strengthening of the competences of the Directorate-General for Health in terms of quality and safety in health, despite the creation of the DQS, the public policies for quality and safety in health included in the National Health Plan 2012-2016, the creation of the new priority programme (Programme for the Prevention and Control of Infections and Antimicrobial Resistance - PPCIRA), the creation of the Quality and Safety Commissions (CQS), the restructuring of the Health Regulatory Authority (ERS) and Law No. 15/2014 of 21 March on the consolidation of the rights and duties of the user of health services and the determination on the adequacy of the provision of health care and the transposition to the legal order of the Directives of the Parliament, the Council and the Commission, determining the guarantee of access to quality and safe health care in the countries of the European Union.

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