

PALLIATIVE CARE IN THE REPUBLIC OF MOLDOVA 2007-2019

*"Palliative home care service is the one
by which you country honors you...".
(Conf. Dr. Daniela Mosoiu)*

Ghenadie Turcanu
Rita Seicas



Authors:

Ghenadie Turcanu, Program Coordinator, PAS Center

Rita Seicas, Program Coordinator, PAS Center

Cover and design:

Vasile Bounegru, IT Coordonator, PAS Center

Palliative Care in the Republic of Moldova, 2007-2019 / Ghenadie Turcanu, Rita Seicas; The center for Health Policies and Studies (PAS Center). - Chisinau: S. n., 2019 ("Foxtrot" typography). - 70 p. : fig. color.

Footnote bibliography references – Published with the financial support of the Soros Foundation Moldova/Public Health Dep.. – 70 copies.

ISBN 978-9975-89-146-2

616-082.8-03(478)

Ț 94

This report was developed within the project "Palliative Care in the Republic of Moldova, 2007-2017", implemented by the Center for Health Policies and Studies (PAS Center) with the financial support of the Soros Foundation Moldova/ Public Health Department. The views and conclusions expressed in this report are those of the authors and do not necessarily reflect the official position of the Soros Foundation Moldova.



Acknowledgements

This report was developed within the activities of the Soros Foundation-Moldova (SFM) to contribute to the integration of palliative care in the health system and to ensure equitable access of the population to such services. These activities are part of the priorities of the SFM Public Health Department of expanding the access to palliative care and supporting advocacy activities for strengthening palliative care in the Republic of Moldova. The report was prepared under the direction of Mrs. Liliana Gherman, Director of the Public Health Department of SFM and Mr. Vitalie Slobozian, Program Coordinator of the same department, however, the information, conclusions and recommendations issued by this report belong exclusively to the authors.

We would like to express our gratitude to Hospice Casa Sperantei from Romania, who has genuinely helped to prepare this report.

Special thanks are due to Mrs. Daniela Mosoiu, Director of Education Strategy and National Development Hospice Casa Sperantei from Romania for reviewing this report.

We would also like to thank Mr. Dumitru Parfentiev, General Director of the National Health Insurance Company, Mr. Iurie Osoianu, Deputy General Manager of the National Health Insurance Company, Mr. Iurie Panzaru, Interim Director of the National Public Health Agency and Eduard Patric, Director of the Center for Centralized Health Procurement, for providing the data that was analyzed in this report.

We give sincere thanks to Mr. Vadim Pogonet, President of the Specialist Commission for Palliative Care, Long-Term Care and Home Health Care of the Ministry of Health, Labor and Social Protection, Mrs. Maria Cumpăna, Deputy Director of the National Public Health Agency, Petru Crudu Head of Health Data Management Department of the National Public Health Agency, Mrs. Doina-Maria Rotaru, Deputy Head of the Contracting Department of the National Health Insurance Company, Mr. Sergiu Negritu, Head of the Department of Economics and Finance of the National Health Insurance Company, Mrs. Maria Lifciu, Head of the International Collaboration Service of the National Insurance Health Company, Mr. Valerian Isac, Director of National Development and Education of the Charity Foundation Hospice Angelus Moldova, Mrs. Raluca Muntean, Executive Director of Hospices of Hope Moldova, Mrs. Natalia Carafizi, Executive Director of the Charity Foundation Hospice Angelus Moldova, Mrs. Elena Stempovscaia, President of the Nursing Association of Moldova, Mrs. Stela Lefter, Lawyer, Mr. Oleg Galbur, Head of the department of Human Resources of the SUMP "Nicolae Testemitanu", for the open-mindedness and pro-active attitude in the process of preparing this report.

Contents

Acknowledgements	3
List of Abbreviations	8
I. Background	9
II. Organization and Management of Palliative Care	10
2.1. Background	10
2.2. Organization	10
2.3. Planification	12
2.4. Cross-sectoral approach	13
2.5. Regulation	14
2.5.1. Provider Regulation	14
2.5.2. Quality regulation	15
2.5.3. Regulation of service procurement	18
2.5.4. Regulations in the field of pharmaceuticals and medical devices	19
2.5.4.1. General framework for the regulation of opioid drugs and medical devices	19
2.5.4.2. Selection and estimation of drug needs	20
2.5.4.3 Medicines and medical devices procurement	22
2.5.4.4. Prescription regulation	27
III. Financing of palliative care	30
3.1. Expenditures	30
3.2. Sources of income	31
3.3. Financial Regulatory Framework	32
3.4. Payment mechanisms	35
3.5. Financial Transparency	35
IV. Physical and human resources in palliative care	38
4.1. Physical resources	38
4.2. Human resources	39
4.2.1. Human resources coverage	39
4.2.2. Human Resources Training	40
4.2.3. Doctor Training Programs	41
4.2.3.1. Integrated Higher Education	
4.2.3.2. Postgraduate Residency Training	
4.2.3.3. Continuing medical education (family doctors)	
4.2.4. Training within post-secondary medical education	43
4.2.5. Continuing medical education of medical staff with specialized secondary education (medical assistants)	43

4.2.6. General health care training (medical assistants with higher education)	44
4.2.7. Training of non-medical staff from the multidisciplinary team	44
V. Delivery of Palliative Care	45
5.1. Access formalities	45
5.2. Basic palliative care	45
5.3. Specialized palliative Care	49
5.3.1. Units with palliative care beds within public HCI and non-profit hospice care providers	49
5.3.2. Mobile hospital teams specialized in palliative care	54
5.3.3. (Mobile) Home Palliative Care Team	54
5.3.4. Outpatient palliative care consulting offices	57
5.4. Pharmaceutical support	58
VI. Evaluation of palliative care	61
6.1. Equity	61
6.2. Economic efficiency	63
6.3. Service efficiency	63
6.4. Satisfaction	65
VII. Conclusions	66
VIII. Recommendations	68

List of Tables

Table 1. National palliative care standards by regulatory areas	15
Table 2. WHO essential health services	19
Table 3. Availability of medicines for palliative care on the pharmaceutical market, in the list of compensated medicines, in the national list of essential medicines and in the list of medicines procured on centralized basis for the needs of PHCI in 2018	24
Table 4. Regulations on the beneficiary information according to the National Palliative Care Standard	28
Table 5. Regulations regarding beneficiary information on the legal provisions regarding the organization of palliative care services	29
Table 6. Structure of tariffs for palliative care services and the components of the expenditures included in their cost	33
Table 7. Personnel costs estimation	34
Table 8. The relative percentage difference between the costs of palliative care services estimated within the "Costing for Change" project, the costs approved by the MoH Order no. 1000 of 24.12.2015 and the costs for the contracted PC services for 2019	34
Table 9. National capital investment costs for the 231 nationally planned palliative care beds (spread over 9 years)	39
Table 10. Topics included in the "Palliative Medicine" course	41
Table 11. Goals in the study of palliative	42
Table 12. Palliative care interventions at the level of PHC in accordance with the Order of the Ministry of Health no. 1022 of 30.12.2015 on the organization of palliative care services	46
Table 13. Interventions applied in Romania by the primary care staff, with basic training in the field of palliative care, certified by completing training programs accredited by competent professional bodies and who occasionally care for patients with progressive chronic diseases and palliative care needs	48
Table 14. The essential package of palliative care services recommended by the WHO for the provision of PHC	48
Table 15. The number of home visits carried out by mobile teams, in accordance with the contracts concluded by the NHIC in 2019 with non-governmental providers and the number of potential beneficiaries of palliative care services calculated according to Stjernsward and Hiegginson, represented by territorial profile	57
Table 16. Morphine consumption (N02AA01) estimated for the period 2011-2018	59
Table 17. Estimated consumption of fentanyl (transdermal patch) in 2011-2018	60
Figure 18. Estimation of palliative care needs by territorial profile according to the data on general mortality registered in 2018	62

List of Figures

Figure 1. Organization of palliative care in the Republic of Moldova, 2019	10
Figure 2. The number of opioid medications (INN + concentration + pharmaceutical form + packaging size) procured from the state budget funds during 2007-2019	24
Figure 3. The share of palliative care (PC) expenditures from the CHI basic fund for the period 2010-2018	30
Figure 4. The share of expenditures for home and inpatient/hospice palliative care (PC) from the total expenditures for PC, 2010-2018,%	30
Figure 5. The costs for palliative care paid by NHIC, depending on type of service delivery, in the period of 2010-2019, Lei	31
Figure 6. Share of financing based on the sources of income of FF MS "Angelus Moldova", in the period 2014-2017,%	32
Figure 7. Number of visits and beneficiaries of home health care (HHC) at the level of PHC, in the period 2008-2018	47
Figure 8. Number of palliative care beds in public hospitals presented as total number and by types of institutions, developments in the period 2011-2018	50
Figure 9. The level of insurance with palliative care beds per 10,000 inhabitants reported per development regions, municipalities, districts and in total per the Republic of Moldova, during the period 2011-2018	51
Figure 10. Total number of bed-days paid by the NHIC to hospital/hospices palliative care providers	52
Figure 11. The number of bed-days and the number of patients who benefited from palliative care in hospitals/hospices, presented by territorial profile, year 2018	52
Figure 12. Share of patients who received palliative care (PE) in hospitals/hospice from the total number of potential patients requiring PE calculated according to Hiegginson and Stjernsward, by territorial profile, year 2018,%	53
Figure 13. Number of hospitalizations of children aged 0-17 years 11 months and 29 days in units with beds/hospices, during 2014-2018	54
Figure 14. Number of people in need of palliative care (PC) (calculated after Stjernsward, Hiegginson) and number of visits in eight ATUs where there are providers of specialized palliative care services - home care mobile teams contracted by NHIC in 2018	55
Figure 15. Number of home palliative care visits carried out by mobile teams contracted by NHIC, in the period 2013-2019	56
Figure 16. Estimated morphine consumption (N02AA01) in the period 2011-2018	59
Figure 17. Estimated consumption of fentanyl (N02AB03 - transdermal patch) in 2011-201	60

List of Abbreviations

CPAA	Central Public Administration Authorities
LPAA	Local Public Administration Authorities
MMDA	Medicines and Medical Devices Agency
PHC	Primary Health Care
NPHA	National Public Health Agency
NPTA	National Palliative Treatment Association
CHI	Compulsory Health Insurance
CCHP	Center for Centralized Health Procurement
NHIC	National Health Insurance Company
INN	International Nonproprietary Name
CHIF	Compulsory Health Insurance Funds
SFM	Soros Foundation Moldova
HCI	Health Care Institution
PHCI	Public Health Care Institution
LCM	List of Compensated Medicines
WHO EML	The WHO Model List of Essential Medicines
NLEM	National List of Essential Medicines
MoH	Ministry of Health
MHLSP	Ministry of Health, Labor and Social Protection
WHO	World Health Organization
NCCP	National Cancer Control Program
NSPC	The National Standard of Palliative Care
TAU	Territorial Administrative Unit

I. Background

According to the World Health Organization, about 40 mln people worldwide are in need of palliative care every year and only 14% of receive it¹. The resolution of the World Health Assembly of 2014² called on the Member States to develop and implement public policies for economically efficient and equitable palliative care services, which would be further integrated in the process of health service provision at all levels. Palliative care is a fundamental human right for all children and adults with life-threatening illness. This service must be an essential component of the healthcare system and must be included in universal health coverage. Implementation of comprehensive universal health coverage could significantly increase access to quality palliative care for everyone who needs it³.

In the context of national efforts to achieve universal coverage in the health system, this report studies the evolution of the integration of palliative care in the health system of the Republic of Moldova during 2007-2019. The report provides a detailed description of the initiated, implemented or ongoing public policies on palliative care through an impartial analysis. However, the report has certain methodology limitations associated with conditions of limited transparency of public authorities, in particular of the Ministry of Health, Labor and Social Protection. Thus, the study was carried out only on the basis of the publicly available documents and the data provided by the National Health Insurance Company, the National Public Health Agency, and the Center for Centralized Health Procurement.

The evolution of palliative care in the period 2007-2019 was examined through different approaches in terms of organization, financing, generation of resources, service provision, as well as in terms of equity, economic efficiency, effectiveness of palliative care services and satisfaction of the beneficiaries. The report highlights the challenges and the areas that need more optimal solutions providing relevant information to support the development of public policies which will enable full integration of palliative care services into the health system.

The report was prepared within the framework of activities to support and promote good governance in the healthcare system through independent and unbiased monitoring of public health policies and services and reflects publicly available palliative care data, policy documents and regulations as of September 2019. The report also aims to support civil society organizations advocating for consistency and inclusion of palliative care in universal health coverage policies and raising awareness among public authorities and citizens on their rights to health, including palliative care, thus increasing the demand for such services.

1 <https://www.who.int/ncds/management/palliative-care/> (accessed on 08.10.2019)

2 SIXTY-SEVENTH WORLD HEALTH ASSEMBLY WHA67.19 Agenda item 15.5 24 May 2014 Strengthening of palliative care as a component of comprehensive care throughout the life course.

3 Universal Health Coverage and Palliative Care. Published in December 2014 by the Worldwide Hospice Palliative Care Alliance, London.

II. Organization and Management of Palliative Care

2.1. Background

Palliative care services in the Republic of Moldova began to develop with the support of external partners, at the end of the 90s, at the level of services provided by non-governmental structures. In 2000, the National Palliative Treatment Association (NPTA) was created, which contributed to the development of social activism and the proactiveness of relevant organizations aimed at expanding palliative care services throughout the Republic of Moldova. For 10 years, non-governmental providers of specialized palliative care services were financially supported only from external sources. By 2008, with the support of external partners, several non-governmental structures that offered specialized home palliative care services to elderly and terminally ill patients were established.

Only in 2007, with the approval of the National Health Policy ⁴ and of the Healthcare System Development Strategy for the period 2008-2017⁵, the premises for the provision of palliative care services as part of the public health system were put in place. In 2010, Law No. 1585 on compulsory health insurance ⁶ was completed with norms that enabled the National Health Insurance Company (NHIC) to contract organizations specialized in palliative care. In the same year, specialized palliative care services as hospice/inpatient palliative care units, mobile teams specialized in home palliative care were included in the Unique Compulsory Health Insurance Program ⁷. The first nongovernmental provider of specialized palliative care ⁸ was contracted by NHIC in 2010, and the first public provider⁹ was contracted by NHIC in 2011. In 2009, with the support of the SFM, the palliative care and psychological support service was opened within the Oncological Institute to assist patients suffering from cancer. Also, in 2011, from the sources of the Global Fund to Fight AIDS, Tuberculosis and Malaria, a palliative care unit was established for people living with HIV infection, within the Clinical Hospital for Infectious Diseases "Toma Ciorba" - currently the ARV treatment department of the Dermatology and Communicable Diseases Hospital. During the implementation of the Healthcare System Development Strategy for the period 2008-2017, the Ministry of Health (MoH) adopted a series of regulations related to the organization and functioning of palliative care, which fostered the supply of palliative care beds within the public health care services (see section 5.3.1.). If there were not any public health care institution (PHCI) providing specialized palliative care services in units with beds in 2007, then in 2019 their number reached to 43 (Figure 1).

2.2. Organization

The structure of palliative care services in the Republic of Moldova represents a series of providers of medical and social-medical services in the public and private/non-governmental sectors, as well as public authorities and agencies involved in the regulation, financing and administration of palliative care services (Figure 1.). The private sector is the only provider that offers both specialized palliative services at home and hospice services, while the public sector provides only hospital services - beds for palliative care. The Ministry of Health, Labor and Social Protection (MoHLSP) carries full responsibility for the organization and regulation of palliative care services, while the National Public Health Agency (NPHA) is responsible for evaluating and accrediting palliative care services and the NHIC for contracting the service providers for delivery of palliative care to the insured persons.

4 Government Decision no. 886 of 06.08.2007, published in the Official Gazette of the Republic of Moldova no. 127-130 of 17.08.2007, art. Nr.931

5 Government Decision no. 1471 of 24.12.2007, published in the Official Gazette of the Republic of Moldova no. 8-10 of 15.01.2008, art. No.43.

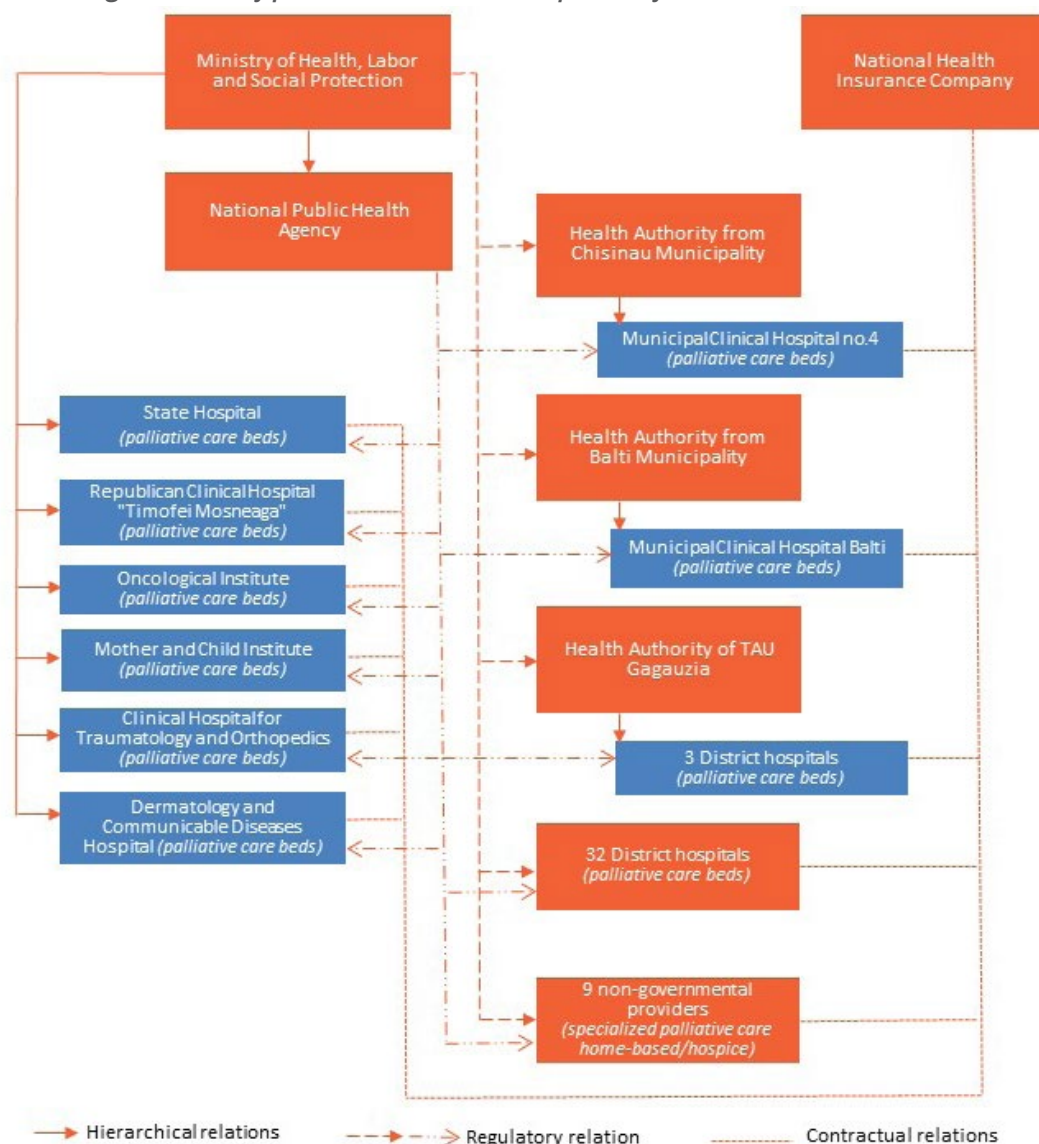
6 Law no.186 for amending and completing certain legislative acts of 15.07.10, published in the Official Gazette of the Republic of Moldova 138-140 of 06.08.2010, art.492

7 Government Decision no. 1099 of 02.12.2010 for the approval of the modifications and completions that are operated in the unique Compulsory Health Insurance Program, approved by the Government Decision no. 1387 of December 10, 2007, published in the Official Gazette of the Republic of Moldova no. 241-246 of 10.12.2010, art. 1219

8 NGO "Prosperare-Zubresti".

9 Municipal Clinical Hospital no.4 from Chisinau.

Figure 1. Organization of palliative care in the Republic of Moldova, 2019



MSMPS The MoHLSP approves the regulations and the list of service providers, regardless of the type of ownership and the legal form of organization, as well as the list of services provided by them. The MoHLSP also develops and approves the entire palliative care policy, which includes standards, clinical protocols and all regulations in the field of palliative care services (see section 2.5.). Most of the palliative care providers in the public sector belong to the local public administration authorities (LPAA), as they are the founders of a larger number of PHCI. At the same time, the competence of the LPAA in the organization and functioning of palliative care services is limited to the establishment of the PHCI, the approval of the organization chart and of the staff list¹⁰. Within the LPAA of Chisinau and Balti, as well as the Autonomous Territorial Unit of Gagauzia (Gagauz-Yeri), there are authorities responsible for the administration of the subordinated health care providers, but they do not effectively exercise their competences in the health department¹¹. For this reason, all public palliative care providers, including those under the PLAA which do not have their own structures for the administration of the healthcare providers in custody, are de facto subordinated to the MoHLSP. The LPAA, as well as the central public administration authorities are not obliged to fund the established institutions, because the activity of the PHCI included in the Compulsory Health Insurance system (CHI) is based on the principle of non-profit self-financing¹². According to the law, the founders of the PHCI included in the CHI have no legal

10 Art. 4, paragraphs (2) and (7) of the Law on health care no.411 of 28.03.1995

11 Soltan V. et al. Health Monitor: Policy study on the degree of administrative decentralization in the field of health, Chisinau 2010.

12 Art.7, paragraph (2) of the Law on health care no.411 of 28.03.1995.

obligation to assure the institutions with financial and technical-material support, thus they also do not held any responsibility regarding the medical assistance and its quality¹³.

By the law the NHIC is obliged to contract health care providers, regardless of their type of property, for provision of health care services, including palliative care, to insured persons and to verify the compliance of the amount, terms, quality and cost of provided assistance with the clauses of the contract for the provision of healthcare services, as well as to manage the financial means stemmed from the compulsory healthcare insurance funds (CHCI), within the limit of the contracted healthcare services¹⁴ (see section 2.5.3.)

NPHA through the Health Authorization and Accreditation Directorate is responsible for evaluating and accrediting palliative care service providers, regardless of the type of ownership and in accordance with the evaluation and accreditation standards for palliative care providers (see section 2.5.2.).

2.3. Planification

The National Health Policy adopted by the Government in 2007¹⁵ is the only document in force that establishes the vision of palliative care development until 2021. According to this document, the access to palliative care is based on the principle of respecting the dignity and specific needs of the terminally ill patients and includes mandatory pain and symptoms control, psycho-emotional and spiritual support, family support, including in the period of mourning. The document also states that the Government facilitates access to the necessary medicines (including opioid analgesics), in forms and doses suitable for medical use, by adjusting the regulatory framework to the standards and recommendations of the Council of Europe and WHO. The Healthcare System Development Strategy for the period 2008-2017¹⁶ maps out actions to improve the payment mechanisms for palliative care (see section 3.4.) and to create palliative care services within the hospital healthcare system (see section 5.3.1.).

In 2008 the MoH approved the Concep of Palliative Care Service Development in the Republic of Moldova and the Plan of Measures for Palliative Care Service Development for 2008¹⁷. This policy document has largely contributed to the development of the regulatory framework for palliative care (see section 2.4.), but it has failed to provide a cross-sectoral mechanism of service delivery based on the level of palliative care interventions. The concept from 2008 estimated that up to 60% of annually deceased people¹⁸ (25,830 patients in total, including 17,642 from the rural area and 8188 from the urban area) would have required palliative care, but in 2018, after 10 years of service implementation, about 37-38% of palliative patients benefited from home palliative care services and about 21-25% benefited from care provided in units with beds/hospice (see section 5.3.).

Six years after the approval of the concept of palliative care service development in the Republic of Moldova, the Draft of National Program for Palliative Care Service Development for the years 2014-2018 was developed. This draft policy document also estimated that 23,235 patients require palliative care services every year, however, in 2013 only 2 thousand patients benefited from this type of services. The main obstacles in the way of palliative care services provision highlighted in the 2014 National Program draft were the shortage of national service providers, the inability of the patient with incurable disease to choose where to spend the last moments of life and the shortage of clinical protocols and quality standards for the provision of palliative care services. Other problems that were mentioned included the fact that primary and hospital healthcare do not provide specialized palliative care services, ignore the criteria for selecting beneficiaries and do not fully implement the national clinical protocol "Palliative Care - Cancer Pain". The draft of the National Program for Palliative Care Service Development for the years 2014-2018 contained four objectives established to rectify the situation: i) Make palliative care service management more efficient; ii) Improve the financing of palliative care services; iii) Cost-efficient delivery of palliative care services; iv) Optimization of

13 Efrim, Rosca and Asociatii (ERA) Associate Lawyers Office, Legal opinion on the national legislative framework regarding the obligation of the central and local public administration authorities to provide financial, technical and material support to public healthcare institutions under the compulsory health care insurance system. Chisinau, 2018

14 Art.12, paragraph (3) letter (a1) and (c) of the Law on compulsory medical insurance no. 1585 of 27.02.1998.

15 Government Decision no. 886 of 06.08.2007 on the approval of the National Health Policy

16 Government Decision no. 1471 of 24.12.2007.

17 MS Order no. 234 of 09.06.2008 on the development of palliative care services in the Republic of Moldova.

18 The estimates were made according to the recommendations of the scientific community in the field (Stjernsward J., Doyle D. et al., "Oxford Textbook of Palliative Medicine", Oxford University, Press edition, 2005).

the resources generation system¹⁹. Although the MoH accepted the draft of the National Program for Palliative Care Services Development for the 2014-2018, it was not submitted for Government approval.

At the same time, the Government approved the National Cancer Control Program for 2016-2025²⁰. The National Cancer Control Program (NCCP), being given the epidemiological situation caused by cancer, has established that 143 doctors and 684 nurses have to be involved in palliative care services, since in 2016 the country employed only about 20 professionals skilled in this field. But even those 20 palliative care professionals were not certified in the country and palliative care was not recognized as a specialization or subspecialization. Caregivers and cancer patients do not receive free basic equipment needed for care (mobile toilets, wheelchairs, fixation equipment for fractures, dressings for bedsores, etc.). The NCCP for 2016-2025 has mapped out the objective to ensure the development of palliative and rehabilitation services and real access of cancer patients to these services.

There was also a Program for the Development of Hospital Healthcare for 2010-2012²¹ which provided for the re-profiling of short-term beds from public hospitals to chronic beds, including beds for palliative care, in order to increase the activity of acute hospital services. However, the program did not reach its objectives and remained only on paper until the end of 2012, when the implementation deadline expired and it was no longer extended.

2.4. Cross-sectoral approach

The policy document in force with the largest possible cross-sectoral impact on the healthcare, including palliative care, is the National Health Policy (see section 2.3.). The National Health Policy establishes that its implementation encompasses a wide range of approaches, strategic elements, legislative, financial, analytical and coordination methods, based on cross-sectoral cooperation, information exchange and reciprocity. This document has contributed to the more active involvement of the development partners in the provision of palliative care services as part of the health system and to the strengthening of the capacities of providers, especially non-governmental palliative care providers (see section 2.1.). Thus, the field of palliative care was among the priorities of the donors, in particular of the SFM, Hospices of Hope Moldova, the US state of North Carolina and other donors who supported the activities of palliative care development as part of the health system.

However, the health authorities have failed to ensure the multidisciplinary approach of palliative care services in the health system. The CHI Unique Program²² includes only medical care and no other multidisciplinary services required by specialized palliative care. Thus, both the public and private providers of specialized palliative do not offer social and psychological support services under contracts concluded with NHIC (see section 2.5.3.). The health authorities did not effectively promote aspects related to palliative care in the policies of social assistance, education, etc. and they have failed to support their efficient implementation in the related sectors to maximize the results in the field of palliative care. The minimum social services package²³ for 2018 includes a number of social services funded from the Population Support Fund, but they do not provide all the social support needed in palliative care. The "Personal Assistance"²⁴ social service, which is part of the minimum social services package, provides support and care services exclusively to people with severe disabilities. The patients are considered eligible for the "Personal Assistance" social service only if they are holders of disability certificate. In the opinion of specialized palliative care providers, if the beneficiary of palliative care does not have a confirmed degree of disability or is not a pensioner, he/she cannot benefit from social services but once, as a recipient of "Monetary Support"²⁵. Also, the remits of the social services - "Community Social Assistance Service", "Social Home Care Service" do not include criteria for acceptance

19 The project of the National Program for the development of palliative care services for the years 2014-2018.

20 Government Decision no.1291 of 02.12.2016 on the National Cancer Control Program for the years 2016-2025.
Government Decision no.379 of 07.05.2010.

21 Government Decision no.379 of 07.05.2010.

22 Government Decision no.1387 of 10.12.2007 on the approval of the Single Program of compulsory health insurance.

23 Government Decision no.800 from 01.08.2018

24 Government Decision no.314 of 23.05.2012 approving the Framework Regulation on organization and functioning of the "Personal Assistance" and "The Minimum Quality Standards" social services

25 Danii Olga, Nicoleta Spinu-Triboi. Access and quality of palliative care services in the Republic of Moldova. Quality study. The Independent Sociology and Information Service OPINIA. 2019.

and provision of assistance in the last stages of the disease and after the death of patients, including assistance for patient's family. The normative framework on temporary incapacity allowances and other social insurance benefits²⁶ does not establish the right to compensation payments for people taking care of a child or of an adult who requires palliative care. In the absence of efficient multisectoral legislative, executive and administrative provisions at the national level to ensure a biopsychosocial model of palliative care services, MoHLSP orders to the heads of PHCI and local public administration health structures to collaborate with the local public administration and social assistance organizations, in order to engage the social workers in the activity of the multidisciplinary palliative care teams²⁷. At the same time, there is not any regulatory framework to govern the competences and attributions of social services in the activity of the multidisciplinary palliative care teams. Thus, the under-measures taken based on the public policies aimed at ensuring the multidisciplinary approach of palliative care do not result in the integration of palliative care services in the flow of the health system, as expected (see section 6.3.).

2.5. Regulation

The exclusive prerogative to regulate palliative care is held by the central public authorities (Parliament, Government, MoHLSP, NHIC, AMED and NPHA), since the LPAA does not have competences to regularize the subordinate palliative care providers (see section 2.2.).

2.5.1. Provider Regulation

Although Parliament establishes the general framework for regulation of health care at all levels, stipulating that home health care is one of the types of health care²⁸, the law does not contain any regulation on palliative care. At the same time, the Parliament establishes the general normative framework for the regulation of the medical service providers, of which palliative care providers are part. Thus, according to this framework, a public or private palliative care service provider can deliver palliative care services only if it has been included in the list of service providers and if it has established rules governing its organization and operation, which must also contain the list of provided services, the both documents should be approved by the MoHLSP²⁹. The private palliative care providers, in addition to the obligation to be included in the List of healthcare service providers, must have a license issued by the Public Services Agency, subordinated to the Government, which establishes the type of palliative care service activities, with compulsory compliance with the conditions for conducting the licensed activity within a predetermined period of time. Also, for being able to deliver palliative care services, providers must hold a health authorization for the practiced type of activity, as well as a certificate of accreditation, both documents are issued by the corresponding structures of the NPHA under the MoHLSP. Accreditation is performed in order to determine the capacity of the palliative care service providers to deliver palliative care to the population and is granted on the basis of standards developed and approved by the MoHLSP, regardless of the type of ownership, the legal form of organization and the administrative subordination. Evaluation and accreditation standards for palliative care providers include mandatory criteria for initiating the evaluation and accreditation procedure (Registration Certificate, Organization and Operation Regulation, Health Authorization, etc.), as well as quality requirements regarding: i) management and administrative services; ii) the rights of the beneficiary; iii) human resources management; iv) technical-material resources, the supply of necessary medical equipment and consumables; v) monitoring and evaluation of services, which would include care organization, quality of care, performance evaluation and improvement, infection and risk control. It should be mentioned that the checked quality requirements included the ability of the provider to deliver palliative care services based on multidisciplinary teams (doctor, nurse, social worker, psychologist, clergyman, volunteer, etc.), well trained in the field, respecting the minimum structure of the multidisciplinary team (doctor, nurse, social worker).

26 Law no. 289 of July 22, 2004 on temporary disability benefits and other social insurance benefits

27 Order No. 1022 of 30.12.2015 on the organization of palliative care services.

28 Art. 21 paragraph (1) of the Law on health care no. 411/1995.

29 Order of the MoH no.1086 of 30.12.2016 regarding the approval of the framework Regulations for the organization and operation of the health service providers; Order no. 163 of 21.02.2013 regarding the approval of the Nomenclature of healthcare institutions; Order no. 1554 of 26.12.2013 regarding the approval of the Nomenclature of institutions subordinated to the Ministry of Health; Order no. 1574 of 27.12.2013 regarding the approval of the Nomenclature of private healthcare institutions, etc.

2.5.2. Quality regulation

Regulations for the quality assurance of palliative care services and for standardizing the healthcare practice pathologies and/or symptoms are the exclusive competence of the MoHLSP, which approves the national clinical standards and protocols. The MoH approved the first and the only National Palliative Care Standard (NPCS) for palliative care providers, which aims to ensure the quality of service delivery, in 2010³⁰. NPCS contains a number of basic requirements to ensure quality palliative services. These are mandatory for any palliative care provider and include 21 standards spread across 14 regulatory areas (Table 1.). NPCS also regulates the structural requirements, provision of palliative care services with beds at home, in day centers and in outpatient palliative care consulting offices. The NPCS dispositions outline a series of basic requirements to ensure the existence of quality palliative services for the incurable patients in advanced and terminal stages, which must be fulfilled by any potential palliative care service to be initiated and by the HCI, as well as by the financiers as a tool for evaluating palliative care services. NPCS establishes by paragraph 6) of Standard no.1, that the providers of palliative care services are specialized units, regardless of type of ownership and legal form of organization, including associations and organizations authorized to provide palliative care services, in the manner established by the legislation in force.

Therefore, **all quality assurance regulations in the National Standard are provided for specialized palliative care**. Moreover, the Order of the MoH that approves the National Standard³¹ establishes for the HCI managers and the health structures of the LPAA that they have the obligation to implement the NPCS according to the provisions of the Order of the MoH no.154 of 01.06.2009 regarding the organization of the palliative care services. For its part, the Order 154/2009 of the MoH stipulates that HCI managers should organize palliative care services within the framework of hospital healthcare, in accordance with the Regulation on the organization of palliative care services and the HCI Nomenclature. At the same time, the Regulation on the organization of palliative care services, approved by the Order of the MoH no.154 of 2009, defines the providers of palliative care services, similarly to NPCS, as specialized units, regardless of the type of ownership and the legal form of organization, including associations and organizations authorized to provide palliative care services in the manner established by the legislation in force.

Therefore, the quality assurance regulations are provided for specialized palliative care and do not address quality assurance adjusted to the level of complexity of palliative care, in particular regarding the basic palliative care that is provided to patients and families by the family doctor and healthcare professionals. Although the Order of the MoH no.154 was repealed in 2015 and replaced by a new Regulation regarding the organization of palliative care services (see section 5.2.), NPCS was not adjusted to the level of palliative care interventions³².

Table 1. National palliative care standards by regulatory areas

Regulatory area	Standard
ACCESS TO PALLIATIVE CARE SERVICES BENEFICIARIES AND PROVIDERS OF PALLIATIVE CARE SERVICES	Standard 1. Palliative care services are provided within the limits of resources available to all eligible patients with their consent and in accordance with the legislation in force. Standard 2. Palliative care service providers follow a protocol for selecting patients from the waiting list.
RIGHT AND ETHICS IN PALLIATIVE CARE	Standard 3. Beneficiaries have the right to adequate care for their needs
	Standard 4. The beneficiaries of palliative care services enjoy the rights provided by the legislation regarding the rights of patients.
	Standard 5. Palliative care services ensure the patient's symptoms and pain control.
	Standard 6. The purpose of palliative care is to improve the quality of life through a positive influence on the evolution of the disease and provision of the necessary support to the patient.
THE FIELD OF PALLIATIVE CARE	Standard 7. The field of palliative care covers a wide range of services (medical, nursing, psychological / emotional, spiritual and social) for eligible patients and their families.

30 MoH Order No. 884 of 30.12.2010 "On the approval of the National Palliative Care Standard".

31 Ibid.

32 MoH Order no. 1022 of 30.12.2015 on the organization of palliative care services.

STRUCTURE AND THE FORM OF ORGANIZATION OF THE SPECIALIZED PALLIATIVE CARE SERVICES	Standard 8. Specialized palliative care services for eligible patients and their families
PROVIDED CLINICAL AND HEALTHCARE SERVICES	Standard 9. Palliative care is provided as long as it is needed; it is based on the initial assessment and periodic evaluation, which can be conducted when necessary.
HUMAN RESOURCES AND TRAINING	Standard 10. Palliative care involves important human resources to ensure accessibility, continuity and quality of medical care. Standard 11. Training is an integral part of palliative care and is provided at an appropriate level for professionals, volunteers, patients, families, carers and the public.
THE INTERDISCIPLINARY TEAM	Standard 12. Palliative care services are provided by an interdisciplinary team.
INFORMATION MANAGEMENT	Standard 13. The activity of palliative care services will be documented and reported in the form and in the manner established by the Regulation regarding the organization of palliative care services.
	Standard 14. Palliative care service providers ensure complete, correct and confidential records of documents related to the services provided, regardless of the location where the patient receives care services.
ORGANIZATION MANAGEMENT	Standard 15. The management of palliative care services is ensured by the entities specified by the statute/regulation of the organization.
PERFORMANCE ASSESSMENT AND IMPROVEMENT	Standard 16. Performance assessment of palliative care service is carried out through the internal and external medical audit.
INFECTION AND RISK CONTROL	Standard 17. Palliative care services develop and implement measures to fight infections, in order to identify and reduce the risks of infection in staff, patients and family members.
	Standard 18. Palliative care service providers are responsible for observing the normative and legislative acts in the field of occupational safety and protection.
COORDINATION AND CONTINUITY OF CARE	Standard 19. In order to ensure the continuity of care, palliative services should be accessible and should have an adequate communication framework in place to ensure the interaction between the staff and the family or other services whenever there is a significant change in the clinical status of the patient.
SOURCES OF FINANCING	Standard 20. Financing of palliative care services
MONITORING AND EVALUATION OF	Standardul 21. Prestatorii de servicii vor prezenta rapoartele în modul și ordinea prevăzute de legislație.
PALLIATIVE CARE	Standard 21. Service providers will submit the reports in the manner and order provided by the legislation.

Source: Order No. 884 of 30.12.2010 "On the approval of the National Palliative Care Standard".

The full application and observance of the NPCS is the responsibility of the head of the palliative care institution or the head of the institutions that provides palliative care services in addition to other medical services. The MoH has assigned to CNEAS (the authority responsible for health assessment and accreditation) the control of the compliance of healthcare service and palliative care providers with the NPCS. Since 2017 CNEAS (the authority responsible for health assessment and accreditation) has become a functional unit of the NPHA named as "Health Authorization and Accreditation Directorate" and is no longer a legal entity³³. In addition, the MoH recommended to NHIC to evaluate the contracted providers' compliance with the NPCS during monitoring control. The delegation of the NPCS compliance checks to the NPHA and NHIC by the MoH can be explained by the fact that there are no authorities responsible for monitoring the quality of provided medical services at the LPAA level, the responsibility for quality assurance being directly attributed to the head of the medical institution providing palliative care services or to the head of the institution specialized in providing palliative care services. In order to solve the problems of lack of standardized quality monitoring, the MoHLSP promoted the establishment of the Department for Management and Control Methodology for Healthcare Institutions³⁴ within the NPHA State Health Control Directorate, as a part of the public health service reform, but this structure has not become functional.

In 2008 the MoH approved the "Standard for palliative care of HIV / AIDS patients"³⁵. Although the document has been denominated a standard, it is rather a guide for the managers and specialists of

³³ Government Decision no.1090 of 18.12.2017 on the organization and functioning of the National Agency for Public Health.

³⁴ Ibid

³⁵ MoH Order no. 260 of June 26, 2008 on the approval of the Standard "Palliative care of HIV / AIDS patients".

the institutions providing healthcare services, which establishes the principles and particularities of palliative care for people with HIV/AIDS, the organization and types of palliative care, human resources training, symptom management etc. In 2009, the MoH approved the National Guidelines for treatment and care of HIV and AIDS infection³⁶, which also included standardized principles of palliative care for AIDS patients, in particular the treatment of pain, the management of symptoms and the care of the dying. In 2016, the MoH approved the Guidelines for palliative care (with special notes on TB, HIV, pediatrics)³⁷, which contains basic information about palliative care, their general principles, types of palliative care, the means of providing palliative care, beneficiaries of this type of care, symptoms management, treatment of specific symptoms, provision of psychological assistance to patients and their families, care of the dying, as well as some particularities of palliative care for TB patients and children.

In 2011, the MoH approved the Guidelines on palliative care for family doctors, whose mission is to provide support in making therapeutic decisions regarding the incurable patient to both family doctors and other palliative care providers. In 2017, other Guidelines were approved - "Palliative Medicine", as educational material for family doctors.

The MoH approved five national clinical protocols in the period of 2011-2017 for the standardization of procedures in palliative care. The MoH approved three national clinical protocols in the field of palliative care in 2011. The approved national clinical protocols were following "Palliative Care in Dyspnea, Terminal Stage"³⁸, "Palliative Care in Gastrointestinal Pathology"³⁹, "Palliative Care in Bedsores"⁴⁰. In 2014 the MoH approved the national clinical protocol "Palliative care - Pain in Cancer"⁴¹. The objective of this protocol is to increase the efficiency of pain treatment in oncology patients, including by increasing the quality of supervision of patients with pain and increasing the accessibility to analgesics of oncological patients. It is important that this protocol standardize not only the medical procedures in cancer pain but also in chronic pain. The protocol, however, is titled "Pain in Cancer" and therefore needs to be updated, similarly to all the national clinical protocols approved since 2011. The most recent national clinical protocol - "Palliative Care for Children"⁴² was approved by the MoH in 2017. The MoH states that all the national clinical protocols are developed in accordance with the current international guidelines and serve as a basis for development of institutional protocols, adjusted to the real possibilities of each institution providing palliative care services. It should be mentioned that neither the public providers of palliative care services nor the ones from the non-governmental sector publish the institutional clinical protocols on their official web pages.

The MoH left the full responsibility for the implementation of the national clinical protocols to the heads of the institutions providing palliative care services. The MoH has delegated the supervision of services' compliance with the national clinical protocols, as in the case of NPCS, to the authority responsible for the evaluation and accreditation in healthcare – a functional structure within the NPHA. In addition, the MoH also recommended that the NHIC should evaluate the compliance of service provision with the clinical protocols during the check-ups carried out among the healthcare service providers contracted within the CHI. Charging the NHIC to evaluate the compliance with national clinical protocols exceeds its scope of competence because according to the legislation in force the NHIC is obliged to verify the compliance of service provision against contract clauses insofar as it relates to the amount, terms, quality and cost of healthcare services provided to the insured persons, as well as the management of the financial means from CHIF, within the limits stipulated in the contract⁴³.

36 MoH Order no.523 of 24.12.2009 on the approval of the National Guide for treatment and care of HIV and AIDS infection.

37 MoH Order no.219 of 30.13.2016 on the approval of the Guidelines for palliative care (with special notes on TB, HIV, pediatrics).

38 MoH Order no.454 of 02.06.2011 on the approval of the national clinical protocol "Palliative Care in Dyspnea, Terminal Stage".

39 MoH Order no. 455 of 02.06.2011 on the approval of the national clinical protocol " Palliative Care in Gastrointestinal Pathology "

40 MoH Order no. 457 of 02.06.2011 on the approval of the national clinical protocol "Palliative Care in Bedsores".

41 MoH Order no. 1181 of 28.10.2014 on the updating of certain national clinical protocols.

42 MoH Order no.329 of 28.04.2017 on the approval of the National Clinical Protocol.

43 Art.12 paragraph (3), letter (c) of Law no.1585 of 27.02.1998 on the Compulsory Health Insurance

At the end of 2015, NHIC has developed a tool for validating the services offered by palliative care providers⁴⁴. It includes seven standards and twenty-seven criteria, which largely repeat the provisions of the NPCCS, but which also contain additional requirements established by NHIC with reference to the its contractual relationship with the supplier. It should be mentioned that the NHIC standards do not clearly stipulate the multidisciplinary approach of palliative care.

The MoH has charged the MMDA with the task to ensure the Republic of Moldova pharmaceutical market with the medicines included in the national clinical protocols, but there is no public information on how the MMDA carries out this activity. Systematic overviews on ensuring the availability of medicines on the Moldovan market are not publicly available neither is the information on the lack or interruption of supply, especially of medicines from essential medicines list and those included in the clinical protocols. In addition, there is no systematic public information on the evolution of drug prices, especially those included on the essential medicines list and those provided by the national clinical protocols.

2.5.3. Regulation of service procurement

For the first time, the palliative care services were included in the CHI Unique Program in 2010⁴⁵. The program establishes the amount of healthcare assistance, granted within the CHI, in accordance with the contract for the provision of healthcare services concluded by NHIC with the healthcare service provider. In 2010, palliative care services were included in the Unique Program as part of home healthcare services. The 2010 Unique Program envisages that home health care service providers can be any HCI, regardless of the type of ownership and legal form of organization, including associations and organizations which are licensed and authorized to provide home healthcare services, including palliative care, in the manner established by the legislation in force and which concluded a contract with NCHI (territorial agencies) for the provision of home healthcare services. In addition, it establishes that inpatient healthcare services are delivered when a patient requires palliative care provided by hospice or specialized units or by specialized palliative care mobile teams within the healthcare facilities. In 2016 the Unique Program was modified and supplemented⁴⁶, and palliative care was included as a component part of community and home healthcare service, it established that beneficiaries of palliative care are patients of all ages, with advanced chronic diseases and other life limiting diseases, who have a life expectancy below 12 months and have uncontrolled symptoms, significant psycho-emotional or spiritual suffering and/or a certain level of dependence. At the same time, the hospital healthcare services have been supplemented by new regulations that established several types of healthcare, including palliative care as part of chronic condition care defined as patient care with primary clinical or treatment goal to optimize the quality of life of the patient suffering from active and advanced pathology that limits his/her life expectancy.

However, from 2010 until now palliative care services are not included in the Unique Program as a basic service within the health system. According to the WHO, palliative care should be included in the list of basic health services (*Table 2.*). On the whole, the structure and content of the Unique Program is outdated, because it is based on the mode of healthcare service provision and not on the principles of healthcare. At the same time, health legislation uses different terminology in regulating the provision of healthcare services. Thus, the law on health protection and the law on compulsory health insurance use the term “medical services” and do not offer a definition of it. The law on the rights and responsibilities of the patient uses a different term - “healthcare services”, for which the following definition is used: «the complex of measures directed towards meeting the people’s needs for the protection and recovery of health with the help of professional medical and pharmaceutical knowledge”. For its part, all the regulations approved by the Government, the MoHLSP, and the NHIC for implementing the law on compulsory health insurance use the term “medical services”. At first glance, there seems to be no difference between “medical services” and “healthcare services”. However, WHO is increasingly using the term healthcare services, in particular in the recommendations for a coordinated and integrated

44 NHIC provision no.375-d of 29.10.2015 on approval of standards for the validation of the services offered by palliative care providers.

45 Government Decision no. 1099 of 02.12.2010 on the approval of the modifications and completions that are operated in the Unique Compulsory Health Insurance Program, approved by the Government Decision no. 1387 of December 10, 2007.

46 Government Decision no. 714 of 06.06.2016 on the modification and completion of Government Decision no. 1387 of December 10th 2007.

organization of healthcare services delivery (Table 2.). The term medical services is used when referring to certain specialties, such as surgery, internal medicine, orthopedics, etc. Probably in the mid-1990s, when the organic laws in the field of health were approved, the term “medical services” borrowed from the Russian term “медицинские услуги” was used instead of adopting the more appropriate - “health services”. It cannot be excluded that for this reason today we are confronted with the purely medical approach in defining the package of services, which is contracted by NHIC, including contracting only part of services provided by the multidisciplinary palliative care team - only the medical part of the services - which does not ensure the consistent and integrated delivery of services. None of the above contribute to solving the problems related to the organization of coordinated and integrated provision of patient-centered health services. (see section 6.3).

Table 2. WHO essential health services

Essential public and individual services
Health protection
Health Promotion
Disease Prevention
Diagnosis
Treatment
Long-term care
Rehabilitation
Palliative care

Source: WWorld Health Organization. Regional Office for Europe & Health Services Delivery Programme, Division of Health Systems and Public Health. (2013). ROADMAP. Strengthening people-centered health systems in the WHO European Region: A Framework for Action towards Coordinated/Integrated Health Services Delivery (CIHSD). Copenhagen: WHO Regional Ofce for Europe. <http://www.who.int/iris/handle/10665/108628>.

2.5.4. Regulations in the field of pharmaceuticals and medical devices

2.5.4.1. General framework for the regulation of opioid drugs and medical devices

The Law on pharmaceutical activity no. 1456 of 25.05.1993 establishes the specific regulations for the production, import and distribution of narcotic substances. It also points out that the Medicines and Medical Devices Agency (MMDA) is responsible for licensing the pharmaceutical activities, including for narcotics and/or psychotropic preparations. The law determines deadline requirements for condition examination and issuing of authorization by the Permanent Committee on Drugs Control and for the license issue.

The regulations regarding the circulation of narcotic substances are established by law no. 382 of 06.05.1999. They stipulate the main concepts, the responsible authorities, the requirements for authorizing the movement of these type of pharmaceuticals, the conditions for suspending or withdrawing of the authorization for the narcotic substances import/export; the requirements for the packaging and markings both on the outside and on the inside of the package, the entities responsible for establishing the list and quantities of substances put into circulation on the territory of the Republic of Moldova and their correlation with the Single UN Conventions from 1961 and 1971; the collaboration and reporting to special international institutions - International Drug Control Council. By the amendments to Law no. 382/1999 carried out in 2017, it was established that the MMDA is the responsible authority in the field of the circulation of narcotic, psychotropic substances and chemical precursors, and exercises its duties through the Permanent Committee on Drug Control. The committee has become a subdivision within the MMDA since 2017, having its activity regulation approved by the director of the MMDA. Previously, the Permanent Committee on Drug Control of the MoH was a delegatee within the Republican Narcology Dispensary as its subordinate subdivision⁴⁷. The determination of the narcotic, psychotropic substances, precursors and analogs, as well as the ethnobotanical products is carried out in the MMDA laboratory. The responsibility of the MMDA

⁴⁷ Order no. 478 of 09.07.2010 regarding the approval of the Regulation of the Permanent Committee on Drugs Control under the Ministry of Health.

Committee also covers the import and export authorization of narcotic and psychotropic substances and the monitoring of these processes. The placing of drugs containing narcotic, psychotropic and precursor substances on the pharmaceutical market is made under the authorization from the MMDA Committee and the import license, once the pharmaceutical products have received the marketing authorization from the MMDA. The export of narcotic and psychotropic substances is also subject to authorization. The authorization for the import/export of narcotic, psychotropic and/or precursor substances is issued free of charge, for each import/export case⁴⁸.

The mode of requesting, granting, suspending and withdrawing the authorization for the import/export of narcotic, psychotropic substances and precursors is established by the law no.160 of 22.07.2011 on the regulation by authorization of the entrepreneur activity. The control of the legal circulation of the narcotic, psychotropic and precursor substances, as well as the control of the activity of the authorization/license holders that carry out activities related to the circulation of narcotic, psychotropic substances and precursors is the responsibility of NPHA, which plans and carries out control activities in accordance with the provisions of the law. no.131/2012 on the state control over the entrepreneurial activity. The tables and lists of narcotic, psychotropic substances and their precursors are subject to control and are approved by the Government decision⁴⁹, which is practically modified annually.

Through its normative acts, the MoH⁵⁰ established that the provision of medicines and consumables necessary for the provision of palliative care services is carried out by the means of CHF and other sources provided by law. In 2016 the Government approved the National Cancer Control Program for 2016-2025 (see section 2.3.)⁵¹, a document that includes a specific objective related to access to devices and opioid drugs needed in pain management. Moreover, this document provides two specific indicators for the monitoring of the access to essential medicines and medical devices: i) the level of supply with specialized devices in palliative care,% and ii) the level of supply with essential pain relief drugs,%.

The placement on the pharmaceutical market and the monitoring of the harmlessness of the medical devices are regulated by the law no. 102 of 09.06.2017 on the medical devices⁵². The law provides for two procedures for placing medical devices on the market: i) medical devices bearing the EC marking are subject to the notification procedure⁵³; ii) medical devices that do not have the EC mark⁵⁴ are subject to conformity assessment and registration. All medical devices admitted on the market are registered in the State Register of Medical Devices. The MoHLSP is responsible for developing, promoting and coordinating the implementation of public policies in the field of medical devices. MMDA is responsible for standardizing medical devices in order to adjust national standards for medical devices to European directives and for coordinating regulations and norms in the field of medical devices. NPHA, as in the pharmaceutical field, is responsible for the supervision and control over medical devices. The Center for Centralized Health Procurement (CCHP) is responsible of centralized procurement of medical devices and maintenance services.

2.5.4.2. Selection and estimation of drug needs

The regulatory framework for the selection and formulation of the list of medicines and medical devices for palliative care consists of the National Clinical Protocols in the field of palliative care and NPCS (see section 2.5.2), National List of Essential Medicines (NLEM), *Regulation regarding the procurement of medicines, other medical products, medical devices, specialized medical transport, maintenance services and information systems included in the Medical Register, medical waste treatment and disposal services for the needs of the health system*⁵⁵ and the MoH Order no.948 of 10.08.2018 on "Organization of centralized procurement".

48 Art.211 paragraph (6) of law no.382 of 06.05.1999 regarding the circulation of narcotic, psychotropic substances and precursors.

49 Government Decision no. 1088 of 05.10.2004 on the approval of tables and lists of narcotic, psychotropic substances and precursors subject to control.

50 MoH Order no. 154 of 01.06.2009 on the organization of Palliative Care Services and Order no. 1022 of 30.12.2015.

51 Government Decision no.1291 of 02.12.2016 on the National Cancer Control Program for 2016-2025.

52 <http://lex.justice.md/md/370883/>

53 MoHLSP Order no. A07.PS-01, Rg 04-201 of 13.10.2017 on the approval of the administrative procedures for the notification of medical devices bearing the EC mark.

54 MoH Order no.212 of 12.03.2019 on the regulation of the registration of medical devices that do not have the CE mark.

55 Annex no. 3 to the Government Decision no. 1128 of October 10, 2016 on the Center for centralized public health procurement.

The MoH approved the latest version of the NLEM in 2011⁵⁶, while WHO has approved 4 editions of the list (2013, 2015, 2017, 2019) since then. When comparing the NLEM and the WHO EML, there are differences in classification of palliative care medicines. Since 2013 the medicines for palliative care have been included in the WHO EML separately from the other medicines in the list. Since the NLEM has not been reviewed for 8 years, palliative care medicines are not classified under a separate group in NLEM. The 2019 edition of WHO EML⁵⁷ contains 22 ICDs for palliative care medicines. WHO recommends several pharmaceutical forms and concentrations for these 22 ICDs of medicines. Thus, the WHO EML provides about 76 medicines (DCI + pharmaceutical form + concentration) that can be prescribed depending on the age (child/adult) and the palliative condition of the patient. 34 of 76 medicines are not registered in the Republic of Moldova and may be imported only under the special conditions provided by the law on pharmaceutical activity⁵⁸, another 47 medicines do not have the producer price registered⁵⁹ in the National Catalog of producer prices for medicines, and 32 medicines have not been included in the NLEM since 2011 (Table 3). From the analysis of the 22 ICDs recommended by WHO EML for palliative care, 4 ICDs are opioid-containing and are represented by 24 drugs out of a total of 76. Of these 24 drugs 12 are not registered in the RM, and 20 drugs do not have their manufacturer price registered in the National Catalog of Manufacturer Prices for Medicines, another 11 are not found in the NLEM. From the list of opioid medicines procured within the NCCP there were 2 drugs that are not part of the WHO EML, but they are supplied for both the NCCP and PHCI needs. These are: tramadol, 50 mg tablets and 100 mg / 2ml injectable solutions and omnopone injectable solution (morphine hydrochloride + codeine hydrochloride + papaverine hydrochloride). It should be noted that the PHCIs opt for the inclusion of the omnopone in health procurement, considering that it consists of 48-50% of morphine and 32-35% of other alkaloids such as codeine, thebaine, papaverine and narcotine.

In 2017, the MoHLSP received support in the estimation of opioid needs used in palliative care⁶⁰. Following this support, at the end of March 2017, the MoH approved the Methodical Recommendations for estimating opioid needs used in palliative care⁶¹. This document address all palliative care providers, regardless of the type of ownership and the form of organization. The provisions of the ministerial order establish that providers are responsible for estimating the needs of opioid medicines for palliative care and for submitting them to the public procurement authority. The primary, emergency and community health care directorate within the MoHLSP and the Specialized Commission in the field of palliative care and home healthcare under the MoHLSP are responsible for the consultative-methodical support in implementing these recommendations. The methodology set forth guidelines for the providers regarding the planning of the opioid medicines needs, the identification of the relevant methods of needs estimation, the obligatory variables that are required to be considered when estimating the needs, the particularities of the estimation of the need for the services offered under inpatient and ambulatory conditions.

Another ministerial normative act establishes the framework for procurement order of medicines and medical devices in the health system⁶² by approving the Regulation on the method of establishing and approval of the medicines and medical devices needs for the implementation of the National Programs and the treatment of rare diseases, as well as the action plan on centralized procurement of medicines, parapharmaceuticals and medical devices, list of specialists responsible for the procurement of medicines organized by the Center for Centralized Health Procurement (CCHP)⁶³. Therefore, these two ministerial normative acts, the MoH Order no.268/2017 and the MoHLSP Order no. 948/2018, establish two ways of submitting the opioid drugs procurement application (the first one - through the

56 Order no. 144 of 28.02.2011 on the modification of annex no. 2 to the order of the Ministry of Health no. 162 of April 23, 2007 "on the "Approval of the regulation and the list of essential medicines".

57 WHO EML 2019 Edition <https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?ua=1> (accessed 18.09.2019).

58 Art.11 paragraph (7) of Law no. 1456 of 25.05.1993 on pharmaceutical activity.

59 The price of goods purchased duty-free (ex works), which was declared by the manufacturer or by its official representative for approval and inclusion in the National Catalog of Manufacturer Prices for Medicines - point 3 of the Regulation on the mode of approval and registration of manufacturer prices for medicines, approved by Government Decision no.525 of 22.07.2010.

60 The project "Control of Severe Chronic Pain through Adequate Access to Opioid Medication in the Republic of Moldova", carried out by the National Palliative Treatment Association, with the financial support of the Soros-Moldova Foundation.

61 MoH Order no.268 of 31.03.2017 on the approval of the Methodical recommendations for estimating the opioid needs used in palliative care.

62 MoHLSP Order no.948 of 10.08.2018 on the organization of centralized procurement.

63 Ibid.

national programs and the other - through the PHCI budgets), but they do not provide a mechanism for verifying overlapping positions in order to exclude the risks of overestimating or underestimating the needs, as well as the risk of leaving non-oncological palliative patients overboard.

In practice, the need for opioid drugs, obtained from the state budget sources within the NCCP is estimated by the PHCI and subsequently consolidated and verified by the pain management specialist within the Palliative Care and Psychological Support Service of the Oncological Institute. The oncologist and the managing pharmacist usually draw up the list at the level of PHCI. The reality is that PHCI doctors advocate for injectable forms, despite the fact that the national clinical protocol "Palliative Care - Pain in Cancer"⁶⁴ provides for the prescription and release of solid forms of opioid drugs, as well. It is worth mentioning that in 2012 the MoH approved the Instructions regarding the Administration of the Oral Morphine⁶⁵, which provides the initial dosing method, the frequency, the dosage in acute conditions, the dose adjustments, etc. for the morphine with immediate release and for the one with the continuous release. The instruction also provides recommendations for the approximate equivalent doses of stage III opioids, the approximate equivalence of oral analgesics against morphine, adverse effects during morphine treatment, steps in the pharmacological treatment of cancer pain and monitoring of patients in pain. The analysis of procurement of medicines containing narcotic substances prescribed in palliative care indicates that the oral pharmaceutical forms of morphine have been included in the NCCP procurement list only starting with 2016⁶⁶.

The collection of data on the opioid medicine needs for NCCP is based on a document which may be modified annually, depending on the situation and the necessary support data, and is not officially approved. Usually, the opioid medicine data collection form includes the number of beneficiaries, the list and the need for opioid medicine, and the remaining stock. Through this form, in addition to the one specified by the Regulation for centralized procurement, the specialist in charge of pain management within the Palliative Care and Psychological Support Service of the Oncological Institute requests additional data which is necessary to correct/validate the data on the need for opioid medicines at the level of territorial administrative units (UAT). In the absence of a comprehensive information system (within the NCCP) for the management of opioid medications and a standardized electronic tool for estimating and planning the procurement of opioid medications, as well as the lack of a reporting, monitoring and evaluation system for medication management poses the medication ordering process to a great amount of risks.

The completion of the list of medicines and medical devices for palliative care that is covered by PHCIs is placed under their own responsibility through the Institutional Pharmacotherapeutic Committee. PHCIs submit the information on medication needs to CCHP, which launches a call to tender for the supply of medicines and medical devices based on a consolidated list from all the PHCIs.

Despite the fact that the MoHLSP has approved several normative acts⁶⁷ for estimating the needs for opioids used in palliative care, so far no pre-established form is approved, following the validation by all providers, for collecting consolidated and disaggregated data regarding the management of opioid medication. The list of indicators for the management of opioid medication to reduce the risks of needs estimation was not developed. There are no such indicators as: i) the period when the opioid medications are not available during the year of administration; ii) the stock of expired opioid medications; iii) the rational consumption of opioid medications; iv) the factual coverage rate of the estimated needs for opioid drugs; v) the percentage of the modification of the treatment schemes vs. the estimated treatment schemes included in the procurement plan, etc. There is no integrated information system for the management of opioid medications and an electronic tool for estimating the needs of opioids with a holistic approach to all classical and specific variables.

2.5.4.3 Medicines and medical devices procurement

The procurements of medicines for palliative care are covered by two sources of financing: i) Opioid medications paid from the state budget, used by NCCP to support the oncological patients in outpatient

64 MoH Order no. 1181 of 28.10.2014 on the updating of several national clinical protocols.

65 MoH Order no. 187 of 29.02.2012 on the approval of the Instruction regarding the administration of the oral morphine

66 The data offered by the Agency for Medicines and Medical Devices by letter no. Rg 02-2507 from 06.09.2019.

67 MoH Order no. 268 of 31.03.2017 on the approval of the Methodological recommendations for estimation of the needs of the opioids in palliative care and the MoHLSP Order no.948 of 10.08.2018 on the organization of centralized procurement.

conditions; and ii) Opioids and other medications prescribed in ambulatory palliative care procured from the PHCI funds.

Medicines and medical devices procurements are carried out by tendering process organized by the CCHP, for both inpatient and outpatient care needs. CCHP plans and conducts the procedures for *public procurement of medicines, other medical products, medical devices, etc., assigns public procurement contracts, evaluates and supervises the execution of the contracts for public procurement of medicines, other medical products, medical devices, etc. for the needs of the health system, these being covered by the state funds, by the budges of LPAA, public institutions and CHIF, as well as by the funds provided through external loans reported to the direct or guaranteed state debts*⁶⁸. Although CCHP makes centralized procurements of opioid medications from the state budget for NCCP outpatient needs and from the PHCI budget for hospital use, it is not a common practice to consolidate the amounts of medicines in order to reduce the expenses and make the tender for procurement more attractive.

In the period 2007-2019 the list of opioid medications for outpatient care was diversified and enlarged from 3 drugs in 2007 to 12 in 2019 (figure 2.), the medicines being procured from the state budget to meet the NCCP needs. According to CCHP, the 12 drugs procured in 2019 included 4 DCI (fentanyl, morphine, tramadol and omnopon) presented in 12 pharmaceutical forms, compared to 2015 when only 3 drugs were procured that included 3 DCI (morphine, tramadol and omnopon) in two injectable pharmaceutical forms and a solid one. The state budget for the procurement of opioid medications, according to the signed contracts, constituted an approximately constant figure: in 2015 - 4500641.77 lei were allocated, in 2017 - 4152519.20 lei and in 2018- 4188668.90 lei, except 2016, when 6136976.23 lei were spent⁶⁹. The results of the public tender no.18 / 03193 of 18.09.2018⁷⁰, organized by CCHP for the procurement of medicines based on the PHCI needs, showed that the latter requested only 3 medications for pain management - morphine, omnophone, tramadol. The results of public tenders from previous years showed that public hospitals requested the same number and denomination of medicines⁷¹. It should be mentioned that in the list of medicines procured on centralized basis by the CCHP for the needs of public hospitals there were also non-opioid, anti-inflammatory medications and symptom-control medications prescribed for palliative patients.

Under ambulatory conditions, a list of compensated medicines are reimbursed by NHIC from the CHIF funds, which includes 148⁷² INNs, of which 6 INNs can be prescribed including for palliative conditions (Table 3). However, the above mentioned 6 INNs (Acetylsalicylic acid, Paracetamol, Amitriptyline, Dexamethazon, Diazepam, Haloperidol) cannot be distributed to all palliative patients, because the principle of inclusion and prescription of medications reimbursement by NHIC is per disease and they can be prescribed only if the patient suffers from the disease provided in the list of compensated drugs. Thus, it can be noted that NHIC funds do not cover the non-steroidal, anti-inflammatory and non-opioid analgesic medications as well as symptom-control medications used in the care of all palliative patients, because the NHIC list of compensated medicines does not set forth a separate group of medicines intended for palliative care.

68 Annex no. 1 to Government Decision no. 1128 of 10.10.2016 regarding the Center for Centralized Health Procurement.

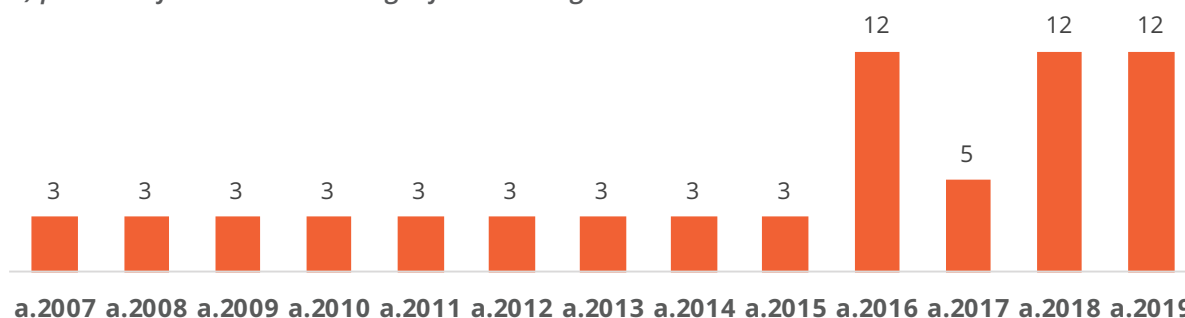
69 The data offered by the Center for Centralized Health Procurement to the PAS Center by letter no.Rg02-2507 from 06.09.2019.

70 http://capcs.md/wp-content/uploads/2016/10/Rezultatele-Licitatiei-publice-nr.-18_03193.pdf (accessed 19.09.2019).

71 <http://capcs.md/wp-content/uploads/2016/10/Rezultatele-Licita-iei-publice-nr.-18-00281-din-07.03.2018.pdf>;
<http://capcs.md/wp-content/uploads/2016/10/Results-LP-no.-17-01869.pdf> (accessed 19.09.2019).

72 Annual report on the execution of the compulsory health care insurance funds, 2018, NHIC http://cnam.md/httpdocs/editorDir/fle/RapoarteActivitate_anual/2019/Raport_anual_2018.pdf

Figure 2. The number of opioid medications (INN + concentration + pharmaceutical form + packaging size) procured from the state budget funds during 2007-2019



Source: Center for Centralized Health Procurement

Table 3. Availability of medicines for palliative care on the pharmaceutical market, in the list of compensated medicines, in the national list of essential medicines and in the list of medicines procured on centralized basis for the needs of PHCI in 2018

No. INN	Medicines recommended in palliative care, according to the WHO Essential Medicines List, 2019 edition	Registered in the Republic of Moldova (number of authorizations)	Registered in the Price Catalogue (number of authorizations)	The List of Compensated Medicines	National List of Essential Medicines	List of Medicines for PHCI/ centralized procurement, 2018
1	Acetylsalicylic acid, Suppositories 50 mg	0	0	No	Yes	No
	Acetylsalicylic acid, Suppositories 150 mg.	0	0	No	Yes	No
	Acetylsalicylic acid, tablets 100 mg	5	3	Yes	Yes	No
	Acetylsalicylic acid, tablets 150 mg.	6	3	Yes	No	Yes
	Acetylsalicylic acid, tablets 500 mg.	9	3	No	Yes	Yes
	Acetylsalicylic acid, tablets 1500 mg.	0	0	No	No	No
2	Ibuprofen, Oral liquid: 200 mg/5 mL.	14	6	No	No	Yes
	Ibuprofen, tablets 200 mg;	14	8	No	Yes	Yes
	Ibuprofen, tablets 400 mg;	17	6	No	Yes	Yes
	Ibuprofen, tablets 600 mg;	1	0	No	No	No
3	Paracetamol*oral liquid: 120 mg/5 mL; 125 mg/5 mL.	7	7	Yes	Yes	Yes
	Paracetamol* Suppositories 100 mg.	2	1	Yes	Yes	Yes
	Paracetamol* Tablets 100 mg	0	0	No	Yes	No
	Paracetamol* Tablets 200 mg	0	0	Yes	No	Yes
	Paracetamol* Tablets 500 mg.	4	3	Yes	Yes	Yes
4	Codeine, Tablets 30 mg (phosphat).	0	0	No	Yes	No
5	Fentanyl* , Transdermal patch: 12 micrograms/hr;	0	0	No	No	No
	Fentanyl* , Transdermal patch: 25 micrograms/hr;	1	1	No	Yes	No
	Fentanyl* , Transdermal patch: 50 micrograms/hr;	1	1	No	Yes	No
	Fentanyl* , Transdermal patch: 75 micrograms/hr;	0	0	No	Yes	No
	Fentanyl* , Transdermal patch: 100 micrograms/hr	0	0	No	Yes	No
6	Morphine*pellets (slow-release): 20 mg (morphine sulfate);	0	0	No	No	No
	Morphine*pellets (slow-release): 30 mg (morphine sulfate);	0	0	No	No	No
	Morphine*pellets (slow-release): 60 mg (morphine sulfate);	0	0	No	No	No
	Morphine*pellets (slow-release): 200 mg (morphine sulfate);	0	0	No	No	No
	Morphine injectable solution: 10 mg (morphine hydrochloride or morphine sulfate) in ampules 1ml;	1	1	No	Yes	Yes

	Morphine oral liquid de 10 mg (morphine hydrochloride or morphine sulfate)/5 ml;	2	0	No	Yes	No
	Morphine tablets (slow release) 20mg (morphine hydrochloride or morphine sulfate);	1	0	No	Yes	No
	Morphine tablets (slow release) 30 mg (morphin hydrochloride or morphine sulfate);	1	0	No	Yes	No
	Morphine tablets (slow release) 60 mg (morphin hydrochloride or morphine sulfate);	1	0	No	Yes	No
	Morphine tablets (slow release) 10 mg (morphine hydrochloride or morphine sulfate);	1	0	No	Yes	No
	Morphine tablets (slow release) 200mg (morphine hydrochloride or morphine sulfate);	0	0	No	Yes	No
	Morphine tablets (immediate release) 10 mg (morphine sulfate). *Alternatives limited to hydromorphone and oxycodone	2	0	No	Yes	No
7	Methadone, tablets: 5 mg; (hydrochloride);	1	0	No	No	No
	Methadone, tablets: 10 mg (hydrochloride);	1	0	No	No	No
	Methadone, oral solution: 5mg/ 5mL; (as hydrochloride)	1	0	No	No	No
	Methadone, oral solution: 10mg/ 5mL (as hydrochloride)	0	0	No	No	No
	Methadone, concentrate for oral solution: 5 mg/ mL; 10mg/ mL (as hydrochloride)	0	0	No	No	No
	Methadone, concentrate for oral solution: 10mg/ mL (as hydrochloride)	0	0	No	No	No
8	Amitriptyline, Tablets 10 mg.	0	0	No	No	No
	Amitriptyline, Tablets 25 mg.	2	2	Yes	Yes	Yes
	Amitriptyline, Tablets: 75 mg	0	0	No	No	No
9	Ciclizine [c], injectable solution 50 mg/ ml; tablets 50 mg.	0	0	No	No	No
10	Dexamethazone, injectable solution 4 mg/ ml in ampoules 1 ml (disodium phosphate salt);	11	9	Yes	Yes	Yes
	Dexamethazone, oral solution 2 mg/5 ml;	0	0	No	No	Yes
	Dexamethazon, Tablets 2 mg [c]; 4 mg.	0	0	No	No	No
	Diazepam, injectable solution 5 mg/ ml;	3	1	No	Yes	Yes
11	Diazepam, oral liquid 2 mg/5 ml;	0	0	No	Yes	No
	Diazepam, rectal solution 2.5 mg; 5 mg; 10 mg.	5	0	Yes	Yes	Yes
	Diazepam, tablets 5 mg	4	2	Yes	Yes	Yes
	Diazepam, tablets 10 mg.	0	0	No	No	No
12	Docusate sodium,capsule 100 mg;	0	0	No	No	No
	Docusate sodium, oral liquid 50 mg/5 ml.	0	0	No	No	No
13	Fluoxetine tablets 20 mg (as hydrochloride).	1	1	No	Yes	Yes
14	Haloperidol, injectable solution 5 mg, fio11 ml;	1	1	No	Yes	Yes
	Haloperidol, oral liquid 2 mg/ ml;	1	0	No	Yes	No
	Haloperidol, tablets 0.5 mg;	0	0	Yes	No	No
	Haloperidol, tablets 2mg;	0	0	Yes	Yes	No
	Haloperidol, tablets 5 mg.	1	1	Yes	Yes	Yes
15	Hyoscine butylbromide, injectable solution 20 mg/ml.	1	1	No	No	Yes

16	Hyoscine hydrobromide [c], injectable solution 400 µg/ml;	0	0	No	No	No
	Hyoscine hydrobromide [c], injectable solution 600 µg/mL.	0	0	No	No	No
17	Lactulose [c], oral liquid 3.1–3.7 g/5 mL.	5	2	No	Yes	Yes
18	Loperamid, tablets 2 mg.	6	4	No	Yes	Yes
19	Metoclopramide, injectable solution: 5 mg (hydrochloride)/ml in ampules 2 ml;	6	4	No	Yes	Yes
	Metoclopramide, oral liquid 5 mg/5 mL.	0	0	No	No	No
	Metoclopramide, tablets 10 mg (hydrochloride).	1	1	No	Yes	Yes
20	Midazolam, injectable solution 1 mg/mL; 5 mg/ mL.	1	0	No	Yes	Yes
	Midazolam, tablets /capsules 7.5 mg;	0	0	No	No	No
	Midazolam, tablets /capsules 15 mg.	0	0	No	No	No
	Midazolam, oral liquid 2mg/ mL [c].	0	0	No	No	No
21	Ondansetron [c] a, Oral liquid 4 mg base/5 ml;	1	1	No	Yes	Yes
	Ondansetron [c] a, injectable solution 2 mg base/ ml in ampules 2 ml (as hydrochloride).	6	3	No	Yes	Yes
	Ondansetron [c] a, tablets eq 4 mg base;	1	1	No	Yes	No
	Ondansetron [c] a, eq 8 mg base. a >1 month.	1	1	No	Yes	Yes
22	Senna	1	1	No	Yes	Yes

Source: The data collected in this study based on the normative acts and public information of the MoHLS, NHIC, MMDA and CCHP.

When providing palliative care services in units with beds, the supply of medical devices is ensured from the financial sources of the providers, based on the contract concluded with the NHIC. The procurement of these products is performed on centralized-basis by the CCHP. The provision of medical devices within the NCCP is ensured from the sources of the state budget, based on the centralized procurements organized by the CCHP.

According to CCHP, 73 000 colostomy bags (systems) were procured for the needs of the Oncological Institute for 2019⁷³. According to the letter no. 02-07/1116 of 30.10.2018 of the Oncological Institute, 80000 units of ostomy systems⁷⁴ have been requested for tendering for 2018. Data on the centralized procurement of colostomy bags and ostomy systems by the CCHP from the sources of other public palliative care providers were not identified on the CCHP website.

According to the existing public information on the procurement of medical devices for the NCCP from the state budget, it was confirmed that there was a request for centralized procurement of sterile syringes with 5 or 6 ml needles, 3 components in the amount of 10,000 units⁷⁵ only for 2019.

The NPCS approves the structure and equipping of home palliative care services, which include an extensive set of recommended medical devices. However, in 28 of the 37 TAUs (see section 5.3.3.) there are no providers of specialized home palliative care services, which means that people who need palliative care cannot have access to the necessary medical devices. It should be noted that the list of drugs compensated by NHIC does not include medical devices used in palliative care.

⁷³ <http://capcs.md/wp-content/uploads/2019/04/Documentatia-de-Atributie-LP19.00028.signed.pdf> (as accessed on 27.09.2019)

⁷⁴ <https://mtender.gov.md/tenders/ocds-b3wdp1-MD-1541065406055?tab=clarification> (as accessed on 27.09.2019).

⁷⁵ <http://capcs.md/wp-content/uploads/2016/10/18-3953Control-cancerului.pdf> (as accessed on 27.09.2019).

2.5.4.4. Prescription regulation

The legislative amendments of 2008⁷⁶ facilitated access to medications containing narcotic and psychotropic substances. Thus, it has been established that each prescription note should provide the amount of medicines needed for 30 days of treatment. It was also specified that the receipt with prescription of substances included in the table no. II (Narcotic substances included in lists no. 1 and no. 2 of the Single Convention on Drugs of 1961. List no.2. Psychotropic substances included in the list no. 2 of The Convention on Psychotropic Substances of 1971. Substances included in other lists and tables of the above mentioned conventions, with the exception of the substances included in the table no.1, where appropriate) is submitted at the pharmacy within 10 days from the date of prescription, and the receipt with medication containing the substances specified in the table no. III (Narcotic substances included in list no.3 of the Single Convention on Drugs of 1961. List no.2. Psychotropic substances included in list no.3 of the Convention on Psychotropic Substances of 1971. List no.3. Psychotropic substances included in list no. 4 of the Convention on Psychotropic Substances of 1971. Other substances, where appropriate) – is submitted within 30 days.

In 2012 the MoH issued a normative act⁷⁷, by which it approved the principles of prescribing drugs containing narcotic and psychotropic substances. Thus, the medications containing narcotic and psychotropic substances⁷⁸, which are under international control on the territory of the Republic of Moldova, according to the International Conventions, and the Government Decision no. 1088 of 05.10.2004 (Table II, lists no. 1 and 2) are prescribed on the prescription form no.2 of strict evidence (Annex to the Particulars of prescribing medication containing narcotic and psychotropic substances). It is permitted to prescribe such medication and to release the necessary quantities for a 30 day treatment period. The doctor may issue a new prescription for the same patient, before the expiry of the 30-day treatment period, but not earlier than the expiry of the validity period of the previous prescription - if the medicine supply is exhausted or if changes in the health condition occur during the treatment period and the patient requires adjustment of doses or medication. A single prescription form no. 2 of strict evidence allows for only one drug from the mentioned groups to be prescribed. Such prescriptions are valid for submission at the pharmacy within 10 days. When prescribing, the "General rules for prescribing medicines", approved by the same normative act, should be considered. These rules stipulate that the medicines are prescribed by the HCl doctors, regardless of the subordination and the form of ownership under which they activate, in case of outpatient treatment it is further specified that the choice of the appropriate medication and doses, as well as the accurate fulfillment of the prescription, rests with the responsibility of the family doctor or the specialist physician. It resides in the fact that all doctors have the right to prescribe medicines, including opioids, but in reality, the doctors who provide palliative care in the non-governmental sector and who have signed contracts with NHIC for the provision of these services, are not empowered to prescribe opioid medications. In fact, the doctors providing palliative care in the nongovernmental sector cannot prescribe any drugs from the list of those compensated by NHIC and any drugs that could be used for palliative patients.

The drugs containing narcotic and psychotropic substances, which are under international control on the territory of the Republic of Moldova in accordance with the International Conventions (Table III, lists no. 1, no. 2 and no. 3), as well as the medicines classified as precursors, approved by the Government Decision no. 1088 of 05.10.2004, are prescribed on the medicine prescription and release form no.1 (Annex no.1 to the General Rules for prescribing medicines) which is initialed by the doctor and further enacted with the stamp "For prescriptions". A single prescription form no.1 can be used to prescribe and release only one medication containing active substances from the mentioned lists, in the quantities needed for up to 30 day treatment period. Such prescriptions are valid for submission in the pharmacy within 30 days. The enacting terms of the above-mentioned normative act order to the heads of the territorial health authorities and leaders of HCIs, regardless of the type of ownership, to ensure the prescription of the narcotic medications to the patients who, according to the submitted transfer request, are registered with the HCl as temporary residents. Thus, if a recipient of opioid medication temporarily changes his or her place of residence, access to medicines cannot be restricted.

76 Law no.246 of 27.11.2008 for amending and supplementing Law no. 382-XIV of May 6, 1999 on the circulation of narcotic and psychotropic substances and precursors.

77 MoH Order no.960 from 01.10.2012 on Prescribing and releasing medicines, Annex no.2

78 Annex no. 2 to the Order of the MoH no. 960 of 01.10.2012.

2.6. Informing the beneficiaries

The patient's right to information is specified by the general legislative framework regarding the patient's rights and responsibilities⁷⁹. The palliative care beneficiaries have the right to the information on health service providers, the profile, volume, quality, cost and method of service provision, as well as to the information regarding the results of examined complaints and requests in the manner established by the legislation. Certain regulations that ensure the informing of the palliative care beneficiaries are stipulated in the NPCS. The nominated standard represents a series of basic requirements, which are meant to ensure the supply of quality palliative services. However, the regulations for informing beneficiaries about palliative care stipulated in the NPCS are not provided as well-defined activities, they are fragmented and do not clearly establish the manner of information delivery (Table 4.). As a result, the NPCS does not contain any clear standard for informing the population and promoting services, including in forms accessible to the beneficiaries of palliative care services and their families, depending on the level of palliative care intervention.

Table 4. Regulations on the beneficiary information according to the National Palliative Care Standard

Standard 2. Palliative care providers have a protocol for selecting patients from the waiting list.	(2) Palliative care service providers shall make the information about offered services available to the public.
Standard 4. The beneficiaries of palliative care services are protected by the law on the rights of patients.	(3) Patients have the right to receive correct information regarding the stage of their disease, the prognosis, and the available treatment, as well as its benefit in relation to the side effects.
Standard 11. Training activities are an integral part of palliative care and shall be provided at an appropriate level: for professionals, volunteers, patients, families, carers and the public.	(5) Palliative care services provide educational materials and information resources to patients, families, carers and the population.

Source: MoH Order No. 884 of 30.12.2010 "On the approval of the National Palliative Care Standard"

The Regulation on the organization of palliative care services⁸⁰ also does not establish clearly the responsibilities for informing palliative care beneficiaries (Table 5.). The MoH charged the PHCI and healthcare managers within the LPAA with the responsibility to inform the population about palliative care, but did not establish efficient procedures and means by which they are to inform the population. The regulation itself does not stipulate clearly how and by what means the beneficiaries of palliative care services or their legal representatives can access (obtain) the information regarding the palliative care service provider, the profile, amount, quality, cost and method of palliative service provision. The insufficient and incoherent nature of the regulations regarding the information of beneficiaries leads to a low level of knowledge about palliative care. A study among the beneficiaries of palliative care services⁸¹ reveals that less than half of the interviewees (49%) know the term "palliative care". The insufficient information regarding palliative care is shown by the fact that only 14% of beneficiaries know the full range of palliative services that they can and have the right to receive under NHIC insurance.

⁷⁹ Law no.263 of 27.10.2005 on the rights and responsibilities of the patient.

⁸⁰ MoH Order No. 1022 of 30.12.2015 on the organization of palliative care services.

⁸¹ Danii Olga, Lilia Plugaru. Access and quality of palliative care services in the Republic of Moldova. Quantitative study. OPINIA Independent Sociological and Information Service. 2019.

Table 5. Regulations regarding beneficiary information on the legal provisions regarding the organization of palliative care services

The ordering part:	
The heads of public health institutions, of district Health Centers/Family Healthcare Centers and rural autonomous Health Centers, the chiefs of the Health Directorate of the Chisinau Municipal Council, the Health and Social Protection Directorate of the TAU Gagauzia, the Health Department of Balti Municipality Council:	3) ensure, through family doctors and community nurses/family nurses, the identification and information of the persons in need of palliative care living in the served localities in order to include them in home palliative care or refer the patients for palliative care to specialized institutions operating in the territory;
Regulation on the organization of palliative care services	
29. The beneficiaries of palliative care services are entitled to:	7) information regarding the provider of palliative care, the profile, amount, quality, cost and method of palliative service provision;
33. Palliative care providers are obliged:	<p>15) to provide information about the delivery of palliative care services under the contract signed with the National Healthcare Insurance Company, about the range of palliative care services provided, the obligations of the provider, as well as the obligations of the beneficiary;</p> <p>17) to ensure the patients or their legal representatives with access to information about provided palliative care services and to organize the beneficiaries' access to the book of complaints and notifications, numbered and initialed as provided by the normative acts in force.</p>

Source: MoH Order No. 884 of 30.12.2010 on the approval of the National Palliative Care Standard".

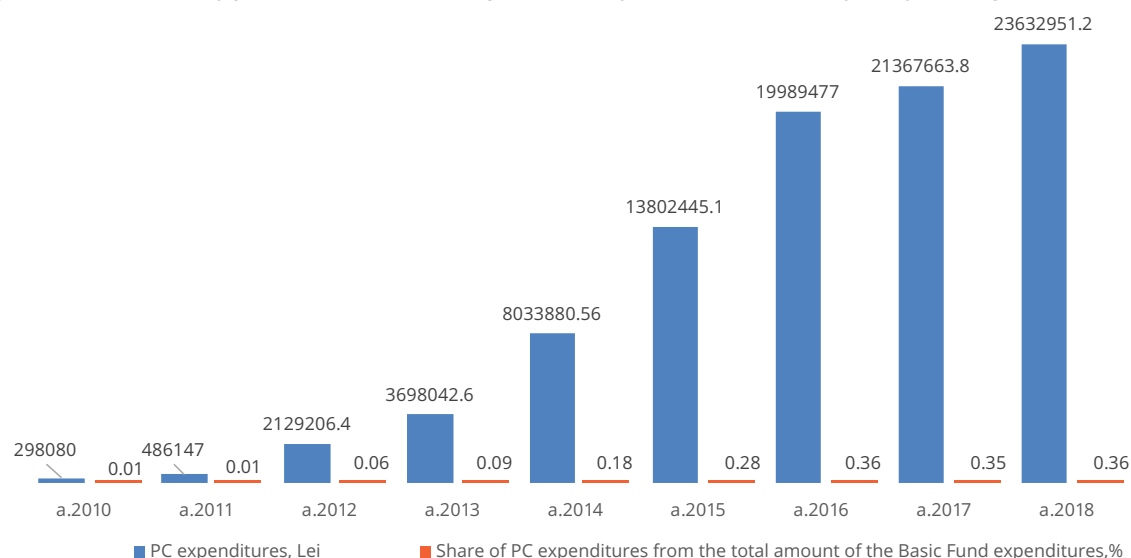
In 2018, with the financial support of the SFM and the Eurasia Program of the Open Society Foundations, the NPTA created the Guide for the information, education and self-care of the incurable patient, intended for the general public and aimed at providing guidance to patients and carers of persons suffering of incurable diseases. This guide comes to solve a number of problems related to the information and education on self-care of the patient and their family, but it cannot substitute the standards of beneficiary information which must imperatively contain the procedures for informing the population, the beneficiaries and their family and which must present the information clearly and in a format accessible to everyone at each level of palliative care services.

III. Financing of palliative care

3.1. Expenditures

During 2010-2018, a steady increase in public expenditures for palliative care services from CHIF was ensured (figure 3.). The registration of public expenses for palliative care services started in 2010, because until this year the palliative care services were financed only from external sources, and NHIC started to contract the providers of such services only after 2010 when the modification of the normative framework was enacted (see section 2.5.3.). The share of expenditures for palliative care services does not exceed 0.5% of the total budget of the CHI intended for healthcare service payment.

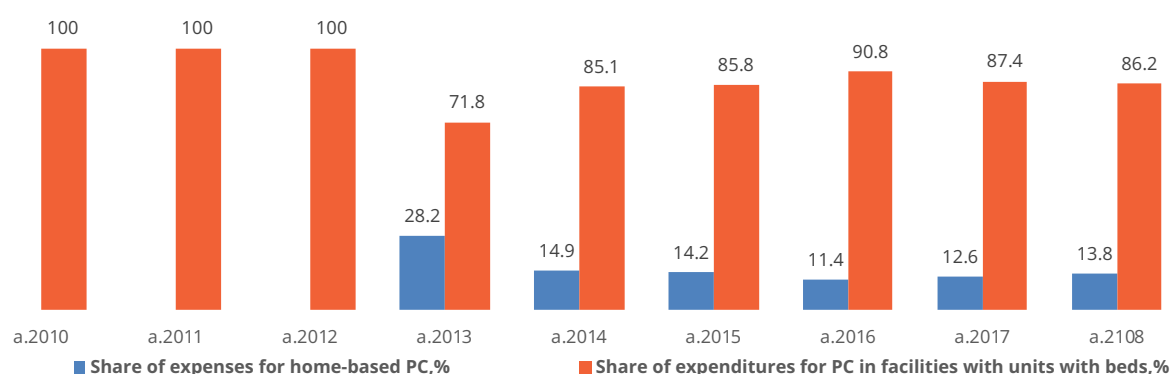
Figure 3. The share of palliative care (PC) expenditures from the CHI basic fund for the period 2010-2018



Source: Calculations made within this study based on data from the National Health Insurance Company

The expenditures for home palliative care services are decreasing, except for 2013, compared to the expenditures for inpatient/hospice care (figure 4.). Reduction of expenses for home palliative care services is not determined by any preferences for contracting hospital services, but by the small number of providers of home care services and their shortage in the most part of the country (see section 5.3.3.).

Figure 4. The share of expenditures for home and inpatient/hospice palliative care (PC) from the total expenditures for PC, 2010-2018, %

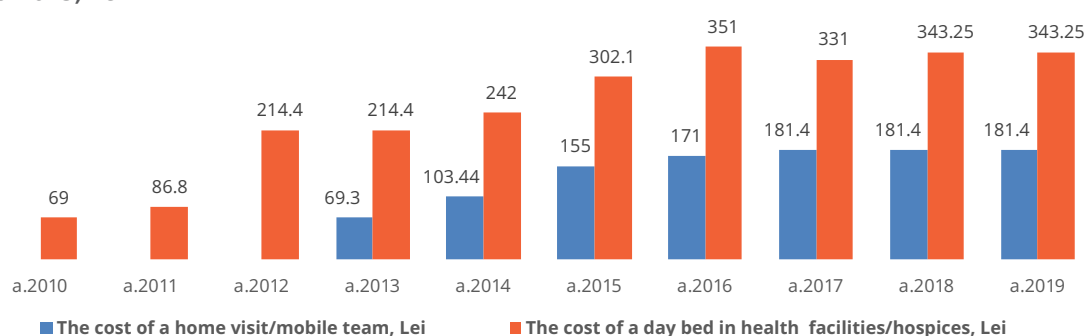


Source: Calculations made in this study are based on data provided by the National Health Insurance Company.

The costs for bed-day for palliative care are higher than for a home/mobile team care, as there are also bed maintenance costs. The prices for a day bed followed a constant increase in the period from 2010 to 2018, and for home/mobile team care the cost had increased since 2013, when NHIC started contracting home palliative care services, so in 2017 the cost per visit reached 181.40 lei, a value that remained constant in the following years (Figure 5.). In 2013, the cost of a home visit constituted 32% of the cost of a day bed, in 2017 - 55%, and in 2019 - 53%. This increase can be explained by improved methodology of cost estimation for health services (see section 3.3.).

Due to the lack of statistical data on the number of patients who benefited from palliative care services⁸² funded by NHIC, we could not estimate the costs of outpatient and inpatient/hospice service per patient.

Figure 5. The costs for palliative care paid by NHIC, depending on type of service delivery, in the period of 2010-2019, Lei



Source: National Health Insurance Company.

3.2. Sources of income

The CHIF are the main public sources assigned for palliative care available to the persons insured by NHIC. The financial sources from grants and fundraising have a significant share in the financing of palliative care, but at the time of this study there was no public data, from which to deduce their share at national level. The providers of palliative care services financed from external sources, with the exception of FF MS “Angelus Moldova”, report only to the donors and do not publish their financial reports on the official website. It should be mentioned that not a single non-government palliative care provider and only some of public providers share information on the received NHIC funds on their official web page, not even the information that must be made available as required by law (see section 3.5).

The Republic of Moldova has national health accounts, but their reports do not separate data according to the type of agencies that finance palliative care, but present it along with the other data on home health care. Moreover, in 2017, after the merger of the National Center for Health Management with other authorities and the creation of NPHA, the reports referring to the national health accounts have disappeared from the public space and it is not known whether the Republic of Moldova continues the implementation of these accounts.

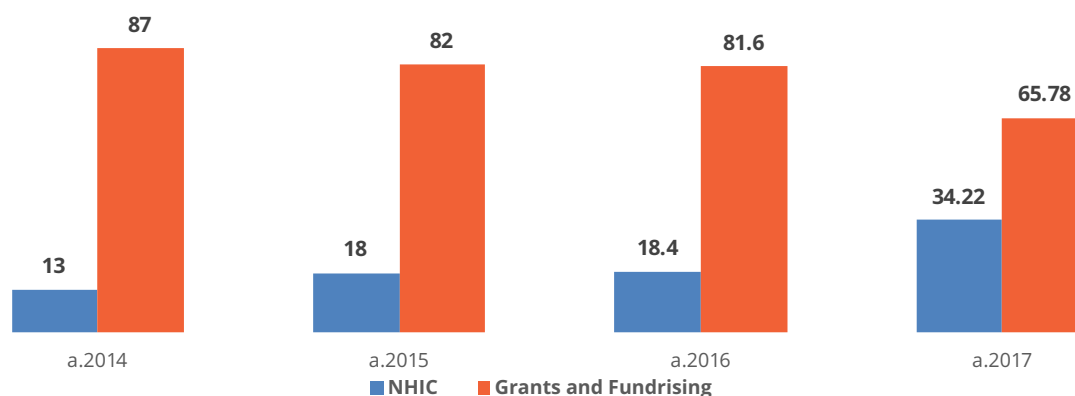
Although it is not possible to estimate at national level the share of funds for palliative care, according to their origin, from the activity reports of FF MS “Angelus Moldova”, published on the official website, it can be concluded that the financial sources from grants and fundraising have been declining in recent years, but they still remain the major source of financing. It should be noted that, although the income from NHIC sources have been constantly increasing during the last years, their share constituted only 1/3 of the total revenues of FF MS “Angelus Moldova” in 2017 (Figure 6.). It is worth mentioning that additionally to the resources provided by NHIC Hospices of Hope Moldova also carry out fundraising to support the activity of the National Network of Palliative Care Services created in 2017 in Ocnita, Orhei, Soroca and in 2018 expanded to Taraclia and Cahul⁸³. Therefore, the health authorities have not reached the financial arrangements for the sustainable development of palliative care which would economically efficient and equitably provided from public financial sources.

⁸² NHIC does not provide the record of the statistical data related to the number of patients who have benefited from home-based and inpatient/hospice palliative care services.

⁸³ <https://hospicesofhope.md/echipa-noastra/> (accessed 30.08.2019)

Direct payments for palliative care services would probably be another source of income for palliative care, especially since the private health expenses accounted for 48.6% of total health expenses⁸⁴ in the Republic of Moldova, but their amount cannot be estimated due to shortage of data. However, the direct payments are not a source of income for palliative care. A study among the beneficiaries of palliative care⁸⁵ reveals that 99% of the respondents did not incur any costs for specialized palliative care. Also, 93.6% of the respondents did not have to pay officially in the cashier of the Health Center for the palliative care services provided by the family doctor and health care assistants.

Figure 6. Share of financing based on the sources of income of FF MS "Angelus Moldova", in the period 2014-2017,%



Source: Activity reports of FF MS "Angelus Moldova" published on the official website.

3.3. Financial Regulatory Framework

The normative system of palliative care financing has evolved starting with only external financial support provided to non-governmental organizations and in 2010 moving to a new stage when the services began to be procured by NHIC (see section 2.5.3.). The first normative act establishing the costs for palliative care services was approved by the MoH in 2010⁸⁶. The second normative act was approved at the end of 2010 and it repealed the previous regulations by establishing the cost of one bed-day for palliative care in the amount of 93 lei⁸⁷ for 2011. The document also provided the cost per assisted case of palliative care for a period of 30 days in the amount of 2790 lei (93 lei x 30 days) and stipulated that palliative care providers will use this cost as a reference in the process of negotiating the services for 2011 with NHIC.

In 2012 the MoH repealed the previous order and establishes the cost of a home palliative care visit by the mobile team in the amount of 69.30 lei and the cost of day palliative care bed under hospital/hospice conditions in the amount of 214.40 lei⁸⁸ for 2012. Although for there were established costs for home palliative care services, no provider, from both the public and non-governmental sectors, was contracted by NHIC for the provision of outpatient services in 2012 (see section 5.3 .3.).

During 2012-2013, with the support of the SFM, a large project - "Costing for Change" - was launched, which provided a comprehensive estimate of the costs for palliative care services. Thus, the costs for hospital mobile team services, inpatient/hospice services and home palliative care services were determined based on the Methodology for establishing the rates for provision of medical and sanitary services, approved by the Government⁸⁹ (Table 6.). Personnel expenses were estimated depending

⁸⁴ Health for All Database (HFA-DB), World Health Organization, 2018

⁸⁵ Danii Olga, Lilia Plugaru. Access and quality of palliative care services in the Republic of Moldova. Quantitative study. The Independent Sociology and Information Service "Opinia". 2019.

⁸⁶ MoH order no. 45 of 25.01.2010 on the approval of an assisted case in medical care provided under hospital /hospice conditions for 2010.

⁸⁷ MoH Order no.875 of 27.12.2010 on cost approval of an assisted case in medical palliative care provided in hospital/hospice conditions for 2011.

⁸⁸ MoH Order no.60 of 25.01.2012 on medical palliative care.

⁸⁹ Government Decision no.1020 of 29.12.2011 on the rates for medical and sanitary services

on the profile, the composition of the multidisciplinary team and the type/form of the palliative care provision (Table 7). The largest share of costs accounts for medicines and medical supplies, followed by expenses for personnel and overhead. The purpose of the mentioned project was to support the MoH in the process of establishing the rates for the provision of palliative care services, based on the clinical standards and protocols in the field of palliative care.

At the end of 2015, the MoH approved new costs for palliative care services⁹⁰ for 2016, but these were slightly lower than those estimated with the support of the “Costing for Change” project (table 8.). The normative act of the MoH, which approved the costs of palliative care services for 2016, as well as all the normative acts mentioned above, does not contain any argumentation notes regarding the elements of the tariffs used in the process of estimating the approved costs. One explanation why the MoH set costs much lower than those estimated under the “Costing for Change” project would be that the personnel costs for the social worker and psychologist, as well as related wear and maintenance costs would have been excluded. The exclusion of the mentioned costs could have been motivated by the fact that NHIC contracts only the medical services from the palliative care service providers, but not the social and psychological support services, which led to the fragmentation of the financing of the palliative care services and to failure to ensure the universal access to quality palliative care services.

Also, a report made for the MoH with the support of the World Bank⁹¹ highlights the inadequate rates for palliative care services as one of the challenges faced at the implementation of the hospital reform.

Table 6. Structure of tariffs for palliative care services and the components of the expenditures included in their cost

Personnel costs / expenditures
Compulsory state social insurance (CSSI) and compulsory health insurance (CHI) contributions
(Direct) material costs/expenditures for medicines and medical supplies
(Direct) material costs/expenditures for short-term (up to one year) inventory
Costs/expenditures related to depreciation/wear and tear of intangible assets and fixed capital
Overhead costs/expenditures (indirect costs)

Source: Costing for Change project data provided by Soros Foundation Moldova.

⁹⁰ MoH Order no.1000 of 24.12.2015 on the approval of costs for the year 2016.

⁹¹ Final report. Consulting Services to Draft a Business Plan for the Rehabilitation and Long Term Health Service Development. UNICON Limited, 2013.

Table 7. Personnel costs estimation

Hospital mobile team for adults	Hospital mobile team for „children	Home-based palliative care	Inpatient/hospices palliative care
4 members (doctor, nurse, social worker and psychologist) led by the coordinating doctor	4 members (doctor, nurse, social worker and psychologist) led by the coordinating doctor	4 members (doctor, nurse, social worker and psychologist) led by the coordinating doctor	14 beds served by a doctor, a senior medical assistant, eight medical assistants, a social worker, a psychologist, and eight nurses, led by the coordinating doctor.
7 working hours per day	7 working hours per day	7 working hours per day	24-hour care.
Part-time coordinating doctor for each mobile team.		Part-time coordinating doctor.	30 working days per month.
approximately 100 minutes of activity with the patient	approximately 100 minutes of activity with the patient	approximately 70 minutes of activity with the patient	
4 visits per team every day	4 visits per team every day	6 visits per team every day	
272 working days in a year and about 22 days in a month	272 working days in a year and about 22 days in a month	272 working days in a year and about 22 days in a month	
Coordinating doctor - 44 visits per month (2 visits per day x for 22 days)		17 visits per month per patient. A total of 20 hours of medical care provided by all team members per month.	
Full-time doctor - 88 visits per month (4 visits per day x 22 days)	Full-time doctor - 88 visits per month (4 visits per day x 22 days)		
Full-time nurse - 88 visits per month (4 visits per day x 22 days)	Full-time nurse - 88 visits per month (4 visits per day x 22 days)		
Part-time social worker - 44 visits per month (2 visits per day x 22 days)	Part-time social worker - 44 visits per month (2 visits per day x 22 days)		
Full-time psychologist - 44 visits per month (2 visits per day x 22 days)	Full-time psychologist - 44 visits per month (2 visits per day x 22 days)		
Average number of visits per team per month - 61.6 visits (2.8 average visits per day x 22 days)	Average number of visits per team per month - 61.6 visits (2.8 average visits per day x 22 days)		
740 visits per team per year (12 months x average monthly visits - 61.6).	740 visits per team per year (12 months x average monthly visits - 61.6).	04 visits per team per year (12 months x 17 visits per month).	365 working days a year.

Source: Data of the “Costing for Change” project provided by the Soros Foundation-Moldova.

Table 8. The relative percentage difference between the costs of palliative care services estimated within the “Costing for Change” project, the costs approved by the MoH Order no. 1000 of 24.12.2015 and the costs for the contracted PC services for 2019

	Estimates of the “Costing for Change” project, Lei	The costs approved by the MoH Order no. 1000 of 12/24/2015, Lei	The relative percentage decrease of costs approved by the MoH Order no. 1000 of 24.12.2015 compared to the costs estimated within “Costing for Change” project	The costs used by the NHIC for procurement of PC services for 2019, Lei	The relative percentage decrease of NHIC contracting costs compared to the costs estimated within “Costing for Change” project
Cost per visit - hospital mobile team, adults	448,74		62%		
Cost per visit - hospital mobile team, children	452,66	171,00	62%	181,40	60%
Cost per home visit	399,75	91,44	77%		
Cost per bed-day	571,65	331,00	42%	343,25	40%

Source: Calculations performed within this stud.

3.4. Payment mechanisms

The mechanisms for services procurement from palliative care providers have evolved over time, starting with the payment of salaries from external sources and the retrospective payment for the services contracted by the NHIC (see section 2.1.). The payment method for the palliative care services procured by the NHIC, as well as for the other medical services provided by the CHI's Unique Program, is established in the Criteria of contracting HCIs within the CHI. They are approved and published in the Official Gazette of the Republic of Moldova every year, within one month from the approval by the Parliament of the CHIF law. The Government establishes that the MoHLSP and the NHIC must approve the Contracting Criteria based on the medical services needs of the population with reference to the capacities of the health system and within the limits of CHIF resources⁹². However, the Contracting Criteria do not contain any information regarding the estimated needs for medical services, including palliative care, except for data on the means of CHI Basic Fund, broken down by type/form of healthcare, payment methods and service procurement.

Contracting Criteria classify home-based palliative care within community and home healthcare services. They set out the total amount allocated for home healthcare and do not specify the actual amount allocated for home-based palliative care. The payment method for home-based palliative care is "per visit", and for services provided in units with beds/hospices, the payment method is based on the number of "bed days". Even in the case of inpatient palliative care, the Contracting Criteria do not stipulate clearly the budget allocated for this type of services.

Although three years have passed since the Government approved new regulations that oblige the MoHLSP and the NHIC to approve the Contracting Criteria based on healthcare needs of the population⁹³, they still do not contain such estimates for 2018⁹⁴ or 2019⁹⁵. Therefore, the Contracting Criteria are not clearly developed and do not distribute CHIF resources according to the basic health services, including palliative care services (see Table 2.), and the needs of the population, as provided by the Government Decision no.1387 of 10.12.2007.

The payment for the home-based palliative care service is made according to the provisions of the Contracting Criteria described in the section "Community and Home Medical Care". Monthly, until the 15th day of the respective month, an advance payment in the amount of up to 80% of 1/12 part of the contractual amount is discharged within the financial means to NHIC. Quarterly, within 1 month from the submission of the fiscal invoices for the last month of the quarter, the full payment for the provision of mobile team home palliative care service (number of visits) is made calculated based on the activity reports submitted by the provider, within the limit of the contractual amount, excluding previous installments. Payment for inpatient/hospice palliative care services is performed monthly and quarterly in the same way as for home-based palliative care, calculations being made based on the number of bed days⁹⁶.

3.5. Financial Transparency

The regulations for ensuring the transparency of the national public budget are established by the law on public finances and budgetary-fiscal responsibility of 2014, which includes CHIF in the national public budget. However, the regulations for ensuring CHIF transparency as part of the national public budget did not have a positive impact on ensuring the financial transparency of health care providers under CHI until 2017, when the CHI law was supplemented with rules meant to ensure the intelligibility of financial information regarding the services contracted by NHIC⁹⁷. According to the new legislative regulations, the NHIC and the healthcare provider is obliged to publish on their official website the information regarding

92 Paragraph 2) of point 2. of the Government Decision no. 1387 of 10.12.2007 on the approval of the Compulsory Health Insurance Unique Program.

93 The Government Decision no. 714 of 06.06.2016 on amending and supplementing Government Decision no. 1387 of 10 December 2007.

94 The MoHLSP and NHIC Order no.1131 / 568A on the approval of the e Criteria for Contracting of Health Care Providers under Compulsory Health Insurance for 2018.

95 The MoHLSP and NHIC Order no.1592 / 594 of 28.12.2018 on the approval of the Criteria for Contracting of Health Care Providers under Compulsory Health Insurance for 2019.

96 Third indent of paragraph 2) of Point 65 of and paragraph 1) and first indent of paragraph 2) of point 63 of the Order of MoHLSP and NHIC no. 1592/594 of 28.12.2018 on the approval of the Criteria for Contracting Health Care Providers within CHI system for 2019.

97 Law no. 247 of 23.11.2017 for the completion of Law no. 1585/1998 on compulsory health insurance.

the number and date of the contract concluded with the insurer/provider of medical services, the range and type of contracted medical services, as well as to the amount and manner of transfer of financial means for contracted medical services. The information should be published within 5 days from the date of conclusion of the contract for healthcare services (provision of medical services).

In 2018, 30 out of 34 district hospitals and 4 out of 5 republican hospitals⁹⁸ published the financial information regarding the contracts signed with the NHIC for the provision of palliative care services. However, the information published by hospitals does not specify the amounts of financial contribution and of palliative care services procured by the NHIC, as they are included in the total amount for the chronic cases. The exception is the information in the annex to the Contract for the provision of medical services for 2018 published by the Oncological Institute, which mentions the number of cases treated through palliative care and the funds contracted from the NHIC for this purpose. In 2019, out of 52 palliative care service providers contracted by NHIC (43 public and 9 non-governmental) only the Republican Clinical Hospital "Timofei Mosneaga" and the Oncological Institute published the full contracts concluded with NHIC, but this time the Oncological Institute did not mention the number of treated cases, but only the number of days-bed and the cost per bed-day.

The absolute majority of public palliative care providers have complied with the legislation to ensure the transparency of financial information within the contracts with NHIC, on the other hand not a single non-governmental provider has published the financial information related to the contract signed with NHIC on the official website neither for 2018 nor for 2019. At the same time, most non-governmental palliative care providers do not have a functional website, and since the end of 2018 the official websites of district hospitals are no longer available and the contract information that was previously published on public hospital websites was saved on the "Your Money in Health" website <http://www.sanatate-bani.pas.md>

In 2018 the NHIC published the list of all contracted PHCIs and private healthcare providers⁹⁹ on the official website, but the information does not allow the identification of expenses for palliative care. The published information contains the name and the level of the HCI, the number and signing date of the contract, the types of healthcare services and the total amount contracted, without specifying the details about palliative care and their costs. Thus, from the published information it is not clear which and how many HCIs are contracted for the provision of palliative care services. In the information published by the NHIC, even the institutions from the non-governmental sector specialized exclusively in the provision of palliative care services are mentioned as being contracted for home-based medical care (HBMC). This situation has not changed in 2019¹⁰⁰ either.

In 2018, there was performed the legal analysis of the regulations meant to ensure the transparency of financial information regarding the contracts with NHIC¹⁰¹, approved by law in 2017. In particular, the analysis referred to the following extract from the legal norm: *"... on the range and the type of contracted medical services, as well as the one regarding the amount and the way of transferring of financial means for the contracted medical services"*¹⁰². The analysis showed that in order to ensure an objective degree of transparency and accuracy, following the bona fide and complete application of legal rules to ensure transparency, the NHIC should exhaustively list the medical services covered by the CHIF funds for each type of care and present the information individually for each contracted HCI. According to the same analysis, it is considered reasonable that the information published by the NHIC should include data on the amount of financial resources allocated from the CHI funds for contracted medical services - per separate service, as provided in the contracts concluded by the NHIC with each contracted HCI, namely as stipulated in the annexes to the contract (annexes to which point 2.2 of the contract refers directly¹⁰³).

98 Generalized information from the website "Your Money in Health" <http://www.sanatate-bani.pas.md> based on the official websites of medical service providers.

99 <http://www.cnam.md/httpdocs/editorDir/file/doc/2018/Lista%20instituti%C5%A3iilor%20medico-sanitare%20contractate%20de%20CNAM%20C3%AEEn%20anul%202018.pdf> (accessed 15.05.2019)

100 <http://www.cnam.md/httpdocs/editorDir/file/doc/2019/1/Lista%20IMS%20Contractate%202019.pdf> (accessed 09.09.2019)

101 Law no. 247 of 23.11.2017 for the completion of Law no. 1585/1998 on compulsory health insurance.

102 Efrim Roșca Asociații: Legal analysis of the provision of art. 12 paragraph. (3) line g) of the Law no. 1585 of February 27, 1998 on compulsory health insurance, in the part concerning "... the range and type of contracted medical services, as well as the one regarding the amount and the way of transferring of financial means for the contracted medical services" <http://www.pas.md/ro/PAS/Studies/Details/83> "http://www.pas.md/ro/PAS/Studies/Details/83"

103 <http://lex.justice.md/index.php?action=view&view=doc&lang=1&id=295888>

The vast majority of public sector palliative care providers contracted by the NHIC do not publish expenditure reports on their official websites and the information made public by several providers is incomplete, unsystematic and provides no data on the cost and amount of provided services. Thus, there is no correlation between the data from the contracts concluded with the NHIC and the volume of services paid by the NHIC and this impairs the transparency of the economic-financial activity of the providers. The Government has approved an Action Plan that obliges the MoHLSP to approve the structure of the Annual Report on the economic and financial activity for self-financed, non-profit HCIs, as well as for institutions financed from the state budget¹⁰⁴. According to the Action Plan, the MoHLSP should have carried out this activity in the fourth quarter of 2018, but it has not been implemented so far. The HCIs should have published the economic and financial activity reports in the first quarter of 2019, and the private institutions should have come with a rationale for the money to be spent from the public budget in the first quarter of 2020, according to the new report format approved by the MoHLSP.

The lack of information on the official websites of palliative care providers on how public money are spent reveals their non-compliance with the principles of financial transparency.

Only one out of eight private palliative care providers contracted by the NHIC in 2018 have published the annual activity reports on their official website and they also included data on income and expenses, including grants and fundraising sources (see section 3.2.), but they were presented in total per organization and did not offer the possibility to track the expenses by amount and type of services provided to the beneficiaries¹⁰⁵. It should be mentioned that in 2019 all previously published reports were deleted from the website of this non-governmental provider.

104 Government Decision no.892 of 12.09.2018 on the approval of the Sectoral Plan for anti-corruption actions in the field of health and compulsory health insurance for the years 2018-2020.

105 <http://www.hospice.md/raport-anual> as of 20.01.2019.

IV. Physical and human resources in palliative care

4.1. Physical resources

NPCS establishes the requirements for physical infrastructure and provision of the wards and the hospice units with beds, requirements for delivery of palliative care services at home, at day care facilities and doctor's office and in outpatient conditions¹⁰⁶. It should be noted that there are no data published by the government institutions regarding the district, municipal and republican hospitals fitted with palliative care beds (see section 5.3.1.), nor data on whether or not the infrastructure of these units with beds has been organized according to the specifics of palliative care. A study conducted in 2019 reveals that palliative care services within district hospitals are provided in conditions that are inadequate for palliative patients¹⁰⁷. According to the study, palliative beds and wards are not adapted to the needs of the patients and lack specific equipment required for the care of palliative patients.

Only one public document of MoH from 2011¹⁰⁸ reveals that, with the support of the Global Fund to Fight HIV / AIDS / STIs, Tuberculosis and Malaria, Round VIII, a palliative care ward was opened for people living with HIV / AIDS in within the Clinical Hospital for Contagious Diseases "Toma Ciorba", 5/1 Costiujeni Street, today the ARV treatment ward of the Dermatology and Communicable Diseases Hospital, rebuilt and equipped according to the needs of a palliative care patient. The ward was equipped with furniture, including medical, information equipment, household appliances and especially with a room for each patient and space for the caregiver/companion, toilet and sink in the room and in the office of the social worker and psychologist, etc.

Regarding the physical infrastructure of non-governmental home-based palliative care providers (see section 5.3.3.), it was largely developed with the support of external partners, which inspires confidence that it would meet the needs of palliative care beneficiaries.

Since 2010, the NHIC has managed a fund for the development and modernization of public health service providers, but, according to the NHIC data, no investment project for the development and modernization of the physical infrastructure of palliative care service providers has been funded. An investment plan for the development of the infrastructure of the palliative care service providers has not yet been developed in the Republic of Moldova and there is no evidence and data on the current situation of the palliative care service provider infrastructure neither in the public nor in the non-governmental sectors.

In 2011, the Ministry of Health benefited from consulting services to draft a business plan for the development of rehabilitation and long-term health services¹⁰⁹. Thus, 80m2 were estimated for a palliative care bed that would be located in the Chronic Disease Care Centers (CDCC) in Briceni, Donduseni and Ocnita (maximum 18 beds), with repair costs of 200 Euro per m2 for existing hospital buildings and equipment costs of 7,680 Euro for a bed. Thus, the amount of the total investments reached 23,680 Euros for a palliative care bed. Therefore, the estimated capital investments in infrastructure and equipment for 7 palliative care beds for CDCC Briceni would amount to 165,760 Euro, for 6 beds of palliative care for CDCC Donduseni to 142,080 Euro and for 5 beds of palliative care for CDCC Ocnita to 118,400 Euro. According to this study, about 5.5 million Euros are needed for the modernization of the infrastructure with 231 palliative care beds at the national level, during a period of 9 years (Table 9.). The financial estimates for other types of palliative care services than palliative care in hospital units has not been estimated.

¹⁰⁶ MoH Order no. 884 of 30.12.201 on the approval of the National Standard of Palliative Care.

¹⁰⁷ Danii Olga, Nicoleta Spinu-Triboi. Access and quality of palliative care services in the Republic of Moldova. Quality study. The Independent Sociology and Information Service OPINIA. 2019.

¹⁰⁸ MoH Order no. 60 of 31.01.2011 on the establishment of the palliative care department for people living with HIV infection.

¹⁰⁹ Final report. Consulting Services to Draft a Business Plan for the Rehabilitation and Long Term Health Service Development. UNICON Limited, 2013.

Table 9. National capital investment costs for the 231 nationally planned palliative care beds (spread over 9 years)

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Total
231 beds	118 915€	356 744€	713 489€	713 489€	713 489€	713 489€	713 489€	713 489€	713 489€	5 470 082€

Source: Final report. Consulting Services to Draft a Business Plan for the Rehabilitation and Long Term Health Service Development. UNICON Limited, 2013.

There is no public information provided by the health authorities whether the automated information system for primary health care (AIS PHC) and the automated information system for hospital health care (AIS HHC), which since 2019 have moved from the MoHLSP to NHIC management¹¹⁰, ensure the information flow, database formation, etc. for palliative care services or whether these systems are operational at national level.

4.2. Human resources

4.2.1. Human resources coverage

In the Republic of Moldova, palliative care is not recognized as a specialty. Most professionals with specialized palliative care skills work for non-governmental providers and all of them have been trained abroad. According to the statistical reports no. 30-san presented in 2018 to NPHA by seven out of eight non-governmental providers of specialized palliative care services contracted by NHIC, 25 doctors of therapeutic profile (full-time - 11) and 53 nurses (full-time - 30) worked in this field. It should be mentioned that the statistical report forms no. 30-san do not contain specifications about the activity of the entire staff of the multidisciplinary team (psychologist, social worker, etc.), which shows that the MoHLSP followed a purely medical approach to palliative care, when they developed and approved this statistical documentation. At the same time, the form no. 30-san does not reveal how many multidisciplinary teams activate among the providers of home-based specialized palliative care services. The ministerial normative act regarding the personnel norms for public medical institutions¹¹¹, which is of recommendatory nature, does not specify the norms for the non-medical staff within the multidisciplinary palliative care team (psychologist, social worker, etc.), although it recommends the staff norms for multidisciplinary team for youth-friendly health centers that include the positions of psychologist, social worker, etc.

There are no statistical reports on the number of doctors, nurses and medical assistants trained in the provision of specialized palliative care services in units with beds within public hospitals. An approximate estimate of these can be made based on the number of beds in these hospitals, if we take into account the norm of 10-15 beds for a doctor, 5 beds for a medical assistant on shift and 1 nurse, approved by the order of the Ministry of Health no. 877 of 27.12.2010. For example, for a number of 14 palliative care beds, which was used to calculate the cost of a day bed (see section 3.3.), one doctor, eight medical assistance and eight nurse positions are established. Reporting these to 243 palliative care beds in all existing public hospitals in 2018, we can estimate a total of 17 doctor, 139 medical assistants and 139 nurse positions. Given that in most public hospitals that provide specialized palliative care services there are on average 6 palliative beds, we can conclude that there is only 0.5 palliative care doctor position in most district hospitals. In this situation, the possibility of district hospitals to offer specialized palliative care services through mobile teams should be considered, since this could ensure full time jobs for palliative care doctors and nurses working in hospitals on a part-time basis which does not ensure the motivation and maintenance of staff in the system. At the same time, the order of the Ministry of Health no. 877 of 27.12.2010 does not establish the norms for non-medical staff (psychologist, social worker) within palliative care units with beds.

In the Republic of Moldova, the number of family doctors and family medical assistants is constantly decreasing. Thus the number of family doctors decreased from 2001 in 2007 to 1682 - in 2018, and that of medical assistants - from 5552 to 4172. It should be mentioned that the Population and Housing Census of 2014 estimated a total number of 2998235 people, including 2789205 of habitual residents

¹¹⁰ Government Decision no. 138 of 27.02.2019 on the transmission of some automated information systems.

¹¹¹ MoH Order no. 100 of 10.03.2008 on the Norms of medical staff.

(lived mainly in the Republic of Moldova in the last 12 months). NPHA calculates the indicators based on the total number of 3,545,124 inhabitants of the Republic of Moldova. Although the population has decreased, as has the number of family doctors, their current distribution in the territory is unfavorable, especially in rural areas. A study published in 2015¹¹² reveals that there is an insufficient number of medical staff in PHC at the national level and it is unevenly distributed, the concentration of family doctors being higher in municipalities and insufficient in rural areas, and vice versa, the Chisinau municipality faces a shortage of family medical assistants. The study also found that the decrease trends in the number of family medical assistants are specific for rural localities, especially in the “North” and “South” Development Region and in ATU Gagauzia. The number of family medical assistants in the municipalities (from Chisinau) is low and the trend for the following years will not improve. It should be noted that the share of family doctors of retirement age is of 40%, and that of family medical assistants of 26%.

Chronic insufficiency of medical staff in the primary health care would be one of the barriers of access to palliative care, and the integration of palliative care into PHC runs the risk of burdening medical staff in PHC with another responsibility and an additional set of tasks while the staff is already overburdened by providing family healthcare services. In order to avoid this situation and to strengthen the PHC system, adequate funding is needed which would make possible to hire a sufficient number of medical staff¹¹³. It is unlikely that the staffing of PHC will improve on the short and medium term, so it is necessary to delegate the palliative care responsibilities in accordance with the existing capacities of the family medicine network.

4.2.2. Human Resources Training

There are no public reports by the MoHLSP or other relevant public institutions on the number of people trained in palliative care or on the activities carried out in this field. Moreover, the normative acts are no longer published on the MoHLSP website starting with 2017. There is an order of the MoHLSP of 2015¹¹⁴ which provides for the organization of a training course for doctors entitled “Competencies in Palliative Care”, in the period 20.11.2015-20.02.2016 held at the National College of Medicine and Pharmacy “Raisa Pocalo”. The annexes of the forum contain the training curriculum, the list of trainers and the list of participants, but these data are not publicly available. The cited normative act ordered to the HCP leaders to delegate the nominees for participation in the training, but a public report on the results of this training does not exist.

At the same time, a scientific article published in 2018¹¹⁵ reveals that the first training course in the field of palliative care was held by the SFM, starting with 2013. Thus in the period of 2013-2017, 2056 people were trained, of which 1851 were doctors (family doctors and oncologists) and 205 were nurses. These trainings covered the medical staff from all ATUs and the structural distribution was the following: 92% were family doctors, 5% - oncologists, 3% - interns or other specialties, 1.5% - institution managers and 0.5 % palliative care physicians. The same scientific article mentions that in 2016, twelve people (from USMF “Nicolae Testemitanu”) were trained and certified as trainers in palliative care within the project “Strengthening Training Capacities in Palliative Care”, funded by the SFM, the training being carried out during a 4-month program, offered by the Study Center for Palliative Care of the HOSPICE Casa Sperantei Foundation Brasov, Romania. Due to this project, the capacities of SUMP “Nicolae Testemitanu” in the development and application of university, postgraduate and continuing education programs were strengthened. Also, in the period 2007-2009 a group of 15 people attended a national palliative care training of trainers course and each participant was issued a certificate by the MoH. This course was organized by the Nursing Association of the Republic of Moldova with the support of the SFM, and delivered by experts from Israel, England, Scotland, USA and Romania¹¹⁶.

112 Providing Primary Health Care with medical staff, National Center for Health Management, Chisinau, 2015.

113 Integrating palliative care and symptom relief into primary health care: a WHO guide for planners, implementers and managers. Geneva: World Health Organization; 2018. License: CC BY-NC-SA 3.0 IGO

114 MoH Order no. 957 of 16.11.2016 on the organization of the training course

115 Buta Galina; Bradu Andrei; Pogoneț Vadim; Carafizi Natalia; Ignat Rodica; Curocichin Ghenadie. Palliative care in the Republic of Moldova - reality and perspectives. In: Public Health, Economics and Management in Medicine. 2018, no. 1-2 (75-76), pp. 24-29. ISSN 1729-8687

116 Nursing Association of the Republic of Moldova.

At the end of 2015, the Ministry of Health issued a normative act¹¹⁷, ordering the SUMP “Nicolae Testemitanu” to ensure the completion of study programs within the university and postgraduate training of students and residents with subjects/themes in the field of palliative care. The order also provided for the elaboration of specialized courses for skills in palliative care, with their inclusion in the Program of continuous professional training of doctors and pharmacists. This normative act was a starting point for the organization of palliative care training within three educational compartments: i) integrated higher studies; ii) postgraduate residency studies and iii) continuing medical education at SUMP “Nicolae Testemitanu”.

The training of medical assistants takes place within the Center of Excellence in Medicine and Pharmacy “Rasia Pacalo” and at the Center for Continuing Medical Education of Medical and Pharmaceutical Staff with secondary education. The “Rasia Pacalo” Center of Excellence in Medicine and Pharmacy provides training for future medical assistants in the field of palliative care at the post-secondary medical education stage. From 2018, the palliative care course is taught as a special module at the Nursing Department by a trainer with special international and national education. The Center for Continuing Medical Education of Medical and Pharmaceutical Staff provide training for medical assistants in the field of palliative care at the stage of continuing professional education.

4.2.3. Doctor Training Programs

4.2.3.1. Integrated Higher Education

The “Palliative Medicine” course¹¹⁸ is integrated and conducted at higher education level and was included in the SUMF curriculum starting with the 2016-2017 academic year, following the implementation of the project “Strengthening the Human Resources in the Field of Palliative Care in the Republic of Moldova”, funded by SFM. The implementation and coordination of this course at the stage of integrated higher education was assigned to the University Center for Simulation in Medical Training (CUSIM). The aim of the course is to familiarize students with the basics of palliative care and the main components of organizing an appropriate management service for patients in terminal conditions (Table 10.). The thematic content of the training program follows the recommendations of the Council of Europe (COE 144/153) and reflects the basic principles established by the European Association for Palliative Care in the definition of palliative care.

Table 10. Topics included in the “Palliative Medicine” course

Basic principles in palliative care
Management of acute and chronic pain in palliation
Symptom management in palliative medicine
Management of the multidisciplinary palliative care team
Psycho-social, cultural, religious and spirituality aspects in palliative care
Applied ethics and communication in palliative care

Source: The curriculum of palliative medicine course approved at the meeting of the Commission for Quality Assurance and Curricular Evaluation, Department of Medicine, Minutes no. 8 of 15.03.2017, at the meeting of the Department of Medicine Council, Minutes no. 4 of 20.03.2017 and at the meeting of the University Center for Simulation in Medical Training, Minutes no.9 of 25.10.2017.

The beneficiaries of the training process are the fifth year students, with major in Medicine, required to attend 60 course hours. The course is composed of theoretical part and practical lessons that include role-play and case solving through healthcare simulation method. Particular attention is paid to the practical work of students based on a new educational approach within CUSIM consisting in consecutive succession of students within three thematic workstations: Station 1 (Ambulatory / Family doctor's office); Station 2 (Hospice), with 2 substations - Hospice/Home Care and Practical Skills, the last one is Station 3 (Virtual). Of the 60 course hours, there are 12 training hours, 14 seminar hours, 14 hours of practical/laboratory work and 20 hours of individual work. The training program plans that

117 MoH Order no. 176-P & 2 of 24.12.2015 on training in the field of palliative care.

118 Curriculum for palliative medicine approved at the meeting of the Quality Assurance and Curricular Evaluation Commission Faculty of Medicine Minutes no. 8 of 15.03.2017, at the meeting of the Faculty of Medicine Minutes no. 4 of 20.03.2017, at the meeting of the University Center for Simulation in Medical Training Minutes no.9 of 25.10.2017

at the end of the study the student will have knowledge and understanding of palliative medicine, will be able to apply the knowledge gained in the course, demonstrating the ability to approach holistically the management of patients in need of palliative care. The training program also ensures the development of certain specific and transversal professional skills. Specific professional competencies refer to aspects related to the medical and social psychology in professional activity, to interpretation of pathophysiological states in advanced and terminal stages of incurable diseases, mobilization of the patient in bed and provision of specific care, assessment of real needs in professional palliative care, recognition of symptoms that require a palliative approach and assessment of pain, early detection and pain relief, etc. The transversal competences refer to the demonstration of a responsible attitude towards the educational activity, application of the principles and norms of professional ethics, assurance of efficient activity in the multidisciplinary team, awareness of the need for continuous professional development, etc. Upon completion of the courses the student should be able to demonstrate knowledge and skills in the field of palliative care (*Table 11*).

Table 11. Goals in the study of palliative

Upon completion of the palliative medicine course, the students will be able:
to make a search for and use the normative acts that regulate the field of palliative care (laws, protocols, guides, standards, etc.)
to be guided by the principles of professional ethics
to demonstrate an attitude of compassion towards the patient and their relatives
to select clinical cases that require specialized palliative care
to approach holistically the suffering of the patient with incurable disease
to assess the real needs of palliative care beneficiaries
to make the prognosis for a patient with incurable disease depending on the diagnosis and other factors
to communicate bad news to patients and their relatives using standardized algorithms
to develop skills of active listening to the interlocutor (patient, his relatives)
to demonstrate empathic communication skills with patients and relatives
to remain calm during communication with the patient
to assess the type and nature of pain by using specialized tools (scales) and clinical thinking
to prescribe analgesic treatment according to WHO principles, in ordinary situations
to detect the symptoms caused by the incurable disease
to determine and establish the diagnosis of terminal condition
to manage and monitor terminal cases
to practice basic and special care in the field of palliative care (change of position in bed, basic hygienic care, care of stomata, trophic wounds and bedsores, etc.)
to coordinate the activities of the multidisciplinary palliative care team
to demonstrate work skills within the multidisciplinary team
to formulate optimal decisions in assisting patients with palliative emergency situations
to apply various ways of psychological and moral support to different types of patients

Source: *The curriculum of palliative medicine course approved at the meeting of the Commission for Quality Assurance and Curricular Evaluation, Department of Medicine, Minutes no. 8 of 15.03.2017, at the meeting of the Department of Medicine Council, Minutes no. 4 of 20.03.2017 and at the meeting of the University Center for Simulation in Medical Training, Minutes no.9 of 25.10.2017.*

4.2.3.2. Postgraduate Residency Training

Following the implementation during 2016-2017 of the project “Strengthening the Human Resources in the Field of Palliative Care in the Republic of Moldova”, funded by SFM, palliative medicine was included in the training program for family doctors through postgraduate studies at SUMF in the module “*Palliative Care for Resident Doctors Specializing in Family Medicine*”¹¹⁹.

The course includes important sections for strengthening the knowledge gained during university studies and getting familiar with new concepts and new approaches in this field. The course touches on the basic principles of palliative care, analyzes the stipulations of legislative and normative acts in the Republic of Moldova, discuss topics related to ethical and deontological, psycho-social and spiritual aspects, deepens topics such as team management, communication peculiarities in palliation, management of symptoms and syndromes frequently encountered in patients with severe diseases, supportive principles in terminal care. An innovative component of the course is the volunteer activity of each resident doctor at HCIs and non-governmental organizations. The practical work of the family doctors is conducted during three days, by consecutive succession and rotation within two thematic workstations.

¹¹⁹ Syllabus of palliative care course for the resident doctors specializing in Family Medicine, 21.01.2016, Chisinau2016, Ministry of Health of the Republic of Moldova, PI State University of Medicine and Pharmacy “Nicolae Testemitanu”.

The course, with the duration of one week, has a combination of interactive theoretical lessons, practical internships, seminars delivered through role playing and case solving using simulation method, the classes being structured on didactic, educational and practical dimensions. The course includes 15 teaching hours, 13 hours of individual clinical activity, 8 hours of CUSIM evaluation and 0.5 months of volunteer activity. The training objectives within the course are: knowledge and understanding of palliative medicine, skills in applying the knowledge in palliative medicine and integration of knowledge and skills for holistic approach in palliative management and care, etc.

4.2.3.3. Continuing medical education (family doctors)

The thematic refresher training course *“Palliative care in the Practice of Family Doctor”*¹²⁰ was implemented due to the same project - *“Strengthening the Human Resources in the Field of Palliative Care in the Republic of Moldova”*, funded by SFM and was conducted in 2016-2017. Thus, within the continuous medical education, the family doctors can access the thematic refresher course *“Palliative Care in the Practice of the Family Doctor”* with a duration of 75 academic hours.

The aim of the course is to contribute to the provision of quality services in the field of palliative care by family doctors by strengthening knowledge and practical skills, as well as by educating the dignified attitude towards patients with evolving incurable diseases and their relatives. Family doctors are trained based on clinical palliative care standards and protocols. The training methods are aimed at the active participation of students in various educational activities, such as case studies, role play and simulation. An innovative component of the course is the volunteer activity of each student at the hospice. The comprehensive evaluation of the course is performed by simulation within CUSIM. The training objectives within the course are: knowledge and understanding of palliative medicine, the ability to apply the knowledge in palliative medicine as well as the integration of knowledge and skills for the holistic approach in palliative care management, etc.

During the 2017-2018 study year, 21 family doctors from 10 districts were trained at the Family Medicine Department¹²¹.

4.2.4. Training within post-secondary medical education

The course *“Palliative Care”* is carried out for the students from the department of Medicine, with Nursing specialization. The course has a total duration of 60 hours, of which 15 are hours of theory, 30 hours of practice and 15 hours of individual study. The specific competencies of the course are: i) studying the normative acts that regulate the provision of palliative care services in the Republic of Moldova; ii) effective communication with the members of the palliative care team; iii) assessment of patients' pain; iv) care of patients with identified digestive symptoms; v) care of patients with identified respiratory symptoms; vi) care of patients with problems in the skin and mucous membranes; vii) implementation of the interdisciplinary care plan.

4.2.5. Continuing medical education of medical staff with specialized secondary education (medical assistants)

The thematic course *“Palliative Care”* is a course designed for nurses, delivered within continuing medical education, which provides a total of 156 training hours, of which 88 hours of theory, 56 hours of practice and 12 hours of individual study. The main themes of the course include the concept of palliative care, ethical, psychological aspects and communication in palliative care, nursing plan, patient mobilization, care, assessment and control of symptoms, medications administered for pain control, etc. There are no public reports on the number of nurses trained in palliative care.

120 Continuing Medical Education Program in Family Medicine, Palliative Care in Family Doctor Practice course, 03.10.2016, Chisinau 2016, Ministry of Health of the Republic of Moldova, PI State University of Medicine and Pharmacy „Nicolae Testemitanu”.

121 Buta Galina; Bradu Andrei; Pogoneț Vadim; Carafizi Natalia; Ignat Rodica; Curocichin Ghenadie. Palliative Care in the Republic of Moldova - reality and perspectives. In: Public Health, Economics and Management in Medicine. 2018, no. 1-2 (75-76), pp. 24-29. ISSN 1729-8687

4.2.6. General health care training (medical assistants with higher education)

In 2017, the curriculum for “Palliative Care and Pain Management”¹²² course was developed for the specialty of general medical care, the Department of Medicine of SUMF “Nicolae Testemitanu”. General health education started at USMF “Nicolae Testemitanu” in 2018 and has the goal to train specialists in the field of professional development of nurses and midwives. The graduates of this study program have the professional purpose of providing primary health care with emphasis on prevention; medical care and diagnostic assistance; intensive care in hospitals; rehabilitation and medical and social care of the chronically ill and people with disabilities; education for people’s health; training of nurses and participation in scientific activities; educating the public on the methods of pre-medical and medical care for sick and disabled people¹²³ etc.

The courses “Palliative Care and Pain Management” consists of a total of 120 study hours, of which 20 are hours of theory, 20 hours of practical/laboratory work, 20 hours of seminars and 60 hours of individual work. Similar to the graduate students, the training program for nurses with higher education ensures that at the end of the study the students will have knowledge and understanding of palliative medicine, will be able to apply the knowledge gained in the course and, at the level of integration, to demonstrate that they can holistically approach the situation of patients in need of palliative care.

4.2.7. Training of non-medical staff from the multidisciplinary team

There is no public information, data or evidence regarding the training of non-medical staff of the multidisciplinary team (social workers, psychologists, volunteers, etc.) in the field of palliative care. Certainly the staff working for non-governmental specialized palliative care providers have received related training and education abroad and/or within the organization. However, there is no public information about these trainings either.

A qualitative study conducted in 2019¹²⁴ found that social workers consider useful courses that provide information on legislative changes and the specifics of social assistance provided to the person/family receiving palliative care and on cooperation between HCI and social assistance services. Also, in the opinion of the social workers, the continuous training of the staff working in social assistance institutions subordinated to LPAA in aspects related to social assistance for the beneficiaries of palliative care is necessary due to the frequent staff changes. In the opinion of the interviewed psychologists, there is a need to train the staff working in psychological services with reference to the psychological assistance of the person/family receiving palliative care. They say that palliative care should be included both as a module in the initial training and in the continuing education of psychologists.

The representatives of the religious cults also consider that trainings for the personnel that offer religious services are necessary on aspects related to the religious/spiritual support of the people who follow palliative care. They say that while the specific activity of the priesthood is to serve and counsel those who are suffering, training on how to address palliative patients and their families would be welcomed and even necessary, especially for young priests who do not have the experience to officiate services for the dying.

The teachers in medical education believe that educational institutions that train psychologists, and social workers do not provide training in addressing people/families who need palliative care services. In their opinion, the training programs in these specialties should be reviewed, and the curriculums should include more focused approaches on issues related to palliative care. The curriculums for psychologists’ and social workers’ at these institutions include fewer topics related to the approach of people/families who need or receive palliative care services compared those in medical education¹²⁵.

122 Curriculum for Palliative Care and Pain Management course, Faculty of Medicine, 20.09.2017, approved at the meeting of the Commission of quality assurance and curricular evaluation of the Faculty of Medicine, at the meeting of the Board of the Faculty of Medicine I, at the meeting of the University Center for Simulation in Medical Training.

123 Medicus, May 2018, special edition, Public Institution State University of Medicine and Pharmacy “Nicolae Testemitanu” from Republic of Moldova.

124 Danii Olga, Nicoleta Spinu. Access and Quality of Palliative Care Services in the Republic of Moldova. Qualitative study. Independent Sociological and Information Service OPINIA, 2019.

125 Ibid.

V. Delivery of Palliative Care

5.1. Access formalities

The way of accessing the palliative care services provided within the CHI is regulated by the Methodological Norms for the Application of the CHI Unique Program which were approved by the MoHLSP and the NHIC in 2016¹²⁶. The general provisions of the Methodological Norms establish the conditions for providing medical assistance to insured and uninsured people, the amount and conditions of medical services at the level of primary health care, as well as for specialized outpatient and hospital health care and for socially-conditioned diseases with major impact on public health, covered by CHI funds. Thus, any person in need of palliative care and who has health insurance from the NHIC can benefit from the full package of palliative care services provided by the Unique Program (see section 2.5.3.). According to the general provisions of the Methodological Norms if a person is not insured, he/she can benefit from free of charge palliative services provided by the family and by hospital/hospice facilities, if the disease belongs to the categories of socially-conditioned and with high impact on public health (AIDS, Tuberculosis, Cancer). However, the provisions of the section "Community and Home Healthcare" of the Methodological Rules, which include palliative care, state that the right to receive healthcare services is held only by insured persons. According to the NHIC, the share of the uninsured in the total population is gradually decreasing - 11.8% in 2018¹²⁷ compared to 13.1% in 2017¹²⁸. Therefore, there is room for interpretation regarding the provision of palliative care services in hospital/hospice conditions for uninsured people with AIDS, tuberculosis and cancer.

The methodological norms stipulate that in order to benefit from palliative care, the patient must have a referral from the family doctor, including in cases when home-based palliative care is recommended by specialized doctors¹²⁹. In its turn, NPCS stipulates that the admission of the beneficiaries to palliative care services takes place based on the referral ticket from the family doctor or from the profile specialist. The Regulation on the Organization of Palliative Care Services¹³⁰ also stipulates that the selection of beneficiaries of palliative care services is made by the family doctor and the specialist doctor, who complete the referral note for the initiation of the provision of palliative care services.

Thus, there are inconsistencies between the provisions of the NPCS, the Regulation on the Organization of Palliative Care Services in 2015 and the Methodological Norms on the application of the Unique Program for service access, even if the Unique Program states that services are provided in accordance with the provisions of regulations approved by the MoHLSP, including the aforementioned Standard and Regulation¹³¹.

At the end of 2018, changes were made in the CHI Unique Program, which established that in case of scheduled admission to the hospital/hospice the patient must have a referral ticket issued by his/her family doctor with the exception in case of emergency hospitalizations¹³².

5.2. Basic palliative care

During the reference period, several regulations were approved for the provision of palliative care at the level of PHC, but these remain debatable. The Methodological Norms for the Application of the CHI Unique Program establish that the family doctor coordinates, organizes and provides, as appropriate, palliative care services at home, depending on the needs of the beneficiary, but the family doctor has the obligation to ensure the provision of these services only when contracted by NHIC¹³³. Thus, the

126 MoH and NHIC Order no.596 / 404 of 21.07.2016 on the approval of the Methodological Norms for the Application of the Unique Program of Compulsory Health Insurance.

127 MoH and NHIC Order no.596 / 404 of 21.07.2016 on the approval of the Methodological Norms for the Application of the Unique Program of Compulsory Health Insurance.

128 The report on the execution of the compulsory health insurance funds for 2017, NHIC.

129 Point 134 of the Methodological Norms for the Application of the Unique Program of Compulsory Health Insurance., approved by Common Order of the Ministry of Health and the NHIC no. 596 / 404A of July 21, 2016.

130 MoH Order no. 1022 of 30.12.2015 on the organization of palliative care services.

131 Point 32 of the Government Decision no.1387 of 10-12-2007 on the approval of the Unique Program of Compulsory Health Insurance.

132 Government Decision no.1020 of 24-10-2018 on the approval of the amendments that are operated in some decisions of the Government.

133 Point 59 of the Methodological Norms for the Application of the Unique Program of Compulsory Health Insurance., approved by Common Order of the Ministry of Health and the NHIC no. 596 / 404A of July 21, 2016.

Methodological Norms do not provide clearly the responsibilities of the family doctor with reference to the provision of palliative care, moreover - in the period 2007-2019¹³⁴ PHC institutions were not contracted by the NHIC for the provision of palliative care services, except for the Health Center - Cimislia which was contracted by NHIC in 2016 for 32 mobile team home visits¹³⁵. For its part, the PHC regulations of 2010¹³⁶ establish the obligation to provide palliative care in the terminal stages of the disease as one of the functions of the family doctors. They stipulate that the basic primary healthcare services within the area of PHC competence, which are based on the family doctor's job description and which can be offered by all family doctors within the medical consultation, also include provision of palliative care in the terminal stage within the multidisciplinary team according to normative acts in force. Also, the same rules governing PHC stipulate that the family doctor ensures the organization and measurement of palliative care. The organization of palliative care, which ensures a decent quality of life for patients, is defined as a requirement for qualification and training in the field of "Diagnosis and treatment of widespread diseases". Among the basic indicators of the family doctor's activity there is the Individual Plan for home-based palliative care, its development is mentioned as one of the practical skills of the family doctor. The PHC regulations also approve the planning and organization of palliative care as a requirement for the qualification of the medical assistant serving in the family doctor's office.

A number of regulations regarding palliative care services attributable to family doctors were approved in 2015¹³⁷ (*Table 12*), which provided for the organization of delivery of palliative care services by the family doctor and his/her team for 2016, including the establishment of mobile teams for specialized home palliative care at the level of district primary HCI with the inclusion of additional functions to the permanent staff list depending on the identified needs and the estimated workload. The normative act of the Ministry of Health orders to the heads of primary health care institutions and health authorities in Chisinau, Balti and ATU Gagauzia to ensure, through family doctors and community /family medical assistants, the identification of persons who need care in served localities and to notify about their inclusion in the home-based palliative care program or about their referral to the territorial institutions specialized in palliative care. The MoH also orders that primary health staff work with the LPAA and social assistance structures in order to engage social workers in the activity of the interdisciplinary home palliative care teams, including for the purpose of identifying additional financial sources for home palliative care, but does not provide any regulatory support for this purpose.

Table 12. Palliative care interventions at the level of PHC in accordance with the Order of the Ministry of Health no. 1022 of 30.12.2015 on the organization of palliative care services

Palliative care services at home are provided by:	
Family doctor team	The teams specialized in home-based palliative care, set up by PHC institutions and/or medical institutions specialized in providing palliative care
Family doctor and his/her team:	Composition of the team:
Carries out the patient assessment immediately after diagnosis and intervenes in aspects such as: explaining the diagnosis and the evolution of the disease, communicating with family and relatives, clarifying issues related to the obtaining the rights of people with cancer diagnosis, support in making decisions about recommended therapy and treatment of symptoms caused by the disease and treatment;	<ul style="list-style-type: none"> - Doctor with palliative care skills; - Medical assistant; - Social worker; - Psychologist; - Kinetotherapist; - Rehabilitologist; - Etc.
Organizes and ensures the provision of palliative care at the beneficiary's home, in accordance with the provisions of the Regulation on the Organization of Palliative Care Services and the National Palliative Care Standards, together with his team (community/family medical assistant), engaging the social worker from the community, the psychologist, volunteers, the priest, the family, etc. in accordance with the normative acts in force.	Mobile teams specialized in home-based palliative care engage volunteers, the priest, the family, etc. in providing these services.

Source: Order of the Ministry of Health no. 1022 of 30.12.2015 on the organization of palliative care services.

¹³⁴ Data provided by the National Health Insurance Company

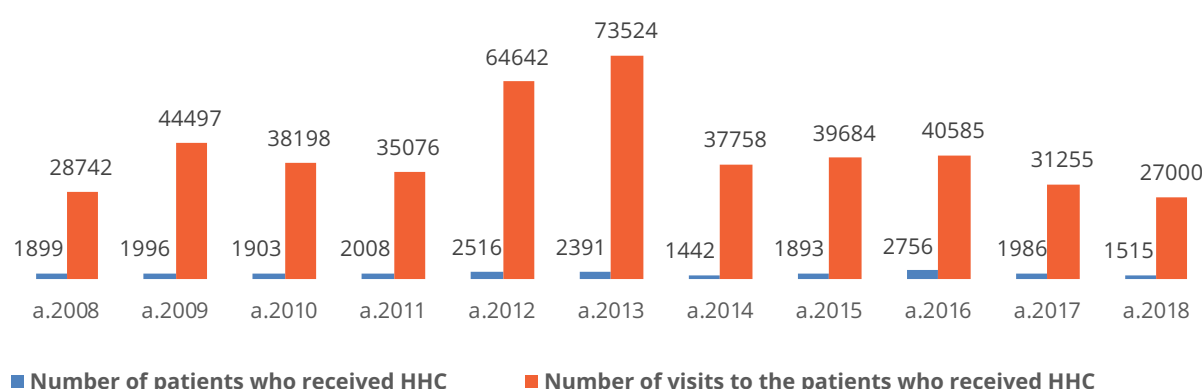
¹³⁵ Ibid.

¹³⁶ MoH Order no.695 of 13.10.2010 on primary health care in the Republic of Moldova.

¹³⁷ MoH Order no. 1022 of 30.12.2015 on the organization of palliative care services.

Although the normative act of the Ministry of Health from 2015 obliges the functional subdivisions of the Ministry of Health and the subordinated institutions to submit proposals for improving the indicators of medical statistics in the field of palliative care services and their integration in SIA PHC, the statistical report No.30-san which is used in the PHC does not foresee data reporting for palliative care, although it does include statistical data for home health care as the number of visits and beneficiaries. It can be assumed that the statistical data on the number of visits and beneficiaries, included in the Statistical Report No. 30-san at the level of PHC contain the visits made for home palliative care as well (Figure 7.). There were on average 20 home care visits per beneficiary during the years 2008-2018. The completion of Statistical Report No. 30-san¹³⁸ with headings such as “Number of patients receiving palliative care at home” and “Number of visits made to patients receiving palliative care at home” under line 1211 (1) and (2) would ensure the record of palliative care services provided by family doctors. It is also required to evaluate the possibility of establishing a special statistical form for palliative care, to be used at all levels of palliative service provision..

Figure 7. Number of visits and beneficiaries of home health care (HHC) at the level of PHC, in the period 2008-2018



Source: National Agency for Public Health.

In 2018, the Parliament approved regulations for the PHC, according to which the family medicine office provides basic medical services, extended medical services and additional medical services as part of primary care, the list and the description of services being approved by the Government¹³⁹. Subsequently, the Government approved the rules for the organization of the PHC by which palliative care was included in the list of extensive medical services¹⁴⁰. At the same time, the Government made changes in the CHI Unique Program and established that the PHC services stipulated in the Unique Program are part of the basic, extended or additional medical services established in the Rules for organizing the PHC, approved by the Government Decision no.988/2018, and are delivered by PHC providers according to the Methodological Norms¹⁴¹. At the same time, the regulations approved in 2010 for PHC, which establish palliative care among the primary care services provided by the family doctor, have not been changed (at least no officially published document attesting to their change has been identified), so that they contravene the Rules for the organization of PHC¹⁴², which include palliative care in the list of extensive medical services provided at the level of PHC. At the same time, the Unique Program does not expressly name the palliative care services that can be delivered within the extended medical services provided by the family doctor and limits itself to one rule according to which the list of community and home care services covered by CHIF is established by the normative acts approved by the MoHLSP. Tables 13 and 14 show the interventions performed by the medical staff from the primary care in Romania and an essential package of palliative care services recommended by the WHO at the level of PHC.

138 MoHLSP Order no. 1269 of 06.11.2018 on the approval of branch medical statistical reports.

139 Law no.191 of 27.07.2018 on the amendment of some legislative acts.

140 Government Decision no.988 of 10.10.2018 on the approval of the Rules of organizing primary health care.

141 Government Decision no. 1020 of 24.10.2018 on the approval of the amendments that are operated in some decisions of Government.

142 Government Decision no.988 of 10.10.2018 on the approval of the Rules of organizing primary health care.

Table 13. Interventions applied in Romania by the primary care staff, with basic training in the field of palliative care, certified by completing training programs accredited by competent professional bodies and who occasionally care for patients with progressive chronic diseases and palliative care needs

- a) holistic assessment: patients' and families' understanding of the disease, burden of symptoms, performance status, comorbidities, communication and decision making, family support and care network, end-of-life fears, disease related education needs;
- b) communication interventions: empathic communication, communication of diagnosis and prognosis, avoidance in communicating the factual diagnosis/prognosis;
- c) symptom management: pain, dyspnea, anorexia, cachexia, depression, anxiety, nausea/vomiting, delirium, fatigue, insomnia;
- d) family and patient education on their social rights, patient mobilization, skin and oral care, medication administration, non-pharmaceutical management of symptoms in terminal care;
- e) maneuvers such as: positioning of subcutaneous butterfly, paracentesis, insertion of the urinary catheter;
- f) patient monitoring;
- g) coordination of care with specialized palliative care services and/or other specialized services;
- h) terminal care;
- i) nursing maneuvers.

Source: Order no. 253/2018 for the approval of the Regulation on the organization, functioning and authorization of palliative care services, Ministry of Health of Romania.

Table 14. The essential package of palliative care services recommended by the WHO for the provision of PHC

Interventions	Needs			
	Social Support	Medicines (a)	Equipment	Human resources (b)
Prevention and relief of pain or other (d) acute or chronic physical distress		Amitriptyline, oral	Pressure relief mattresses	Doctors (with basic training in palliative care)
		Bisacodyl (senna), oral	Nasogastric drainage and feed tubes	Medical assistants (with basic training in palliative care)
		Dexamethasone, oral and injectable	Urinary catheters	Community health workers, if available)
		Diazepam, oral and injectable	Safe boxes for opioids	
		Diphenhydramine (chlorpheniramine, cyclizine, or dimenhydrinate), oral and injectable	Flashlights with rechargeable batteries (if there is no access to electricity)	
		Fluconazole, oral	Diapers for adults or cotton and plastic	
		Fluoxetine (sertraline or citalopram), oral		
		Furosemide, oral and injectable		
		Haloperidol, oral and injectable		
		Hyoscine butylbromide, oral and injectable		
		Ibuprofen (naproxen, diclofenac or meloxicam), oral		
		Lactulose (sorbitol or polyethylene glycol), oral		
		Loperamide, oral		
		Metoclopramide, oral and injectable		
		Metronidazole, oral, to be crushed for topical use		
		Morphine, oral with immediate release and injectable		
		Naloxone, injectable		
		Omeprazole, oral		
		Ondansetron, oral and injectable (f)		
		Oxygen		
		Paracetamol, oral		
		Vaseline		

Prevention and relief of pain or other (d) acute or chronic physical distress	Amitriptyline, oral	Diapers for adults or cotton and plastic	Doctors (with basic training in palliative care)
	Dexamethasone, oral and injectable		Medical assistants (with basic training in palliative care)
	Diazepam, oral and injectable		Trained and supervised social workers, psychologists, grief (mourning) and/or lay counselors
	Diphenhydramine (chlorpheniramine, cyclizine or dimenhydrinate), oral and injectable		Community health workers, if available
	Fluoxetine (sertraline or citalopram), oral		
	Haloperidol, oral and injectable		
	Lactulose (sorbitol or polyethylene glycol), oral		
Prevention and amelioration of acute or chronic social suffering.	Cash aid and support in kind (c)		Social workers
			Community health workers, if available
Prevention and relief of spiritual suffering			Local spiritual counselors

a - Based on the WHO Essential Medicines List of 2015 (43). Alternative medicines that are acceptable are indicated in brackets: ().

b - Doctors can be general practitioners, family physicians, pediatricians, clinical officers or nursing assistants, and others.

c - Only for patients living in extreme poverty and only one caregiver per patient. Includes money transfers to cover living, children's tuition, transportation to medical institutions or funeral costs; food packages and other in-kind aids (blankets, mattresses, footwear, soap, toothbrushes, toothpaste).

d - Other physical ailments include shortness of breath, weakness, dizziness, vomiting, diarrhea, constipation, itching, bleeding, sores, and fever..

e - Psychological distress includes anxiety, depression, confusion and delirium, dementia and complicated grief.

f - Only in hospitals that provide chemotherapy for cancer or radiation therapy.

Source: Integrating palliative care and symptom relief into primary health care: a WHO guide for planners, implementers and managers. Geneva: World Health Organization; 2018. Licence: CC BY-NC-SA 3.0 IGO.

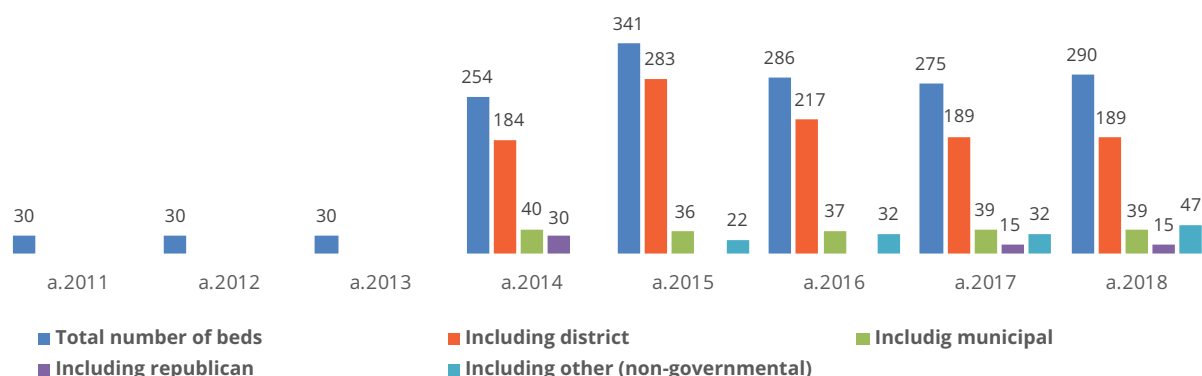
5.3. Specialized palliative Care

5.3.1. Units with palliative care beds within public HCI and non-profit hospice care providers

The widest activity of arranging palliative care services by organizing units with beds in hospitals began on January 1st, 2014, when by an order of the MoH¹⁴³ the districts HCIs installed beds specialized in palliative care. The Order of the Ministry of Health provided for the designation of palliative care beds, within the limit of existing beds, based on the number of served population - 7 beds per 100,000 population. Although the above-mentioned Order referred to the establishment of palliative care beds in district-level hospitals, starting with 2014, 30 palliative care beds were created in republican hospitals as well, but they were reduced to 15 by the year 2018. It should be mentioned that NPCS establishes the norm of 8 beds per 100,000 inhabitants (it should be taken into account that the norm is recommended at the national level which also include republican hospitals), with a minimum number of 5 beds per ward and an average number of 30 days of care per year for a patient. Prior to the creation of palliative care beds in district hospitals, the first 30 palliative care beds were opened in municipal hospitals starting with 2011, the first being Municipal Hospital no. 4 in Chisinau and the number of beds increased to 32 (+7 beds in the Balti Municipal Clinical Hospital) by 2018. Although the NHIC has been contracting palliative care beds from non-governmental providers since 2010, the NPHA started to gather the medical statistical evidence of the number of palliative care beds (hospices) within non-governmental providers in 2015, when it was established that there were 22 beds, a figure that increased to 47 in 2018. Therefore, the total number of palliative care beds increased from 30 in 2011 to 290 in 2018, except in 2015 when they were 341. By 2018 the largest number of palliative care beds were installed in district hospitals - 65%. (Figure 8.).

143 MoH Order no. 1570 of 27.12.2013 on the organization of palliative care.

Figure 8. Number of palliative care beds in public hospitals presented as total number and by types of institutions, developments in the period 2011-2018



Source: National Public Health Agency.

In 2018, the level of insurance with palliative care beds per 10,000 inhabitants was of 0.4 in municipalities and of 0.7 in districts. The development region of ATU Gagauzia has the highest level of insurance with palliative care beds per 10,000 inhabitants - 1.0, and at the opposite pole is the "South" Development Region with 0.6 beds per 10,000 inhabitants. In total, the level of insurance with palliative care beds in the country has been constant in the last three years and is of 0.8 per 10,000 inhabitants, so that the level recommended by NPCS of 0.8 beds was reached, except for 2015, when this indicator was higher and constituted 1.0 bed per 10,000 inhabitants (Figure 9.). It should also be considered that, according to the data of the last Census, the real number of the population is lower than the one used by NPHA and therefore when recalculating the indicator based on the new data about the population, its value will increase.

Figure 9. The level of insurance with palliative care beds per 10,000 inhabitants reported per development regions, municipalities, districts and in total per the Republic of Moldova, during the period 2011-2018

Source: The calculations made in this study were based on data from the National Public Health Agency.

The creation of palliative care beds, especially in district hospitals, has ensured a better access to specialized palliative care services at the hospital compared to the period up to 2014. The total number of bed-days for palliative care beneficiaries practically doubled in 2014 compared to the previous year, and by 2018 their number increased almost five times (Figure 10).

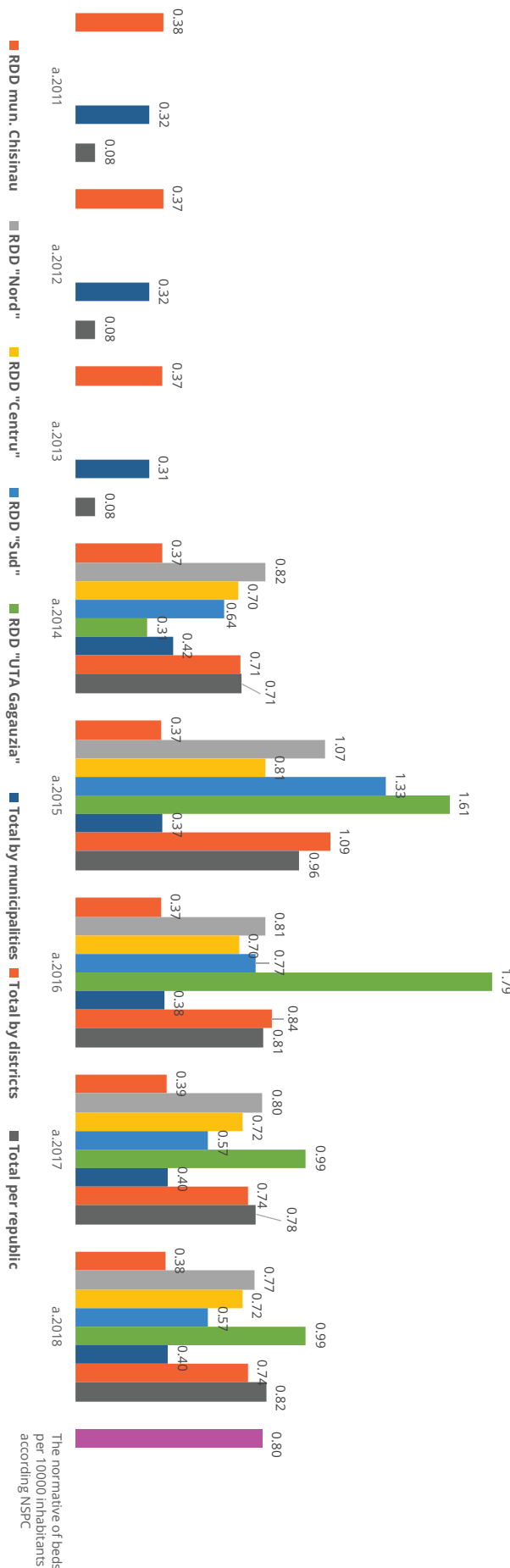
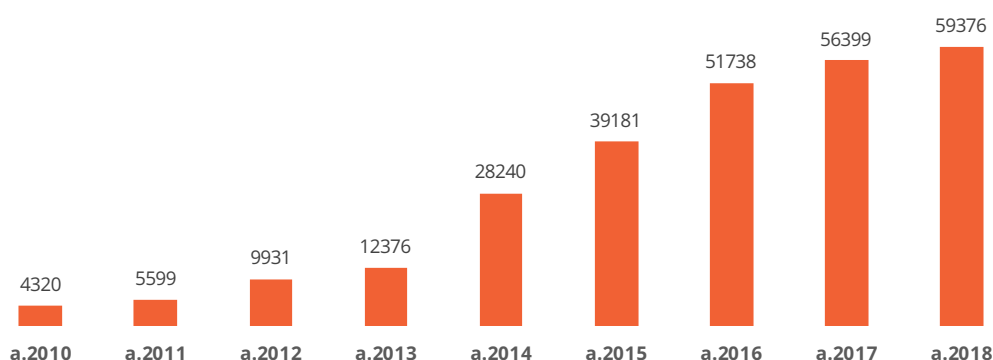


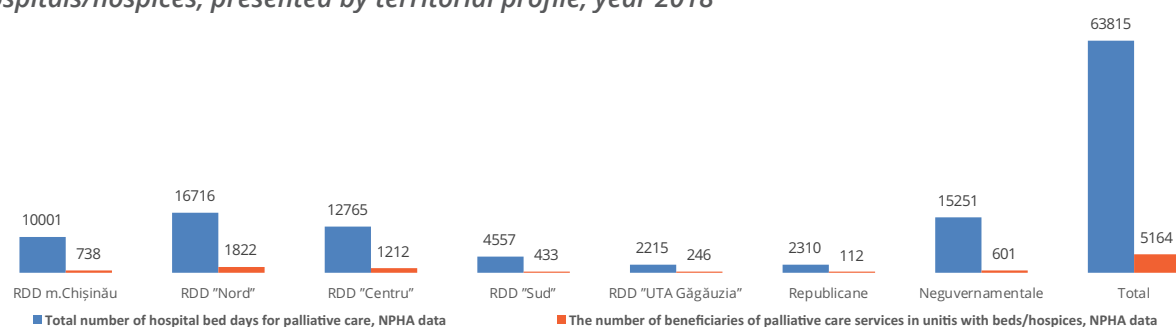
Figure 10. Total number of bed-days paid by the NHIC to hospital/hospices palliative care providers



Source: National Health Insurance Company.

The NHIC does not have data on the number of unique beneficiaries of palliative care provided in units with beds/hospices, nor on outpatients + deceased, as a result the access to specialized palliative care services provided with public money cannot be analyzed, because the reporting is done only on the number of bed-days which meets the contract concluded by the palliative care service provider with NHIC. For its part, the medical statistics on the bed-days number performed in units with beds/hospices held by NPHA differ from the one presented to the NHIC. NPHA gathers only the statistical data for the number of patients discharged + deceased. According to NPHA, in 2018 the number of patients discharged + deceased from units with beds/hospices was of 5164 (figure 11.): 88% of them benefited from services provided by the public sector and 12% - by the non-governmental sector. Proceeding from territorial profile, the largest share of total beneficiaries recorded in the country was from the "North" DR (35%). The share of the number of hospital bed days in public and non-governmental healthcare institutions is 76% and 24%, respectively. The average length of hospital stay is of 25 days for non-governmental providers and of 11 days for the public sector. The average length of hospital stay in the HCIs in the Development Regions is 10 days compared to 21 days - in republican institutions. According to NPCS the average number of care days per year "per patient" cannot exceed 30 days.

Figure 11. The number of bed-days and the number of patients who benefited from palliative care in hospitals/hospices, presented by territorial profile, year 2018

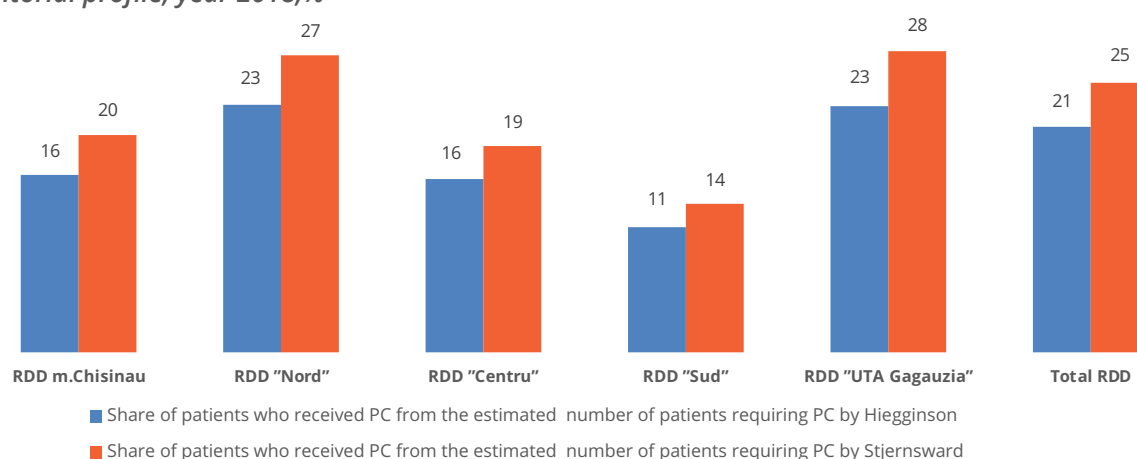


Source: National Public Health Agency.

An attempt to estimate the share of patients receiving palliative care in units with beds/hospice indicates that 21% or 25% of the total number of patients requiring palliative care at national level would have had access to such services - index calculated after Hiegginsin and Stjernswärd (see Table 18.), respectively (Figure 12). Proceeding from territorial profile, this indicator is lower in the "South" DR compared to "ATU Gagauzia" and the "North" DR, where the indicators exceed the estimated average in the country. The data obtained in this estimation attempt are not in line with reality, because the number of outpatients + deceased that was used for these calculations does not represent a unique number of patients, but a figure that includes all those re-admitted and discharged during a year. Thus, the actual share of patients receiving specialized palliative care in units with beds/hospice compared to the estimated number of patients requiring palliative care, calculated after Hiegginsin and Stjernswärd, could actually be lower. However, the estimation showed that virtually every fourth (5164

of 20958 estimated according to Hiegginsin) or every fifth patient (5164 of 25139 estimated according to Stjernsward) benefited from specialized care services in hospital/hospice conditions. According to NPHA, the share of discharged + deceased persons in units with beds/hospices in 2018 (with medical insurance from NHIC) constituted on average 98.1% in the country, practically 100% were insured in "ATU Gagauzia DR", at the opposite pole were those from Chisinau municipality DR - 93.4%. It should be mentioned that neither NHIC nor NPHA have statistical records by the area of residence - urban and rural and/or by sex.

Figure 12. Share of patients who received palliative care (PE) in hospitals/hospice from the total number of potential patients requiring PE calculated according to Hiegginsin and Stjernsward, by territorial profile, year 2018,%



Note: Calculations performed within this study.

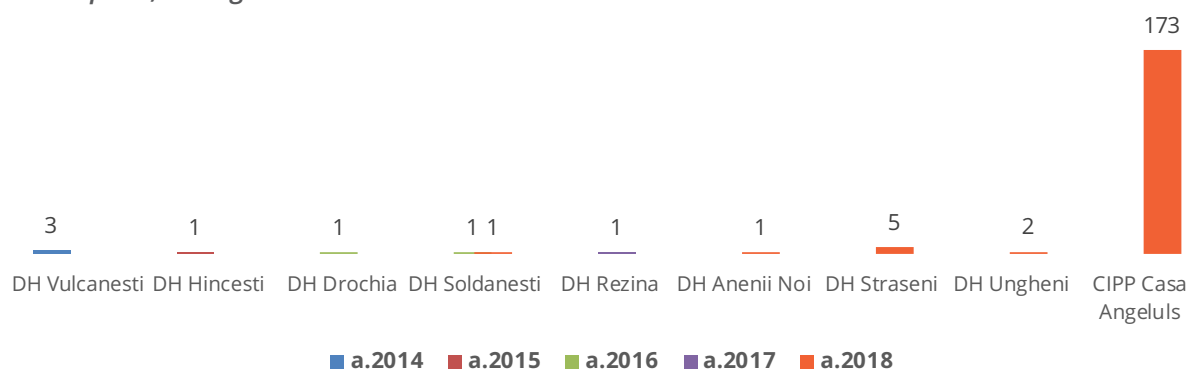
A report by the Global Alliance for Palliative Care and the WHO classified the level of development of palliative care for children in the Republic of Moldova in the same group with the countries without palliative care services for children (information available as of 2011)¹⁴⁴. The number of children who had access to specialized palliative care services in units with beds/hospices has increased substantially since the summer of 2017, when in the village of Isacova Orhei district the Center for Pediatric Palliative Care (CPPC) Casa Angelus (15 beds) was opened - a non-governmental provider contracted by the NHIC since its opening. This center offers non-stop medical and social assistance services for a period of at least 14 days, to children with progressive and advanced incurable diseases, with the possibility of readmission. CPPC Casa Angelus has the capacity to hospitalize up to 15 children together with a relative in case of need. In order to benefit from free pediatric care, the patients need to provide: i) the copy of the identity card of a parent/legal representative; ii) the copy of the child's birth certificate or identity card; iii) the form no. 027/e completed by the family doctor¹⁴⁵. As related to units with beds/hospices date, the NHIC holds medical statistics only for the number of bed-days. NPHA has data on the number of children hospitalized in this center only for 2018, which was of 173 (Figure 13).

Also, the medical statistical data of NPHA show that until the opening of the nominated center, the hospitalizations of children for palliative care in units with beds were sporadic and in the last five years they were registered in only eight ATUs. According to the NPHA, the statistical reports no. 30-san presented by the Oncological Institute and the Mother and Child Institute do not contain statistical data on palliative care services provided to children. It can be stated that with the opening in the summer of 2017 of CPPC Casa Angelus, children's access to inpatient palliative care by has improved significantly compared to the previous period. As medical statistics on the number of hospitalizations of children in units with beds/hospice also include readmissions, the number of unique beneficiaries cannot be estimated. Similarly, the number of children in need of palliative is also difficult to estimate. The methodology for estimating the need for palliative care in children is based on the prevalence of certain groups of diseases with the inclusion or exclusion of certain diseases from that group. Due to the fact that there is not an integrated medical information health system in the Republic of Moldova, there are no data on the prevalence of these diseases.

144 Global Atlas of Palliative Care at the End of Life. January 2014.

145 <https://hospice.md/casa-angelus/> (of 30.08.2019).

Figure 13. Number of hospitalizations of children aged 0-17 years 11 months and 29 days in units with beds/hospices, during 2014-2018



Source: National Public Health Agency.

5.3.2. Mobile hospital teams specialized in palliative care

The Oncological Institute from Chisinau has been providing palliative care services through the hospital team since 2009, when the Center for Palliative Care and Psychological Support was established. The services are provided for patients admitted to this hospital, but outpatient consultations are also offered for people who are referred to this service from the districts and municipalities of the country. The contract signed by the Oncological Institute with the NHIC mentions only the item "palliative care (hospice)" and nothing about the provision of specialized palliative care services through hospital teams¹⁴⁶. Also, the medical statistical data held by NPHA do not contain anything about the palliative care services provided by the mobile hospital team and about the outpatient consultations offered by the Center for Palliative Care and Psychological Support within the Oncological Institute.

5.3.3. (Mobile) Home Palliative Care Team

Specialized palliative care services by home care mobile team are provided only by non-governmental providers, although a normative act of the MoH at the end of 2015 provided for the establishment of mobile teams specialized in home palliative care within district PHC medical institutions, with the inclusion of additional responsibilities for the main staff based on the identified needs and the estimated workload (see section 5.2.).

2013 was the first year when specialized palliative care services began to be provided on public money through the home care mobile team. In the same year, 7 non-governmental providers were contracted by the NHIC, the number of which fluctuated up to 10 in 2015, after which it decreased to 8 in 2017-2018 and then increased to 9 in 2019¹⁴⁷. The highest number of home visits is carried out by FFMS Angelus Moldova, followed by the NGO Medlife, which provides specialized palliative care services - mobile team home care in Chisinau and Balti (figure 15.), followed by other non-governmental providers of such services in ATU Soroca, Orhei, Taraclia, Ungheni, Straseni, Ocnita, Ceadar-Lunga. The NHIC does not have data on the number of people who received specialized palliative care services through home care mobile teams and therefore the access to services cannot be analyzed. The total number of people who needed palliative care services in the 8 ATUs with mobile specialized palliative care services in place, would be of 7857 (37%) after Stjarnsward and 9517 (38 %) after Hiegginson in 2018. They received a total of 17,928 visits (figure 14.).

Thus, in 2018, the mobile team would have made 2 home visits on average for a potential beneficiary of palliative care, estimated after Stjarnsward and Hiegginson, except for the districts of Orhei, Straseni and Ceadar-Lunga, where less than 2 visits were carried out for a potential beneficiary. It should be mentioned that the NHIC established a ceiling of 36 visits of the contracted mobile home care team per one beneficiary per year, but this indicator cannot be used to accurately estimate the number of final beneficiaries in the ATU, where there are service providers of specialized home palliative care contracted by the NHIC. It is not excluded that the providers of specialized palliative care services

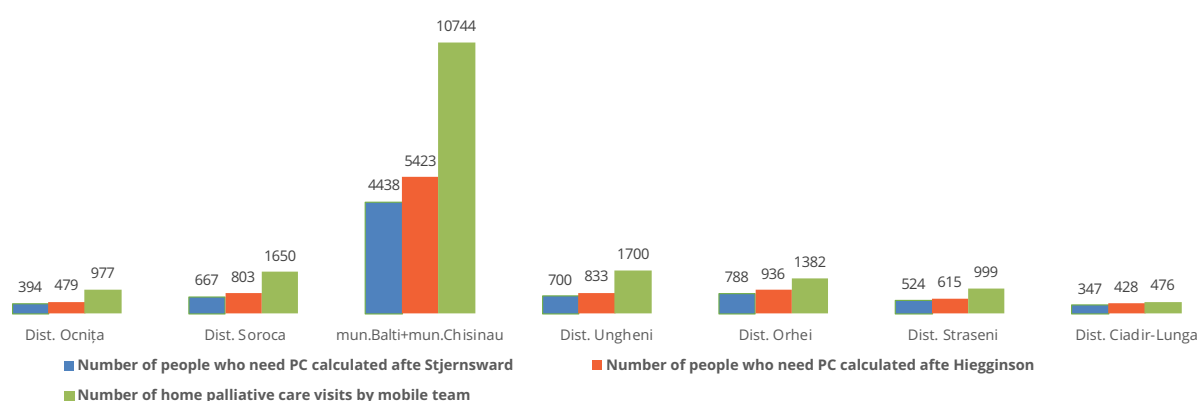
¹⁴⁶ Annex no. 2 to the Contract for provision of medical assistance (for provision of healthcare services) under the compulsory health insurance no. 05-08 / 369 of December 28, 2018.

¹⁴⁷ Ibid.

- home care mobile teams – have provided services to people from other territories, as is the case with hospices, but their statistical evidence is not provided at the level of relevant authorities. In the other 28 ATUs, where there are no providers of specialized home palliative care services, the situation regarding ensuring access to the services of multidisciplinary teams is precarious (*Table 15.*). Estimates according to Hiegginson show that out of the 28 ATUs, where there are no providers of specialized home palliative care services, in 2 there are over 800 people who do not have access to specialized home palliative care services, in other 4 there are over 700 people, in 6 - over 600, in 6 - over 500 and in 10 ATUs there are between 200 and 500 palliative patients.

We can see that out of the total number of potential beneficiaries of palliative care services in the Republic of Moldova, estimated for 2018 in the number of 20958 - after Stjernsward and 25139 - after Hiegginson, only 39% can have access to specialized home palliative care services (8118 of those calculated according to Stjernsward and 9833 - according to Hiegginson). Therefore, the Republic of Moldova failed to implement an efficient model of providing specialized palliative care services at home, which would ensure access to services of all potential beneficiaries of palliative care and which is currently focused only on units with beds development (*see section 5.3 .1.*).

Figure 14. Number of people in need of palliative care (PC) (calculated after Stjernsward, Hiegginson) and number of visits in eight ATUs where there are providers of specialized palliative care services - home care mobile teams contracted by NHIC in 2018



Source: The calculations performed in this study based on data from the National Health Insurance Company*

***Note:** One specialized home palliative care provider delivers services in both Chisinau and Balti municipality and therefore the data on visits were merged with the data of another palliative care provider in Balti municipality, because NHIC collects the information by providers and does not have separate information by administrative-territorial units.

Figure 15. Number of home palliative care visits carried out by mobile teams contracted by NHIC, in the period 2013-2019

Source: National Health Insurance Company.

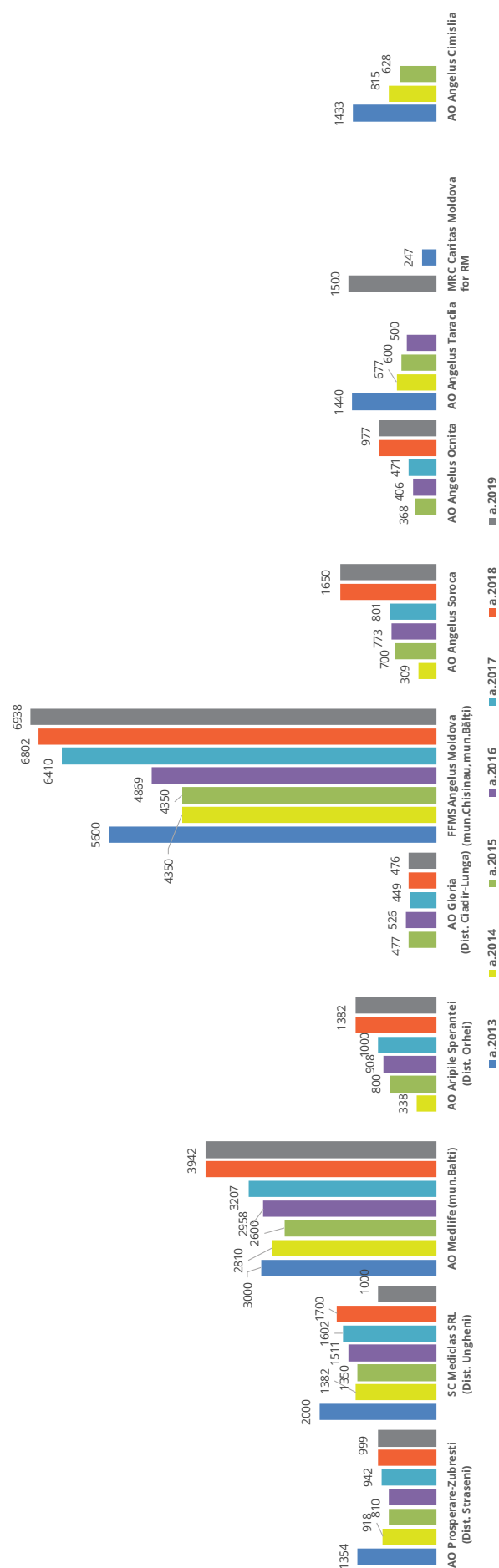


Table 15. The number of home visits carried out by mobile teams, in accordance with the contracts concluded by the NHIC in 2019 with non-governmental providers and the number of potential beneficiaries of palliative care services calculated according to Stjernsward and Hiegginson, represented by territorial profile

Territorial Administrative Unit	Number of people requiring PC after Stjernsward	Number of people requiring PC after Hiegginson	Number of home care visits by mobile team
Chisinau mun. + Balti mun.	4438	5423	10880
Briceni	568	675	0
Donduseni	361	426	0
Drochia	637	768	0
Edinet	635	760	0
Falesti	647	773	0
Floresti	630	755	0
Glodeni	394	469	0
Ocnita	394	479	977
Rascani	517	614	0
Sangerei	545	651	0
Soroca	667	803	1650
Anenii Noi	496	595	0
Calarasi	514	602	0
Criuleni	448	536	0
Dubasari	204	240	0
Hancesti	770	905	0
Ialoveni	521	624	0
Nisporeni	419	502	0
Orhei	788	936	1382
Rezina	316	374	0
Straseni	524	615	999
Soldanesti	311	363	0
Telenesti	444	527	0
Ungheni	700	833	1000
Basarabeasca	150	183	0
Cahul	678	813	0*
Cantemir	331	393	0
Causeni	570	679	0
Cimislia	436	526	0
Leova	317	376	0
Stefan-Voda	436	516	0
Taraclia	261	316	1500
Comrat	388	473	0
Ceadar-Lunga	347	428	476
Vulcanesti	158	191	0
Total	20958	25139	18864

Source: Calculations made in this study in regard to the number of people in need of palliative care estimated after Stjernsward and Hiegginson (Table 18.) and NHIC data on the number of home care visits by contracted mobile team by territorial profile for 2019.

* Hospices of Hope Moldova supports the activity of the multidisciplinary team in Cahul, but data on the number of visits are not published. The multidisciplinary team from Cahul is not among the palliative care service providers contracted by NHIC for 2019.

5.3.4. Outpatient palliative care consulting offices

De Specialized palliative care services at outpatient palliative care consulting offices are accessible only to people in territories where there are non-governmental providers of specialized palliative care services - home care mobile team (see section 5.3.3.). Only two public hospitals contracted by the NHIC for the provision of specialized palliative care services in units with beds - the Municipal Clinical Hospital no. 4 in Chisinau and the Mobile Team of the Cahul District Hospital offer outpatient palliative

care consultations¹⁴⁸. The patient can go to these specialized offices to receive stoma bags of all types, accessories to stoma bags, external breast prostheses after mastectomy. In order to benefit from this support, you need to submit the 027-e form which contains data about the patient - confirmation of the diagnosis (performed surgery) and a simple copy of the identity document and the insurance policy. The NHIC does not have medical statistics on the number of visits made to outpatient palliative care consulting offices, because it does not contract such services. The medical statistical data held by the NPHA do not contain information about the number of visits to outpatient palliative care consulting offices at the two public hospitals mentioned above, and of the eight non-governmental providers of specialized palliative care only two reported to the ANSP by Forma 30-san the visits made to outpatient palliative care consulting rooms. According to the NPHA, not even the Oncological Institute, which offers outpatient palliative care consultations (see section 5.3.2.) for all patients countrywide, provides data on the number of outpatient consultations in the statistical report no. 30-san submitted to the NPHA.

The lack of medical statistics on the number of visits to outpatient palliative care offices shows that these services are not contracted with public money, and that the medical statistics does not contain specialized palliative care services through outpatient palliative care consulting offices in the Statistical Report no. 30-san.

5.4. Pharmaceutical support

Pharmaceutical support with drugs containing narcotics, psychotropic substances and precursors is provided only by licensed pharmaceutical companies and/or institutions¹⁴⁹. The activity with narcotics and psychotropic substances and precursors may be carried out by institutions other than enterprises and/or pharmaceutical institutions, but only on the basis of the authorization issued by the Permanent Committee on Drug Control of AMDM, with the obligation to ensure the record keeping and storage conditions for these type of substances and preparations.

In 2018, there were 18 holders of the GDP Certificate through which they were authorized for the distribution of medicines, including the procurement, possession and supply of medicines. Eleven of them had authorization for the distribution of drugs containing psychotropic substances and precursors, for comparison, in 2017 there were only 7 holders of such authorization¹⁵⁰. In 2018, 61% of the total list of drug distributors were authorized to store drugs with psychotropic content and precursors. This list does not include SA SANFARM-PRIM, which is a deposit with a state share of 99.11%¹⁵¹ and which is one of the participants and winners of public tenders for some opioid drugs.

There are 1262 community pharmacies + branches authorized to provide pharmaceutical support to the population¹⁵². These data are only for 2015, because since then MMDA has no longer published the statistical yearbook on the resources and activity of the pharmaceutical system in the Republic of Moldova. Outpatient opioid medications are delivered through pharmacies (medicine care departments) within Health Centers/Family Doctor Centers at the district level. According to the same statistical yearbook published in 2015, there are 741 medicine care departments at the Health Centers/Family Doctor Centers + branches in the country.

The country lacks a functional tool for the record of drug utilization statistics, including for palliative care, and decisions to improve their rational use, despite the fact that in 2012 a government act established the development by MMDA of a drug utilization data collection system based on ATC/DDD criteria¹⁵³ by 2014. In this report we tried to estimate the consumption of morphine and fentanyl based on the number of packaging units purchased through public procurement in 2011-2018¹⁵⁴. When estimating the total morphine consumption including different forms and concentrations purchased through public procurement in the period 2011-2018 were taken into account. The total consumption

148 Guide for information, education and self-care of the incurable patient, Chisinau, 2018. National Association of Palliative Treatment –NAPT.

149 Art.13 of Law no.382 of 06.05.1999 on the circulation of narcotics, psychotropic substances and precursors.

150 Report of the Medicines and Medical Devices Agency.

151 Data on joint stock companies, of which the state is a shareholder - holding part of the social capital, according to the Register of Public Assets, as of 01.01.2019, Public Property Agency (accessed on 20.09.2019).

152 Statistical Yearbook 2015. Resources and Activity of the Pharmaceutical System of the Republic of Moldova, MMDA.

153 Government Order no. 28-d of 11.04.2012 The Roadmap of the Medicines Agency for the Years 2012-2014, The Reform of Regulatory System in the Fields of Medicine and Medical Devices.

154 Results of public procurement tenders published by CCHP and MMDA.

of morphine (ATC class N02AA01) was estimated by route of administration (oral and parenteral forms) and by Defined Daily Dose - DDD per 1000 inhabitants per day (table 16. and figure 16.), based on the ATC/DDD System¹⁵⁵, which is recommended by the WHO and which serves as a tool for monitoring and studying the consumption of medicines in order to improve the quality of consumption. DDD per 1000 inhabitants per day means that a certain number of drug DDDs are used on average, on any day of the year, within the representative group of 1000 inhabitants.

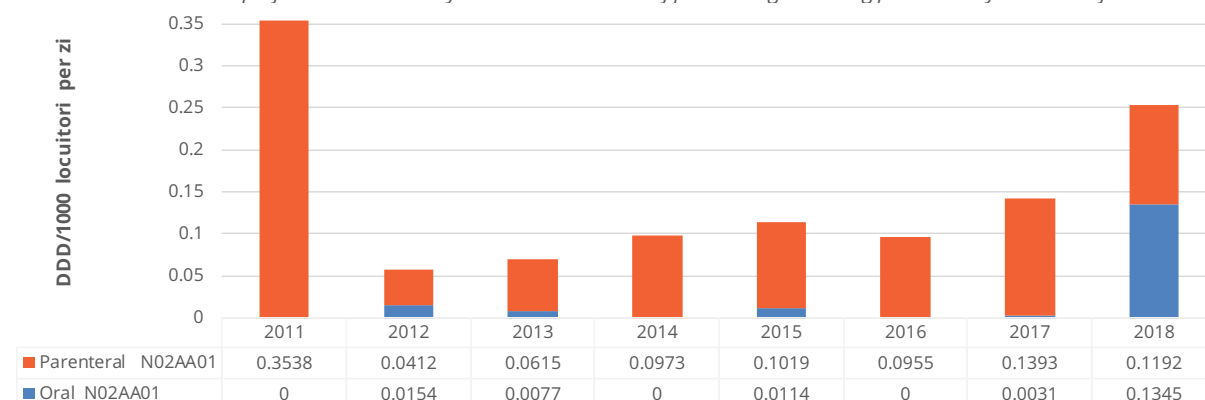
Table 16. Morphine consumption (N02AA01) estimated for the period 2011-2018

Morphinum Mode of administration	Consumption in DDD							
	2011	2012	2013	2014	2015	2016	2017	2018
Parenteral N02AA01	0,3538 (100%)	0,0412 (73%)	0,0615 (89%)	0,0973 (100%)	0,1019 (90%)	0,0955 (100%)	0,1393 (98%)	0,1192 (47%)
Oral N02AA01	0%	0,0154 (27%)	0,0077 (11%)	0%	0,0114 (10%)	0%	0,0031 (2%)	0,1345 (53%)
Total	0,3538	0,0566	0,0691	0,0973	0,1133	0,0955	0,1424	0,2537

Source: The calculations performed in this study based on the results of public drug tendering published by the Center for Centralized Public Health Procurement, the Agency for Medicines and Medical Devices and according to the stable population number reported by the National Bureau of Statistics.

Figure 16. Estimated morphine consumption (N02AA01) in the period 2011-2018

Source: The calculations performed in this study based on the results of public drug tendering published by the Center for Centralized



Public Health Procurement, the Agency for Medicines and Medical Devices and according to the stable population number reported by the National Bureau of Statistics.

The data show a considerable fluctuation from year to year of total morphine consumption: from 0.3538 DDD in 2011 - the highest reported consumption, to 0.2537 DDD in 2018, the most significant decreases being recorded in 2012 - 0, 0566 DDD and in 2013 - 0.0691 DDD. Total consumption, analyzed according to the route of administration, indicates that the consumption of parenteral forms predominates compared to oral. Thus, in 2012 the consumption of parenteral forms would have been of 73%, compared to 27% - consumption of oral forms; in 2017, 98% of parenteral forms were administered versus 2% of oral forms, followed by a significant increase in the consumption of oral forms, which in 2018 reached up to 53% and, respectively, 47% - parenteral forms. At the same time, the oral forms are not present in the results of the public drug tenders for each year of the examined period but they were reported in the results of the public drug tenders for 2012, 2013, 2015, 2017 and 2018 with a fluctuation of consumption between 0.0154 DDD in 2012 and 0.1345 DDD in 2018, the lowest rate of consumption - of 0.0031 DDD being recorded in 2017. In the case of oral forms of morphine, the fluctuation of consumption can be explained by the registration of products in the country, by the amount required by centralized procurements, as well as by their import in quantities covering a period of more than one year, especially if considering the increase of oral forms consumptions of morphine up to 53% in 2018. In 2011 and in the following years there are obvious

¹⁵⁵ DDD per 1000 inhabitants per day was calculated using the following equation: The defined daily dose per unit of package - DPP at the product level (DPP = [unit strength × pack size] / DDD) was determined. The number of packages for each medicinal product placed on the market in a year is multiplied by the number of DDDs per pack (DPP) to calculate the total number of DDDs for each product. These are aggregated to provide the total number of DDDs at the desired ATC code level for each year. The total number of inhabitants in the country served as a denominator (stable population - annual average). Subsequently, the unit of measurement of the results was calculated, DDD / 1000 inhabitants per day at the product level.

oscillations in the total consumption of morphine, regardless of the pharmaceutical form, except for 2018, when the increase and diversification of the pharmaceutical forms of morphine occurred.

At estimating the total fentanyl consumption, the number of packaging units purchased through public procurement in 2011-2018 was also taken into account. According to the results of public drug tendering, fentanyl is presented in parenteral form (solution for injection) and in therapeutic forms - transdermal patches. Parenteral forms of fentanyl (ATC group NO1H01) do not have DDD established by WHO, therefore injectable solutions have not been included in the estimation of the total fentanyl consumption in DDD per year. Thus, the total consumption of fentanyl was examined only for the forms of transdermal patches (ATC group N02AB03), being estimated by Defined Daily Dose - DDD per 1000 inhabitants per day (table 17. and figure 17.). It should be mentioned that the total estimated consumption of fentanyl in the form of transdermal patches, in the period 2011-2018, attests a notable increase from 0.0160 DDD in 2014 to 0.0895 DDD - in 2018, which demonstrates an improvement of the population access to this opioid drug.

At the same time, according to the estimation of the total morphine consumption in the Republic of Moldova (parenteral and oral forms) of 0.2537 DDD in 2018 (Table 16.) per 1000 inhabitants, reveals that 0.025% of the population administered this drug every day of that year. Estimates of fentanyl consumption (transdermal forms) in the Republic of Moldova, which in 2018 amounted to 0.0895 DDD (Table 17.), showed that 0.0089% of the population received this drug daily. For comparison, in Israel the consumption of fentanyl was of 2.33 DDD and morphine of 0.15 DDD in 2016¹⁵⁶, which reveals that 0.23% of the population received fentanyl and 0.015% - morphine every day of that year.

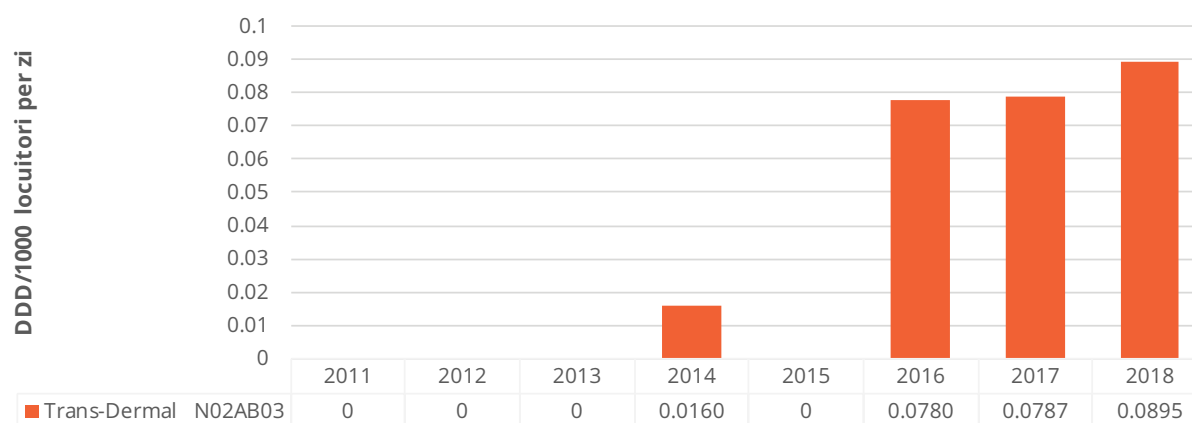
Table 17. Estimated consumption of fentanyl (transdermal patch) in 2011-2018

Fentanylium Route of administration	Consumption in DDD							
	2011	2012	2013	2014	2015	2016	2017	2018
Parenteral NO1AH01*	0	0	0	0	0	0	0	0
Transdermic N02AB03	0	0	0	0,0160	0	0,0780	0,0787	0,0895
Total	0	0	0	0,0160	0	0,0780	0,0787	0,0895

Source: The calculations performed in this study based on the results of public drug tendering published by the Center for Centralized Public Health Procurement, the Agency for Medicines and Medical Devices and according to the stable population number reported by the National Bureau of Statistics.

*Fentanyl in parenteral form is present in the results of public drug tendering for each year.

Figure 17. Estimated consumption of fentanyl (N02AB03 - transdermal patch) in 2011-2018



Source: The calculations performed in this study based on the results of public drug tendering published by the Center for Centralized Public Health Procurement, the Agency for Medicines and Medical Devices and according to the stable population number reported by the National Bureau of Statistics.

¹⁵⁶ Alexander M. Ponizovsky, Eli Marom, Abraham Weizman, Eyal Schwartzberg. Changes in consumption of opioid analgesics in Israel 2009 to 2016: An update focusing on oxycodone and fentanyl formulations. *Pharmacoepidemiol Drug Saf.* 2018 May; 27(5):535-540. doi: 10.1002/pds.4415. Epub 2018 Feb 28.

VI. Evaluation of palliative care

6.1. Equity

As early as 2007, the Republic of Moldova received assistance in estimating the needs for palliative care services, which showed that about 25,000 patients need such services¹⁵⁷ every year. The estimations made in this report show that the needs for palliative care services remain virtually the same - 25,139 patients/year calculated after Hiegginson (Table 18.). However, neither the MoHLSP nor the NHIC have developed and implemented a system for measuring equity in the field of palliative care, and there is no public report demonstrating the situation regarding the elimination of inequalities. Today, after 10 years of development and implementation of public policies in the field of organization, financing, training of human resources and provision of palliative care services, we can see, unequivocally, that in 28 ATUs, where 60% of people in need of palliative care live, there are inequalities resulting from differences in access to specialized home palliative care services. Patients who reside in localities where specialized palliative care providers are not in place do not have access to quality palliative care services to maintain the best possible quality of life until death. The only study conducted among the beneficiaries of specialized palliative care in 2019¹⁵⁸ shows that in the districts where there are providers of specialized home palliative care services, 58% of beneficiaries consider that their health is satisfactory and good, compared with only 34% of those living in the territories where there are no such services or where there are only services provided in units with beds. At the same time, the beneficiaries of palliative care in the localities where there are no specialized home care providers self-assess their health condition as bad and very bad considerably more often (66%) compared to those living in the localities where the providers are available (42%).

In general, 80% of beneficiaries living in territories where specialized home palliative care services are available reported being very satisfied with their quality of life since they started to receive the services, while only 48% report satisfaction in territories where such services are lacking or are provided only in units with beds.

It should be noted that the inequities resulting from the differences in access to specialized palliative care services in the territory do not ensure the financial protection of patients. Thus, only 64% of respondents in territories where there are no specialized home palliative care services stated that everything was free of charge and that they did not incur any expenses for such services, compared to 90% of those where such services are available. Recipients of palliative care in territories where there are no specialized home care services take greater pain in bearing the costs, because they receive such care in the hospital for a limited period of time, they also pay extra for transportation and often have to buy parapharmaceutical supplies during hospitalization. On the contrary, beneficiaries of specialized palliative care provided at home by non-governmental organization receive both consumables and medicines, so the patients reported to have received medicines and consumables from the non-governmental provider in 46% of cases, compared to only 2% of beneficiaries of hospital palliative care living in localities where no specialized home services are available.

Patients who have received specialized palliative care services in district hospitals, compared to those in territories with specialized home care services, feel the lack of medical consultations from specialists, they do not have free access to all medicines, suffer from insufficient visits at home and the need for psychological counseling. Moreover, 60% of the respondents who received specialized palliative care in the hospital stated that the medical worker did not visit them during hospitalization, and 32% of the beneficiaries interviewed stated that the doctor visited them less than once a week. This is while 58% of the beneficiaries from the territories where there are providers of specialized home palliative care services are visited by the doctor several times or even daily by the nurse from the multidisciplinary team. There are clear differences between the level of satisfaction with the dose of medication administered to patients under the supervision of specialized home palliative care providers - 88% and the level of satisfaction of patients regarding the dose of analgesic drugs prescribed and administered in palliative care units - 56%.

157 Dr. Daniela Mosoiu, Assessment of Palliative Care Needs in the Republic of Moldova. Chisinau, 2007.

158 Access and Quality of Palliative Care Services in the Republic of Moldova. Qualitative study. Independent Sociological and Information Service OPINIA, 2019.

It has also been found that the plan for pain medication administration prescribed to patients in territories where there are specialized home care providers is more effective, and patients who follow the prescribed medication on time no longer feel pain and are able to prevent it more effectively. 66% of the interviewed beneficiaries from the territories where with providers specialized in home palliative care are also satisfied with the training received on how to care for the patient at home and the actions they can undertake in different situations. At the same time, only 26% of respondents who benefited from specialized palliative care solely in hospital condition state that their family or caregivers received relevant training while another 36% mention that they were only provided with general information that proved insufficient.

A qualitative study among palliative care providers¹⁵⁹ shows that the most vulnerable categories of patients who need palliative care but do not benefit from it are primarily unidentified people, especially the elderly who live alone and belong to the lower quintile of well-being. These people do not go to the family doctor, encounter difficulties when they have to travel to the district center or Chisinau for diagnosis and consultations with specialists and often endure the pain and come to terms with the thought that they have to endure the suffering and await their death alone. Family doctors report that children and their families often face inequitable access to palliative care services, especially in case of neurological conditions.

There is no other public data and/or records of the MoHLSP, NHIC, or of other stakeholders in the field of palliative care that would show how equity in palliative care in the Republic of Moldova is ensured.

Figure 18. Estimation of palliative care needs by territorial profile according to the data on general mortality registered in 2018

	Total deceased	Including of cancer	Including injures and poisoning	Total deceased, without injures and poisoning	Number of people requiring PC after Stjernsward *	Number of people requiring PC after Hiegginson**
RDD mun. Chisinau	6542	1347	340	6202	3721	4551
RDD Nord	11855	1949	671	11184	6710	8044
mun. Balti	1250	246	56	1194	716	872
Briceni	1003	149	57	946	568	675
Donduseni	630	85	29	601	361	426
Drochia	1121	197	59	1062	637	768
Edinet	1116	181	58	1058	635	760
Falesti	1131	181	53	1078	647	773
Floresti	1116	183	66	1050	630	755
Glodeni	712	105	56	656	394	469
Ocnita	695	134	38	657	394	479
Râscani	918	135	57	861	517	614
Sângerei	982	150	73	909	545	651
Soroca	1181	203	69	1112	667	803
RDD Centru	11545	1621	788	10757	6454	7651
Anenii Noi	890	147	64	826	496	595
Calarasi	904	107	47	857	514	602
Criuleni	795	127	48	747	448	536
Dubasari	371	45	31	340	204	240
Hâncesti	1382	169	98	1284	770	905
Ialoveni	928	150	60	868	521	624
Nisporeni	743	120	44	699	419	502
Orhei	1430	204	117	1313	788	936
Rezina	577	78	51	526	316	374
Straseni	930	113	57	873	524	615
Soldanesti	551	62	33	518	311	363
Telenesti	795	113	55	740	444	527
Ungheni	1249	186	83	1166	700	833
RDD Sud	5686	895	388	5298	3179	3801

159 Danii Olga, Nicoleta Spinu-Triboi. Access and Quality of Palliative Care Services in the Republic of Moldova. Qualitative study. Independent Sociological and Information Service OPINIA, 2019.

Basarabasca	271	54	21	250	150	183
Cahul	1228	197	98	1130	678	813
Cantemir	599	83	47	552	331	393
Causeni	1005	152	55	950	570	679
Cimislia	773	138	47	726	436	526
Leova	564	80	36	528	317	376
Stefan-Voda	774	106	47	727	436	516
Taraclia	472	85	37	435	261	316
RDD UTA Gagauzia	1572	321	83	1489	893	1092
Comrat	687	135	40	647	388	473
Ceadar-Lunga	603	137	25	578	347	428
Vulcanesti	282	49	18	264	158	191
Total by municipalities	7792	1593	396	7396	4438	5423
Total by districts	29408	4540	1874	27534	16520	19716
Total per republic	37200	6133	2270	34930	20958	25139

Source: Calculations made in this study based on mortality data provided by NPHA.

**The calculation after Stjernsward method showed that 60% of people who died, except for deaths from injury and poisoning, required palliative care.*

***The calculation after Hiegginson method showed that all patients who died of cancer and another 2/3 of patients who died of other causes, except for deaths from injury and poisoning, require palliative care.*

6.2. Economic efficiency

The efficiency of the resources allocated to the health system needs to be monitored in order to determine whether the financial means are actually used to finance an optimal combination of health services which ensure the highest health outcomes at a certain total cost¹⁶⁰. The share of expenditures for palliative care services does not exceed 0.36% of the total expenditures of the basic fund of the NHIC intended for the payment of medical services for 2018. Starting from this intermediate goal of the health system, namely to ensure economic efficiency, then palliative care contributes to the profitability of the system as a whole. Due to the lack of data on the number of beneficiaries of palliative care through specialized home care services and those provided in units with beds, it is not possible to estimate the costs for assisted outpatient and inpatient care per beneficiary and therefore it is impossible to analyze the cost-effectiveness of the means allocated by to the NHIC for palliative care. In 2018, out of the total expenses for palliative care (23,632,951 lei), the NHIC allocated 14% (3,252,139 lei) for specialized home palliative care services and 86% (20,380,812) - for services provided in units with beds/hospices, but NHIC does not have records of how many people have benefited from these services at home and in the units with beds/hospices. The certain thing is that specialized home palliative care services are more cost-effective than those offered in hospitals/hospices, because they can cover a larger number of patients at lower costs, and their integration into PHC would further increase profitability. The focus on the predominant financing of palliative care services in units with beds in the 36 ATUs and the lack of specialized home palliative care services in 28 ATUs indicates major problems in ensuring technical efficiency of palliative care¹⁶¹.

There is sufficient evidence that palliative care, whether provided in hospital/hospice or at home, contributes to lower costs for hospital care and, consequently, for the health system, due to the reduction in the number of unsubstantiated hospitalizations and prevention of medication use at the emergency units. Palliative care services for residents of nursing homes can also reduce the number of hospitalizations. This means that providing palliative care services actually leads to decrease in medical costs and at the same time - ensures a better quality of life for patients in palliative care.

6.3. Service efficiency

Eficiența The efficiency of palliative care services is undebatable, because from a medical and social point of view they maintain the best quality of life until death and reduce the need for difficult and aggressive treatments, especially if initiated early. However, the results of the palliative care services'

¹⁶⁰ Health system efficiency. How to make measurement matter for policy and management. Copenhagen: WHO Regional Office for Europe, 2016.

¹⁶¹ Planning and implementing palliative care services: a guide for programme managers. World Health Organization 2016.

activity depend on the way in which the authorities implement the model of their organization, financing and provision. The policies for organization, financing and provision of palliative care services implemented in the Republic of Moldova do not ensure the expected results, because most of those who need palliative care cannot benefit from them. The country has not been able to implement the full range of palliative care services, especially specialized home services, which are not available for patients in 28 ATUs out of 37 in total. This inconsistency in the organization of palliative care services has led to the fact that practically 2/3 of the patients in need of palliative care did not benefit from specialized home care in 2018.

The fact that the expected results of covering the needs of palliative care at national level by 2019 was not achieved is partly a direct consequence of the organization of the health system in the Republic of Moldova, which being inherited from the USSR represents a biomedical model, and during 28 years of statehood the health system failed to implement a biopsychosocial model, the only one capable of coping with the problems caused by demographic, economic, political, epidemiological, legal and regulatory, socio-cultural and technological changes. The Health Care Law No. 411 approved in 1995, which continued the USSR inherited biomedical model of organizing the health system is a barrier in organizing a person-centered health system because it focuses on purely biological factors related to health. By ignoring the patient's psychology, environmental and social influences on health, a care provider can only see a "patient" or a "case" and not the real person behind it.

The focus on purely medical factors is demonstrated by the organization, provision and financing of palliative care services that are practiced in the last 10 years. The normative acts that regulate the organization of palliative care services within PHCI do not provide for social and psychological services. Public palliative care providers deliver only the medical part of services and do not include social services and psychological support. Also, NHIC contracts only medical services from public or private providers of specialized palliative care, which does not ensure efficiency in the activity of palliative care services which, in addition to the medical factor, must address the social, psychological and spiritual condition of the patients and their family¹⁶².

In order to make the model of palliative care implemented in the Republic of Moldova really useful, the organization of the health system must be radically changed so as to include the factors mentioned above. It is necessary to transform the biomedical health system into one based on the biopsychosocial model, which de jure and de facto recognizes psychological and social factors as an inherent part of patient care. It should be noted that the biopsychosocial model of the health system, although often criticized, it essentially influences the basic aspects of medical practice, education and research in many fields of medicine¹⁶³. One of these fields is the palliative care training modules implemented in the Republic of Moldova, which develop valuable psychological counseling and social assistance skills in medical workers, which is a relevant example to examine modern challenges associated with the practical application of the biopsychosocial model.

Unfortunately, the Republic of Moldova has not taken this approach in the training of psychologists and social workers. It is necessary to implement palliative care training modules both in initial training and in continuing development for social workers and psychologists. At the same time, the successes of the Republic of Moldova in the field of medical staff training for palliative care risk to defy the results of the multidisciplinary approach of palliative care services, because the trained doctors and nurses cannot apply their knowledge in practice because the model of palliative care in the public sector is not a biopsychosocial one.

¹⁶² Derick T Wade, Peter W Halligan. Do biomedical models of illness make for good healthcare systems? *BMJ*. 2004 Dec 11; 329(7479): 1398–1401.

¹⁶³ Albert Farre, Tim Rapley. The New Old (and Old New) Medical Model: Four Decades Navigating the Biomedical and Psychosocial Understandings of Health and Illness. *Healthcare (Basel)*. 2017 Dec; 5(4): 88.

6.4. Satisfaction

Un A study conducted among the beneficiaries of palliative care services and their family members¹⁶⁴ reveals that less than half of respondents are highly satisfied with the palliative care services provided by the family doctor and the family doctor's assistants, namely: i) the provision of information on social rights; ii) support to benefit from specialized care; iii) surveillance of symptoms; iv) information on general care; v) medical consultation; vi) communication with the family doctor; vii) communication with the family doctor's medical assistants. Thus, only 47.9% of the beneficiaries are very satisfied with the communication with the family doctor and 46.8% - with the communication with the family doctor's medical assistants. 41.5% of palliative patients are very satisfied with the medical consultation provided by the family doctor, and another 40.4% are partially satisfied. Every second beneficiary is less satisfied with the surveillance and monitoring of the symptoms after taking the prescribed medication. 29.8% of respondents are not satisfied at all with the information on social rights provided by the family doctor, 24.5% are not satisfied with the guidance to specialized palliative care services and 23.4% of respondents are not satisfied with surveillance of symptoms.

48.9% of the beneficiaries in the ATU where there are providers of specialized palliative care, and only 19.1 % of respondents from territories where such services are lacking report to be highly satisfied with the information activities and family doctor's support in accessing specialized palliative care at home or in units with beds/hospices.

The same study¹⁶⁵ revealed the satisfaction of the beneficiaries of the services of specialized palliative care at home and in hospice. Thus, 82% of the respondents are very satisfied with the communication with the doctor from the specialized palliative care providers, and 78% - with the communication with the medical assistant. Due to the fact that not all respondents benefited from the services of a psychologist, social worker, volunteer or religious representative, but also because not all specialized service providers included such specialists in their teams, few respondents were able to assess the level of satisfaction in relation to their attitude, instead those who have benefited from the services of these members of the multidisciplinary teams are satisfied with the approach shown towards the palliative patient.

The highest degree of satisfaction is registered in the ATUs with specialized home and hospice palliative care providers, where the beneficiaries have continuous specialized care, a family and friendly attitude of the multidisciplinary team, patients invoking more confidence in the knowledge and qualification of team members who provides more support and assistance than the staff in district hospitals who often treat palliative patients similarly to the other patients hospitalized in the ward and where services are not focused on the needs of the patient and his/her family. The study also shows that multidisciplinary specialized palliative care teams effectively contribute to improving the quality of life of beneficiaries and their families. Recipients of palliative care provided by multidisciplinary teams feel safer than those in districts where there are no such teams. Safety is perceived in terms of continuous communication with the multidisciplinary team that provides the care needed by the patient and his family in a friendly manner (100% vs 64% satisfaction rate regarding the communication with the doctor and 56.0% - communication with the medical assistants from the districts where there are only units with palliative care beds), in terms of care with which the services are performed as a whole (98% - satisfied with the services provided by the multidisciplinary team vs. 56% - with the services provided on palliative care beds in hospitals), of safer symptoms supervision (96% - satisfied with the services provided by the multidisciplinary team vs. 28% of those satisfied with the services provided on palliative care beds in hospitals), of real support to the family on patient care, by involving the family members in the decision-making process related to the treatment plan and its adaptation depending on the general state and the needs of the patient (88% - very satisfied with the services provided by the multidisciplinary team and 32% - with the services provided on palliative care beds in hospitals).

164 Danii Olga, Lilia Plugaru. Access and Quality of Palliative Care Services in the Republic of Moldova. Quantitative study. Independent Sociological and Information Service OPINIA, 2019.

165 Ibid.

VII. Conclusions

The Republic of Moldova has committed to undertaking a series of legislative, executive and administrative measures to ensure the provision of person-centered palliative care services. The measures were aimed at investing resources in structural systems, processes, outputs and results. Investing resources in structural systems included staffing and financial coverage. Process-related measures focused on creating a model for providing palliative care services. An impressive volume of policy documents and regulations on the organization, funding, training of doctors and nurses and the provision of palliative care have been developed to achieve these objectives, even if some of them have not been of the quality to ensure the coherence and predictability of regulations. The interim and final results regarding the provision of palliative care services were aimed maintaining and improving the quality of life of patients for as long as possible.

Among the most important achievements are **the trainings conducted for doctors and nurses at the level of higher, post-secondary and continuous medical education**. The training curricula in palliative care have been developed and implemented within medical education, but have not been included in the education of psychologists and social workers. The approval of the National Palliative Care Standard and several clinical protocols on various aspects has also contributed to the improvement of the quality of palliative care services, but these standardized procedures are not regularly reviewed and updated. The financial coverage measures resulted in motivating the NHIC to contract non-governmental providers of specialized palliative care. Thus, non-governmental providers, whose capacities and experience have been consolidated over several years only from external financial sources, are currently contracted from public money for the provision of palliative care. The palliative care funding model has also managed to engage public hospitals in the provision of palliative care. However, the Republic of Moldova has not made a financing arrangement to ensure the efficient organization and provision of palliative care services, and the NHIC continues to contract exclusively medical services from both the public and non-governmental palliative care providers. This inadequacy in the organization of palliative care funding has led to a deviation from the multidisciplinary principles of palliative care delivery. **The services of the psychologist, social worker and other non-medical staff within the multidisciplinary team of non-governmental providers are not contracted by the NHIC and they may not be delivered if providers cannot identify external financial sources to keep the specialists in the team.** The purely medical approach to the organization and financing of palliative care has also resulted in the **total absence of social and psychological care services within public palliative care provision**.

Primary care services at the level of family doctor and family medical assistants are funded per capita and are limited to the palliative approach of the patient, although the regulations approved by the MoHLSP in this regard provide for services that are rather specialized home care in nature, which leaves room for disproportionate interpretations of the normative framework for organizing palliative care at the level of family medicine. However, basic palliative care entails specifically a palliative approach to the patient, especially through the services of the family doctor and the family doctor's medical assistant. These specialists provide consultations, prescribe medication, sometimes carry out symptom management and refer the person for specialist palliative care, including due to the **fact that palliative care has been incorporated in the curriculum of the basic training and continuing development for family doctors and medical assistants**. Therefore, **family medicine is taking steps in the right direction and in conjunction with the removal of regulatory inconsistencies, it is necessary to develop close cooperation procedures with providers of specialized home palliative care**.

Drawing up obligations for the heads of the public PHC institutions to collaborate with LPAA and social assistance structures for the involvement of subordinate social workers in the activity of multidisciplinary teams and for identifying additional financial sources necessary for home palliative care, **without central level public policies for their implementation**, do not ensure the effectiveness of palliative care. Since 2017, the Government's areas of activity for health care, social protection, labor and family relations are led by a single ministry, but this forum has not yet managed to develop efficient policies which would effectively integrate at least the necessary social support into palliative care services delivery and financial coverage.

The regulatory framework for organizing the provision of specialized palliative care in public hospitals is also in reality limited to the medical approach of palliative care and **does not include the multidisciplinary component of providing palliative care services**. The forced administrative transformation of public hospital beds into palliative care beds - without preparing and economically motivating these hospitals to provide palliative care - has mainly led to the provision of health care services for the chronically ill and not for palliative conditions. Thus, **the financial sources for palliative care provided in the units with beds of most public hospitals were in fact used to finance long-term care**.

The **physical infrastructure of most palliative care units in public hospitals has not been adapted to the needs of the palliative patients**. Only the physical infrastructure and specialized palliative care services provided by non-governmental providers, both in outpatient and hospice conditions, are provided on multidisciplinary patient-centered principles. Their successes, however, are due to the professionalism, enthusiasm and desire to achieve the best quality of life for its beneficiaries, including through activities to mobilize external financial resources to ensure the work of multidisciplinary teams in full scale.

The **measures in diversifying the pharmaceutical forms of opioid-containing medicines for both adults and children and to simplify their prescription have significantly improved the management of palliative pain**, but a sustainable mechanism for monitoring opioid use has not been implemented, thus failing to ensure decision-making regarding their rational use and the access to opioids for non-cancer patients. At the same time, **palliative care drugs are not classified under a separate group in the NEML**. Not all patients undergoing palliative care can benefit from compensated medicines under the CHI. Also, **the list of compensated medicines covered by the CHI does not include consumables needed for palliative care**.

The Republic of Moldova has set up a model for providing palliative care services within the health system, but this is a biomedical one organized around the disease case and not a biopsychosocial system based on health values and the needs and expectations of people and community. For this reason, the Republic of Moldova has not so far achieved the interim results regarding the provision of palliative services based on the principles of integrated care and multidisciplinary teams and the final maximum improvement of the palliative patients' quality of life of **and failed to ensure the universal coverage with palliative care services fully integrated into the health system**. However, despite the difficulties faced by the health system in the Republic of Moldova, due to the influence of socio-economic, demographic, epidemiological, political and other factors, **through the measures taken in the last 12 years it has succeeded to cover 1/3 of all patients in need with quality home palliative care provided by multidisciplinary teams**.

A report by the Worldwide Hospice Palliative Care Alliance and the WHO ranked Moldova as one of the countries with separate palliative care centers (information available as of 2011). This group of countries is characterized by sporadic initiatives and as having only palliative care centers that do not receive sufficient support and thus largely depend on donors' contributions, with insufficient palliative care resources in relation to the needs of the population¹⁶⁶. At present, it can be stated with certainty that the Republic of Moldova has moved forward in the diversification of palliative care financing, has managed to improve access to opioid-containing drugs by diversifying pharmaceutical forms, has advanced in the training of medical specialists and has a specialized home palliative care service in place even if it is not present in most territories. However, it has failed to fully **integrate palliative care through multidisciplinary teams into basic health system**, in order to ensure effective coverage of the population's needs for such care. **The Republic of Moldova has not yet succeeded in developing a critical mass of specialized home palliative care providers and in ensuring a comprehensive way to provide and finance all the necessary palliative care services, and has as well failed to provide equitable access to all medicines and consumables needed by the palliative patient**. The health system did not manage to **promote and upgrade health policies as cross-sectoral policies in regard to palliative care** which would insure the allocation of resources and other activities so that no child or adult, especially from vulnerable groups, is excluded or marginalized in access to the required palliative care services.

VIII. Recommendations

The following measures should be taken to ensure the full integration of person-centered palliative care into the health system and universal coverage with palliative services:

1. 1. At the level of public and individual health services:

Plan activities for the development of palliative care services based on the real needs of adult and children patients;

Identify and address palliative care needs that require support outside the health care system;

Expand the opportunities to protect the right of adults, children and their families to quality palliative care services by providing knowledge on health rights as part of the fundamental human rights, including by regulating these services within the legislative framework on the minimum free medical assistance guaranteed by state to the citizens of the Republic of Moldova;

Provide support for making informed choices regarding palliative care services through a careful approach of socially vulnerable groups and ensuring the necessary support for the patient and family/ caregiver in making joint decisions on palliative care.

2. 2. At the level of the palliative care services delivery process:

Develop a coherent and predictable regulatory framework for specialized palliative care services, including by incorporating them in the list of basic services for individual and public health. Periodically update and diversify the standards for palliative care services provision and the clinical protocols. Clearly establish the patient's itinerary in his access to palliative care services provided at all levels and adapt it to the needs of the patients and their families;

Encourage the activity of palliative care providers and improve the conditions of care provision, including by creating or reorganizing other existing services for economic reasons, to accumulate the critical mass of specialized home palliative care providers, including by examining the possibility of their establishment in addition to specialized care provided in the public hospitals from the localities with no specialized home care providers. Also, in regard to non-governmental home palliative providers, they need to be supported, adequately funded and used as education centers for other palliative care suppliers;

Specify the spectrum of basic palliative care provided by the family doctor and ensure the development of specialized services in hospitals/hospice - for adults and children - in accordance with the pre-established standards for each level of service provision. Ensure the multidisciplinary approach of the child, adult and family care by clearly demarcating the scope of activity of palliative care providers at all levels and ensuring the continuity and mutual exchange of information between them;

Support the palliative care services delivery by providing sufficient and adequate financial, human and physical resources, in particular by ensuring the connection between all actors involved at each level, by motivating them economically for the increased demand for such child and adult care services and for the long-term maintenance of patients' quality of life; Streamline the activity of specialized palliative care services by implementing the theoretical knowledge of multidisciplinary approach and ensure the continuous improvement of multidisciplinary team members through continuous training programs adapted to the experience of modern practice and science.

3. At the level of the factors that contribute to the integration of palliative care services in the health system:

Develop the functional framework to ensure accountability by establishing clear competencies for each actor in the field of palliative care services, by providing the necessary resources and tools to achieve these competencies and creating instruments to collect data and evidence on the effectiveness of services;

The approval by all actors of the principles of distribution of financial sources and service procurement mechanisms by the National Health Insurance Company, as a premise for the efficient multidisciplinary provision of specialized palliative care services and basic palliative care services at

the level of family doctors, including by incorporating the subprogram “Palliative Care” into the law on compulsory health insurance, the law on compulsory health insurance funds and the normative acts for their implementation;

Continuous supply of qualified human resources for the activity of multidisciplinary teams, family doctors’ offices and medical assistants in the provision of specialized and basic palliative care services, ensure adequate working conditions for practical use of professional skills of each specialist involved, including through continuous training in the field of palliative care. There is an urgent need for continuous education programs in palliative care to be sustained and well-enframed in the requirements for the assessment and accreditation of any palliative care services;

Supervise the rational use of medicines by monitoring access, especially to medicines containing opioids in pharmaceutical forms suitable for both children and adults, completing the list of medicines for palliative care within the National List of Essential Medicines and the List of Compensated Medicines by the National Health Insurance Company, including the necessary consumables for palliative child and adult care. Improve the processes of prescribing, releasing and administering drugs by ensuring the appropriate approach to the needs of patients and families;

Implement advanced technologies in the field of palliative care taking over the experience of economically and socially developed countries;

Develop and integrate information systems in healthcare, especially automated ones (SIA AMP and SIA AMS), adopt standardized information flow for palliative care, including by ensuring the compatibility and convenience of these platforms for all users, regardless of the level of palliative care service delivery of which they are a part. Information systems are to be developed in such a way as to obtain operative tools for collecting relevant indicators and data in order to improve the capacity to monitor the equitable distribution of palliative care services for all sections of the population, especially the poorest. The collection of standardized and routine data on palliative care should be included in existing tools, such as health surveys and institutional evaluation.

4. At the level of change management to ensure the full integration and universal coverage with palliative care services:

Implement Implement the strategic planning of palliative care to ensure the person-centered approach and consider all factors that influence health, including psychological, environmental and social factors. Create an environment that encourages change, joining of efforts and engagement of all involved actors, in particular palliative care providers, and subsequently adopt principles of a planned approach towards the strategic design and sectoral policy documents;

Make changes by developing and implementing public policies to ensure access to quality palliative care services, which can be applied with maximum efficiency for both the beneficiary and the provider. Participate in a coordinated way in the functioning of the health system and other sectors of social life, in particular the social and education sectors, civil society, developmental partners and ensure the mutual exchange of information in order to maximize results;

Implement sustainable transformations for universal palliative care coverage through the use of national palliative care platforms and coalitions, the development of tools to address failures and the use of levers to ensure continuity of change aimed at improving the access equity to services of the highest possible quality and protection against the financial risks associated with palliative care services.

