

(E) Education & Train Medical schools with mandatory PC teaching	ning 13/39
Nursing schools with mandatory PC teaching	<u>56/56</u>
PC Full Professors	©2
Recognition of PC specialty	
B Policies	
National PC plan	
Responsible authority for PC in the Ministry of Health	
Inclusion of PC in the basic health package at the primary care level	
Empowerment of people and communities	
Ω	
Groups promoting the rights of PC patients	Advanced care planning-related policies

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#### Ind1

Existence of groups dedicated to promoting the rights of patients in need of PC. their caregivers. and disease survivors.

 $\bigcirc \bigcirc \bigcirc 4$ Strong national and sub-national presence of palliative care advocacy and promoting patient rights (as a professional association of Palliative Care, i.e.). There are several groups promoting the rights of patients with palliative care needs. The major associations present in Italy are the Italian Society of Palliative Care (SICP), the Federation of Palliative Care (FCP), and the Maruzza Lefebvre D'Ovidio Foundation.

#### Ind 2

Is there a national policy or guideline on advance directives or advance care planning?

There is a national policy on advance care planning.

Italy has national policies and guidelines regarding AD and ACP. In 2018, Law No. 219/2017 on "Informed Consent and Advance Directives," recognised the right of individuals to express their wishes regarding medical treatments in case they become unable to make decisions. This law allows citizens to create a Disposizioni Anticipate di Trattamento (AD), where they can outline their preferences for care, including end-of-life decisions and the refusal of life-sustaining treatments. The law also deals with informed consent, patient autonomy, and shared decision-making. It encourages individuals to engage in ACP and appoint a 'trustee' (a legally designated person) to ensure that their wishes are respected if they are no longer able to communicate. However, several challenges hinder implementation.

#### Ind 3

3.1. There is a current national PC plan, programme, policy, or strategy.

3.2. The national palliative care plan (or programme or strategy or legislation) is a standalone.



actively evaluated or audited.

### $\bigcirc \bigcirc \bigcirc 4$

Yes, there is a standalone national palliative care plan AND there is national palliative care law/legislation/government decrees on PC.

#### Main approved national laws and norms include: 1s) Law 15

March 2010, N.38 (Law on access to palliative care and pain therapy), 2nd) the Formal Agreement between Ministry of Health and Regional Health Services "decree defining the organisational model of Regional and Local Palliative Care Networks (July 2012), 3rd) the Decree of January 12 2017 on defining the essential levels of care and assistance that must be guaranteed in Italy;and 4th) the agreements at the the State-Regions Conference on 27 July 2020 and 25 March 2021, on 'Accreditation of Palliative Care Networks for Adults' and 'Accreditation of Paediatric Pain Therapy and Palliative Care Networks'. The National Agency for Regional Health Services (AGENAS) is responsible for periodic monitoring of palliative care networks since 2010. The last report Investigation on the state of implementation of law 38/2010 regarding the palliative care network was published in 2022, and contains indicators calculated for the LEA\*

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3.3. There are indicators in the national plan to monitor and evaluate progress, with measurable targets.

The indicators to monitor and evaluate progress are

currently imple-

mented.

## Ind 4

PC services are included in the list of priority services for Universal Health Coverage at the primary care level in the national health system.

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Palliative care is included in the list of health services provided at the primary care level in the General Health Law.

#### Ind 5

5.1. Is there a national authority for palliative care within the government or the Ministry of Health?

5.2. The national authority has concrete functions, budget and staff.

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The coordinating entity for palliative care is a well-defined and has a good structure (scientific & technical).

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There are concrete functions and staff. but do not have a budget.

The Section O of the Technical Health Committee of the MoH assess the implementation of Law 38/2010 on PC and Pain Therapy. The Section O carries out monitoring activities to evaluate the trend in the prescription of drugs used for pain therapy, the level of implementation of national guidelines, andd the state of development of PC networks. It pays particular attention to territorial inequalities and to the provision of PC in neonatal, paediatric and adolescent age, evaluating: a) data relating to the prescription and use of medicines in pain therapy, and opioids; b) development of national networks (with reference to verifying compliance with indicators and criteria); c) state of progress of the two networks, also with reference to the level of integration; d) the services provided and their outcomes; e) training activities, f) information campaigns; g) research; and h) economic aspects. It is composed by 14 members designated by the MoH: 10 experts and 4 representatives of the Ministry.

2019 survey and the specific indicators identified by AGENAS relating to the hospital dimension of palliative care, hospice and home care provided to cancer patients (\*LEA refers to services that the National Health System provides to all citizens, free of charge or against a small fee (ticket). Furthermore, the document contains a specific report on the implementation of the palliative care networks, to which the all 21 Italian regions and the all 99 Local Health Units (ASL) responded.

Through Decree of 12 January 2017, PC became part of the essential levels of assistance guaranteed by the National Health Service. Levels of assistance were described in article 21 (Integrated care pathways: access to health and social services is guaranteed (...); article 23 (Home PC: Basic and specialist level of care is provided by PC Units and no longer by general home care service); article 31 (Specialist palliative care centres: Hospices guarantee local assistance to patients in the terminal phase of life), article 38 (Hospitalization for acute patients: PC is expressly mentioned as clinical, pharmaceutical and instrumental services that must be guaranteed; and article 15 (Specialist outpatient care: The National Health System provides for the PC first multidisciplinary examination). The Ministerial Decree 77/2022 (DM77), launched the new model of territorial healthcare organisation and defined standards of care.

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#### Ind 6

**Existence of congresses** or scientific meetings at the national level specifically related to PC.

At least one national conference specificallv dedicated to palliative care every year, with multidisciplinary attendance.

The Italian Society of Palliative Care (SICP) organizes an annual national congress, which is a prominent event focused on developments, research, and training. In addition to SICP's events, there are numerous national meetings and conferences organized in partnership with SICP or under its patronage. The Federation of Palliative Care (FCP) also develops an annual training programme aimed at non-profit organisations and volunteers directly or through the network of member organisations in the area. These gatherings aim to expand PC education and involve collaborations with universities, health organisations, and other professional societies. Another key event is the Maruzza Foundation International Congress on Pediatric Palliative Care, every two years in Rome, providing an international forum on paediatric aspects of PC.

#### Ind 7.1

Estimation of the level of peer-reviewed articles focusing on PC research published in any language in the past 5 years with at least one author from the country.

#### Represents a considerable amount of articles published.

Research has significantly grown, prompted by increased attention to end-of-life care needs and the establishment of national PC networks. Italian scholars contribute to several dozen publications annually and a recent report found that theypublished numerous studies addressing the challenges of PC within the healthcare system, both in Italian and international publications. The focus includes paediatric PC (ie. PALLIPED project).

Ind 7.2

Inclusion of PC topics in national research calls.



They do exist national research calls that do include palliative care topics.

Active projects include: 1st) Observatory on PC: central hub for research designed to gather and analyze data, promote best practices, and foster collaboration among professionals, policymakers, and researchers; 2nd) Demetra Project: focused on enhancing quality of life for patients in PC settings, combining clinical practice with educational initiatives and, 3rd) INSPIRE Project by the National Cancer Institute of Milan.

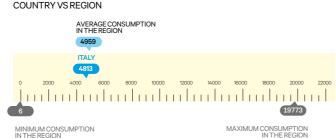
#### Ind 8

-Reported annual opioid consumption -excluding methadone-in S-DDD per million inhabitants per day.



Average consumption of opioids, in defined daily doses (S-DDD) for statistical purposes 2020-2022.

#### COUNTRY VS REGION



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#### Ind 9

-9.1. Percentage of health facilities at the primary care level in Urban areas that have pain and PC medications as defined in the WHO Model List of Essential Medicines.

-9.2. Percentage of health facilities at the primary care level in rural areas that have pain and PC medications as defined in the WHO Model List of Essential Medicines.



#### Ind 10.1

10.1.1. Percentage of health facilities at the primary care level in urban areas that have immediaterelease oral morphine (liquid or tablet).

10.1.2. Percentage of health facilities at the primary care level in rural areas that have immediaterelease oral morphine (liquid or tablet).

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#### Ind 10.2

10.2.1. Percentage of health facilities at the primary care level in urban areas that have different opioids and in different formulations.

10.2.2 Percentage of health facilities at the primary care level in rural areas that have different opioids and in different formulations.

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Availability of various opioids in different formulations at the primary care level in urban areas is relatively high. Estimates suggest that about 80%-90% of facilities have access to essential opioids in multiple formulations, such as oral tablets, patches, and injectable solutions. Urban centres have comprehensive healthcare services, ensuring morphine, oxycodone, fentanyl, and buprenorphine for pain and PC. However, factors such as regulatory processes, prescription monitoring, and awareness can influence the distribution and usage of opioids. Occasional administrative and logistical barriers might slightly impact supply. In rural areas, availability is lower due to challenges in logistics, infrastructure, and healthcare workforce distribution. It is estimated that 60%-70% rural healthcare facilities have access to these opioids.

According to national regulations, urban health facilities are generally equipped with a variety of essential medicines. The Italian healthcare system mandates their provision in hospitals and local health units. Medicines such as morphine, oxycodone, paracetamol, and ibuprofen are commonly available. Moreover, medications like codeine, fentanyl, and midazolam are also included in primary care settings. Reports from the MoH indicate that percentage of health facilities in urban areas providing these medications is high, though disparities exist. While metropolitan regions have comprehensive access due to better infrastructure, rural and less developed urban fringes may experience gaps in consistent supply. Bureaucracy, public concerns, and uneven healthcare protocol implementation challenges persist.

Data from the INCB indicates that Italy's per capita opioid use, measured in OME, has historically been lower than other nations. This is due to a combination of regulatory, cultural, and healthcare system factors. The National Health Service ensures that opioids are available through hospitals, pharmacies, and specialised programmes but still opioid use is sometimes limited by public perception, concerns about addiction, insufficient training among providers, and overly restrictive prescription regulations. The MoH has implemented measures to address these, including educational initiatives for healthcare professionals and regulatory adjustments, IR oral morphine in rural areas is lower compared to urban areas due to challenges in logistics, infrastructure, and healthcare workforce distribution.

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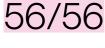
#### Ind 11

11.1. The proportion of medical schools with COMPULSORY teaching in PC (with or without other optional teaching)

- 11.2. The proportion of medical schools with **OPTIONAL** teaching in PC.
- 11.3. The proportion of nursing schools with COMPULSORY teaching in PC (with or without other optional teaching).
- 11.4. The proportion of nursing schools with OPTIONAL teaching in PC.
- 11. 5. PC Full Professors
- 11.6. Legislation/ PC education



25/39



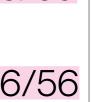
N/A

regulations concerning



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Yes



to PC were included in 75% and 80% of Nursing and Paediatric Nursing courses, respectively. There are 48 Universities with at least one Degree Course in Nursing and 8 with at least one Degree Course in Paediatric Nursing. Whilst all nursing schools should provide mandatory teaching, no data is available. There are two full professors and many adjunct professors. Related legislation includes Law 38/2010 (establishing the need to train healthcare professionals specialised in PC and promoting integration into the educational pathways; the Inter Ministerial Decree No. 1109/2021 (establishing the School of Specialisation in Medicine and PC, and making Paediatric PC course manda-

tory in the paediatric specialisation programmes); the Ministerial Guidelines by the MoH (to integrate PC into the curricula of undergraduate healthcare professions); and the State-Regions Agreements between the State and Regions defining training standards for PC networks and requirements for professionals working in PC services.

(MIUR), with note no.13244 of 26 April, sent a recommendation

to the Degree Courses in Nursing, Paediatric Nursing, Physio-

therapy and Occupational Therapy for the integration of PC in

ence of the Degree Courses of the Health Professions approved

a motion in favour of the MIUR recommendation and urged the

Coordinators/Presidents to integrate the study plans with spe-

In a 2021 survey based on 2019 data, training objectives related

cific training programmes in the field of PC and pain therapy.

their teaching plans. On 15 May 2018, the Permanent Confer-

#### Ind 12

Existence of an official specialisation process in palliative medicine for physicians, recognised by the competent authority in the country.



Palliative medicine is a speciality or subspeciality (another denomination equivalent) recognised by competent national authorities.

The long process of implementing the art. 8 of law 38/2010 concluded with the establishment of the specialisation school in "Medicine and Palliative Care" starting from the 2021-2022 academic year and the introduction of the Paediatric Palliative Care Course as part of the compulsory school courses of specialisation in paediatric (art. 5-ter of the Legislative Decree of 19 May 2020, no. 34, converted with law no. 77 of 2020). There are 68 doctors candidates to become specialists in medicine and palliative care starting from 2026 between those enrolled in the first and second year.

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#### Ind 13

13.1. There is a system of specialised PC services or teams in the country that has a GEOGRAPH-IC reach and is delivered through different service delivery platforms.

13.2. Are available in HOSPITALS (public or private), such as hospital PC teams (consultation teams). and PC units (with beds), to name a few examples.

13.3. Free-standing HOSPICES (including hospices with inpatient beds).

#### 13.4. HOME CARE teams (specialised in PC) are available in the community (or at the primary Healthcare level), as independent services or linked with hospitals or hospices.

13.5. Total number of specialised PC services or teams in the country.

#### Ind 14

14.1. There is a system of specialised PC services or teams for children in the country that has geographic reach and is delivered through different service delivery platforms.

14.2. Number of pediatric specialised PC services or teams in the country.

#### Generalised provision: Exists in many parts of the country

but with some gaps.



Ad hoc/in some parts of the country.

Strong presence of free-standing hospices in all parts of the country.

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Found in many parts of the country.

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Generalised provision: palliative care specialised services or teams for children exist in many parts of the country but with some gaps.

icata, Campania, Emilia Romagna, Lazio, Liguria, Lombardia, Piemonte, Sardgna, Sicilia, Toscana and Veneto. According to the PalliPed study, there are 19 specialised PPC teams.

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PPC TEAMS Development is uneven with noticeable shortcomings in home care. The 306 hospices (52.9% in the North, 27.45% in the Centre, 19.6% in the South), around 500 palliative doctors and over 2,100 nurses work, are in line with the provisions of ministerial decree 43 of 2007, but insufficient according to the standards by ministerial decree 77 of 2022. Despite laws intended to improve networks (law 106/2021, ministerial decree 77 of 2022, and law 197/2022), and also the SICP recommendation on Staffing Standards, numbers remain under the need. 592 specialised services are in place: 1st ) Hospital PC teams/units in most regions, 2nd) Free-standing hospices in all regions, and 3rd) Home PC teams in most regions.

