



PALLIATIVE SEDATION- AN EUROPEAN PERSPECTIVE

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(on behalf of the Palliative Sedation EU Horizon2020 Project)

Why palliative sedation?

In some cases, the available standard treatments are no longer effective, the benefits are not reached in sufficient time, or treatments provoke more negative effects than benefits: **Symptoms are very burdensome, no longer tolerable for the patient and can be considered refractory...**

Original Article

PALLIATIVE
MEDICINE

European Association for Palliative Care (EAPC) recommended framework for the use of sedation in palliative care

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Abstract

The European Association for Palliative Care (EAPC) considers sedation to be an important and necessary therapy in the care of selected palliative care patients with otherwise refractory distress. Prudent application of this approach requires due caution and good clinical practice. Inattention to potential risks and problematic practices can lead to harmful and unethical practice which may undermine the credibility and reputation of responsible clinicians and institutions as well as the discipline of palliative medicine more generally. Procedural guidelines are helpful to educate medical providers, set standards for best practice, promote optimal care and convey the important message to staff, patients and families that palliative sedation is an accepted, ethical practice when used in appropriate situations. EAPC aims to facilitate the development of such guidelines by presenting a 10-point framework that is based on the pre-existing guidelines and literature and extensive peer review.

What is it palliative sedation?



Is a medical intervention aimed at **relieving refractory suffering** at the end of life through the monitored **proportional use of medications** intended to reduce the patient's consciousness.

Why an European perspective?

- **Incidence vary :**
 - 2.5% Denmark, 8.5% in Italy (Miccinesi, 2006),
 - Between 7% and 18% of deaths of PC patients (Deschepper, 2013)
 - 10%–18% of all deaths in Europe, although great diversity in its use (Payne, Hasselaar, 2020)
- **Variations in quality and evidence of procedural guidelines** (Abarshi, 2017) (De Benedictis, 2008) (Payne, Haseelaar, 2020).
- Guidelines are **differently known and used by clinicians** across countries (Abarshi, 2014).
- Unknown what is the **use of medicines like** for palliative sedation
- **Not clear how palliative sedation is regulated:** is it regarded as a normal healthcare practice?

Comparison in health is useful: allows identifying good practice examples

Objective

To reach an overview of local **guidelines**, **medicines**, and **regulations**, used in Palliative sedation in eight European countries

- The Netherlands, Belgium, Spain, Hungary, United Kingdom, Germany, Romania, Italy.



The survey



Desk review

- to find any National and International surveys/questionnaires on Palliative Sedation.
- in English (2005 onwards),
- in PUBMED and Google Scholar using the search terms: “palliative sedation” AND “survey”



Internal and partners consensus

- internal discussion on items to be included
- discussion all research participants (PI's) of the project
- final consensus



32 questions:

<https://www.surveymonkey.com/r/9RHTRSF>

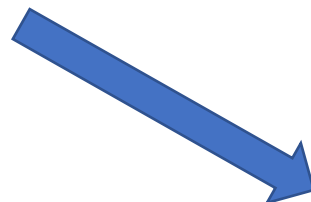


The Sample

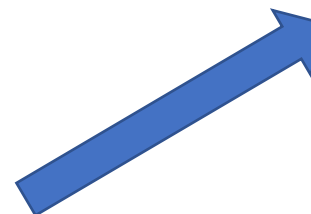
Expert Clinicians, 18 per country

Knowledge on use of PS guidelines, diverse backgrounds*.

Field*	Setting	Profile (n)
Anesthesiology	Hospital	Doctor (1) + Nurse (1)
Intensive care	Hospital	Doctor (1) + Nurse (1)
Internal medicine	Hospital	Doctor (1) + Nurse (1)
Oncology	Hospital	Doctor (1) + Nurse (1)
Primary care	Primary	Doctor (1) + Nurse (1)
Palliative Care	Hospital	Doctor (1) + Nurse (1)
Palliative Care	Home	Doctor (1) + Nurse (1)
Palliative Care	Nursing home	Doctor (1) + Nurse (1)
Palliative Care	Hospice	Doctor (1) + Nurse (1)



Consortia members decided **optimum responders** in their respective countries, based on their knowledge, strict criteria (*Nat Ass, PS workforces, national non-pc) societies, guidelines authors*)



Key Persons, 2 per country

- 1st KP: legal knowledge (legal advisor of the Official Medical/nursing College (or equivalent body))
- 2nd KP: national-level knowledge (PC National Association representative)



Analysis



Guidelines

- What guidelines?
- Most cited
- % clinical staff using guidelines
- Awareness and use of EAPC guideline



Medicines

- Use of benzodiazepines, neuroleptics, anticonvulsants, barbiturates, co-medications (opioids and non-opioids), etc.



Regulations

- What regulations?
- Regulations with Explicit reference to PS (synonyms), description,
- EAPC principles
- Guidelines
- Country reports

The informants

139/223 (62%) completed the survey

- profiles mean 10,5/19, *min-max: 4-18*
- participants mean 19, *min-max: 9-37*

Field	Setting	Profession	BE	DE	ES	UK	HU	IT	NL	RO
Anesthesiology	Hospital	Physician	1	1	1	-	1	3	1	1
Anesthesiology	Hospital	Nurse	-	-	-	-	-	-	-	-
Intensive care	Hospital	Physician	-	-	1	-	2	1	-	1
Intensive care	Hospital	Nurse	-	-	1	-	-	1	-	-
Internal Medicine	Hospital	Physician	-	-	1	-	-	1	-	-
Internal Medicine	Hospital	Nurse	-	-	1	-	1	1	1	-
Oncology	Hospital	Physician	-	-	1	-	3	2	1	3
Oncology	Hospital	Nurse	-	-	1	-	1	1	-	-
Primary care	Primary	Physician	1	1	2	-	1	1	1	1
Primary care	Primary	Nurse	1	-	1	-	-	-	-	-
Legal expert	Any	Expert	3	2	1	3	2	1	2	1
Palliative care	Hospital	Physician	1	1	1	2	4	6	2	4
Palliative care	Hospital	Nurse	2	-	1	-	1	-	6	1
Palliative care	Home	Physician	1	1	1	2	1	5	-	2
Palliative care	Home	Nurse	1	1	1	-	1	1	2	1
Palliative care	Residence	Physician	1	1	1	-	-	-	2	-
Palliative care	Residence	Nurse	-	-	1	-	-	-	-	-
Palliative care	Hospice	Physician	1	1	1	9	1	13	3	1
Palliative care	Hospice	Nurse	-	-	1	-	-	1	-	1
Profiles (n experts)	-	-	10 (13)	8 (9)	18 (19)	4 (12)	12 (13)	14 (37)	10 (18)	11 (18)

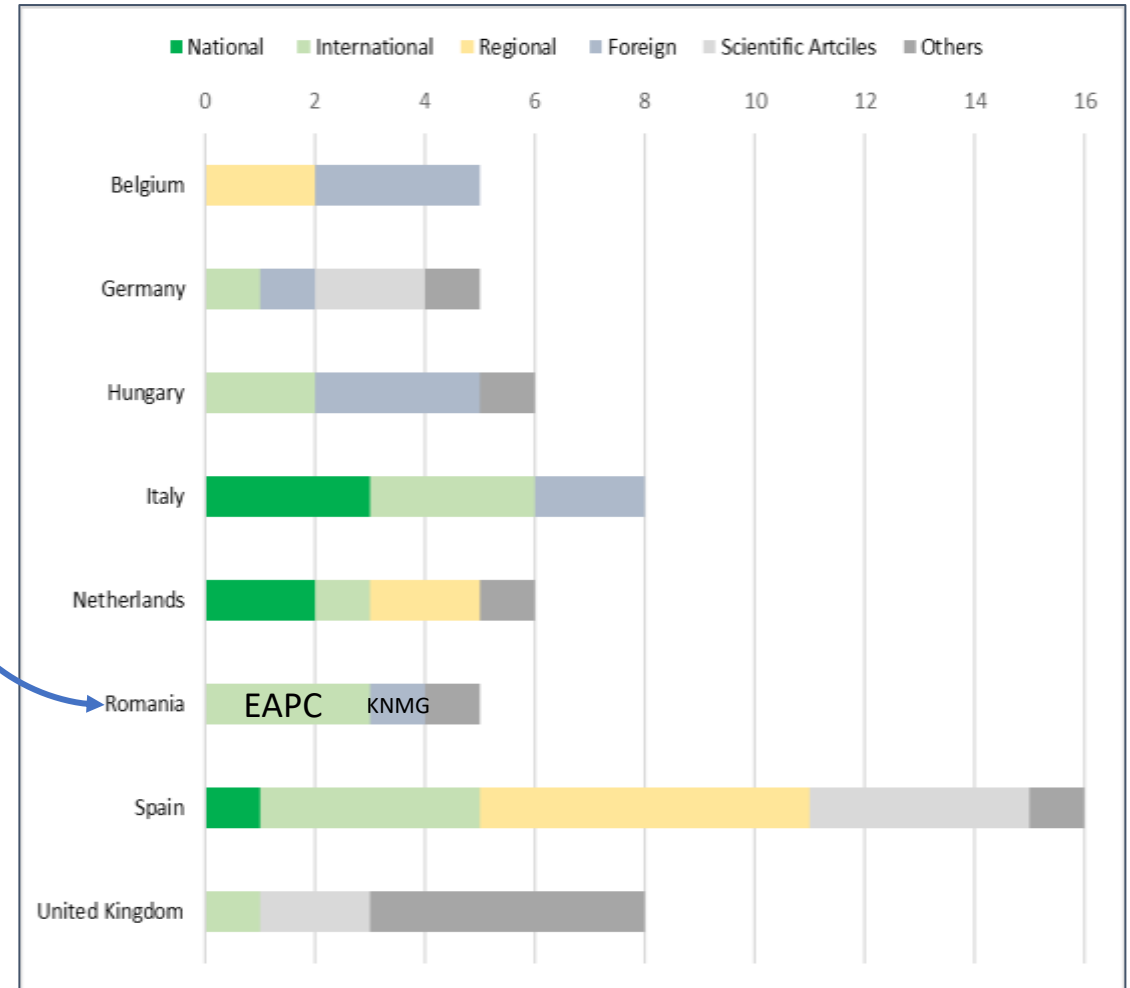
Few nurses working outside PC



Guidelines

Overall findings

- 5-8 documents per country (44 different documents in total).
- Some by experts from several countries: EAPC framework¹ (5 countries), ESMO⁶, Royal Dutch Medical Association (KNMG)⁷ (4), and the Integraal Kankercentrum Nederland (IKNL) (2)⁸.
- Four countries (Germany, Hungary, Romania, UK) did not have national/regional guidelines.



Guidelines

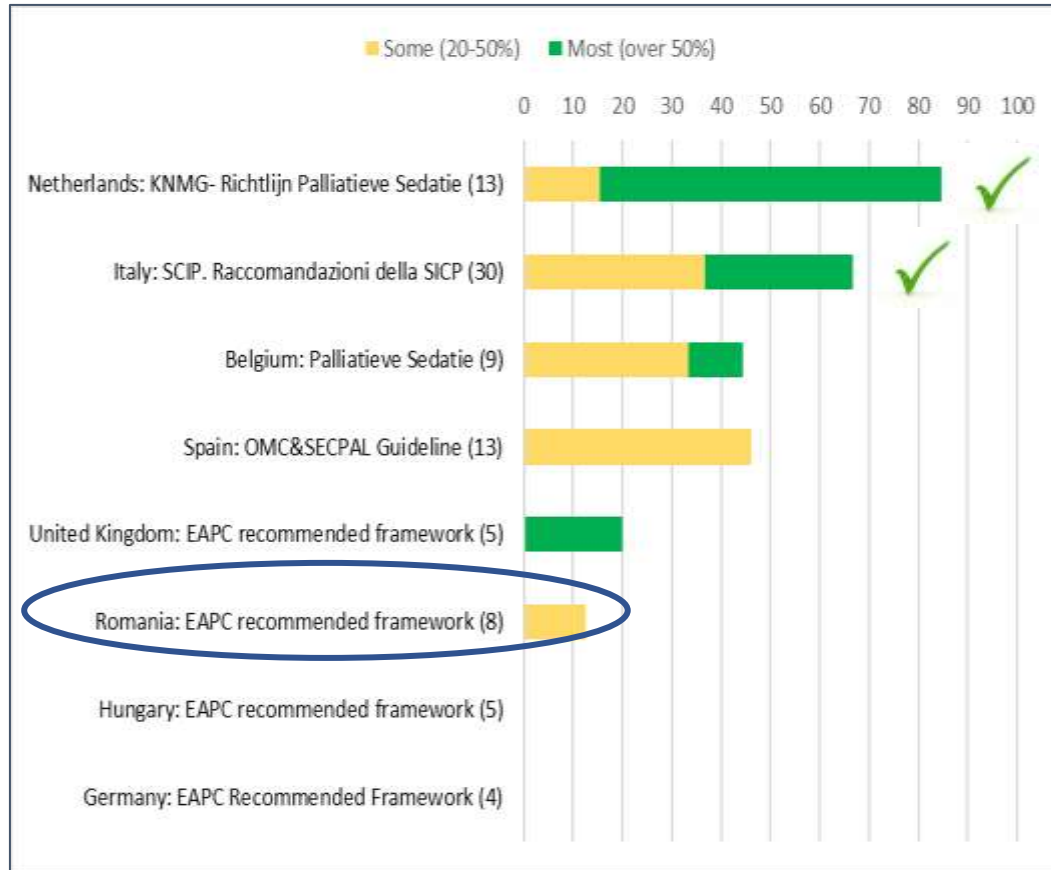
The three most cited guidelines

Belgium	Palliatieve Sedatie, pallialine.be, Flanders (FPZV)	Integral Cancer Centre IKNL (Pallialine.nl, Dutch)	KNMG Guideline for Palliative Sedation Royal Dutch Medical Association
★ Germany	EAPC recommended framework for the use of sedation in palliative care	Erweiterte S3-Leitlinie. Palliativmedizin für Patienten mit einer nicht-heilbaren Krebserkrankung Langversion 2.0 – August 2019	Palliative Sedierung Arbeitsgemeinschaft heimbetreuende (Palliativ-)Ärzte (AG HPA) des Netzwerkes Palliativmedizin Essen (npe) (Guideline Pall Sed Home teams) ESSEN
★ Hungary	EAPC recommended framework for the use of sedation in palliative care	ESMO Clinical Practice Guidelines for the Management of refractory symptoms at the end of life and the use of palliative sedation	KNMG Guideline for Palliative Sedation Royal Dutch Medical Association
Italy	SICP Raccomandazioni della SICP sulla Sedazione Terminale/Sedazione Palliativa	EAPC recommended framework for the use of sedation in palliative care	ESMO Clinical Practice Guidelines for the Management of refractory symptoms at the end of life and the use of palliative sedation
Netherlands	KNMG Guideline for Palliative Sedation Royal Dutch Medical Association	IKNL. Palliatieve sedatie. Landelijke richtlijn, Versie: 2.0 KNL	ESMO Clinical Practice Guidelines for the Management of refractory symptoms at the end of life and the use of palliative sedation
Romania	EAPC recommended framework for the use of sedation in palliative care	ESMO Clinical Practice Guidelines for the Management of refractory symptoms at the end of life and the use of palliative sedation	KNMG Guideline for Palliative Sedation Royal Dutch Medical Association
Spain	Guía de Sedación Palliativa (OMC y SECPAL), 2011	Guía Clínica de Sedación Palliativa del PRCPEX. Uso y recomendaciones. 2015	Guía de sedacion paliativa: recomendaciones para los profesionales de la salud de las Islas Baleares. Regional Ministry of health,
★ UK	EAPC recommended framework for the use of sedation in palliative care	Adult palliative care network guidelines (book.pallcare.info)	Palliative Care Formulary v6 (Twycross et al)

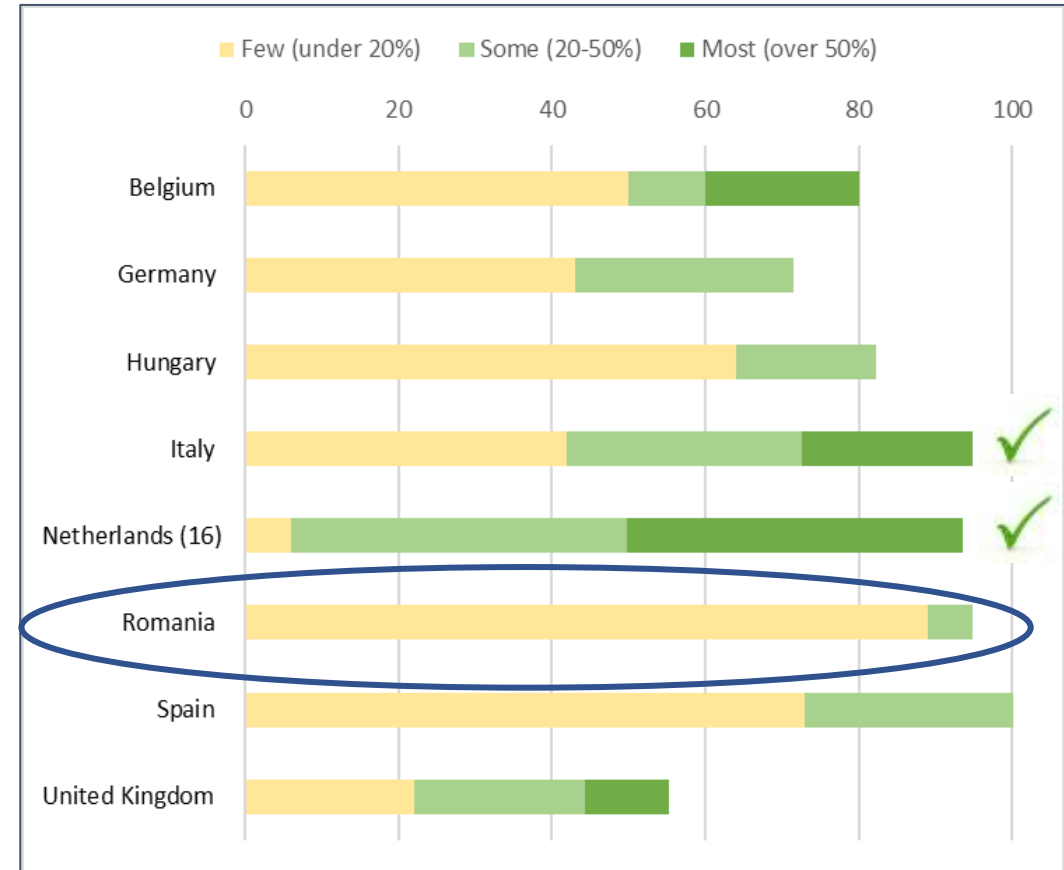
Guidelines

Perception of the use of guidelines by clinical staff

% clinical staff using most used guideline

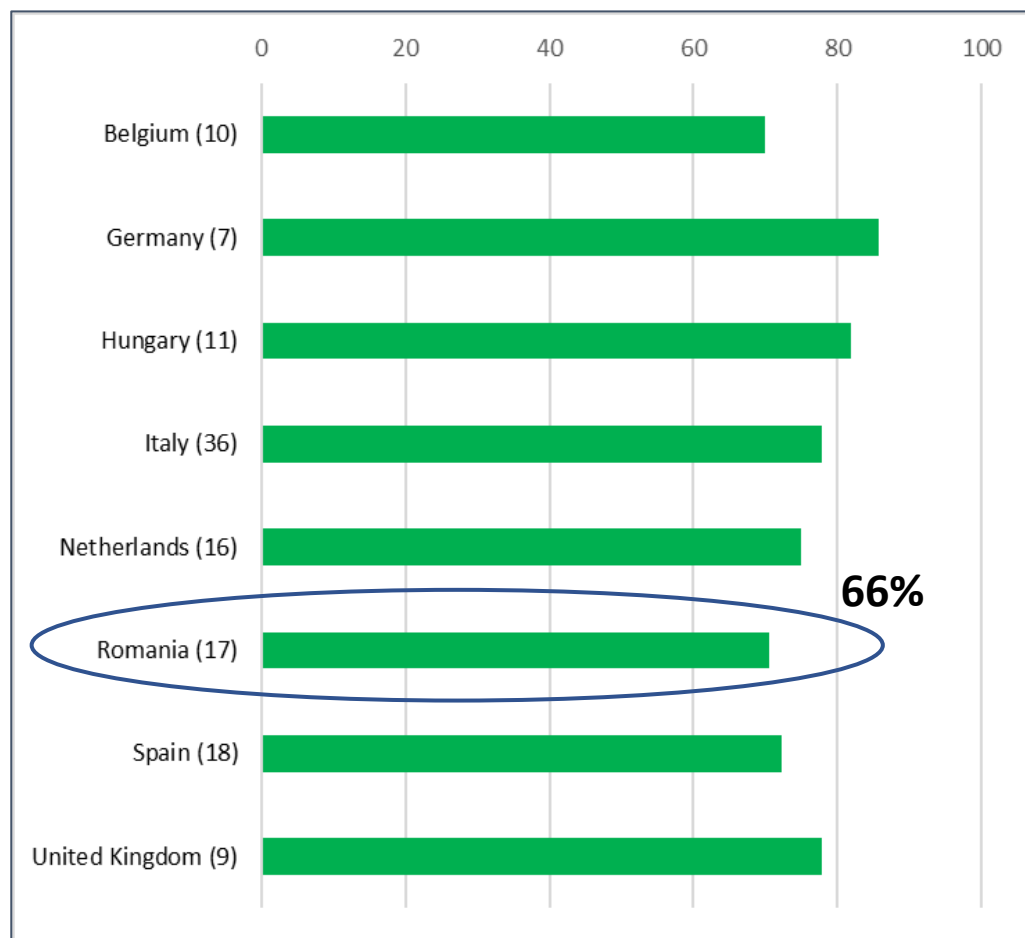


% clinical staff using any guideline in each country



Guidelines

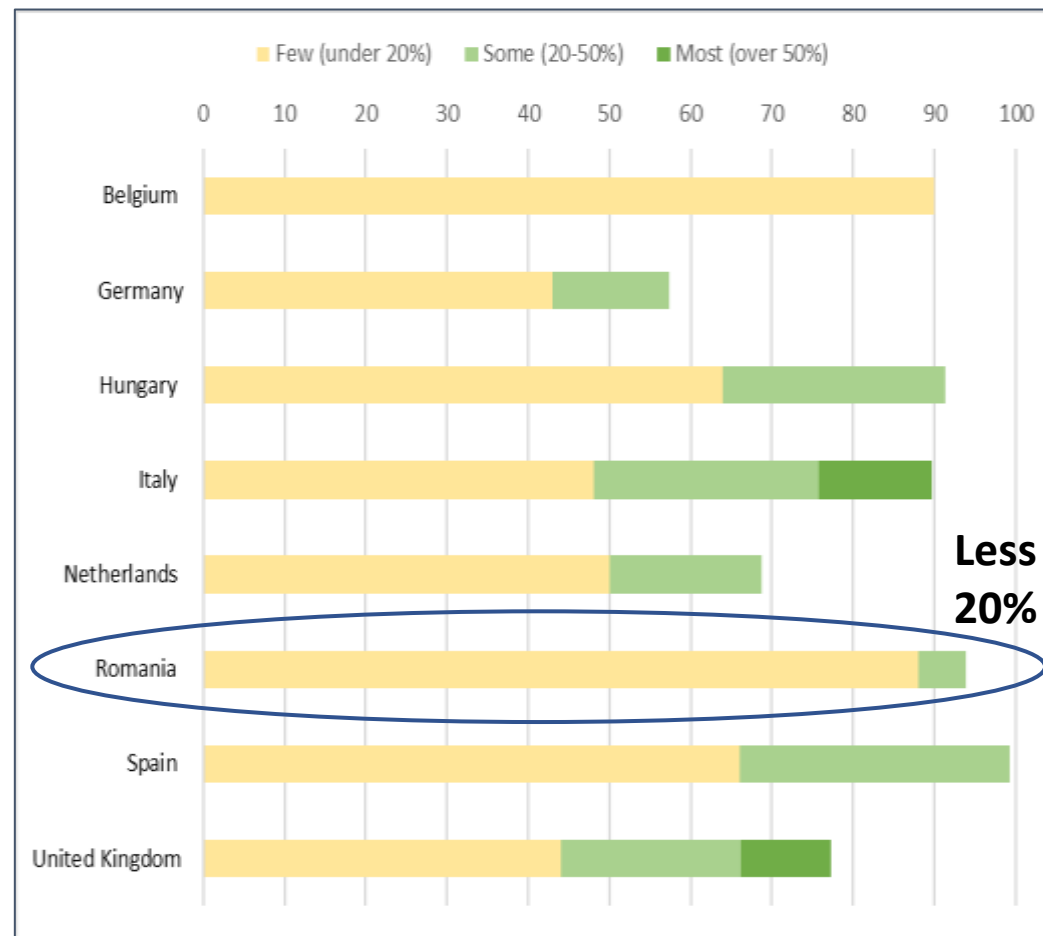
EAPC Framework knowledge



70% to an 86%, (Abarshi, 2014)

VS

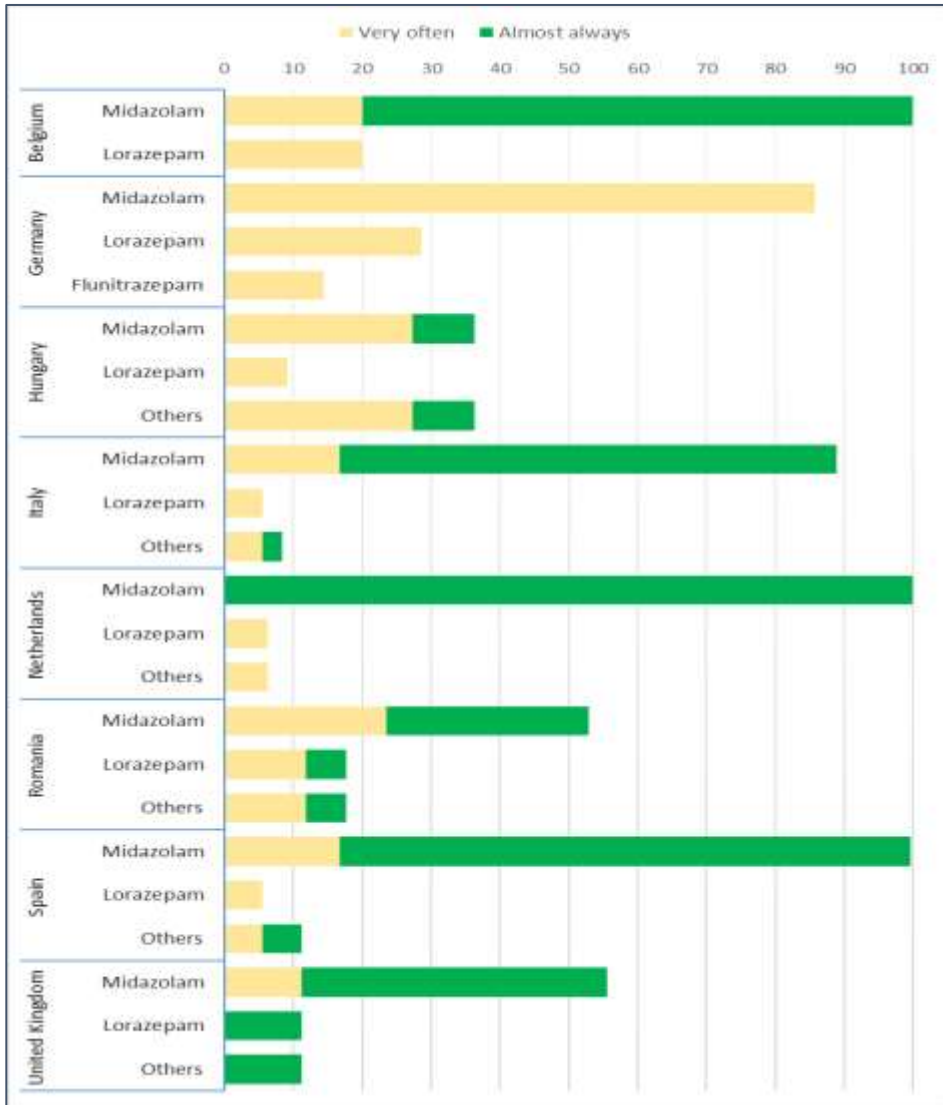
EAPC framework Adoption



Under 20% have adopted it

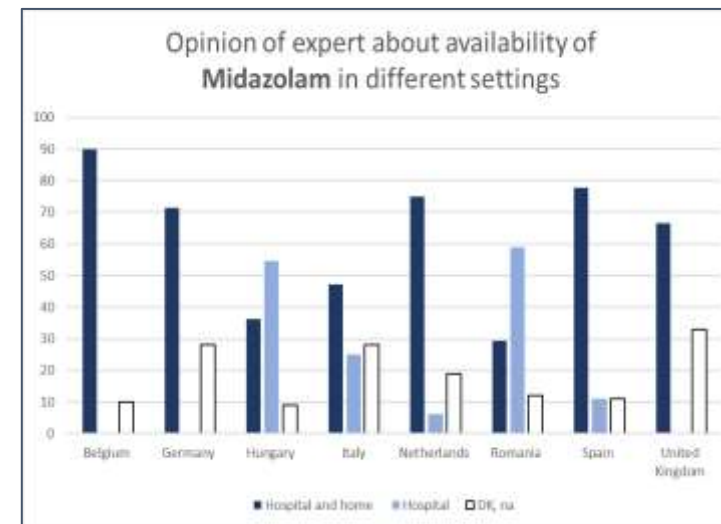
Medicines

Main benzodiazepines use



- In the Netherlands, Belgium and Spain all experts reported that midazolam is used very often or almost always by clinical staff
- In Germany and Italy, it is perceived to be used a little less (still almost always or very often)
- In Hungary, Romania and the UK, about a 50% of experts think midazolam is used very often or nearly always

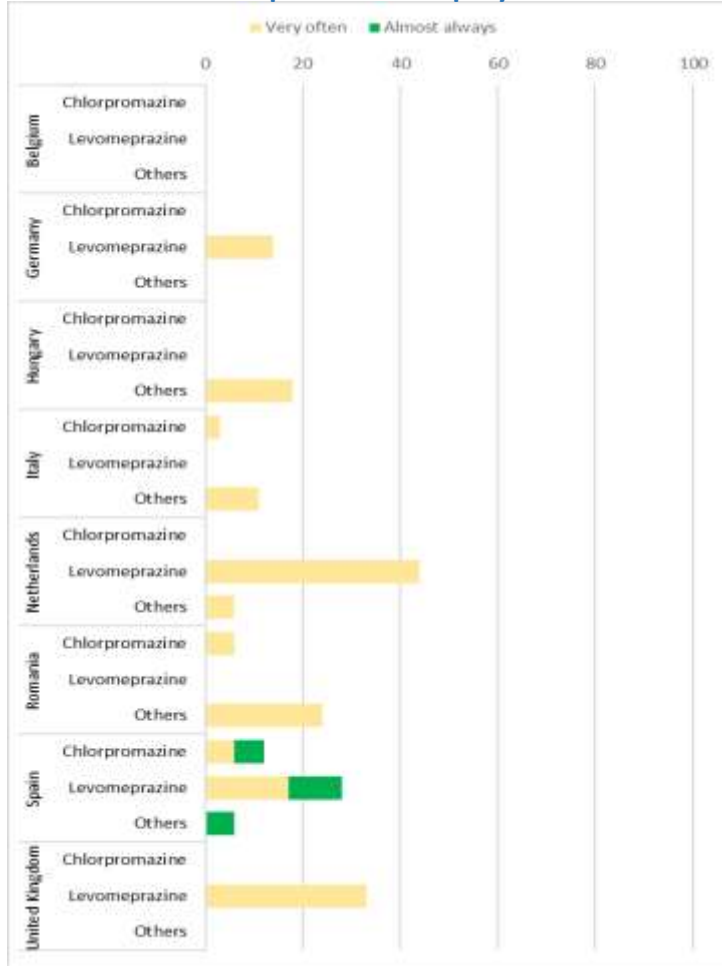
Midazolam availability per settings



Midazolam seems to be available both at the hospital and at home (less common in Hungary and Romania, only in hospital).

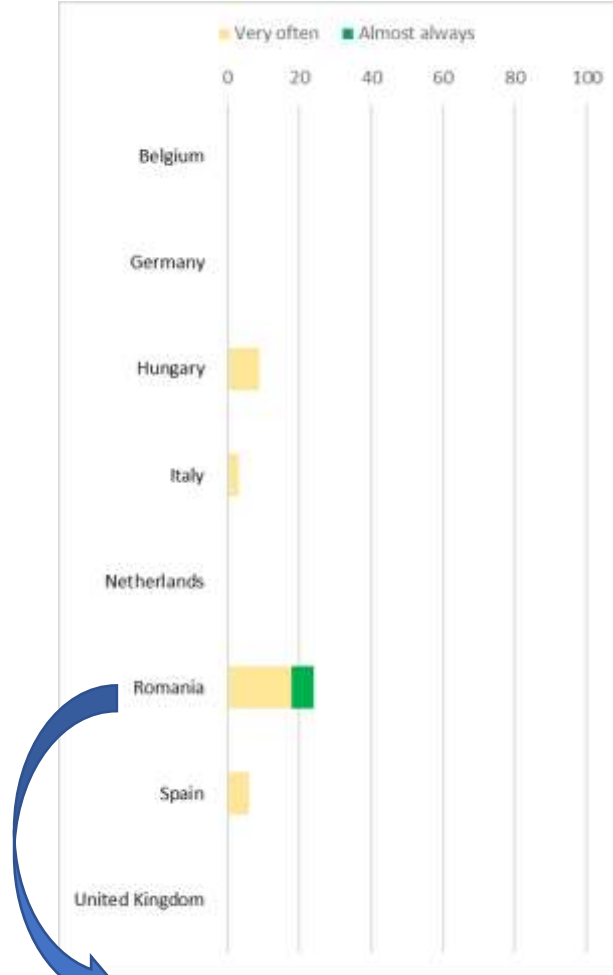
Medicines

Main neuroleptics/antipsychotics use



Levomeprazine somewhat used in the Netherlands, Spain, Germany and UK, not reported in Romania

Anticonvulsants use



Some experts perceive a frequent use of anticonvulsants in Romania

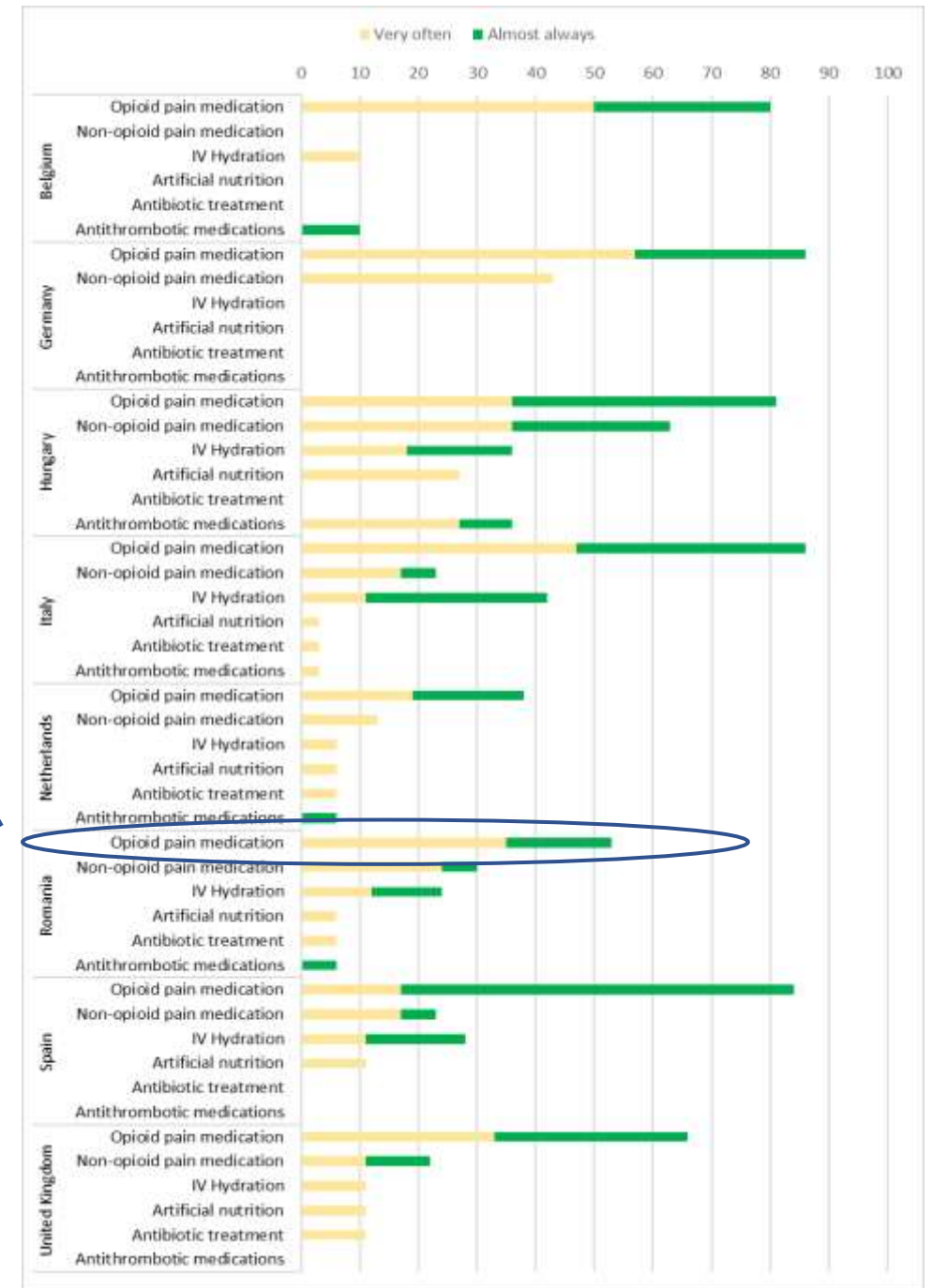
Barbiturates use



Some experts perceive a frequent use of fenobarbital in Romania

Medicines

- Opioid medications are widely used as co-medication during palliative sedation
 - 65-85% of countries' participants (little less in the Netherlands, Romania), estimate that opioid medications are very often or nearly always used during PS.
 - Romania, around 50% of experts reported a very often use of opioids in PS



Regulations

Participants identified up to 32 documents regulating palliative sedation (2-6 per country)


- Spain (n=11), The Netherlands (n=5), United Kingdom (n=4), Italy (n=4), Belgium (n=3), Hungary (n=2), and Germany (n=2).
- Romanian experts did not report any document.

Country (n)	Title of regulation	Type	Year	Institution or organization
Spain (11)	Ley general de Sanidad, 1986 [26]	General law	1986	Ministry of Health
	Law on Rights and Guarantees of Persons in the Process of Dying from Madrid Community (4/2017) [27]	EoL	2017	Madrid Regional Government
	Ley de derechos y garantías de la dignidad de la persona en el proceso de la muerte, Andalusian Community (Ley 2/2010, de 8 de abril) [28]	EoL	2010	Andalucía Regional Government
	Ley 5/2015, de 26 de junio, de derechos y garantías de la dignidad de las personas enfermas terminales [29]	EoL	2015	Galicia Regional Government
	Ley de derechos y garantías de la dignidad de la persona en el proceso de morir y de la muerte Ley Aragón 2011 [30]	EoL	2011	Aragón Regional Government
	Ley de derechos y garantías de la dignidad de la persona en el proceso de la muerte, Navarra 2011 [31]	EoL	2011	Navarra Regional Government
	Ley de derechos y garantías de la dignidad de la persona en el proceso de la muerte, Canarias 2015 [32]	EoL	2015	Canarias Regional Government
	Ley 4/2015 de Derechos y Garantías de la persona en el proceso de morir [33]	EoL	2015	Baleares Regional Government
	Ley 5/2018 sobre Derechos y Garantías de la dignidad de las personas en el proceso del final de la vida (Asturias) [34]	EoL	2018	Asturias Regional Government
	Ley 11/2016 de garantía de los derechos y de la dignidad de las personas en el proceso final de su vida [35]	EoL	2016	Euskadi Regional Government
Ley 16/2018 de derechos y garantías de la dignidad de la persona en el proceso de atención al final de la vida [36]	EoL	2018	Valencia Regional Government	
United Kingdom (5)	National Palliative Care guideline [44]	Guideline	2016	National Institute for Health and Care Excellence
	Treatment and care towards the end of life: good practice in decision making (decision-making, advanced care directives, nutrition and hydration)[45]	Guideline		General Medical Council* (statutory regulator for the medical profession in UK)
	Palliative Care Formulary version 6 [46]	Guideline	2018	/
	EAPC Framework for Palliative Sedation [2]	Guideline	2009	European Association for Palliative Care
	Mental Capacity Act 2005 and related code of conduct [43]	General law	2005	

Regulations

1st) Explicit reference/description of palliative sedation in regulation

- Spain (laws on rights and guarantees of the person in process of dying)
- Italy (informed consent & advance directives)



Artículo 11. Derecho del paciente a recibir cuidados paliativos integrales y al tratamiento del dolor.

1. Todas las personas en situación terminal o de agonía tienen derecho a recibir cuidados paliativos integrales de calidad.
2. El paciente tiene derecho a recibir la atención idónea que prevenga y alivie el dolor, incluida la sedación si el dolor es refractario al tratamiento específico.
3. El paciente en situación terminal o de agonía tiene derecho a recibir sedación paliativa, cuando lo precise.

2nd) General laws regulating medical practice (some EAPC PS principles)

- Obligation of physicians to respect advance directives (*all countries*),
- Informed consent of the patient (*Belgium, Germany, Hungary, Italy, the Netherlands, Romania, and Spain*),
- Decision-making process (*Belgium, Hungary, Italy, Netherlands, Spain and UK*),
- Obligation to document the whole treatment process (*Belgium, Germany, Italy, the Netherlands, and UK*).

3rd) Professional standards: guidelines (legal significance)

- In Germany, the Netherlands and the UK (binding as good practice in terms of disciplinary law)

Regulations

Country reports (3 samples)



Spain: Palliative sedation is regulated through **regional end-of-life regulations on rights and guarantees of persons in the process of dying** (right to receive PS when there are refractory symptoms) Informed consent and the obligations of clinical staff of informing and respecting advance directives are generally observed. Besides, **the law 41/2002 on Patients Autonomy** (art. 9.3a.) refers to the adequate consent for PS, and the **General Health Law 1986** mentions PS specifically [26].

Netherlands: PS is considered a normal medical practice. There is a **general health law on the agreement of medical treatment** applicable to PS. It regulates the informed consent, the duty to respect the patient's right, the transparency of the decision-making process (the patient's right to information), the collegial decision-making, the documentation of the entire decision-making process in medical files, and the obligation of physicians to take into account advance directives (art 450)

By implication, **the Dutch Medical Association (KNMG) guideline** for PS is part of the physician's professional standard(s). By law, the physicians (and also nurses) are obliged to act according to professional standard(s) as for its legal status and significance.

Romania: The **patients' rights law 46/2003** includes the right to informed consent and the right to refuse healthcare or certain medical treatments. Guidelines established by the PC protocols are used only locally in PC services. To date, no discussions about legal aspects of PS are in place.

What have I learnt?

Few European clinicians are aware of PS guidelines, and even lesser use them



- Only the Netherlands and Italy over 50% of clinical staff uses guidelines.
- The EAPC framework is known by 76% of participants, but under a 20% of their country's clinical staff have adopted it (over in UK and Italy).

Midazolam was the most frequently used medicine



- In the Netherlands, Belgium, Spain, (Germany & Italy less), midazolam is very often used.
- Other medicines are less used.
- Opioid medications are widely used as co-medication (65-85%)

PS is regulated in three ways



- Specific references in End of life regulations (right of the patient when experiencing refractory symptoms).
- Normal healthcare practice (general law of medical practice and patients autonomy-related laws).
- Professional guidelines.

ADAPTED resources needed:

- Evidence-based guidelines
- Availability&accessibility of medicines in all settings
- PS can be differently regulated. A synergy between the quality guidelines, and their regulatory power can be a good idea



Mulțumesc
pentru
ascultare!