The route of opioids in Greece - National situation

A. Vadalouca, Assoc Prof of Anaesthesia, Pain Management and Palliative Care University of Athens, President of PARH.SY.A
Chair of the Advisory board of WIP
ESRA Past President
e-mail _athinajv@ath.forthnet.gr
6.7 million deaths
10.9 million new cases
24.6 million people living with cancer

By 2020 cancer could kill 10.3 million

WHO 2003
83% of world's population: inadequate access to treatment for moderate to severe pain

5.5 million pts, no adequate pain mgnt.

Lancet Onc.WHO 2014
50% of hospitalized cancer patients experience untreated pain the last 3 days.

Foley K., Palliat.Med., 2011
11m \( \frac{1}{30} \) (USA), undergoing cancer treatment

Downward arrow

65%

expected to live at least five years
Pain

Opioids
Cornerstone of pain control

Slide courtesy of Professor Vadalouca
Outline

• Availability
• Accessibility and regulatory restrictions
  ▫ And doctor’s problems
  ▫ -Pharmacists problems
  ▫ -Patients problems
  ▫ -Law pitfalls
  ▫ Other Barriers
• Alertness on consumption of opioids in Greece
• Affordability
Availability
Table 1. Opioid analgesics on essential drug lists

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<tr>
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<th>WHO essential medicine 2007</th>
<th>IAHPC 2007</th>
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<tbody>
<tr>
<td>Codeine 30 mg tabs+ paracetamol</td>
<td>X</td>
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<td>Morphine, PO immediate release (tablet or liquid)</td>
<td>X</td>
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<td>Morphine, PO controlled release</td>
<td>X</td>
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<td>Injectable morphine</td>
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<td>Oxycodone, PO immediate release</td>
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<td>Fentanyl, TD</td>
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<td>Methadone, PO immediate release</td>
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</table>

WHO, World Health Organization; IAHPC, International Association for Hospice and Palliative Care; PO, oral; TD, transdermal.
Availability? No choice

- No single opioid is optimal for all
- Change in opioid might be necessary at some point:
  when the selected opioid has failed to provide adequate analgesia or has unacceptable adverse side effects (opioid switching)
  or
  when after a period of chronic treatment with the selected opioid the analgesic benefits are diminishing (opioid rotation).
Opioid rotation in cancer patients; a review of the current literature

...opioid rotation may be useful in opening the therapeutic window and establishing a more advantageous analgesia/toxicity relationship

Vadalouca A et al, J.Opioid Manag., 2008
Accessibility
Morphine is heavily regulated

- Every licensed practitioner can prescribe morphine
- Carnet of numbered special prescription forms
  - available though the hospital’s pharmacy for doctors appointed to the NHS
  - for the private sector a nightmare to chase due to bureaucracy
Down the road

- All morphine prescriptions must be approved by the “Diefthynsi Ygieinis” of the “Nomarchiaki Aftodioikisi” (equivalent of the County Health Office)
- The permit is valid for one month
- Each prescription covers the daily dose for 5 days only
- Emergency prescription or by fax not an option

<table>
<thead>
<tr>
<th>Country</th>
<th>Maximum number of days supplied on one prescription</th>
<th>Maximum number of days supplied on one prescription</th>
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</table>

Figure 7. Prescription limits (days).
Doctor’s problems and fears

Special forms

Fear of criminal involvement often exaggerated

Under prescription or Prescription Avoidance
Under treatment
The pharmacist’s problem

- To obtain morphine Pharmacists themselves or their legal representative must go to the State Deposit of Pharmaceuticals (State Monopoly)
- Controlled prescriptions must be kept for 3 years (even today with electronic prescription at last on line)
- Charges with minor offences are overwhelming
Patients and caregivers: “the golden trophy”

Have to jump one hoop after the other, to obtain it

- Often no alternative than to go to hospitals just for the prescription
  - chase doctors
  - chase after permits
  - try to find inconveniently located pharmacies
  - return for frequent refills or for any correction
Patients and caregivers Result?

- Gaps in availability of drugs
- Loss of time (Long lines to the emergency Departments and pain Centres)

- inordinate trouble
- inconvenience
TD Fentanyl

- Controlled prescription, up to 300μg/hr for 15 days
- No need for permission by the regulatory body (less stigma less inconvenience)
- Thus it is preferred by Doctors, Pharmacists, Patients, Caregivers
- Good analgesic efficacy, But is more expensive than sustained release morphine

Koyyalagunta D, et al 2012
• Goes back to a law of 1932, almost unchanged
  (Νόμος 5539/32 «Περί Μονοπωλίου Ναρκωτικών Φαρμάκων και του ελέγχου αυτών» (άρθρα 4, 5, 7 και 13))
• Is prepared by the ministry of health (co-signed by the ministry of Health)
• Mostly concerned with abuse and addiction
  A ‘criminalization model’, rather than a ‘public health model’ to facilitate care and reduce harm
Substances used for medical purpose are listed under the term “narcotics” not distinguished from illegal drugs, adding the stigma of illegality to those in need.

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<thead>
<tr>
<th>Country</th>
<th>Regulations require patient permit/registration to receive opioid prescription out pts in pts</th>
<th>Hospice pts</th>
<th>Physicians need a permit to prescribe opioids</th>
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The advisory body
“Narcotics Committee”

- Composition that goes back again to the law of 1932
- Members
  - one civil servant
  - Representative from the National Organisation of medicines (ΕΟΦ)
  - chemist,
  - pharmacologist,
  - forensics expert
  - psychiatrist
  - police officer
- but not a pain specialist, an anaesthesiologist or an oncologist
Paradox

- Clinicians having the knowledge and expertise, who are in the front line, phase to phase with the patients and their pain, and the main prescribers of the “narcotics” have no say in the “narcotics” policy, despite of all the advice from of the International bodies and Scientific Societies
Law pitfalls, Any progress?

New bill was put under public consultation (2011)

no changes proposed for controlled substances used for medical reasons
The central principle of ‘balance’

- Many controlled medicines are essential medicines and are absolutely necessary for the relief of pain, treatment of illness and the prevention of premature death.
- A dual obligation of governments to establish a system of control that ensures the adequate availability of controlled substances for medical and scientific purposes, while simultaneously preventing abuse, diversion and trafficking.
- Governments should both enable and empower healthcare professionals to prescribe, dispense and administer them according to the individual medical needs of patients, ensuring that a sufficient supply is available to meet those needs.

World Health Organization, 2011 a(p. 11)
ΕΚΔΙΔΩΜΕ ΤΟΝ ΑΚΌΛΟΥΘΟ ΝΟΜΟ ΠΟΥ ΨΗΦΙΣΕ Η ΒΟΥΛΗ:

ΜΕΡΟΣ Α'
ΝΟΜΟΣ ΠΕΡΙ ΕΞΑΡΤΗΣΙΟΓΟΝΩΝ ΟΥΣΙΩΝ
ΚΕΦΑΛΑΙΟ Α'
ΝΑΡΚΩΤΙΚΑ ΚΑΙ ΠΡΟΔΡΟΜΕΣ ΟΥΣΙΕΣ

Άρθρο 1
Ορισμός ναρκωτικών

Με τον όρο «ναρκωτικά», κατά την έννοια του νόμου αυτού, νοούνται ουσίες με διαφορετική χημική δομή και διαφορετική δράση στο κεντρικό νευρικό σύστημα και με κοινά χαρακτηριστικά γνωρίσματα τη μεταβολή της θυμικής κατάστασης του χρήστη και την πρόκληση εξάρτησης διαφορετικής φύσης, ψυχικής ή και σωματικής και ποικίλου βαθμού, καθώς και την ανακούφιση των χρονίως πασχόντων από τα συμπτώματα συγκεκριμένης νόσου, για την οποία αυτές κρίνονται ιατρικά επιβεβλημένες
The advisory body “Narcotics Committee” has changed:

- one civil servant
- Representative from the National Organisation of medicines (ΕΟΦ)
- chemist,
- pharmacologist,
- forensics expert
- psychiatrist
- police officer
- a pain and palliative care specialist
Consumption
Unofficial information!!!

Please allow

Total morphine powder consumption:
• 13,100 gm the last 5 years (mean 2,657.50 gm / year), mainly prescribed to outpatients
• Consumption 2011: 2470 gms by pharmacies + 370 gms by the hospitals = total 2840 gm
• 0.2867 mg morphine /capita, based on total population 9,903,268 of “legal inhabitants”.
EURO Consumption of Morphine, 2010

Mg/capita

EURO mean, 12.4285 mg  Global mean, 5.9912 mg

Sources: International Narcotics Control Board; World Health Organization population data
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2012
The figure stated in the University of Wisconsin study is 0.3581 mg/capita (ref vii)
Guessing the consumption of injectable morphine and pethidine

- In 2011, the ministry of health published an invitation to tender for the processing of 3,000 gm of morphine powder into 300,000 morphine amps 10 mg and of 30,000 gm of pethidine powder into 300,000 amps pethidine (100 mg)
- Possibly an estimation of injectable morphine and pethidine consumption/year (Mostly for hospital use)
- Estimated value 287,550 Euros according to the contract notice

ΑΔΑ: 4Α3ΚΘ-ΒΦ Αθήνα, 14 - 06 – 11 Αριθ. Γεν. Πρωτ.ΔΥ6β/οικ. 66523 Αριθμ. Διακήρυξης: 12 /2011
Sales TTS Fentanyl 2009-10-11 (packages)

FENTANYL PATCHES TOTAL (UNITS)

by IMS http://www.imshealth.com/portal/site/ims

-6.3%
Sales TD Fentanyl 2009-10-11 (Values -€)
FENTANYL PATCHES TOTAL (VALUES)

-25.4%

Values Year/2009: 6,003,178
Values Year/2010: 4,476,120
Values Year/2011: 3,195,844
Sales 2009-10-11: all other Fentanyl formulations (transmucosal, sublingual, nasal - total packages)

TOTAL SALES ABSTRAL, ACTIQ, INSTANYL

**Units Year/2009: 16,261**

**Units Year/2010: 15,414**

**Units Year/2011: 20,025**

-5.2% to +29.9%
Sales all other Fentanyl formulations 2009-10-11 (values -€)

TOTAL SALES ABSTRAL, ACTIQ, INSTANYL

Values Year/2009: 3,290,618
Values Year/2010: 2,932,760
Values Year/2011: 3,981,459

10,9% decrease
35,8% increase

health analysis and servises http://www.imshealth.com/portal/site/ims
Fentanyl total sales 2011 mg

<table>
<thead>
<tr>
<th>Units Year/2011 (Absolute)</th>
<th>MG</th>
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<tr>
<td>Fentanyl TD</td>
<td>119,659</td>
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<tr>
<td>Fentanyl others</td>
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Total Fent sales /2011 2,222,827 mg
Consumption 2011 0.224 mg/capita
EURO Consumption of Fentanyl, 2010

Sources: International Narcotics Control Board; World Health Organization population data
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2012

Euro mean 0.746 mg/capita 2011
Greece 0.224 mg/capita
Affordability
Affordability

• Prescriptions given under the diagnosis of cancer pain, **but not chronic pain** due to other causes, are free of charge for insured people
• Number of Greek citizens and illegal immigrants with no access to the health system unknown
• Present figures of unemployment 25.1% (July 2012)
• For them the cost does not matter as they cannot face it no matter how low it is

GLOBAL EXCHANGE

Access to and Use of Opioids for Pain Management in Greece

Eriphili Argyra, Chryssoula Staikou, and Athina Vadalouca

C Staikou (corresponding author): 1st Department of Anesthesiology, Aretaieio Hospital, Medical School, University of Athens, Fleming 3, Ateni, 14569 Greece; c_staiou@yahoo.gr

E Argyra, A Vadalouca: 1st Department of Anesthesiology, Pain Relief and Palliative Care Unit, Aretaieio Hospital, Medical School, University of Athens, Greece

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Barriers

- The main barrier is legislation
- Availability ???
- Attitudes! Knowledge deficit of all involving parts! Studies does not exist
- Opiophobia
- Lack of organised Palliative Care network might be important too and needs investigation

E. Argyra, C. Staikou, A. Vadalouca: Access to and Use of opioids for Pain Management in Greece
Thank God there is always someone sitting beside me holding my hand. That’s the way I want to pass away.
ΕΛΛΗΝΙΚΗ ΕΤΑΙΡΙΑ ΘΕΡΑΠΕΙΑΣ ΠΟΝΟΥ ΚΑΙ ΠΑΡΗΓΟΡΙΚΗΣ ΦΡΟΝΤΙΔΑΣ  ΠΑΡΗ.ΣΥ.Α.

HELLENIC SOCIETY OF PAIN MANAGEMENT AND PALLIATIVE CARE PARH.SY.A

www.grpalliative.gr

- Collective Member of EAPC
- Member of ECEPT
- Member of WIP
• Training of health professionals
• Education
• Awareness-raising
• Home Care
Joint commitment to effectively addressing and countering the World Drug Problem
We note with concern that the availability of internationally controlled drugs for medical and scientific purposes, including for the relief of pain and suffering, remains low to non-existent in many countries of the world.
• ...We highlight the need to enhance national efforts and international cooperation at all levels to address that situation by promoting measures to ensure their availability and accessibility for medical and scientific purposes
• .... within the framework of national legal systems,

• while simultaneously preventing their diversion, abuse and trafficking
Increase awareness regarding the importance of appropriate access to opioid medicine for a country's public health
• Recommend appropriate amendments to governments in order to improve access and
• rational use of opioid medicine
“In this world nothing can be said to be certain, except death and taxes”

Benjamin Franklin 1706 - 1790

There are three certainties in life – taxes, suffering and death