Assuring Availability of Opioid Analgesics for Palliative Care

Report on a WHO Workshop

Budapest, Hungary
25–27 February 2002

2002

ABSTRACT

Regulatory problems in making opioid analgesics available and a series of policy and professional barriers often prevent proper treatment for people who suffer from severe pain. Over 40 experts from Bulgaria, Croatia, Hungary, Lithuania, Poland and Romania, along with experts from WHO and other organizations, attended the Workshop to evaluate national policies for opioid control and to develop action plans to improve the availability of these drugs for palliative care in their countries. The participants discussed the changes that might need to be made in laws and regulations or drug distribution to achieve this goal. They recognized the need to balance the regulatory requirements for control with the need to make opioids accessible for appropriate pain relief. The participants urged governments to ensure the accessibility of opioids for their population while complying with all international regulatory obligations.

Keywords

PAIN – drug therapy
NEOPLASMS – drug therapy
ANALGESICS, OPIOID – distribution and supply
PALLIATIVE CARE
EUROPE, CENTRAL
EUROPE, EASTERN

WHO Regional Office for Europe, Copenhagen

CONTENTS

1. Background and introduction

This is a report on a World Health Organization (WHO) workshop on opioid availability for palliative care for six central and eastern European countries that was held in Budapest, Hungary in February 2002.

Studies around the world have consistently shown that all types of pain (acute, cancer, and chronic non-cancer) are routinely under-treated. There are many reasons for this, including lack of knowledge about how to treat pain on the part of healthcare practitioners, patient fears and misunderstanding of the medications that are used to treat moderate to severe pain (opioid analgesics), and national regulatory barriers that restrict the availability of opioid analgesics.

In 1999, the World Health Organization Collaborating Center for Policy and Communications in Cancer Care (WHOCC) in the USA, under contract from the WHO Essential Medicines Department, prepared an initial draft of guidelines that could be used to evaluate national policy for its ability to ensure adequate availability of narcotic drugs while at the same time preventing their diversion to licit channels. An international expert workgroup reviewed the guidelines in late 1999, and in 2000, were published by the WHO. Titled "Achieving Balance in National Opioids Control Policy," they were the basis of a PAHO workshop on opioid availability for palliative care for six Latin American countries in Quito, Ecuador in December 2000.

On that basis, a similar workshop was organized for six central and eastern European countries in Budapest, Hungary by the WHO Regional Office for Europe (EURO) together with the Essential Drugs and Medicines Policy department in WHO Geneva, in collaboration with the Open Society Institute (OSI) and the WHOCC.

2. Objectives

The desired outcomes were to provide participants with the knowledge necessary to evaluate their national opioids control policies, to encourage collaboration between representatives of national, government, and pain relief and palliative care organizations, and to formulate an action plan in each of the six participating countries to improve the availability of opioid medications for relief of pain and suffering of cancer and AIDS patients at the end of life.

3. Workshop development

Representatives of the WHO Regional Office for Europe, OSI, and WHOCC met in July 2001 to begin the planning process for the "Workshop on Assuring Availability of Opioid Analgesics for Palliative Care." Following the meeting in Denver, the remainder of the workshop arrangements were accomplished via email and telephone communication. The workshop was funded by OSI; meeting arrangements were coordinated by the Regional Office, and the content of the meeting was prepared by WHOCC, in consultation with all partners involved. The workshop was held at the Central European University Centre in Budapest, Hungary on 25–27 February 2002.

The following countries participated in the meeting, taking into consideration their health care systems, and interest in pain management and palliative care: Bulgaria, Croatia, Hungary, Lithuania, Poland and Romania. It was planned that each country group consisted of representatives of the Ministry of Health for narcotics control, cancer control, and pain and palliative care, as well as several clinicians and non-governmental organizations working in the latter fields. Several observers and temporary advisers, including representatives of the International Association for the Study of Pain, European Association for Palliative Care, and Eastern and Central Europe Palliative Task Force, were invited to assist with the programme. The programme benefited from their participation (Annex 9).

Each country completed a country report about palliative care and opioid availability (Annex 1) prior to attending the workshop.

4. Programme

The mornings of the first and second day of the workshop (Annex 2) consisted of presentations by experts in pain management and opioid availability (Annex 3), and included statistics on the consumption of opioid analgesics in eastern and central Europe and the world (Annex 8). Country reports were presented to the group on the afternoon of the first day (Annex 4). For the remainder of the workshop, the country groups convened to discuss opioid availability in their own country, complete the country action packet (Annex 5), create their action plans (Annex 6), and present their plans to all participants.

5. Conclusions and recommendations

- The workshop participants concluded that patients have the right to have their pain treated and their symptoms controlled, and opioid drugs should be available and accessible for that purpose when necessary.
- Governments should make pain relief and palliative care an institutional priority in the health care system, and adopt a national policy on cancer pain and palliative care.
- The patient's need to have severe pain relieved and quality of life restored is at the heart of the need for availability of opioid pain medications.
- To maximize pain relief, the importance of education cannot be overlooked. Information and education campaigns are needed to stress the need for and ways to achieve appropriate pain treatment. These activities should be directed at both health professionals and the public in general.
- Participants recognized the need to balance the regulatory requirements for the control of narcotic drugs with the need for making opioids accessible for appropriate pain relief.
- The speakers stressed that governments should ensure accessibility of opioids to patient populations within their health care system, while complying with regulatory obligations. Accessibility to opioid analgesics should be ensured by national narcotics policies, their administration and an effective distribution system.

- Medical use, or consumption, of opioid analgesics varies widely *among* countries throughout Europe, as does the degree to which pain management and palliative care is developed. *Within* a single country, there may also be great differences in what is available between urban and rural settings, and between hospital and at-home settings. A country's consumption can be used as an indicator of progress to improve pain treatment, but opioid consumption data do not provide a complete picture.
- The participants indicated that in some cases, the most cost-effective drugs are not being used for treating pain. Indeed, market conditions, dispensing practices and regulations are important factors that will affect the local availability.
- Countries indicated that national narcotic prescription and dispensing regulations should be reviewed, as they may be too restrictive, impeding accessibility of opioids. Some of the provisions for review include:

  (1) limits on the quantity of drug prescribed at one time,
  (2) limits on how long a patient may be treated with opioids,
  (3) period of validity of the prescription,
  (4) limits on the type of patient (i.e., only with cancer or "incurable") that may be treated.
  (5) limits on the type of physician who is authorized to prescribe opioids to the patient. In some cases, home-care team physicians are not authorized to prescribe, which may be an impediment to the patient receiving needed medications.
- Country representatives agreed to begin implementation of their action plans, recognizing that there will be needs for resources and technical assistance.
- The WHOCC will follow-up with the liaison person identified by the country groups, and will inform the workshop sponsors of progress.
- The participants determined that there is a need for collaboration among the national and international partners in this endeavour:
- At the national level, among government policy makers and regulators with the health professionals.
- At the international level, to include the INCB and WHO, especially on advocacy and policy, as well as through technical assistance.

6. Workshop evaluations completed by the participants

Thirty of the 36 participants completed workshop evaluations. The participants rated highly the quality and usefulness of the workshop, and made a number of useful suggestions for improvement (Annex 7).

Annex 1

OUTLINE FOR COUNTRY REPORT

A. Description

The country report is to be prepared by one or more individuals from the country team. It is recognized that some of the information may not be available. The report should be written and submitted on disk, and also summarized in slides or overheads for presentation in the early part of the workshop. Preparation and presentation may require two persons because there are two different areas of content and expertise: cancer/palliative care and narcotics control.

B. Purposes

1. To acquaint the participants of a country with information about the nature and extent of opioid availability or unavailability and potential resources to address the problem by asking them to obtain and present that information which is reasonably accessible;
2. To provide a starting point for a country delegation to develop a more refined statement of the problem and to develop preliminary objectives and action plans that are aimed at what is known about the problem and the resources that are available;
3. To provide a basis for comparison between countries.

C. Outline for the country report

1. Cancer, pain and palliative care *(This information, to the extent that it is available, should be obtained from the WHO country or regional office, the national cancer program, institute or hospital, or national societies for cancer, pain relief and palliative care).*

    a. What is the estimated prevalence and types of cancer in the country, and the prevalence of pain?
    b. Is there a national cancer control plan or program; if so, when did it start? Are pain relief and palliative care addressed? Is opioid availability addressed? What is the name of the office and person in charge?
    c. Has the government endorsed the WHO method for relief of cancer pain? Has the government sponsored or endorsed training programs in cancer pain relief and palliative care?
    d. Describe in brief terms the availability of pain relief and palliative care services in the country and comment on the extent to which the needy population has access to such services.
    e. Identify national associations (non-governmental organizations) that have a primary interest in pain relief and/or palliative care, and mention their relevant activities.

2. Opioid availability *(This information, to the extent that it is available, should be obtained from the national office for narcotics control, i.e., the "Competent Authority,"1 and from pain and palliative care programs.)*
    a. Identify the national office that is the Competent Authority for narcotics control for the country. Who is in charge of the office, and who is in charge of submitting the annual estimate of medical requirements for narcotic drugs to the International Narcotics Control Board?
    b. What opioid analgesics are approved in the country, and in what dosage forms? List all licensed manufacturers for the needed opioids. What opioids are not available?
    c. For those opioids that are available, are they sufficiently available in the places where cancer patients are treated in the country, i.e., all hospitals with cancer units, hospices, pain clinics, palliative care programs, etc.?
    d. What are the national statistics for the consumption trends of strong opioid analgesics (morphine, pethidine, fentanyl, etc) for the last five years?2
    e. What are the basic requirements for a physician to prescribe an opioid such as morphine?

        i. What licenses are required?
        ii. Are special prescription forms required?
        iii. Is special training required?

    f. What are the other requirements for writing a prescription for an opioid such as morphine?

        i. Is there a maximum amount that can be prescribed at one time, for example a limitation on the number of dosage units or number of days?
        ii. Is there a maximum length of time that a patient can receive opioids?
        iii. What is the period of time that a prescription for an opioid such as morphine is valid?
        iv. Are there different legal requirements for prescribing, dispensing or purchasing different dosage forms of the same opioid, i.e., oral, transdermal, injectable?
        v. What is the minimum and maximum penalty for a physician or pharmacist who violates the prescribing laws or regulations?
        vi. Does the national law or regulation require reporting names of patients who receive opioid prescriptions to the government?

    g. What, if any, changes have been made in laws, regulations or commercialization to improve the medical use and availability of opioid analgesics?

1 United Nations. *Competent National Authorities Under the International Drug Control Treaties, 1999*. New York, NY: United Nations; 2000.
2 Statistics will also be provided by the WHOCC

Annex 2

AGENDA

Sunday, 24 February 2002 evening

18:00 – 19:00 Welcome and Reception, hotel

Monday, 25 February 2002

7:00 Breakfast – included in hotel

8:00 Opening of the workshop
Welcome - *Minister of Health, or his representative*
Kees de Joncheere, WHO Regional Office for Europe

8:15 Introduction of all participants/Warm-up exercise, *Kees de Joncheere*

9:15 Objectives of the workshop, *Kees de Joncheere*

9:30 Availability of opioid analgesics: One of the key components of the WHO Palliative Care Programme, *by Cecilia Sepulveda*, WHO-Geneva

9:45 Problem of pain in AIDS, *by Kathleen Foley*, OSI

10:00 Break

10:30 Undertreatment of pain, background and reasons.
Assessment and management of pain; role of opioids, pharmacology and myths
by Kathy Foley

11:30 Discussion

11:45 Opioid availability in Eastern Europe, *by David Joranson*

12:00 Role of various UN agencies in ensuring the availability of opioid analgesics
by Dr Tokuo Yoshida, WHO-Geneva, EDM/QSM

12:30 Lunch

13:30 Dependence and control of drugs: Application of WHO terminology about dependence; medical use of opioid analgesics for pain relief from cancer
by Tokuo Yoshida

13:45 Country reports on availability of opioids for palliative care:

Bulgaria
Croatia
Hungary

15:15 Break

15:45 Continuation of country reports:
Lithuania
Poland
Romania

17:15 Recess

19:00 Dinner

Tuesday, 26 February 2002

7:00 Breakfast

8:00 Overview of the new WHO Guidelines for evaluation of national narcotics control policy, *by Tokuo Yoshida*

8:15 Review and application of the Guidelines, Part I. Evaluation of national policy and administration
Guideline 1: Governments should review their drug control policies in order to identify excessive restrictions
Guideline 2: Opioids are necessary for palliative care
Guideline 3: Obligation of governments to ensure availability of opioids
Guideline 13: Establish a national cancer control program with a palliative care component
Guideline 14: Terminology related to pain, drug dependency and abuse
Guideline 15: Eliminate requirements that impede the practice of medicine and patient care
Guideline 16: Eliminate restrictive requirements of prescriptions
by David Joranson

9:00 Discussion

9:15 Review and application of the Guidelines, Part II. Estimation of annual national opioids requirements according to the Single Convention of 1961

Guideline 5: Development of realistic estimates of medical needs for opioids

Guideline 6: Provision of annual estimates to the INCB
Guideline 7: Use of supplementary estimates if requirements increase
Guideline 8: Reporting statistics (production, manufacture, sale and stocks)
by Tokuo Yoshida

10:00 Discussion

10:15 Break

10:45 Review and application of the Guidelines, Part III
Obtaining and distributing opioids.

Guideline 4: Designation of an administrative authority
Guideline 9: Dialogue with health professionals
Guideline 10: Cooperation between regulators and health professionals
Guideline 11: Eliminate shortage and interruption of supply
Guideline 12: Maximize access and prevent abuse and diversion
by David Joranson

11:30 Discussion

12:00 Lunch

13:00 Developing national action plans: Objectives for the country groups
by David Joranson

13:30 Country groups, first session

15:00 Break

15:30 Country groups, second session

18:00 Recess *

19:00 Dinner

Optional continuation of country group meetings
Group facilitator(s) may meet with individual country coordinators

Wednesday, 27 February 2002

7:00 Breakfast

8:00 Country groups, third session
Country reports – Action plans
Each country presents for 15 minutes, followed by a 15-minute discussion

11:30 Discussion

12:30 Lunch

13:30 Closing remarks *by Kathleen Foley, David Joranson and Kees de Joncheere*

14:00 Meeting adjourns

Annex 3

FACULTY PRESENTATIONS

1) **DR KATHLEEN M. FOLEY**
   - HIV/AIDS
   - PAIN

2) **MR TOKUO YOSHIDA**
   - TERMINOLOGY
   - UN AGENCIES

3) **DR DAVID JORANSON**

4) **DR CECILIA SEPULVEDA**
   - CANCER

DR KATHLEEN M. FOLEY

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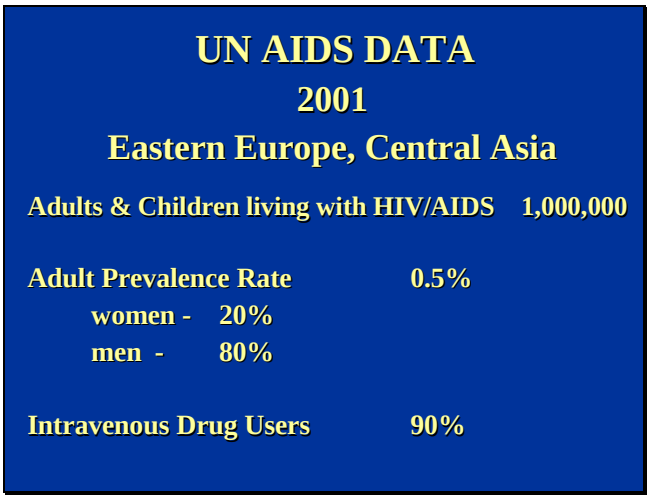

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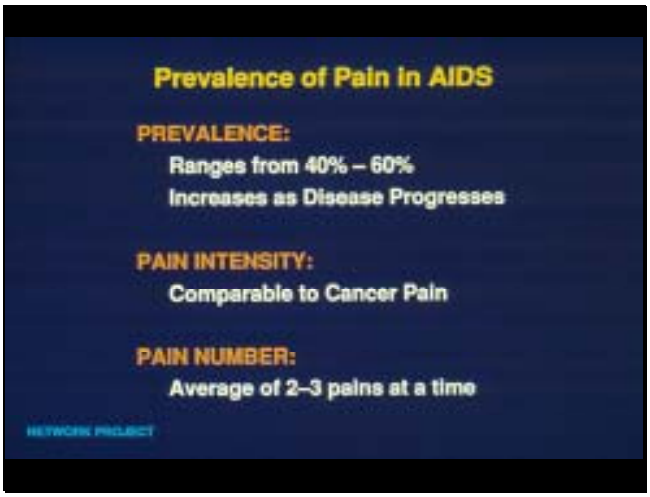

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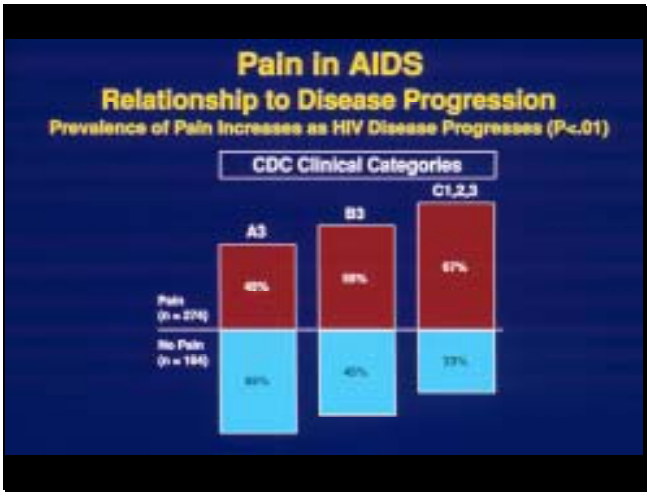

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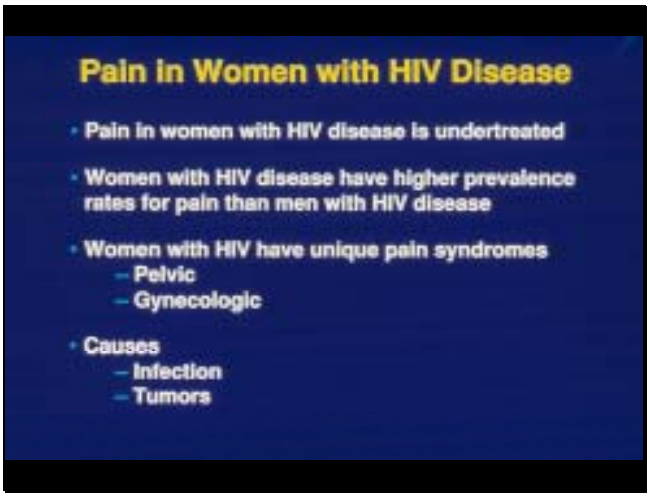

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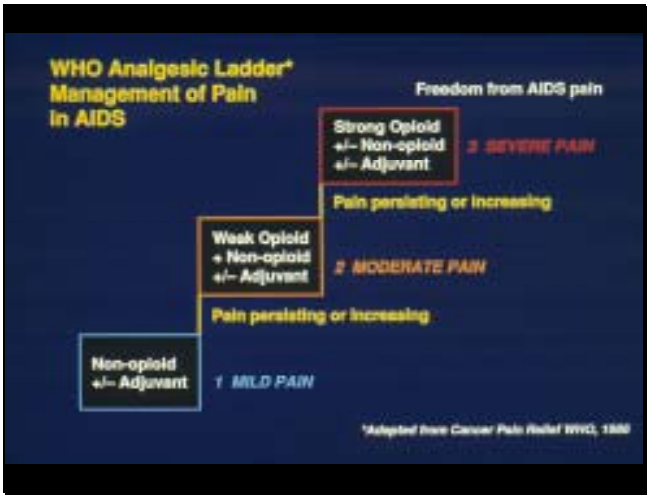

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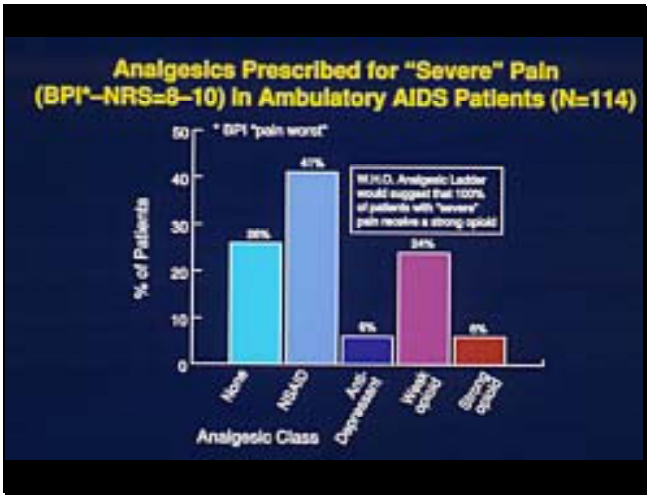

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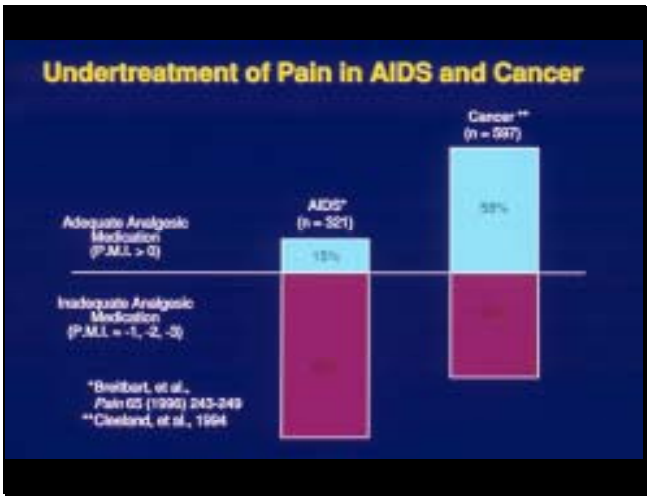

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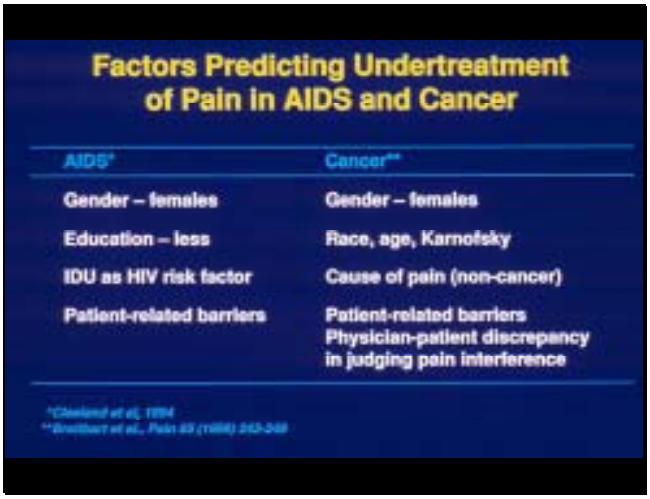

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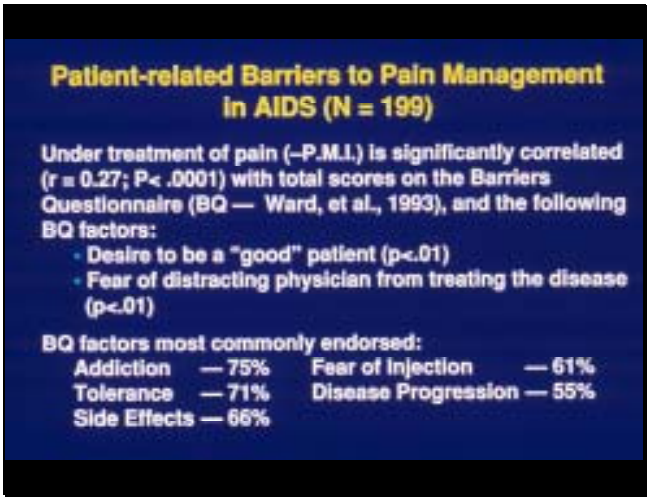

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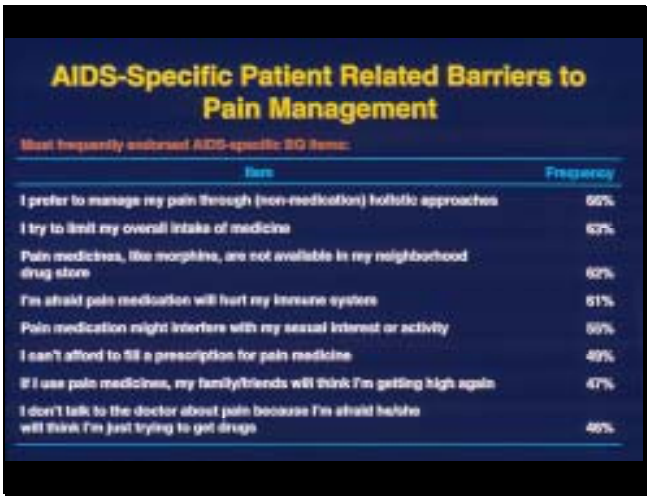

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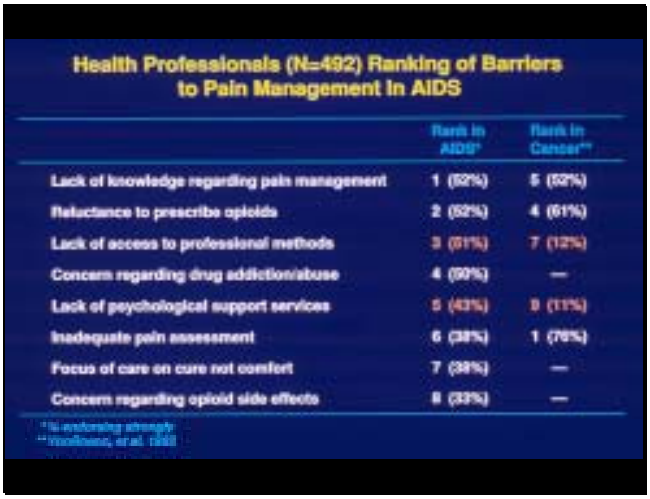

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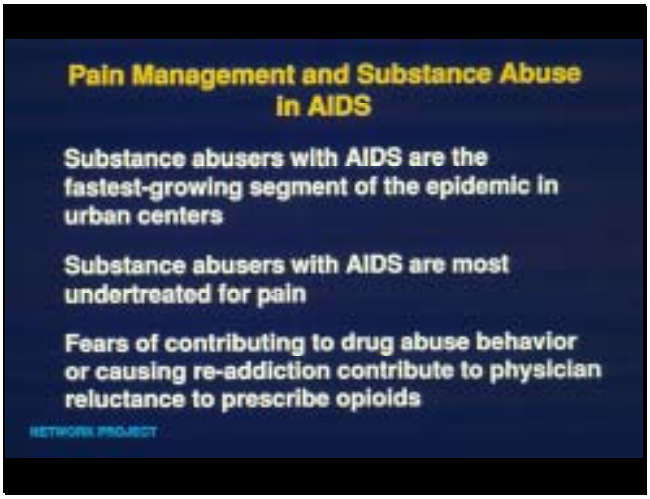

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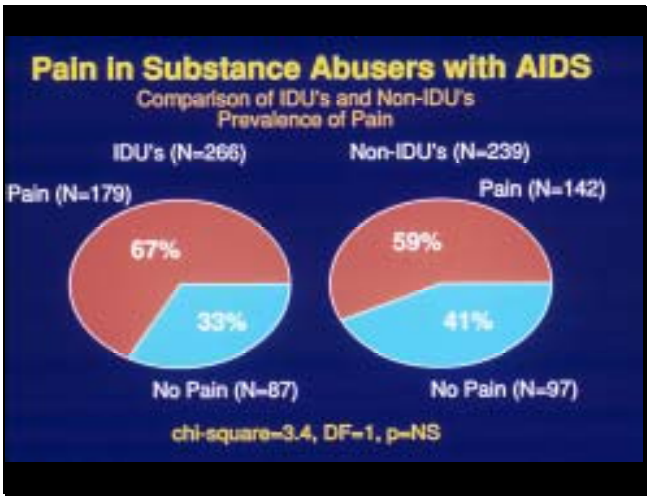

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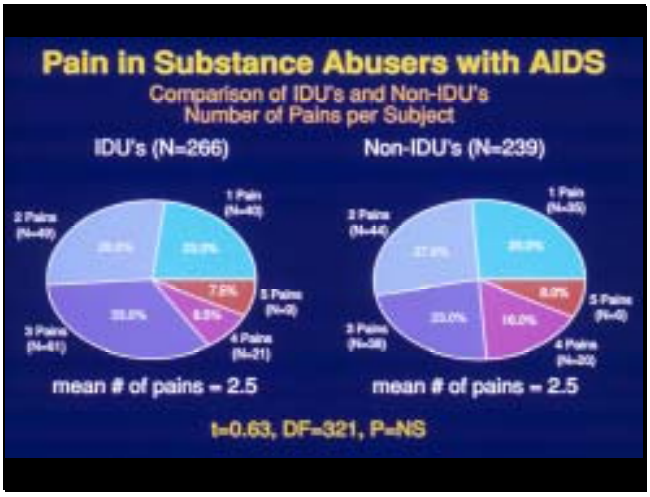

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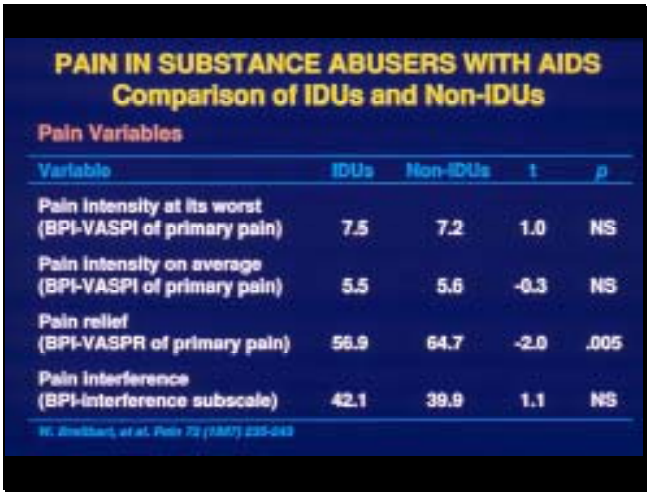

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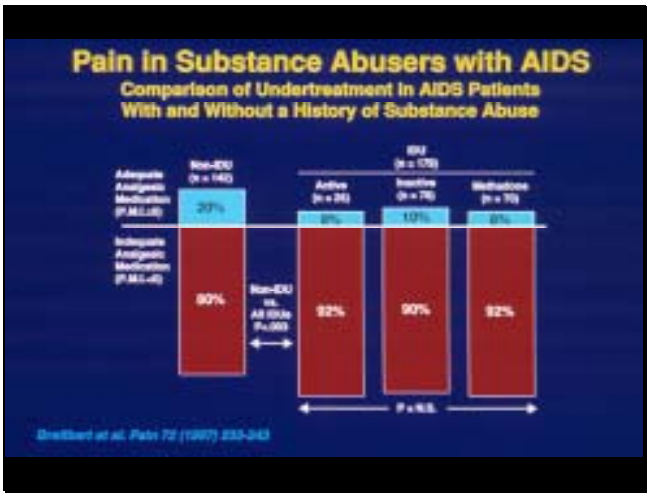

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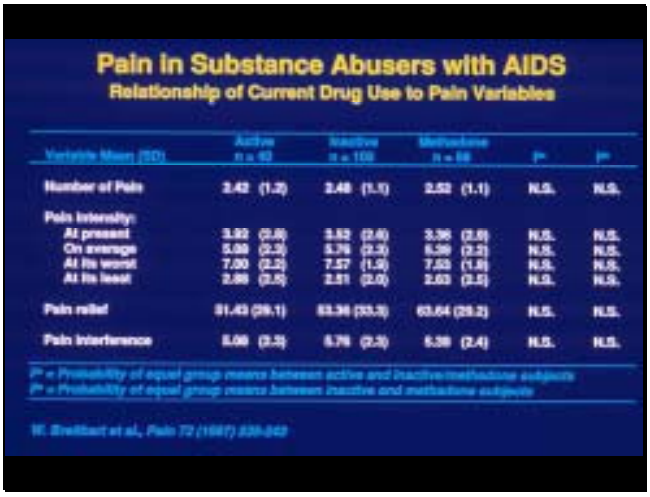

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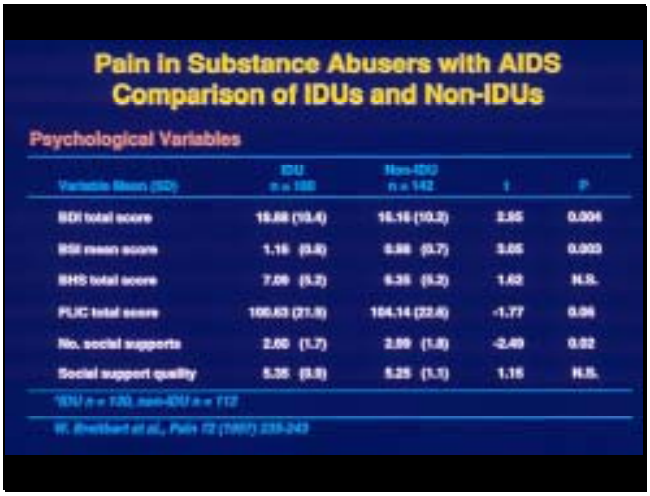

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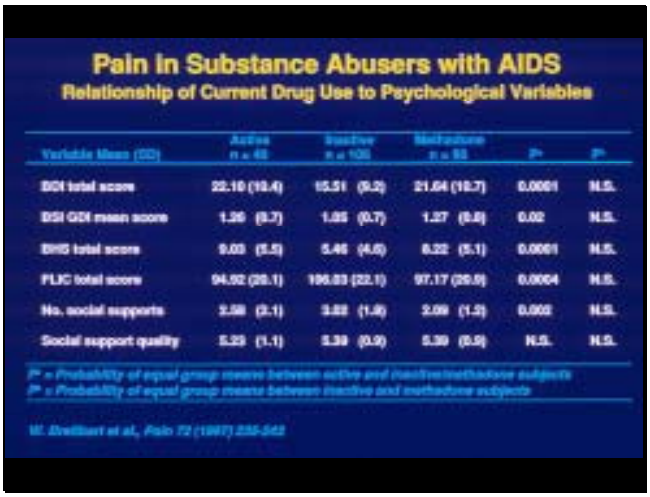

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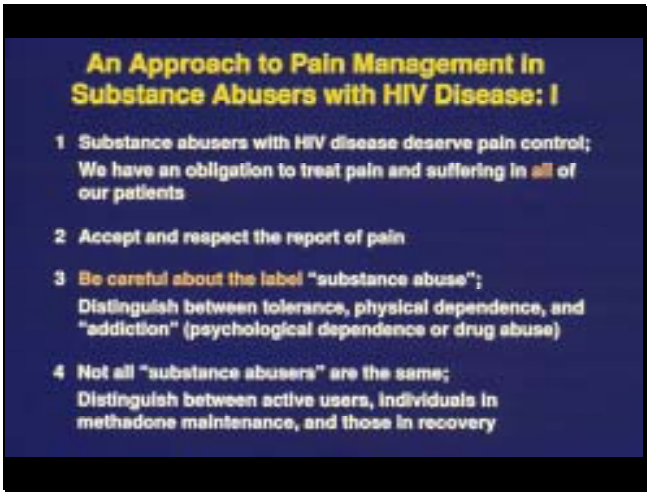

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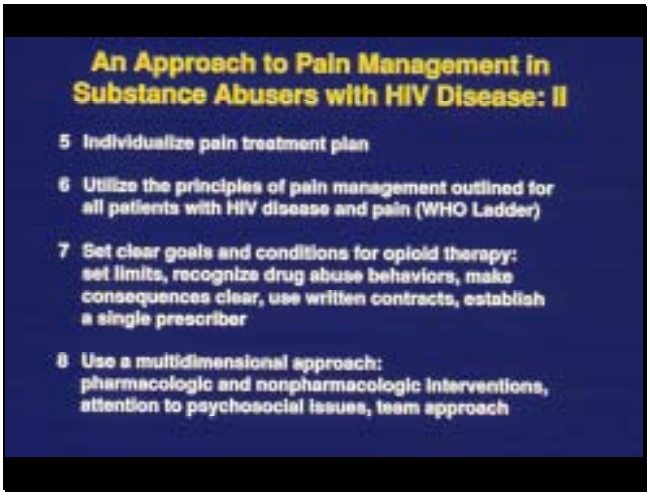

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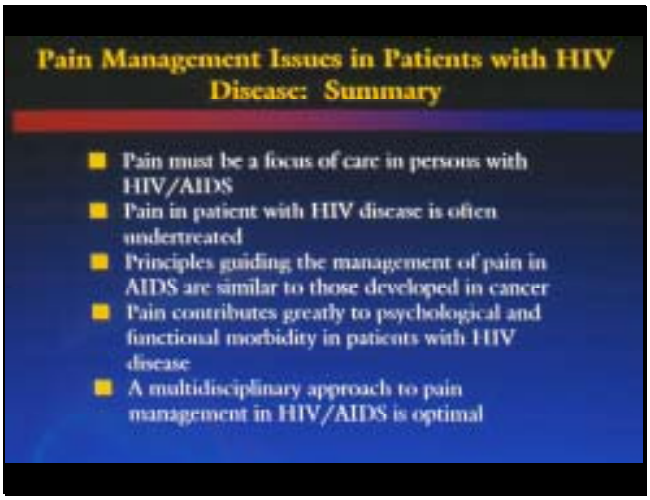
Pain Management Issues in Patients with HIV Disease: Summary
Pain must be a focus of care in persons with HIV/AIDS
Pain in patient with HIV disease is often undertreated
Principles guiding the management of pain in AIDS are similar to those developed in cancer
Pain contributes greatly to psychological and functional morbidity in patients with HIV disease
A multidisciplinary approach to pain management in HIV/AIDS is optimal

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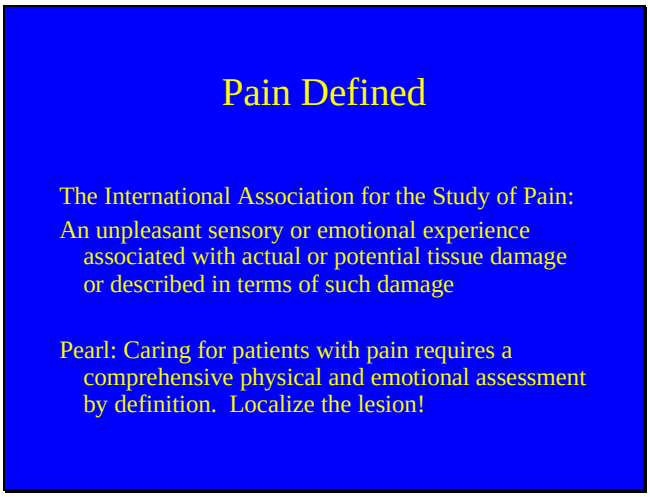

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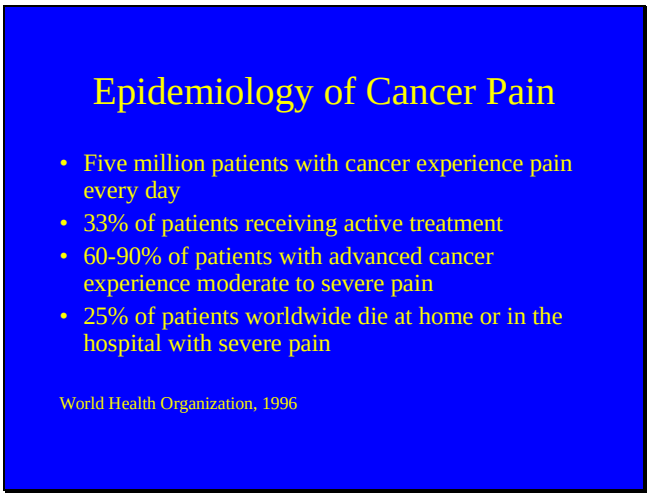

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Eastern Cooperative Oncology Group Physician Study (n=897)

- 86% reported that the majority of their patients with pain were under-medicated
- Only 51% believed that pain control in their practices was good or very good
- 31% would wait until their patient's prognosis was six months or less before starting maximum-tolerated analgesia

Van Roenn et al., Ann Intern Med 1993;119:121-6

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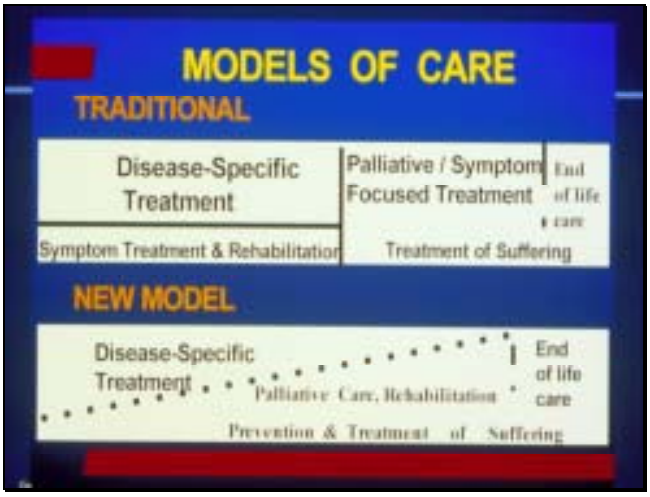

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Clinician-Related Barriers

- Lack of pain assessment skills
- Lack of knowledge of current therapeutic approaches
- Uncertainty about the role of opioid therapy
- Deficiencies in knowledge of opioid therapy
- Overestimation of risks of addiction
- Concern about tolerance
- Concern about managing side effects
- Concern about regulation of controlled prescription drugs

The Network Project, MSKCC 1996

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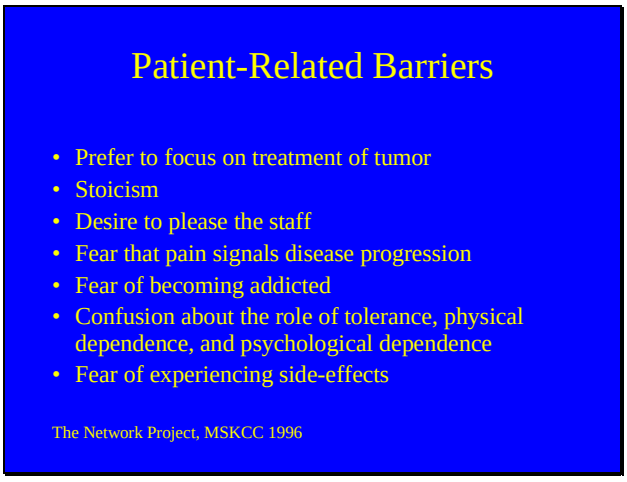

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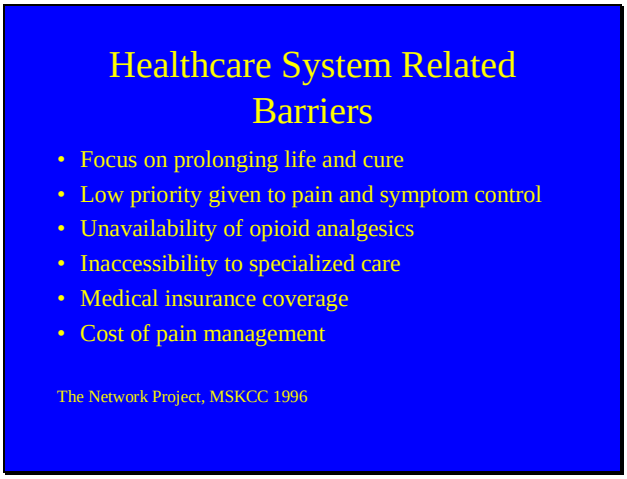

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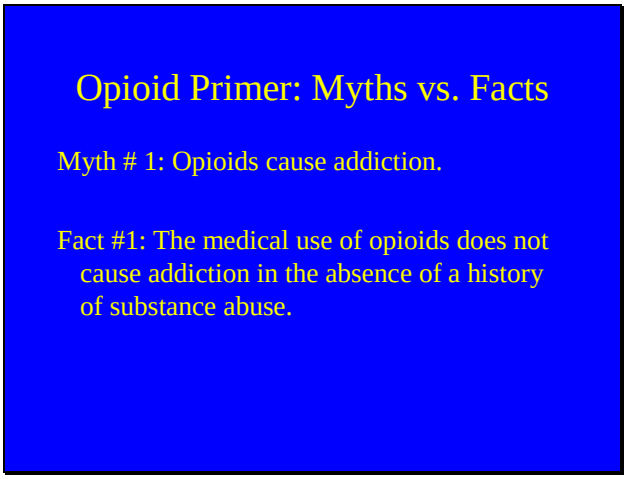

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Table 2
Addiction Due to Medically Administered Opioids

Author	Ref.	Frequency	Percent
Porter and Jick	18	4 out of 11,882 hospitalized patients	0.03%
Pegelow	21	1 of 510 sickle cell patients	0.2%
Brecevic et al.	22	0 of 610 sickle cell patients	0.0%
Vichinsky et al.	23	3 of 101 sickle cell patients	3.0%
Schug et al.	24	1 of 550 cancer patients	0.2%
Kanner and Foley	25	0 of 86 cancer pain patients	0.0%
Evans	26	7 of 130 cancer and nonmalignant pain patients	5.4%
Taub	27	5 of 313 chronic nonmalignant pain patients	1.6%
Zenz et al.	28	0 of 100 chronic nonmalignant pain patients	0.0%
Moulin et al.	29	0 of 46 chronic nonmalignant pain patients	0.0%
Portenoy and Foley	30	0 of 36 chronic nonmalignant pain patients	0.0%
Kanner and Foley	25	0 of 15 chronic nonmalignant pain patients	0.0%
France et al.	31	0 of 16 chronic nonmalignant pain patients	0.0%
Chapman and Hill	32	0 of 26 bone marrow recipients	0.0%
Perry and Heidrich	33	0 of >10,000 burn patients	0.0%
Sun et al.	34	0 of 538 patients given opioids	0.0%
Medina and Diamond	35	3 of 23 chronic headache patients	13.0%

*Drayer et al. JPSM 1999;17:434-40

Slide 11

Opioid Primer: Myth vs. Fact

Myth #2: Opioids hasten death

Fact #2: Opioids have never been demonstrated to hasten death and may prolong life

Wilson WC et al., JAMA 1992;267:949-953
Brescia FJ et al., J Clin Oncol 1992;10:149-155
Portenoy RK, J Pall Care 1996; 12:44-46
Bercovitch M et al., Cancer 1999
Sykes et al., Lancet 2000;356:398-399

Slide 12

Opioid Primer: Myth vs. Fact

Myth #3: "I'm afraid to use the medication now because it won't work later when I really need it."

Fact #3: Opioids may be safely and effectively used at all stages of disease.

Foley KM. Changing concepts of tolerance to opioids: What the cancer patient has taught us, Raven Press Ltd., NY 1993

Slide 13

Opioid Pharmacotherapy

- Tolerance
- Physical Dependence
- Psychological Dependence
- Pseudoaddiction

Slide 14

Opioid Analgesics: Tolerance

Definition: A change in the dose-response relationship induced by exposure to the drug and manifest as a need for a higher dose to maintain an effect

Key points:

Opioids should never be reserved only for patients with advanced disease

Tolerance rapidly develops to all opioid side-effects except constipation

Analgesic tolerance is rarely a problem; in the absence of worsening pathology, opioid doses usually remain stable

Modified from The Network Project, MSKCC 1996

Slide 15

Opioid Analgesics: Physical Dependence

Definition: The development of an abstinence (withdrawal) syndrome following dose reduction or administration of an antagonist

Key points:

Should always be assumed to exist following repeated dosing of opioids for more than three days

Not a clinical problem if abstinence is avoided and the patient is reassured

Should not be confused with “addiction”

Modified from The Network Project, MSKCC 1996

Slide 16

Psychological Dependence (i.e., addiction)

- Usage out of control
- Obsession with obtaining a supply
- Use causes personal and legal difficulties
- Use continues despite problems
- User denies taking the substance
- Quality of life is NOT improved

The World Health Organization

Slide 17

Pseudoaddiction

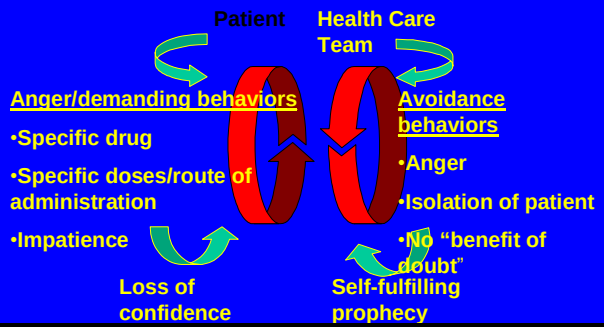
Patient behaviors that are reminiscent of addiction, but are driven by under treatment of pain and disappear with adequate analgesia.

Weissman et al., Pain 1989;36:363-6

Slide 18

Concept of "Pseudoaddiction"

Inadequate pain management

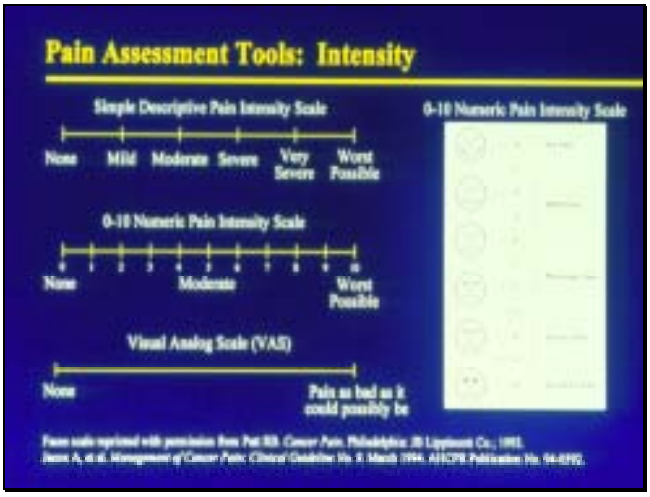


Slide 19

Pain Evaluation Essentials

- Believe the patient's complaint
- Take a careful history focusing on pain characteristics and underlying disease
- Perform a careful medical and neurological examination
  Localize the lesion!
- Order and personally review appropriate diagnostic tests
- Evaluate the extent of disease
- Perform a thorough psychological and social assessment
- Understand what the pain means to the patient
- Manage the pain during the assessment
- Reassess early and often

Slide 20



Slide 21

Pain Characteristics

Clinician should assess:
Pain intensity
Pain quality
Pain distribution
Factors that increase or decrease the pain
Temporal characteristics
Inferred pathophysiology

The Network Project, MSKCC 1996

Slide 22

Impact of a Comprehensive Pain Evaluation

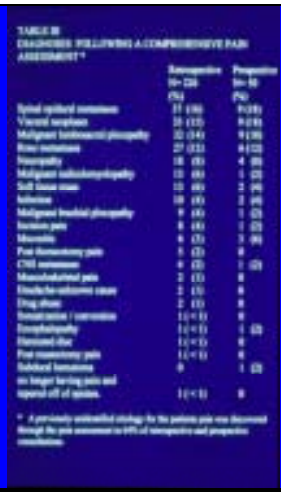
In 276 consecutive consultations:

64% identified a new lesion and of these more than 50% were neurologic

18% received radiation, surgery, or chemotherapy as a result of the consultation

Gonzales et al., Pain 1991;47:141-144

Slide 23



Slide 24

Pain Management Strategies

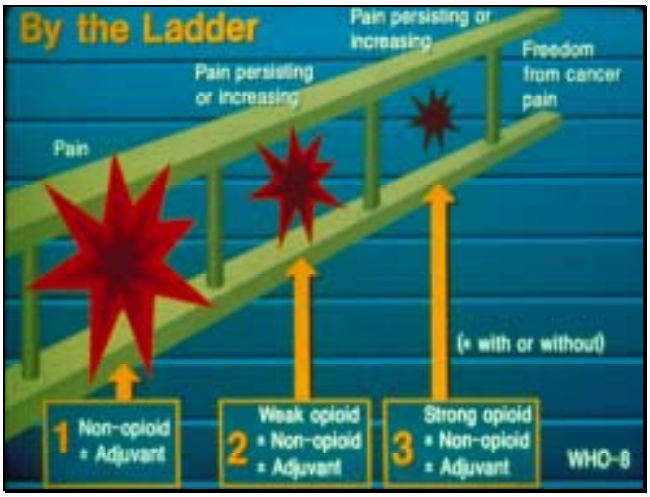
Primary treatment of etiology
- Radiotherapy
- Surgery,
- Chemotherapy
- Antibiotics

Analgesic Approaches
- Pharmacotherapy
- Anesthethic Techniques
- Surgery
- Rehabilitation
- Psychological interventions

Sedation for refractory symptoms at the end of life

The Network Project, MSKCC, 1996

Slide 25



Slide 26

WHO Ladder: Step One

For the treatment of mild pain:

Acetaminophen, NSAIDS

Benefits:

- No tolerance or physical dependence
- Additive analgesia when combined with an opioid

Caution:

Ceiling effect for analgesia

Slide 27

WHO Ladder: Step Two

For the management of moderate pain:

Codeine

Hydrocodone

Propoxyphene

Oxycodone (in combination with a non-opioid)

Tramadol

Slide 28

WHO Ladder Step Three:

For the management of severe pain:

Morphine

Hydromorphone

Fentanyl

Methadone

Oxycodone

Meperidine (parenteral)

Slide 29

Morphine is the Gold Standard

In the management of severe pain morphine should be used first except:

- In elderly populations
- In the setting of renal or hepatic insufficiency
- When contraindicated due to allergy or other adverse consequences from past exposure

Slide 30

Meperidine

Not recommended for acute or chronic pain due to its toxic metabolite, normeperidine

Normeperidine:

- A convulsant and weak analgesic
- Long-half life, accumulation after repetitive dosing
- CNS excitability, mood effects, tremor, myoclonus, seizures,
- Naloxone does not reverse normperidine-induced seizures
- Administration with MAO inhibitors may lead to hyperpyrexia and death

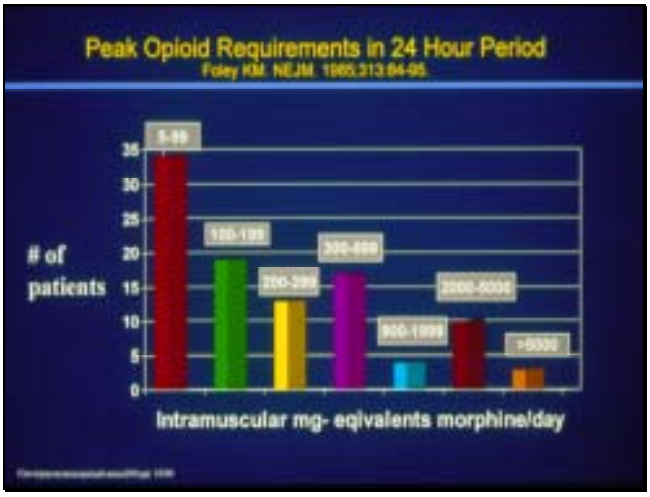
Adapted from The Network Project, MSKCC 1996

Slide 31

Opioid Dosing Guidelines 1

- Opioids have no ceiling effect. The right dose is the dose that provides maximal pain relief with minimal adverse effects
- Individualization of analgesic therapy is a critical guiding principle

Slide 32



Slide 33

Opioid Dosing Guidelines 2

- Avoid the common error of providing only long-acting or short-acting analgesic medication
- Adjust the controlled release medicine based upon the patient's usage of the immediate release drug.
- The dose of the immediate release drug should represent 15-20% of the 24 hr. long-acting dosage.
- e.g., MS Contin 30mg TID, MSIR 15-30mg po q 3hrs. prn

Slide 34

Breakthrough Pain

Definition: A transitory exacerbation of severe pain over a baseline of moderate to mild pain

Incidence: 2/3 of cancer patients with controlled baseline pain

Patients with chronic pain require a controlled-release medication a short-acting drug for breakthrough pain

Slide 35

Opioid Side-Effects

- Constipation
- Nausea/Vomiting
- Myoclonus
- Respiratory Depression
- Mental Clouding/Confusion/Sedation

Pearls:

Tolerance rapidly develops to all except constipation. Softeners AND Laxatives are essential from day one.

Aggressive side effect management is often an essential component of patient care

Slide 36

Side Effect Management

- Treat a single side effect
- Change the drug for multiple side effects
- Reserve Naloxone for hemodynamically unstable patients. ABCs come first.
- No one ever died of respiratory depression while awake!
- Manfredi PL, Inappropriate use of naloxone in cancer patients with pain J Pain Symptom Manage 1996 Feb, 11:131-134.

Slide 37

Opioid Rotation

Reasons to change:

- Dose-limiting toxicity
- Refractory and multiple side-effects
- Convenience (e.g., transdermal route preferred)
- Less-invasive route desired
- Strategy: Calculate the equi-analgesic dosage and decrease by 50% (assuming adequate pain control)
- Rationale: Cross-tolerance among opioids is incomplete

Slide 38

Frequency of Opioid Rotation

In the management of cancer pain:

- 80% of patients require one switch
- 44% of patients require two switches
- 20% of patients requires three or more switches

Pearl: Treat single side-effects. Rotate for multiple side effects.

Cherny NJ., et al., Cancer 1995;76:1288-93.

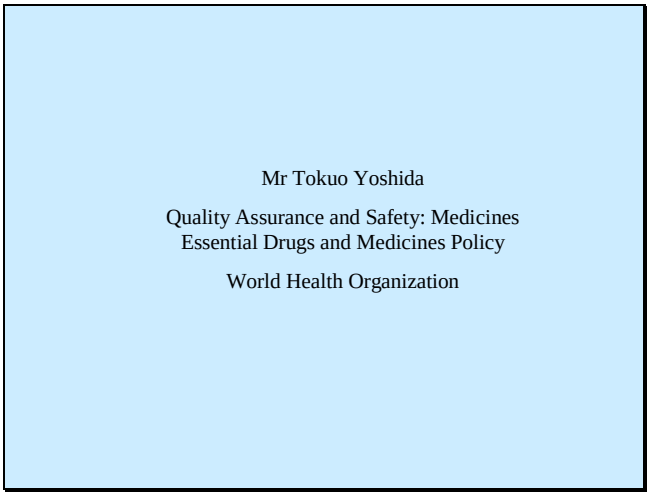
Slide 39

Recent Advances in Analgesia

- Transmucosal fentanyl for breakthrough pain
- COX-2 inhibitors for pain and arthritis
- Topical lidocaine for post-herpetic neuralgia
- Opioid efficacy in neuropathic pain
- N-methyl D-aspartate antagonists as analgesic agents

MR TOKUO YOSHIDA

Slide 1



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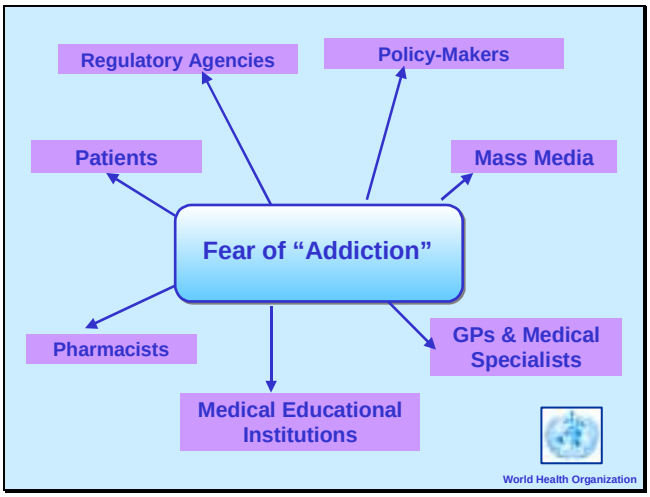

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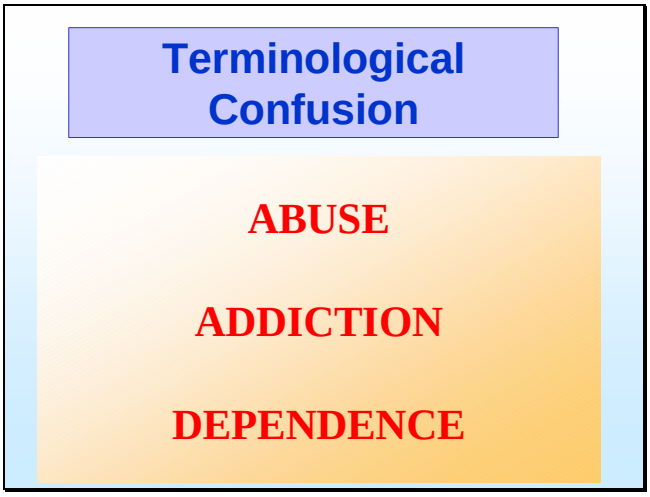

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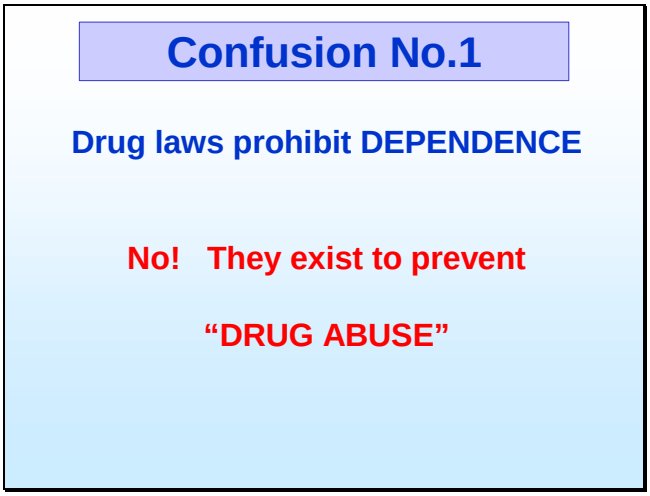

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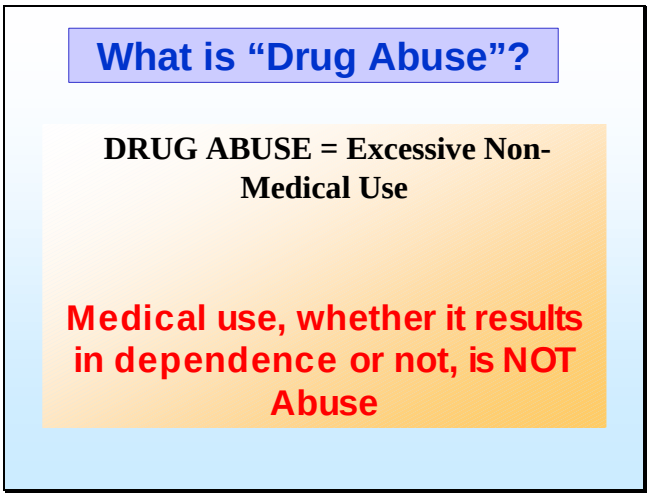

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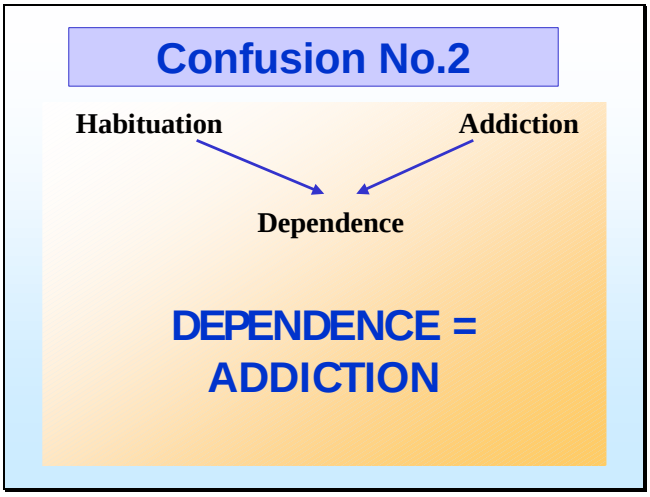


Slide 8

Slide 9

Confusion No.3

Withdrawal -> "Physical dependence"

Physical dependence = Dependence

WITHDRAWAL = DEPENDENCE

Slide 10

No! Withdrawal is NOT Dependence!

WITHDRAWAL is only one of the 3 requirements for

"DRUG DEPENDENCE"

Slide 11

Definition of "Dependence"

"A need for repeated doses of the drug to feel good or to avoid feeling bad" **(Lexicon)**

"A cluster of physiological, hebavioural and cognitive phenomenon in which the use of a psychoactive substance or a class of substances takes on a much higher priority for a given individual than other behavjours that once had greater value" **(Exp. Committee)**

Slide 12

ICD-10 Guidelines

DEPENDENCE SYNDROME

"Three or more of the following have been experienced at some time during the previous year"

Slide 13

Six symptoms of Dependence

(a) strong desire/sense of compulsion to take the drug

(b) difficulty in controlling drug-taking behaviour

(c) physiological withdrawal state

(d) tolerance

(e) neglect of alternative interests

(f) persistent use despite trouble

Slide 14

Confusion No. 4

Repeated use develops dependence

No ! It may, but not always. Cancer patients rarely develop dependence.

Slide 15

WHY SO RARE???

They do not feel “opiate euphoria”

They can take “withdrawal discomfort” much better than others

They are under medical supervision

Slide 16

“Drug Dependence” in ADR database

Butorphanol 570
Nicotine resin 515
Diazepam 462
Alprazolam 376
Lorazepam 278
Tramadol 236
Flunitrazepam 201
Methadone 46
Codeine 34
Morphine 24

Slide 17

“Withdrawal Syndrome” in ADR database

Paroxetine 1,644
Alprazolam 799
Hyoscine 503
Venlafoxine 464
Sertraline 430
Fluoxetine 343
Methadone 292
Tramadol 222
Morphine 19
Pethidine 11

Slide 18

CONCLUSIONS

BENEFIT >>> RISK

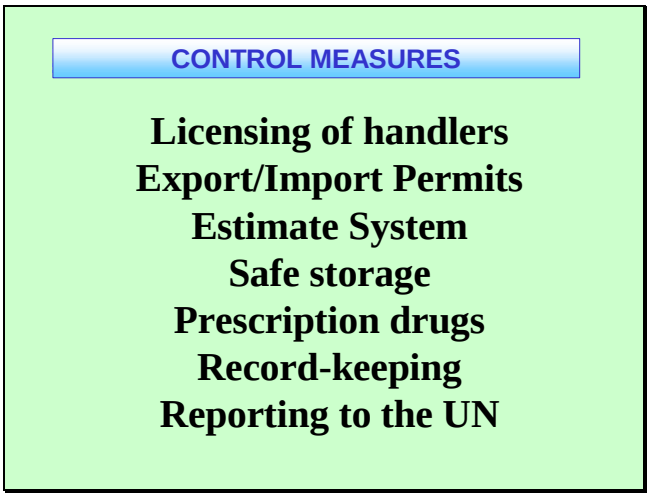
Dependence is one of the common Adverse Drug Reactions. It rarely occurs in cancer patients receiving opioid analgesics.

If it ever occurs, it can be managed by gradual dose reduction.

Slide 1

Slide 2

Slide 3



Slide 4

ROLES OF AGENCIES

United Nations

- **Commission on Narcotic Drugs (CND)**
- **ECOSOC/General Assembly**
- **UNDCP (Secretariat)**

INCB (International Narcotics Control Board)

- **Independent body to ensure successful implementation of the conventions**

WHO

- **Only specialized agency given a specific role**

Slide 5

ROLE OF WHO

Updating of the lists ("Schedules") of Narcotic Drugs & Psychotropic Substances

- **Shared mandate with CND**

  WHO recommends, CND decides

- **Proposal from Governments ("Parties") reviewed first by WHO**

Shared responsibility for successful implementation of the Conventions (WHA resolution)

Slide 6

DRUGS UNDER CONTROL

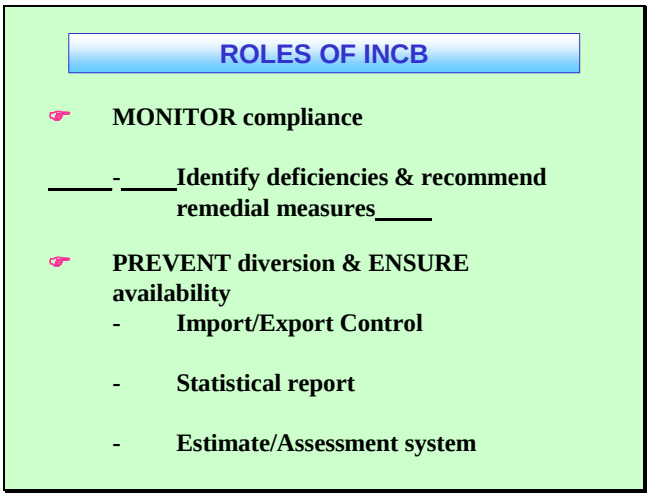
Narcotic drugs

	Sch. I	Sch. II	Total
1948	19	2	21
2002	107	10	117

Psychotropic substances

	Sch.I	Sch.II	Sch.III	Sch.IV	Total
1971	10	6	5	11	32
2002	28	16	9	62	115

Slide 7



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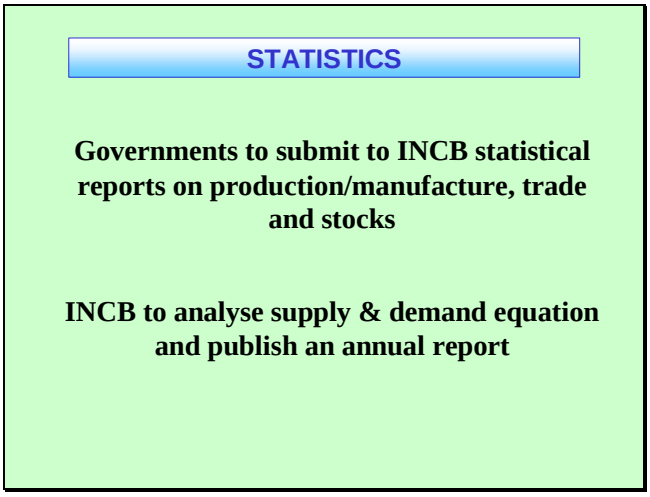


Slide 10

ROLE OF CONVENTIONS

Conventions themselves do not improve drug availability but define the procedures to follow in ensuring the availability of controlled medicines.

Therefore, manpower and expertise to comply with the conventions is indispensable if Governments are to ensure their availability for medical use.

Slide 11

ROLE OF INCB IN ENSURING AVAILABILITY

ADVOCACY - dual objectives of the conventions

LEGAL/TECHNICAL ADVICE - reduce excessive control measures

MONITOR DEVELOPMENTS - Statistics showing improvement or identifying problem areas

Slide 12

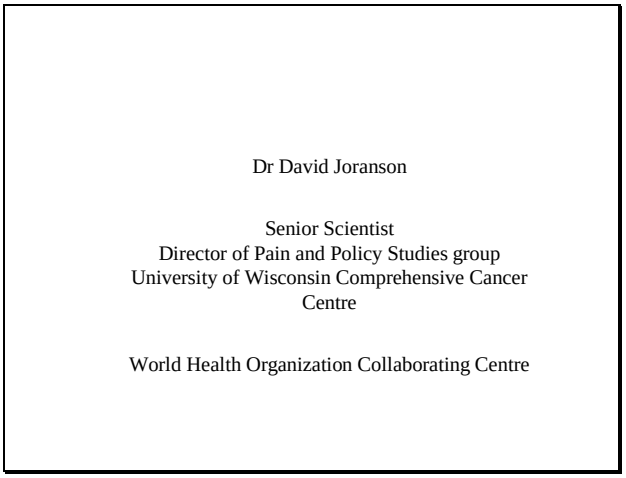
ROLE OF WHO IN ENSURING AVAILABILITY

ADVOCACY - collaboration with INCB

TECHNICAL ADVICE
for
(1) reducing excessive fear of addiction
(2) promoting appropriate use of medication
(3)supporting development of national drug policies and effective supply systems

DR DAVID JORANSON

Slide 1



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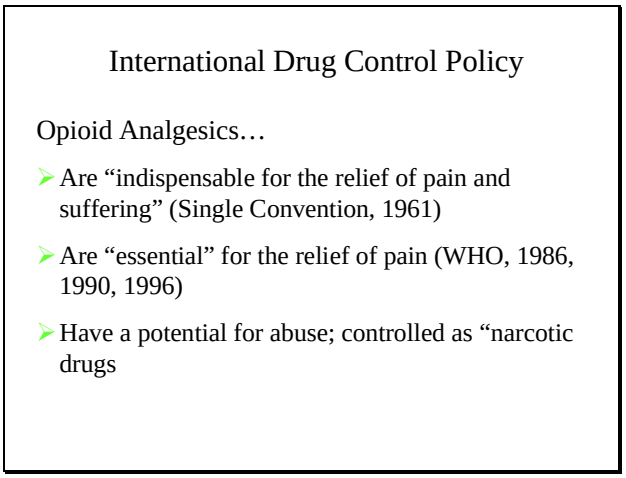

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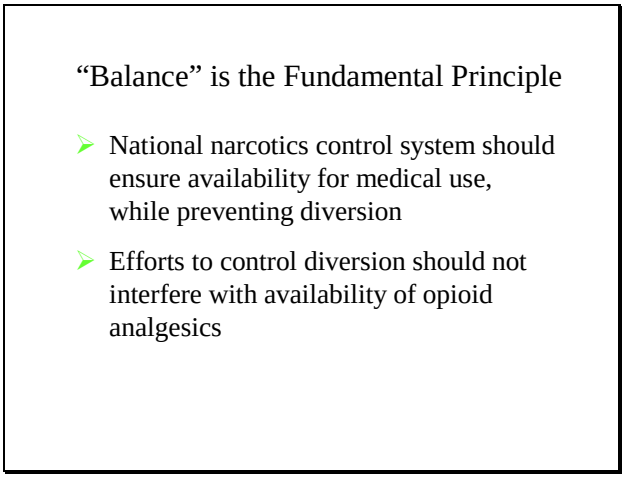


Slide 4

The Government Obligation to Ensure Availability of Opioids

an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes"

- International Narcotics Control Board, 1995.

By: University of Wisconsin Pain & Policy Studies Group/WHO Collaborating Center, 2000

Slide 5

Survey of National Governments (INCB 1996)

- identify barriers to improving availability of opioids for relief of pain
  - Only 48% of national policies recognize opioids as "indispensable"
  - 59% identify excessively strict laws and regulations as barriers
  - 72% identified concern about addiction as a barrier to improving opioid availability

Slide 6

Highlights of INCB Survey
(INCB, 1996)

Top 5 Impediments Ranked by 32 Governments

72%) Concern about addiction to opioids
2. (59%) Insufficient training of HCP about opioids
(59%) Restrictive laws over manufacture, prescribing and dispensing
3. (47%) HCP reluctance due to concerns about legal sanctions
4. (38%) HCP reluctance due to concerns about theft or robbery
5. (34%) Burden of regulatory requirements
(34%)

Slide 7

National Drug Control Policy

Governments have a duty to…

- Ensure that adequate amounts are available to meet national medical needs
- Establish a system of controls that limits use to legitimate medical and scientific purposes; prevent diversion and abuse
- Empower practitioners to provide opioid analgesics in the course of professional practice, allowing them to prescribe, administer, or dispense according to individual medical needs of patients

Slide 8

The distribution system for opioid analgesics is as strong as its weakest link

By: University of Wisconsin Pain & Policy Studies Group/WHO Collaborating Center, 2000

Slide 9

Distribution System-Ensuring Availability

International Narcotics Control Board
- Plan poppy cultivation
- Confirm national estimates

National "Competent Authority"
- Estimate requirements, report statistics
- License products, all entities in distribution chain

Manufacturers and Importers
- Produce/import sufficient amounts
- Distribute promptly to retail level

Hospitals, Pharmacies, Palliative Care
- Obtain license, training
- Purchase adequate supplies
- Dispense according to prescription
- Anticipate needs

Physicians/Nurses
- Assess patients' pain
- Prescribe, dispense according to need

Patients

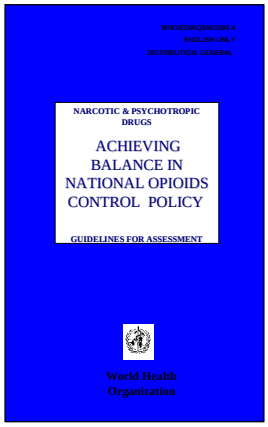
Slide 10

Method for Improving Availability of Opioid Analgesics

1. Examination
2. Diagnosis
3. Treatment
4. Follow

By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2000

Slide 11



Slide 12

"Achieving Balance in National Opioids Control Policy"
WHO, 2000

1. Evaluate national narcotics control policy
2. Estimate annual requirements (by Mr. Yoshida)
3. Administer an effective distribution system to the patient

By: University of Wisconsin Pain & Policy Studies Group/WHO Collaborating Center, 2000

Slide 13

Evaluate National Policy/Admin

- ***Guideline 1***: Government should conduct examination for overly restrictive policies
- ***Guideline 2:*** National policy should recognize opioids as necessary
- ***Guideline 3:*** National policy should recognize govt's obligation to ensure availability
- ***Guideline 4:***

Slide 14

Evaluate National Policy/Admin

- ***Guideline 13:*** Establish NCCP with palliative care
- ***Guideline 14***: Terminology should not confuse pain relief and drug dependency
- ***Guideline 15:*** Avoid restricting prescription amount or duration of treatment
- ***Guideline 16:*** Avoid prescription requirements that restrict physician

Slide 15

Obtaining and Distributing Opioids

- ***Guideline 9:*** Dialogue with health professionals
- ***Guideline 10:*** Cooperation between regulators and health professionals
- ***Guideline 11***: Eliminate shortage, interruption of supply
- ***Guideline 12:*** Maximize patient access and prevent abuse and diversion

Slide 16

1. List institutions, programs that provide care for patients with cancer, AIDS
   (hospitals, outpatient, hospice, home care, elder homes)
2. Is each authorized to prescribe, dispense opioids to their patients?

By: University of Wisconsin Pain & Policy Studies Group/WHO Collaborating Center, 2000

Slide 17

Diversion of Opioid Analgesics (Global)

Despite the large quantities of substances involved and the large number of transactions no cases involving the diversion of narcotic drugs from licit international trade into the illicit traffic were detected

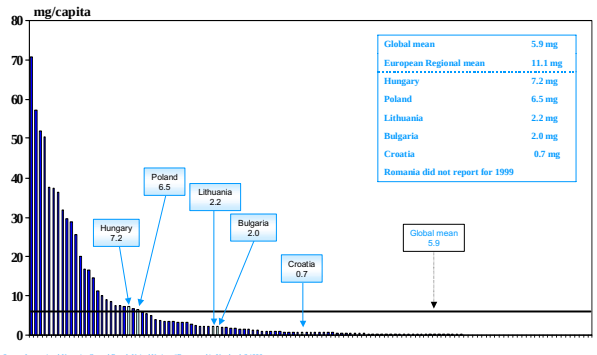
Slide 18

WHOCC
www.medsch.wisc.edu/painpolicy

- Links to WHO, INCB documents
- Monographs, consumption trends
- Global efforts to achieve “balance”
- *Cancer Pain Release*

Slide 19

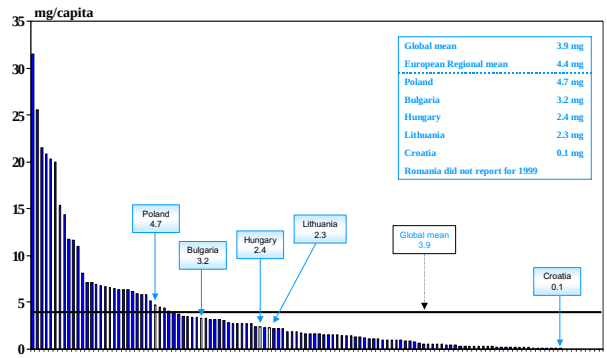
Per Capita Global Consumption of Morphine, 1999



Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

Slide 20

Per Capita Global Consumption of Pethidine, 1999



Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

Slide 21

Consumption of Selected Opioid Analgesics, 1999 (mg/capita)

	Fentanyl	Methadone	Morphine	Oxycodone	Pethidine
Global mean	0.1	6.9	5.9	3.1	3.9
Europe Regional mean	0.1	9.3	11.1	1.7	4.4
France	0.2	2.7	31.8	0.1	1.3
Germany	0.4	9.3	16.8	1.8	2.7
Italy	0.0	12.9	2.4	6.0	0.4
Switzerland	0.2	43.4	25.7	?	11.7
United Kingdom	0.3	11.1	20.0	0.1	6.6
Bulgaria	0.0	0.8	2.0	?	3.2
Croatia	0.0	?	0.7	0.0	0.1
Hungary	0.1	0.2	7.2	0.0	2.4
Lithuania	0.0	2.3	2.2	?	2.3
Poland	0.0	0.2	6.5	0.0	4.7
Romania	?	?	?	?	?

Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

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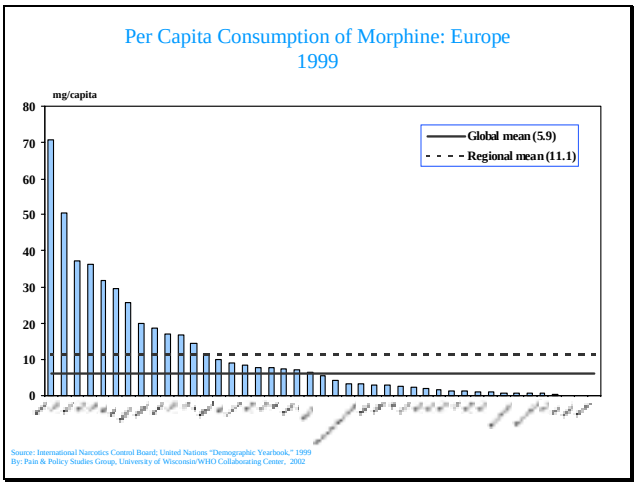

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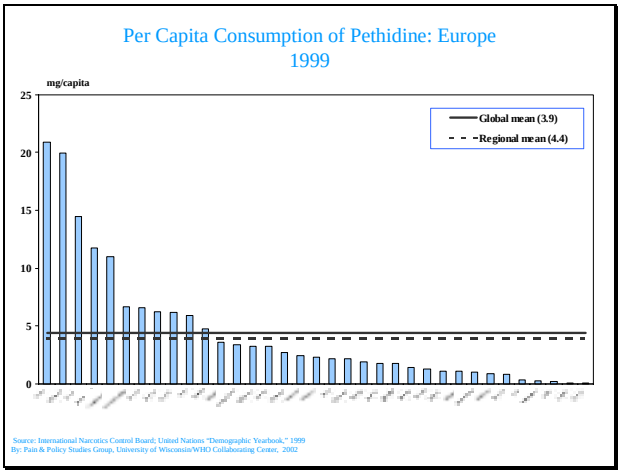

Slide 24

Status of Adherence to Conventions, Receipt of Statistics, and Estimates

	Adherence			
	Single Convention 1961	As amended 1961/72	Consumption Statistics for 1999	Estimated requirements for 2001
Bulgaria	●	●	●	●
Croatia	●	●	?	?
Hungary	●	●	●	●
Lithuania	●	●	●	●
Poland	●	●	●	●
Romania	●	●	?	?

Source: International Narcotics Control Board, Narcotic Drugs, Estimated World Requirements for 2001, Statistics for 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

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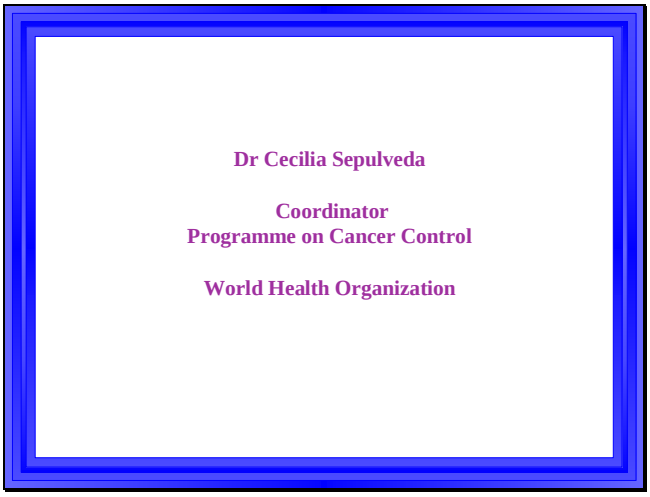
Estimated requirements for selected opioids, 2001 and 2002 (in grams)

Country & Population	Year	Fentanyl	Methadone	Morphine	Oxycodone	Pethidine
Bulgaria 8,208,000	**2001**	300	10,000	58,842	947	52,156
	2002	300	14,000	50,000	500	35,000
Croatia 4,554,000	**2001**	200	80,000	10,000	?	12,000
	2002	1800	120,000	10,000	?	12,000
Hungary 10,068,000	**2001**	1,750	519	9,958,000	1,689	189,889
	2002	1,850	10,000	5,770,000	3,000	53,000
Lithuania 3,699,000	**2001**	120	10,888	12,000	1,000	6,000
	2002	75	10,000	13,000	1,000	11,000
Poland 38,654,000	**2001**	3,000	30,000	1,205,014	3,000	324,951
	2002	3,000	30,000	1,200,014	2,000	300,000
Romania 22,458,000	**2001**	375	1875	22,500	?	375,000
	2002	188	938	11,250	?	187,500

Source: International Narcotics Control Board
Quarterly Supplement, International Narcotics Control Board Estimated World Requirements of Narcotic Drugs for 2001
Advance Copy, International Narcotics Control Board Estimated World Requirements of Narcotic Drugs for 2002
United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

DR CECILIA SEPULVEDA

Slide 1



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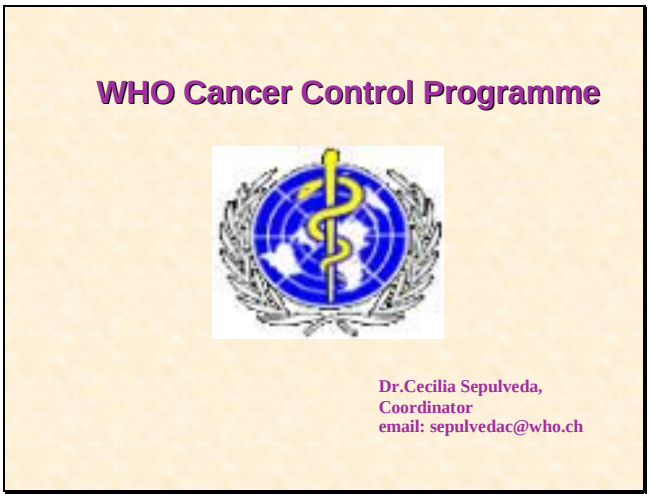


Slide 3

CANCER IS A GLOBAL PROBLEM

Worldwide there are 10 million new cases of cancer and 6 million deaths annually

60% of deaths occur in developing countries where the majority of cases are dignosed in advanced stage

The burden will double in 20 years time

Cancer Control Programme

Slide 4

WHO Cancer Control Programme

Main Activities

- Advocacy for policy development,
- Technical Assistance for programme implementation
- Resource Mobilization
- Networking

Cancer Control Programme

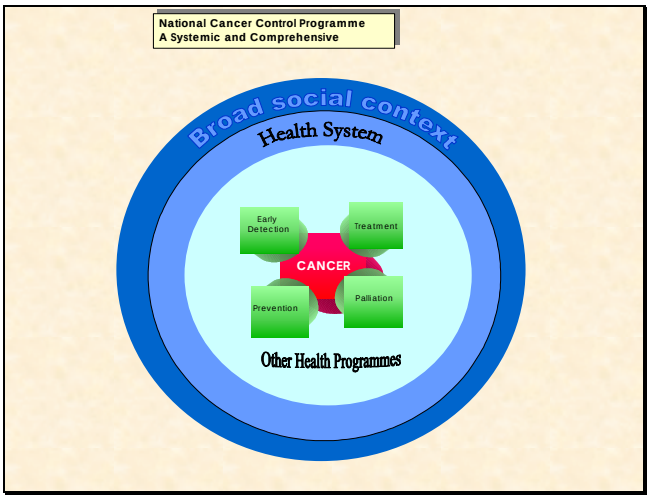
Slide 5

WHO Cancer Control Programme

Priorities

- Comprehensive Cancer Control Programmes
- Primary prevention (tobacco control,healthy diet,regular exercise)
- Early Detection of Cervical & Breast cancer
- Curable tumors
- Pain Relief & Palliative Care

Slide 6



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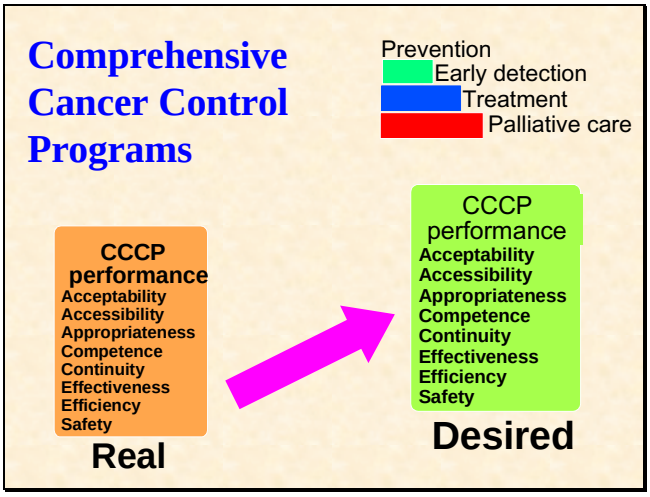

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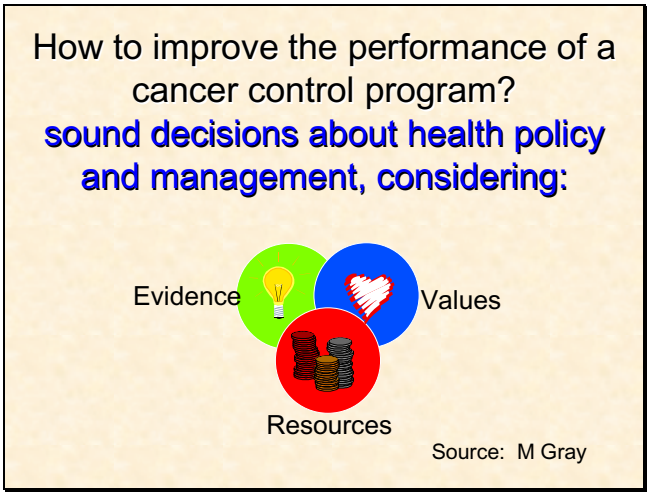

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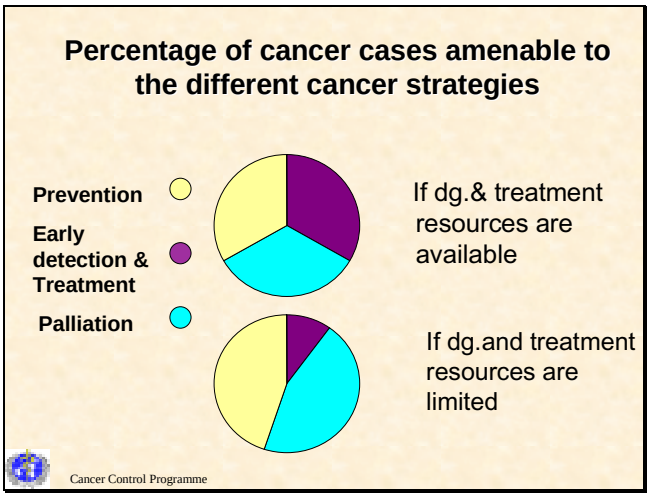

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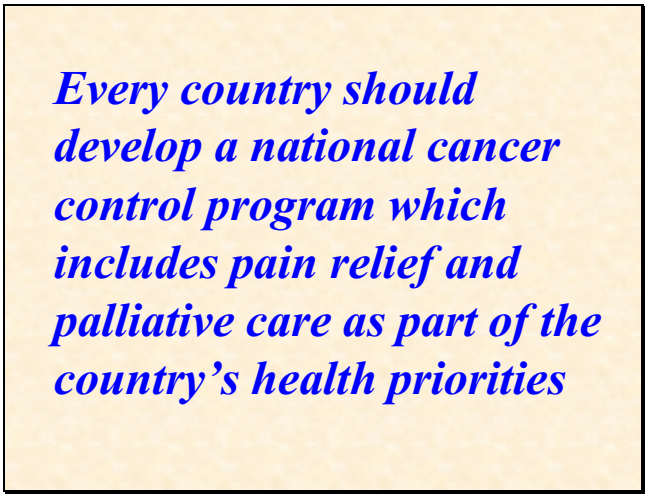

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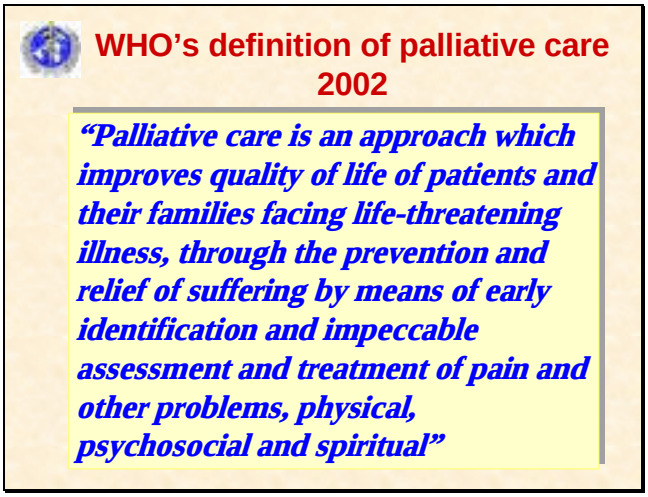

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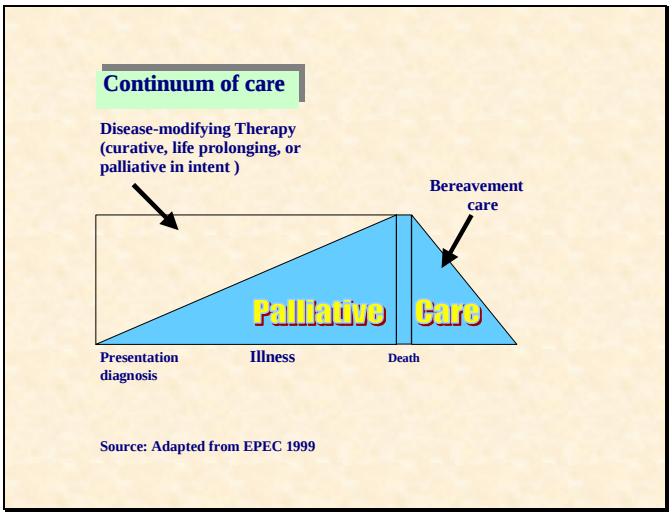

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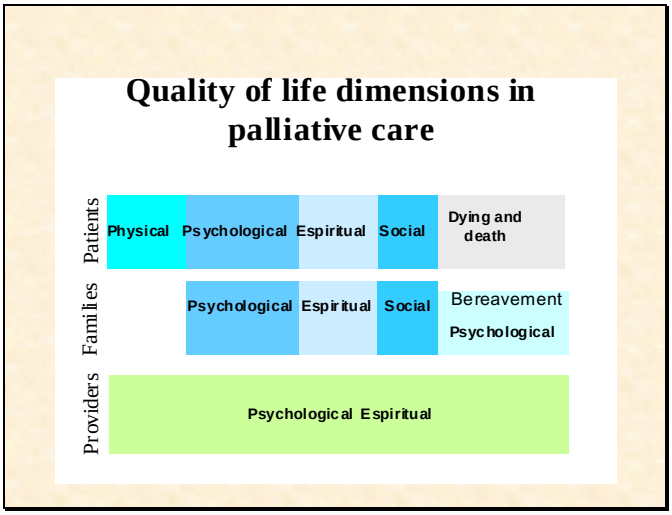

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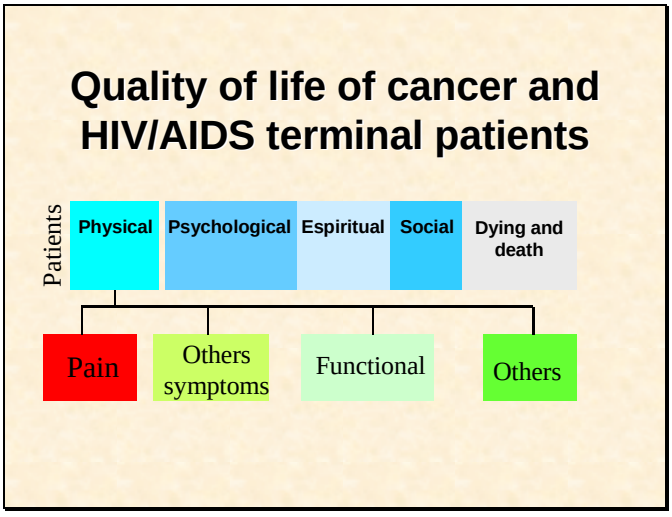


Slide 15

Relief from cancer pain can be achieved in about 90% of patients

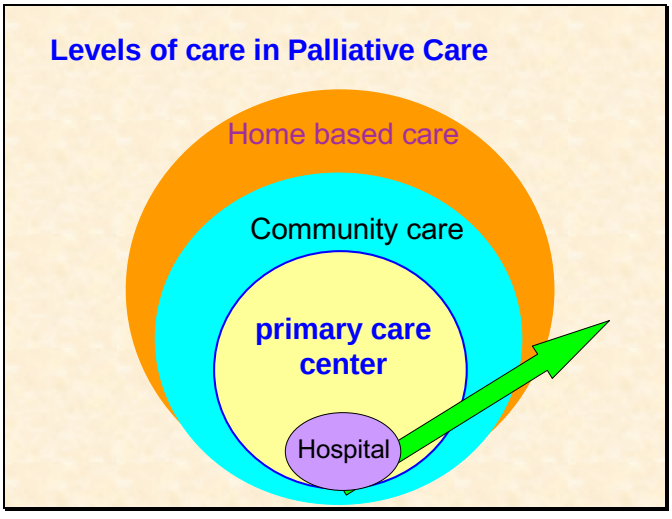
The main obstacles to pain relief are:

• insufficient availability of opioid drugs due to regulatory and pricing obstacles,

• ignorance and false beliefs.

Slide 16

Slide 17



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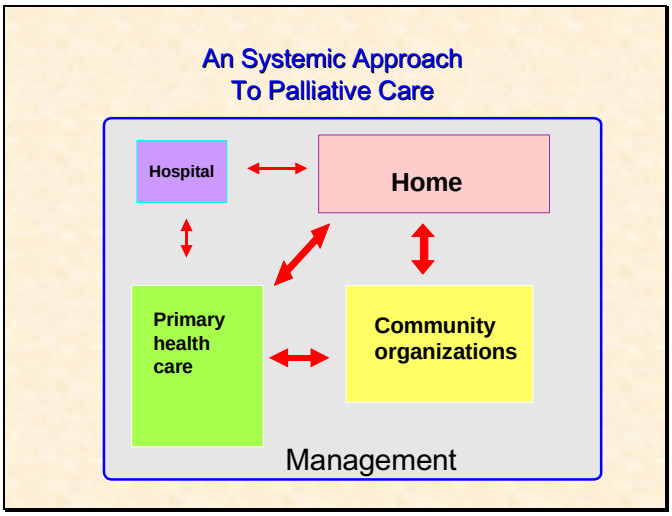

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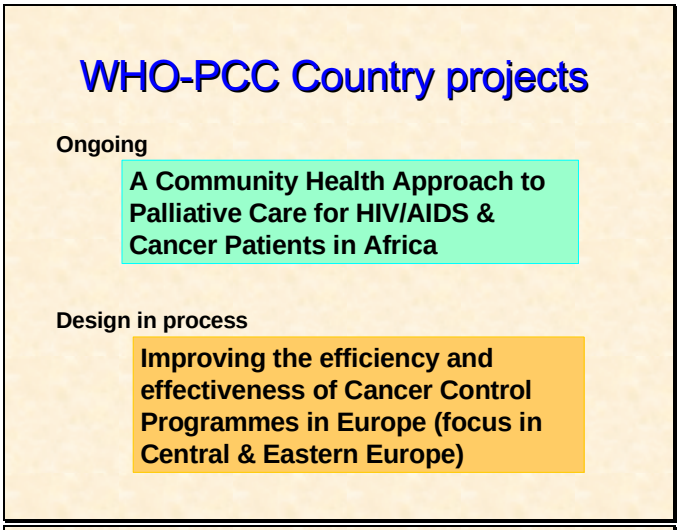

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Palliative Care Project in Africa

Participating Countries

Country	Population Millions 2000 (1)	Life expectan-cy at birth (years) 1999 (2)	Cancer		HIV/AIDS(5) in 1999		
			Incidence (3) N°	Mortality (4) N°	Adult prevalence rate %	People living with	Deaths
Ethiopia	62.9	42.4	64657	39920	10.63	3,000,000	280,000
Tanzania	35.1	45.0	33409	21002	8.09	1,300,000	140,000
Uganda	23.3	42.1	17058	10504	8.30	820,000	110,000
Zimbabwe	12.6	40.4	13030	8648	25.06	1,500,000	160,000
Bostwana	1.5	39.4	1168	810	35.80	290,000	24,000

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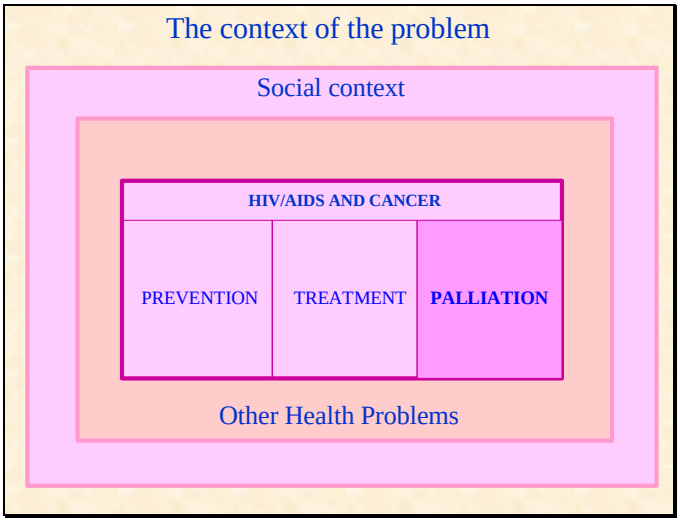

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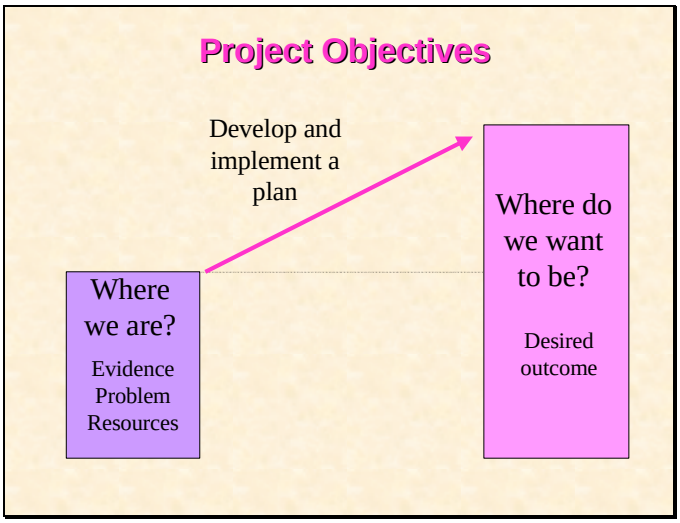

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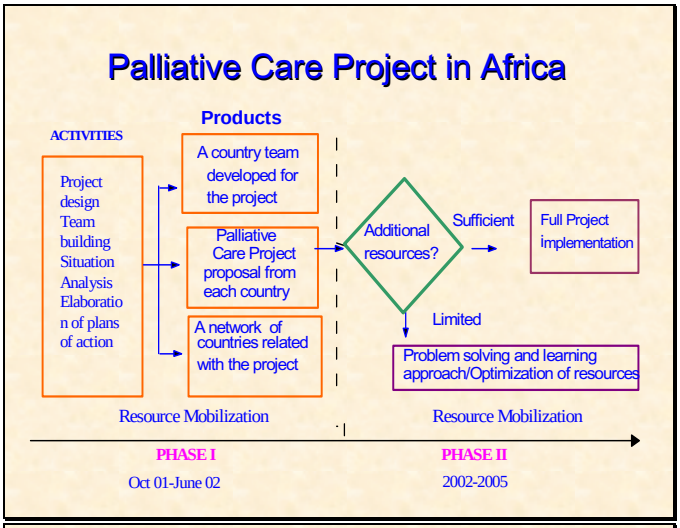

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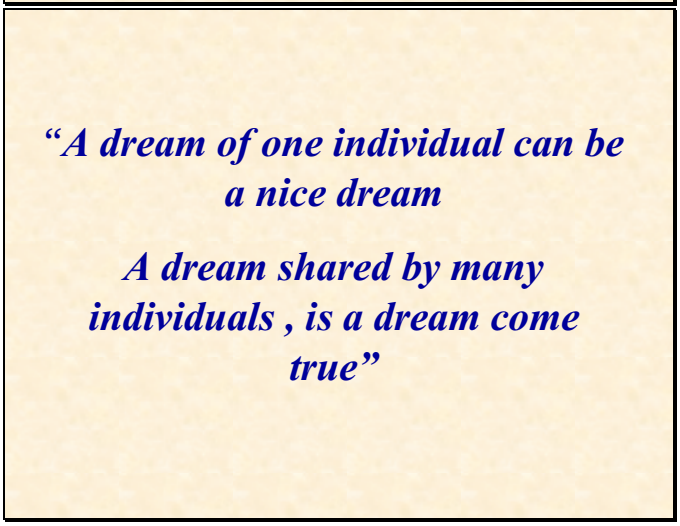
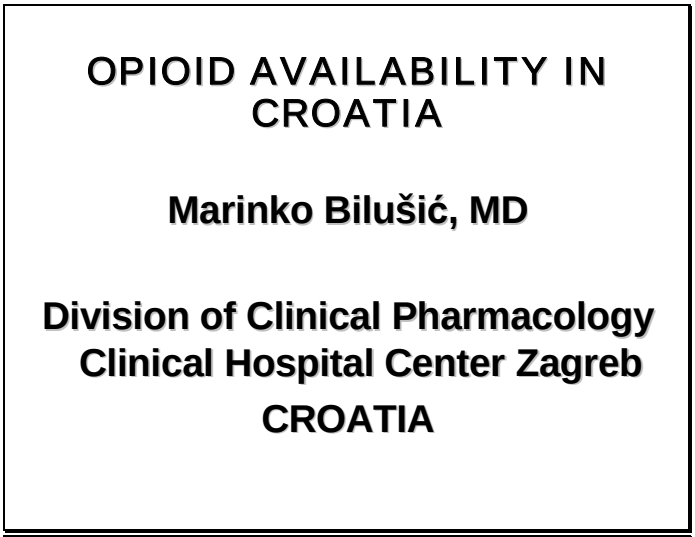


Annex 4

COUNTRY REPORTS

CROATIA

Slide 1



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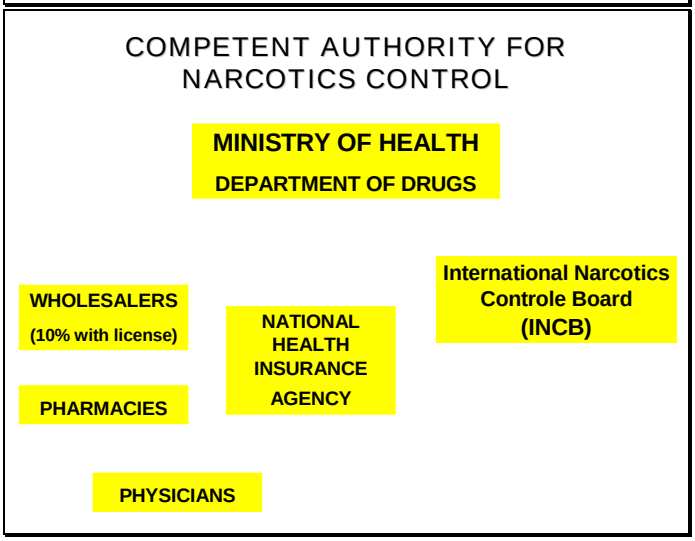

Slide 3

MINISTRY OF HEALTH

- **QUARTERLY STATISTICS OF IMPORTS AND EXPORTS OF NARCOTIC DRUGS**
- **ANNUAL ESTIMATES OF REQUIREMENTS OF NARCOTIC DRUGS**
  - **Quota has been practically constant till 2000**
  - **In the period 2000-2002 quota substantially increased, except for codeine:**

	2000	2002	%
• MORPHINE	12.12	50 kg	+313%
• METHADONE	50	120 kg	+140%
• PETHIDINE	4	12 kg	+200%
• CODEINE	595	500 kg	- 16%

- **ANNUAL STATISTICS OF PRODUCTION,**

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OPIOIDS REGISTRATED IN CROATIA

DRUG	DOSAGE FORMS	MANUFACT.	MAX. AMOUNT PER PRESCR.
MORPHINE chloride	Amp. 10, 20 mg	Alkaloid, Merck	-
MORPHINE sulfate continuous	Caps. 20, 50, 100 mg	Glaxo SmithKline	2.0 g
PETHIDINE	Amp. 100 mg	Aventis Pharma	-
PENTAZOCINE	Amp. 30 mg; Tbl. 50 mg	Krka	- 5.0 g
FENTANYL	Amp. 0.1, 0.5 mg; Patch 2.5, 5, 10 mg	Janssen Cilag	- 0.05 g
TRAMADOL	Amp. 50, 100 mg; Caps. 50, 100 mg; Sol. 100 mg/ml Supp. 100 mg	Belupo, Bayer Pharma, Mundipharma, Razvitak	Not under narcotic regimen

Slide 5

NATIONAL HEALTH INSURANCE AGENCY

- **STATISTIC OF OPIOID CONSUMPTION (data for 2001)**
  1. **PRESCRIPTION**

DRUG	CONSUMED IN PCS.
MORPHINE SULPHATE	200 000 caps.
PENTAZOCINE	128 600 caps.
METHADONE	2 947 000 tblts. 950 000 mL
FENTANYL	7 500 patches*
CODEINI PHOSPHATE	50 210 tbls.
TRAMADOL**	7 617 000 caps. 760 000 mL 37 500 supp.

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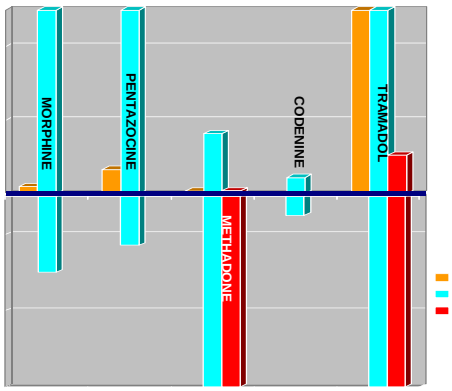
2. HOSPITALS

DRUG	CONSUMED IN PCS.
MORPHINE CHLORIDE	19 900 amp.
MORPHINE SULFATE	560 000 caps.
PENTAZOCINE	66 000 amp. 687 300 caps.
METHADONE	8 300 amp. 164 000 tblts. 8 850 mL
PETHIDINE	30 000 amp.
CODEINI PHOSPHATE	45 000 tblts.
TRAMADOL	587 800 amp. 6 900 000 caps. 105 000 mL 17 500 supp.

Slide 7



Slide 8

PRESCRIBING REQUIREMENTS FOR OPIOID ANALGESICS

PRESCRIBERS

- THERE ARE NO STRICT REQUIREMENTS FOR GENEAL PRACTITIONERS TO DECIDE WHEN TO PRESCRIBE OPIOID ANALGESICS.
  - IT IS MOST OFTEN A PAIN IN MALIGNANT DISEASE NOT RESPONDING ON OTHER ANALGESICS
  - PARTICULAR LICENSE FOR PHYSICIANS WHO PRESCRIBE OPIOID ANALGESICS IS NOT REQUIRED
  - SPECIAL EDUCATION FOR PHYSICIANS WHO PRESCRIBE OPIOID ANALGESICS IS NOT REQUIRED

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PRESCRIBING REQUIREMENTS FOR OPIOID ANALGETICS

PRESCRIPTIONS

- **PRESCRIPTION IN DUPLICATE**
- **SEPARATE BOOK WITH ALL PATIENTS RECEIVING OPIOID ANALGETICS** (KEEP BY PHYSICIAN WHO PRESCRIBE OPIOID ANALGETICS)
- **PRESCRIPTION FOR OPIOID ANALGETIC IS VALID FOR 5 DAYS**
- **AMOUNT PER PRESCRIPTION IS LIMITED**
- **DURATION OF TREATMENT IS NOT LIMITED**

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Conclusions

- **OPIOID ANALGETICS ARE SUFFICIENTLY AVAILABLE**
- **THERE ARE NO PARTICULAR REGULATORY RESTRICTIONS WHICH DISABLE AVAILABILITY**
- **LACK OF "IMMEDIATE RELEASE" MORPHINE FORMULATION**
- **ADDITIONAL EDUCATION OF PHYSICIANS WHO PRESCRIBE OPIOID ANALGETICS**

Slide 11

Hospice movement and palliative care in Croatia

Slide 12

Hospice movement and palliative care in Croatia

The development is possible to opserve through

- 1. organisation of different associations;
- 2. Symposia, Conferences, Courses, Single lectures;
- 3. publications;
- 4. through developing practical activity of home care visits in a single families and at the retired people home.

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Hospice movement and palliative care in Croatia

OrganisatioHns

1994 Croatian Society for hospice /Palliative care as part of Croatian Medical Association. The branches were organised at Virovitica 1997 and at Koprivnica 2001. Their members are dealing first of all with professional development /education and promotion of hospice ideas. The Association is member of EAPC and inviting the lecturers from abroad to take part at conferences and sending the member to courses in London, Poland , USA, Budapest and so on.

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Hospice movement and palliative care in Croatia

- **1997 Society Friends of Hope** was founded for fund rising purposes at the city level.
- **1999 Croatian Society of hospice friends** was founded to enter into the republic budget.
- **2000 Croatian Society for pain treatment** as the part of Croatian medical Association developed from the former Section for pain treatment of Croatian society for hospice/palliative care into the independent society.

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Hospice movement and palliative care in Croatia

Ad 2. The education/ promotion activities

Symposia on hospice and palliative care
(2 to 4 days duration, coordinator Anica Jušić): 1994, 1996, 1999, 2001.

Symposia on malignant pain treatment
(1 day duration , coordinator Marijana Persoli-Gudelj): 1997, 1998, 1999 , 2000, 2001

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Hospice movement and palliative care in Croatia

The education/ promotion activities

Conferences (1-2 days) two on" Volunteers in palliative care", on "Psychological support", on "Palliative home care", on "Difficult decisions in palliative care, spirituality and bereavement", " First Zagreb's conference on neurological palliative care". " Nurses conference on palliative care", Virovitica, the first in 2001, should be repeated twice a year.

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Hospice movement and palliative care in Croatia

The education/ promotion activities

Courses

1997, 3 days *for nurses,*
1999, 5 weekend's modules, *for volunteers,*
2001, every Tuesday, 3 months, twice a year
2002, bereavement course, every Friday, 2 months

postgraduate courses for physicians:
Differential diagnostics and pain treatment in malignancy, 2000, 2001, 2002, 6 or 3 days,
postgraduate course in palliative care for physicians, nurses, social workers (all in english) 2001

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Hospice movement and palliative care in Croatia

The education/ promotion activities

Guest speakers from abroad were:

England -	Nigel Sykes, Virginia Gumley (London), David Oliver, Ann McMurray, Chris Humphreys, Fliss Murthagh (Kent)
Canada -	Robert Buckman, John Morgan, Susan Flower-Kerrry
USA -	Kathleen Foley, Nessa Coyle, Joanne Coury
Italy -	Vittorio Ventafridda
Germany -	Eberhard Klaschik, Inger Herman
Holland -	Henk ten Have
Poland -	Jacek Luczak, Krystyna de Walden-Galuszko
Czech rep. -	Zdenek Bistricky, Darie Dytrychova
Bulgaria -	Irena Hadjiiska
Romania -	Gabriela Ticu

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Hospice movement and palliative care in Croatia

The education/ promotion activities

Many single lectures : Public health school, Faculty of law- Study centre for social work, High nursing school - Department for physical and occupational therapists, People's open university, Senat of Academy of medical sciences, Retired university teachers club, Rottary club, Former A.v. Humboldt felows club, Military and Hospital order of St. Lazarus of Jerusalem, Zagreb's classical gymnasium society, Croatian society of catholic physicians and so on. Many hospitals or Health homes in Zagreb and in different croatian cities.

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Hospice movement and palliative care in Croatia

The education/ promotion activities

Oncology congresses with special session on palliative care:

Central European Oncology Congress, Opatija 2000; First croatian congress on radiotherapy and oncology, Plitvice 2001 (Terminal oncology patient and General /family practise - the foreign guest David Oliver); First croatian congress of oncology, Zagreb 2001 (the foreign guests Kathleen Foley and Nessa Coyle).

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Hospice movement and palliative care in Croatia

The education/ promotion activities

Courses/seminars abroad attended by the members of palliative care societies

- Palliative Cancer Care Course, Oxford: 3 students
- Overseas colleagues week, London: 6 students
- Hospice Bufallo, 2001: 5 students
- Puszczykowo: 1999, 2 students; 2000, 4 students; 2001, 1 student
- Budgosze 2001, 1 student
- Schweizer - OSI seminar Ljubljana, 2000: 10 students
- Schweizer - OSI seminar Budapest, 2000: 5 students
- EAPC congress Geneva, EAPC congresses London, Palermo, Berlin

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Hospice movement and palliative care in Croatia

Ad 3. Publications

Books edited by "Školska knjiga"

- **Anica Jušić i sur**: Hospicij i palijativna skrb, 1995 (selected proceedings of 1st Symposium on hospice and palliative care, plus translation of Mary Baines: Drug control of common symptoms)
- **Cicely Saunders and Nigel Sykes**: Palijativna skrb u završnom stadiju maligne bolesti, 1996 (The management of terminal malignant diseases, 3rd ed.)
- **Robert Buckman**: Ne znam što reći. Kako pomoći i podržati umiruće, 1996 (I don't know what to say. How to help and support someone who is dying, 7th ed.)

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Hospice movement and palliative care in Croatia

Publications

Books and periodicals edited by Croatian society for hospice/palliative care

Olakšavanje boli izazvane rakom i palijativna skrb kod djece, 2001 (Cancer pain relief and palliative care in children, 1998, World Health Organisation)

prepared for print: Cancer pain relief, 2nd ed. and Symptom relief in terminal illness

BILTEN for palliative medicine/care, 10 issues (now 40 pages) plus Suplement No 1, editor Anica Jušić

Slide 24

Hospice movement and palliative care in Croatia

Publications

Chapters in textbooks by Anica Jušić in Psychological medicine, Oncology,Hospice care on the International Scene (by C. S. and R.K). Prepared for print are: Internal medicine, Medical oncology.

More than 50 **articles in different periodicals**: Liječnički vjesnik (14), Liječničke novine, Acta medica croatica, Libri oncologici, Medicus, Medix, Pharmaca, Obnovljeni život by Anica Jušić, Marijana Persoli-Gudelj, Valentin Pozaić, Desa Grubić-Jakup-čević and oth.

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Hospice movement and palliative care in Croatia

Ad 4. Practical activities

Hospice home care visits - during 2001

18 volunteers (physicians, nurses, physical therapist, social worker, other professions) have done 771 visits in 57 patients. The visits lasted one to four hours, sometimes overnight. Telephon consultations with physicians more than 1000, and with nurses 691.

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Hospice movement and palliative care in Croatia

Practical activities

Retired people home visits - during the 2001, with the aim to introduce the palliative care there. 23 volunteers were visiting 20 people making in all 10.880 visits. The single visit lasted half to one hour, the whole visiting time was two hours, repeated every Tuesday, with supervision meeting afterwards lasting for another two hours.

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ROMANIA

COUNTRY REPORT

Budapest, 25- 27 February 2002

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CANCER, PAIN AND PALLIATIVE CARE

What is the estimated prevalence and types of cancer in the country and the prevalence of pain?

- **Cancer represents the second cause of death in Romania**
- **Mortality evolution**
  - **1970 - 123,3 / 100000**
  - **1980 - 135/ 100000**
  - **1989 - 141,6 / 100000**
  - **1995 - 165,5 / 100000**
  - **2000 - 184,04/ 100000**
- **Main causes of cancer**
  - **Lung**
  - **Gastric**
  - **Breast**
  - **Uteri**
  - **Cervix and prostate**
- **No official statistics regarding the prevalence of pain**

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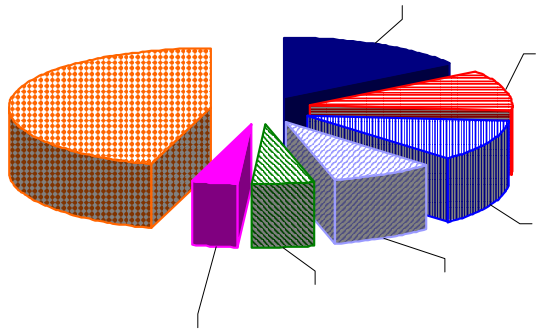
CANCER, PAIN AND PALLIATIVE CARE



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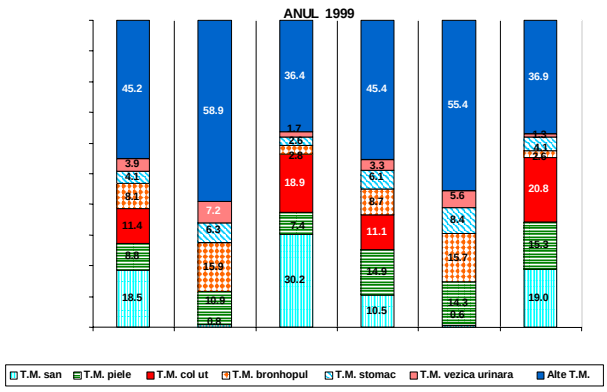
CANCER, PAIN AND PALLIATIVE CARE



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CANCER, PAIN AND PALLIATIVE CARE

Is there a national cancer control plan or program?

- *1980 – THE NATIONAL PROGRAMME ON PREVENTION AND CONTROL OF ONCOLOGIC PATHOLOGY*
- **pain management and palliative care are not specifically addressed in this program**

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CANCER, PAIN AND PALLIATIVE CARE

Has the government endorsed the WHO method for relief of cancer pain?

NO

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CANCER, PAIN AND PALLIATIVE CARE

Has the government sponsored or endorsed training programs in cancer pain relief and palliative care?

- **The government has not sponsored any palliative care or pain training program**
- **Has endorsed the educational programs developed by the Study Centre for Palliative Care in Brasov by**:
  - *accrediting it as the National Resource and Training Centre in Romania*
  - *officially recognising palliative care as a medical subspecialty in Nov 1999*
  - *offering credits of continuing medical education (CME) for all the palliative care courses run at the Study Centre in Brasov*

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CANCER, PAIN AND PALLIATIVE CARE

Has the government sponsored or endorsed training programs in cancer pain relief and palliative care?

- ***The government has supported the activities of the Romanian Association for the Study of Pain by:***
  - ***accrediting RASP and the Anesthesiology and ICU clinic at the Bucharest University Hospital to organise the National Fellowship on Pain Management (2001)***
  - ***offering CME credits for the courses held (2-3/ year) held in different cities and for different medical specialties***

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CANCER, PAIN AND PALLIATIVE CARE

Palliative care services in the country

Hospice " Casa Sperantei" in Brasov is the first pioneering palliative care service in Romania

- ***4 home care teams in Brasov, Oradea, Cluj, Bucharest;***
- ***4 pediatric palliative care services: 2 homecare services in Brasov and Ordea for children with cancer and other terminal conditions (i.e.- neuromuscular diseases, congenital diseases, etc.)***
- ***2 services in pediatric oncology hospitals in Tg. Mures and Iasi.***
- ***The first free standing Romanian Hospice to be opened in May 2002 in Brasov.***
- ***Beds for symptom control in 5 oncology hospitals: Tg. Mures, Cluj, Bucharest, Birlad, Miercurea Ciuc***

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CANCER, PAIN AND PALLIATIVE CARE

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CANCER, PAIN AND PALLIATIVE CARE

Pain Centres:

two Pain Centers

- **University Hospital in Bucharest (1992)**
- **University of Medicine " Gr. T. Popa" in Iasi (2001).**

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CANCER, PAIN AND PALLIATIVE CARE

National associations that have a primary interest in pain relief and /or palliative care

- ***Romanian Association for the Study of Pain(RASP) NGO funded in 1990 is currently having 325 members - IASP full chapter since 1997***
- ***National Association for Palliative Care founded in 1998***

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CANCER, PAIN AND PALLIATIVE CARE

ASOCIATIA ROMANA PENTRU STUDIUL DURERII

Romanian Association for the Study of Pain

- ***organised 4 national symposiums on pain (1994, 1996, 1998, 2000)***
- ***Is organizing CME credit courses every year***
- ***Optional course of Algesiology for medical students in Iasi*** *,Pain control is part of the Anesthesiology Course for the students of the 6th year in Bucharest*
- ***Organization of the Fellowship on Pain Management with 16 trainers accredited by MFH***
- ***web portal www.arsd.ro***
- ***three publications:***
  - *"Durerea" (6 issuesl year),*
  - *Journal of Acute and Chronic Pain (2 issuesl year)*
  - *Newsletter (2 issuesl year)*

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CANCER, PAIN AND PALLIATIVE CARE

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CANCER, PAIN AND PALLIATIVE CARE

National Association for Palliative Care

- **4 national conferences(1998, 1999, 2000 and 2001)**
- **2 National Lobby conferences in 1999 and 2001**. As a result, *palliative care was recognized as a medical subspecialty*, 10 national trainers were accredited. A consensus was signed by all the parties involved
- a Balkan palliative care conference in 2001
- annual newsletter
- Web page **www.hospice.ro**
- Credited palliative care courses
- Informational leaflets for the patients

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CANCER, PAIN AND PALLIATIVE CARE

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OPIOID AVAILABILITY

Competent authority for narcotics control in the country

- **Romania adhered the 1971 and 1988 International Conventions on the use of narcotics and psychotropic drugs**
- **The General Pharmaceutical Direction (GPD) inside the MHF from Romania is the highest national authority in charge with the survey of special substances**

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OPIOID AVAILABILITY

Opioid analgesics are approved in the country

29 opioid containing commercial products

- **Fentanyl, vials**
- **Morphine- vials, immediate and slow release tablets,**
- **hidromorphon vials,**
- **hidromorphon atropine, vials**
- **hidromorphon scopolamine, vials**
- **pethidine- vials,**
- **metahdone- tablets,**
- **codeine – tablets,**
- **DHC- slow release tablets,**
- **tramadol and tramal sustained release,(vials and tablets)**
- **pentazocine - vials and tablets**

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OPIOID AVAILABILITY

Opioids not available:

- **Dextropropoxiphen**
- **Oxycodon**
- **morphine oral solution**
- **fentanyl patches**
- **Buprenorphine**
- **nalbuphine**
- **preservervative free opioid solutions for spinal delivery; long term opioid delivery devices**

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OPIOID AVAILABILITY

Opioids that are available, are they sufficiently available in the places where cancer patients are treated in the country?

NO

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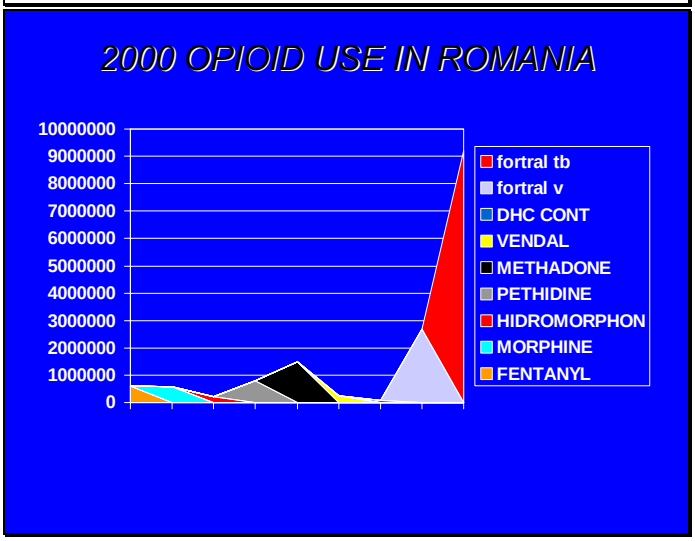

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OPIOID LEGISLATION IN ROMANIA

- Legal opioid use - law 72/1969
- MFH statements for its application nb.103/1970
- 2000- law 143 - control of illegal drug use.
- new law regarding opioid precursors in debate in Parliament

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Penalties for not respecting law 143

- 3-10 years for individual persons
- 15- 25 years for proved association with the purpose of illegal drug use

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OPIOID AVAILABILITY

The basic requirements for a physician to prescribe an opioid such as morphine

For the hospitalized patient opioids may be prescribed by any graduated specialist. The prescription is made on a special register; the pharmacist delivers the narcotics through the hospital pharmacy and the medical staff strictly surveys the administration of the drug

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OPIOID AVAILABILITY

The basic requirements for a physician to prescribe an opioid such as morphine

For the outpatient cancer patient

authorization is delivered by the District Public Health Department (DPHD) on the basis of the medical report released by the oncologist physician.

The authorization is valid **three months.**

The oncologist physician designed by the DPHD prescribes the narcotics on **a receipt with impressed stamp, for max. 15 days.**

The receipt is delivered on the basis of one of the **4 copies** of the authorization and of the receipt with impressed stamp by the **hospital pharmacy through the national oncology program is running (the part financed by the National Health Insurance House).**

Prescribing and delivery of the narcotics used in medical purpose is **verified by a team made up of representatives of the Ministry of Internal Affaires, MFH and Department of Public Health.**

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Annex 4

SUMMARY OF COUNTRY REPORTS

BULGARIA

1.Cancer, pain and palliative cares

In Bulgaria a specialized oncological health care system exists from 1952. It includes 13 Regional Oncological Centers and National Oncological Centre. Compulsory registration of malignant neoplasm in Bulgaria has been introduced in the same year, 1952. In the National Oncological Centre, in the Department of Cancer Control and National Cancer Register from all over the country are send "Rapid notification" for each case – newly diagnosed, suspected or dying of malignant neoplasm, and since 1975 for cancer in situ as well. At the National Cancer Register the date are verified and checked up for duplicates and inconsistency between clinical diagnosis, morphological diagnosis and topography of the malignancy.

The total number of registered with oncological diseases to the end of 2000 year – 201 226.

The most frequent locations:

Men	Women
1. lungs – 21%	1. breast cancer – 25%
2. stomach – 9%	2. uterus cancer – 9%
3. prostate – 8%	3. cancer of coli uteri- 8%
4. colon –6%	4. ovary cancer – 6%

By now it doesn't exist cancer control programme.
In Bulgaria patients receive opioids free of charge, prescribed by their GP and the specialists in dispensaries.

2. Opioid availability

a) The National Service of drug control is a specialized Institution authorized by the Ministry of health to control production, import, export, transport, trade, preservation, report, transfer and use of plants, drugs and medicines included at the Annexes 1,2,3 from the Law of control of drugs and precursors.

The Service helps the Minister of Health to exercise control on the Bulgaria obligations by the international contracts.
The National Drug Council by the name of Bulgarian Government prepares statistical reports and plans assessments for drugs and opioids to the UN International Council of Drug Control.
The chief of National Service of Drugs is MD Fani Emilova Michailova.

The following opioid substances are available in the Republic of Bulgaria.

Activ substance	Medicine
1	**3**
Fentanyl	patch 100 mcg/h x 5
Fentanyl	patch 25 mcg/h x 5
Fentanyl	patch 50 mcg/h x 5
Fentanyl	patch 75 mcg/h x 5
Fentanyl	sol.inj. 50mcg/ml - 2ml
Fentanyl	sol.inj.0.05mg/ml -2mlx10
Fentanyl	sol.inj.0.05mg/ml-5mlx50
Morphine	tabl. SR 100mg x 20; x 100
Morphine	tabl. SR 10mg x 20; x 100
Morphine	tabl. SR 30mg x 20; x 100
Morphine	tabl. SR 60mg x 20; x 100
Morphine	caps.modif.20mg x 20; x60
Morphine	caps.modif.100mg x 20; x 60
Morphine	caps.modif.50mg x 20; x 60
Morphine	tabl.modif.100mg x 60
Morphine	tabl.modif.10mg x 60
Morphine	tabl.modif.30 mg x 60
Morphine	tabl.modif.60mg x 60
Morphine	sol.inj.10mg/ml - 1ml x 10; x 1
Morphine	sol.inj.20mg/ml - 1ml x 10; x 1
Morphine	sol. 10mg/5ml - 100 ml; - 250m
Morphine	sol. 20 mg/ml - 20ml; - 100 ml
Morphine	tabl. 10 mg x 60
Morphine	tabl. 100 mg x 60
Morphine	tabl. 30 mg x 60
Morphine	tabl. 60 mg x 60
Morphine	sol. 10 mg/5 ml x 25
Morphine	sol. 100 mg/5 ml x 25
Morphine	sol. 30 mg/5 ml x 25
Morphine	tabl.10mg x 56
Morphine	tabl.20mg x 56
Morphine	caps. prolong 60mg x 14
Morphine	caps.prolong 100mg x 14
Morphine	caps.prolong 10mg x 14
Morphine	caps.prolong 30mg x 14
Morphine	tabl.prolong.100mg x 30; x 60
Morphine	tabl.prolong.30mg x 10; x 20; x
Morphine	tabl.prolong.60mg x 30; x 60
Oxycodone	tabl.modif.10mg x 28; x 56

Oxycodone	tabl.modif.20mg x 28; x 56
Oxycodone	tabl.modif.40mg x 28; x 56
Oxycodone	tabl.modif.80mg x 28; x 56
Pethidine	sol.inj.50mg/ml - 2ml x 10; x 5
Piritramide	sol.inj.7,5mg/ml - 2ml x 5
Remifentanil	powd.inj.1mg -3ml x 5
Remifentanil	powd.inj.2mg - 5ml x 5
Remifentanil	powd.inj.5mg - 10ml x 5
Tilidine	drops 100mg/ml - 10ml
Tramadol	caps.50mg x 10
Tramadol	sol.inj.100mg - 2ml x 5
Tramadol	sol.inj./inf.50mg/ml-1ml x5; x100
Tramadol	sol.inj./inf.50mg/ml-2ml x x100
Tramadol	supp.100mg x 10
Tramadol	sol.100mg/ml - 10ml
Tramadol	caps. 50 mg x 10; x 20
Tramadol	caps. 50 mg x 20
Tramadol	drops 100 mg/ml - 10ml
Tramadol	sol.inj. 50 mg/ml - 1ml x 5
Tramadol	sol.inj. 50 mg/ml - 2ml x 5
Tramadol	supp.100 mg x 5
Tramadol	tabl.prolong.100mg x 30
Tramadol	caps. 50mg x 10;x 30; x 50
Tramadol	drops 100mg/ml - 20ml
Tramadol	sol.inj. 50 mg/ml - 2 ml x 5
Tramadol	tabl.film 50mg x 10; x 30
Tramadol	caps.50mg x 30; x 60
Tramadol	drops 100mg/ml - 10ml x 1; x 3
Tramadol	sol.inj.50mg/ml - 2ml x 10
Tramadol	caps. 50mg x 20
Tramadol	drops 100mg/ml - 10ml
Tramadol	sol.inj. 50mg/ml - 1ml
Tramadol	sol.inj. 50mg/ml - 2 ml
Tramadol	supp.100mg x 5
Dihydrocodeine	tabl.modif.60mg x 56
Dihydrocodeine	tabl.modif.90mg x 56
Pentazocine	sol. inj. 30mg/ml - 1ml x 10
Pentazocine	sol. inj. 30mg/ml - 2ml x 10

The producer of opioid analgesics in the country is “SOPHARMA”Ltd. It is the only company that produces morphine, petidine and tilidine. Tramadol Lannacher 50 (50 mg.) is produced by the Pharmaceutical company Milve, together with “Lannacher Heilmittel”.

c) The available quantities of opioid analgesics are enough for the needs of onco- patients. The country budget covers all treatment with opioid analgesics.

d) The following are the statistics of consummation at last 5 years:

	Dihydrocodeine	**Fentanyl**	**Morphine**	**Pethidine**	**Tilidine**
1995	638 g	58 g	8259 g	17547 g	32241 g
1996	0 g	42 g	5301 g	18498 g	14495 g
1997	480 g	74 g	10640 g	22240 g	22258 g
1998	1350 g	62 g	14492 g	17418 g	38040 g
1999	2948 g	71 g	16685 g	26383 g	31417 g
2000	4947 g	69 g	21705 g	26852 g	19545 g

e) At the regional centers, we keep special registers for the doctors who prescribe opioid substances without requirement to have special licenses.

According to the Law, the opioids can be prescribed only on triplicate yellow prescriptions. This prescription has code protection of the stamp, number and note that it is register on special reports.

All medicines that have a registration number from local health centers have permission to prescribe drug products.

f) A basic requirement for prescribing drugs according to Article 14 of Regulation for conditions and prescribing medicine that contains drug substance of MH is “quantities of the medicine that contains drug can not be more than therapeutically dose for 15 days.”

According to Article 11 from the same Regulation, the validity time limit of the prescription is no more than 7 days after the printing the prescription.

The law for the drug control doesn’t provide punishments for doctors that break the law. At the moment are prepared changes in that law.

Every hospital leads statistic with names of patients that take opioid analgesics. The Ministry of Health collects all information for all patients and consummation of opioid analgesics substances.

g) In Bulgaria, the law in this area is comparatively new. The law for control of drugs and precursors is from 1999. The regulations are in force since 2000 and 2001g.
In the near future there will be changes in the law so to improve it.

SUMMARY OF COUNTRY REPORTS

HUNGARY

PART 1

Concerning Outline for Country Report my special area is the pain management, therefore I am not responsible the whole subject. In our Country there is a National Cancer Control Program, including rehabilitation and pain relief. Fortunately in Hungary the opioids are widely available:

- oral immediate release morphine tablet (10, 20 mg)
- *oral controlled release morphine tablet (10, 30, 60, 100, 200 mg)*
- morphine injectable
- methadone tablet, inj.
- pethidine tablet, inj.
- Durogesic patch (25, 50, 75, 100 microg/h)

The above-mentioned opioids are provided free of charge - except immediate release morphine tablet - for cancer patients.

A duplicate prescription is needed and permission has to be obtained from the National Health Institute, which is valid for 3 months, and possible to extend as required. Also are available:

Oxycontin tablet 10, 20, 40 mg, but the patients have to pay for it.

The WHO method for relief of cancer pain has been translated in Hungarian and widely distributed to the general practitioners.

In the last 8 years, more than 300 lectures were given by me, about cancer pain management, every part of Hungary was covered.

PART 2

OPIOID AVAILABILITY/NARCOTICS CONTROL

All the information and data presented here were provided - to the extent that they are available - by the so called “Competent Authority” of Hungary.

Actually the national office, i.e. the “Competent Authority” for narcotics control for the country is the Ministry of Health, Department of Narcotic Drugs. Chief of the Department is Dr. Ferenc Fábián and the chief of the Maindepartment of Pharmacy to which the Department of Narcotic Drugs belongs, is Dr. Attiláné Kelemen. The chief of the Department of Narcotic Drugs is in charge of the office and is in charge of submitting the annual estimate of medical and scientific requirements for narcotic drugs to the International Narcotics Control Board (INCB).

The opioid analgesics approved in Hungary (in different dosage forms) are the following:(see Annex I)

The “narcotic licence” holders, and among them the licensed manufacturers for the needed opioids are: (see Annex II)

All the opioids needed for medical treatments are available in Hungary. They are manufactured in Hungary, or they are imported. Furthermore, in special cases are individually imported preparates, which are not approved (they are no more, or not yet approved) in Hungary.

According to the evidences of the Competent Authority, the opioid analgesics must be sufficiently available in the places where cancer patients are treated in the country. In the last year, no restrictions were made when manufacturers or wholesalers requested import licences for amounts included in the national estimates. In a few cases, modification of estimates was proposed and relatively great quantities of preparations containing opioids and CPS were exported. The Competent Authority prohibited a poppy straw import planned to be made by a manufacturer against the 1961 Single Convention on Narcotic Drugs, without to be affected the availability of opioid analgesics needed for medical treatments in Hungary.

The consumption trends of strong opioid analgesics (e.g. morphine, pethidine, fentanyl) for the last five years presents no substantial changes. Only fentanyl presents a growing amount from year to year as reflected in the reports submitted to the INCB (see the table below):

Consumed quantity (grams)

	1996	1997	1998	1999	2000
Morphine	54991	58017	60527	72372	45950
Pethidine	18532	25835	25064	24220	35178
Fentanyl	119	203	489	623	874

The basic requirements for a physician to prescribe an opioid such as morphine are the following:

Licences required: A medical doctor does not need any special licence to prescribe an opioid such as morphine. If the patient needs a treatment longer than 10 days, then the prescription must be approved by the local public health authority (not the national “Competent Authority!”).

Special prescription forms are not required. The actual national regulation contains detailed rules that must be followed by the medical practitioner who prescribes narcotics, e.g.: prescription must be written manually with ink, signature and stamp on all copies, name of the patient and his/her age, dosage form, active ingredient content of the preparation with numbers and letters, doses that will be taken by the patient, the amount of narcotic substance, proposed duration of the treatment, etc. A special remark it must be made, if the maximum doses recommended are exceeded.

No special training is required for the medical staff.
Other requirements for a physician to prescribe an opioid such as morphine are - e.g. - the following:

There are fixed maximum amounts that can be prescribed at one time. Greater amounts must be justified and a special note will be applied on the prescription.

There is a time limit of 10 days that a patient can receive opioids or other narcotics without approval from the local public health authority, but no maximum length of time for overall treatment is established.

The period of time, that a prescription for an opioid such as morphine, or other narcotic is valid, theoretically extends to 30 days, as well in the case of other pharmaceutical preparations. Please note that without approval from the local public health authority, only an amount of narcotic drug enough for 10 days can be prescribed. In case of a longer treatment, the maximum length of the approved period is 3 months, but if needed, the approval can be repeated several times. In such treatments extended on longer periods of time, every 10 days a new prescription is issued by the medical doctor, and all prescriptions must be kept in the pharmacy. The approval usually is valid for one single pharmacy.

There are no different legal requirements for prescribing, dispensing or purchasing different dosage forms of the same opioid (e.g. oral, transdermal, injectable). The rules mentioned above that must be followed, are the same for the different dosage forms of the same opioid.

The penalty for a physician or pharmacist who violates the regulations can be 50.000 - 100.000 Ft, or several years of prison. There were only a very few cases, when physicians or pharmacists violated the regulations.

The national regulation does not require reporting names of patients who receive opioid prescriptions, to the government.

The Hungarian national regulation is planned to be substantially modified in the near future. In the year 2002. will be newly regulated the legally used narcotics on a higher - government order - level. Availability of narcotics for suffering people will be facilitated, but with a parallel enhancement of the control measures, to avoid diversion and abuse.

Annex I

OPIOID ANALGESICS APPROVED IN HUNGARY

INN	Name	Licence owner	TK	ATC	kábítószer
tramadol	ADAMON SR 50 mg kapszula	Asta Medica	6970	N02AX02	0
tramadol	ADAMON SR 100 mg kapszula	Asta Medica	6971	N02AX02	0
tramadol	ADAMON SR 150 mg kapszula	Asta Medica	6972	N02AX02	0
tramadol	ADAMON SR 200 mg kapszula	Asta Medica	6973	N02AX02	0
codeine+	ARDINEX tabletta	Abbott	7229	N02AA59	0
buprenorphine	BUPREN 0,2 mg szublinguális tabletta	ICN Hungary	6993	N02AE01	-1
tramadol	CONTRAMAL 150 mg retard filmtabletta	Biogal Rt	8177	N02AX02	0
tramadol	CONTRAMAL 200 mg retard filmtabletta	Biogal Rt	8178	N02AX02	0
tramadol	CONTRAMAL 50 mg injekció	Biogal Rt	4976	N02AX02	0

tramadol	CONTRAMAL 50 mg kapszula	Biogal Rt	4975	N02AX02	0
tramadol	CONTRAMAL 100 mg injekció	Biogal Rt	4977	N02AX02	0
tramadol	CONTRAMAL 100 mg végbélkúp	Biogal Rt	6864	N02AX02	0
tramadol	CONTRAMAL 100 mg/ml adagolópumpás cseppek	Biogal Rt	6863	N02AX02	0
tramadol	CONTRAMAL 100 mg/ml cseppek	Biogal Rt	6862	N02AX02	0
tramadol	CONTRAMAL GRÜNENTHAL 100 mg injekció	Grünenthal	K-1855	N02AX02	0
tramadol	CONTRAMAL GRÜNENTHAL 100 mg végbélkúp	Grünenthal	K-1858	N02AX02	0
tramadol	CONTRAMAL GRÜNENTHAL 100 mg/ml cseppek	Grünenthal	K-1857	N02AX02	0
tramadol	CONTRAMAL GRÜNENTHAL 50 mg injekció	Grünenthal	K-1854	N02AX02	0
tramadol	CONTRAMAL GRÜNENTHAL 50 mg kapszula	Grünenthal	K-1856	N02AX02	0
tramadol	CONTRAMAL RETARD filmtabletta	Biogal Rt	6865	N02AX02	0
methadone	DEPRIDOL tabletta	Extractum-Pharma	Tsz.: 02826	N02AC02	-1
Dihydrocodeine	DHC CONTINUS 120 mg retard tabletta	Extractum-Pharma	6699	N02AA08	-1
dihydrocodeine	DHC CONTINUS 90 mg retard tabletta	Extractum-Pharma	6698	N02AA08	-1
dihydrocodeine	DHC-CONTINUS 60 mg retard tabletta	Extractum-Pharma	K-1635	N02AA08	-1
pethidine	DOLARGAN injekció	Sanofi-Synthélabo Rt	Tsz.:12707	N02AB02	-1
pethidine	DOLARGAN tabletta	Sanofi-Synthélabo Rt	Tsz.:12706	N02AB02	-1
morphine	DOLTARD 10 mg retard filmtabletta	Nycomed	7855	N02AA01	-1
morphine	DOLTARD 30 mg retard filmtabletta	Nycomed	7856	N02AA01	-1
morphine	DOLTARD 60 mg retard filmtabletta	Nycomed	7857	N02AA01	-1
morphine	DOLTARD 100 mg retard filmtabletta	Nycomed	7858	N02AA01	-1
dihydrocodeine	HYDROCODIN tabletta	ICN Hungary	Tsz. 11596	N02AA08	-1
morphine	M-ESLON 10 mg retard kapszula	EGIS	K-2311	N02AA01	-1
morphine	M-ESLON 30 mg retard kapszula	EGIS	K-2312	N02AA01	-1
morphine	M-ESLON 60 mg retard kapszula	EGIS	K-2313	N02AA01	-1
morphine	M-ESLON 100 mg retard kapszula	EGIS	K-2314	N02AA01	-1
morphine	M-ESLON 200 mg retard kapszula	EGIS	5966	N02AA01	-1
morphine	MORETAL 30 mg retard filmtabletta	ICN Hungary	8312	N02AA01	-1
morphine	MORETAL 60 mg retard filmtabletta	ICN Hungary	8313	N02AA01	-1
morphine	MORETAL 100 mg retard filmtabletta	ICN Hungary	8314	N02AA01	-1
morphine	MORPHINUM HYDROCHLORICUM 1 % inj.	Biogal Rt	Tsz.:12716	N02AA01	-1
morphine	MORPHINUM HYDROCHLORICUM 2 % inj.	Biogal Rt	Tsz.:12717	N02AA01	-1
morphine	MORPHINUM HYDROCHLORICUM 3 % inj.	Biogal Rt	Tsz. 11538	N02AA01	-1
morphine	MST CONTINUS CR 100 mg gran.szuszp.-hoz	Extractum-Pharma	5957	N02AA01	-1
morphine	MST CONTINUS CR 20 mg gran.szuszp.-hoz	Extractum-Pharma	5954	N02AA01	-1
morphine	MST CONTINUS CR 200 mg gran.szuszp.-hoz	Extractum-Pharma	5958	N02AA01	-1
morphine	MST CONTINUS CR 30 mg gran.szuszp.-hoz	Extractum-Pharma	5955	N02AA01	-1
morphine	MST CONTINUS CR 60 mg gran.szuszp.-hoz	Extractum-Pharma	5956	N02AA01	-1
morphine	MST UNO 120 mg retard kapszula	Extractum-Pharma	6963	N02AA01	-1
morphine	MST UNO 150 mg retard kapszula	Extractum-Pharma	6964	N02AA01	-1
morphine	MST UNO 200 mg retard kapszula	Extractum-Pharma	6965	N02AA01	-1
morphine	MST UNO 30 mg retard kapszula	Extractum-Pharma	6960	N02AA01	-1
morphine	MST UNO 60 mg retard kapszula	Extractum-Pharma	6961	N02AA01	-1
morphine	MST UNO 90 mg retard kapszula	Extractum-Pharma	6962	N02AA01	-1
morphine	MST-CONTINUS 30 mg retard tabletta	Extractum-Pharma	K-2188	N02AA01	-1
morphine	MST-CONTINUS 60 mg retard tabletta	Extractum-Pharma	K-2189	N02AA01	-1
morphine	MST-CONTINUS 10 mg retard tabletta	Extractum-Pharma	K-2187	N02AA01	-1

morphine	MST-CONTINUS 100 mg retard tabletta	Extractum-Pharma	K-2190	N02AA01	-1
nalbufine	NUBAIN 20 injekció	Torrex	K-1313	N02AF02	0
oxycodone	OXYCONTIN 10 mg retard tabletta	Extractum-Pharma	7166	N02AA05	-1
oxycodone	OXYCONTIN 20 mg retard tabletta	Extractum-Pharma	7167	N02AA05	-1
oxycodone	OXYCONTIN 40 mg retard tabletta	Extractum-Pharma	7168	N02AA05	-1
oxycodone	OXYCONTIN 80 mg retard tabletta	Extractum-Pharma	7169	N02AA05	-1
morphine	SEVREDOL 10 mg tabletta	Extractum-Pharma	5876	N02AA01	-1
morphine	SEVREDOL 20 mg tabletta	Extractum-Pharma	5877	N02AA01	-1
codeine+	SOLPADEINE kapszula	GSK Cons. Health	K-1713	N02AA59	0
codeine+	TALVOSILEN CSECSEMŐKNEK végbélkúp	Bene	4748	N02AA59	0
codeine+	TALVOSILEN FELNŐTTEKNEK végbélkúp	Bene	4751	N02AA59	0
codeine+	TALVOSILEN FORTE kapszula	Bene	4752	N02AA59	0
codeine+	TALVOSILEN FORTE végbélkúp	Bene	4753	N02AA59	0
codeine+	TALVOSILEN ISKOLÁS GYERMEKEKNEK	Bene	4750	N02AA59	0
codeine+	TALVOSILEN kapszula	Bene	4746	N02AA59	0
codeine+	TALVOSILEN KISGYERMEKEKNEK végbélkúp	Bene	4749	N02AA59	0
codeine+	TALVOSILEN szirup	Bene	4747	N02AA59	0
codeine+	TALVOSILEN tabletta	Bene	4745	N02AA59	0
tramadol	TIAL cseppek	Lindopharm	7920	N02AX02	0
tramadol	TRAMADOL AL 50 kapszula	Aliud	7869	N02AX02	0
tramadol	TRAMADOL AL 100 injekció	Aliud	7602	N02AX02	0
tramadol	TRAMADOL AL cseppek	Aliud	7603	N02AX02	0
tramadol	TRAMADOL B 100 mg injekció	Biogal Rt	6859	N02AX02	0
tramadol	TRAMADOL B 100 mg végbélkúp	Biogal Rt	6856	N02AX02	0
tramadol	TRAMADOL B 100 mg/ml cseppek	Biogal Rt	6857	N02AX02	0
tramadol	TRAMADOL B 50 mg injekció	Biogal Rt	6858	N02AX02	0
tramadol	TRAMADOL B 50 mg kapszula	Biogal Rt	6855	N02AX02	0
tramadol	TRAMADOL SL 50 mg/1ml injekció	Slovakofarma	7624	N02AX02	0
tramadol	TRAMADOL SL 100 mg/2 ml injekció	Slovakofarma	7625	N02AX02	0
tramadol	TRAMADOL SL kapszula	Slovakofarma	7747	N02AX02	0
tramadol	TRAMADOL-K 100 mg végbélkúp	Krka	7202	N02AX02	0
tramadol	TRAMADOL-K 100 mg/1 ml cseppek	Krka	7203	N02AX02	0
tramadol	TRAMADOL-K 100 mg/2 ml injekció	Krka	7200	N02AX02	0
tramadol	TRAMADOL-K 50 mg kapszula	Krka	7201	N02AX02	0
tramadol	TRAMADOL-K 50 mg/1 ml injekció	Krka	7199	N02AX02	0
tramadol	TRAMADOL-ratiopharm 100 injekció	ratiopharm	7727	N02AX02	0
tramadol	TRAMADOL-ratiopharm 50 injekció	ratiopharm	7726	N02AX02	0
tramadol	TRAMADOL-ratiopharm 50 mg kapszula	ratiopharm	7728	N02AX02	0
tramadol	TRAMADOL-ratiopharm cseppek	ratiopharm	7724	N02AX02	0
tramadol	TRAMADOL-ratiopharm cseppek adagolópumpával	ratiopharm	7725	N02AX02	0
tramadol	TRAMADOLOR 100 ID retard tabletta	Hexal	8179	N02AX02	0
tramadol	TRAMADOLOR 150 ID retard tabletta	Hexal	8180	N02AX02	0
tramadol	TRAMADOLOR 200 ID retard tabletta	Hexal	8181	N02AX02	0
tramadol	TRAMADOLOR 50 mg pezsgőtabletta	Hexal	7859	N02AX02	0
tramadol	TRAMALGIC cseppek	Nycomed	6566	N02AX02	0
tramadol	TRAMALGIC injekció	Nycomed	6564	N02AX02	0
tramadol	TRAMALGIC kapszula	Nycomed	6565	N02AX02	0

Annex II

"NARCOTIC LICENCE" HOLDERS IN HUNGARY

(not all companies listed are manufacturers, some of them are wholesalers!)

Bellis Gyógyszerkereskedelmi Rt.
Béres Gyógyszergyár Rt.
Biogal Gyógyszerkereskedelmi Rt.
Chinoin Gyógyszer és Vegyészeti termékek Gyára RT.
Csanád Pharma Kft.
Euromedic Pharma Gyógyszernagykereskedelmi RT.
Exractum-Pharma Gyógyszergyártó, Forgalmazó és Szaktanácsadó RT.
Fúzió-Pharma Gyógyszer-Gyógytermék Nagy- és Külkereskedelmi RT.
Gyógyszeripari Ellenőrző és Fejlesztő Laboratórium Kft.
Hajdú Gyógyszerkereskedelmi RT.
Human Oltóanyagtermelő és Gyógyszergyártó RT.
Hungaropharma Gyógyszerkereskedelmi RT.
ICN Magyarország RT.
Janssen Cilag Division of Johnson & Johnson Kft.
Medimpex Gyógyszer-nagykereskedelmi RT.
Medimpex Kereskedelmi RT.
Naturland Magyarország Kft.
Pannonmedicina Gyógyszerellátó Vállalat
Papp Gyógyszer-nagykereskedés
Parma Produkt Kft.
Pharmachom Gyógyszernagyker. Kft.
Phoenix Pharma Gyógyszerkereskedelmi RT.
Richter Gedeon Vegyészeti Gyár Rt.
Sanovita Gyógyszer-Nagykereskedelmi RT.

SUMMARY OF COUNTRY REPORTS

LITHUANIA

Part 1. Cancer, pain and palliative care

Year 1999: Population of Republic of Lithuania 3.699.600. There were 13.888 new cancer cases, including 2.911 in IV stage of disease, and 7.686 deaths from cancer (Lithuanian Cancer Registry, 2000). Cancer pain statistic is problematic, cancer pain – about 6.000-7.000 cancer patients, severe pain – 2.000-3.000 patients.

The first National cancer control program was prepared in 1991. The other two such programs were prepared for 1996-2000, and 2001-2002. Unfortunately, pain relief, palliative care and opioids availability problems were not included in these programs.

Now the National cancer control and palliative care program for 2003-2010 is in the process of preparation. The coordinator of this program is Prof. Elona Juozaityte, the Head of Department of Oncology, Kaunas University of Medicine.

The Government has not endorsed the WHO method for relief of cancer pain, nor any training programs in cancer pain relief and palliative care. On the other hand, non-governmental organizations have done very big initiatives in this field.

Pain and palliative care services are not developed in Lithuania until now. Only one pain clinic functions since 1994 as the part of Anesthesiology department at the university hospital in Vilnius, the capital of the country. The main obstacles to development of such services are lack of financial support from government and lack of coverage of these services according to the state sickness fund scheme. As a result, more than 50 percent of cancer pain patients are under-treated and most dying patients do not receive adequate care. The situation may improve following the creation of pain and palliative care working group (task force) at the Ministry of Health in 2001.

The Lithuanian Pain Society (LPS), a non-governmental organization, was established in 1998. It functions as the National Chapter of the International Association for the Study of Pain. Main activities of the Society are related to education of health professionals by conferences and teaching seminars on various pain topics. Over 2.200 health professionals were among participants in these meetings in 2001 only. In the period 1998-2001, three annual meetings of the LPS with the international faculty were organized. In 2000-2002 is running the project related to development of Palliative care services in the Baltic countries. This project is the grant of the program of the Open Society Institute in New York. Another two non-governmental organizations taking an active part in the process of palliative care development are: the Lithuanian Palliative Medicine Society, and Lithuanian Oncology Society.

Part 2

In Lithuania, the Competent Authority for narcotics control is the Narcotics Commission of the State Medicines Control Agency at Ministry of Health, established in 1996. The head of this Commission is in charge and is responsible for submitting the annual estimate of medical requirements for narcotic drugs to the INCB.

The following opioid analgesics are registered in Lithuania:
Alfentanyl, Codeine, Dihydrocodeine, Ethylmorhine, Fentanyl, Methadone, Morphine, Pethidine, Piritramide, Remifentanyl, Tilidine.

Dosage forms are: solution for injection, oral tablets, oral capsules, oral solution (e.g. Methadone), suppositories, transdermal patches. All together in Lithuania, there are 82 different forms and dosages of enumerated opioid analgesics registered.

In Lithuania, the manufacture of opioids is not performed; one manufacture (AB Endokrininiai preparatai, Kaunas) is licensed for preparation of the solution of morphine for injections from imported substance.

According to our data, there is not any shortage of registered opioid analgesics in Lithuania in places where cancer patients are treated.

The data about consumption trends in Lithuania 1996-2000.

Narcotic drug	1996	1997	1998	1999	2000
COCAINE	640,8 G	325 G	475 G	46,3 G	-
CODEINE	708,7 G	883 G	232 G	77 G	160 G
DIHYDROCODEINE	-	101 G	21 G	5 G	24 G
ETHYLMORPHINE	752,5 G	24 G	49 G	-	-
FENTANYL	25 G	38 G	36,5 G	40,9 G	45,85 G
METHADONE	5525 G	4408 G	6540 G	8610 G	7083 G
MORPHINE	4435,3 G	5357 G	7870 G	7995 G	9753 G
PETHIDINE	-	2623 G	5666 G	8521 G	9513 G
PIRITRAMIDE	1247 G	1819 G	1080 G	383 G	1134 G
REMIFENTANIL	-	-	-	-	1 G
TRIMEPERIDIN	2656,6 G	678 G	-	-	-

The order of prescription of narcotic drugs in Lithuania is regulated by 27 12 1997 Decree of MoH No705 (Suppl.1). According to this order, every physician in principle can prescribe narcotic for the patient if this patient needs it according to health status. For prescription of narcotics, there are special prescription forms. On one prescription form is allowed only one name of narcotic drug narcotic substance.

Other requirements of writing a prescription for an opioid:

i. It is prohibited to prescribe narcotic drugs for the treatment course longer than 7 days (in the new prescribing order that will appear in the nearest future it is changed: the prescription of transdermal patches is allowed for 30 days); there is given a maximum amount of active substance that can be prescribed at one time.

For the incurable patients, the amount of narcotics can be prescribed is thrice higher as usually.
The prescription of narcotic drugs shall be valid for 5 days.
The prescription as for all reimbursed medicines is valid in the regional territorial patient fund pharmacies.
In the new prescribing order that will appear in the nearest future, the prescription of transdermal patches shall be allowed for 30 days.
The penalties for physician who violates prescribing law or regulations are not established; for the pharmacist who violates prescribing law may be cancelled private license and the same can be applied for pharmacy.
National law or regulations do not require reporting the names of patients to any institution.

The last Decree of MoH regarding medical use and availability of opioid analgesics was issued on 23 12 1997 (No705), after them some changes are done on 29 04 1999 (No198) and in the first quarter of 2002 will appear a new Decree of MoH with some changes mentioned above.

SUMMARY OF COUNTRY REPORTS

POLAND

38,6 millions of inhabitants
385.853 deaths a year
deaths from cancer 82.600 (2000)

1. CANCER, PAIN AND PALLIATIVE CARE

a) Prevalence and types of cancer and the prevalence of pain

The number of newly diagnosed patients with cancer is rising each year; 110.000 in 1996, about 125.000 cases in 2000.The leading cancers:

- women: cancer of breast (19%), colorectal (11,2%), cervical (8%), lung (8%), ovarian (6%) and uterine (6%).
- men: lung (29%), colorectal (17,7%), gastric (7%), prostate (5%), bladder (5%) and larynx (5%).

The prevalence of pain-about 150.000 cancer patients.

In only 30% of newly diagnosed patients in Poland is the cancer curable (data from 1996). Among 125.000 of newly diagnosed patients, 42.000 patients had curable and 83.000 had incurable cancer. The total number of patients with incurable cancer consists of above mentioned 83.000 causes and 110.000 patients diagnosed as incurable in last years. There is also in Poland another group of 200.000 patients with curable cancer (survivors). All together there are about 435.000 cancer patients each year in Poland.

Taking into consideration the 70 % incidence of pain in incurable cancer and about 30% in actively treated patients, the number of patients with cancer pain in Poland yearly is about 150.000 (all mentioned above data obtained from Wronkowski Z. and all report on Epidemiology of malignant neoplasm published in the project of national programme of cancer 2001)

b) National cancer control plan, program. Program of pain relief and palliative care addressed opioid availability, name of the office and person in charge.

National cancer control program is developing by Polska Unia Onkologii, President
Janusz Meder, MD, Roentgena 5,cod 02-718 Warszawa, but not started yet.
There were some programmes, for example on the use of oral morphine in cancer pain, included to the governmental programmes worked out by Center of Oncology in Warszawa, but comprehensive programme of pain relief and palliative care was not developed as a part of National Cancer control programme.

2. CANCER PAIN RELIEF AND PALLIATIVE CARE

Cancer pain relief and palliative care are addressed in the Ministry of Health Programme of developing hospice palliative care in Poland * prepared by the National Council for Hospice and Palliative Care, an advisory body for Ministry of Health in 1998. Professor Jacek Luczak, medical director of Palliative Care Department in Poznań, Chairman of National Council for Hospice and Palliative Care together with other members of this Council, founded in 1993, is actively working in improving the availability of opioids and cooperating with the Ministry of Health since 1991.

c) The role of government in endorsement of the WHO method for relief of cancer pain and in sponsoring and endorsing the training programs in cancer pain and palliative care

The Ministry of Health (government) has endorsed the WHO method for relief of cancer pain –in 1994, the handbook; Cancer pain management (Zwalczanie bólów nowotworowych Kujawska Tenner Janina, Luczak Jacek, Kotlinska Aleksandra, Dangel Tomasz), which also includes pharmacotherapy of cancer pain in children. More than 150.000 of copies of this book supplemented by recommendations of Ministry of Health have been distributed free of charge to physicians, nurses and pharmacists. It was followed by translation and publication of WHO brochures: Cancer pain relief and palliative care (1994) and Cancer pain relief and palliative care in children (2001).

The Ministry of Health since 1994 has endorsed and sponsored training programs in cancer pain and palliative care developed by University of Medical Sciences units: Palliative Care Department in Poznan linked with WHO palliative care collaborating center –Sir Michael Sobell House in Oxford, Section of Palliative Medicine in Gdansk, in Bydgoszcz. and recently in Katowice, also in other palliative care and hospice units including Kraków, St-Lasarius Hospice, Elblag St George Hospice, Palliative Medicine out patients and home care unit and stationary hospice in Szczecin , Wroclaw's Palliative Care out patients and home care unit and Home Care Hospice, Stationary Oncological Hospice and Intensive Pain Therapy ward and Cancer pain clinic at the Oncological Center in Warszawa. All mentioned above units are designated by the Ministry of Health as centers for education and training for doctors specializing in palliative medicine and nurses specializing in palliative care (programmes started in 2000). Other sources of funding include Stefan Batory Foundation, and Open Society Institute (George Soros funding) in NY, Polish Hospices Fund and Polish Association for Palliative Care.

d) *description of availability of pain relief and palliative care services, access to services*

Hospice and palliative care services in Poland in 2000

All together 240 units

In bedded units	number	beds
Nonpublic	22	250
Public	50	508
Planning	18	new units with 160 beds

3. PALLIATIVE CARE HOME SERVICES

There are 149 palliative care home services (64 nonpublic and 85 public), among them 100 outpatients pain and palliative care clinics.
There are 8-day care centers and a few hospital supporting teams, 4 lymphoedema clinics and 7 pediatric palliative care home care services.
There are four academic palliative medicine sections: in Poznań (since 1991), Gdansk (1995) Bydgoszcz (1995), Katowice (2001) and two professors in palliative medicine. Palliative medicine became a physician specialization and palliative care specialization for nurses since 1999.
In 2000, cancer caused 82.600 deaths; more than 55% of pts' died in hospitals, 7,6% died in hospices, 21 % died at home cared for by hospice/palliative care services, about 35-40% of terminally ill cancer patients used hospice/palliative care services.

There are differences in distribution of hospice and palliative care services, less in rural areas, more in central (Warszawa, Bydgoszcz,Lublin) western (Poznan, Gdansk)and south (Kraków, Katowice, Wroclaw) regions of country.

e) *national associations (NG-organisations)– promoting pain relief and hospice palliative care***

-The Forum of Independent Hospice Movement (Ogólnopolskie Forum Ruchu Hospicyjnego ORFH), which represents the voluntary hospice movement, was founded in 1991. It is a meeting place for all independent hospices, helps their members to carry out their aims and has representatives in the National Council for Hospice and Palliative Care Services.
-The Polish Association for Palliative Care established in 1989 in Poznan. Branches of the society have been set up in 16 regions of the country. Its activities include: propagating hospice philosophy and fund raising, organizing various forms of education in palliative /hospice care, cooperating with EAPC.
-Polish chapter of IASP chaired by Maciej Hilgier MD, PhD promoting the idea of pain relief, is involved in education on cancer pain management; since 2000 the journal BOL (pain) is edited.

ECEPT-Eastern and Central Europe Palliative Care Task Force*** is a international organization formed under Polish law, which embraces 120 members from 17 countries all committed to realizing the aims of the Poznan's Declaration, which include development of national polices, promoting cancer pain relief and palliative care, fundraising and developing educational programmes for medical students, doctors nurses and the general public.

There are several initiatives performed by the national consultant in palliative medicine in cooperation with above mentioned organizations in cooperation with Ministry of Health, which promote cancer pain relief and palliative care****

SUMMARY OF COUNTRY REPORTS

ROMANIA

Mortality from cancer represents the second cause of death in Romania and has been having a constantly growing evolution in the latest 30 years from 123.3 $^{0}/_{0000}$ in 1970 to 135 $^{0}/_{0000}$ in 1980, 141.6 $^{0}/_{0000}$ in 1989, 165.5 $^{0}/_{0000}$ in 1995 and 184.04 $^{0}/_{0000}$ in 2000.
The main diseases within this group are broncho-pulmonary cancer, gastric cancer, breast cancer, uteri, cervix and prostate cancer.
As for age groups, it is noted that there is a constant growth of the frequency of death cases for each 10 years of life.

Since 1980, Romania has a **National Program on Cancer**, called Programme of Prevention and Control in the Oncologic Pathology, updated on a regular basis.

Description of the programme
The programme objective is to increase the case detections from the advanced stages III and IV to initially curable stages (0, I, II) and to update the normative acts concerning the evidence of cases and the circulation of information on the oncologic pathology.

Purpose

To improve the survival of persons with oncologic affections

Objectives
To increase the number of the cases diagnosed in stage I and II;
To update the National Cancer Register;
To update and complete the existing legislation;
Screening programmes for other cancers with significant incidence.

Coordinating departments. General department of medical assistance, Programmes and Medical Integrated Services

Institutions responsible for the implementation of the programme:
The Oncology Institute from Bucharest and the Oncology Institute from Cluj
District Public Health departments (41) through the Oncologic Department Centres Cluj, Dolj, Iasi, Tirgu Mures, Timis and Bucharest.
Oncology departments from territorial hospitals

Financing of the programme.
State budget, donations and other sources, according to the law

Indicators.
Incidence of the cases diagnosed on stages;
Updated and improved National Cancer Register.

Physical indicators

Number of persons put through screening (cervix cancer and mammary gland)
Number of cases in evidence in the National Cancer Register

Palliative care

In the classified list of specialties of the Ministry of Health and Family, the over specialization "palliative care" has been introduced for family physicians or for other medical specialties.
Both during the University education and during the oncology specialty training "Diagnosis and treatment of pain" represents a fundamental chapter.
In every oncologic department in the hospitals, there are a number of beds for the symptomatic treatment of pain.
Every medical unit has a specialists commission that establishes the diagnosis and the therapeutic indications, including the symptomatic treatment and pain treatment. Usually, the already registered patients who, because of the evolution of their disease, need treatment, are hospitalized in order to test their medication, the therapeutic response and the secondary effects, after which they may be discharged and follow the treatment at home under the strict supervision of the family physicians.
At the level of the Ministry of Health and Family, there is a Commission of Oncology that came with proposals for the improvement of medical oncologic care and palliative care.

Opioid analgesics

The authorization of prescription and delivery of narcotics is delivered by the District Public Health Departments (DPHD) and the Public Health Department of the Municipality of Bucharest on the basis of the medical report made up by the oncologist physician and of the medical certificate delivered by the medical unity (hospital). The authorization is valid for three months. On the basis of this authorization, the oncologist physician designed by the DPHD prescribes the narcotics on a receipt with impressed stamp, for a period of 10-14 days.
The receipt is delivered on the basis of one of the 4 copies of the authorization and of the receipt with impressed stamp by the hospital pharmacy through which the national oncology programme is running (the part financed by the National Health Insurance House).
Prescribing and delivery of the narcotics used in medical purpose is verified by a team made up of representatives of the Ministry of Interior and Ministry of Health and Family and the Department of Public Health.
Within the hospitals, the prescription of opioids is made on a special register, the pharmacist through the hospital pharmacy makes delivery of the narcotics, and the medical staff strictly surveys the administration of the treatment. The maxim quantity per day is presented in the Romanian Pharmacopoeia.

Cancer, pain and palliative care

Are pain relief and palliative care addressed?
Not in the National cancer control program

Has the government endorsed the WHO method for relief of cancer pain?
No

Has the government sponsored or endorsed training programs in cancer pain relief and palliative care?
The government has not sponsored any palliative care training programs but has endorsed the educational programs developed by the Study Centre for Palliative Care in Brasov by:

- accrediting it as the National Resource and Training Centre in Romania
- officially recognising palliative care as a medical subspecialty in Nov 1999
- offering credits of continuing medical education for all the palliative care courses run at the Study Centre in Brasov

Describe in brief terms the availability of pain relief and palliative care services in the country and comment on the extent to which the needy population has access to such services

Hospice “Casa Sperantei” in Brasov is the first pioneering palliative care service in Romania and the one that is leading the palliative care movement
Palliative Care services today:

- 4 home care teams in Brasov, Oradea, Cluj, Bucharest. All are NGO’s offering palliative care for cancer patients. They are charities, with the main part of their budget being raised outside Romania, and a small part of it locally through fund-raising events in the community
- 4 paediatric palliative care services: 2 homecare services in Brasov and Oradea for children with cancer and other terminal conditions like neuromuscular diseases, congenital diseases, etc.
- 2 services in Paediatric oncological hospitals in Tg Mures and Iasi
- the first free standing Romanian Hospice to be opened in May 2002 in Brasov. Will be a centre of excellence of clinical practice and an educational unit for practical placements associated with the National Resource and Training Centre in Brasov
- Beds for symptom control in 5 oncological hospitals Tg Mures, Cluj, Bucuresti, Birlad, Miercurea Ciuc, and in a general hospital in Campina
- Day -centre in Brasov

There is just a small coverage of the needy population and an active involvement of the national medical authorities would be necessary in order to speed up the development of these services. Including palliative care services in the package of services paid by the National Insurance House will be a major step forward.

Identify national associations (non-governmental organisations) that have a primary interest in pain relief and/or palliative care, and mention their relevant activities.
The Nation Association for Palliative Care founded in 1998 has organised:

- 4 National conferences in 1998, 1999, 2000, 2001
- 2 National Lobby conferences in 1999 and 2001. As a result, palliative care was recognised as a medical subspecialty, 10 national trainers in palliative care were accredited. A consensus as signed by all the parties involved.
- Balkan palliative care conference in 2001
- Annual newsletter

The Romanian association for the Study of Pain **(vezi Dr Elena Copaciu)**

Opioid availability

What opioid analgesics are approved in the country, and in what dosage forms?
CODEIN tablets
DIHIDROCODEINE slow released tablets
TRAMAL tablets, vials, suppositories, solution
PENTAZOCINE tablets, vials
Morphine immediate and slow released tablets, vials
Hidromorphone vials
Methadone tablets
Pethidine vials

List all licensed manufacturers for the needed opioids.

What opioids are not available?
Dextropropoxifen
Oxycodon
Morphine solution
Fentanyl patches
Buprenorphine

For those opioids that are available, are they sufficiently available in the places where cancer patients are treated in the country, i.e., all hospitals with cancer units, hospices, pain clinics, palliative care programs, etc.?

NO

What are the basic requirements for a physician to prescribe an opioid such as morphine?
What licenses are required?
Are special prescription forms required?
Is special training required?
Only oncologists specially appointed working in out patients clinics are allowed to prescribe strong opioids for use outside hospitals. They write an authorisation in 3 copies that includes the

name of the opioid, the dosage per tablet/vial and the total daily dose. One of these copies goes to the GP who one a special prescription copies the recommended dose for 15 days not being allowed to make any changes. With this special prescription and the second copy the family goes to a special appointed pharmacy and takes the drugs

What are the other requirements for writing a prescription for an opioid such as morphine? See above

Is there a maximum amount that can be prescribed at one time, for example a limitation on the number of dosage units or number of days? Yes just for 15 days and in some parts of the country the maximum dose per day is 60mg of morphine.

Is there a maximum length of time that a patient can receive opioids?
No

What is the period of time that a prescription for an opioid such as morphine is valid?
3 months for the authorisation.

What, if any, changes have been made in laws, regulations or commercialisation to improve the medical use and availability of opioid analgesics?
No changes

Annex 5

COUNTRY ACTION PACKET

(This packet contains all the materials you will need to complete these steps)

Country:_____

Coordinator name:_____(see Step 1)

Step (1) Select a Coordinator by filling in the blank above. The role of your country coordinator is to:

(a) guide your country group's discussion to formulate a final Action Plan,
(b) review the necessary steps and keep track of the time available to complete the tasks,
(c) present your country group's Action Plan to all workshop participants on the last day,
(d) submit your country group's Action Plan to the meeting sponsors, and
(e) designate, if needed, another person in your country group to assist with note-taking, etc.

Step (2) Complete the self-assessment of your country's national policy using the checklist. Achieve consensus in your group on each item, if possible. In the case of differing opinions, proceed to the next item and return later. Please avoid using "information not available" if possible.

Step (3) Identify the requirements for prescribing opioid analgesics by completing the matrix.

Step (4) Identify each item on the checklist (from Step 2) that is a problem ("No" responses for items 1-13; "Yes" responses for items 14-16) using the provided form. Briefly elaborate on each problem and its impact on adequate opioid availability, and list the reasons for or causes of the problem. Then prioritize the top **3-5** needs that present the most severe barriers to opioid availability and those with the most potential for positive impact and early success (less than one year).

Step (5) Prepare the Action Plan using the form provided. For each of the top **3-5** priority items that have been listed in Step 4, (a) state the objective (re-state the barrier as a desired outcome); (b) discuss, decide and then list the action steps needed to achieve the objective; (c) list who has responsibility for each step; (d) provide a timeline for each step; (e) identify needs for technical assistance, and who should provide it; and (f) list additional resources that are needed to achieve the objective.

Step (6) Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives, using the form provided. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

Step (7) Decide who will report the workshop results in your country and to which persons and organizations, using the form provided.

Step (8) Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Step 2

Complete the self-assessment of your country's national policy using this checklist. Achieve consensus in your group on each item, if possible. In the case of differing opinions, proceed to the next item and return later. Please avoid using " information not available" if possible.

Governments or other interested groups, including health care professionals, may use the following checklist to guide their analysis of national drug control policies.

1. Has the government conducted an *examination* to determine if there are overly restrictive provisions in national (and state, if applicable) drug control policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments?

□ Yes □ No □ Information not available

2. Is there a provision in national drug control policies that recognizes that narcotic drugs are *absolutely necessary* for the relief of pain and suffering?

□ Yes □ No □ Information not available

3. Is there a provision in national drug control policies that establishes that it is the government's obligation to make *adequate provision* to ensure the availability of narcotic drugs for medical and scientific purposes, including for the relief of pain and suffering?

□ Yes □ No □ Information not available

4a. Has the government established *administrative authority* for implementing the obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes, including licensing, estimates and statistics? 1

1 **In some cases, the government's policy may be found in either the law or administrative policies, or in both.**

□ Yes □ No □ Information not available

4b. Are *adequate personnel* (employees) available for the implementation of this responsibility?

□ Yes □ No □ Information not available

5a. Does the government have a *method to estimate* realistically the medical and scientific needs for narcotic drugs, including for the opioid analgesics which are needed for pain relief and palliative care?

□ Yes □ No □ Information not available

5b. Has the government *critically examined* its method for assessing medical needs for narcotic drugs, as requested by the INCB?

□ Yes □ No □ Information not available

5c. Has the government established a satisfactory *system to collect information* about medical need for opioid analgesics from relevant facilities?

□ Yes □ No □ Information not available

6. Does the government furnish *annual estimates* to the INCB of need for narcotic drugs for the next year in a timely way?

□ Yes □ No □ Information not available

7. If it appears that the medical need for opioid analgesics will exceed the estimated amount which has been approved and confirmed by the INCB, is it government policy to furnish a request for a *supplementary estimate*?

□ Yes □ No □ Information not available

8. Does the government submit to the INCB in a timely way the required annual *statistical reports* respecting production, manufacture, trade, use and stocks of narcotic drugs?

□ Yes □ No □ Information not available

9a. Has the government *informed health professionals* about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns?

□ Yes □ No □ Information not available

9b. Has the government identified and addressed concerns of health care professionals *about being investigated* for prescribing opioids?

□ Yes □ No □ Information not available

10. Is there *cooperation* between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes?

□ Yes □ No □ Information not available

11. Has the government taken steps, in cooperation with licensees, to ensure that there are *no shortages* of supply of opioid medications caused by inadequate procurement, manufacture and distribution systems?

□ Yes □ No □ Information not available

12. Do national drug control policies provide for the licensing of an adequate number of individuals and entities to support a distribution system that will *maximize* physical *access* of patients to pain relief medications?

□ Yes □ No □ Information not available

13a. Has the government established a *national cancer control programme* to which it allocates health care resources?

□ Yes □ No □ Information not available

13b. Has the government taken steps to ensure the practice of the WHO Analgesic Method for cancer pain relief by continuing *education* programmes and by its inclusion in medical, pharmacy and nursing curriculum?

□ Yes □ No □ Information not available

14. Is there *terminology* in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence?

□ Yes □ No □ Information not available

15. Are there provisions in national drug control policy that *restrict* the *amount* of drug prescribed or the *duration* of treatment?

□ Yes □ No □ Information not available

16. Are there prescription requirements in national drug control policy that may unduly *restrict* physician and patient *access* to pain relief?

□ Yes □ No □ Information not available

Step 3

Identify the requirements for prescribing opioid analgesics.

REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS

(Draft – preliminary information)

Country	*Does national policy require the use of a special prescription form?*	*Does the physician or institution have to pay for the special prescription forms?*	*Does national policy establish a validity period for opioid prescriptions? If so, what is the period?*	*Does national policy establish a maximum amount that can be prescribed at one time? If so, what amount?*	*Does national policy limit the length of time that a patient may be treated with an opioid? If so, how long?*
Bulgaria	**Yes, triplicate form for opioids**		**Yes, 7 days**	**Yes, 15 days therapeutic dose**	**NO**
Croatia					
Hungary					
Lithuania	**Yes, for narcotics**		**Yes, 5 days**	**Yes, 7 days per prescription (30 days for fentanyl patch)**	**7 days?**
Poland	**Yes, duplicate form for opioids**		**Yes, 30 days**	**Yes, 10 times the single maximum dose as specified in the Polish Pharmacopoeia**	**NO**
Romania	**Yes, triplicate form for opioids**		**Yes, 3 months**	**Yes, 15 days. In some parts of the country, maximum daily dose of morphine is 60 mg**	**NO**

Step 4

Identify each item on the checklist (from Step 2) that is a problem ("No" responses for items 1-13; "Yes" responses for items 14-16). Briefly elaborate on each problem and its impact on adequate opioid availability, and list the reasons for or causes of the problem. Then prioritize the top 3-5 needs that present the most severe barriers to opioid availability and those with the most potential for positive impact and early success (less than one year).

Write the short title of each item that is a problem	*Briefly elaborate on the situation*	*Describe how the situation affects opioid availability*	*List the reasons for the situation*	*List the 3-5 highest priorities for action*
(1)				
(2)				
(3)				
Write the short title of each item that is a problem	*Briefly elaborate on the situation*	*Describe how the situation affects opioid*	*List the reasons for the situation*	*List the 3-5 highest priorities for action*

		availability		
(4)				
(5)				
(6)				
(7)				
Write the short title of each	*Briefly elaborate on the*	*Describe how the*	*List the reasons for*	*List the 3-5 highest*

item that is a problem	*situation*	*situation affects opioid availability*	*the situation*	*priorities for action*
(8)				
(9)				
(10)				

Step 5

Country Action Plan

Prepare the Action Plan. For each of the top 3-5 priority items that have been listed in Step 4, (a) state the objective (re-state the barrier as a desired outcome); (b) discuss, decide, and then list the action steps needed to achieve the objective; (c) list who has responsibility for each step; (d) provide a timeline for each step; (e) identify needs for technical assistance, and who should provide it; and (f) list additional resources that are needed to achieve the objective.

State the objective	*What action steps are needed to reach the objective?*	*Who is or should be responsible for taking action?*	*Timeline, date of completion*	*What technical assistance is needed, and from whom?*	*What resources are needed to complete the objective?*
(1)	(a)				
	(b)				
	(c)				
(2)	(a)				
	(b)				

	(c)				
State the objective	*What action steps are needed to reach the objective?*	*Who is or should be responsible for taking action?*	*Timeline, date of completion*	*What technical assistance is needed, and from whom?*	*What resources are needed to complete the objective?*
(3)	(a)				
	(b)				
	(c)				
(4)	(a)				
	(b)				
	(c)				

(5)	(a)				
	(b)				
	(c)				

Step 6

Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

Mechanism needed:

Members:

Step 7

Decide who will report the workshop results in your country, and to which persons and organizations.

Step 8

Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Contact person:_____

Annex 6

Completed country action packets

Country: **BULGARIA**

Resource Person: ***Tokuo Yoshida***

Coordinator: **Elena Milanova**

WHO GUIDELINES SELF-ASSESSMENT CHECKLIST

1. Has the government conducted an *examination* to determine if there are overly restrictive provisions in national (and state, if applicable) drug control policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments? **Yes**

2. Is there a provision in national drug control policies that recognizes that narcotic drugs are *absolutely necessary* for the relief of pain and suffering? **Yes**

3. Is there a provision in national drug control policies that establishes that it is the government's obligation to make *adequate provision* to ensure the availability of narcotic drugs for medical and scientific purposes, including for the relief of pain and suffering? **Yes**

4a. Has the government established *administrative authority* for implementing the obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes, including licensing, estimates and statistics? **Yes**

4b. Are *adequate personnel* (employees) available for the implementation of this responsibility? **Yes**

5a. Does the government have a *method to estimate* realistically the medical and scientific needs for narcotic drugs, including for the opioid analgesics which are needed for pain relief and palliative care? **Yes**

5b. Has the government *critically examined* its method for assessing medical needs for narcotic drugs, as requested by the INCB? **Yes**

5c. Has the government established a satisfactory *system to collect information* about medical need for opioid analgesics from relevant facilities? **Yes**

6. Does the government furnish *annual estimates* to the INCB of need for narcotic drugs for the next year in a timely way? **Yes**

7. If it appears that the medical need for opioid analgesics will exceed the estimated amount which has been approved and confirmed by the INCB, is it government policy to furnish a request for a *supplementary estimate*? **Yes**

8. Does the government submit to the INCB in a timely way the required annual *statistical reports* respecting production, manufacture, trade, use and stocks of narcotic drugs? **Yes**

9a. Has the government *informed health professionals* about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns? **Yes**

9b. Has the government identified and addressed concerns of health care professionals *about being investigated* for prescribing opioids? **N/A**

10. Is there *cooperation* between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes? **Yes**

11. Has the government taken steps, in cooperation with licensees, to ensure that there are *no shortages* of supply of opioid medications caused by inadequate procurement, manufacture and distribution systems? **Yes**

12. Do national drug control policies provide for the licensing of an adequate number of individuals and entities to support a distribution system that will *maximize* physical *access* of patients to pain relief medications? **Yes**

13a. Has the government established a *national cancer control programme* to which it allocates health care resources? **No**

13b. Has the government taken steps to ensure the practice of the WHO Analgesic Method for cancer pain relief by continuing *education* programmes and by its inclusion in medical, pharmacy and nursing curriculum? **Info not available**

14. Is there *terminology* in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence? **No**

15. Are there provisions in national drug control policy that *restrict* the *amount* of drug prescribed or the *duration* of treatment? **Yes**

16. Are there prescription requirements in national drug control policy that may unduly *restrict* physician and patient *access* to pain relief? **No**

COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS

1) Does national policy require the use of a special prescription form? **Yes, triplicate form for opioids.**
2) Does the physician or institution have to pay for the special prescription form? **No**
3) Does national policy establish a validity period for opioid prescriptions? **Yes**
If so, what is the period? **7 days**

4) Does national policy establish a maximum amount that can be prescribed at one time? **Yes**
If so, what amount? **15 days therapeutic dose**
5) Does national policy limit the length of time that a patient may be treated with an opioid? **No**
If so, how long? _____

COUNTRY ACTION PLAN

Objective 1: Develop the National Cancer Control Program (NCCP)

a. Action Step: Prepare a report to the Minister of Health on the conclusions at the workshop emphasizing the need for National Cancer Control Program

Who is responsible? Elena Milanova (NDC), Fani Michailova (NSDC)

Timeline: March 15, 2002

b. Action Step: To establish a working group authorized by the Minister of Health to develop the NCCP

Who is responsible? Minister of Health

Timeline: ???

c. Action Step: To identify expert resources – technical and financial – and to develop collaboration network between them.

Who is responsible ???

Timeline: ???

Objective 2: To evaluate the impact of the "15 days" prescription and modify a regulation, as appropriate

a. Action Step: To prepare a letter to the Minister of Health to establish an expert group of oncologists

Who is responsible? Fani Michailova (NSDC)

Timeline: March 15, 2002

b. Action Step: The expert group will formulate recommendations on this matter

Timeline: By the end of April 2002

c. Action Step: The recommendation should be sent to the working group responsible for drafting the new regulation

Who is responsible? ???

Timeline: By the end of April 2002

Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

Mechanism needed: National Drug Council/The Secretariat will supervise the process of implementation of the objectives

Members: NDC/Secretariat/ - Elena Milanova

Decide who will report the workshop results in your country, and to which persons and organizations.

Eilia Lolova
Elena Milanova
Fani Michailova

Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Elena Milanova

Country: **CROATIA**

Resource Person: ***Harald Breivik***

Coordinator: **Marinko Bilusic**

WHO GUIDELINES SELF-ASSESSMENT CHECKLIST

1. Has the government conducted an *examination* to determine if there are overly restrictive provisions in national (and state, if applicable) drug control policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments? **No**

2. Is there a provision in national drug control policies that recognizes that narcotic drugs are *absolutely necessary* for the relief of pain and suffering? **Yes**

3. Is there a provision in national drug control policies that establishes that it is the government's obligation to make *adequate provision* to ensure the availability of narcotic drugs for medical and scientific purposes, including for the relief of pain and suffering? **Yes**

4a. Has the government established *administrative authority* for implementing the obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes, including licensing, estimates and statistics? **Yes**

4b. Are *adequate personnel* (employees) available for the implementation of this responsibility? **Yes**

5a. Does the government have a *method to estimate* realistically the medical and scientific needs for narcotic drugs, including for the opioid analgesics which are needed for pain relief and palliative care? **Yes**

5b. Has the government *critically examined* its method for assessing medical needs for narcotic drugs, as requested by the INCB? **Yes**

5c. Has the government established a satisfactory *system to collect information* about medical need for opioid analgesics from relevant facilities**?** **Yes**

6. Does the government furnish *annual estimates* to the INCB of need for narcotic drugs for the next year in a timely way? **Yes**

7. If it appears that the medical need for opioid analgesics will exceed the estimated amount which has been approved and confirmed by the INCB, is it government policy to furnish a request for a *supplementary estimate*? **Yes**

8. Does the government submit to the INCB in a timely way the required annual *statistical reports* respecting production, manufacture, trade, use and stocks of narcotic drugs? **Yes**

9a. Has the government *informed health professionals* about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns? **Yes**

9b. Has the government identified and addressed concerns of health care professionals *about being investigated* for prescribing opioids? **Yes**

10. Is there *cooperation* between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes? **Yes**

11. Has the government taken steps, in cooperation with licensees, to ensure that there are *no shortages* of supply of opioid medications caused by inadequate procurement, manufacture and distribution systems? **Yes**

12. Do national drug control policies provide for the licensing of an adequate number of individuals and entities to support a distribution system that will *maximize* physical *access* of patients to pain relief medications? **Yes**

13a. Has the government established a *national cancer control programme* to which it allocates health care resources? **No**

13b. Has the government taken steps to ensure the practice of the WHO Analgesic Method for cancer pain relief by continuing *education* programmes and by its inclusion in medical, pharmacy and nursing curriculum? **No**

14. Is there *terminology* in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence? **No**

15. Are there provisions in national drug control policy that *restrict* the *amount* of drug prescribed or the *duration* of treatment? **No**

16. Are there prescription requirements in national drug control policy that may unduly *restrict* physician and patient *access* to pain relief? **No**

COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS

1) Does national policy require the use of a special prescription form? **Yes, duplicate for opioids, but not special?**
2) Does the physician or institution have to pay for the special prescription form? **No**
3) Does national policy establish a validity period for opioid prescriptions? **Yes**
If so, what is the period? **5 days**
4) Does national policy establish a maximum amount that can be prescribed at one time? **Yes**
If so, what amount? **2 g morphine, 0.05 g fentanyl patch, 0.2 g methadone per prescription**
5) Does national policy limit the length of time that a patient may be treated with an opioid? **No**

COUNTRY ACTION PLAN

Objective 1: Improve education in pain treatment

a. Action Step: Include pain treatment education in the graduate and postgraduate education

Who is responsible? Scientific board

Timeline: 1-2 years

b. Action Step: Various courses, seminars, workshops

Who is responsible? Societies

Timeline: Ongoing

Technical assistance: Funds, technical assistance from WHO, government, pharmaceutical industry

c. Action Step: Written material

Who is responsible? WHO, societies

Timeline: 6-12 months

Technical assistance: Funds, technical assistance from WHO, government, pharmaceutical industry

Objective 2: Establish a National Cancer Control Board (NCCB)

a. Action Step: Evaluation of experience of WHO and the countries that have already established the NCCB. Collecting information from WHO etc. according to NCCB and influence governmental authorities.
Who is responsible? Societies, governmental institutions

Timeline: 1 year

Technical assistance: WHO, funds, technical assistance, expert opinions, various countries

b. Action Step: Start the process of creating the core of the board

Who is responsible? Societies, governmental institutions

Timeline: 2 years

c. Action Step: Develop the functioning of the board

Who is responsible? Societies, governmental institutions

Timeline: Continuing

Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

Mechanism needed: Establish a governmental board (a person) who will manage the implementation and coordinate all efforts to achieve the objectives.

Members: Members who will participate in the achievement include all societies already involved in these activities, universities, governmental members.

Decide who will report the workshop results in your country, and to which persons and organizations.

Minister of Health; Director of National Health Insurance; Dean of Medical School; Rectors of Universities, Societies for Pain Treatment, palliative care, clinical pharmacology, oncology, haematology; Croatian Medical Society; Croatian Medical Chamber; Pharmaceutical Society; Anesthesiological Society

Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the

workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Mia Balija

Country: **HUNGARY**

Resource Person: ***Friedemann Nauck***

Coordinator: **Erzsébet Podmaniczky**

WHO GUIDELINES SELF-ASSESSMENT CHECKLIST

1. Has the government conducted an *examination* to determine if there are overly restrictive provisions in national (and state, if applicable) drug control policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments? **No**

2. Is there a provision in national drug control policies that recognizes that narcotic drugs are *absolutely necessary* for the relief of pain and suffering? **Yes**

3. Is there a provision in national drug control policies that establishes that it is the government's obligation to make *adequate provision* to ensure the availability of narcotic drugs for medical and scientific purposes, including for the relief of pain and suffering**?** **No**

4a. Has the government established *administrative authority* for implementing the obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes, including licensing, estimates and statistics? **Yes**

4b. Are *adequate personnel* (employees) available for the implementation of this responsibility? **Yes**

5a. Does the government have a *method to estimate* realistically the medical and scientific needs for narcotic drugs, including for the opioid analgesics which are needed for pain relief and palliative care? **Yes**

5b. Has the government *critically examined* its method for assessing medical needs for narcotic drugs, as requested by the INCB? **Yes**

5c. Has the government established a satisfactory *system to collect information* about medical need for opioid analgesics from relevant facilities? **Yes**

6. Does the government furnish *annual estimates* to the INCB of need for narcotic drugs for the next year in a timely way? **Yes**

7. If it appears that the medical need for opioid analgesics will exceed the estimated amount which has been approved and confirmed by the INCB, is it government policy to furnish a request for a *supplementary estimate*? **Yes**

8. Does the government submit to the INCB in a timely way the required annual *statistical reports* respecting production, manufacture, trade, use and stocks of narcotic drugs? **Yes**

9a. Has the government *informed health professionals* about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns? **Yes**

9b. Has the government identified and addressed concerns of health care professionals *about being investigated* for prescribing opioids? **No, there were none**

10. Is there *cooperation* between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes? **Yes**

11. Has the government taken steps, in cooperation with licensees, to ensure that there are *no shortages* of supply of opioid medications caused by inadequate procurement, manufacture and distribution systems? **Yes**

12. Do national drug control policies provide for the licensing of an adequate number of individuals and entities to support a distribution system that will *maximize* physical *access* of patients to pain relief medications? **Yes**

13a. Has the government established a *national cancer control programme* to which it allocates health care resources? **Yes**

13b. Has the government taken steps to ensure the practice of the WHO Analgesic Method for cancer pain relief by continuing *education* programmes and by its inclusion in medical, pharmacy and nursing curriculum? **No**

14. Is there *terminology* in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence? **No**

15. Are there provisions in national drug control policy that *restrict* the *amount* of drug prescribed or the *duration* of treatment? **No**

16. Are there prescription requirements in national drug control policy that may unduly *restrict* physician and patient *access* to pain relief? **No**

COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS

1) Does national policy require the use of a special prescription form? **No, it requires a duplicate of the usual prescription form**
2) Does the physician or institution have to pay for the special prescription form? **No**
3) Does national policy establish a validity period for opioid prescriptions? **Yes**
   If so, what is the period? **30 days**
4) Does national policy establish a maximum amount that can be prescribed at one time? **No**
   If so, what amount? _____
5) Does national policy limit the length of time that a patient may be treated with an opioid? **No**
   If so, how long? _____

COUNTRY ACTION PLAN

Objective 1: Guideline 13b. Include the WHO Analgesic Method for cancer pain relief in medical, pharmacy, and nursing curriculum.

a. Action Step: Influence initiatives on taking part in the proper course.

Who is responsible? Hungarian Medical Association (HMA)

Timeline: near future

Technical assistance: proper course materials.

Resources: teach the teachers

Objective 2: Guideline 16. Remove barriers in the prescriptions for every day general practice

a. Action Step: Teaching and educations programs.

Who is responsible? ????

Timeline: ???

Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

Mechanism needed: There are no major formal barriers in the availability of opioid analgesics in Hungary. But there is an absolute need for the continuous education of health care providers in the field of pain relief, in the form of: successive postgraduate courses, written materials (books, leaflets, guidelines) for health personnel, patient and public education in the form of descriptive booklets.

Members: There is no governmental body but the task is delegated to the Hungarian Medical Association (HMA). Proposed members of the task force: HMA, ETI (Institution responsible for the continuing education of health professionals), Hungarian Hospice Association, Hungarian Anticancer League, other NGO's.

Decide who will report the workshop results in your country, and to which persons and organizations.

Ferenc Fábián to the Ministry of Health
Erzsébet Podmaniczky to the National Institute of Oncology and to the HMA
Katalin Muszbek to the NGO's
László Vimlati to the Medical Universities

Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Ferenc Fábián

Country: **LITHUANIA**

Resource Person: ***Karen Ryan***

Coordinator: **Vytautas Basys**

WHO GUIDELINES SELF-ASSESSMENT CHECKLIST

1. Has the government conducted an *examination* to determine if there are overly restrictive provisions in national (and state, if applicable) drug control policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments? **No**

2. Is there a provision in national drug control policies that recognizes that narcotic drugs are *absolutely necessary* for the relief of pain and suffering? **Yes**

3. Is there a provision in national drug control policies that establishes that it is the government's obligation to make *adequate provision* to ensure the availability of narcotic drugs for medical and scientific purposes, including for the relief of pain and suffering? **Yes**

4a. Has the government established *administrative authority* for implementing the obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes, including licensing, estimates and statistics? **Yes**

4b. Are *adequate personnel* (employees) available for the implementation of this responsibility? **Yes**

5a. Does the government have a *method to estimate* realistically the medical and scientific needs for narcotic drugs, including for the opioid analgesics which are needed for pain relief and palliative care? **Yes**

5b. Has the government *critically examined* its method for assessing medical needs for narcotic drugs, as requested by the INCB? **No**

5c. Has the government established a satisfactory *system to collect information* about medical need for opioid analgesics from relevant facilities? **Yes**

6. Does the government furnish *annual estimates* to the INCB of need for narcotic drugs for the next year in a timely way? **Yes**

7. If it appears that the medical need for opioid analgesics will exceed the estimated amount which has been approved and confirmed by the INCB, is it government policy to furnish a request for a *supplementary estimate*? **Yes**

8. Does the government submit to the INCB in a timely way the required annual *statistical reports* respecting production, manufacture, trade, use and stocks of narcotic drugs? **Yes**

9a. Has the government *informed health professionals* about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns? **Yes**

9b. Has the government identified and addressed concerns of health care professionals *about being investigated* for prescribing opioids? **Yes**

10. Is there *cooperation* between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes? **Yes**

11. Has the government taken steps, in cooperation with licensees, to ensure that there are *no shortages* of supply of opioid medications caused by inadequate procurement, manufacture and distribution systems? **Yes**

12. Do national drug control policies provide for the licensing of an adequate number of individuals and entities to support a distribution system that will *maximize* physical *access* of patients to pain relief medications? **Yes**

13a. Has the government established a *national cancer control programme* to which it allocates health care resources? **Yes**

13b. Has the government taken steps to ensure the practice of the WHO Analgesic Method for cancer pain relief by continuing *education* programmes and by its inclusion in medical, pharmacy and nursing curriculum? **No**

14. Is there *terminology* in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence? **No**

15. Are there provisions in national drug control policy that *restrict* the *amount* of drug prescribed or the *duration* of treatment? **No**

16. Are there prescription requirements in national drug control policy that may unduly *restrict* physician and patient *access* to pain relief? **No**

COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS

1) Does national policy require the use of a special prescription form? **Yes, triplicate for reimbursed narcotics**
2) Does the physician or institution have to pay for the special prescription form? **No**
3) Does national policy establish a validity period for opioid prescriptions? **Yes**
   If so, what is the period? **5 days**
4) Does national policy establish a maximum amount that can be prescribed at one time? **Yes**
   If so, what amount? **7 days per prescription (30 days for fentanyl patch)**
5) Does national policy limit the length of time that a patient may be treated with an opioid? **No**
   If so, how long? _____

COUNTRY ACTION PLAN

Objective 1: To include a provision in the Ministry of Health decrees to examine whether there are overly restrictive provisions.

a. Action Step: Issue new Ministry of Health decree

Who is responsible? State Medicines Control Agency and Dept. of Pharmacy at Ministry of Health.

Timeline: 2002-2003

Technical assistance: May need to discuss the possibility of a longer maximum prescription period, from 7 days, to perhaps 2 weeks.

Resources: Human resources

Objective 2: To encourage the government to critically examine its method for assessing medical needs for narcotic drugs.

a. Action Step: Develop or adapt a questionnaire to assess its estimation method.

Who is responsible? Narcotics Commission of State Medicines Control Agency.

Timeline: 2004

Technical assistance: INCB

Resources: Human resources, materials to print, copy, and send.

Objective 3: To ensure that the government supports the WHO Analgesic Method by continuing education programs and inclusion in practitioner curriculum.

a. Action Step: Learn more about other nations' experiences.

Who is responsible? Ministry of Health Group on Pain and Palliative Care

Timeline: 2004

Technical assistance: IASP, WHO Cancer Programme

Resources: Human resources, technical support

Objective 4: To begin a new Public Education Initiative

a. Action Step: Develop a message for dissemination for mass media.

Who is responsible? Ministry of Health would give a mandate to the Public Health Information Center.

Timeline: 2005

Technical assistance: WHO-Geneva, or WHOCC. Also, local public health centers.

Resources: Money (from OSI?), various programs or foundations.

Objective 5: To include a provision in the law (Preamble) that narcotics are absolutely necessary

a. Action Step: Amend the national law of narcotic and psychotropic substances control.

Who is responsible? State Medicines Control Agency – Department of Pharmacy

Timeline: 2004

Resources: Human resources

Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

Mechanism needed: Strategy Group of Pain and Palliative Care of the Ministry of Health - was created in 2001.

Members: Representatives of NGO's, chief specialists of the Ministry of Health, university health professionals.

Decide who will report the workshop results in your country, and to which persons and organizations.

Anzelika Balciuniene at Ministry of Health
Vytautas Basys at State Medicines Control Agency
Dalia Normantiene at Pharmaceutical Activities

Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Anzelika Balciuniene
Vytautas Basys

Country: **POLAND**

Resource Person: ***Mary Callaway***

Coordinator: **Jacek Luczak**

WHO GUIDELINES SELF-ASSESSMENT CHECKLIST

1. Has the government conducted an *examination* to determine if there are overly restrictive provisions in national (and state, if applicable) drug control policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments? **Yes**

2. Is there a provision in national drug control policies that recognizes that narcotic drugs are *absolutely necessary* for the relief of pain and suffering? **Yes**

3. Is there a provision in national drug control policies that establishes that it is the government's obligation to make *adequate provision* to ensure the availability of narcotic drugs for medical and scientific purposes, including for the relief of pain and suffering? **Yes**

4a. Has the government established *administrative authority* for implementing the obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes, including licensing, estimates and statistics? **Yes**

4b. Are *adequate personnel* (employees) available for the implementation of this responsibility? **No**

5a. Does the government have a *method to estimate* realistically the medical and scientific needs for narcotic drugs, including for the opioid analgesics which are needed for pain relief and palliative care? **No**

5b. Has the government *critically examined* its method for assessing medical needs for narcotic drugs, as requested by the INCB? **No**

5c. Has the government established a satisfactory *system to collect information* about medical need for opioid analgesics from relevant facilities? No

6. Does the government furnish *annual estimates* to the INCB of need for narcotic drugs for the next year in a timely way? **Yes**

7. If it appears that the medical need for opioid analgesics will exceed the estimated amount which has been approved and confirmed by the INCB, is it government policy to furnish a request for a *supplementary estimate*? **Yes**

8. Does the government submit to the INCB in a timely way the required annual *statistical reports* respecting production, manufacture, trade, use and stocks of narcotic drugs? **Yes**

9a. Has the government *informed health professionals* about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns? **No**

9b. Has the government identified and addressed concerns of health care professionals *about being investigated* for prescribing opioids? **Yes**

10. Is there *cooperation* between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes? **Yes**

11. Has the government taken steps, in cooperation with licensees, to ensure that there are *no shortages* of supply of opioid medications caused by inadequate procurement, manufacture and distribution systems? **Yes**

12. Do national drug control policies provide for the licensing of an adequate number of individuals and entities to support a distribution system that will *maximize* physical *access* of patients to pain relief medications? **Yes**

13a. Has the government established a *national cancer control programme* to which it allocates health care resources? **No, developing**

13b. Has the government taken steps to ensure the practice of the WHO Analgesic Method for cancer pain relief by continuing *education* programmes and by its inclusion in medical, pharmacy and nursing curriculum? **Yes**

14. Is there *terminology* in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence? **Yes**

15. Are there provisions in national drug control policy that *restrict* the *amount* of drug prescribed or the *duration* of treatment? **No**

16. Are there prescription requirements in national drug control policy that may unduly *restrict* physician and patient *access* to pain relief? **No**

COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS

1) Does national policy require the use of a special prescription form? **Yes, duplicate form for opioids**
2) Does the physician or institution have to pay for the special prescription form? **Doctors, no; institutions, yes**
3) Does national policy establish a validity period for opioid prescriptions? **Yes**
If so, what is the period? **30 days**
4) Does national policy establish a maximum amount that can be prescribed at one time? **Yes**
If so, what amount? **10 times the single maximum dose as specified in 1992 Polish Pharmacopoeia**
5) Does national policy limit the length of time that a patient may be treated with an opioid? **No**
If so, how long? _____

COUNTRY ACTION PLAN

Objective 1: Establish administrative capacity in Public or Politic Health Department (Ministry of Health) for implementing the obligations, or task force could develop estimation and data collection method.

a. Action Step: Present need and make proposal to vice-minister. Set up the Task Force Group, which consists of the Polish participants in the Budapest workshop.

Who is responsible? Jacek Luczak

Timeline: April 15, 2002

Technical assistance: From the INCB,(International Narcotics Control Board) WHO(CancerControl) and country palliative care person to train the new person in the MOH(Ministry of Health).

Resources: Materials, palliative care training for new person.

b. Action Step: Create job description for Public or Politic Health Department officer which includes establishing methods of estimation needs data collection and informing health professionals. Cooperate with the Department of Drug Policy.

Who is responsible? Task force will assist in the development of this method.

Timeline: Uncertain, up to 6 months

Technical assistance: From the INCB and WHO, to develop methods of estimation.

Objective 2: Develop with two comprehensive cancer pain and palliative care programs in cooperation: Cancer Care Program (Polish Oncological Union) and Hospice-Palliative Care Program (Council of Hospice and Palliative Care Program with contribution of National Consultant in Palliative Medicine, Polish association of palliative care and Polish Forum of Hospice Movement, Polish chapter of IASP), which includes education (also public) in cancer and non-cancer pain management and palliative care.

a. Action Step: Submit request for approval to Ministry of Health and Parliament.

Who is responsible? Jacek Luczak and National Hospice-Palliative Care Organizations; Polish chapter of IASP, Polish Oncological Organization, WHO in Poland representative and other NGO organizations (e.g. Physician Chamber).

Timeline: Up to 1 year

Technical assistance: To lobby Parliament and Society.

Resources: Funding and lobbying education.

Objective 3: Get the Department of Health Policy to inform health care professionals regarding changes in drug prescribing laws and consult with task force before finalizing.

a. Action Step: Send letters from 3 organizations to MOH requesting improvement in communication with health care professionals regarding changes in prescribing laws.

Who is responsible? Three organizations (National Council for Hospice and Palliative Care; Polish Oncological Union, Polish Chapter of IASP) and/or task force.

Timeline: within 6 months

Objective 4: Increase the number of available strong opioids to improve cancer pain treatment – use in opioid rotation.

a. Action Step: (1) Encourage reimbursement for pharmaceutical companies. (2) Do pilot studies in selected centers to make registration faster and easier.

Who is responsible? Task force in cooperation with MOH.

Timeline: 1 to 3 years.

Objective 5: Improve and implement minimal standards for cancer and non-malignant pain treatment.

a. Action Step: Collect and examine existing standards and modify as needed.

Who is responsible? Societies in cooperation with NGO's. and representative of WHO in Poland

Timeline: 1 year

Technical assistance: Independent consultant from abroad (to be confirmed, Dr. Portenoy ?,).

Resources: Collect existing standards from US, Canada, Australia, UK, other countries.

Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

Mechanism needed: Establish Task Force from existing members plus additional members as needed.

Members: Jacek Luczak, Jerzy Jarosz, Maciej Hilgier, Adam Bozewicz

Decide who will report the workshop results in your country, and to which persons and organizations.

Each member will present to their own organization:

Jerzy Jarosz to Polish Union of Oncology
Maciej Hilgier to IASP Polish chapter
Piotr Jablonski to MOH
Jacek Luczak to National Council for Hospice and Palliative Care and ECEPT (Central and Eastern Europe Palliative Care Task Force)
Adam Bozewicz to General Pharmaceutical Inspectorate

Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Jacek Luczak and ECEPT

Country: **ROMANIA**

Resource Person: ***David Clark***

Coordinator: **Daniela Mosoiu**

WHO GUIDELINES SELF-ASSESSMENT CHECKLIST

1. Has the government conducted an *examination* to determine if there are overly restrictive provisions in national (and state, if applicable) drug control policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and made the necessary adjustments? **No**

2. Is there a provision in national drug control policies that recognizes that narcotic drugs are *absolutely necessary* for the relief of pain and suffering? **No**

3. Is there a provision in national drug control policies that establishes that it is the government's obligation to make *adequate provision* to ensure the availability of narcotic drugs for medical and scientific purposes, including for the relief of pain and suffering? **No**

4a. Has the government established *administrative authority* for implementing the obligation to ensure adequate availability of narcotic drugs for medical and scientific purposes, including licensing, estimates and statistics? **Yes**

4b. Are *adequate personnel* (employees) available for the implementation of this responsibility? **No**

5a. Does the government have a *method to estimate* realistically the medical and scientific needs for narcotic drugs, including for the opioid analgesics which are needed for pain relief and palliative care? **No**

5b. Has the government *critically examined* its method for assessing medical needs for narcotic drugs, as requested by the INCB? **No**

5c. Has the government established a satisfactory *system to collect information* about medical need for opioid analgesics from relevant facilities? **No**

6. Does the government furnish *annual estimates* to the INCB of need for narcotic drugs for the next year in a timely way? **Yes**

7. If it appears that the medical need for opioid analgesics will exceed the estimated amount which has been approved and confirmed by the INCB, is it government policy to furnish a request for a *supplementary estimate*? **Yes**

8. Does the government submit to the INCB in a timely way the required annual *statistical reports* respecting production, manufacture, trade, use and stocks of narcotic drugs? **Yes**

9a. Has the government *informed health professionals* about the legal requirements for the use of narcotic drugs, and provided an opportunity to discuss mutual concerns? **No**

9b. Has the government identified and addressed concerns of health care professionals *about being investigated* for prescribing opioids? **No**

10. Is there *cooperation* between the government and health care professionals to ensure the availability of opioid analgesics for medical and scientific purposes? **No**

11. Has the government taken steps, in cooperation with licensees, to ensure that there are *no shortages* of supply of opioid medications caused by inadequate procurement, manufacture and distribution systems? **Yes**

12. Do national drug control policies provide for the licensing of an adequate number of individuals and entities to support a distribution system that will *maximize* physical *access* of patients to pain relief medications? **Yes**

13a. Has the government established a *national cancer control programme* to which it allocates health care resources? **Yes**

13b. Has the government taken steps to ensure the practice of the WHO Analgesic Method for cancer pain relief by continuing *education* programmes and by its inclusion in medical, pharmacy and nursing curriculum? **No**

14. Is there *terminology* in national drug control policy that has the potential to confuse the medical use of opioids for pain with drug dependence? **No**

15. Are there provisions in national drug control policy that *restrict* the *amount* of drug prescribed or the *duration* of treatment? **Yes**

16. Are there prescription requirements in national drug control policy that may unduly *restrict* physician and patient *access* to pain relief? **Yes**

COUNTRY REQUIREMENTS FOR PRESCRIBING OPIOID ANALGESICS

1) Does national policy require the use of a special prescription form? **Yes, triplicate form for opioids**
2) Does the physician or institution have to pay for the special prescription form? **No**
3) Does national policy establish a validity period for opioid prescriptions? **Yes**
If so, what is the period? **3 months**
4) Does national policy establish a maximum amount that can be prescribed at one time? **Yes**
If so, what amount? **15 days. In some parts of the country, maximum daily dose of morphine is 60mg**
5) Does national policy limit the length of time that a patient may be treated with an opioid? **No**
If so, how long? _____

COUNTRY ACTION PLAN

Objective 1: Government should recognize pain relief and palliative care as priorities within health care.

a. Action Step: Elaborate long-term action plan and identify short-term realistic goals. Identify a working group to include Ministry of Health, National College of Physicians and Pharmacists, National Commission for Cancer Control, Romanian Pain Society, Romanian Palliative Care Association.

Who is responsible? Nania-Luminita Tronaru

Timeline: end of March 2002 to establish the working group.
The Minister of Health and Family has already signed the order to initiate this Committee

(working group) that will elaborate the project of the National Programme on Palliative

Care and Pain Management

Technical assistance: MFH, WHO, IASP, EAPC

Resources: Financial, secretarial work

Objective 2: Change and update the norms that restrict opioid prescriptions.

a. Action Step: Create proposals to come from NGO's

Who is responsible? Romanian Association for the Study of Pain, Romanian Palliative Care Association.

Timeline: Proposal by end of May 2002; Completion, difficult to predict.

Technical assistance: Department of Foreign Relations/MFH

Resources: Logistic support

Objective 3: Inform health care professionals about legal requirements for opioid prescriptions and WHO Analgesic Ladder for cancer pain relief.

a. Action Step: Produce and distribute 2 types of leaflets.

Who is responsible? Romanian Association for the Study of Pain, Romanian Palliative Care Association.

Timeline: end of September 2002

Technical assistance: Ministry of Health and Family

Resources: Financial assistance for printing the leaflets.

Identify the mechanism needed in your country to actively coordinate, foster cooperative efforts, monitor and communicate to achieve the objectives. Is there an existing governmental body able to manage this? Is there a need to establish a working committee or task force? Who should be members, both governmental and non-governmental?

Mechanism needed: No existing government body. Establish a working group to ensure that opioids are available, and that pain relief and palliative care must be health care priorities.

Members: Nania-Luminita Tronaru is responsible for organizing this working group. Members will be MFH authorities, College of Physicians, NGO's (IASP, Palliative Care Association).

Decide who will report the workshop results in your country, and to which persons and organizations.

Nania-Luminita Tronaru to Ministry of Health and Family, President of National Health Insurance House, College of Physicians and Pharmacists.

Decide who in your country group will be the follow-up contact person. The role of the follow-up contact person is to maintain central contact with country members following the workshop, and to liaise with the meeting sponsors and those who may provide technical follow-up assistance to the country group.

Elena Copaciu

Annex 7

SUMMARY OF WORKSHOP EVALUATION

1. How would you rate the overall quality of the workshop?

□ Excellent 12 □ Good 11 □ Average □ Poor

2. How probable is it that you will apply to your job what you have learned at the workshop?

□ High probability 15 □ Somewhat probable 5 □ Low probability 2 □ Not probable No Answer Given = 1

Please explain:

a. As an NGO representative, I will know in what areas and how to promote community participation in policymaking for palliative care.
b. By the objectives I'll try my best to incorporate the approaches of the workshop to my work.
c. I will participate at morning group for relief of restrictive limit for 15 day prescriptions according objective 2 of the Bulgarian Action Plan.
d. There are barriers which I'm suspicious have political nature, far from my work as a specialist. The administrative obstacles are not clear for me.
e. I'll try to implement in my country a National Program to Palliative Care (with ??
f. According to our country action plan.
g. It is so more clear about availability and using of opioids in practical use.
h. Comprehensive view/presentation/guidelines/materials very useful, excellent work of every countries representatives.
i. I have been working in the cancer pain management for 21 years.

3. The workshop was relevant to the needs in my country.

□ Totally agree 12 □ Partially agree 9 □ Undecided No Answer Given = 2 □ Partially disagree □ Totally disagree

4. How valuable was the presentation about the undertreatment of pain?

□ Very valuable 18 □ Somewhat valuable 5 □ Not very valuable □ Not at all valuable

5. How valuable was the presentation about opioid availability in Eastern Europe?

□ Very valuable 19 □ Somewhat valuable 4 □ Not very valuable □ Not at all valuable

6. How valuable was the presentation about the role of U.N. agencies in opioid availability?

□ Very valuable □ Somewhat valuable □ Not very valuable □ Not at all valuable

19 3 l

7. How valuable was the presentation about WHO terminology regarding dependence?

□ Very valuable □ Somewhat valuable □ Not very valuable □ Not at all valuable

18 3 l No Answer Given = 1

8. How valuable were the presentations about the WHO guidelines?

□ Very valuable □ Somewhat valuable □ Not very valuable □ Not at all valuable

18 3 1 No Answer Given = 1

9. How would you rate the country group meeting to develop your action plan?

□ Very valuable □ Somewhat valuable □ Not very valuable □ Not at all valuable

19 4

10. Did you find the "Country Action Packet" to be helpful to the process of developing your action plan?

□ Very helpful □ Somewhat helpful □ Not very helpful □ Not at all helpful

16 6 1

If you answered "Not very helpful" or "Not at all helpful," please explain why?

a. Some questions might be more precisely defined pointing out the obstacles of availability which are not visible but subjective.

11. What was the *most* valuable part of the workshop?

a. To see the big differences concerning palliative care facilities and opioid availability among the significant countries.
b. Working together with the MHF to develop all action plans. Networking opportunity.
c. Presentation of guidelines / work in groups with country reports
d. To get information about opioid availability in different countries. To meet professionals, to have discussions, brainstorming.
e. Country reports on availability of opioids for palliative care.

f. Country reports.
g. Developing action plans.
h. Country reports on availability of opioids for palliative care.
i. The presentation about the undertreatment of pain.
j. Methodology of the workshop. Because it's easier with action plans. Continue with activities in each country.
k. Difficult to stress out the point but certainly very valuable is to acquire a knowledge about other countries' experiences and to meet the people responsible in various areas within the WHO, and within the countries participants.
l. Meeting people from different countries, compare situations in countries, have a chance to contact some people from WHO and maybe get some needed help. It is excellent that we managed not just to recognize problems, but also did start some ways to solve them and to find solutions.
m. Meeting new people and see various ways of functioning.
n. Organization of the workshop.
o. Country reports.
p. The presentation of the comprehensive guidelines.
q. To prepare the action plan of our country.
r. Working in groups with the advisor to prepare an action plan according to the guidelines.
s. The presentation of the guidelines and work with the advisor to prepare an action plan.
t. Discussions.
u. Discussions, share experiences.
v. Putting together people from different backgrounds and making them exchange practices and ideas.
w. WHO techniques.

12. What was the *least* valuable part of the workshop?

a. The whole workshop was valuable.
b. Tuesday morning.
c. No ?
d. Overview of the WHO Guidelines
e. Any suggestions.
f. The luck of lectures materials (theses, abstracts).
g. Not any.
h. A luck of lectures materials (abstracts).
i. About WHO terminology.
j. No one was the last.
k. We can't expect unique and same countries. Many things function for decades, and function very well considering history, wars. Sometimes it is a good thing to have varieties.
l. It is a very long distance between hotel and city center.
m. The sightseeing (!)
n. The presentation of the comprehensive guidelines.
o. None
p. None
q. Lunch break.

13. Any suggestions for future workshops, topics to be covered, methodology of the sessions:

a. Topics to be corrected: opioid side effects, how to at them. One lecture should be devoted to the adjuvant analgesics of radionucleoids (e.g. Streamline) to relief, ??????????
b. Follow up workshop. Interactive discussions.
c. Follow-up after 1-2 years.
d. Some more time for workshops (small groups) and for personal discussions.
e. Problems of monitoring of the use of narcotics and analgesics.
f. Concepts on pain management and palliative care.
g. Problems of monitoring of the use of narcotics and analgesics.
h. Other symptoms - relief in terminal illness.
i. Problem with medicines at home which are not used – need for international agreements and regulations (laws).
j. Working on better endpoints, i.e. endpoints which will describe and characterize the pain treatment much more accurately than simply estimation of opioid consumption within the countries.
k. Some sightseeing please. Maybe a topic: Dispensing of opioid drugs left at patients home after patient's death.
l. It's very good that this workshop showed, not just the problems, but also some concrete ways to solve it.
m. Methodology of collecting data about relief pain. Questions of the self-assessment checklist to be more clear (there are questions which have 2 other questions inside)
n. About team working, creating contacts with different authorities.
o. What will happen with the opioids after the dead of the patients.
p. I think that the topics of the discussions should be analyzed in order to develop new topics. Maybe new topic to cover the question what will happen with the opioid qualities after the death of the patient.
q. Comparison and analysis of national regulations concerning supply with narcotics and psycho tropics, methods of establishing estimates, import-export issues.
r. Please refine questions no. They have double meaning or are too restrictive in options for answer. A team building interactive games would be very helpful before starting the country group meetings.

14. **How can WHO, the WHO Collaborating Center, and OSI be of further assistance to you in your work?**

a. To provide and send up-to-date information, brochures, videotapes, and selected publications.
b. Offering technical assistance. Providing the work of the partnership (work group) that will develop the national policy.
c. Continuing support.
d. Better communication on palliative care needs to the government.
e. Sent the whole infrastructure on the analyzed subject.
f. Sent the information.

g. WHO in pushing the government of member states to develop and implement policies on pain and palliative care. WHO Collaborating Center technical assistance, sending materials on internet experience. OSI arriving prognosis on required policy development grants.
h. Sent the whole information on the pain relief, palliative care and others.
i. Share information about palliative care: guidelines, CD-Rom, brochures, booklets, organize seminars, conferences, and workshops.
j. Support our action plan in our government, e.g. ministry of health, give us technical support, and organize workshops in our country.
k. Guidelines in pain treatment, in national cancer control board establishment, use of their authority, technical assistance or help.
l. It would be great to have a contact person if there is some problem. We appreciate the ideas about a letter to the Minister of Health, and it would be helpful if maybe someone from WHO came to Croatia and show new ideas.
m. By contacting, maybe send some materials, maybe by conning some of your members to one of our congresses or meetings.
n. Technical and financial support.
o. Email information about medical use of narcotic drugs, palliative care (studies in different countries), persons or committees in charge with these problems. Technical support.
p. To choose a supervisor of our coordinator.
q. By providing a methodological and technical assistance.
r. By providing a methodological and technical assistance.
s. By providing a methodological and technical assistance. To help us in our reform of transforming hospitals into hospices.
t. Thank you. We will have some proposals later.
u. Access to information and teaching materials for nurses, social workers. Assistance in developing national programs and teaching programs.
v. Sending written materials, leaflets, and guidelines.

Your country: Bulgaria=5, Croatia=4, Hungary=5, Lithuania=5, Poland=1, Romania=2

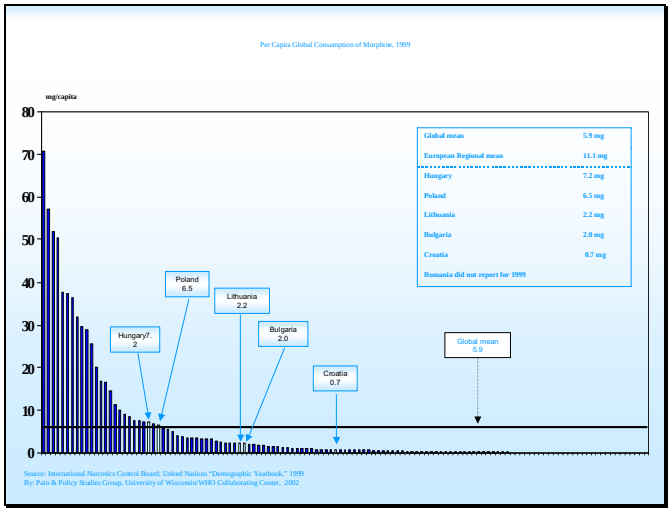
Your name (optional):_____

THANK YOU FOR YOUR PARTICIPATION IN THE WORKSHOP

Annex 8

Availability of opioid analgesics in Eastern Europe and the world

Slide 1



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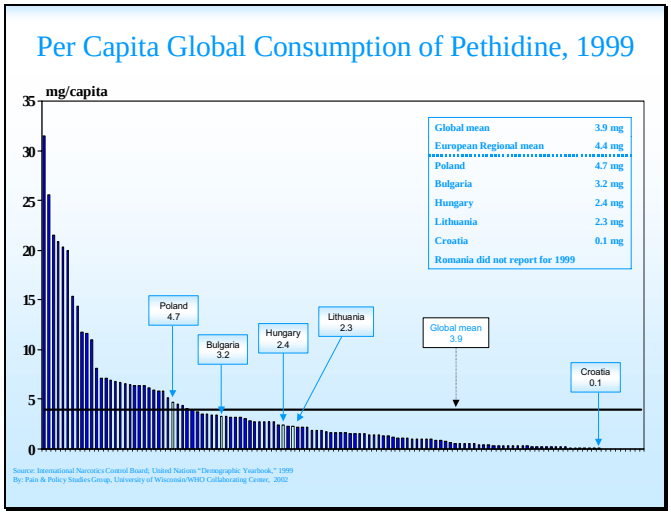


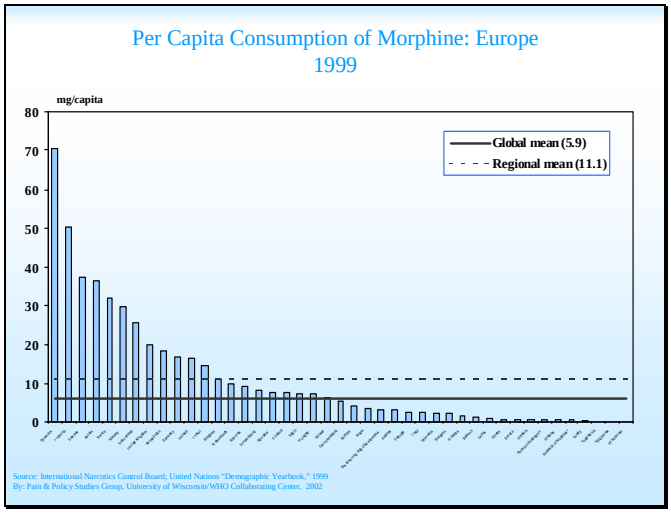
Slide 3

Consumption of Selected Opioid Analgesics, 1999 (mg/capita)

	Fentanyl	Methadone	Morphine	Oxycodone	Pethidine
Global mean	0.1	6.9	5.9	3.1	3.9
Europe Regional mean	0.1	9.3	11.1	1.7	4.4
France	0.2	2.7	31.8	0.1	1.3
Germany	0.4	9.3	16.8	1.8	2.7
Italy	0.0	12.9	2.4	6.0	0.4
Switzerland	0.2	43.4	25.7	?	11.7
United Kingdom	0.3	11.1	20.0	0.1	6.6
Bulgaria	0.0	0.8	2.0	?	3.2
Croatia	0.0	?	0.7	0.0	0.1
Hungary	0.1	0.2	7.2	0.0	2.4
Lithuania	0.0	2.3	2.2	?	2.3
Poland	0.0	0.2	6.5	0.0	4.7
Romania	?	?	?	?	?

Source: International Narcotics Control Board; United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

Slide 4



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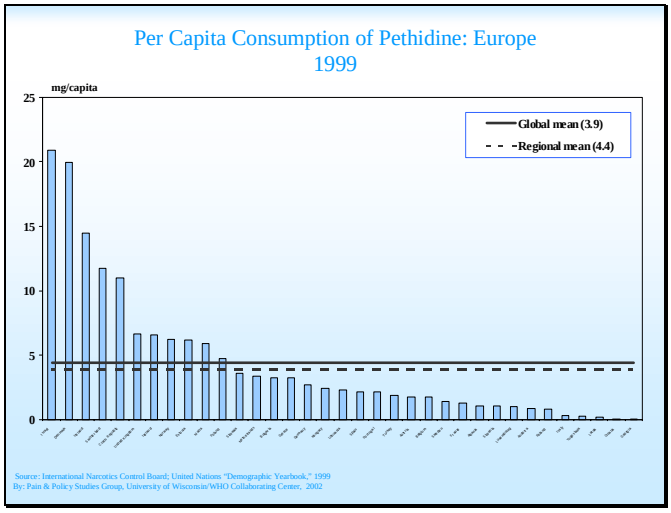

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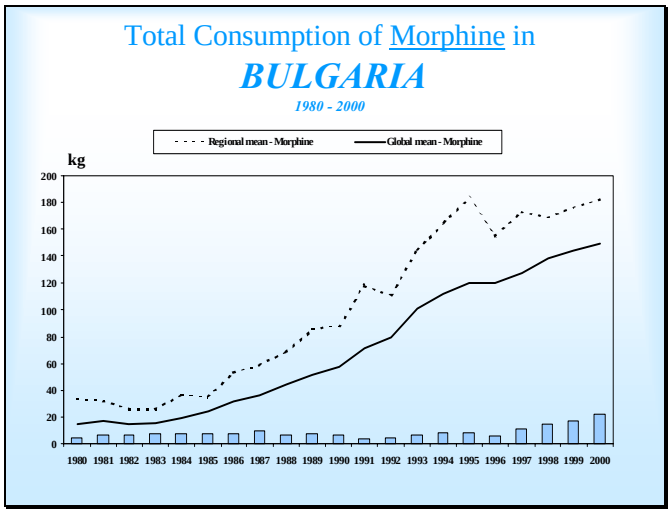

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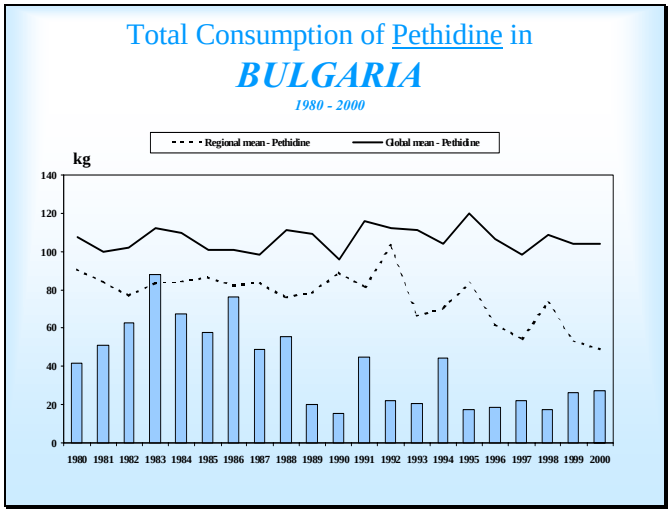

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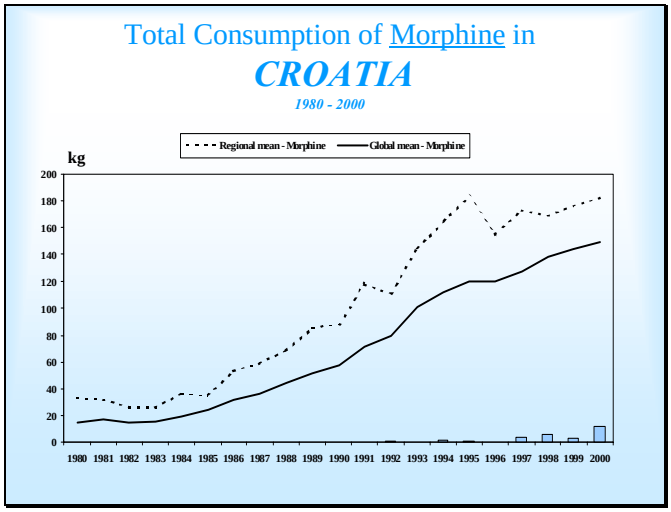

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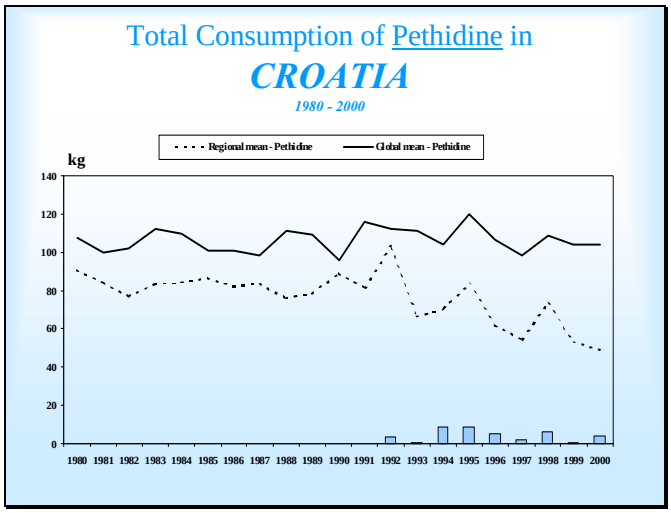
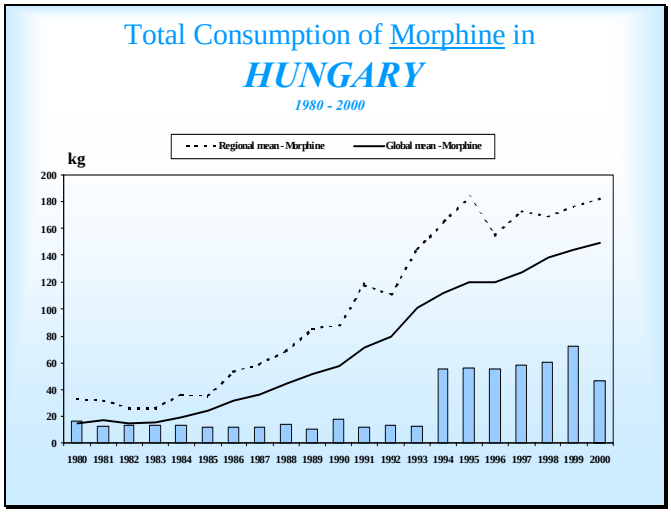


Slide 10



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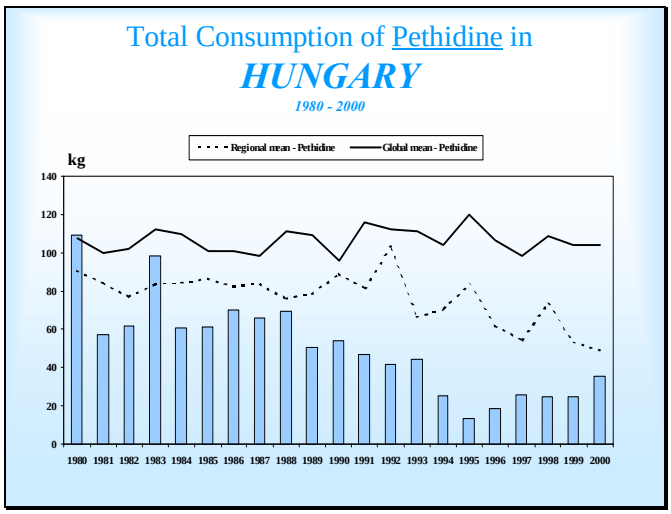

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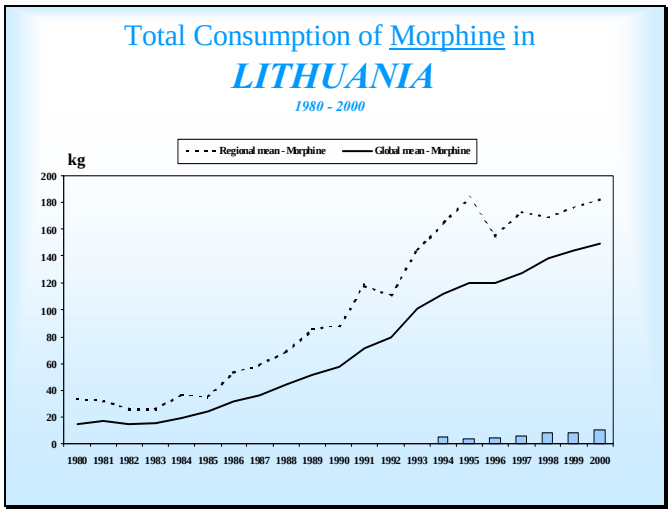

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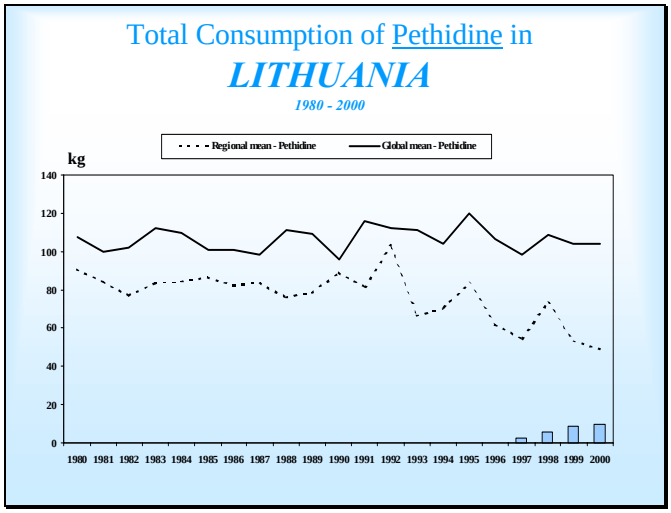

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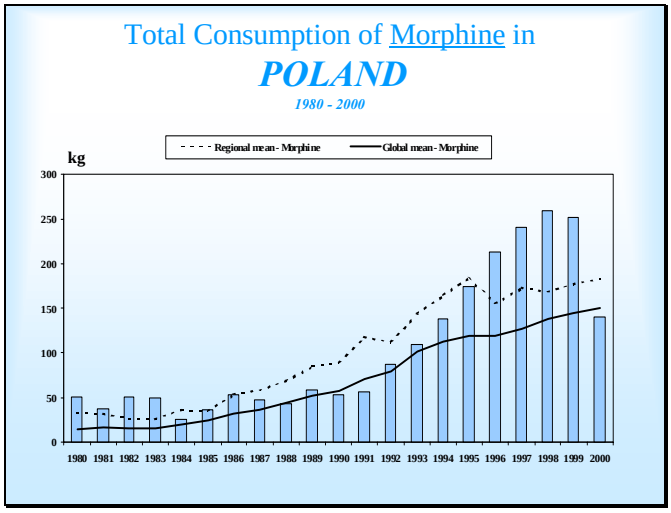

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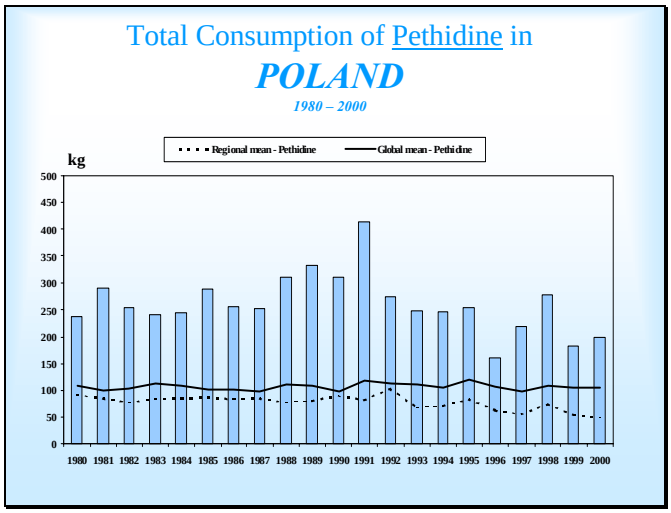

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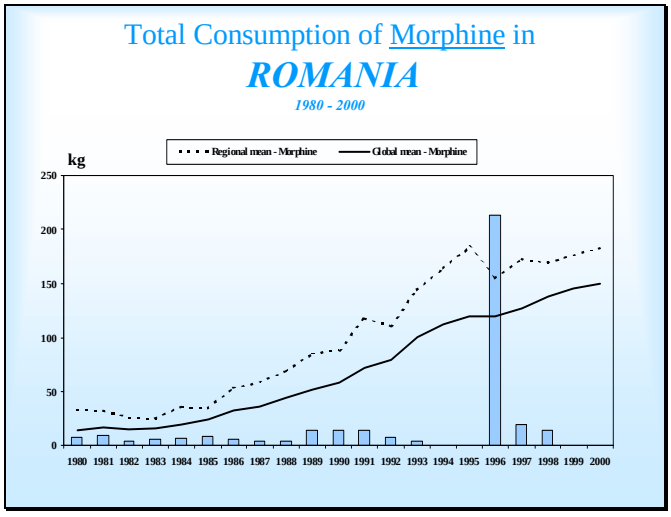

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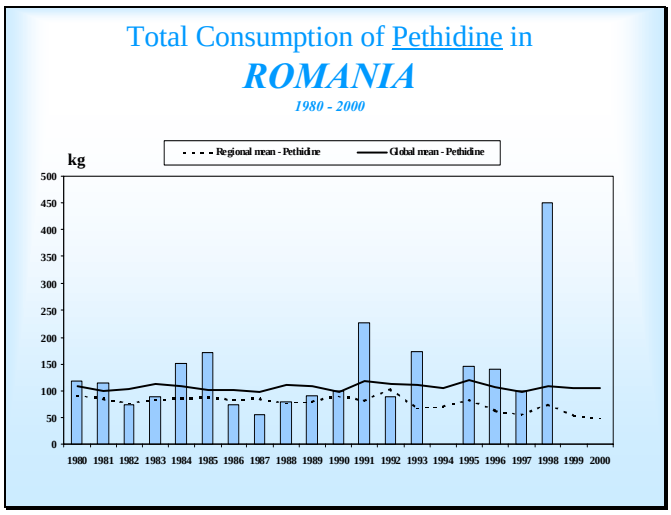

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Status of Adherence to Conventions, Receipt of Statistics, and Estimates

	Adherence			
	Single Convention 1961	As amended 1961/72	Consumption Statistics for 1999	Estimated requirements for 2001
Bulgaria	●	●	●	●
Croatia	●	●	?	?
Hungary	●	●	●	●
Lithuania	●	●	●	●
Poland	●	●	●	●
Romania	●	●	?	?

Source: International Narcotics Control Board, Narcotic Drugs, Estimated World Requirements for 2001, Statistics for 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

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Estimated requirements for selected opioids, 2001 and 2002 (in grams)

Country & Population	Year	Fentanyl	Methadone	Morphine	Oxycodone	Pethidine
Bulgaria 8,208,000	**2001**	300	10,000	58,842	947	52,156
	2002	300	14,000	50,000	500	35,000
Croatia 4,554,000	**2001**	200	80,000	10,000	?	12,000
	2002	1800	120,000	10,000	?	12,000
Hungary 10,068,000	**2001**	1,750	519	9,958,000	1,689	189,889
	2002	1,850	10,000	5,770,000	3,000	53,000
Lithuania 3,699,000	**2001**	120	10,888	12,000	1,000	6,000
	2002	75	10,000	13,000	1,000	11,000
Poland 38,654,000	**2001**	3,000	30,000	1,205,014	3,000	324,951
	2002	3,000	30,000	1,200,014	2,000	300,000
Romania 22,458,000	**2001**	375	1875	22,500	?	375,000
	2002	188	938	11,250	?	187,500

Source: International Narcotics Control Board
Quarterly Supplement, International Narcotics Control Board Estimated World Requirements of Narcotic Drugs for 2001
Advance Copy, International Narcotics Control Board Estimated World Requirements of Narcotic Drugs for 2002
United Nations "Demographic Yearbook," 1999
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2002

Annex 9

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