A Global Policy Approach to Freedom from Cancer Pain

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ESMO Congress

Vienna

September 29, 2012

Freedom From Cancer Pain

"Nothing would have a greater impact than using the knowledge we have now to improve the care of the patient with cancer pain"

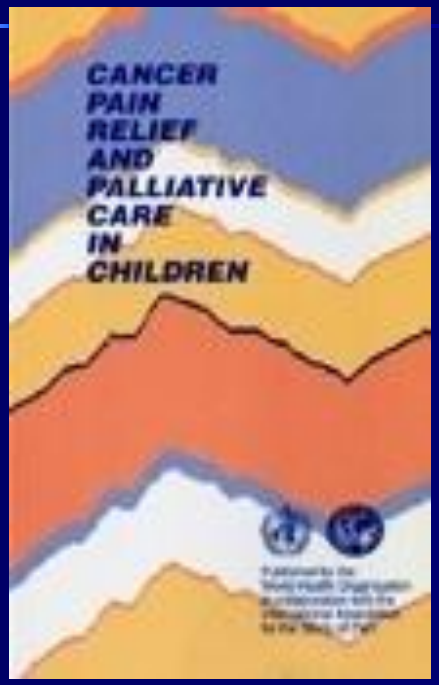
Dr. Jan Stjernsward

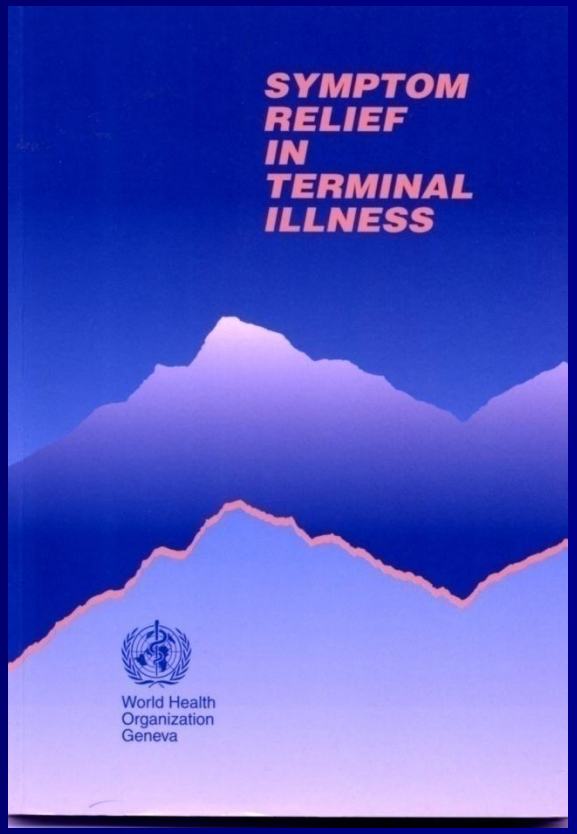
Chief, Cancer Unit, WHO,1986

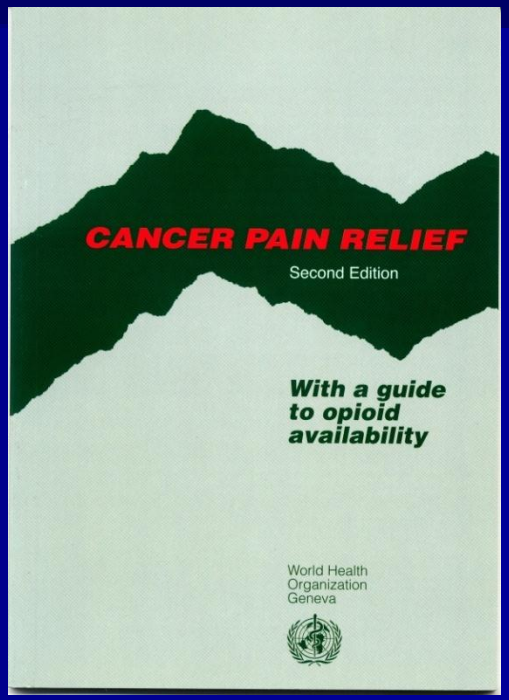
WHO Three-Step Analgesic Ladder

Source: World Health Organization, 1990.

WHO MONOGRAPHS

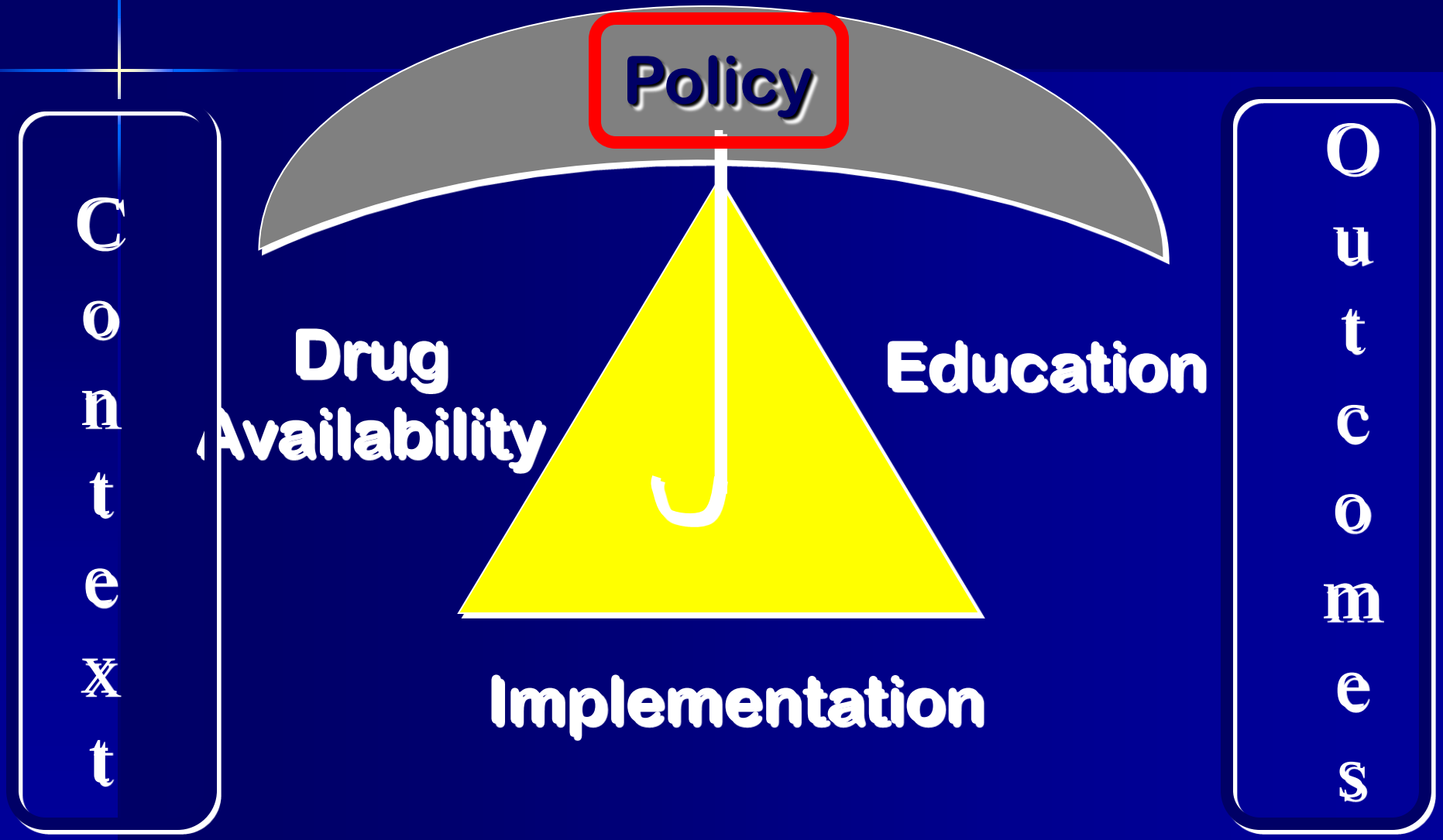






World Health Organization

WHO Public Health Model



WHO Public Health Model

Policy

- Palliative care part of national health plan, policies, related regulations
- Funding / service delivery models support palliative care delivery
- Essential medicines

(Policy makers, regulators, WHO, NGOs)

Drug Availability

- Opioids, essential medicines
- Importation quota
- Cost
- Prescribing
- Distribution
- Dispensing
- Administration

(Pharmacists, drug regulators, law enforcement agents)

Implementation

- Opinion leaders
- Trained manpower
- Strategic & business plans – resources, infrastructure
- Standards, guidelines measures

(Community & clinical leaders, administrators)

Education

- Media & public advocacy
- Curricula, courses – professionals, trainees
- Expert training
- Family caregiver training & support

(Media & public, healthcare providers & trainees, palliative care experts, family caregivers)

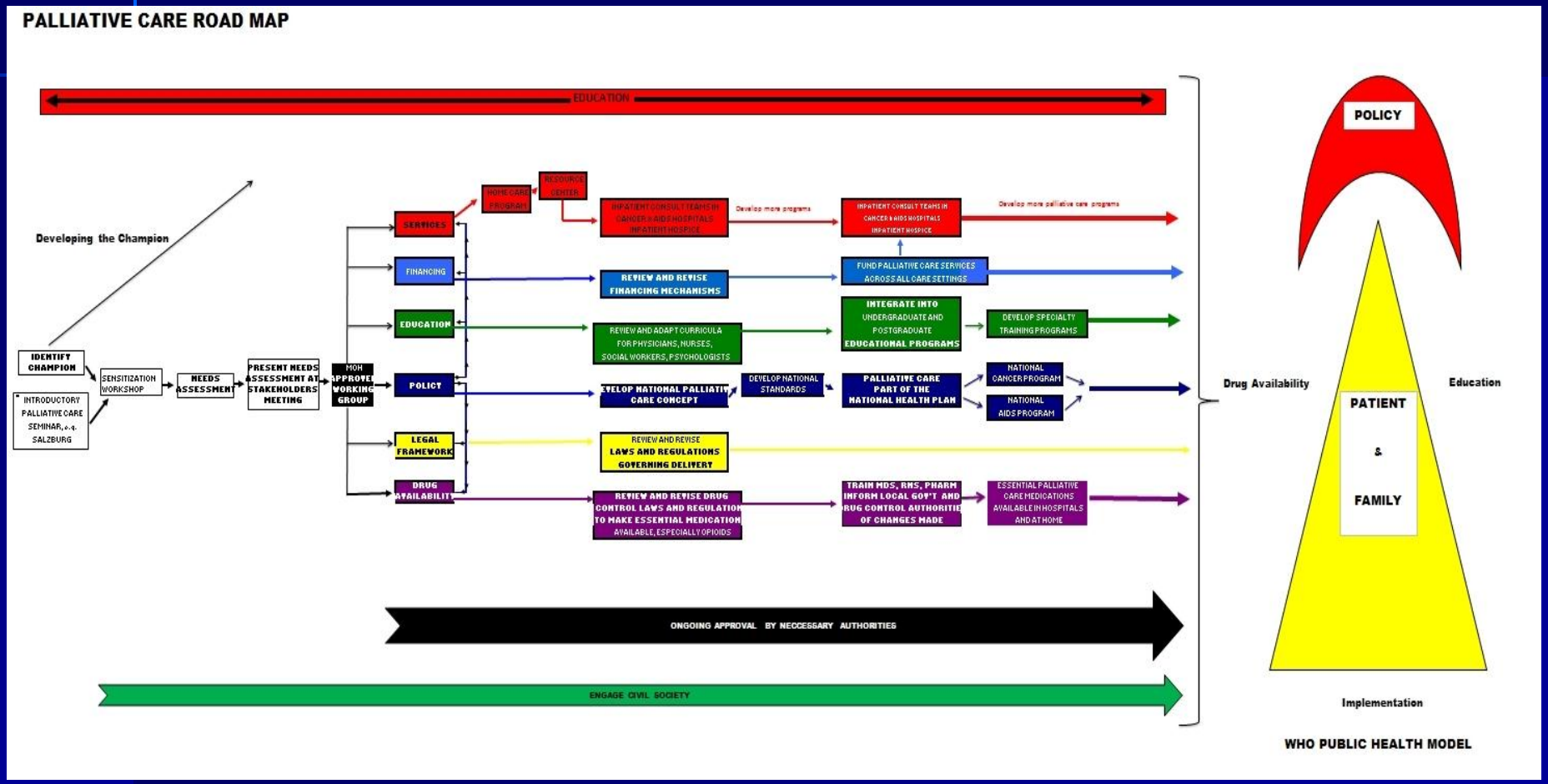
Palliative Care Roadmap

- Identify National Champions
- Complete a Country Needs Assessment
- Hold a National Stakeholders Meeting
- Create Various Government Task Forces
- Development of a Palliative Care Concept

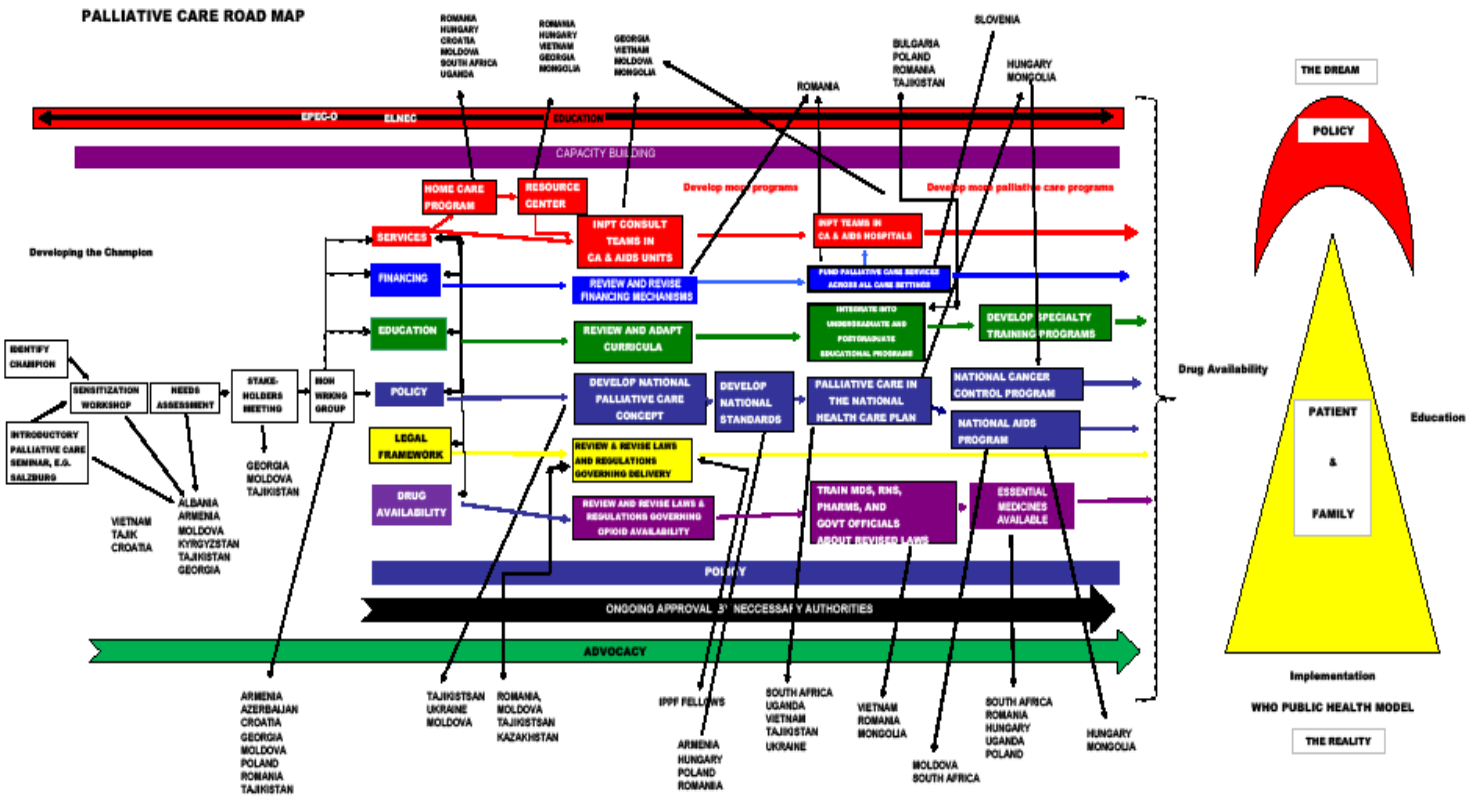
Elements of Policy Work

- International documents with symbolic language
- International documents to guide policy development
- Passionate committed champions
- Financial support for technical expertise

Palliative Care Roadmap



Palliative Care Roadmap



Council of Europe Recommendation 24

"Organization of Palliative Care" 12 November 2003

- Palliative care needs further development
- Insufficient availability of opioids
- Governments should identify legal barriers
- Legislation should make opioids available
- Fear of abuse should not hinder access

Pain & Policy Studies Group/World Health Organization Collaborating Center, 2004

INCB
Annual Report for 2004

"In view of the continued inadequate global consumption of opiates for the treatment of pain, the Board reiterates that it would welcome a further increase in global demand for opiates. The Board encourages Governments to take steps to increase the medical use of opiates in their countries in order to meet their real needs for the treatment of pain."

2005 United Nations Resolution "Treatment of pain using opioids"

Impediments include national drug regulations

Many countries have not examined impediments or removed regulatory barriers

WHO/INCB document "Achieving Balance in National Opioids Control Policy"

ECOSOC 2005

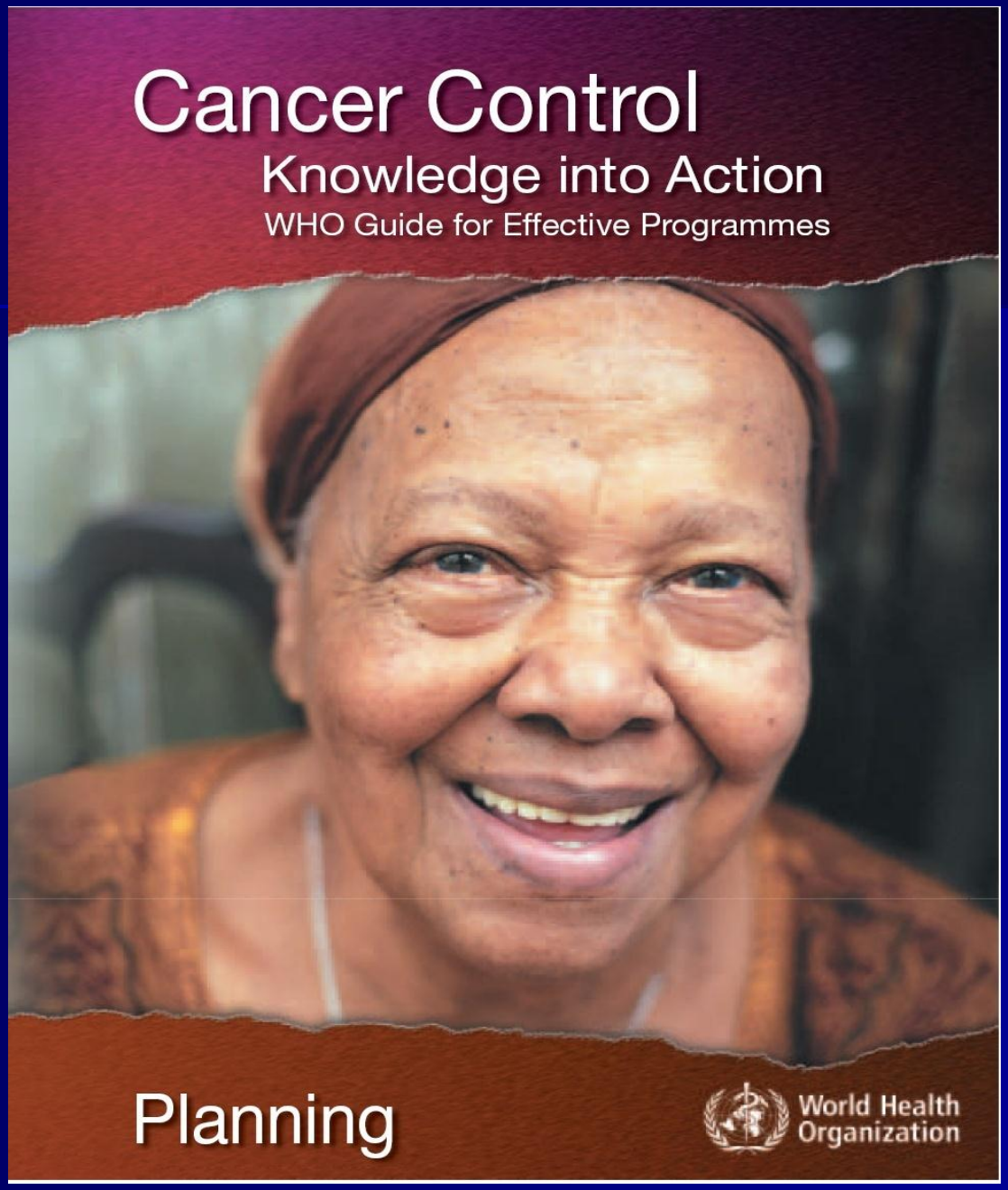
On May 2005 the World Health Assembly Adopted a Cancer Prevention & Control Resolution (WHA58.22) which:

- emphasizes the need for reinforcing cancer control worldwide
- recognizes the provision of palliative care as an urgent humanitarian responsibility
- stresses the need for improving opioid availability

Committee on Narcotic Drugs (CND)

Resolution 53/4 (March, 2010)

- Promoting adequate availability of internationally controlled illicit drugs for medical scientific purposes while preventing their diversion and abuse


Cancer Control
Knowledge into Action
WHO Guide for Effective Programmes
Planning
World Health Organization

Cancer Control

Knowledge into Action

WHO Guide for Effective Programmes

Palliative Care

World Health Organization

A sense of urgency from UN Organizations

- International Narcotics Control Board
- World Health Organization
- World Health Assembly
- UN Economic and Social Council
- Commission on Narcotic Drugs

Meeting the Challenge

- Unquestioned need to relieve pain
- Solid scientific and medical basis
- Clear Guidelines from UN Bodies
- International Narcotic Control Board
- World Health Assembly

  -Economic, Social and Cultural Council

  -UN Human Rights Rapporteurs for Health and Torture

  -Committee on Narcotic Drugs
- Acceptance of pain relief and palliative as human rights issues

United Nations Special Rapporteur on the Right to the Highest Attainable Standard of Health

- Dr. Paul Hunt, Special Rapporteur, strongly supports palliative care as a human rights issue at the UN Human Rights Council in March, 2008, he said “Many other human rights issues need urgent attention such as palliative care.” He urged that on October 11, World Hospice and Palliative Care Day that this issue would receive its proper attention.

Reasons for unavailability of opioids

- Inadequate method for assessing needs
- Unduly strict drug regulations
- Burdensome administrative procedures
- Exaggerated fears of addiction
- Fear of investigation, penalties
- Lack of training in pain management

INCB, 2002

WHO Criteria for Assessing Policy

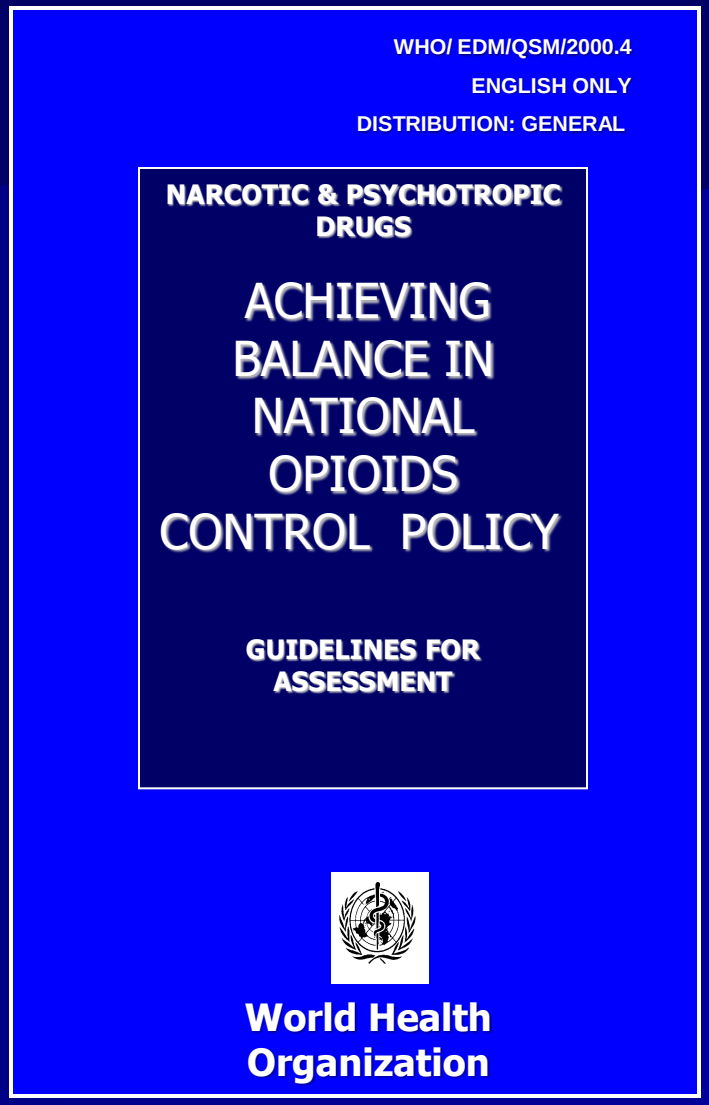
- ✓ Opioids absolutely necessary
- ✓ Gov't obligation to ensure availability
- ✓ Designate Competent Authority
- ✓ Estimate requirements; report statistics
- ✓ Address fear of legal sanctions
- ✓ Use correct terminology regarding addiction
- ✓ Avoid restrictions that limit medical decisions
- ✓ Avoid unduly strict prescription requirements
- ✓ Cooperation to ensure availability

Main Parts to Achieving Balanced Policy WHO, 2000

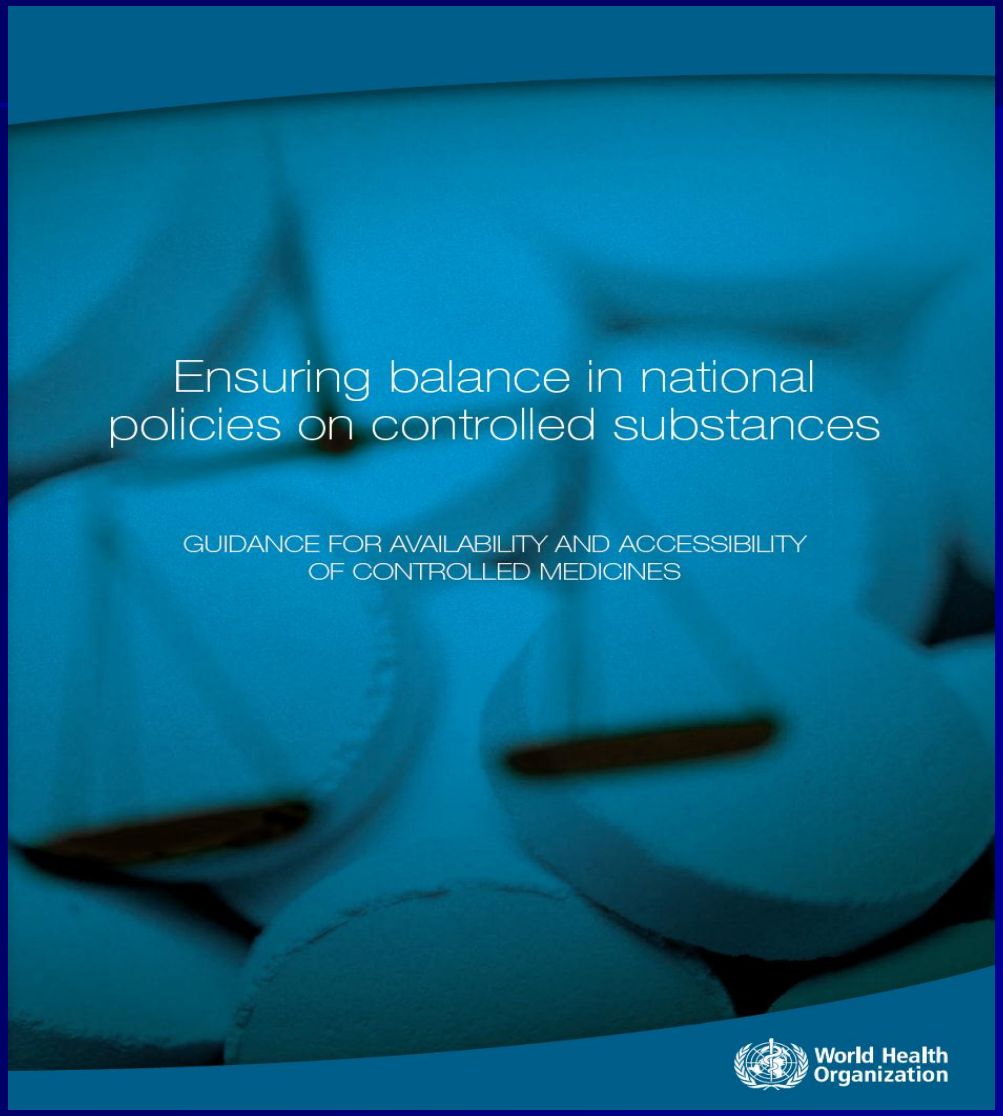
1. Evaluate national drug control policy

2. Estimate annual requirements; report consumption statistics

3. Administer an effective distribution system to patients



www.who.int/medicines/areas/quality_safety/GLs_Ens_Balance_NOCP



An introduction

12 country teams
10 partners
5 years
1 vision

The ATOME project aims to improve access to opioids across Europe. A consortium of academic institutions and public health organizations is working to help governments, particularly in Eastern Europe, identify and remove barriers that prevent people from accessing medicines that could improve end of life care, alleviate debilitating pain and treat heroin dependence.

ATOME 12 Target Countries

GAPRI | Global Access to Pain Relief Initiative

www.gapri.org

Global Access to Pain Relief Initiative (GAPRI)

Goal

Universal access to essential pain medicines by 2020

Objectives

1. Strengthen government leadership

by providing staff (fellows) and technical assistance directly to health ministries

2. Reduce cost and improve availability of medicines

by negotiating with suppliers and providing technical assistance to buyers

3. Improve clinical and regulatory policies and practice

by advocating on international, national, and facility levels

4. Improve skills and motivation of individual clinicians

by improving access to information and to other clinicians interested in pain treatment

Strategy

- Develop high-profile projects in countries with large unmet need; prompt change in neighboring countries and adoption by other organizations

UICC'S GAPRI Strategy

GAPRI Fellowship Program: Nigeria

Population: 155 million
Deaths in pain: 177,000
Coverage: <1%

Three-year partnership with the Federal Ministry of Health (FMOH)

- Placed a consultant in the Department of Food and Drug Services, FMOH as Special Assistant to the Director for Access to Pain Relief
- Placed first order for morphine in 4 years, improving regulations, training clinicians
- Working with HIV and cancer communities to integrate pain relief

GAPRI Supply Project: Uganda

Population: 33 million
Deaths in pain: 6
C %

In 2010 GAPRI brokered a deal between government and an NGO to create a national morphine production program

- Government's cost of purchasing morphine has been reduced by 40%
- Increased stability of supply and expanded access
- Morphine is now free for all patients
- Finalized a donation of morphine powder that will generate 170,000 USD to upgrade production facility and ensure its sustainability

IMPORTANT INFORMATION FOR PHYSICIANS AND NURSES

ALL HEALTH-CARE PROFESSIONALS WHO TREAT OR CARE FOR CHILDREN WITH PAIN

Persisting pain in children

Highlights for physicians and nurses extracted from the *WHO guidelines on the pharmacological treatment of persisting pain in children with medical illnesses*

World Health Organization

IMPORTANT INFORMATION FOR POLICY-MAKERS

POLICY-MAKERS AND MEDICINES REGULATORY AUTHORITIES
HOSPITAL MANAGERS
HEALTH INSURANCE MANAGERS

Persisting pain in children

Highlights for policy-makers extracted from the *WHO guidelines on the pharmacological treatment of persisting pain in children with medical illnesses*

World Health Organization

IMPORTANT INFORMATION FOR PHARMACISTS

Persisting pain in children

Highlights for pharmacists extracted from the *WHO guidelines on the pharmacological treatment of persisting pain in children with medical illnesses*

World Health Organization

International Pain Policy Fellowship
Pain and Policy Study Group
University of Wisconsin

2006 Nigeria, Serbia, Panama, Uganda,
Argentina, Columbia Sierra Leone

2008 Kenya, Moldova, Guatemala, Georgia,
Armenia, Nepal, Jamaica

2012 India, Bangladesh, Sri lanka, Albania,
Kyrgyzstan, Ukraine

Old and New Policy in Romania

35-year-old policies

- No independent prescribing authority beyond 3-day period
- Opioid analgesics limited by patient diagnosis (3)
- Limit of 60 mg per day of morphine
- 10-day prescription possible, but with very complex authorization process (expires in 90 days).
- Burdensome for physicians and patient family

New policies

- Prescribing authority granted for 30-day period

  (for physicians with specific specialties or who have received training)
- Not limited by patient diagnosis
- No limit of daily dose
- Less burdensome for physicians and patient family

Progress in Colombia

Prescription amount from 10 days to 30 days of medication, 15 December 2005

Working to improve distribution of morphine supply from warehouses in Bogota to rural areas.

Success in ensuring at least one pharmacy in each district stocks opioids 24 /7.

Actively engaging with Government authorities to address opioid access.

Colombian Senate passes new palliative care law 16 April 2009

Advocacy in 2010

- *"Cancer is killing us. Pain is killing me because for several days, I have been unable to find injectable morphine in any place. Please, Mr. Secretary of Health, do not make us suffer anymore…"*

published in Columbian Newspaper

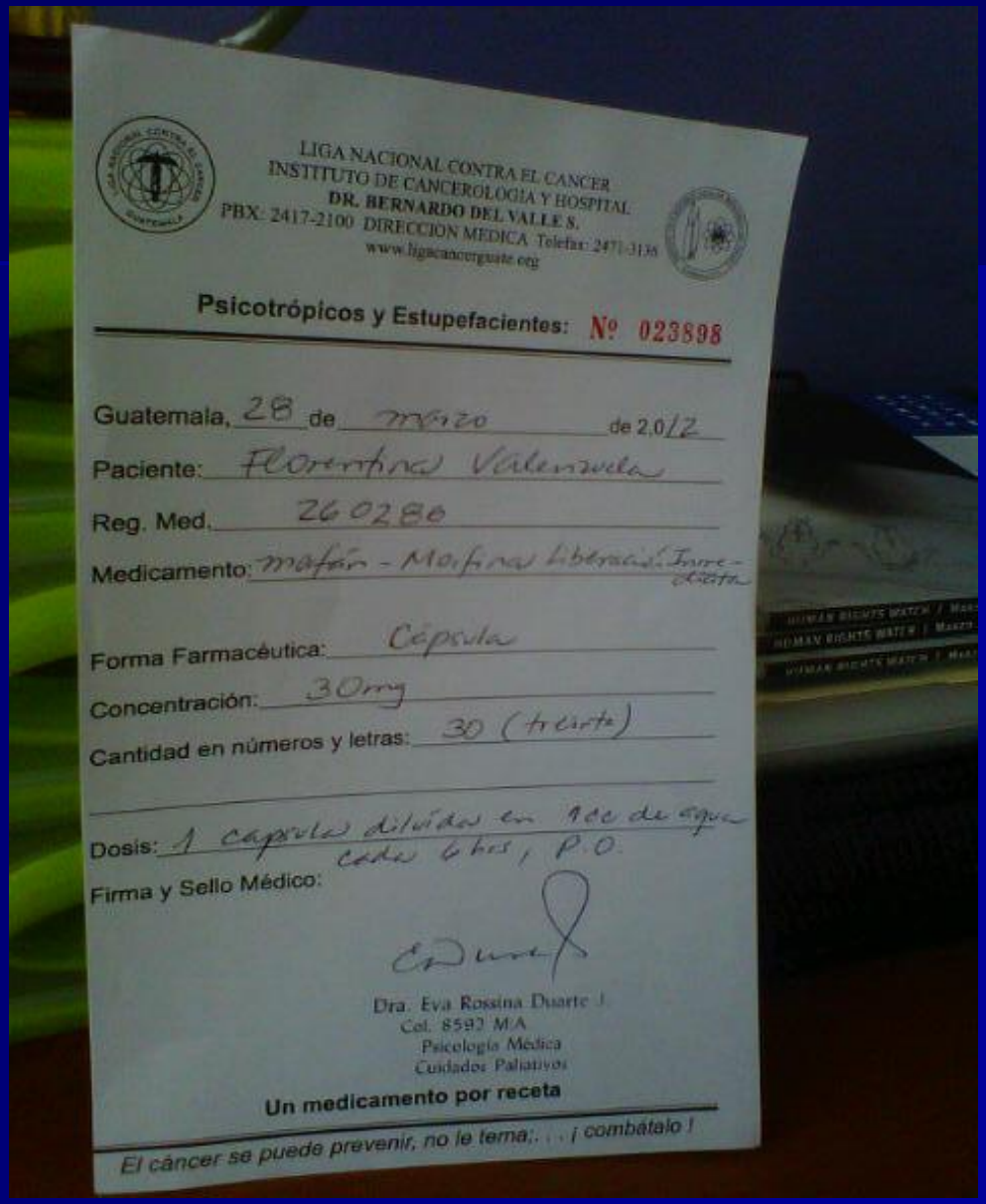
Progress in Guatemala

Working to improve distribution of morphine supply from Guatemala City to rural areas.

Efforts for training and further education around Guatemala on modern pain management, including appropriate prescribing and dispensing of opioids.

In 2009, requested by government to assist with calculating national estimated requirement for morphine.

The FIRST prescription ever written in Guatamala for immediate release oral morphine was written yesterday by Dr. Eva Duarte (OSF's International Pain Policy Fellow (IPPF) and Leadership Development Fellow) for a 72 year old woman with advanced head and neck cancer.


LIGA NACIONAL CONTRA EL CANCER
INSTITUTO DE CANCEROLOGIA Y HOSPITAL
DR. BERNARDO DEL VALLE S.
PBX: 2417-2100 DIRECCION MEDICA Telefax: 2471-3138
www.ligacancerguate.org

Psicotrópicos y Estupefacientes: Nº 023898

Guatemala, 28 de marzo de 2012

Paciente: Florentina Valenzuela

Reg. Med. 260280

Medicamento: Mafán - Morfina liberación Inmediata

Forma Farmacéutica: Cápsula

Concentración: 30mg

Cantidad en números y letras: 30 (treinta)

Dosis: 1 cápsula diluida en 100 cc de agua cada 6 hrs, P.O.

Firma y Sello Médico:

Dra. Eva Rossina Duarte J.
Col. 8593 M.A
Psicología Médica
Cuidados Paliativos

Un medicamento por receta

El cáncer se puede prevenir, no le tema;. . . ¡ combátalo !

Progress in Nigeria

Working to improve distribution of morphine supply from Lagos to rural areas.

Safety concerns in transporting the opioid pain medications are important.

Working with government authorities to begin a pilot project to transport and distribute morphine in 6 regions, under safe, controlled conditions.

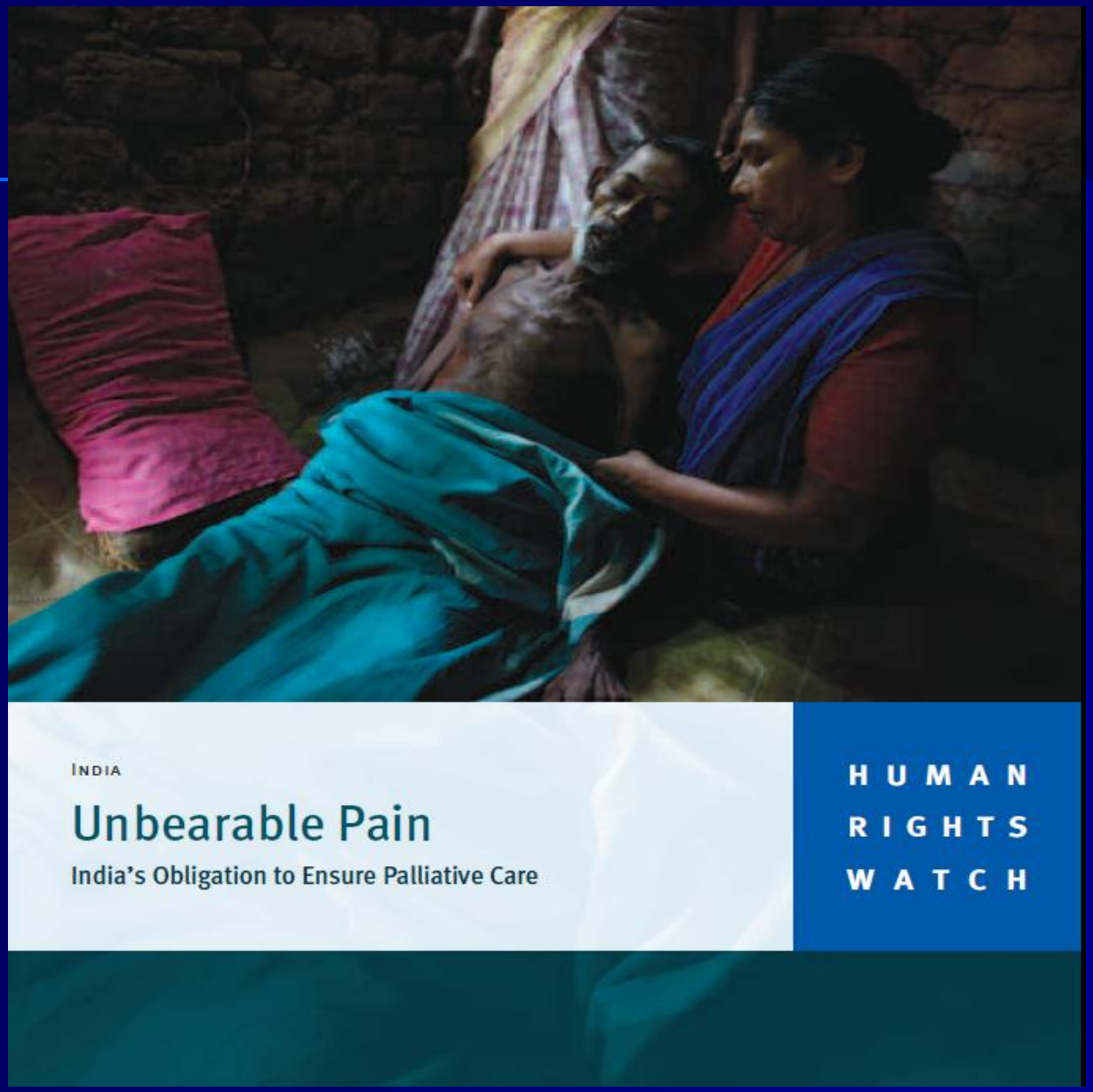
Progress in Serbia

- Central pharmacy for Belgrade region imports unregistered formulations of oral morphine, tablets. Only available to patients in the Belgrade area.
- On March 5, 2009, Government of Serbia approved and adopted National Palliative Care Strategy that recognizes:
  - opioids as essential for pain relief and palliative care, and
  - the need to examine national drug control policies and bring them into harmonization them with international conventions and EU requirements.

Progress in Armenia

- National Institute of Health (NIH) sponsored a Roundtable meeting on palliative care - 3 March 2009. Address Essential Medicines List to include oral opioids.
- Pharmacy (importer) has agreed to import if the Govt guarantees a certain amount to be purchased.
- Continuing education for physicians and pharmacists on Palliative Care accepted at NIH

http://www.hrw.org/sites/default/files/reports/health1009webwcover.pdf



The Morphine Manifesto

A call for affordable access to immediate release oral morphine.

PRESS RELEASE – 3 February 2012

KERALA, INDIA / WISCONSIN, USA — Millions of people all over the world are in needless pain because simple inexpensive medication is denied to them.

In conjunction with **World Cancer Day 2012** (4 February 2012), Pallium India, the International Association for Hospice and Palliative Care, and the Pain & Policy Studies Group / WHO Collaborating Center at the University of Wisconsin have released a Morphine Manifesto.

Signed by leading organizations and foundations from around the world, including cancer, pain management, and hospice & palliative care organizations, this Manifesto calls for an end to the unethical practice of promoting access to expensive opioid analgesics without also making available low cost immediate release oral morphine.

Furthermore, it calls upon governments, health care institutions, and the pharmaceutical industry to assure the accessibility of immediate release morphine to patients in need at a cost that the individual and community can afford.

Dr. M.R. Rajagopal, Chairman of Pallium India, and the driving force behind the creation of the Morphine Manifesto, states: *"Prolonged unrelieved pain destroys the mind; destroys the body; destroys families. Inexpensive and effective immediate release morphine can relieve most of such pain. We cannot call ourselves a cultured or ethical society if we deprive this relief to those in pain; or worse yet, benefit financially from this suffering by forcing expensive, unaffordable alternatives on them."*

Ms. Liliana De Lima, Executive Director of the IAHPC remarks: *"We hope that the manifesto will motivate governments to eliminate excessive and unnecessary regulatory requirements which affect access to opioids and to work with the pharmaceutical industry to facilitate the production and distribution of immediate release oral morphine to all patients in need."*

Dr. Jim Cleary, Director of the University of Wisconsin Pain & Policy Studies Group, asserts: *"The Institute of Medicine's recent statement that 'effective pain management is a moral imperative, a professional responsibility, and the duty of people in the healing professions' applies to the entire world. Access to low-cost immediate release oral morphine would be a great start in bringing effective pain management to the 83% of the world's population with low or non-existent access to opioid analgesics."*

Dr. Eric Krakauer of Harvard Medical School, member of the drafting team, adds: *"Access to pain relief is a human right. Making immediate release oral morphine accessible by all is a moral imperative."*

We encourage additional signatures from individuals and organizations.

Your signature will convey to government officials, health care workers, and the pharmaceutical industry that steps must be taken to guarantee the accessibility of immediate release morphine to patients at an affordable cost.

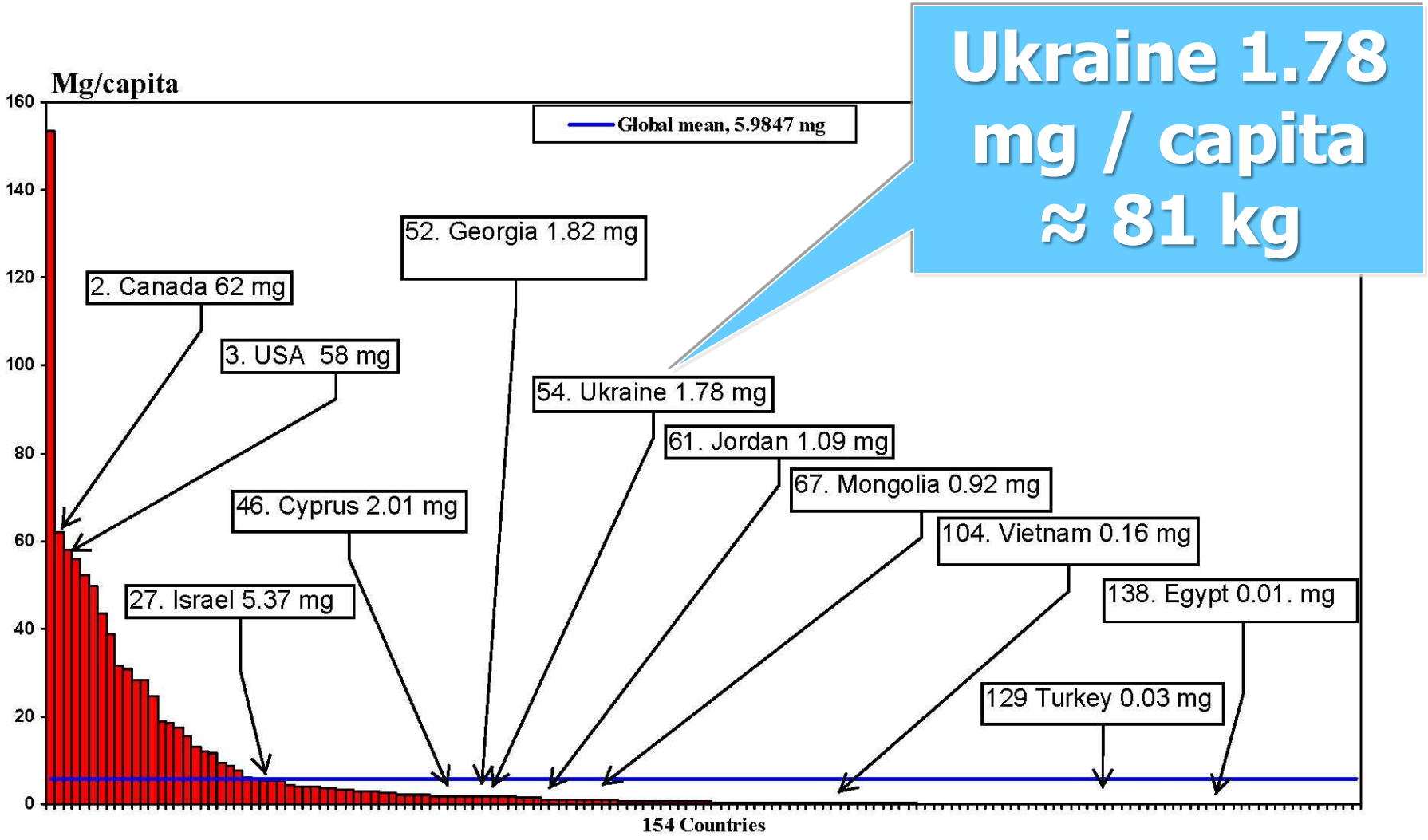
READ & SIGN THE MORPHINE MANIFESTO ONLINE AT

palliumindia.org/manifesto

Patient in South India presenting at a palliative care clinic

Patient after a dose of morphine sitting up and enjoying tea

2006 Global Consumption of Morphine



Sources: International Narcotics Control Board; United Nations population data
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2008

Uncontrolled Pain
Ukraine's Obligation to Ensure Evidence-Based Palliative Care

http://www.hrw.org/reports/2011/05/12/uncontrolled-pain

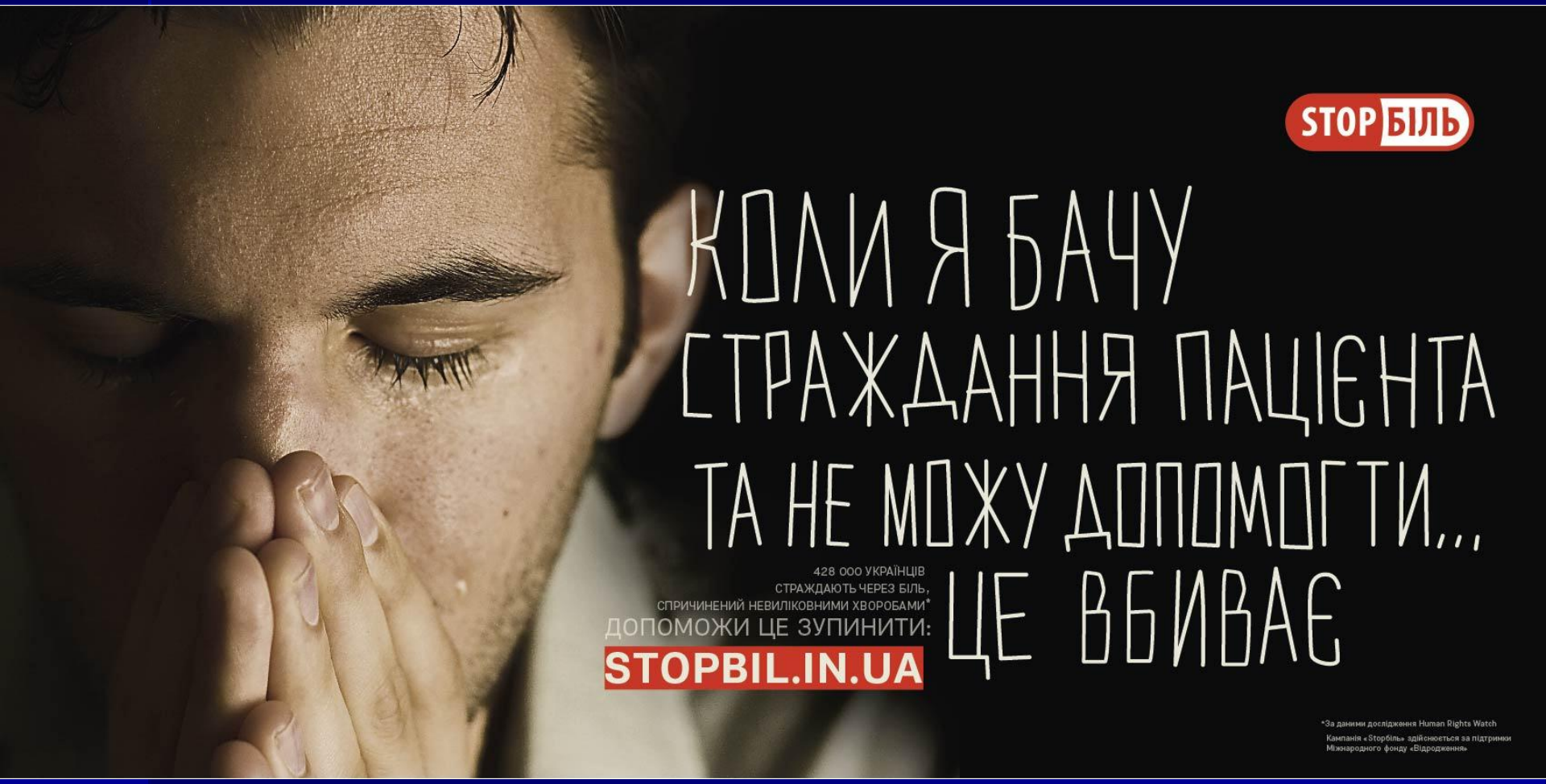
STOP TORTURE IN HEALTH CARE

People with debilitating illnesses are left to die in excruciating pain as a result of restrictions on pain medicines. Health care workers must be allowed to provide patients with relief from severe pain

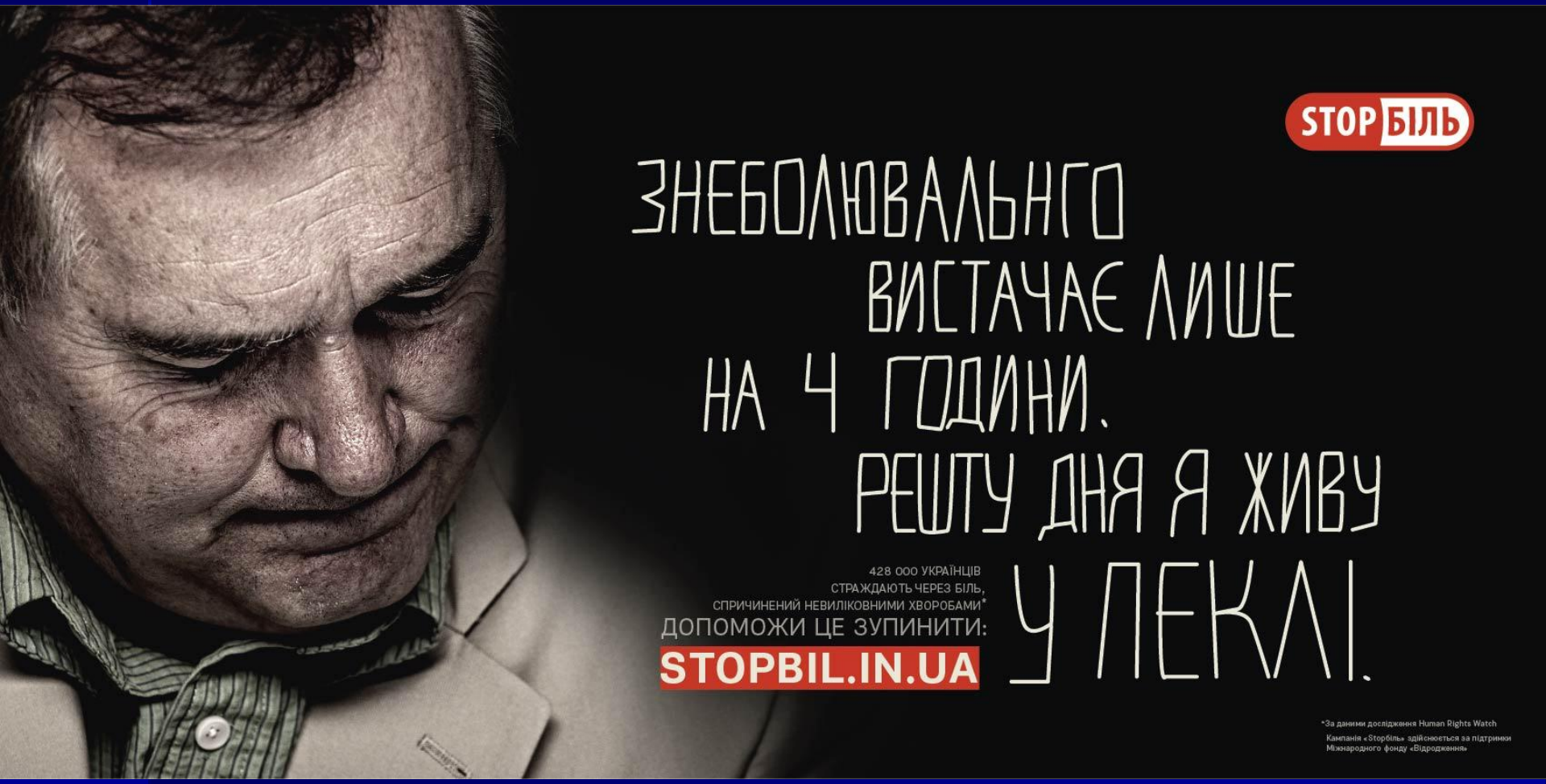
Vlad is suffering from incurable brain cancer. Despite his chronic pain, doctors in Ukraine are only allowed to prescribe 50 mg of pain medicine. In another country, doctors would typically prescribe more than 2,000 mg for a patient like Vlad.

http://www.stoptortureinhealthcare.org/

Pain crippled me more than cancer…..



Seeing my patients' suffering and not being able to help … killing me



Pain relief lasts only for 4 hours. The rest of the day I live in hell

Unlike to my illness, my pain could be treated

Uganda Case Example

- 1998 Ugandan government officials and NGO'S and WHO:
  - developed a national palliative care and pain relief policy:
  - developed new drug regulations
    updated their essential drug list
    developed country estimates for medical needs of morphine and requested additional amounts from the INCB

Uganda Case Example

- Strategic Health Plan of Uganda included palliative care as an essential service

  -added liquid morphine to the essential

  -drug list

  -adopted new set of guidelines for handling

  -morphine

  -authorized prescription by nurses(2009)

  -79 nurses and clinical officers received

  -training and 34/56 districts have drug

Policy Initiatives to Improve Access to Oral morphine in Georgia

- 2009: oral morphine available
- New regulation allows different opioids to be prescribed on a single prescription
- Primary health care physicians can prescribe independently without oversight by an oncologist or head of the medical facility

Challenges to access to oral morphine in Georgia

- Lack of dissemination of policy change
- Lack of education about oral doses for morphine
- Requirement that drugs are available at the local police station
- Requirement that prescriptions are limited to one week supply

Vietnam Case Example

- 2005- rapid assessment analysis of need for palliative care published
- 2006- MOH issued detailed guidelines to practitioners in palliative care and pain management
- 2008- government approved new guidelines on opioid prescribing and a package of training courses

American Journal of Law & Medicine
American Journal of Law & Medicine
Journal of Palliative Medicine
Journal of Palliative Medicine
Journal of Palliative Medicine
Journal of Supportive Oncology
Journal of Pain & Symptom Management
Journal of Pain & Symptom Management
Journal of Pain & Symptom Management
The Journal of Pain
The Journal of Law, Medicine & Ethics