

International Law and Access to Controlled Medications

**Advocacy for Palliative Care in Africa
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Overview

- The drug control system
- Controlled medicines
- Important to whom?
- International law and access
- WHO's Access to Controlled Medications Programme
 - Main focus
 - Priorities
 - How can the ACMP assist *you*?



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The Drug Control System

A Bit of History

- Until 19th century: colonial powers traded opium in Asia
- Drug Control goes back on
 - 1909 Shang Hai conference
 - 1912 Opium Convention (The Hague)



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Drug Control

- Single Convention on Narcotic Drugs (1961)
- Convention on Psychotropic Substances (1971)
- Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)

"Single" in *Single Convention* refers to unification of multiple treaties (1925-1931-1936-1946-1948-1953)



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Drug Control

1961 and 1971 Conventions

- Prohibition as basic principle
- Healthcare professionals and patients don't need a licence

Countries may apply stricter measures



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Drug Control

1961 and 1971 Conventions:

Two goals:

1. Prevention of harm from drug dependence
2. Availability for rational medical use

Any control measure taken should aim at the optimum for availability *and* prevention



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The UN system and drugs

- Commission on Narcotic Drugs (CND)
- International Narcotics Control Board (INCB)
- United Nations Office on Drugs and Crime (UNODC)
- World Health Organization (WHO) - Geneva



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Role of WHO

- Substance evaluation
 - Scheduling recommendations to the CND
 - Expert Committee on Drug Dependence
- Nomination of 3 INCB members



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Expert Committee on Drug Dependence (ECDD)

Links to all ECDD reports 1949 – 2006 at

www.who.int/medicines

Go to: Quality and Safety

then to: Substances under international control

Report of 34th ECDD (March 28-31, 2006):

English version available

French, Spanish, Russian and Chinese to follow soon



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Controlled medicines

Categories of Controlled Medicines

- Opioid analgesics
- Opioids for substitution treatment
opioid dependence
- Ergotamine and ephedrine
emergency obstetrics
- Benzodiazepines
anxiolytics and hypnotics
- Phenobarbital
anti-epileptic



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Opioid analgesics

All moderate to severe pain:

- Cancer pain
- AIDS/HIV
- Surgery
- Traffic and other accidents
- Myocardial infarction
- Sickle cell anaemia
- Chronic pain
 - neuropathies (some)
 - post-surgery pain



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Opioid analgesics

WHO Three step ladder on cancer pain (1986)
– still actual

1. Non-opioid + adjuvant e.g. paracetamol
If pain persisting/increasing:
2. Weak acting opioid (e.g. codeine, tramadol)
If pain persisting/increasing:
3. Strong acting opioid (e.g. morphine, methadone)
Increase dosage until freedom from pain
(no maximum)



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Substitution therapy

Methadone solution

(not: tablets)

Buprenorphine sublingual tablets

(not: injections)

Supervised

Prevention of use of contaminated needles

- Injected Drug Use (IDU) threatens individual *and public* health
- IDU HIV epidemics link to sexually transmitted HIV epidemics



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Substitution therapy

- Prevents transmission of HIV and Hepatitis C
- Reduces death rate of dependence patients to about normal
- Reduces public nuisance and petty crime

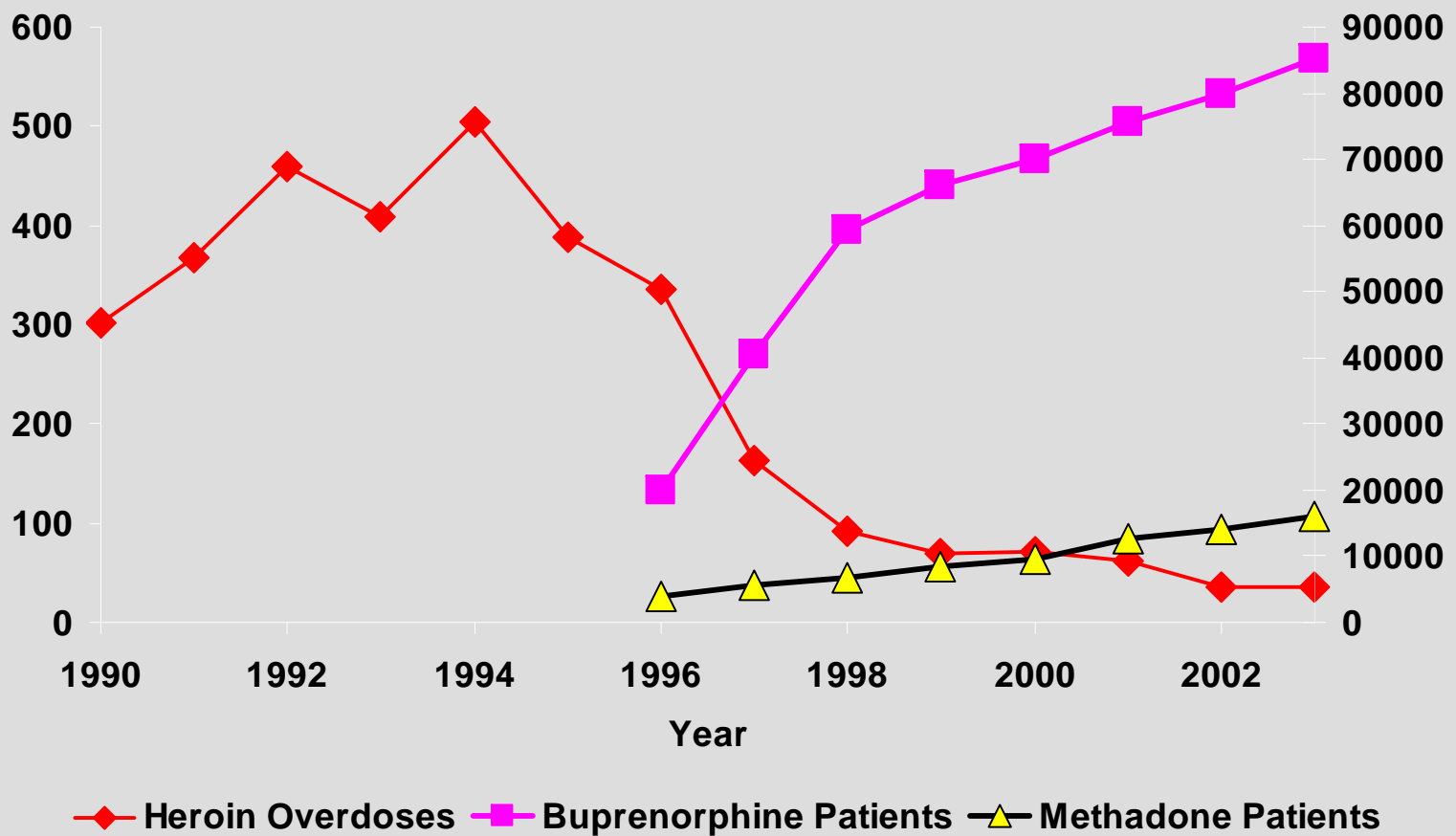
Most evidenced based medication there is



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Important to opioid dependent patients

IDU mortality in France



With acknowledgement to Patrizia Carrieri, INSERM, Marseille, France



World Health Organization

Substitution therapy

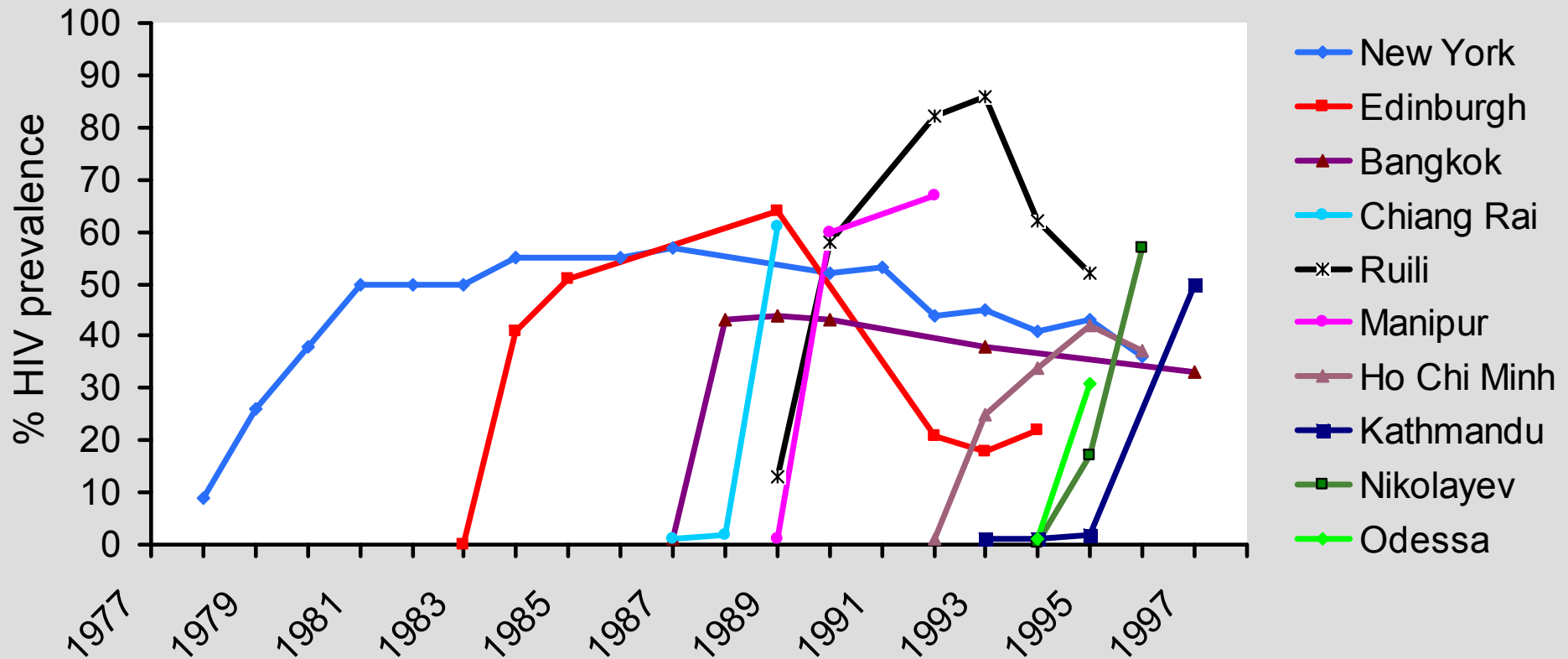
- Globally 30% of all new HIV cases are IDU related
- In Russian Federation: 90%
- Africa: low, but should not be neglected

New programmes: China, Iran



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Opioid dependence and HIV



The HIV prevention challenge

Rapid increases in HIV prevalence among IDU's
> 40% may be reached within two years
Uncontrolled epidemics



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Delivery



Photo WHO/Antonio Suárez Weise

Obstetrics

- Ergotamine
 - stops excessive bleeding after giving birth
 - used in LSD production
- Ephedrine
 - if blood pressure falls during anaesthesia in giving birth
 - used in methamphetamine production
- Can be life saving
- 1988 Convention



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Precursors

- Ergotamine
 - stops excessive bleeding after giving birth
 - used in LSD production
- Ephedrine
 - if blood pressure falls during anaesthesia in giving birth
 - used in methamphetamine production
- 1988 Convention
- Can be life saving



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Access important to whom?

Millions have a drug problem

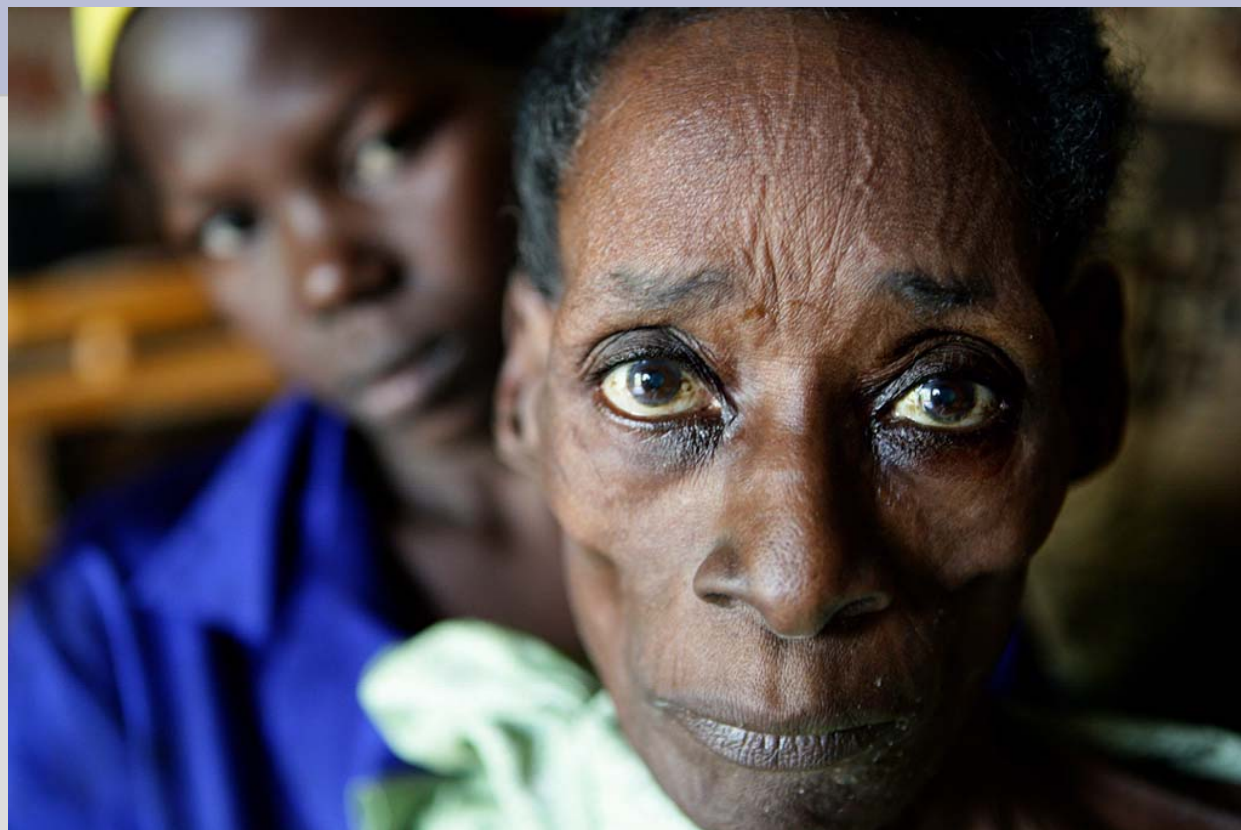


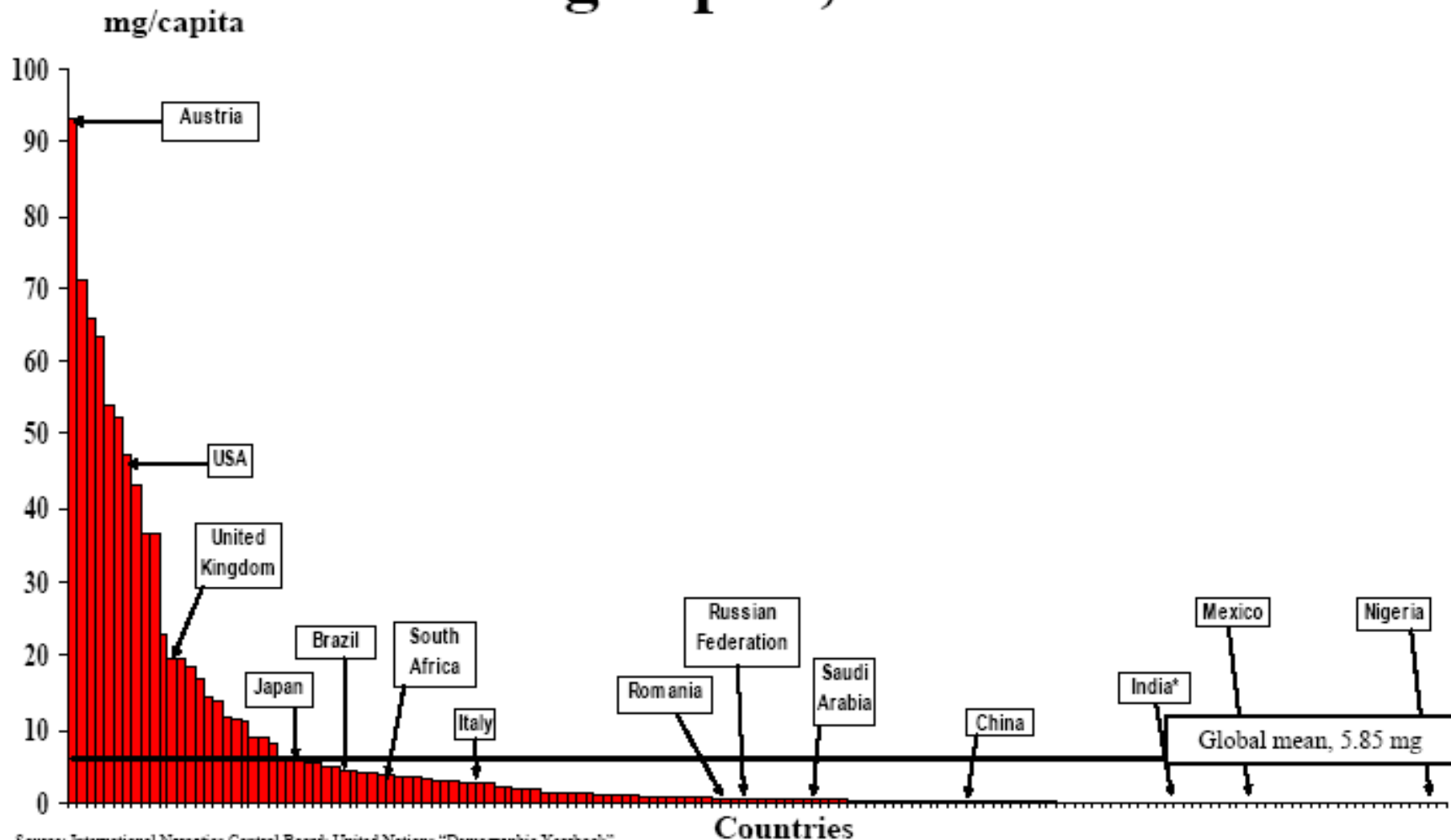
photo: WHO/Marko Kokic

They can't get any



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Global Consumption of Morphine mg/capita, 2003



Source: International Narcotics Control Board; United Nations "Demographic Yearbook"
By: Pain & Policy Studies Group, University of Wisconsin/WHO Collaborating Center, 2005
* 2001 Reporting Data

The global mean is calculated by adding the individual mg/capita statistics for all countries and then dividing by the number of countries



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Important to cancer patients

Cancer pain

- 12 % of all death causes (globally; increasing!)
= 7.5 mln cancer deaths annually
- 80% have no access to opioid analgesics
- 80% terminal stage cancer patients suffer from moderate to severe pain

→ 7.7% (= $0.12 \times 0.8 \times 0.8$) of all people in the world will suffer from cancer pain **that can be treated, but will not be treated** (4.8 mln annually)

Sources: based on cancer and HIV/AIDS deaths in 2001, WHR 2002 and INCB statistics



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Important to HIV patients

HIV in developing countries:

- Terminal HIV/AIDS patients: 2,866,000
- Almost 100% have no access to opioid analgesics
- 50% terminal stage AIDS patients suffer from moderate to severe pain

→ 1,433,000 HIV/AIDS patients will suffer from pain that can be treated, but will not be treated

Sources: based on cancer and HIV/AIDS deaths in 2001, WHR 2002 and INCB statistics



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Important to all pain patients

- Cancer and HIV/AIDS pain:
6,233,000 untreated (annually)
576 million untreated (lifetime)
- Other moderate/severe pain:
? million untreated

All avoidable with controlled medications



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Important to prevention of HIV and HCV

HIV/AIDS and its transmission

- 13,1 million IDUs globally
- 5 % of all people living with HIV/AIDS are IDUs
- 1,400,000 new infections annually (2005; excl. sub-Saharan Africa)¹
- *30% of all new cases* outside sub-Saharan Africa are IDUs (20-90%) = *420,000 annually*
Treatment of dependence w/ contr. medications prevents many of these new HIV cases

¹ Source: UNAIDS Global Facts and Figures 06



Important to opioid dependent patients

- Opioid dependence (by injection)

2 – 3 % mortality rate

Over 90 % avoidable w/ controlled medications



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" Have halted by 2015 and begun to reverse the spread of HIV/AIDS "

Millennium Development Goals, target 7



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Important to pregnant women and their families

- Maternal mortality:
500 000 deaths (annually)

*Some of them avoidable with contr. medications
(130.000?)*



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**" To reduce by three quarters
maternal mortality ratio between
2006 and 2015 "**

Millennium Development Goals, target 6



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Important to *everybody*

(annual prevalence)

Cancer pain	4,800,000
HIV/AIDS pain	1,433,000
Other mod-severe pain	Millions ?
HIV transmission	420,000
Maternal mortality	130,000?
Opioid dependence mortality	2-3% → 0.2–0.3%



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Important to *everybody* (lifetime)

Cancer pain	540 mln
HIV/AIDS pain	36 mln
Other mod-severe pain	Hundreds of millions?
HIV transmission	Tens of millions

ws3



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Slide 35

ws3

UNAIDS global fact and figures 06 :in 2005 there are 38.6 mln people living with HIV/AIDS, of which 2 mln in western Europe and Northern America. The remainder almost none of them will have access to opioid analgesics.

Willem Scholten, 10/2/2006

10 % of World Population affected

In total affected

- ***Over 6,500,000 (annually)***
- ***Between 600 million to 1 billion (lifetime)***



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***Is there anybody who has NO
interest in good access to
controlled medications?***



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Causes

Barriers for access

- Fear of diversion
- Fear of dependence



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Political and Regulatory Barriers

Inappropriate laws and regulations

- Malfunctioning of estimate system (afternoon)
 - Too much red tape
 - Limitations on prescriptions
 - Prescription forms
- and much more...



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Attitude and Knowledge Barriers

Physicians

- Fear for dependence
 - Not prescribing
 - Pseudo-dependence (too low dosage → not pain free → patient asks for next dose → doctor believes patient is dependent)
- Unfamiliarity
 - Technique of treatment
- Learned not to treat symptoms

Patient and family

- Association morphine \leftrightarrow impending death
- Conviction that suffering is purifying



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Economical and Procurement Barriers

- General issues as for other medicines
- Separate distribution systems for controlled medicines



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Access and International Law

Drug conventions

Recognizing that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes ...

(Preamble Single Conv. on Narcotic Drugs)



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Drug conventions

Recognizing that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted...

(Preamble Psychotropic Substances Convention)



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Viewpoint of INCB

“In many countries, consumption [of opioid analgesics] remains extremely low in comparison to medical need, and many national governments have yet to address this important deficit.”

(International Narcotics Control Board, 1996)



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The Right to Health

“The State Parties to the present covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health....”

(International Covenant on Economic, Social and Cultural Rights, article 12, para. 1)



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The Right to Health

- Chronically and terminally ill
 - Spare avoidable pain
 - Die with dignity
- Access to Essential Medicines included
- Non-discrimination
 - Women, children, prisoners, HIV-patients, drug dependents et cetera
- Protection against drug abuse
- Government responsible, not MoH only
- States, treaties and UN-bodies should promote right to health internationally

(General Comment 14 to the International Covenant on Economic, Social and Cultural Rights)



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The Access to Controlled Medications Programme

(ACMP)

Programme description

Framework to the ACMP
(WHO in agreement with the INCB)

Joint report by INCB and WHO to the
CND and World Health Assembly

Operational Plan for Phase I (2008 –
2013)



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Programme activities

- Advocacy workshops
- Review of national legislation
- Training for making estimates and statistics
- Procurement workshops
- Development of clinical guidelines on pain
- Training of health-care professionals



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Priority countries

Principle of *return on investment*:

First finish, where advocacy workshops (et cetera) were held already

e.g.

certain African countries

Eastern Europe

India

Some other countries



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How can the ACMP assist you?

Assistance with

Review of legislation

Organization of training (estimates, health-care professionals)

Procurement

Curriculum of Medical/Pharm/Nurses schools

Training

And other. ASK!!!



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"... our independence is meaningless unless it is linked up with the total liberation of the African Continent"



Dr Kwame Nkrumah,
6 March 1957



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**"... and freedom from pain should
be part of this liberation..."**

..starting 9 May, 2007



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