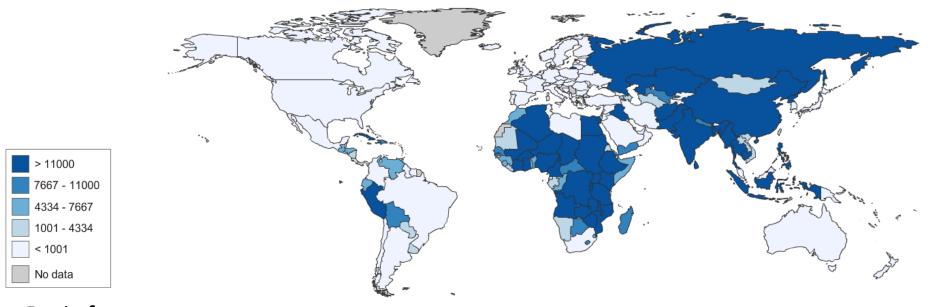


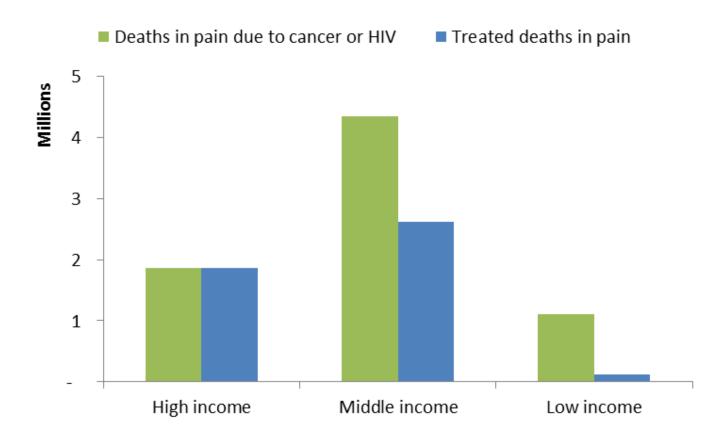
Meg O'Brien, Ph.D.
October 2013

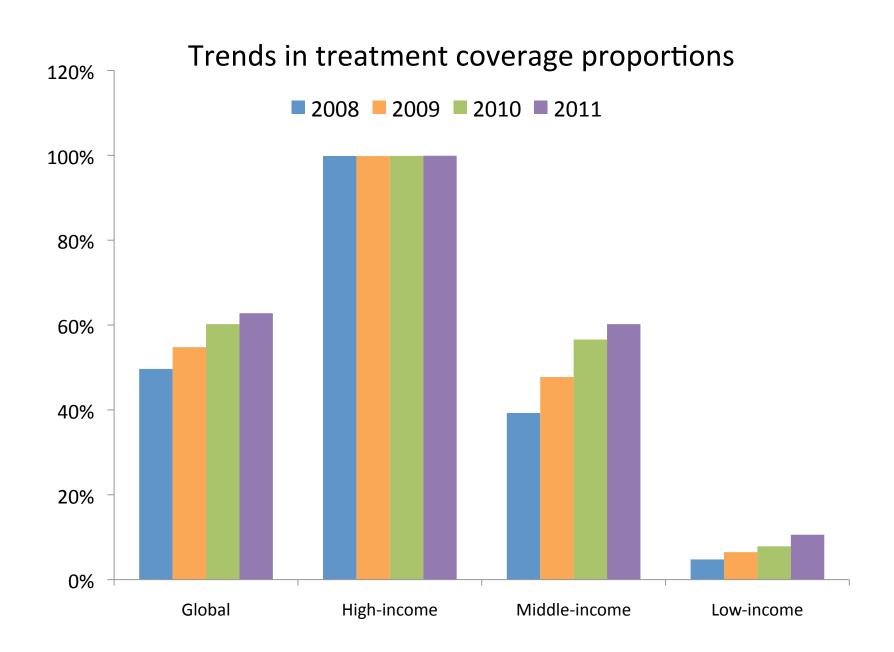
Data: Untreated deaths in pain in 2011



Basic facts

- Globally, 7.3 million people die of HIV or cancer with moderate to severe pain each year
- 2.7 million of these deaths in pain were untreated in 2011
- More than 99% of untreated deaths in pain are in low or middle-income countries
- Low and middle-income countries are home to 70% of cancer deaths and 99% of HIV deaths, but consume just 7% of the world's opioids





Overview

Goal

Universal access to essential pain medicines by 2020

Strategy

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

Objectives

1. Strengthen government leadership

by providing staff and technical assistance 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

The MORPHINE framework

















Mindset| Organize |

Regulations

rocurement

Healthworker

Initiation

Nationalization

Empowerment

Ensure that policy makers understand the issues and are prepared to take a lead role Consult stakeholders to map process and barriers to access

Ensure that they are up-to-date or identify needed changes

Establish budget for drug purchase, storage, and distribution. Estimate quantities, identify suppliers, secure product registrations, develop tenders, place and pay for orders, and receive and distribute to regional medical stores

Organize awareness-raising activities, in-service training, and continuing medical education; develop reference materials and guidelines Establish pain treatment by trained clinicians, usually at large clinical centers or specialized clinical units Integrate into service delivery at regional and district hospitals and ensure adequate geographical coverage to make pain relief accessible to all who need it Create a sustainable stakeholder base





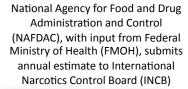
INCB approves morphine quantity



MOH Pharmacy Dept places order with international supplier and NAFDAC approves importation



Drugs received by Central Medical Stores in Lagos





Patient receives monitoring and follow-up



Patient fills prescription







Clinician writes prescription



Patient reports pain



Powder is reconstituted into solution



Registered pharmacist, on behalf of a health facility, gets approval from state MOH



Registered pharmacist, on behalf of a health facility, gets approval from Central Medical Stores Lagos



Registered pharmacist picks up drugs at Central Medical Stores Lagos



National Agency for Food and Drug Administration and Control (NAFDAC), with input from Federal Ministry of Health (FMOH), submits annual estimate to International Narcotics Control Board (INCB)



INCB approves morphine quantity

MOH is not ordering; last order expired before use

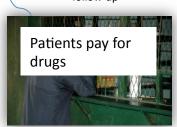
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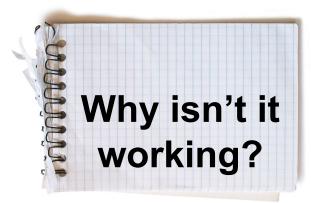
Drugs received by Central Medical Stores in Lagos



Patient receives monitoring and follow-up



Patient fills prescription



Clinician asks about pain



Clinician writes prescription

Lack of awareness from patients; lack of trained clinicians

Patient reports pain

Limited capacity for reconstitution outside of large facilities; lack of quality control

Powder is reconstituted into solution



Registered pharmacist, on behalf of a health facility, gets approval from state MOH



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Supplier identification and negotiation



Patient receives monitoring and follow-up



Patient fills prescription



Clinician writes prescription



Integrate pain treatment into HIV and cancer care

Clinician asks about pain

Lack of

Collaborate with NGOs to improve awareness

Patient reports pain

for reconstitution putside of large acilities; lack of uality control

Powder is reconstituted into solution

Users did not know morphine was available

Communication of availability



Streamline approvals

a health facility, gets approval from state MOH

Track and monitor stocks



Improve distribution

Central Medical Stores Lagos

Difficult for facilities far from Lagos

Registered pharmacist picks up drugs at Central Medical Stores Lagos

Process step	Challenges	Solutions
1. National Agency for Food and Drug Administration and Control (NAFDAC), with input from Federal Ministry of Health (FMOH), submits annual estimate to International Narcotics Control Board (INCB)	Annual estimates of demand are far below need and approved quantities are not procured	 Create credible forecasts of need and demand Monitor stocks to update forecasts and prevent stock-outs and overstocks
2. INCB approves morphine quantity	None identified	None needed
3. MOH Pharmacy Dept places order with international supplier and NAFDAC approves importation	 No order has been placed in >1 year Lack of registered suppliers for drugs High price of morphine powder 	 Place an immediate emergency order for morphine powder Identify potential suppliers and negotiate more favorable terms for FMOH for long- term procurement
4. Drugs received by Central Medical Stores in Lagos	 End users, such as pharmacists and hospital administrators, have not been aware that morphine powder was in stock 	 Create a system to communicate availability to end users and respond to questions or problems
5. Registered pharmacist, on behalf of a health facility, gets approval from state MOH	Approvals take a long time	 Streamline the approvals process by creating pre-approvals of facility-level quotas
6. Registered pharmacist, on behalf of a health facility, gets approval from Central Medical Stores Lagos	 Transportation and lodging costs are high, particularly for end users far from Lagos 	 Reduce time spent in Lagos by streamlining approvals
7. Registered pharmacist picks up drugs at Central Medical Stores Lagos	 Transportation and lodging costs are high, particularly for end users far from Lagos 	 Reduce time spent in Lagos by streamlining approvals
8. Powder is reconstituted into solution	Limited capacity for reconstitution outside of large facilities Quality control is limited	 Implement quality assurance and quality control program in cooperation with reconstituting centers Refurbish national production facility to centralize reconstitution
9. Clinician asks about pain	 Lack of awareness about pain and evidence- based treatment 	 Improve clinical training by integrating pain relief into in-service and continuing medical education
10. Patient reports pain	Lack of awareness and fear that palliative care means giving up treatment	Work with non-governmental organizations and civil society groups to sensitize patients
11. Clinician writes prescription	None identified	None needed
12. Patient fills prescription	Morphine may be too costly for patients	 Pass on lower prices from suppliers to patients
13. Patient receives monitoring and follow-up	Limited community health resources	 Integrate effective pain relief into HIV and cancer treatment programs

Progress highlights

Nigeria

- Government has procured and is distributing 21kg of morphine
- Price for patients has decreased by 80-90%
- A second procurement of 16kg of morphine is underway

Uganda

- Initial government contract completed: 47kg of morphine distributed over two years; contract renewed
- Facilitated a product donation of 85kg to supply for the next two years
- Brokered a product donation of 50kg of bronopol preservative used in oral morphine solution that will be stored in Uganda and made freely available to countries starting up morphine production in the region

Kenya

- Sponsored a government delegation to Uganda to learn from their progress
- Trained 25 pharmacists and pharmacy technicians
- Supporting government procurement of 22kg of morphine

India

• Initial results from the first cancer center implementing the Pain-Free Hospital Initiative, Malabar Cancer Centre in Thalaserry, show a 65% decrease in average pain scores among inpatients after just three months.

Person-days of treatment

311,000 237,000

696,000

1,259,000

326,000

Total: >2.8 M days

The MORPHINE framework

















rganize | indset

egulations

Procurement

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Integrate into service delivery at regional and district hospitals and ensure adequate geographical coverage to make pain relief accessible to all who need it

Create a sustainable stakeholder base

- · Start with a clear, concise statement of the situation including numbers of patients, consumption of pain relief drugs, and unmet need—and communicate with all relevant government divisions
- Make clear that morphine is on the WHO list of essential drugs, and note if it is on the equivalent national list (country factsheets with this information are available from the Global Access to Pain Relief Initiative website)
- Useful for identification of interventions that have the best chance of improving
- Can be timeconsuming, so start early to update regulations as needed
- International Narcotics Control Board is expected to produce new model law recommendations, and the African Palliative Care Association has produced regulation guidelines
- Establishment of supply is a necessary, but not sufficient, condition for any other interventions to
- Many national procurement departments struggle with unresponsive suppliers and little experience with non-standard drugs
- Distribution of drugs to health facilities can be challenging, especially for sites that are a great distance from central medical stores
- Poor capacity and breakdowns of communication can hamper stock tracking. order fulfillment, and timely reordering

- Very important, but expensive, difficult, and timeconsuming
- Integration with existing programs and structures is advisable when possible
- Scope for innovation
- Early initiators become champions for change in clinical practice
- Early programs offer opportunities to generate local data for potential effects and to refine systems and approaches
- Multivear step that requires substantial effort and investment
- Standalone systems seldom last and integration into existing training. procurement, data management systems, and clinical guidelines is crucial for widespread effectiveness
- Nurture national palliative care associations, health ministry staff, patient advocacy groups, and clinical experts to continue to develop and support high-quality, evidence-based pain treatment
- Support for these groups must be consistent, preferably through government funding mechanisms
- Access is not achieved until this step is realized

Developed by Treat the Pain, a program of the American Cancer Society