

**Access to Medicines:
The reasons for the disparity and some
modest proposals for change**

Focus on Corruption

**Canadian Conference on the Public Health and Law
November 7 2006**

Jillian Clare Cohen, PhD

Assistant Professor Leslie Dan Faculty of Pharmacy

jillianclare.cohen@utoronto.ca

Introduction

- Access to medicines is often a life and death issue
- Despite international aid and a plethora of programs devoted to improving global pharmaceutical access, there is a morally concerning drug gap
- About 2 billion people or one-third of the global population lack regular access to medicines
- WHO estimates that by improving access to essential medicines (and vaccines) about 10 million lives per year could be saved
- Corruption contributes to the drug gap

The Impact of Corruption in the Pharmaceutical System

- Corruption limits a country's ability to improve drug access and the health of its population
- The poor in developing countries are most susceptible to its detrimental effects
- Lewis (2006) points out that lack of concern for governance in health care can limit impact of well-intentioned spending

Why the Pharmaceutical System is Susceptible to Corruption

- No mystery - pharmaceutical sales can mean a lot of income
- Greed may inspire illegal action if insufficient checks and balances
- The system is complex and demands knowledge of good governance practices
- If knowledge is limited, the potential for corruption is higher

Why the Pharmaceutical System is Susceptible to Corruption

- Advances in technology are making it harder to distinguish authentic pharmaceutical products from counterfeit or sub-standard ones
- The WHO estimates that about 25 percent of drugs consumed in poor countries are counterfeit or substandard
 - High cost of medicines
 - ↑ demand ↓ supply/shortage

Why the Pharmaceutical System is Vulnerable to corruption

- Lack of legislation/enforcement (light penalty)
- Little liaison between law enforcement, customs and drug regulators
- Poor information dissemination (public and health workers)
- Complex trading, no documentation (paper trail)
- Little critical evaluation of fake drug statistics

Source: Newton, P. Green, M et al. Counterfeit anti-infective drugs. The Lancet. Vol 6: September 2006. pp 602-613.

The Good News

- Corruption is now a “mainstream” topic in development and pharmaceuticals specifically
- Improvement on past disregard
- “Too complicated”
- “I’ll know it when I see it”
- “How can you distinguish the difference between corruption and inefficiency?”

The International Community is Focusing on the Issue

- IBRD collection on health and corruption
- 11th International Anti-corruption Conference in Seoul 2003
- WHO Pharmaceutical Governance Methodology
- Rome Declaration
- Transparency International Global Corruption Report 2006
- World Bank chapter on pharmaceuticals (Cohen, Mrazek and Hawkins) in forthcoming edited volume “ The Many Faces of Corruption : Tracking Vulnerabilities at the Sectoral Level”

Bid Rigging
Teacher Absenteeism
Accounts Falsification
Collusion
Bid Rigging
Illegal Logging
Money Laundering
Collusion
Accounts Falsification
Electricity Theft
Collusion
Illegal Logging

**The Many Faces of
Corruption**

**Tracking Vulnerabilities
at the Sector Level**

Edited by
**J. Edgardo Campos
Sanjay Pradhan**





GLOBAL CORRUPTION REPORT 2006

Special Focus

Corruption and Health

 **TRANSPARENCY
INTERNATIONAL**



Global Examples

- A pharmaceutical manufacturer in Brazil was found to be manufacturing sub-standard contraceptive drugs
- In June 2004, the New York State Attorney General's Office accused GlaxoSmithKline of fraud by concealing information to physicians about the adverse impact of the anti-depressant Paxil® (paroxetine) when prescribed for depression in children and adolescents

Counterfeit Medicines: the Bad and Ugly

- If institutions weak more likely find counterfeit medicines in the market
- Regulators may receive kickbacks to ignore makers of counterfeits
- Regulators may be intimidated by counterfeit producers

Counterfeit Medicines (2)

- Thailand, substandard medicines account for 8.5 percent of the market
- China had 500 illegal manufacturers
- India plans to introduce the death penalty

Nigeria's Story (1)

- Nigeria is notorious for being a major supplier of counterfeit medicines
- During the late eighties and nineties, the Nigerian pharmaceutical market was increasingly taken over by illegal actors specialized in selling counterfeit and substandard drugs

Nigeria's Story (2)

- Studies consistently showed that more than 50% (the highest reported number being 80%) of drugs sampled in drugstores and pharmacies were not compliant with pharmacopeia standards
- Some of these drugs had no active ingredient at all, others were mislabeled (for example paracetamol labeled as the antimalarial drug Fansidar), or had only a small amount of active substance (50 mg ampicillin instead of 250)

Source: A. Seiter

Nigeria's Story (3)

- In 2004 government officials prevented 32 containers of counterfeit drugs hidden in spare car parts and imported shirts stuffed with painkillers from entering the market
- Nigeria is also implementing new import controls and trying to engage the National Agency for Food and Drug Control (NAFDAC) more fully in measures against counterfeit drugs

Procurement Corruption

- In Eastern Europe, the rapid deregulation and privatization of the pharmaceutical sector, combined with an often unstable economic and political environment created opportunities to engage in corruption
- It was also a survival strategy for many government and health sector workers

Purpose of Corruption Framework

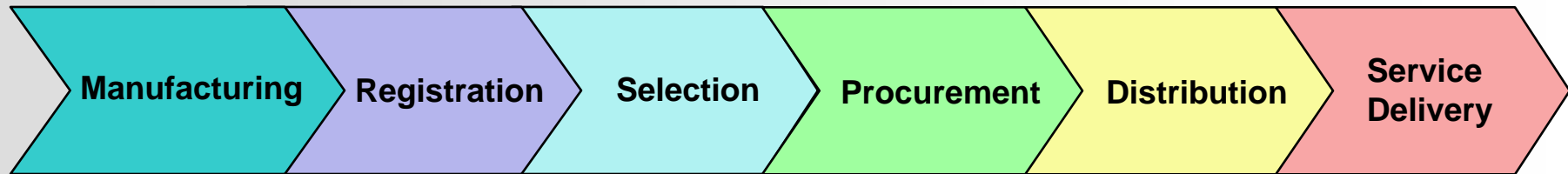
- The pharmaceutical system is technically complex
- Need to know what are the best practices in the core decision points so ignorance cannot foster corruption
- Decision makers and practitioners need to be familiar with the potential areas where corruption can occur in the pharmaceutical system

Pharmaceutical System Corruption Assessment Tool

- First methodology done by Cohen, Cercone and Macaya (2002) in Costa Rica and which has been revised and applied in South East Asia by the WHO in 2005
- Includes use of questionnaires that are designed to assess the vulnerability of each decision point in the pharmaceutical system

Pharmaceutical Assessment Tool

- Built on Klitgaard's formula:
- Monopoly(M) + Discretion (D) – A (Accountability) – T (Transparency) = Corruption



- GMPs
- Quality Assurance
- Master batch and laboratory control records
- Production and in process controls
- Track complaints

- Efficacy
- Labeling
- Marketing
- Use
- Warnings
- Full registration of older drugs
- Reevaluation of older drugs

- Determine budget
- Assess morbidity profile
- Determine drug needs to fit morbidity profile
- Cost/benefit analysis of drugs
- Consistency with WHO criteria

- Determine model of supply/ distribution
- Reconcile needs and resources
- Develop criteria for tender
- Issue tender
- Evaluate bids
- Award supplier
- Determine contract terms
- Monitor order
- Make payment
- Quality assurance

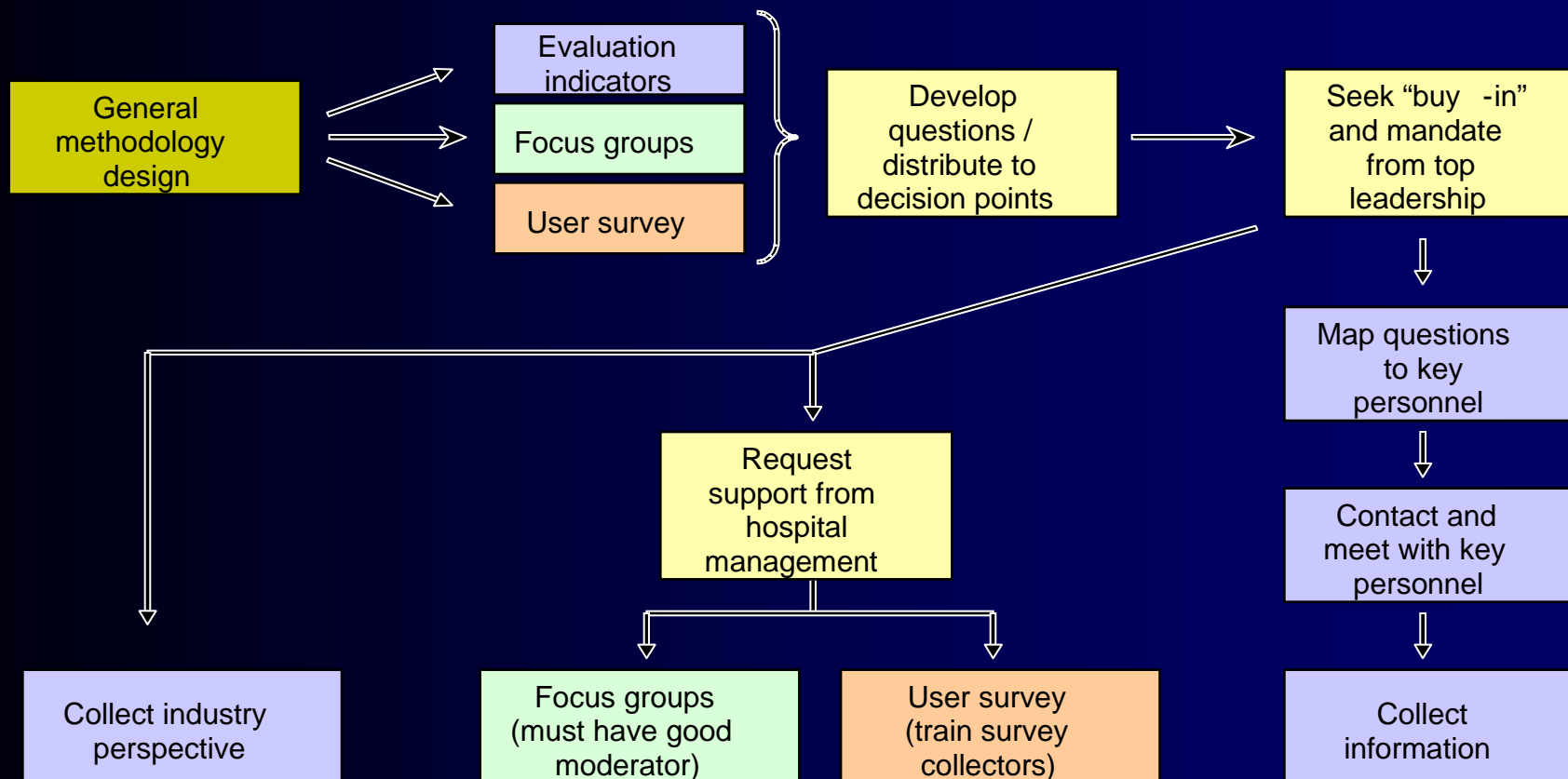
- Receive and check drugs with order
- Ensure appropriate transportation and delivery to health facilities
- Appropriate storage
- Good inventory control of drugs
- Demand monitoring

- Consultation with health professional
- In-patient care
- Dispensing of pharmaceuticals
- Adverse drug reaction monitoring
- Patient compliance with prescription

Methodology

Gaining Support

We obtained support from the central government and the hospital management prior to launching our pilot study in order to guarantee access to information



Recommendations

- Understand that the pharmaceutical system is technically complex
- It is comprised of a number of core decision points: manufacturing, registration, selection, procurement, distribution, and prescribing and dispensing
- Need to know what are the best practices so ignorance cannot foster corruption
- Ensure transparency – think of Chile

Recommendations

- Know the system
 - Facilitate forensic investigation of bad drugs
 - Improve public awareness of issue (e.g. Ontario case)
 - Harmonize standards and best practices in pharmaceutical systems
 - Strengthen cooperation between sectors, government and industry (e.g. Declaration of Rome 2006)
-
- Source: Newton et al 2006

Finally... even small measures in themselves
can pay off and make good governance
“contagious”

Based on idea from Malcolm Gladwell [The Tipping Point](#),
Little Brown & Company, 2000