Measuring the Impact of Counterfeit Drugs: Applying the Patient Safety Reporting System Approach

Bryan A. Liang, MD, PhD, JD
Institute of Health Law Studies, California Western School of Law, USA
San Diego Center for Patient Safety, University of California San Diego School of Medicine, USA
Partnership for Safe Medicines, USA
Counterfeiting and Piracy
WIPO/OECD Expert Meeting on Measurement and Statistical Issues
17-18 October 2005
Geneva Switzerland

Counterfeit Drugs

- At least $32/€27 billion annually.
- $88/€73 million a day.
- Estimates: grow to $75/€62 billion annually in 5 years.
- Up to 60% of drugs in developing countries are counterfeit.
- Up to 90% artemesinate in Southeast Asia fake.
- Up to 20% of drugs sold in some developed countries counterfeit.
- Up to 15% of all drugs around the world are counterfeit.
- All are guesstimates—no hard data on incidence, prevalence, or economic burden.
What Kinds?

- Originally, was lifestyle drugs: Viagra, Oxycontin.
- Now ...
- AIDS/HIV therapy, over-the-counter pain medications, antibiotics, insulin, cholesterol drugs, hormone replacement therapy, over-the-counter flu medications, cancer drugs, anti-arthritis drugs, cardiac drugs, anti-parasitic drugs, antihistamines ... and more that are undiscovered.
- Gone from lifestyle drugs to lifesaving drugs.

Where?

- Almost everywhere. Detected in:
  - Asia
  - Australia
  - Europe
  - North America
  - South America
- Not yet reported in Antarctica ...
Implications

- Tremendous patient, provider, public, and private costs:
  - human cost.
  - provider burden.
  - public health burden.
  - health delivery system cost.
  - law enforcement burden.
  - industry losses.
- Supports international crime and terrorist activities.

Detection

- Critical need to detect counterfeit drugs from patient, provider, public, and private perspectives.
- Is there a model to integrate these stakeholder data needs?
- Yes: patient safety reporting systems.
- Helped determine public and private burden, scope and boundaries of the problem.
Detection

- Patient safety reporting systems:
  - use standardized, simplified forms.
  - can report using paper/mail, fax, web, email, and by phone.
  - anyone can report, anyone can access data.
- Has resulted in determining systems weaknesses and conclusions regarding medications, including:
  - economic and social burden of adverse drug events.
  - epidemiology of circumstances surrounding therapeutic failures and/or treatment issues (locale, patient diagnosis, harm, surrounding circumstances, patient outcome, methods to remediate harm).

Counterfeit Drug Application

- Successful reporting systems:
  - Lay foundation of education to relevant parties about issue and reporting system.
  - Provide tools to make reporting simple.
  - Make access easily available.
  - Use single site for data collection and coordination (national; or international by region).
Counterfeit Drug Application

Part I: Education

- Public health initiative to educate patients and providers on the problem of counterfeit drugs.

Provide easy checklist regarding counterfeits and contact information for reporting.
Counterfeit Drug Application

- Part II: Create simple form for reporter use.
- Note: this can be altered as circumstances and reporters change (e.g., providers, law enforcement, industry personnel).
- Disseminate form/availability to stakeholders.

Counterfeit Drug Application

- Online forms may employ drop down menus and other ease of use tools.
Counterfeit Drug Application

- Part III: Set up single data repository site.
- Web based reporting and html email can be automated for database entry.
- Fax, phone, text email will require individual data entry input.
- Access through Internet.
- Can integrate rapid alert systems from WHO, email alerts from Safemedicines.org.
- Key advantage: repository may keep reporter identities confidential for security purposes.

Results

- Data can be analyzed:
  - Epidemiology of counterfeits.
    - Locale, type, materials.
  - Public economic burden.
    - Patient harm, remediation methods.
  - Private economic burden and tracing.
    - Drugs counterfeited, materials used using international database may allow identification of path.
  - Easy applicability to GIS systems.
    - Thematic mapping for epidemiology, public health, and investigation purposes.
  - Stakeholder raised awareness, education, and cooperation.
Conclusion

- Counterfeit drugs large economic and social burden.
- To understand scope and burden, need reporting systems.
- Patient safety model of reporting errors and system weakness directly applicable.
- Three part process can result in infrastructure to provide useful information to all stakeholders.