



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

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Counterfeiting and Piracy

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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% artesunate 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).

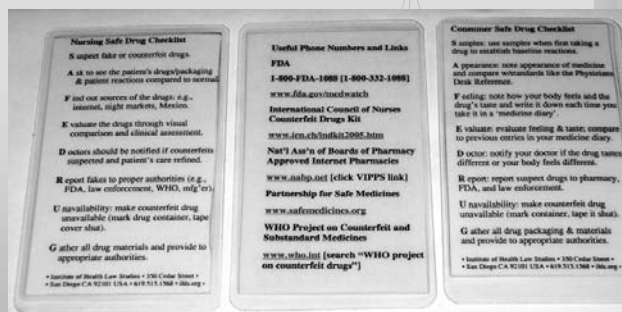
Counterfeit Drug Application



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

Counterfeit Drug Application

- Part I: Education
 - 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.

Drug Safety Reporting Form

Reporter Information
 Name: _____ Date: _____
 Location: _____ Contact information:
 Phone: _____
 FAX: _____
 Email: _____

Patient Information
 Patient diagnosis: _____
 Suspect Drug: _____
 Drug Purchased/Obtained at: _____
 Sample Available? _____
 Harm: [e.g., renal failure; toxic reaction] _____
 Patient Outcome: [e.g., additional sickness; death] _____
 Necessary treatment changes: [e.g., new prescription; additional treatment] _____

Any additional information or reports of potential counterfeit drugs: _____

Please fax to: 888-888-8888 or Email to: abc@safemedicines.org or by post to: Safe Medicines Europe, XYZ, CITY, COUNTRY

This form is available on the Internet and can be filled in there at www.safemedicines.org/counterfeits.

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

REPORTING FORM ON COUNTERFEIT MEDICINES : for the RAPID ALERT SYSTEM
 Please fill up in the required space *

Part A : Please explain/describe your findings (text)* :
 [] Please explain or describe your findings regarding counterfeit drug.

Part B : Information about reporter

1. NAME OF THE REPORTER (optional) : [] Provide your name if you want.

2. HEALTH PROFESSIONAL* : [] Choose "Yes" if you are the health professional or specify if not.
 Yes No (pl specify : [])

3. COUNTRY* [Please select->] [] Select your country.

4. E-MAIL ADDRESS : [] Enter your e-mail address. Check the option if you would like us to send you any news regarding your report.
 Please inform me any related news about my report

Part C : Information about product (important for intensified surveillance and further investigation)

1. DATE WHEN CASE WAS DISCOVERED* : [] Enter the date when the case was discovered.
 dd / month / yyyy

2. COUNTRY WHERE THE PRODUCT WAS IDENTIFIED/ FOUND* : [] Select the country where the case was discovered.
 [Please select->] []

3. PLACE WHERE THE PRODUCT WAS IDENTIFIED/FOUND* : [] Select the place where the product was identified/ found. Please specify if you choose "other".
 [Please select->] [] Fill in the product name, classification, indication, type of packaging, dosage form and the manufacturer's name of the drug.

4. INFORMATION ABOUT THE PRODUCTS

a. NAME* []
 b. DRUG CLASSIFICATION* [Please select->] []
 c. INDICATION OF DRUG* []
 d. TYPE OF PACKAGING* [Please select->] []
 (Others, please specify : [])
 e. DOSAGE FORM* [Please select->] []
 (Others, please specify : [])

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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.
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