A Model of Burden of Disease (BoD) and Counterfeit Activity

B & R Research Brief

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Overview

This paper looks at the linkage between Burden of Disease and counterfeit activity. The objective is the construction of a formal model that measures the impact that counterfeit activity has on burden of disease, and by extension, the impact(s) on patient safety.

A Primer on Burden of Disease

> The burden of disease measures the overall impact of diseases and injuries on a population. It goes beyond simply counting the number of people who die from a particular cause. Instead, it considers both the number of people affected and the severity of their conditions, including premature death and disability. Burden of disease considers both mortality and morbidity:
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> Mortality: This measures how many people die from a disease.
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> Morbidity: This measures how many people live with a disease and the impact it has on their health and well-being.

Why is it important?

> Understanding the burden of disease helps us to:
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> Prioritize healthcare resources: By identifying the diseases and injuries that cause the most significant burden, countries can allocate resources effectively to prevention, treatment, and research.
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> Track progress: By measuring the burden of disease over time, healthcare professionals can assess the impact of public health interventions and track progress in improving population health.
>
> Compare populations: Burden of disease allows us to compare the health of different populations, both within and between countries, and identify areas where disparities exist.

How is it measured?

The most common metric used to measure burden of disease is the Disability-Adjusted Life Year (DALY). One DALY represents the loss of one year of healthy life, whether due to premature death or living with a disability. DALY = YLL + YLD where YLL is the years of life lost due to premature mortality and YLD is the years lost to disability. YLL is calculated by multiplying the number of deaths by the standard life expectancy at the age of death. YLD is calculated by multiplying the average number of people with a disability by the disability weight of that condition and the average duration of the disability.

Factors influencing the burden of disease

Socioeconomic factors: Poverty, malnutrition, lack of sanitation, and poor living conditions contribute significantly to the burden of disease.

Environmental factors: Pollution, unsafe water, and exposure to toxins can increase the risk of various diseases.

Lifestyle factors: Diet, exercise, smoking, and alcohol consumption play a role in the development of chronic diseases.

Access to healthcare: While access to quality healthcare is important, it's just one factor among many that influences the burden of disease.

A lower burden of disease for certain conditions / diseases may suggest that a country has better treatments and healthcare systems in place.

Counterfeit medicine and the burden of disease

Counterfeit medicines have a significant impact on the burden of disease, particularly in countries with weak regulatory systems and limited access to quality healthcare. Examples include:

Treatment failure: Counterfeit medicines often contain incorrect ingredients, insufficient amounts of active ingredients, or no active ingredients at all. This can lead to treatment failure, prolonging illness, increasing the risk of complications, and potentially leading to death.

Adverse reactions: Counterfeit medicines may contain harmful substances, such as toxins or contaminants, that can cause adverse reactions, including poisoning, allergic reactions, and organ damage.

Drug resistance: The use of counterfeit medicines with subtherapeutic doses of active ingredients can contribute to the development of drug resistance, making it more difficult to treat infections in the future.

Loss of trust: The widespread use of counterfeit medicines can erode public trust in healthcare systems and legitimate pharmaceutical products, making it more difficult to ensure adherence to treatment regimens and control disease outbreaks.

Counterfeit medicine and burden of disease – hypothetical model of patient impact

The following model illustrates the relationship between the incidence of counterfeit medicine and the burden of disease. This model focuses on a single disease/condition for simplicity.

Static Model

Variables:

- **C:** Incidence of counterfeit medicine (e.g., percentage of medicines in circulation that are counterfeit). Ranges from 0 (no counterfeit medicine) to 1 (all medicine is counterfeit).
- **I:** Incidence of the target disease/condition in the population (e.g., number of new cases per 100,000 people per year). We assume this would be the incidence *without* counterfeit medicines.
- **E:** Effectiveness of genuine medicine for the target disease (ranges from 0 to 1; 1 means 100% effective, 0 means completely ineffective).
- **B:** Burden of disease (a composite metric).

Assumptions:

1. Counterfeit medicines are completely ineffective (contain no active ingredient or insufficient amounts).
2. The presence of counterfeit medicine does not *increase* the incidence (I) of the disease itself. It only affects the *outcome* of the disease in those who are already afflicted.
3. For simplicity, the model ignores potential harm from counterfeit medicines due to toxic ingredients, etc.

Specification

1. Number of people receiving counterfeit medicine: `C * I` (assuming a constant population size for simplicity
2. Number of people receiving genuine medicine: `(1 - C) * I`
3. Number of people effectively treated: `(1 - C) * I * E` (Only those receiving genuine medicine *and* for whom the medicine is effective are treated successfully).
4. Number of people *not* effectively treated (contributing to burden): `I - (1 - C) * I * E = I * (1 - (1 - C) * E)`
5. Burden of Disease (B): `B = [I * (1 - (1 - C) * E)] / I = 1 - (1 - C) * E`

Interpretation:

When C = 0 (no counterfeit medicine), **B = 1 - E**. The burden of disease is simply due to the fact that the genuine medicine is not 100% effective.

When C = 1 (all medicine is counterfeit), **B = 1**. The burden of disease is 100% because no one is effectively treated.

As C increases from 0 to 1, B increases from 1-E to 1. The higher the incidence of counterfeit medicine, the higher the burden of disease.

Estimation

C is derived from the model of loss due to counterfeiting. The incident rate can also be derived from incidence reports.

I is derived from the Global Buren of Disease Study (https://www.healthdata.org)

E is derived from clinical data

B is computed for each therapeutic category of disease

Example:

Let's say the incidence of a disease (I) is 100 per 100,000 population. The genuine medicine is 80% effective (E = 0.8).

- If C = 0 (no counterfeit), B = 1 - 0.8 = 0.2. 20% of those with the disease are not effectively treated.
- If C = 0.5 (50% counterfeit), B = 1 - (0.5 * 0.8) = 0.6. 60% of those with the disease are not effectively treated.
- If C = 1 (all counterfeit), B = 1. 100% of those with the disease are not effectively treated.

Limitations:

- This is a very simplified model. It doesn't account for disease dynamics, multiple diseases, varying effectiveness of medicines, harm from counterfeit medicines themselves, or the complex interplay of social and economic factors.

Econometric / Statistical model

This approach considers a statistical model that specifies a relationship between the burden of disease and counterfeit medicine activity using evidence from epidemiological studies, economic analyses and regulatory data.

Epidemiological Foundations of Counterfeit-driven Disease Burden

Variables

Burden of Demand measures Disability-Adjusted Life Years (DALYs) and Years lived with disability (YLD).

Counterfeit Activity as measured by loss due to counterfeit pharmaceutical trade or estimates derived from seizure data and / or incidence data.

Other explanatory factors

Healthcare system capacity or effectiveness as measured by Healthcare Access and Quality Index (HAQ)

Socioeconomic status as measured by Socio Demographic Index (SDI)

Disease prevalence or incidence in the population, derived from Global Burden of Disease Study

Policy measures such as corruption perception index, represented by CPI

Specification

$$BoD_{ij} = \beta_0 + \beta_1 * CA_{ij} + \beta_2 * HAQ_{ij} + \beta_3 * SDI_{ij} + \beta_4 CPI_{ij} + e_{ij}$$

Where i represents a country and j represents a specific disease category.

This specification provides a direct impact analysis of the costs of counterfeit activity on patient safety as measured by the impact on the burden as well as the benefit associated with a reduction of counterfeit activity on the burden of disease (proxy for patient safety).