VALUE FOR MONEY OF POST-MARKET SURVEILLANCE OF MEDICINES: EVIDENCE FROM INDONESIA

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STARmeds website   Data collection toolkit

Background

Post-market surveillance activities (PMS) - conducted to collect and evaluate medicines that have already been placed on the market - have a very important role in **tackling the prevalence of substandard and falsified medicines (SFM)**. For countries striving to achieve Universal Health Coverage (UHC), the prevalence of SFM represents a drawback as it wastes resources in medicines that do not have the intended target product profile and may even be harmful to patients. [1]

The project Systematic Tracking of At Risk Medicines (STARmeds) implemented in four provinces of Indonesia aimed to contribute to the improvement of PMS in the region by developing a surveillance system which expands the national medicine regulator's model.[2]

In this study, we use STARmeds medicine surveillance activities to **study financial and economic costs of implementing PMS**.

Objectives:

- Estimate **total and unit costs of PMS** along several outcomes (total costs, costs per study phase, per sample collected and per week of fieldwork).
- Study the potential of PMS in **detecting out-of-specification samples** (costs per out-of-specification sample found).
- Provide information on the **budget implications** of PMS (sensitivity analysis).

Collection and analysis of medicine samples

- **Timeline:** Oct 2021 – June 2022: planning and preparation, data collection and reporting and analysis. [March - May 2022: fieldwork]
- **Location:** rural, urban and online retail outlets in seven districts, of four Indonesian provinces – North Sumatera, Jakarta, East Java, East Nusa Tenggara (NTT).
- **Samples collected:** 1,335 medicine samples for five molecules - amlodipine, amoxicillin, cefixime, dexamethasone and allopurinol.
- **Testing:** laboratory analyses for concentration of active pharmaceutical ingredient and dissolution tests - SFM prevalence estimates.

Figure 1: Data collection map

Methods

- **Activity-based costing model**, conducted from the healthcare regulator perspective (excluding research costs), using STARmeds activities data.
- Cost data sources:
  - **Financial costs:** Administrative project data - National Institute for Health and Care Research (NIHR) expenses reports from Oct.2021 to June 2022.
  - **Economic costs:** Focus groups and questionnaire with STARmeds staff.

- We used a **micro costing (bottom -up) approach**, aggregating costs by type - i.e. expenses with salaries were aggregated by multiplying salaries by FTEs, equipment was aggregated by quantity and price, etc. (see diagram on the right).
- We allowed for uncertainty in number of samples collected per day by bootstrapping (sampling with replacement, n=500 iterations) the number of samples collected during each day, stratified by type of outlet location (**rural, urban, and online**), with 95% confidence interval.

Figure 2: Costing diagram

Results

- The total cost of PMS activities, as implemented by STARmeds, was **USD 712 963**.
- Laboratory costs represented the largest share (70%), followed by other direct costs (11%) and salaries (8%).
- Lab costs refer to privately contracted laboratory tests for all medicine samples.
- Other direct costs include allowances for sample collectors, the cost of purchasing medicines from outlets, and a wide range of services and consumables e.g., barcoding samples, mobile data packages for the field team.

Costs per outcome

- On average, it cost STARmeds USD 472 (95%CI 454 to 514) to collect one medicine sample and USD 9 442 (95%CI 9075 to 10 275) to identify one out-of-specification sample.
- In terms of time, it cost about USD 10 380 per fieldwork day and USD 51 901 per fieldwork week – these costs also include the distribution of laboratory costs.

Costs per area and study phase

- Online sampling has a higher cost per sample and was more time consuming relative to rural and urban areas. In rural areas, we estimate an average of 16 medicines collected per day, in urban areas 26, and online only 7. (counter-intuitive: online shopping implied back-and-forward communication with sellers, medicines delivered often didn't match the order, sellers took time to reply.)
- Analysis and reporting (that includes the medicines lab testing) was the most resource intensive phase, while preparation and study setup combined accounted for about 20% of total costs.
- Data collection was the most time intensive phase, with staff reporting having to work extra-time for an average of 4 out of 5 working days, during the two months of data collection.

Table 1: Main Results

	Economic costs	Details
By cost components		**% of total cost**
Salaries	$54 944,7	8%
Equipment	$2 974,9	0%
Consumables	$17 747,0	2%
Travel	$21 660,0	3%
Lab	$481 703,5	68%
Other direct costs	$82 733,8	12%
Indirect	$51 200,0	7%
Total	**$712 964,0**	**100%**
Study setup	$37 295,5	5%
Preparation	$62 733,6	9%
Data collection	$110 320,6	15%
Analysis and reporting	$502 614,3	70%
Total	**$712 964,0**	**100%**
Estimated unit costs	**Avg.**	**(CI 95%)**
Per sample collected	$472,1	(453,7; 513,7)
Per out-of-specification sample	$9 441,5	(9074,9; 10274,6)
Per fieldwork day (all)	$10 380,1	(9977,0; 11296,0)
Per fieldwork day (active)	$12 757,5	(12262,1; 13883,2)
Per fieldwork week	$51 900,7	(49885,1; 56480,2)

[a]Field work (all): all calendar days; Field work (active): days when at least one sample was collected.

Figure 3: % Costs per study phase

Sensitivity Analysis

- To understand how our results would change if some key expenses varied we perform a sensitivity analysis, with three different alternative scenarios, where we change the A) Costs of medicines, B) Preparations costs, and C) Prevalence estimates, alternately (keeping all other costs constant).
- The medicines sampled by STARmeds are relatively cheap compared to the whole market. In alternative A), costs of medicines purchased from the different outlets are multiplied by 10.
- From a regulator perspective, the study design and preparation phase can become easier and faster to conduct with time and repetition. In alternative B), preparation costs are divided in half.
- Prevalence estimates can vary with medicines types. In alternative C), prevalence is increased to 10% instead of the 2% found in STARmeds lab testing (assuming the same cost of laboratory testing).

Panel 1 - Cost per sample collected   Panel 2 - Cost per out-of-specification

Figure 4: Sensitivity analysis

Implications

This study shows that medicines **out-of-specification are difficult to find**, **PMS activities are expensive** and budget decisions need to be carefully taken to ensure resources are allocated efficiently.

Lab costs are the most expensive component, whereas collecting the medicines from the outlets is relatively accessible. This questions the **potential of screening processes** to better target medicines out-of-specification to be sent to the lab.

Collecting **costs data systematically and consistently** can be extremely useful to inform efficient decision-making for medicine surveillance in the future.

The **flexibility and dedication of the team in the field were extremely important** for the timely and correct collection of samples. This was particularly true for online sampling, an intense and exhaustive task for the staff, that is a low-cost activity to execute from a merely financial point of view.

Next steps

This study will inform the development of an **open access dashboard visualisation tool** that will allow external agents (from regulatory authorities to researchers) to plan their PMS activities and budget needs.

References

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