

Interventions to overcome the challenges for identifying Substandard, Spurious, Falsely Labeled, Falsified and Counterfeit drugs (SSFFC). A Systematic Review

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Objective

- To systematically review the evidence on the effectiveness of interventions to combat the challenges of substandard, spurious, falsely labeled, false, and counterfeit drugs (SSFFC).

Introduction

- The prevalence of SSFFC medications poses a serious and growing threat to millions of people in the global healthcare system as they not only threaten patient health but also prevent attempts to treat illnesses such as chronic and infectious diseases.
- Several techniques for detecting SSFFC drugs differs, including cost, resource usage, sensitivity, specificity, and the capacity to recognize drugs according to their chemical composition.

Method

- The protocol was registered in PROSPERO: CRD42024598808
- The inclusion factors were based on the recognized PICO (Problem, intervention, comparator, and outcomes) tool. The problem considered for the review included SSFFC drugs.

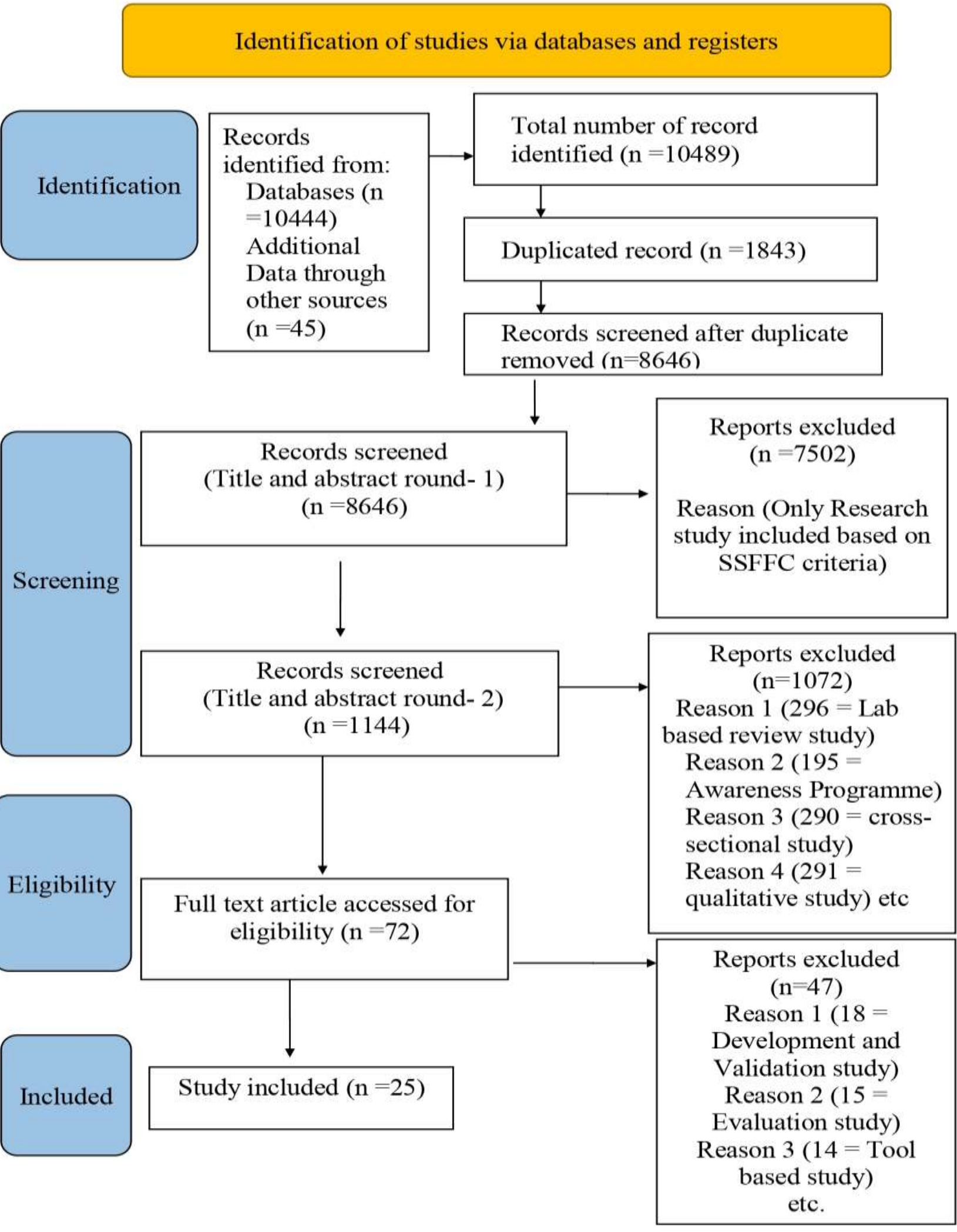
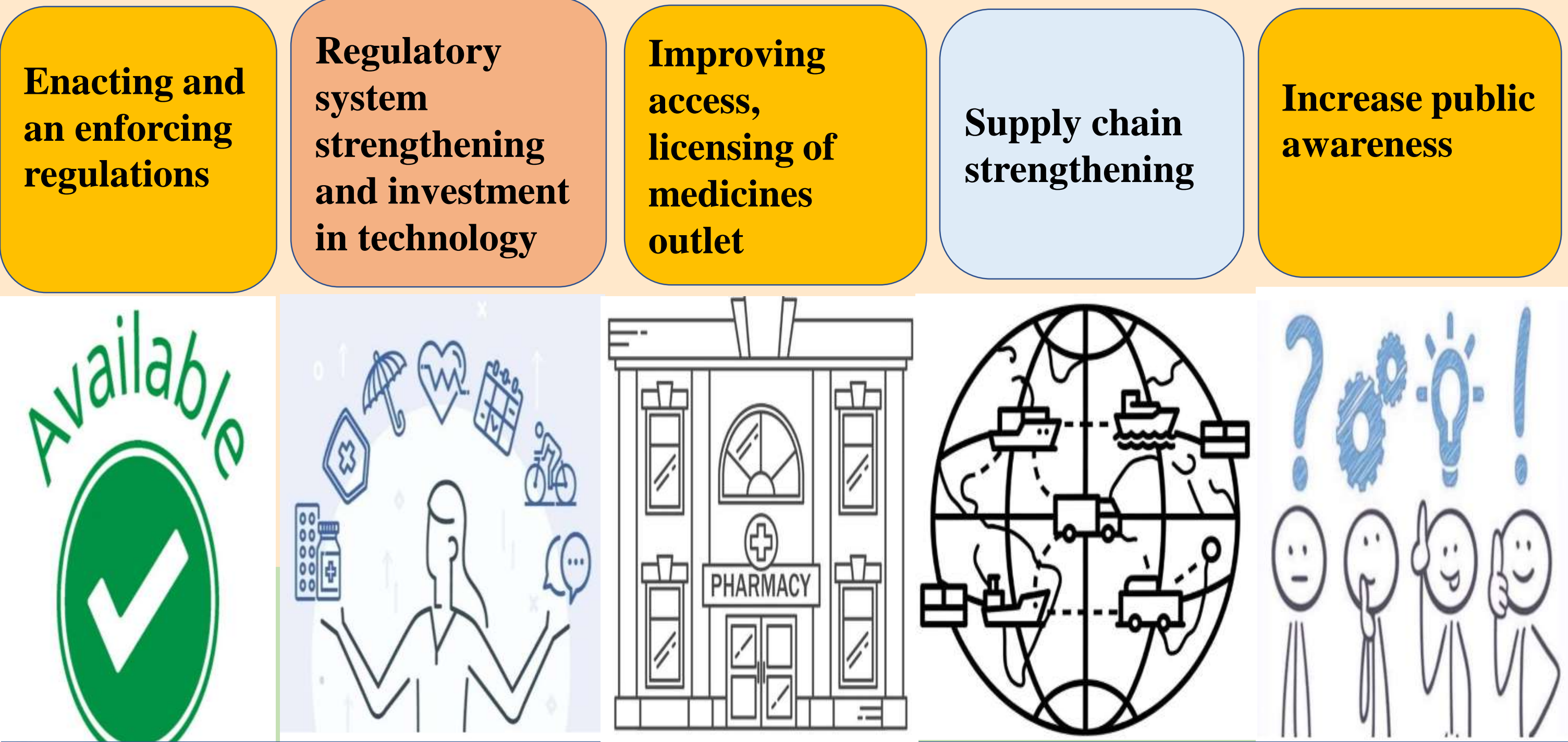


TABLE 1: PRISMA FLOW CHART

Strategies to increase the quality of drugs

TO CHECK



INTERVENTION

National legislation and regulations for drugs
Awareness programme
Testing Technology
Track and trace systems
Surveillance
National Alert systems and
Inspection and quality control of manufacturing unit

FIG 1: Types of interventions

| TEST CATEGORY | DESCRIPTION | TYPES OF TEST | EXAMPLES | COST |
|---------------|--|-----------------------|---------------------|------------------|
| Screening | Fundamental quality tests, primarily utilizing chromatographic and spectrometric techniques, along with visual inspection, among other methods | Identification | Visual examinations | N/A |
| | | Assay, disintegration | TLC,HPTLC | Inexpensive |
| | | Assay, disintegration | GPHF MiniLab | Inexpensive |
| | | Identification | RHS | Moderate Cost |
| | | Identification | CD3 | Inexpensive |
| | | Identification | DSC | Moderate Cost |
| | | Identification | XRD | Moderate Cost |
| Confirmatory | Methods outlined in the pharmacopeia that are exclusively carried out in a laboratory setting by qualified personnel, with outcomes that are measurable and quantifiable | Assay | HPLC | Highly expensive |
| | | Dissolution | Dissolution | Moderate Cost |
| | | Assay | MS | Highly expensive |
| | | Assay | LC–MS | Highly expensive |

TABLE 2: The details of analytical instruments and tests

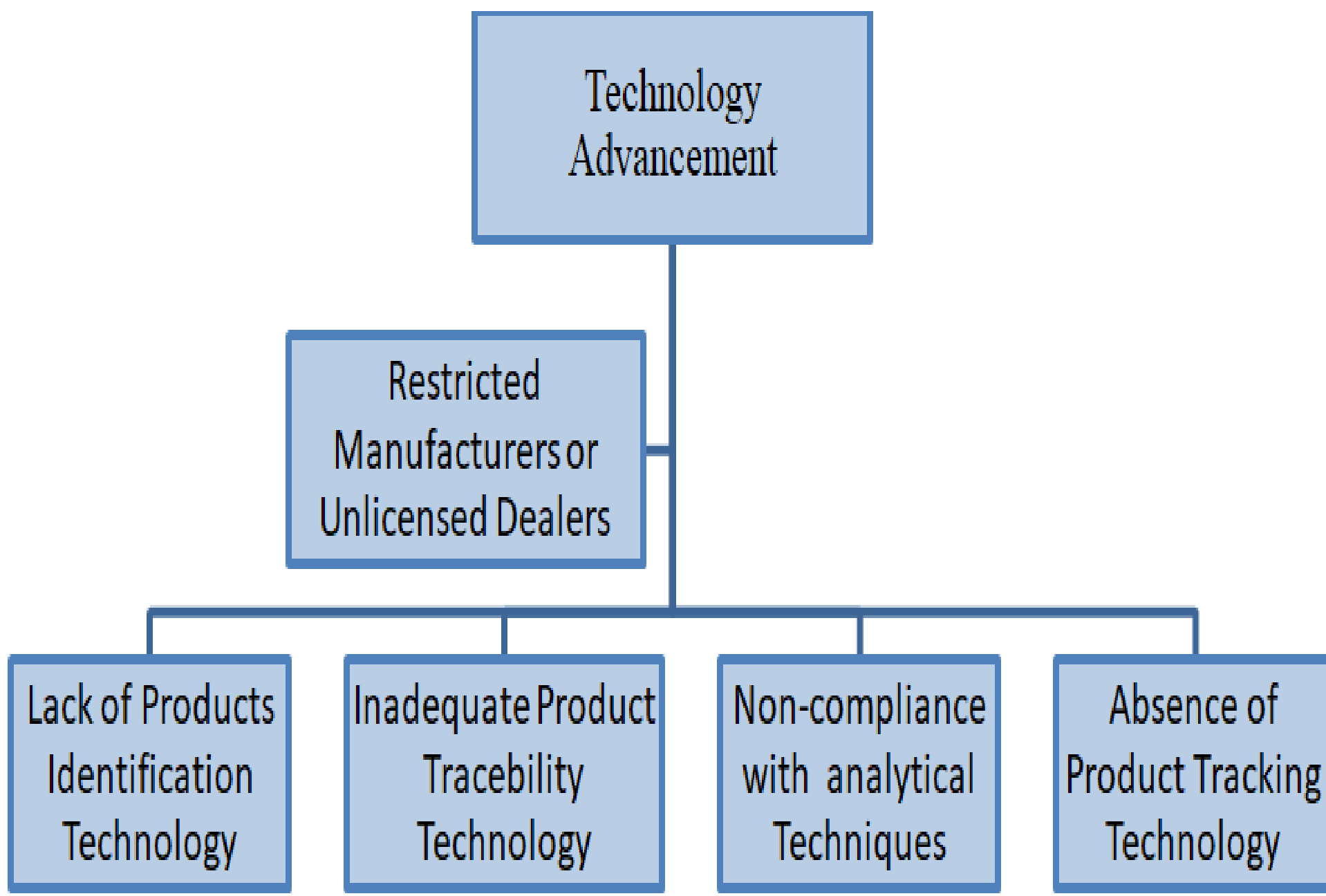


FIG 2A: Challenges of Technology Advancement

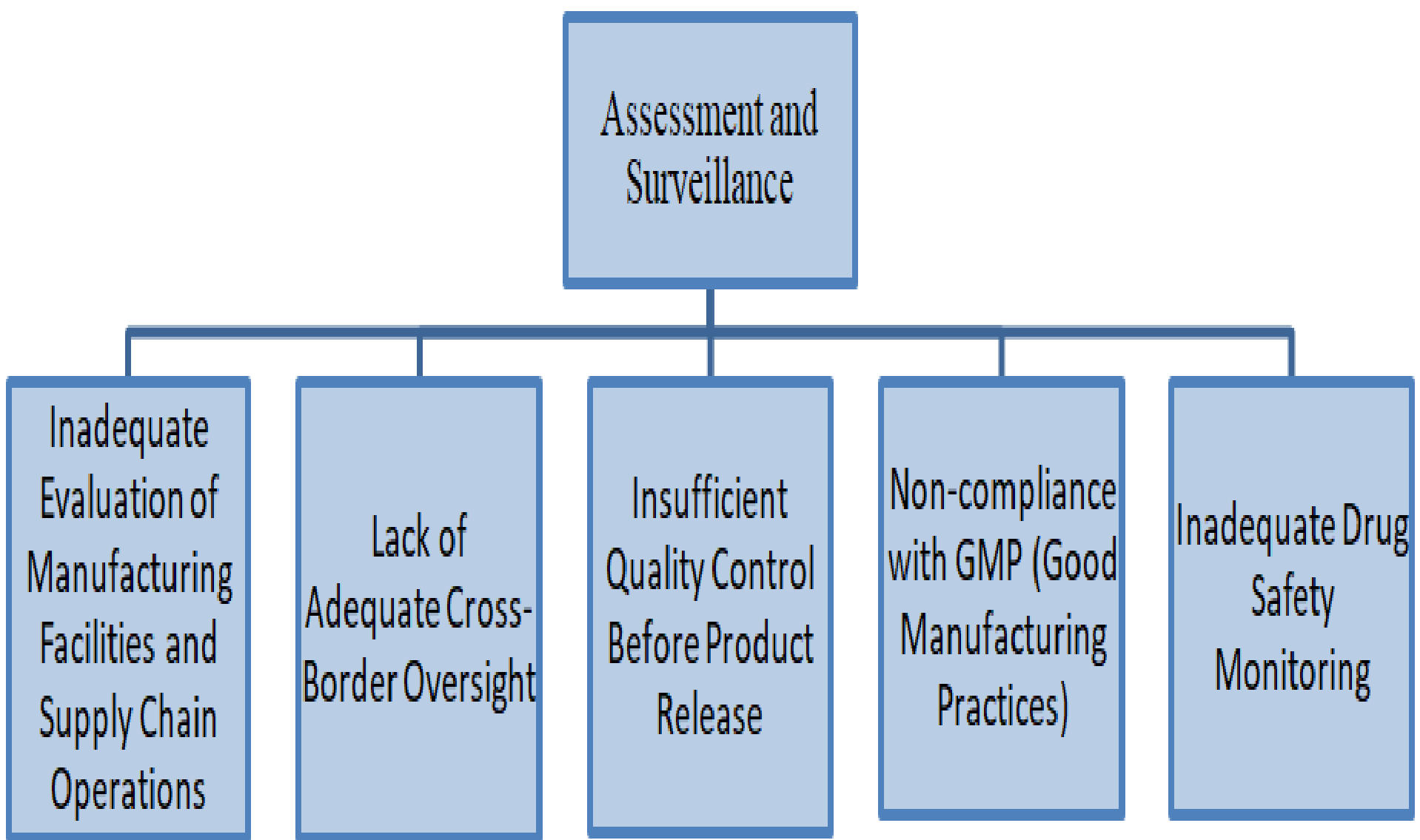


FIG 2B: Challenges of Assessment and Surveillance

Results

- The majority (84.62%) of them focused on analytical techniques, followed by pharmacosurveillance and product development.
- Analytical studies faced challenges with methods suitable only for crystalline substances, confirmatory test failures due to overlapping spectra and limited applicability to certain drug samples.
- Pharmacosurveillance struggled to track falsified drugs outside official channels, while product development dealt with issues like complex sample preparation and pending of regulatory approvals.
- The cost of materials and the verification procedure are more costly and challenging for end users.

Reference

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