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

*Shailee Dewan¹, Amatha Sreedevi¹, Elstin Anbu Raj S², Manthan D Janodia¹, Pradeep M. Muragundi¹

¹Department of Pharmaceutical Regulatory Affairs and Management Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal-576104, Karnataka, India. ²Center for Evidence-Informed Decision Making, Prasanna School of Public Health, Manipal Academy of Higher Education, Manipal-576104, Karnataka, India.

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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.

\square Method • The protocol was registered in PROSPERO: CRD42024598808 • The inclusion factors were based on the recognized (Problem, intervention, comparator, and outcomes) tool. The problem considered for the review included SSFFC drugs. Identification of studies via databases and registers Total number of record identified (n = 10489) identified from: Identification Databases (n =10444)Additional Duplicated record (n = 1843) Data through other sources (n = 45)Records screened after duplicate removed (n=8646) Reports excluded Records screened (n = 7502)(Title and abstract round- 1) (n = 8646)Reason (Only Research study included based on SSFFC criteria) Screening Reports excluded Records screened (n=1072)(Title and abstract round- 2) Reason 1 (296 = Lab (n = 1144)based review study) Reason 2 (195 = Awareness Programme) Reason 3 (290 = crosssectional study) Reason 4 (291 = Eligibility

qualitative study) etc Full text article accessed for eligibility (n = 72) Reports excluded (n=47)Reason 1 (18 = Development and Validation study) Study included (n =25) Reason 2 (15 =Evaluation study) Reason 3 (14 = Tool

based study) **TABLE 1: PRISMA FLOW CHART** Strategies to increase the quality of drugs TO CHECK **Improving** Increase public access, Supply chain licensing of awareness

strengthening medicines outlet

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

TABLE 2: The details of analytical instruments and tests

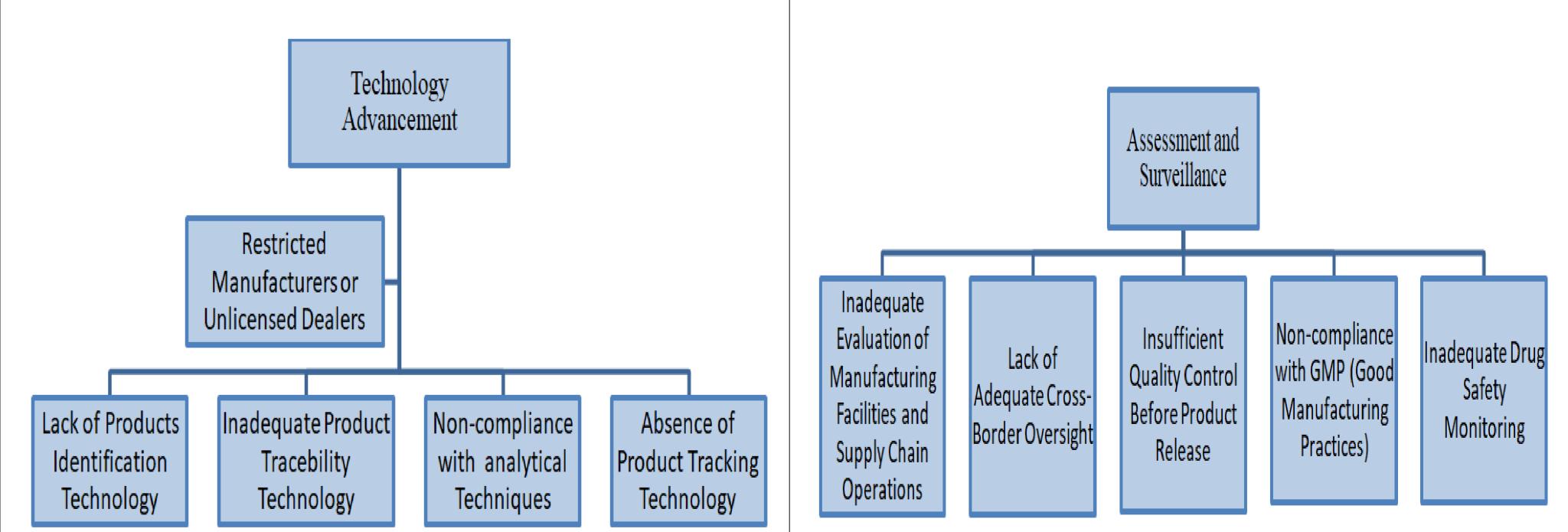


FIG 2A: Challenges of Technology Advancement

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.

□ <u>Reference</u>

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Regulatory

strengthening

in technology

and investment

system

Enacting and

an enforcing

regulations