



Lessons Learned in the Design and Implementation of Opioid RMPs

Patricia Robinson, MD, MS

Aparna Mohan, MD, PhD

Erica Gooch, PharmD

Reema Jain, PharmD

Dawn Sanderson-Bongiovanni, PharmD

Benefit Risk Management

A Division of Johnson & Johnson

Pharmaceutical Research and Development, LLC

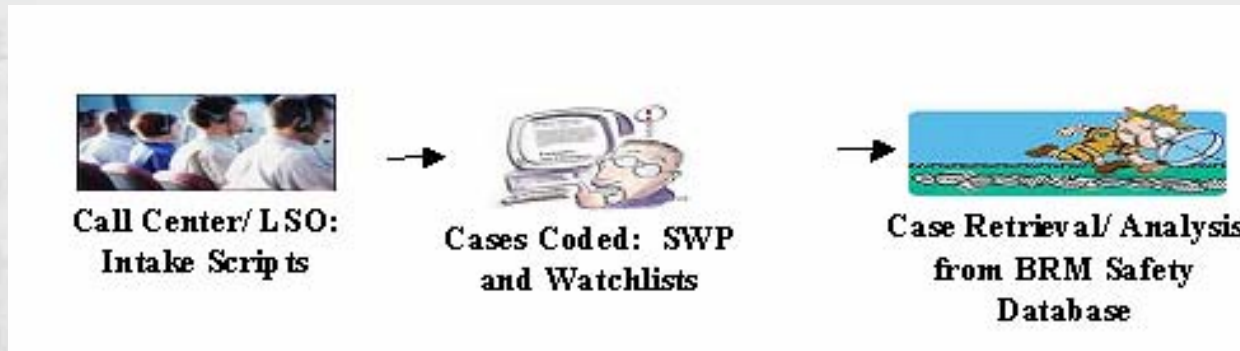
Key Lessons

- **The surveillance plan is key to monitoring RiskMAP effectiveness.**
- **An effective surveillance plan should maximize the amount of information on identified risks, possibly warranting the use of multiple data sources.**
- **When multiple data sources are used, a coordinated approach is required for data retrieval, summary, analysis, and reporting.**

Measuring RMP Effectiveness Using Surveillance Plan

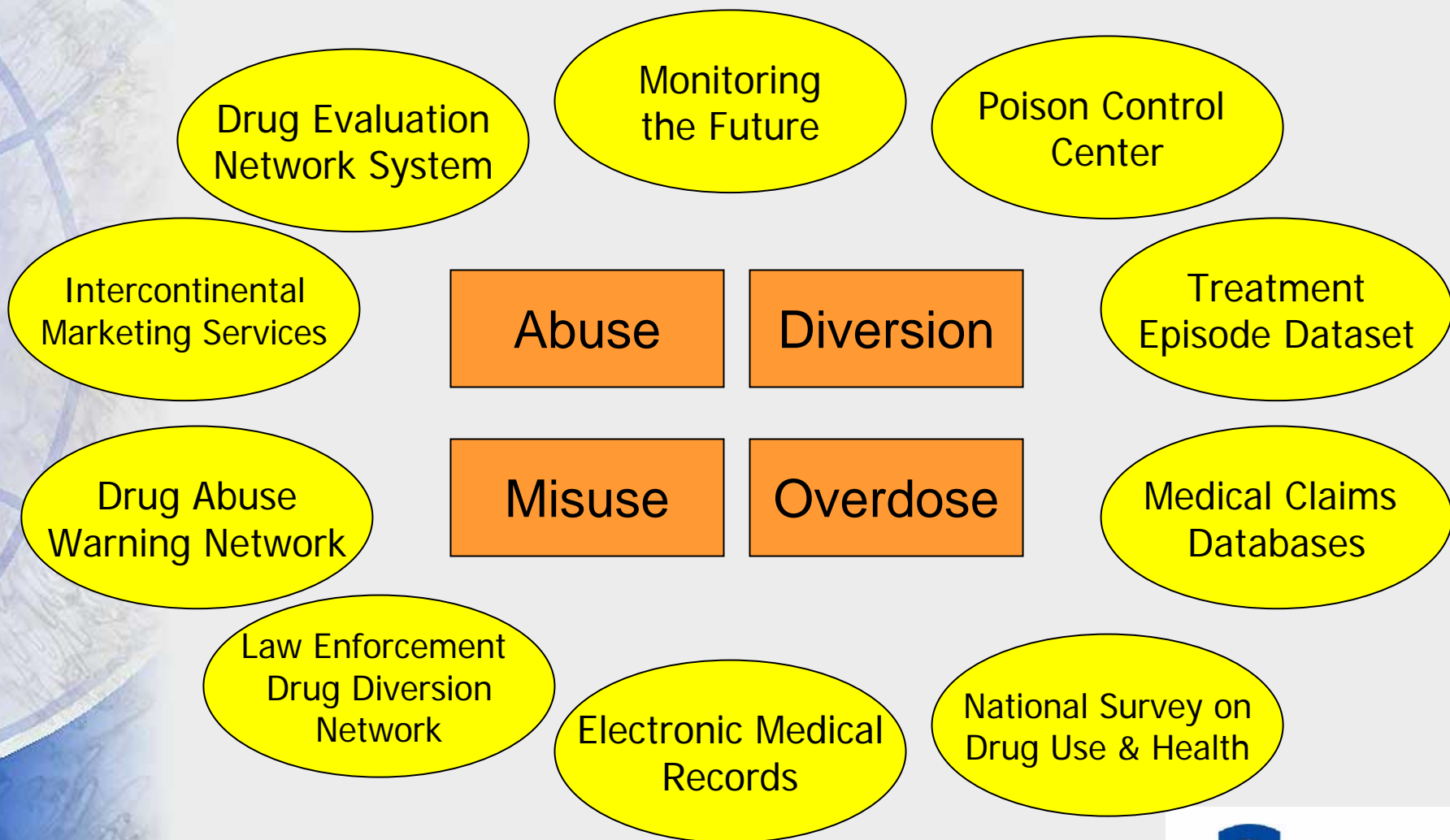
- **Surrogate measures are commonly used to evaluate the effectiveness of the RiskMAP**
 - **E.g. The effectiveness of physician education program to address ‘off-label use’ may be measured by physician comprehension surveys following the educational campaign. The survey does not measure the effect of the educational program on the actual risk**
- **A well thought out surveillance program will be able to assess the effectiveness of the RiskMAP by directly measuring the risk**
 - **E.g. Is there any change in off-label use before and after the educational campaign?**

Measuring RMP Effectiveness via Company Safety Database



- Translate risks into measurable terms.
- Standardize data entry into and retrieval of cases from the Company database for reports associated with identified risks.
- Use trend analysis of comprehensive data to identify changes over time-direct marker for success of the RMP.

Selecting Additional Databases



Databases Selected for Opioid Surveillance

Risk	J&J PM Data	FDA AERS	PCC	NFLIS	IMS	DAWN
Abuse	X	X	X			X
Overdose	X	X	X			X
Misuse	X	X	X		X	
Diversion	X	X		X		

PM: Postmarketing
 FDA: US Food & Drug Administration
 AERS: Adverse Event Reporting System
 PCC: Poison Control Center
 NFLIS: National Forensic Laboratory Information System
 IMS: Intercontinental Marketing Services Database
 DAWN: Drug Abuse Warning Network

Databases considered, but not selected

- **Prescription/Medical Claims Databases and Electronic Medical Records**
 - Under-coding may occur
 - Cash payments and street drug use may not be captured
 - Data may not be generalizable (e.g. Medicaid, EMR)

Summary

- **Surrogate measures are usually employed to evaluate effectiveness of a RiskMAP**
- **An effective surveillance plan is key to monitoring RiskMAP effectiveness and provides a direct measure of its effect.**
- **Multiple data sources may be needed to capture information on all the identified risks, necessitating the need for coordinated data retrieval, analysis, and reporting.**