

Signal Management

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What is Risk Management?

- **FDA Definition**

- *an iterative process of assessing a product's benefit-risk balance, developing and implementing tools to minimize its risks while preserving benefits, evaluating tool effectiveness and reassessing the benefit-risk balance, and making adjustments, as appropriate, to the risk minimization tools to further improve the benefit-risk balance.*

- **EMA Definition**

- *a set of activities and interventions designed to identify, characterize, prevent or minimize risks relating to pharmaceuticals, and the assessment of the effectiveness of those interventions.*

What is a Signal?

1. An indication
2. A sign or event fixed or understood as the occasion for prearranged combined action
3. Anything which incites to action

Webster's Dictionary Unabridged

Sources of Information

- Pharmacovigilance
 - Healthcare providers
 - Patients
 - Literature
 - Media
 - Company representatives
- Non-traditional sources
 - Supply chain
 - Internet
 - Law enforcement
 - Media
 - Federal surveys
 - Poison Control Centers
 - Drug abuse treatment programs
 - Key informants

Non-traditional Sources

- Supply chain
 - Manufacturer
 - Shipping
 - Warehouse
 - Pharmacy
 - Drug recipient
 - Reverse distributors
 - Internet
 - Counterfeit
 - Bait and switch
 - Real drug

Non-traditional Sources

- Internet
 - Chat rooms about drug abuse
 - Chat rooms about specific drugs
 - List serves
 - Sales sites
 - Blogs
 - MySpace
 - Facebook

Non-traditional Sources

- Law enforcement
 - Federal
 - State
 - Local
 - Private sources

Non-traditional Sources

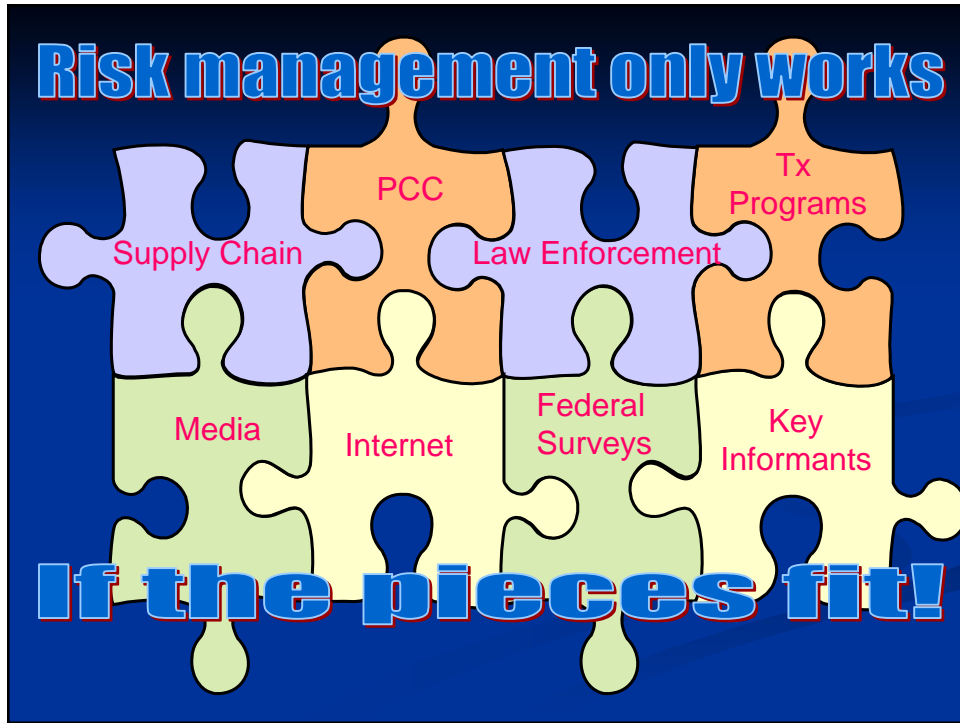
- Media
 - National and local
 - Print
 - Newspapers
 - Magazines
 - Journal articles
 - Electronic
 - Television
 - Blogs
 - Radio

Non-traditional Sources

- Federal and state surveys
 - National Survey of Drug Use and Health (NSDUH the survey formerly known as NHSDA)
 - New Drug Abuse Warning Network (DAWN)
 - DAWN Live!
 - Monitoring the Future (MTF)
 - Treatment Episode Data Set (TEDS)
 - National Drug Intelligence Center (NDIC)
 - State student surveys

Non-traditional Sources

- Poison Control Centers
 - Toxic Exposure Surveillance System (TESS)
 - Private sources
- Drug abuse treatment programs
 - TEDS
 - Private sources
- Key informants
 - Private sources
 - Regulatory Agencies

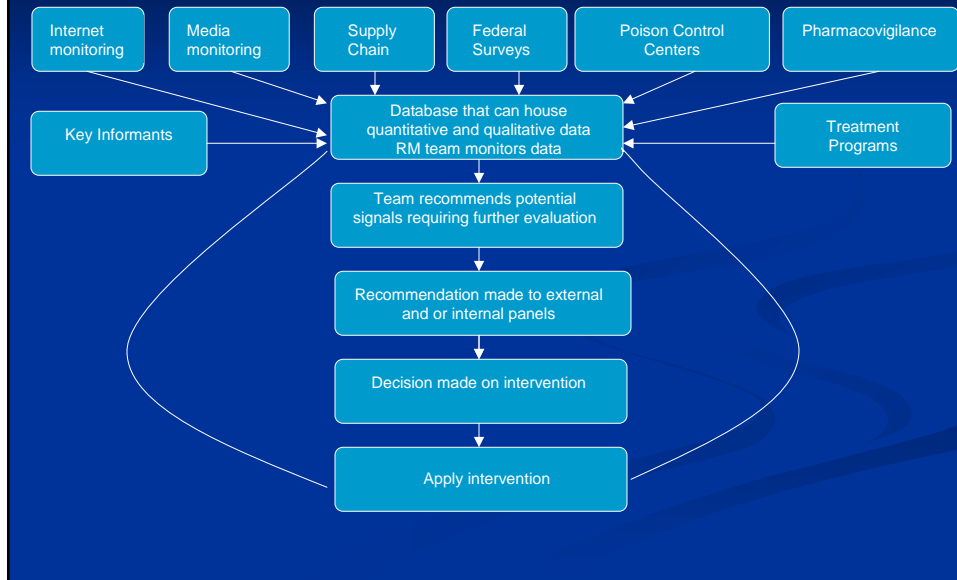


Assessment of Sources of Information

- Intensity
- Frequency
- Timeliness
- Multiple sources
- Geographic location

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Model for Evaluation and Response of Potential Signals Identified through Risk Management Surveillance and Monitoring



Thank you

Time to Discuss