Building Blocks for a Post-Market Surveillance System

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There is Currently No “System”

- Pharmaceutical industry captures observations of AE’s and are mandated to follow up and report to FDA
- No look at misuse, overuse, off label use
- Much is learned from studies – randomized, case-control or observational that are performed post market
This was acceptable in 1970 but not now – given scope and magnitude of pharmaceutical use.

Need to rapidly understand impact of introduction of new drug into system.
Opportunity

- New Opportunities – unprecedented
  - Basic science
  - E-HR and automation in healthcare

- Important that new system not be just problem count→ learning, improvement, understanding root cause (misprescribing, inherent risk, individual risk, over Rx, etc.)
What Should We Ask of New System

- **Capacity**
  - Rapid signal detection
  - Capacity for confirmatory studies

- **Scope**
  - Broad population coverage – diversity in population and settings
  - Broad range of products and interventions
What Should We Ask of New System

- **Science Based**
  - Capacity for research; strong links to academia
  - Research component for continuous improvement
  - Link to basic science → mechanistic studies

- **Operation**
  - Transparent and public
  - Consensus methods for detection and analysis
  - Broad stakeholder input and oversight
What Should We Ask of with New System

- Communication and Implementation
  - Findings broadly disseminated
  - Collaboration of health plans, medical journals and outreach method
Organizational Design

- Convenor hub (non- or quasi- governmental), ability to engage in PPP
- Oversight board
- Data Management organization (contract)
- Research group
- Communication group
- Methodologic group—consensus methods and analyses
- Possible DMB-type structures to oversee analyses
Is This Possible?