Expert Workshop: Communicating Findings from Active Medical Product Surveillance

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Tom Menighan, RPh, MBA, ScD, FAPhA
Executive VP and CEO
American Pharmacists Association

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ADE Today

- Adverse Drug Event Overview: U.S.
- - ~500,000 Adverse Drug Event (“ADE”) reports annually to
- – Most from Health Care Providers
- - 95% of ADE reported first to manufacturers (5% reported direct to FDA via MedWatch)
- – Most ADEs reported to manufacturers via 800#
- – After triage manufacturers report to FDA
- – For every ADE reported to FDA >2 others were triaged and not reported
- – MedWatch has 1-size fits all form with follow up issues
- - Current reporting is difficult for providers
- – Slow, time consuming (typically phone + phone tag)
- - Current reporting is difficult and expensive for manufacturers
- – Cost of call centers + follow up + reporting to FDA + missed ADEs
- - <10% of ADEs are actually reported according to studies
- – Low reporting due in part to difficult ADE system
- – Studies show that EHR adoption = increase ADE reporting

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Panel I: Patient, Consumer, and Health Care Provider Perspectives

- At what point will the public, patients and health care providers want information derived from active surveillance to be communicated to them?
  - Health care providers, including pharmacists, need information as it evolves, not just when regulatory decisions are made by FDA and sponsors
  - Info should be delivered when evaluation indicates clinical significance of reported events. Ranking?
  - Increased interest in newly approved drugs and AE not identified until drug is broadly used. Emerging signals unique to specific populations of particular interest.

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Panel I: Patient, Consumer, and Health Care Provider Perspectives

- How can the residual uncertainty associated with active surveillance findings be best communicated?
  - Communications of risks or safety signals should not be delayed
    - Health care providers can use evolving information as they balance drug information with patients' needs, desire, literacy and other factors to optimize therapy
  - Communication should optimize the benefit of evolving signals & balance patients' rights. Health professionals must balance emerging info with fears of uncertain risks
    - Misplaced or overstated fears may limit appropriate and necessary therapies
    - Feedback loop is essential to promote reporting.

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Panel I: Patient, Consumer, and Health Care Provider Perspectives

- What are the unique concerns from your perspective related to communicating findings from active surveillance, and how can these be addressed?
  - Given the under-reporting of ADE, providing feedback on emerging risk would show practitioners that their vigilance and reporting are making a difference and encourage more active reporting
  - Pharmacists work in environments where information is readily available electronically – use to patient advantage
  - Pharmacists have demonstrated value in practice-based research network and post-market surveillance activities
  - APhA is leading a broad collaborative effort to integrate pharmacists in all practice settings into existing and future EHR systems

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APhA Background

- Represent pharmacists in all practice setting; over 62, 000 members
- Pharmacists play an important role in monitoring medication use as part of the patient's health care team
- APhA supports FDA's efforts to streamline data collection processes and ADE reporting
- APhA is part of the FDA MedWatch Partner Program
- Published *Adverse Event Reporting – Why and How* tool for pharmacists and patients (available on pharmacist.com)

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APhA Policy

2009 Pharmacist's Role in Patient Safety

- It is APhA's position that patient safety initiatives must include pharmacists in leadership roles.
- APhA encourages dissemination of best practices derived from nationally aggregated reporting data systems to pharmacists for the purpose of improving the medication use process and making informed decisions that directly impact patient safety and quality.
- APhA encourages the profession of pharmacy to continually review and evaluate ways to enhance training, curricula, continuing education and accountability of pharmacists to improve patient safety.

APhA Policy (continued)

2009 Pharmacist's Role in Patient Safety

- APhA encourages risk management and post-marketing surveillance programs to be standardized and include infrastructures and compensation necessary to allow pharmacists to support these patient safety programs.
- APhA supports the creation of voluntary, standardized and interoperable reporting systems for patient safety events to minimize barriers to pharmacist participation and to enable aggregation of data and improve quality of medication use systems. The system should be free, voluntary, non-punitive, easily accessible, and user friendly for all providers within the healthcare system.
- APhA supports the elimination of hand-written prescriptions or medication orders.

(JAPhA NS49(4):492 July/August)

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APhA Policy

2008 Pharmacy Practice-based Research Networks

- APhA supports establishment of pharmacy practice-based research networks (PBRNs) to strengthen the evidence base in support of MTM and pharmacy primary care services.
- APhA encourages collaborations among stakeholders to determine the minimal infrastructure and resources needed to develop and implement local, regional and nationwide networks for performing pharmacy practice-based research.
- APhA encourages pharmacy residency programs to actively participate in pharmacy practice-based research networks.

(APhA NS48(4):470 July/August 2008)

Adverse Events

- Any undesirable experience associated with the use of a medical product in a patient
- **Serious** adverse events are defined by federal regulations as events that result in the following patient outcomes:
  - Death
  - Life-threatening condition
  - Hospitalization (initial admission or prolongation of stay)
  - Disability
  - Congenital anomaly
  - Intervention to prevent permanent impairment or damage

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Risk Evaluation and Mitigation Strategies (REMS)

- FDA-required REMS programs are intended to ensure the benefit of the drug continues to outweigh the risk
- REMS are implemented by frontline physicians, other prescribers, and pharmacists
- APhA has taken a lead role in working with FDA and other stakeholders to improve REMS program design, standardization, and implementation
- As REMS programs evolve to better capture outcomes measures, both successes and failures, Sentinel could serve as a data source

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References

- APhA Comment letter to FDA re: Docket No. 2007N-0480. Maximizing the Public Health Benefit of Adverse Event Collection Throughout a Product's Marketed Life Cycle (Feb. 29, 2008)
- APhA One Minute Counselor: Adverse Event Reporting, Why and How
- APhA's REMS White Paper, 2009
- Establishing Pharmacist Practice-Based Research Networks, APhA Foundation White Paper (Schommer), May 2010

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