AMCP Biosimilars Collective Intelligence

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Biosimilar Collective Intelligence System: Utilizing Data Consortiums to Monitor Safety and Effectiveness of Biosimilars

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• Real World Data is not going to go away.
• Data Consortiums are:
  • Future keys to Demonstrating value, Driving innovation, Ensuring patient safety and Gaining customer insights
  • Successful consortiums provide Timely Access, Collaboration, Transparency
• Why AMCP Biosimilars Collective Intelligence?
  • Proactive, Large, Active, Early, Focused
  • Managed care organizations have devoted significant resources to developing an infrastructure that makes active surveillance in distributed research networks possible
  • It is important for managed care pharmacy to marshal these resources for the important public health benefit inherent in monitoring biosimilar safety and effectiveness

  Our strength: our large managed care databases, and our primary focus on biosimilars, and their active and early surveillance.

Our Mission: Furthering Biosimilar adoption by assuring physicians and the public that managed care and industry are working together to monitor biosimilars
AMCP Biosimilars Collective Intelligence Consortium Approach

• Off-the-shelf approach using proven network tools and technology to provide Active, Early and Focused surveillance
  • Operational Distributed Research Networks (DRNs): HMO Research Network, Mini-Sentinel
  • Still Developing DRNs: PCORnet, NIH Health Care Systems Collaboratory
• Tested machine learning technologies that are able to distinguish Real vs Background noise

AMCP Surveillance Method

• Prospective, Active, Sequential analysis of accumulating data based on a potential safety signal observed with the same or a similar medical product
  • Start reviewing data as early as possible.
  • Over time, more observational information is added to the surveillance database.
  • Data are extracted, manipulated, summarized, and analyzed continuously as more information accumulates to search for safety signals.
  • Requires specific data analysis methodology (e.g., sequential probability ratio testing) as the same data are being subjected to repeated statistical testing.
• Simply identifies the signal, allowing one to then investigate prediction and causality.
AMCP Biosimilars Collaboration

- No single entity is capable of pulling this off.
  - Strength is in the number of managed care organizations and their enormous combined patient population
  - Key is to develop trust and respect, with all partners working towards a common mission.
    - Managed Care has consistently demonstrated an ability to drive such partnerships
  - To gain that trust, each partner must be transparent and frank regarding the potential and limitations of their organization’s data.
  - When entering these collaborations, no one partner can dominate decision making.

Governance Structure—Advisory Council

- To guide and govern the work of an off-the-shelf data coordinating center
- To consider recommendations of research subcommittee statistical methods recommendations
- Oversee the functional and technical requirements by ensuring collaboration among clinicians and technologists.
- Composed of key stakeholders (managed care, industry, researchers, PBMs, patient advocacy, regulatory)
- Use of existing consortium models for legal, business and other governance structures
Biosimilars Pathway: *The Key Issues*

1. Guidelines
2. Totality of Evidence
3. Clinical Program
4. Global Studies
5. Immunogenicity
6. Multiple Pathways
7. Extrapolation
8. Common Reference Product
9. Common INN (international nonproprietary name)
10. Interchangeability
Challenges in Conducting Research

• Resource availability and feasibility influences study design and analysis, which influences the validity and generalizability of conclusions

• Retrospective observational studies, especially claims-based, are relatively fast and cheap but have a greater risk of bias (inadequate clinical data; potentially non-comparable populations or delivery of interventions; confounding)

• Prospective studies are expensive and slower

• RCTs (efficacy) typically conducted in non-generalizable settings with short-term outcomes
Governance & Informatics Challenges

- Privacy and proprietary considerations limit data sharing across organizations
- End-users of research rarely involved in specifying research questions, especially outcomes of interest
- Variability in data quality
- Data standardization and interoperability across EHRs remains an important area of activity
- Variability in IRB decision-making complicates multi-site research or QI projects
- Distributed research is a viable alternative to traditional research but does not solve all problems
Rationale for CER

- Large gaps in knowledge of the impact of therapeutics and diagnostics on patient outcomes in the real-world
  - Lack of alignment in goals of researchers, clinicians, policymakers; short-term outcomes, one-off projects; information and expertise is in silos; end-users need to be involved to ask “right” questions
  - Limitations in existing data infrastructure and study methods
Changing Milieu in Health Care Delivery & Research

• Increased EHR adoption (meaningful use incentives); interest in “mobile” health
• Increased focus on PCOR and CER (PCORI, AHRQ)
• Resource constraints and desire for demonstrating value – multi-functional electronic data infrastructure (clinical care, QI, research)
• Moving to a user-driven research paradigm; need appropriate incentives to engage end-users early in the research process
Objectives of the Electronic Data Infrastructure Projects

- Link multiple healthcare delivery sites
- Connect multiple databases
- Focus on priority populations and conditions
- Prospective, patient-centered outcomes
- Conduct CER
- Valid and generalizable conclusions
- Focus on governance and sustainability
- For registries: also conduct QI; leverage existing registry
- For DRNs: multiple diseases and populations; near-real time data collection and analysis
• test
Collective Intelligence Outline

• Need for post marketing surveillance
• Why multisite studies
• Surveillance and sequential analysis
• Mini-Sentinel
Biosimilars At Approval: Knowns & Unknowns

• We know
  – Within a small, well-defined population in a controlled environment, and short-term exposure, the drug is
    • Relatively safe
    • More effective than placebo

• We don’t know
  – Real-world safety
  – Real-world effectiveness
  – Comparative effectiveness
  – Cost-benefit
We know that we don’t have a **reliable** system for actively monitoring and investigating what we don’t know.
Benefits of a Surveillance System

If we had a reliable system to generate post marketing evidence

– Change the risk-benefit calculation for stakeholders and the FDA
– Improve use of medications via evidenced-based medicine
– Encourage drug development
“A principal goal of our post approval drug-safety system should be to minimize the delay between approval and the discovery of these serious risks.”

Sometimes Multi-site Studies Are Needed

- Rare exposures
- Rare outcomes
- Sample size (speed)
- Sub-group analyses
- Analytic flexibility
When multi-site studies are needed

Distributed networks aren’t far behind
Some distributed networks

• CDC’s Vaccine Safety Datalink (VSD)
• HMO Research Network
• FDA’s post-market safety programs
• Meningococcal Vaccine Safety Study
• EU-ADR
• Scalable PArtnering Network for CER: Across Lifespan, Conditions, and Settings (SPAN)
• Post-licensure Rapid Immunization Safety Monitoring (PRISM)
• FDA Mini-Sentinel
• NIH Health Care Systems Collaboratory
• PCORI National Clinical Research Network
Distributed network approach

• Standardize data
• Data partners maintain physical control of their data
• Data partners control all uses of their data
• Data partners control all transfer of data
• Computer programs should run at multiple sites without modification
DRNs: Key Success Factors & Characteristics

- Engagement with data partners
- Coordinating center support
- Analytic tools
- Data, epidemiologic, and statistical expertise
- Type of data source (insurer, delivery system)
- Data refresh frequency
- Self-aware learning system
- Operational efficiency
Active Surveillance of Vaccine Safety
A System to Detect Early Signs of Adverse Events

Robert L. Davis,† Margarete Kolczak,‡ Edwin Lewis,† James Nordin,§ Michael Goodman,§ David K. Shay,‡ Richard Platt,¶ Steven Black,† Henry Shinefield,† and Robert T. Chen‡

Background: There currently are no population-based systems in the United States to rapidly detect adverse events after newly introduced vaccines. To evaluate the feasibility of developing such systems, we used 5 years of data from 4 health maintenance organizations within the Centers for Disease Control and Prevention (CDC) Vaccine Safety Datalink.

Methods: Within every year, each week’s vaccinated children were followed for 4 weeks, and rates of adverse events were compared with rates among children of similar ages before the introduction of the new vaccine. We assessed risks for intussusception after rotavi-

Conclusions: We conclude that it is feasible to develop systems for rapid and routine population-based assessments of new vaccine safety. (Epidemiology 2005;16: 336–341)

Recent events in the United States have underscored the need for surveillance systems that detect adverse events as soon as possible after the introduction of new vaccines (eg,
Real-Time Vaccine Safety Surveillance for the Early Detection of Adverse Events

Tracy A. Lieu, MD, MPH,*† Martin Kulldorff, PhD,* Robert L. Davis, MD, MPH,‡
Edwin M. Lewis, MPH,§ Eric Weintraub, MPH,‡ Katherine Yih, PhD, MPH,* Ruihua Yin, MS,*
Jeffrey S. Brown, PhD,* and Richard Platt, MD, MSc,* for the Vaccine Safety Datalink Rapid Cycle
Analysis Team

Background: Rare but serious adverse events associated with vaccines or drugs are often nearly impossible to detect in prelicensure studies and require monitoring after introduction of the agent in large populations. Sequential testing procedures are needed to detect vaccine or drug safety problems as soon as possible after introduction.

Conclusions: Real-time surveillance combining dynamic data files, aggregation of data, and sequential analysis methods offers a useful and highly adaptable approach to early detection of adverse events after the introduction of new vaccines.

Key Words: vaccine safety, active surveillance, sequential analysis, meningococcal vaccine, drug safety
Early detection of adverse drug events within population-based health networks: application of sequential testing methods†,‡

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Adverse drug event surveillance pilots

Observed & expected events: rofecoxib vs naproxen users: 2000-2005

Signal after 28 events (16 expected) among new users of drug

Brown *et al.* (2007) PDS; Adjusted for age, sex, health plan. Outcome: AMI.
Post-Market Safety Surveillance

Signal identification:
Potential safety concern identified

Signal Refinement:
Initial evaluation of safety concerns

Signal evaluation:
Formal assessment of potential safety concerns

Passive Surveillance (FAERS)

REMS and other assessments

Data Mining

Summary Tables
Modular Programs
PROMPT
Protocol-based Evaluations

Mini-Sentinel
Rapid response querying and surveillance

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Mini-Sentinel Partner Organizations

Lead – HPHC Institute

Data and scientific partners

Scientific partners

www.amcp.org
Cross functional staff of programmers, research associates, analysts, research assistants and vendors support the Data Group and workgroups
# Mini-Sentinel Common Data Model

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<thead>
<tr>
<th>Lab Results</th>
<th>Person ID</th>
<th>Dates of order, collection &amp; result</th>
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<td>Test type, immediacy &amp; location</td>
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<td>Inpatient data model</td>
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[25 years celebrating a quarter century of success!](www.amcp.org)
Data QA and characterization

1. Develop QA Package
2. Execute QA Package
3. Review Output & Submit to MSOC
4. Track Receipt & Metadata
5. Execute Internal Programs
6. Review Output
7. Create Report
8. Execute Internal Programs
9. Review Output
10. Annotate Report
11. Review Report & Finalize
12. Review Report & Investigate Issues
13. Comment on Report
14. Review Report & Comment
15. Approve ETL
16. Track Approval & Metadata

*Program Development Team Follows MS SAS Program Development SOP to Create QA Package

MSOC

Data Partner

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celebrating a quarter century of success!
Mini-Sentinel infrastructure systems

- Operations are all based on SOPs
- Tools are treated like software
  - Bug tracking system for all changes to code and code development
- FISMA compliant secure portal
- Activity tracker
- Secure distributed query tool
Mini-Sentinel querying tools

- **Summary table queries**
- **Modular programs**
  - Utilization patterns and cohort identification
  - Rate of adverse events following exposure
  - Background rates
- **“macro” library**
- **Prospective Routine Observational Monitoring Program Tools (PROMPT)**
  - Self-controlled design (exposure indexed)
  - Cohort design, with propensity score (exposure) matching
  - Cohort design, with regression adjustment (GEE)
  - Cohort design, with IPT weighted regression adjustment
Multiple networks sharing infrastructure
This assessment [...] FDA’s Mini-Sentinel pilot...
Dabigatran and Postmarketing Reports of Bleeding

Mary Ross Southworth, Pharm.D., Marsha E. Reichman, Ph.D., and Ellis F. Unger, M.D.

“In the months following the approval of the oral anticoagulant dabigatran ... in October, 2010, the FDA received through the FDA Adverse Event Reporting System many reports of serious and fatal bleeding events associated with use of the drug.”

FDA Drug Safety Communication: FDA approves label changes to include intestinal problems (sprue-like enteropathy) linked to blood pressure medicine olmesartan medoxomil

View and print full Drug Safety Communication (PDF - 64KB)
en Español

Safety Announcement

[7-3-2013] The U.S. Food and Drug Administration (FDA) is warning that the blood pressure drug olmesartan medoxomil (marketed as Benicar, Benicar HCT, Azor, Tribenzor, and generics) can cause intestinal problems known as sprue-like enteropathy. FDA has approved changes to the labels of these drugs to include this concern.

Symptoms of sprue-like enteropathy include severe, chronic diarrhea with substantial weight loss. The enteropathy may develop months to years after starting olmesartan, and sometimes requires hospitalization if a cause is found. Discontinuation is required in all patients.

Olmesartan medoxomil is an angiotensin II receptor blocker (ARB) approved for the treatment of high blood pressure, alone or with other antihypertensive agents, and is one of eight marketed ARB drugs. Sprue-like enteropathy has not been detected with ARB drugs other than olmesartan.

FDA will continue to evaluate the safety of olmesartan-containing products and will communicate again if additional information becomes available.
FDA Releases Final Study Results of a Mini-Sentinel Postlicensure Observational Study of Rotavirus Vaccines and Intussusception

FDA Safety Communication — June 13, 2013

FDA Releases Final Study Results of a Mini-Sentinel Postlicensure Observational Study of Rotavirus Vaccines and Intussusception

FDA Approves Required Revised Labeling for RotaTeq Based on the Study Results

Purpose: To inform the public and healthcare providers that FDA is releasing final study results from a Mini-Sentinel postlicensure observational study of intussusception (a form of bowel obstruction) after vaccination with RotaTeq (Merck and Co., Inc.) and Rotarix (GlaxoSmithKline Biologicals).

RotaTeq and Rotarix are vaccines for the prevention of rotavirus gastroenteritis in infants 6 weeks to 32 weeks of age (RotaTeq) and infants 6 weeks to 24 weeks of age (Rotarix). The study was conducted in Mini-Sentinel’s Postlicensure Rapid Immunization Safety Monitoring (PRISM) program, the largest vaccine safety surveillance program in the United States.

FDA has approved required revisions to the Prescribing Information and Patient Information for RotaTeq as a result of the new safety data from this Mini-Sentinel PRISM study. New information was added to the Highlights, the existing intussusception subsections section, and the Post-Marketing Experience section of the Full Prescribing Information and Patient Information. The Mini-Sentinel PRISM study is the largest study of rotational intussusception to date and identified an increased risk of intussusception in the 21-day time period after the first dose of RotaTeq, with most cases occurring in the first 7 days after vaccination. No increased risk was found after the second or third doses. These findings translate into 1 to 1.5 additional cases of intussusception per 100,000 first doses of RotaTeq.

The data from the Mini-Sentinel PRISM study regarding the risk of intussusception following the use of Rotarix were inconclusive. Based on this study, no changes were made to the Prescribing Information or to the Patient Information for Rotarix. However, based on data from an observational study previously conducted in Mexico, it is estimated that 1 to 3 additional cases of intussusception would occur per 100,000 vaccinated infants in the United States within 7 days following the first dose of Rotarix. In September 2012, FDA announced that it had approved revisions to the Prescribing Information and to the Patient Information for Rotarix to include these results from the study in Mexico.
AMCP Position on Biosimilars Naming

Where We Stand on Biosimilar Drug Therapies

The Academy of Managed Care Pharmacy (AMCP) supports an abbreviated licensure pathway for the approval of biosimilar biologic drug therapies by the U.S. Food and Drug Administration (FDA). Biological products are certain to play an increasingly important role in the country’s health care system – both in terms of scientific improvements in the treatment of disease and increased drug costs. The Academy believes that an expedited approval process for biosimilar products provides a needed incentive for the development of new therapeutic products that hold the promise of preventing, treating or curing otherwise inevitable, untreatable and incurable diseases. Such a process will help ensure greater access to new therapies at costs expected to be below those of a FDA-approved biological product (a “reference product”).

It is important for the approval process to support an appropriate balance between bringing safe and effective drugs to market and maximizing patient access to affordable drugs. The regulatory process must be designed to rigorously examine the safety and efficacy of a biosimilar applicant, but not prove so burdensome in either the length of time required for review or in added costs for the manufacturers seeking the biosimilar license that manufacturers are discouraged from filing for approval. To this end, the FDA may request additional clinical studies prior to approval.

Manufacturers of approved biosimilars should be allowed to use the same government-approved name/international nonproprietary name as the reference product (e.g. epoetin alpha for Procrit®). This will hopefully ease confusion among prescribers and patients and help to encourage substitution of biosimilar products. In addition, it is important to use current mechanisms such as manufacturer name, national drug code (NDC) numbers and lot numbers to effectively differentiate batches for safety monitoring purposes.

*As defined by the FDA: “A biosimilar biological product is a product that has clinically similar differences from the reference product in terms of safety, purity, and potency of the product.”

*As defined by the FDA: “Biological products can include a wide range of products including vaccines, blood and blood components, allergens, somatic cells, gene therapy, tissue, and protein. Unlike most traditional, small-molecule prescription drugs that are made through chemical processes, biological products are generally made from human and animal materials. Biological products are usually larger than and have a more complex structure than small-molecule prescription drugs. Such products may be manufactured through biotechnology, derived from natural sources, or, in some cases, produced synthetically.”

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Biosimilars Naming

Potential Solutions To Avoid Misclassifying Newly Approved Biologics

- Report NDC codes submitted in Block 19 in Medicare physician file along with J codes
- Assign specific J codes immediately when infusion drugs approved

- EMA: “main drive for an additional code appeared to be added safety, but with many biosimilars now appearing on the market it could be confusing for prescribers as to what a biosimilar actually is, when confronted with multiple qualifiers.”
Key AMCP Biosimilars Activities

• AMCP Biosimilars Data Consortium: Providing *evidence* of the value and safety of biosimilars

• Ensuring patient access and data integration by actively participating in regulatory and policy-making decisions on key biosimilar topics including:
  • Nomenclature
  • Patient/Provider notification requirements
  • Electronic Prior Authorization

• Providing information on the value of Biosimilars to managed care pharmacists, providers, patients, and other managed care stakeholders

• Partnering with key companies and organizations to pool resources to achieve our desired outcomes and objectives
• AMCP desires to work with all biosimilar manufacturers to bring the products to the marketplace to improve access and control costs for healthcare consumers.

• To schedule an individual meeting with your organization’s biosimilars team, please contact Charlie Dragovich at cdragovich@amcp.org