Pediatric Medical Devices: The FDA Postmarket Perspective

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Brief Overview of Surveillance Tools

- Reporting of Adverse Events and Product Problems
  - Medical Device Reporting
  - Medical Product Surveillance Network

- Post-approval Studies

- “Postmarket Surveillance”
  - Section 522 of the Federal F, D and C Act
Medical Device Reporting System

- >200,000 individual reports per year
- ~95% of reports from manufacturers
- ~4% are known pediatric reports (birth to 21 years)

Medical Product Safety Network (MedSun)

- A national network of 350 user facilities
- Connection to clinical community
- Each facility has program liaisons; specifically trained to recognize & report
- Electronic reporting to reduce burden
- Robust program of feedback
- Emphasis on use issues, near misses
MedSun Initiatives

Developing sub-networks: targeted reporting

- **KidNet** – pediatric and neonatal intensive care units
  - Initiated June 2007
  - Number of hospitals: 42 hospitals (1/2 pediatric only)
  - Action taken: firm issued customer letter to address NICU monitor screens spontaneously going blank

http://www.fda.gov/cdrh/MedSun/
Post-approval Studies (PAS)

- Required studies on highest risk devices [class III Premarket Approval (PMA) devices]
- Ordered at time of approval with agreed upon protocol as goal
- Authority under CFR Title 21 Section 814.82 (a) FDA may impose post-approval requirements at the time of approval of the PMA ...
  (2) Continuing evaluation and reporting on the safety, effectiveness, and reliability of the device for its intended use. . .
Characterization of PAS

- About 1/2 of PMAs have these requirements
- Since 2005, ~75% (73/99) of PAS involve pediatrics (only ~10% under age 12)
- Studies may be surveillance-based, descriptive, analytic
- Examples of devices under study
  - Amplatzer VSD occluder: 5 y f/u pivotal cohort and new registry (procedural success, complications, shunt status)
  - Olympic Cool-cap for HIE: registry noting cooling rx, major complications, LOS, hospital discharge dx
- PAS help inform device’s performance and potential opportunity for further device improvements

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm
“Postmarket Surveillance”
(Section 522 of F, D and C Act)

- Studies ordered on class II/III devices
- FDA may require Section 522 for...
  - failure...reasonably likely to have serious adverse health consequences OR
  - expected to have significant use in pediatric populations OR
  - implanted > 1 year OR
  - life-supporting/life-sustaining used outside device user facility
Characterization of Section 522

- 35 studies currently ordered on 6 device types
- Two studies involve pediatric patients
  - Automatic external defibrillator: experience with OTC usage noted via survey
  - Overnight orthokeratology contact lenses: microbial keratitis incidence based on retrospective survey of practitioners and users
Current Landscape

Passive and enhanced reporting systems address...

- Out-of-box failures; software glitches; manufacturing defects; packaging error; labeling error; design-induced use error; misconnects/disconnects; poor maintenance…but
- Need continued and better documentation in reports

Mandated postmarket studies address...

- Rates of clinical outcomes (e.g., complications), but
- Small in scope, time limited

Health-related electronic records largely untapped

- Device identifiers generally not captured/not available
- Purchasing/inventory files or stand-alone product-specific files (like implant logs) not linked to patient records
- Documentation poor (e.g., device problems, clinical/procedural information)
- Widespread off-label use presents challenges
Current Landscape

Claims data of some utility though…

- Procedure codes not intended to capture device
  - Occasionally they do, e.g., insert synthetic graft
  - Occasionally may capture 1st-of-kind device
- Adjusting for patient mix challenging
  - Selection factors, disease severity, residual confounding
- Assessing outcomes challenging
  - Validated algorithms crucial
  - Need for additional data (e.g., radiology results)

Use data of limited utility

- Market share data
  - Brand-specific data limited
  - Age breakdowns not available
  - Indications not available
- Manufacturer data
  - Numbers manufactured, distributed
Current Landscape: Registries

Critical role

- May provide product-specific identifiers
- Provides clinically rich information (about patient and procedure)
- May be longitudinal (if integrated/linked to appropriate sources)
- Provides rate information on clinical outcomes
- Fills critical void in absence of unique device identifier (UDI)

CDRH pediatric efforts

- Foster registry development/enhancement
  - IMPACT (Improving Pediatric and Adult Congenital Rx)
- Assess pediatric registries
  - Compendium of 37 U.S. based registries
Thanks for Your Attention!

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