Registries for Medical Device Evaluation

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Registry Data
Embedding Studies in Registries

- FDA trials
- Public Health Clinical Trials
- Basic Registry Data QI, Surveillance, etc.

Legal and Regulatory Frameworks:
- 21 CFR Part 50: Common Rule
- HIPAA
Proposed Specific Actions to Strengthen Device Postmarket Surveillance

1. Establish UDI System and Promote the Incorporation of UDI into Electronic Health Information

UDI critical for various surveillance efforts (including attributes)

UDI critical to leveraging distributed data sources

2. Promote the Development of National and International Device Registries for Selected Products

Critical in development of proof-of-concept active surveillance efforts

Need to be linked to other longitudinal data sources for effective ongoing and prospective surveillance
3. Modernize Adverse Event Reporting and Analysis

- Automated methods may enhance reporting and case ascertainment
- Bi-directional surveillance may amplify potential signals

4. Develop and Use New Methods for Evidence Generation, Synthesis, and Appraisal

- Surveillance operating characteristics vary by study design, parameter specification, and data source
- Need to understand and account for learning curve effects
MDEpiNet Public-Private Partnership provides global leadership in innovative data source development and analytic methodologies for implementation of medical device research and surveillance to enhance patient-centered outcomes.
CDRH Registry Efforts

- Use existing registries for PAS studies and surveillance
  - INTERMACS (NIH, CMS, FDA)
  - Total Joint Replacement Registry (Kaiser)
  - Australian National Joint Replacement Registry
  - UK National Joint Replacement Registry
  - TVT Registry

- Facilitate new registry development
  - AED Registry
  - TVT Registry (ACC/STS/CMS/Industry)
  - IMPACT Registry (ACC)
  - PROFILE (ASPS)
  - National Breast Implant Registry (ASPS, industry)
  - PFDR (AUGS, ACOG, industry)

- Use existing registries for discretionary studies
  - ICD Registry
  - Society of Thoracic Surgeons Registry
  - Kaiser National Joint Replacement Registry
CDRH Registry Efforts (cont)

- Explore registry capabilities
  - Active surveillance: short-term and longitudinal (DELTA)
  - Linkages studies with Medicare claims data (TVT)

- Build methodological infrastructure for registries
  - International Consortium of Orthopedic Registries (ICOR) – 30 registries from 15 nations
  - International Consortium of Cardiovascular Registries (ICCR) – 6 registries

- Directly access de-identified patient-level registry data for public health surveillance
  - Grant of Authority under HIPAA to University of Washington to Collect AED and patient outcome data
  - ACC/STS TVT registry linked to CMS claims accessed as condition of approval

- Use registry data to expand indications
  - ACC/STS TVT Registry data used to expand Edwards’ Sapien Valve indications
High-Performance Integrated Virtual Environment (HIVE)

Discrete Data

Big Data

Regulatory Decision-making

Bio-compatibility
Lab tests
AE and other clinical data
Imaging

Ad hoc bench testing

Patient Demo graphics
The gaps

• The interpretation of current federal regulations (particularly the Privacy and Common Rules) by various IRBs has created significant obstacles for existing registries.

• New trial designs and data sources rely on development of methodology for analysis.

• Rules and regulations regarding direct FDA access to data need to be developed in concert with pre- and post-market review procedures.

• Effective public health analysis in the Big Data era requires robust and active collaboration among ALL stakeholders.
Thank you!

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