# Active Surveillance Opportunities

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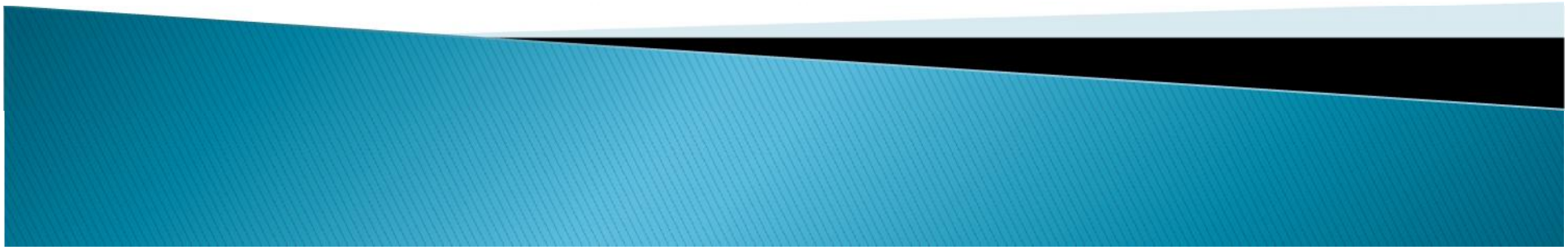


# Outline

- Definitions, Elements and Attributes of Surveillance Systems
- Case Example
- Regulatory Opportunities
- Final Remarks

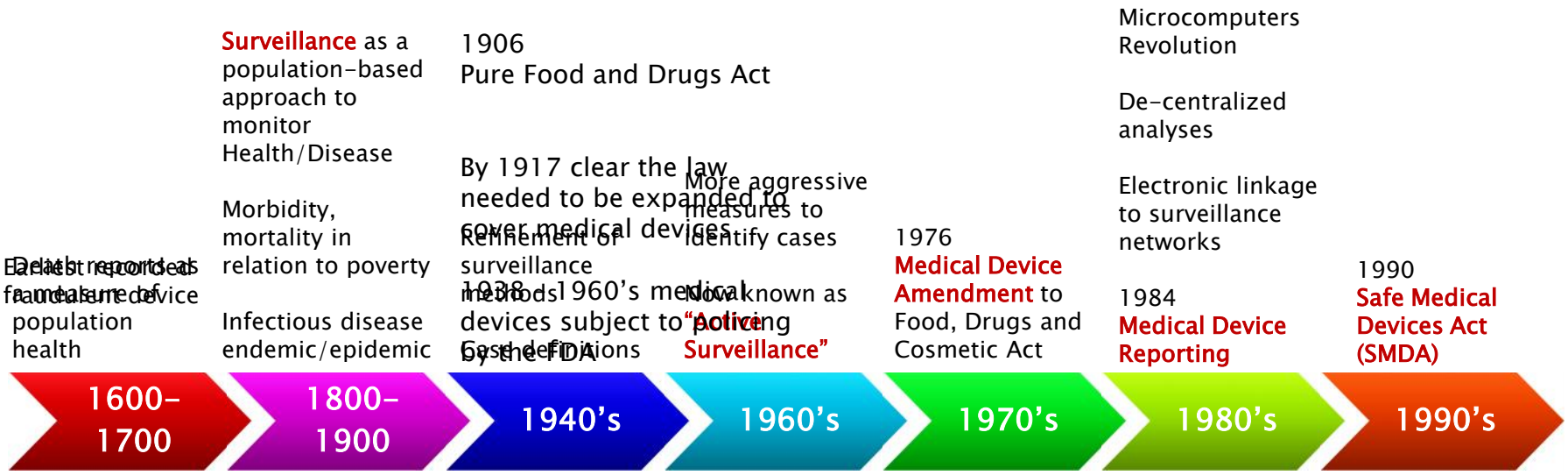
# Epidemiologic Surveillance

- Surveillance
  - Continuous and systematic collection, analysis, interpretation and dissemination of information for monitoring health problems.
- Surveillance System
  - Network of people and activities that maintain this process and may function at a range of levels from local to national or international.
- Public Health Surveillance
  - Most surveillance systems are operated by public health agencies that use surveillance to guide disease prevention and control activities.
  - Basis for public health policy.

# Epidemiologic Surveillance

- Modern surveillance concepts were shaped by programs addressing infectious diseases
- Health problems monitored today reflect diversity of epidemiology and public health responsibilities
  - Acute and chronic diseases, reproductive health, injuries, environmental and occupational hazards, behaviors
  - **Medical products/technology**
- Diverse methods to obtain surveillance information
  - Traditional case reporting (active, passive)
  - Analysis of data already collected such as electronic health records, registry data, etc.

# History of Public Health Surveillance and Medical Devices Regulation




Development of methods for surveillance: for example, required reporting of communicable diseases, national health surveys, disease registries, pregnancy registries, networks for sentinel physician practices.

# Opportunities for Surveillance of Medical Devices

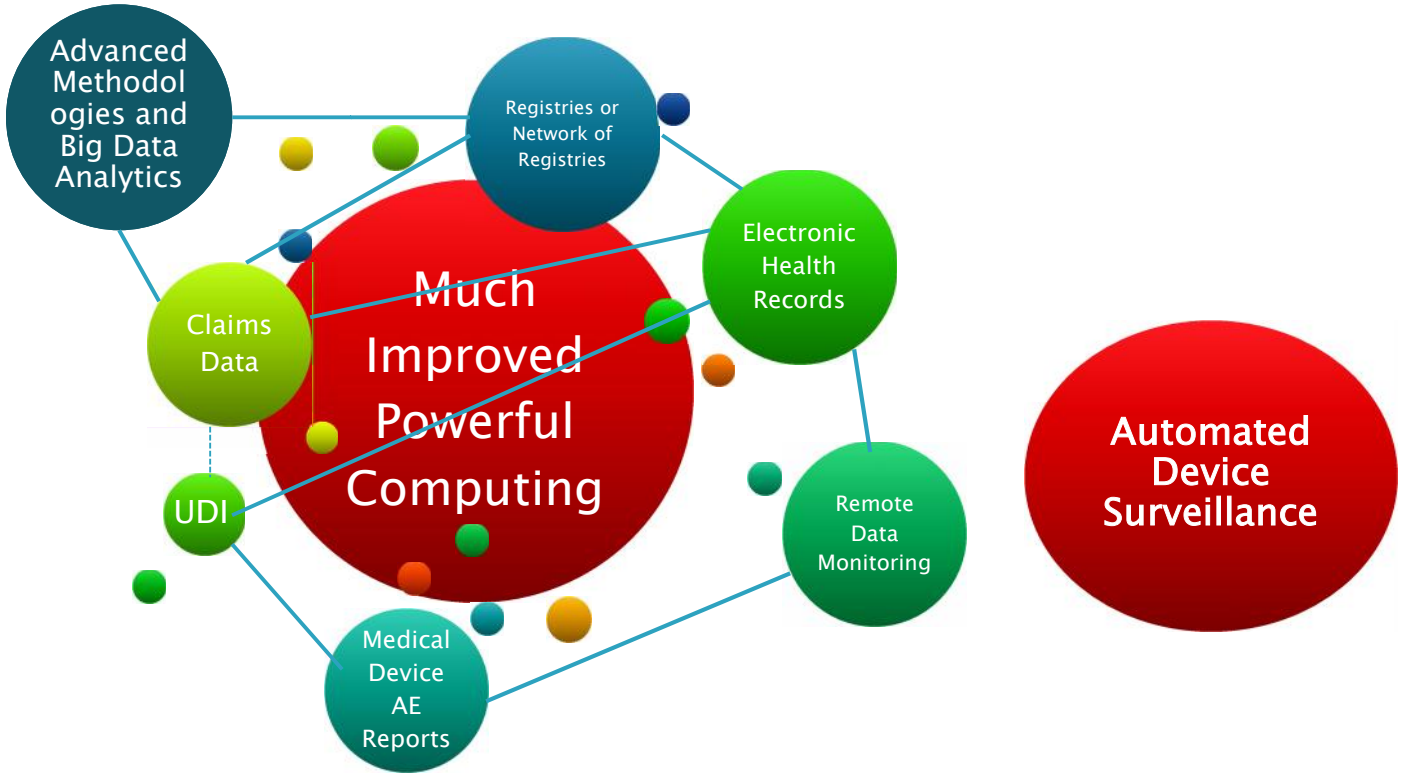
Rapid dissemination of new medical device technology

Passive reporting of medical device adverse events

Lack of standards in data collection

Amendments to medical device regulation

2000's




Development of advanced methods for surveillance

# Elements of a Surveillance System

- Objective
- Case Definition
- Population under Surveillance
- Time Period
- Data to be collected
- Who provides the data?
- How is data transferred and stored?
- Who analyzes the data and how often?
- How is the data analyzed?
- How are findings (reports) disseminated (frequency and to whom)?
- Confidentiality
- Incentives to Participation

# Automated Surveillance System

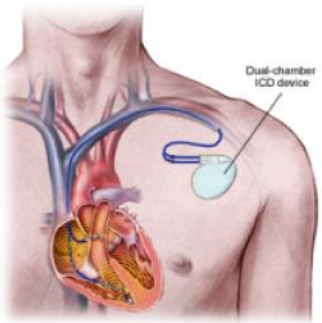
- System that can automate the process of identifying adverse events (cases) by using data in existing infrastructure such as Electronic Health Records or Registries.
- Ability to identify low frequency adverse events for which intervention “X” may present an increased relative risk for, compared to alternatives.
- Ability to identify the adverse events in a near real-time basis.
- Ability to be used in different device areas, as data sources become available.
- Ability to be used nationwide and with international data sources.

# Automated Surveillance for Leads

## Case Example

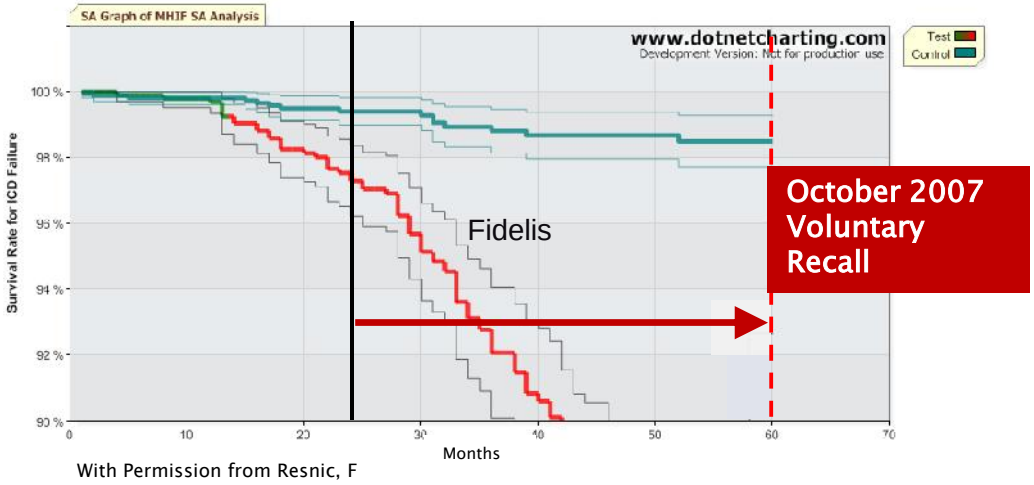
# Medtronic Fidelis 7fr ICD Lead

- Innovative Medtronic Fidelis 7fr ICD Lead approved in 2004 on basis of bench testing
- Initial reports of lead fractures from several high volume centers prompted more detailed review in March 2007
- Lead continued to be marketed
- By October 2007, Medtronic noted that 668 lead fracture events were reported, with 5 deaths possibly due to device failure.
- Voluntarily recalled October 2007
- 268,000 Fidelis Leads sold worldwide.




# Public Health Impact of Automated Surveillance for Pacing Leads: A Case Example

- Using pooled data from *three* high volume centers, DELTA performed a propensity matched analysis.
- 859 Fidelis lead implants versus alternative leads.
- By 25 months of analysis 3% of Fidelis leads had fractured (red line) whereas only 0.1% (1 of 859) alternative ICD leads had fractured.




With Permission from Resnic, F

Hauser et al. Early detection of an underperforming implantable cardiovascular device using an automated safety surveillance tool; *Circ Cardiovasc Qual Outcomes* 2012: 5(1)

# Public Health Impact of Automated Surveillance for Pacing Leads: A Case Example

- If a prospective automated surveillance system was in place, the poorly performing device could have been identified within **25 months** of surveillance and intervention could have taken place **35 months** earlier.
- The delay in intervention resulted on an estimated **70,000 patients** in the U.S. receiving the defective ICD lead.

# Automated Surveillance Opportunities

- Existing Efforts
  - MDEPINet
    - DELTA ACC NCDR
    - PASSION
  - NCDR ICD Registry
    - Leveraged for mandated studies
    - Potential for automated surveillance, **if linked to other data sources**
- Endpoints of Interest
  - Revisions
  - Lead fracture
  - Perforations
- Remote Data Monitoring
  - Elevated pacing capture threshold, electrical dysfunctions
  - Not harmonized across manufacturers
  - Distributed network model

# Final Remarks


- Take advantage of available technology and tools. Catch up with advanced surveillance methodologies.
- Successful surveillance systems depend on effective collaborative relationships and the usefulness of the information.
- Feed information back to those who participate and relevant parties.
- More efficient and effective surveillance can yield improved technology, improved patient outcomes.

# Contact

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