Strengthening Patient Care: Building an Effective National Medical Device Surveillance System

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Planning Board Membership

- Members were selected through a public nomination process
  - Open and transparent call for nominations
  - Final selection was made by third party expert group
- Membership includes a broad array of stakeholders in the medical device ecosystem
  - Representatives from patients, clinicians, researchers, provider organizations, health plans, industry, and experts in health information systems
  - Representative from key government agencies including FDA, NIH, AHRQ, CMS, and ONC
- The Planning Board consists of 22 members volunteered their time and expertise over nine months to develop the report

Planning Board Charge

- Develop the long-term vision for sustainable national system for medical device postmarket surveillance including the governance principles, operational components, and business models characteristics
- Final report was publically released February 2015

Envisioning a 21st Century System

- Essential component of a learning health care system
- Seamlessly uses information collected at the point of care
- Minimizes data capture burden
- Driven by the need to improve public health and patient care
- Meets the diverse evidentiary needs of stakeholders

Planning Board System Mission

*The **National Medical Device Postmarket Surveillance System (MDS)** supports optimal patient care by leveraging the experiences of patients to inform decisions about medical device safety, effectiveness, and quality in order to promote the public health.*

- Key System Functions:
  - Provide better evidence on the benefits and risks of medical devices to enable active safety surveillance and more effective decision-making throughout the total product life cycle (TPLC)
  - Support postmarket evidence generation activities that better balances pre- and postmarket data collection, provide benefit/risk assessments, and facilitate device innovation
  - Support high-priority evidence needs such as product tracking and utilization, clinical quality improvement, and economic analyses of medical device-related care

Key Recommendations from the Planning Board

- Creation of a multi-stakeholder public-private entity to implement and manage coordinating center to effectively support meaningful evidence develop for medical device
  - Drive through coordination and collaboration a harmonized national approach to medical device evidence development
  - Leverage existing tools and programs to create a collaborative, interconnected network of data sources
  - Integrate with the national health information infrastructure and the learning health care system
- Proposed 2-Phase Implementation Strategy
  - Years 1-2: A short-term incubator phase
  - Years 3-8: Implementation of the long-term MDS PPP

Guiding Principles for the System

- Support FDA device priorities
- Patient and clinician-focused
- Integrated component of a broader national effort
- Multi-stakeholder collaboration
- Forward looking and continually evolving
- Clear expectations and transparent communication
- Maximizing utility and minimizing burden
- Respecting and protecting data privacy and security

Governance Characteristics

- System governance
  - Addressing conflicts of interest
  - Creating public transparency
  - Developing reliable data and methods
- Data governance
  - Protecting patient privacy
  - Building data integrity and security
  - Managing proprietary information and intellectual property
  - Balancing transparency and confidentiality

Key Areas for Continued Development

- Data network/model development
  - Planning Board Recommendation
    - Tier I: core set of data elements to support surveillance priorities
    - Tier II: enriched data set for more sophisticated analyses
    - Tier III: comprehensive data set to enable studies that require advanced evidentiary needs
- Creating the methods and tools to link diverse data sources to develop meaningful information
  - Multi-pronged implementation of UDIs in electronic health system
- Creating value for different stakeholder groups