THE
PEW
CHARITABLE TRUSTS

Josh Rising, MD
Director, Healthcare Programs
August 24, 2015

The Pew Charitable Trusts

The Pew Charitable Trusts is an independent, non-profit research and public policy organization.

Pew seeks to enhance medical device safety and foster device innovation that benefits patients.

- Unique device identifier
- Medical device registries
- Accelerating patient access

Need Better Data on Device Quality

Critical time to improve device safety and facilitate innovation

- Recent high-risk device failures

- Total Product Life Cycle (TPLC) regulation to expedite patient access

- Dearth of information for clinicians and patients to make informed decisions

- Emergence of better, electronic data sources and methods

Figure 1
High-profile Device Failures
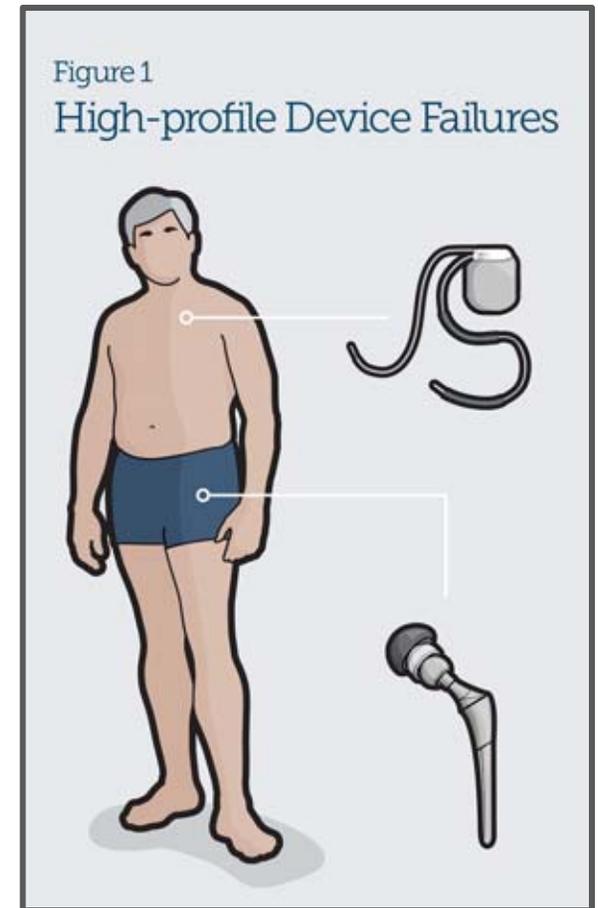
Recommendations Reflect Findings

Findings in the Medical Device Task Force report reinforce findings from Pew and Pew-sponsored research

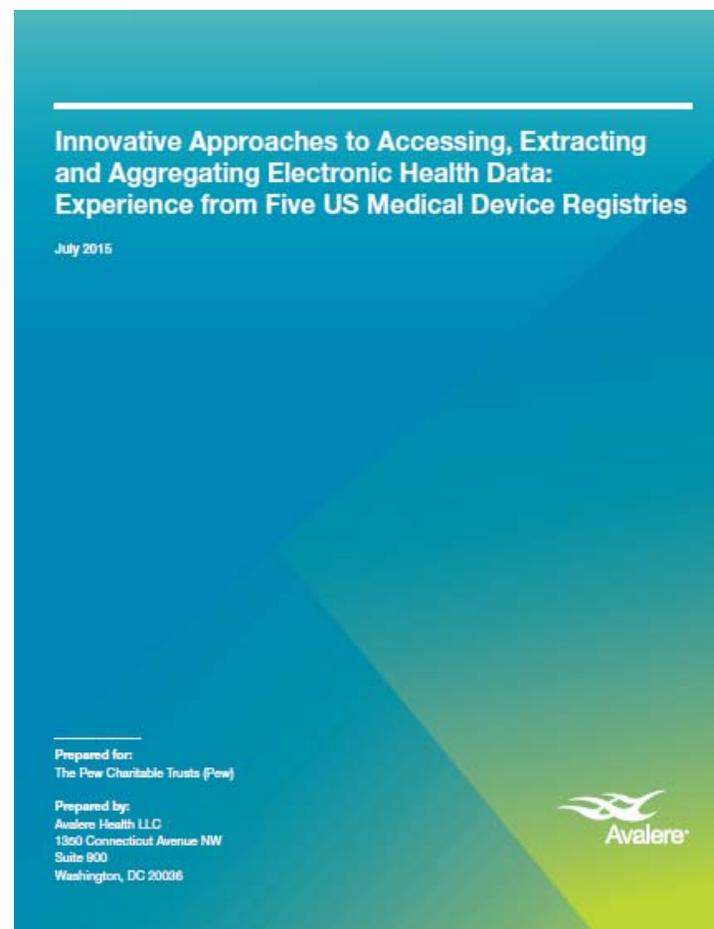Pew-MDEpiNet-Blue Cross Blue Shield Association report

- Streamline registry data collection through better integration & interoperability
- Standardized definitions
- Coordinate registries with other national efforts
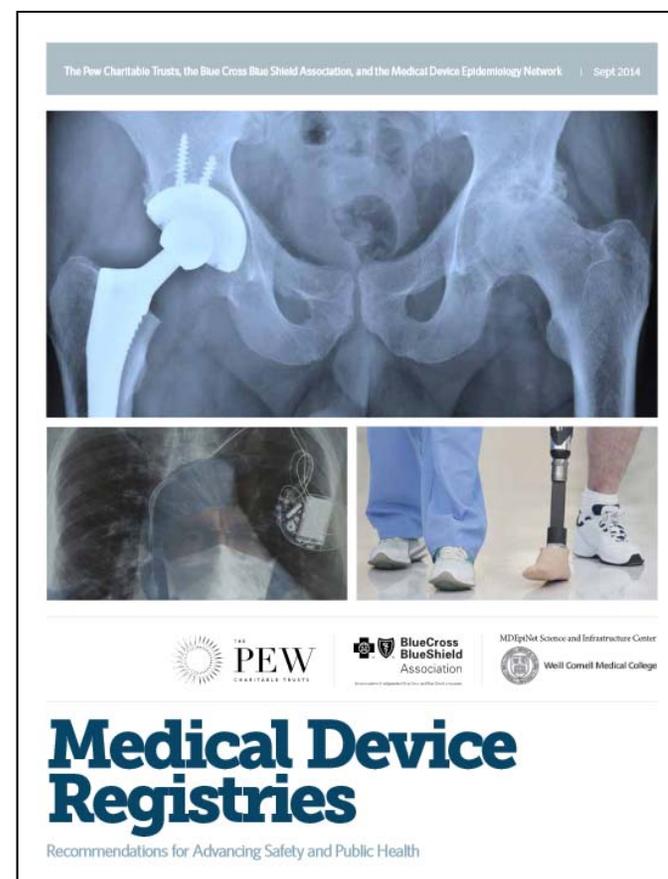
Recommendations Reflect Findings, cont.

Pew-funded report from Avalere Health

- Develop a common data model, and ensure its use

- Implementation of UDI across data sources

- Proprietary vendor systems lack interoperability

- **Webinar:**

  September 15th, 2015

  11:30 a.m. - 12:30 p.m., EST

  medicaldevices@pewtrusts.org

Innovative Approaches to Accessing, Extracting and Aggregating Electronic Health Data: Experience from Five US Medical Device Registries

July 2015

Prepared for:
The Pew Charitable Trusts (Pew)

Prepared by:
Avalere Health LLC
1350 Connecticut Avenue NW
Suite 900
Washington, DC 20036

MDRTF: Better Data for CRNs

Can achieve more, better data for Coordinated Registry Networks (CRNs) by:

1) Use of a common data model by registries, FDA, EHRs, manufacturers, others

2) Adoption of UDI in electronic health information sources

3) Coordination of registry and postmarket surveillance efforts

Next Steps: Common Data Model

Encourage the use of common data models by registries, manufacturers, FDA, EHR developers and others

- ONC Common Clinical Data Set
    - A base data set for registries

- CDISC
    - Could be adopted for both premarket and postmarket applications
    - FDA and manufacturers could accelerate this effort through the user fee program

Enhance patient matching to accurately link data

Next Steps: UDI Adoption

Encourage UDI adoption into registries, EHRs and claims

- EHRs
  - Finalize ONC proposal to include UDI in EHRs
  - Finalize UDI inclusion in CCDS, and encourage its exchange

- Claims
  - Multi-stakeholder support
  - Provides registries with longitudinal data

- Need pilots to demonstrate feasibility and utility of UDI capture
  - Consider user fees and other funding sources

Next Steps: Device Data Entity

Multiple reports have suggested that a single entity coordinate and leverage multi-stakeholder efforts to enhance device data collection

- Must leverage and enhance existing data collection

- Must develop best practices and policies to accelerate better data

- Must have value for and be supported by multiple stakeholders:
    - Manufacturers, regulators, payors, registries, clinicians, etc.
    - Requires multi-sourced funding
    - May require seed funding to establish self-sustaining business plan, governance, etc.
    - Multiple potential seed funding models, including user fees

Conclusion

Registries have tremendous potential to improve data collection—both pre- and postmarket

- With the shift to a TPLC approach, more efficient data collection is all the more critical

- Must have benefits to patients, clinicians, innovators and others

- All stakeholders need to work together and invest time and resources to achieve the potential of registries
  - Will not happen on its own without leadership from HHS, Congress and the private sector
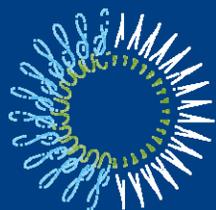
THE **PEW**
CHARITABLE TRUSTS

For additional questions or information, please contact:
Josh Rising
jrising@pewtrusts.org
202-540-6761