The BUILD Initiative:
Next Steps in Supply Chain Innovation & Medical Device Evaluation

April 19, 2016
Overview

- Mercy
- MDEpiNet
- First round of MDEpiNet demonstrations
- MDEpiNet Public Private Partnership
  - PASSION
  - SMART Informatics Think Tank
- HTG
- Mercy UDI Demonstration
- BUILD Initiative
- Future Shock
34 ACUTE CARE HOSPITALS
4,396 LICENSED BEDS
36,917 CO-WORKERS
185 PHYSICIAN PRACTICE LOCATIONS
4,659 MEDICAL STAFF MEMBERS
1,235 INTEGRATED PHYSICIANS
$4.6 OPERATING REVENUE (Billions USD)
The Mercy UDI Strategy

- Integration of UDI into EHR
- Creation of data sets containing clinical & device information
- Linkage to other health systems & national registries (Distributed Data Network)
The Mercy Multidisciplinary UDI Team

- Research
- Clinicians (Cardiac Cath Labs)
- Health Information Technology
- Supply chain (ROi)
- Performance Solutions
What was MDEpiNet?

- Part of the Epidemiology Research Program (ERP) at the FDA’s Center for Devices and Radiological Health (CDRH)

- Collaborative program through which CDRH and external partners share information and resources to enhance our understanding of the safety and effectiveness of medical devices after they are marketed
MDEpiNet is now a Public Private Partnership
MDEpiNet PPP: Predictable And Sustainable Implementation Of National Cardiovascular Registries (PASSION)

• Demonstrate the goals of MDEpiNet by using cardiovascular medical device registries to bridge evidence gaps across the medical device total product life cycle

• Registry Assessment of Peripheral Interventional Devices (RAPID) → Infrastructure/feasibility
  – Society for Vascular Surgery Patient Safety Organization
  – Professional Societies (ACC, SIR, SVS)
  – Governmental agencies (FDA, CMS)
  – Manufacturers
MDEpiNet PPP: SMART Informatics Think Tank
February, 2015

1. Building UDI Into Longitudinal Data for Surveillance and Research (BUILD)
   - Extension of UDI Implementation Pilot
   - Electrophysiology structured reporting providing UDI for Leads and devices using industry Standards to Electronic Health Records and CVIS systems (EPulse)
   - Medical Device Data Capture and Exchange: Leading Practices and Future Directions

2. An Internal Hospital Unique Device Identifier Registry: Workflow and Infrastructure Redesigns

3. EHR Minimum Data Set and Structured Data Capture for Registries

MDEpiNet
Report to FDA: Coordinated Registry Networks
The Healthcare Transformation Group (HTG)

- Alliance of 5 major health systems (Geisinger, Intermountain, Kaiser, Mayo, & Mercy) to accelerate Supply Chain Management (SCM) standards adoption and implementation
- Leadership team of supply chain management executives at each institution
- An Adoption and Implementation team made up of those driving these efforts at each institution
- HTG R&D team to make full use of supply chain data for device evaluation
- Members of HTG are individually participating in various aspects of MDEpiNet, FDA Sentinel Initiative, and the HMO Research Network.
Key Components of UDI Demonstration

- Create prototype UDIs & associate with attributes in the FDA’s Global UDI Database (GUDID)
- Create clinically meaningful supplemental attributes to be stored in a reference database
- Create UDI data flow through ERP to cath lab to EHR to UDI data set
- Create UDI fields in the CathPCI Registry
- Perform studies to demonstrate validity and reliability of data
- Identify obstacles to incorporating UDIs into EHR and explore solutions
What do we need to do?

- Create partnerships to establish a UDI system
  - Health Systems (HTG: Mayo, Geisinger, Intermountain, Kaiser-Permanente, Mercy)
  - Professional Societies (American College of Cardiology and the Society for Cardiovascular Angiography & Interventions)
  - National Registry (National Cardiovascular Data Registry’s CathPCI Registry)
  - Industry (Abbott, Boston Scientific, Medtronic)
  - FDA

- Propose and appropriate governance of the UDI system for long term sustainability
Performance Solutions - What we did...

Changes to Cath Lab Process

- The UDI project required us to make changes to how the Cath Lab process works
- The changes we made improved many aspects of the workflow in the Cath Lab
Mercy Device Data Flows

**Glossary:**
- ADT = Admit/Discharge/Transfer
- DI = Device Identifier
- EHR = Electronic Health Record
- ERP = Enterprise Resource Planning
- GUDID = Global UDI Database
- ID = Integrated Patient Datastream
- MPI = Master Patient Index
- MRN = Medical Record Number
- SUDID = Supplemental UDI Database
- UDI = Unique Device Identifier
- UDIR = UDI Research Database
The UDI Research Database (UDIR)
Device attribute: DES Combined
Patient characteristics: All
Outcome: Mortality

Drug eluting stents: 1361 patients/35 deaths

Bare metal stents: 184 patients/18 deaths
Building UDI Into Longitudinal Data for Medical Device Evaluation (BUILD)

Lead Investigators: Joseph P. Drozda, Jr. (Mercy) & James E. Tcheng (Duke)

Sub-project Principal Investigators: Jove Graham (Geisinger), J. Brent Muhlestein (Intermountain), Natalia Wilson (Arizona State), David Slotwiner (Weill Cornell)
Components of BUILD

- Extension of UDI Implementation Pilot
- Electrophysiology structured reporting providing UDI for Leads and devices using industry Standards to Electronic Health Records and CVIS systems (ePulse)
- Medical Device Data Capture and Exchange: Leading Practices and Future Directions (The BUILD Consortium)
The BUILD Distributed Data Network
Status of BUILD

- Funding from FDA (Grant # 1U01FD005476-01)
- Work on 3-year initiative begun on 1/1/2016
- Investigative team in place (lead investigators, IT & supply chain professionals, academics, industry representatives, FDA)
- Workgroups developing plans for UDIR & the distributed data network
- Coordinating with RAPID and VANGUARD
What’s Next? (Things we’d like to do)

• Tap into other data streams
  – Patient reported outcomes
  – Claims

• Apply methodology to other devices

• Collaborate
  – Sentinel
  – PCORnet
  – ICOR and other registries and registry networks

• Add hospital partners to the network
  – HTG systems
  – Others
The National Medical Device Evaluation System
Thanks!

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References:

