

Realities of UDI Capture: The Mercy/BUILD Experience

RAPID Workgroup, April, 2016

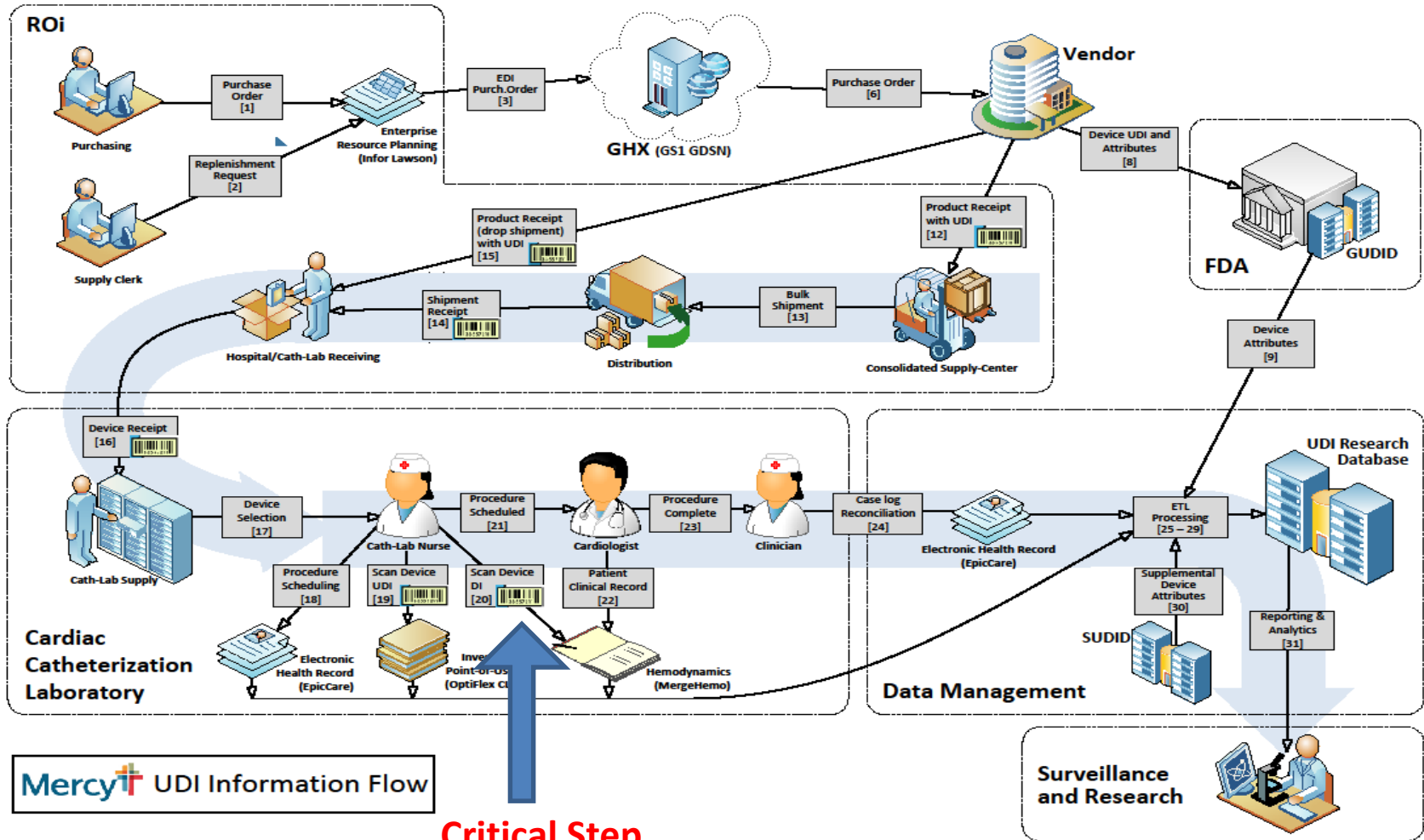
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The Mercy/BUILD UDI Strategy

- **Integration of UDI into multiple systems**
- **Creation of data sets containing clinical & UDI-associated device information**
- **Linkage among 3 health systems (Geisinger, IHC, Mercy) & to national registries (Distributed Data Network)**

Mercy Demonstration UDI Data Flow





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

Challenges and Opportunities

| Challenge | Detail | Solutions |
|--|---|---|
| <i>Technology Integration</i> | No bnterface between inventory management and hemodynamic software systems | Clinical staff “double scan” products. Ongoing discussions with software vendors |
| <i>Capturing Information</i> | Software limitations for capturing device data (UDI lineage and attributes) | Await solutions by vendors Capture data in the UDI Research Database |
| | Two barcode standards (GS1 & HIBC) | Link items in enterprise resource processing software to inventory management software with vendor item numbers |
| <i>Inventory Management Application and Data Limitations</i> | Software requirement for serial numbers but serial numbers not used by manufacturers on coronary stents | Mercy created “dummy barcodes and serial numbers” (Not sustainable) |
| | Conflicting facility numbering systems, i.e., FDA use of DUNS® numbers versus Mercy’s GS1’s Global Location Numbers (GLNs). | DUNS® to GLN cross-reference database |
| | Non-standardized device descriptions | Standard device descriptions created for coronary stents. |
| <i>Implementation Effort</i> | Greater than anticipated need for assistance by Cath Lab personnel | One Cath Lab team member dedicated to implementation |

Challenges and Opportunities

| Challenge | Detail | Solutions |
|---------------------------|--|---|
| <i>Training Methods</i> | Requirement for training of Cath Lab personnel on the new point of use system. | <p>In person classroom sessions</p> <p>eLearning modules to supplement classroom sessions</p> <p>eLearning modules for refreshing knowledge</p> |
| <i>Charging / Billing</i> | Cath Lab personnel confusion over meaning of item uniqueness (function versus catalog number) and use of incorrect charge codes. | UDI and point of use system (UDIs are unique to the individual item.) |
| <i>Product barcodes</i> | No barcodes on some items | Barcodes generated internally for coronary stents and items with no codes |
| <i>Inventory Value</i> | <p>Confusion created by multiple barcodes on some items</p> <p>Cath Lab personnel underestimation of inventory prior to point of use system implementation</p> | <p>Cath lab personnel training on identification of correct barcodes</p> <p>Accurate and complete Cath Lab inventories with point of use system</p> |
| <i>Expired Inventory</i> | Difficulty identifying expired items prior to point of use implementation | Automated expiration date tracking by point of use system allowing transfer to another facility or return to vendor. |
| <i>Overall Complexity</i> | Lack of familiarity of Cath Lab personnel with point of use information systems, e.g., business intelligence and third party software | Training of Cath Lab personnel by internal operational consultants on systems followed by continued coaching until personnel were proficient |

Challenges and Opportunities

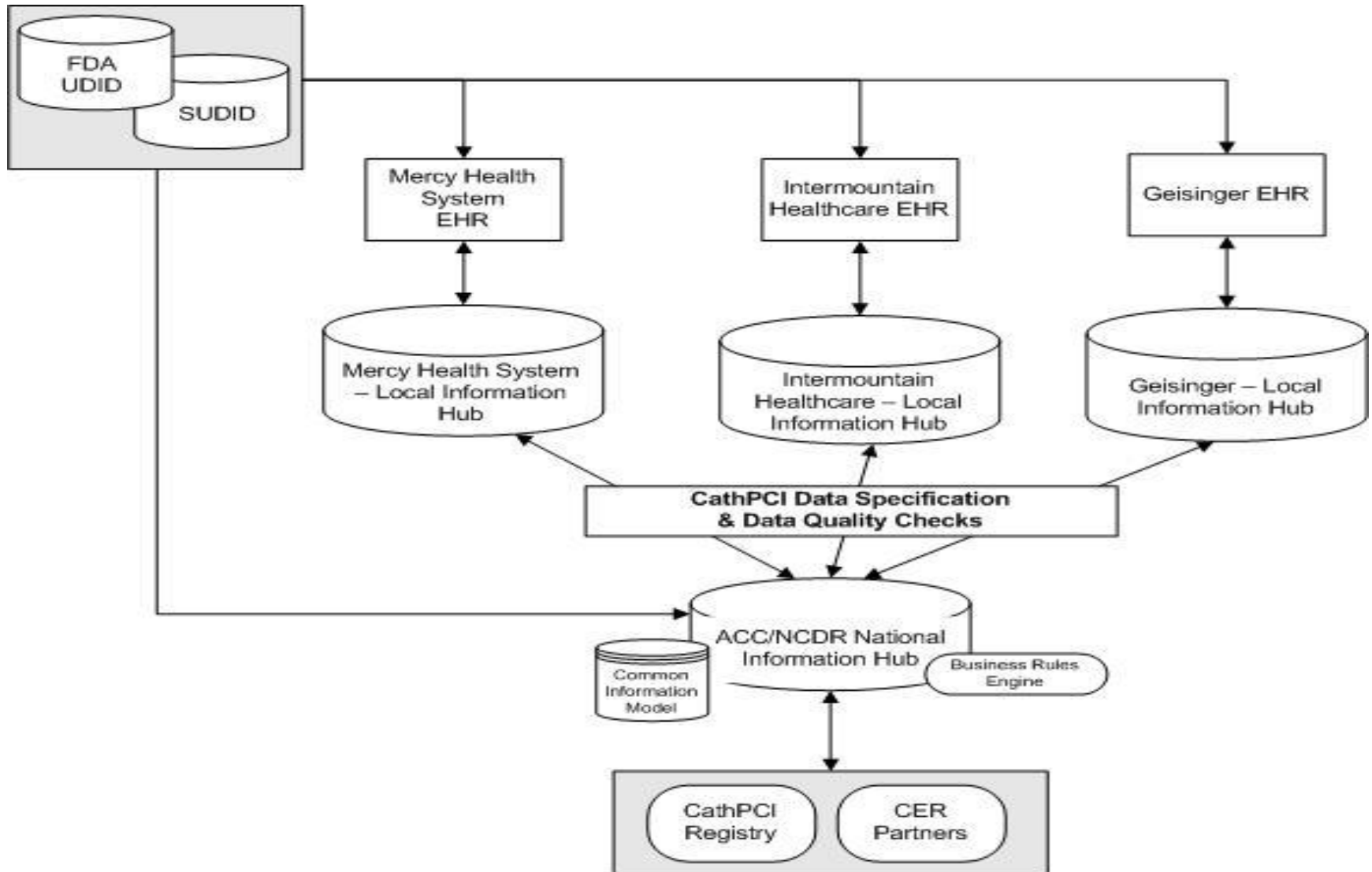
| Challenge | Detail | Solutions |
|---|--|---|
| <i>Perspectives of Mercy Cath Lab Directors</i> | Cumbersome inventory and reorder processes prior to point of use system implementation occasionally resulting in last minute replenishment | Automated reorder process by point of use system |
| | Directors' lack of visibility to inventory by location and by vendor | Actionable operational and ad hoc reports produced by point of use system |

The BUILD Initiative

(Building UDI into Longitudinal Data for Surveillance)

- **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 Distributed Data Network



Thanks!

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