The Global Language of Business

UDI Implementation Reality - Data Quality

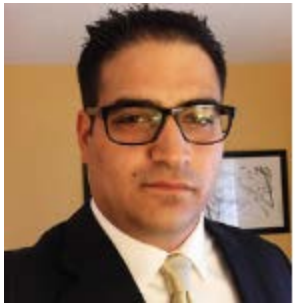
Panel Session
Tuesday, 17 October 3:30 -5:00

GS1 Healthcare Conference Chicago

Panelists

Cyndi Poetker
Director Enterprise Standards and Traceability
Abbott Laboratories

Terrie Reed
Senior Advisor for UDI Adoption,
U.S. FDA



Joseph Costagliola
Project Manager Central Master Data Team,
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James Phillips
Consulting Manager, The Office of Data Standards & Interoperability
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Kevin Capatch
Director Supply Chain Technology & Process Engineering,
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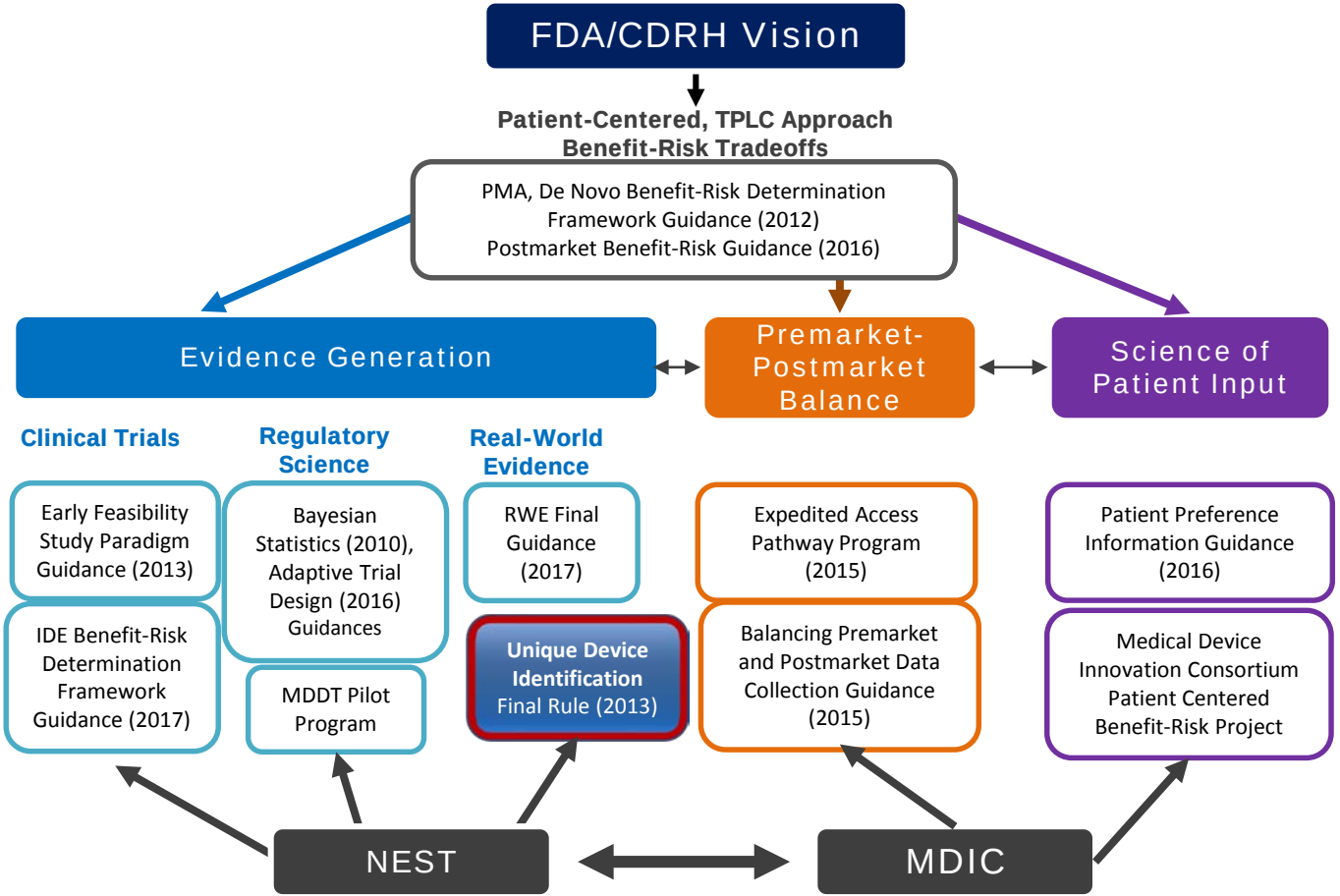
UDI and Data Quality

Center for Devices and Radiological Health (CDRH)

US Food and Drug Administration (FDA)

Terrie L. Reed, Senior Advisor

Flexible Regulatory Paradigms across the Device Lifecycle



Goal of the UDI System

Use UDI and data from AccessGUDID to

accurately identify a device from manufacturer through distribution, use on a patient and as a means to evaluate devices over time

Successful UDI Implementation

- **Capturing, recording and transmitting UDI in all systems directly or indirectly involved in patient care**
- **Using UDI as the primary means of identifying a device**
- **Using AccessGUDID as the standard reference source linked to the DI of UDI**

UDI Program and Data Quality

- Data in GUDID will be of **acceptable quality** to realize value across the device ecosystem and in generation of real world evidence

- **Sufficient confidence** in the accuracy and completeness of the data to ensure UDI integration into **REAL WORLD DATA** - from manufacturing through supply chain to patients, Electronic Health Records (EHRs) and claims.

UDI in U.S. Real World Data

Regulatory

- Office of National Coordinator for Health IT
  - EHR Certification
- CMS - Meaningful Use, Common Clinical Data Set

Infrastructure

- 4 Standards Messages - HL7 Fast Healthcare Information Resource, Orders &Observations, Consolidated Clinical Document Architecture, Integrating the Healthcare Enterprise
- Controlled Vocabularies – GMDN, SNOMED, DUNs, UCUM

UDI in U.S. Real World Data

Demonstrations and Early Adoption

- 14 Major EHRs – Cerner, Epic, McKesson, Allscripts
  - 100+ hospitals implementing on their own
- 410+ members of Association for Healthcare Resource & Materials Management (AHRMM) Learning UDI Community
- 1 Registry includes UDI (Vascular Quality Initiative) as core data
- Demonstration Projects in 5+ device areas – Cardiovascular, Gastrointestinal, Prostate, Peripheral Artery, Women's Health Technology

UDI in U.S. Real World Data

Vendor	Software
Allscripts	Allscripts Professional
[illegible]	[illegible]
[illegible]	[illegible]
Epic Systems Corporation	EpicCare Ambulatory EHR Suite
[illegible]	[illegible]
Epic Systems Corporation	EpicCare Inpatient EHR Suite
[illegible]	[illegible]
Cerner Corporation	FirstNet (Clinical)
MEDHOST	MEDHOST Enterprise
Henry Schein Medical Systems	MicroMD

Materials Management:
Improved Recall Management

Nursing:
Operating Room Efficiency

Clinical Engineers:
Improved Tracking

Vendor	Software
Net Tec	[illegible]
McKesson	Paragon® for Hospitals 2015 Certified EHR
Cer	[illegible]
SRS	[illegible]
Gre LLC	[illegible]
Alls	[illegible]
Alls	[illegible]
Medical Tra Cor	[illegible]
[illegible]	[illegible]
Evident	Thrive EHR
Evident	Thrive Provider EHR

Quality:
Workflow Improvements

Information Systems:
Meaningful Use

Risk Management:
Patient Safety Projects

Researchers:
Medical Device Registries

AccessGUDID as US Reference

It Starts with Good Data

- Inaccurate data threatens patient safety and can lead to increased costs, inefficiencies, and poor financial performance.
    - Assessing and Improving EHR Data Quality (Updated). AHIMA, 7/5/2014

Examples of Issues

GUDID Data Element(s)	Data Quality Issue
Primary DI , Package DI Number	DI construct does not follow the issuing agency's specifications such as wrong check digit
GMDN Code/Term	GMDN code not consistent with other information on record; codes not available in GUDID
Product Code	Product Code does not match with Premarket data set
Brand Name	DI record Brand Name completely different than names provided in premarket application or Registration and Listing)
Version or Model Number	Many DI records with the same data values including same Version and Model, but different DI's
Size Value	contains an erroneous and/or is missing a Size Value in structured way
Description	No description given or inconsistent

Data Quality – What we've learned

Improving Data Quality

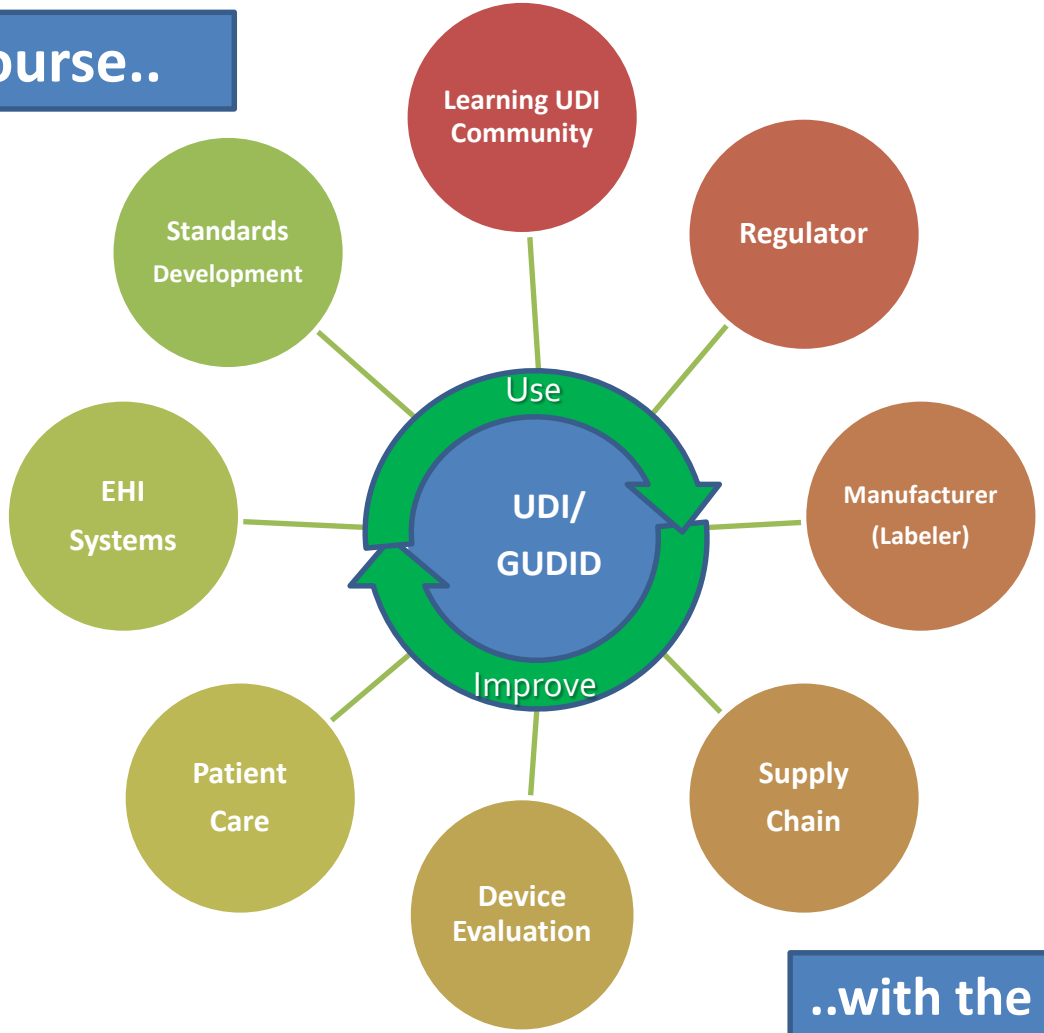
- Focus on downstream data use – clinical, researchers, patients
- Set expectation of continuous improvement and going beyond compliance
- Provide public access to GUDID database in multiple forms

Data Quality – What we've learned

Improving Data Quality

- Partner with supply chain and clinical community to set up Learning UDI Community framework for shared best practices
- Align across government agencies to establish harmonized and standards-based implementation
- **Rely on demonstration projects for harmonization, ROI analysis, and incorporation into real world data sources**

Setting the Course..

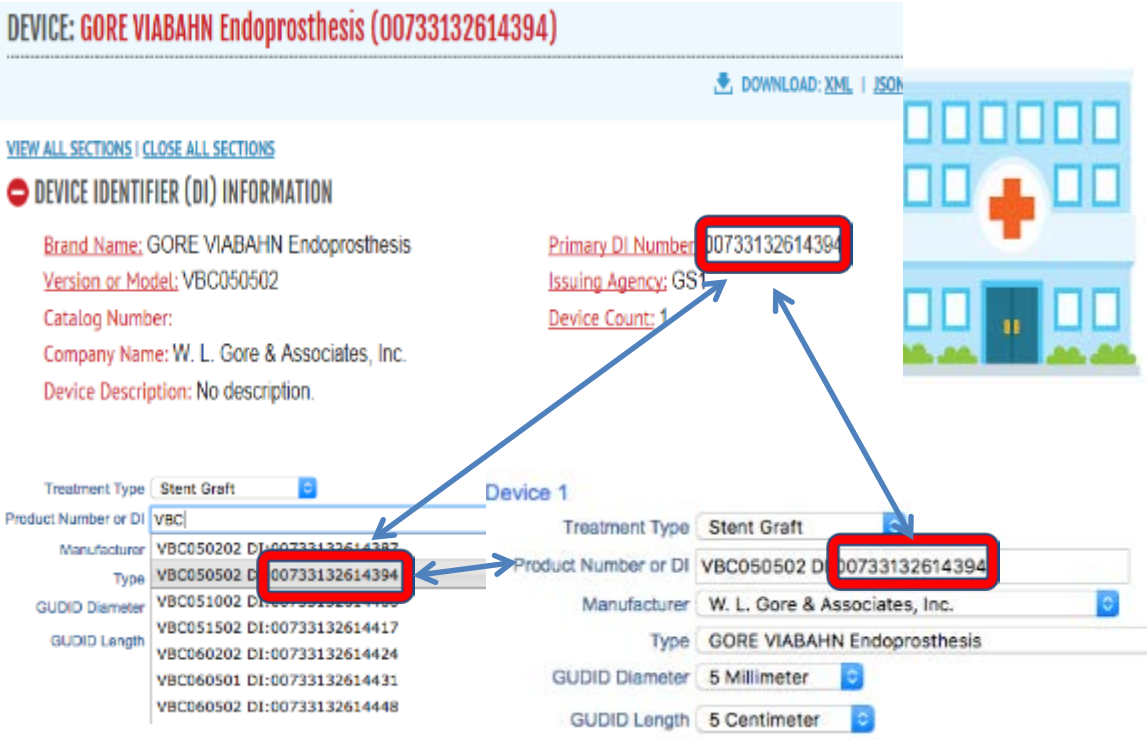


..with the users in mind

Success Story: Using UDI for Device Evaluation
Enter quality data ONCE at point of use & reuse

WL GORE

Vascular Quality Initiative



UDI Implementation reality

Joe Costagliola

October 17, 2017

Agenda

- Recipe for Data Quality
- Data Governance
- Roles and Responsibilities
- Data Management
- Data Quality
- Key Takeaways

Master Data Management

Where do we start???

How do we define success???

What data do I have and what do I need to start collecting???

What are customers looking for???

How do we ensure compliance???

Foundational Ingredients for Success

Data Governance

Roles and Responsibility

Enterprise-wide Data Management

Data Quality

Data Governance Program

Centralized MDM Department

- Created **central** point of **focus**
- Organized to support current and future strategy around **Data Quality** / **Data Governance**
- It is really a different way of thinking…… Corporate **culture change**

Roles and Responsibilities

Who is able to create/ modify/approve data?

What am I responsible for ?

What fields are editable?

Are we organized to support our responsibilities?

Define Data Dictionary / RACI → **Establish Roles for Data Stewards with Policy** → **Edit Rules and Data Standards** → **Organizational Structure**

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger	Data Owners R	A	C	I
Product Code	Classification for devices issued by the FDA.	Enter all applicable Product Codes, three-letter code. For all PMA and 510k devices, Product Codes are assigned in the FDA approval or clearance letter, respectively. For Class I and exempt devices, the device Product Code may be self-identified.	Add Delete Edit	Conditionally Required*	Type: Alpha Length: 3	FDA Product Code list	NO				
FDA Listing Number	Number assigned by FDA during Registration and Listing to all devices in commercial distribution, regardless of pre-market authorization requirements per 21 CFR 807.28(f).	Enter all relevant listing numbers that enable the labeler to commercially distribute the given version or model of device. Listing number is optional for HCT/P devices, Kits and IVDs with a BLA premarket number.	Add	Conditionally Required*	Type: Alphanum. Length: 7	NA	NO				
For Single-Use	Indicates that the device is intended for one use or on a single patient during a single procedure.	Choose Yes/No from the drop down list.	None	Required	Type: Boolean	Yes/No	YES				

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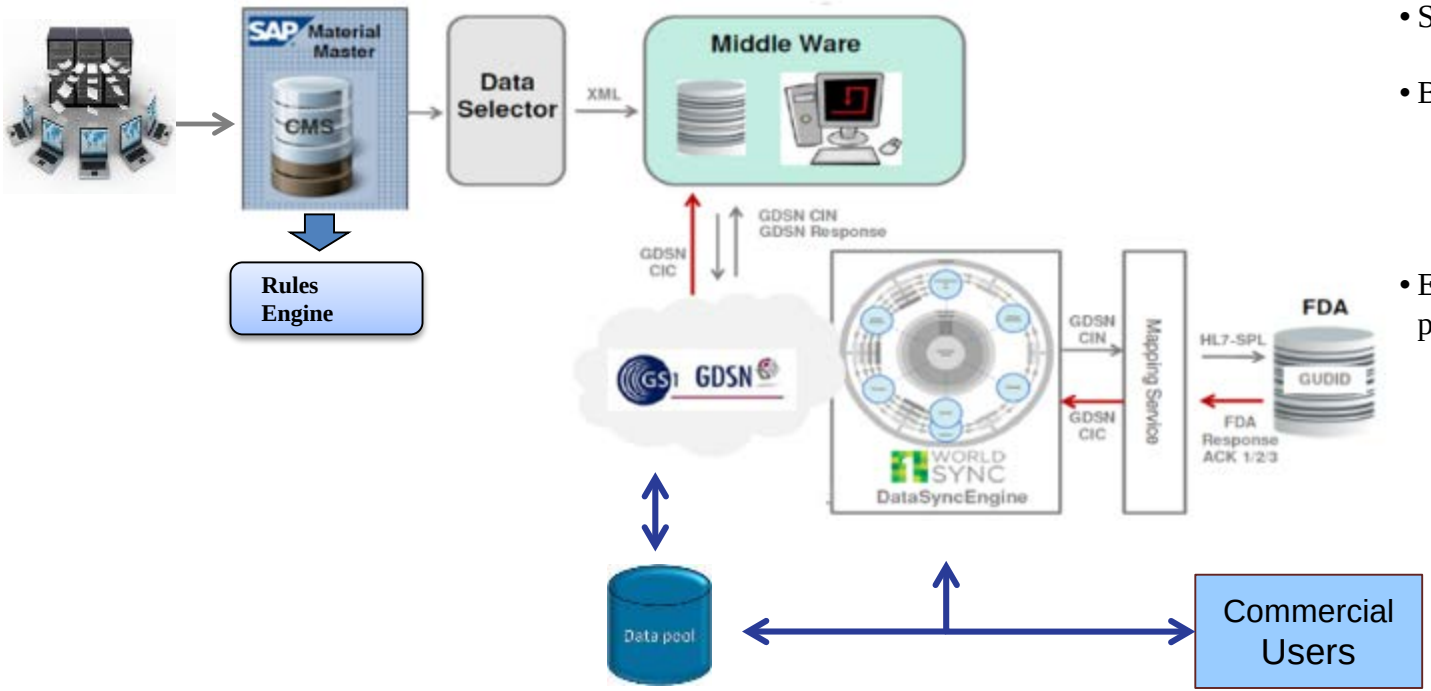
Enterprise-wide Data Management



- SSOT – Single Source of Truth
- Business rules engine
  - Derivation logic
  - Editing rules in data capture process
- Electronic submission / publication tools
  - Real time updates to ensure accuracy (data decay)
  - Compliance monitoring
  - Inbound and outbound messaging

Data Quality

Achieving the same level of data quality as the quality of your products!!!
…. YES it is that important!

What does good master data quality do?

- Helps avoid patient safety errors and risks
- Key for Supply Chain efficiencies
  - Speed to market
  - Customer satisfaction
  - Process costs, etc.

Good data quality is…

- Fit for the intended purpose
- Complete
- Consistent
- Accurate
- Timely
- Within industry standards

Measuring Data Quality

- Quality, Accuracy, Completeness & Verification

- Measurement Tools
  - Data scorecards
  - Completeness reports (database / submission tool)
  - Internal auditing fields to quantify progress
  - Validated process flow

Sustainable and **consistent processes** are essential for **successful data quality**!!!

Goal	Target	Owner	Review Frequency	Jan-17	Feb-17	Mar-17	YTD-17
Data Completeness							
Class I	50%	John	Monthly	30%	49%	50%	43%
Class II	100%	Rita	Monthly	100%	99%	100%	100%
Class III	100%	Sarah	Monthly	98%	99%	100%	99%
Error Messages							
GDSN	0%	Joe	Monthly	3%	2%	1%	2%
FDA	0%	Joe	Monthly	0%	0%	3%	1%
UDI Required Fields							
Brand Name	100%	Sarah	Monthly	100%	100%	100%	100%
MRI Saftey Statement	100%	Sarah	Monthly	100%	100%	100%	100%
Product Contains Latex	100%	Sarah	Monthly	100%	100%	100%	100%

Key Takeaways

Every end user is dependent on your data quality!

- Data quality and management is really a **culture change** for an organization
- Submission deadlines are not the end, but rather the beginning of a **data management process**
- Data quality is the end game and requires **consistent effort** and **management** to maintain
- Edit rules are important to understand and incorporate into your **change control process** to ensure quality can be maintained
- Viewing **UDI** / **data management** from the **end user** / **patient perspective**

B BRAUN SHARING EXPERTISE

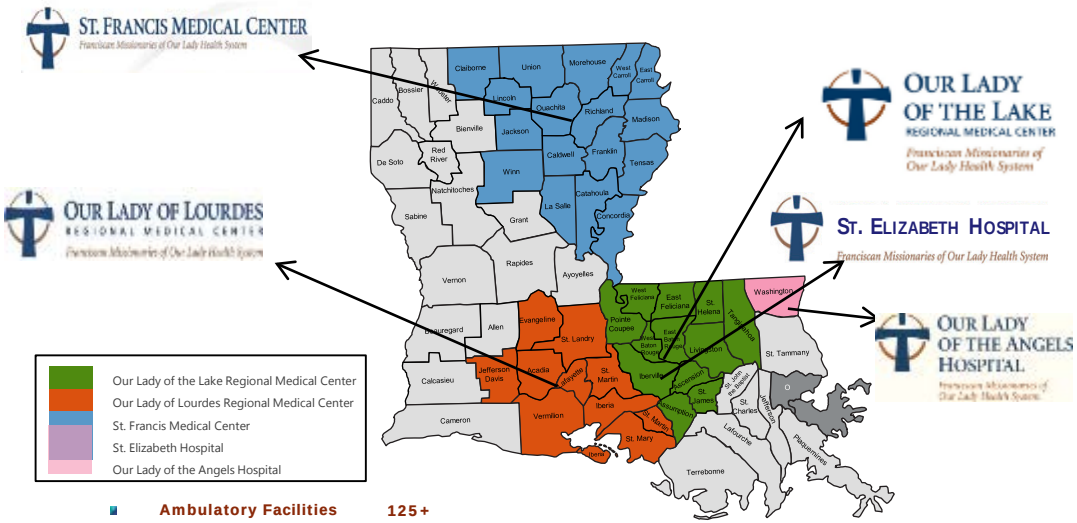

Thank you for your time.
B BRAUN
SHARING EXPERTISE

The Global Language of Business

James Phillips
Consulting Manager,
The Office of Data Standards & Interoperability
FMOLHS

FMOLHS Overview

The System's service area is diverse and encompasses over 2.4 million people, over 50% of the State's population.



Ambulatory Facilities	**125+**
Net Patient Revenue	**$1.9 Billion**
Co-workers	**13,000+**
Medical Staff	**1,750+**
Beds	**1,750 licensed beds**
Annual Spend	**$400+ million in supplies & drugs; $400 million in services**

Data Quality

Data quality is about having confidence in the quality of the data that you record and the data you use.

- Data should be
  - Accurate
  - Complete
  - Reliable
  - Accessible

The importance of Data Quality in internal hospital processes

- Using UDI to reduce order errors
- Data Capture at Point of Care with Validation & Interoperability
- Device, Drug and Supply Integration to Electronic Health Record (UDI, GTIN, HIBBC, NDC)
- Actual Cost Per Episode of Care

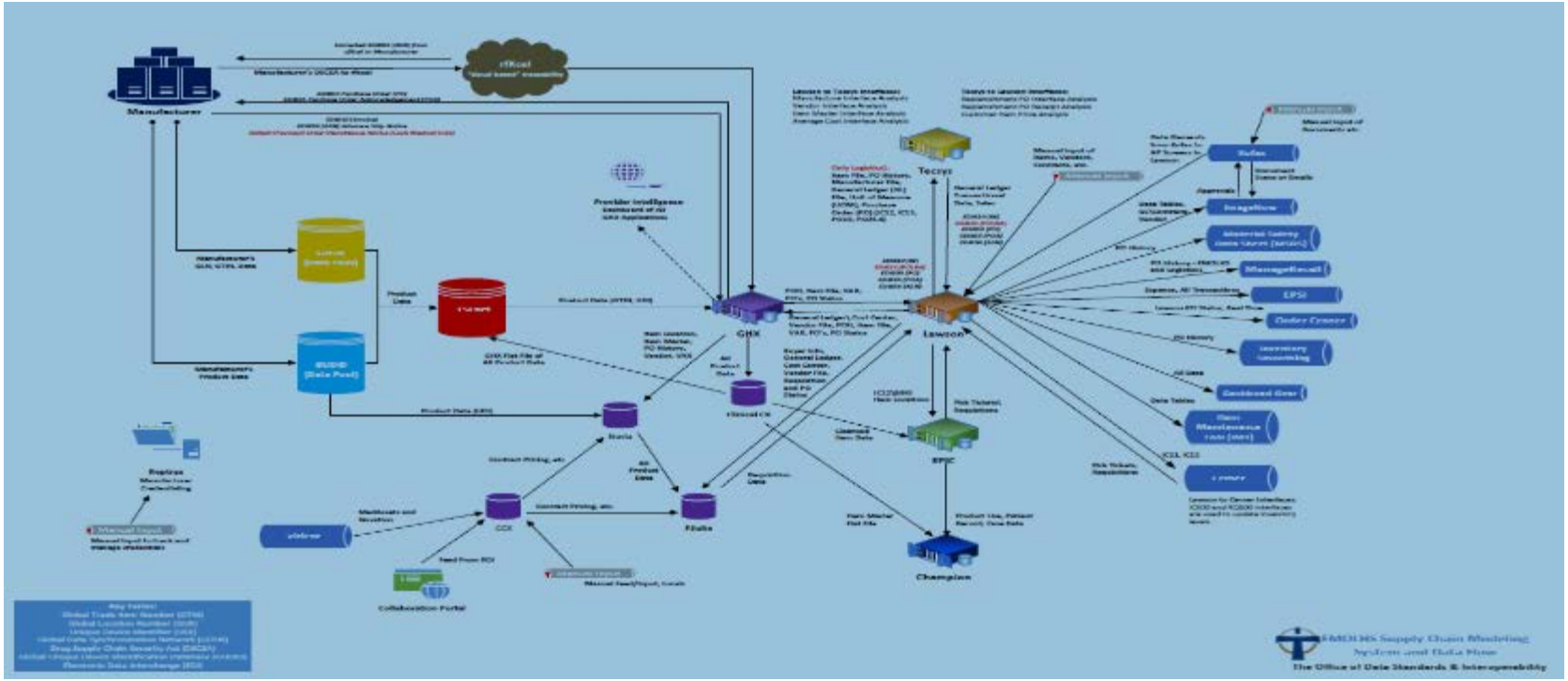
Continued

- Linked to Quality Outcomes per Episode of Care
- Category Management and Standardization to Address Clinical Variation
- Direct Access to Manufacturer Supply Chain teams
- Alignment of goals to reduce total cost of ownership
- Optimizing Master Data Maintenance

Lessons Learned / Next Steps

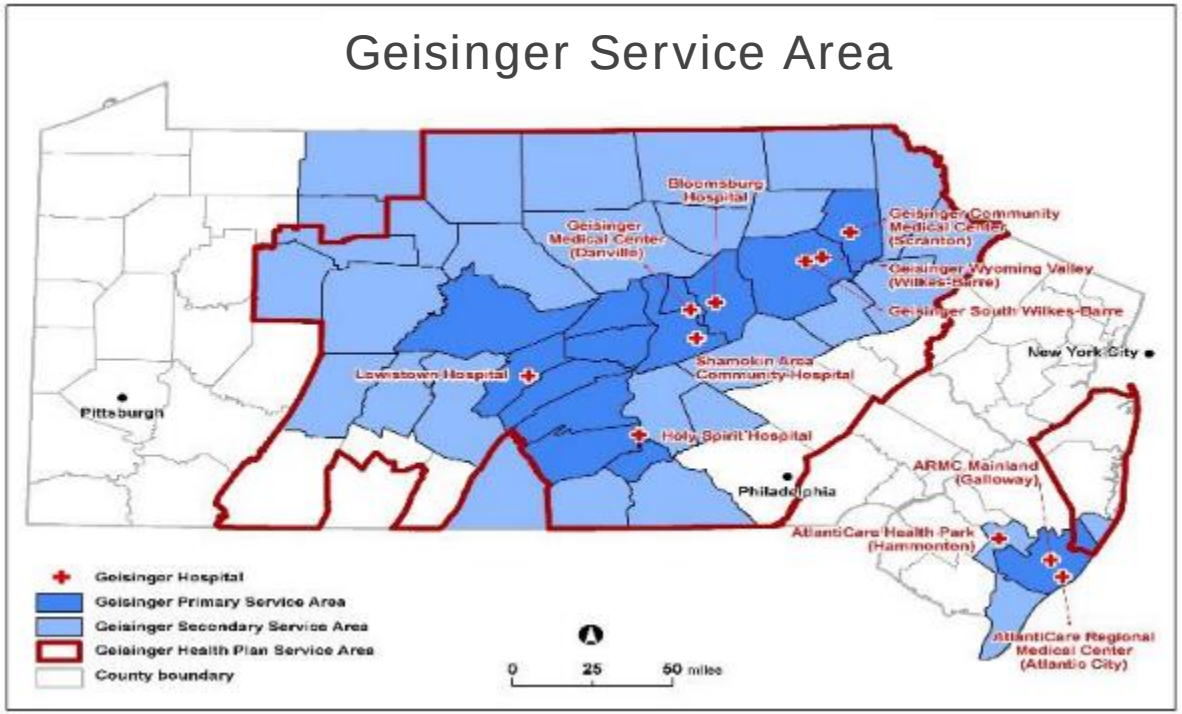
- Couldn’t do this by ourselves
- Collaborative debate challenges status quo
- Measuring and Celebrating progress is important
- Setbacks occur……deal with them!
- Integration of Virtual Item Master to EHR
- Total Cost per Episode of Care

Supply Chain Process Mapping



Kevin Capatch
Director Supply Chain Technology & Process Engineering, Geisinger

Kevin Capatch – Geisinger



- **PA**
  - 9 Hospitals
  - 138 clinics
  - 45 of PA's 67 counties
- **NJ**
  - 78 Clinics
  - 3 Hospitals

Geisinger Medical Center Danville, PA

Geisinger, PA - Fast Facts

	Hospital	Beds	IP Visits	ED Visits	Surgeries	OP Visits	Clinics	Employees	Providers	A.P.s	Nurse	GHP Members	Eco. Imp.
PA	*8	2,200	97,323	307,297	72,133	2,563,476	138	30,000	1,697	900	5,964	500,000	$8.9 Bil.

* In 2017 added Geisinger Jersey Shore, now at 9 hospital.

For source or more information:

https://www.geisinger.org/en/about-geisinger/news-and-media

Geisinger, PA - Fast Facts

Geisinger Supply Chain

- Spend = > $720 Million / year
  - Device = $360 Million /year
  - Drug = $360 Million / year
- Item Master Total = 95,721 Items
  - Stock = 23,823 Items
  - Non-Stock = 71,898 Items
- Stock POS = > 200,000
- Contracted Spend = >70%
- Inventory Receipts = 520,000 lines
- Inventory Issues = 1.9 million transactions

Geisinger & HTG since 2010

HTG Summit Historv

Location	Year	Month	Days	Comment
Mercy	2011	May	3&4	Tornado April 22, 2011
Mercy	2012	May	1&2	Mercy Conf Center
Mercy	2012	Dec	13&14	IT Summit
IM	2013	May	29&30	IM Distribution Center
KP	2014	Sep	17&18	KP Innovation Center
GHS	2015	Aug	18&19	Pine Barn & Knoebels
Mayo	2016	Sep	28&29	Come on - It's Mayo!
Mercy	2017	Sep	27&28	Mercy Conf Center

SCANH – September 2017

Kevin Capatch – Geisinger

Data Quality

- **Definition**
  - @ HTG Summit 2017 – the same attributes in GUDID and GDSN must have definitions that match and the method for verification must be consistent.
  - Personally, prefer Information Quality
    - I collect data, we need to provide information that drives actions.
- **Intended Use**
  - No loss of fidelity or visibility as the product moves from source to patient related records.
    - We are not retail, we do revisions and explants.
      - The DI is not reusable
- **Usefulness**
  - Never lags, or confuses
  - Machine to Machine
- **Unintended Use**
  - Have not even got to the level retail has discovered
    - Ex. Allergies, meal planning, preparation, and you bought this, you may need this to?

Kevin Capatch – Geisinger

Start with the end in mind – Capturing/Scanning

Fortunately early on Geisinger realized scanning a barcode in healthcare requires assistance:

- We standardized on 2D barcode scanners.
- In our medication at bedside, we repackaged.
- In our non-OR procedural areas we used QSight as a Point of Care interface
  - 22 Installations since 2010

Note: QSight maintains a purified catalog source related to the label, but at a cost to maintain; so we may not see all the label challenges our HTG peers see.

Kevin Capatch – Geisinger

The importance of Data Quality in internal hospital processes, EHR, clinical systems, etc.

What is the hospital experience with data and specifically GUDID data?

- We have a GDSN connection
- We have extracted minimal amounts from GDSN and GUDID
- We are working on interface strategies to retrieve the data and provide the data
- We need to feed critical EHR attribution
  - Ex. We will pass latex free from source, but not be the source!

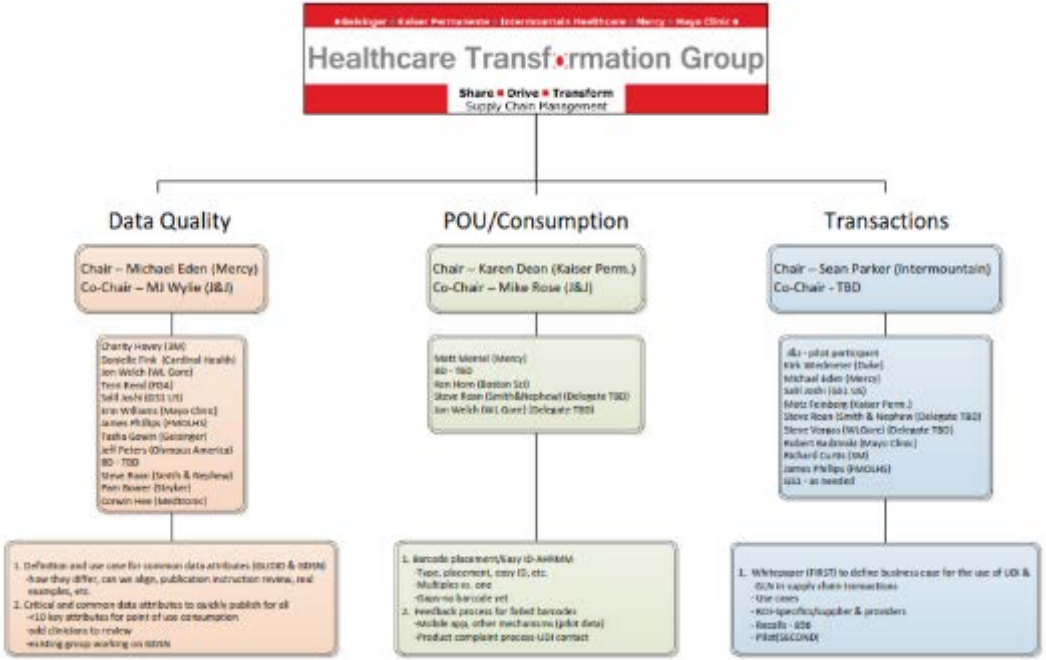
What are hospitals learning from use of GUDID data?

- We will do the work over and over again if we do not protect the information that results post-consumption!

Kevin Capatch – Geisinger

What's Next HTG

- HTG
  - Validated Data Quality
  - Know what barcode to scan
  - Transaction Efficiency



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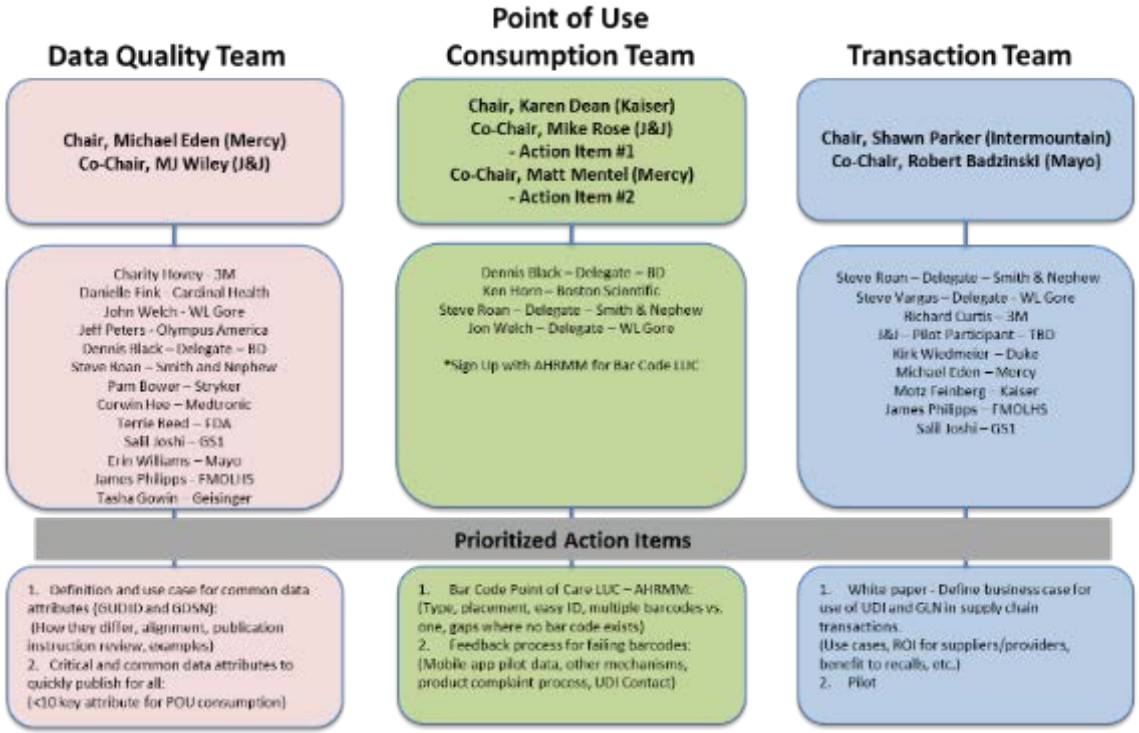
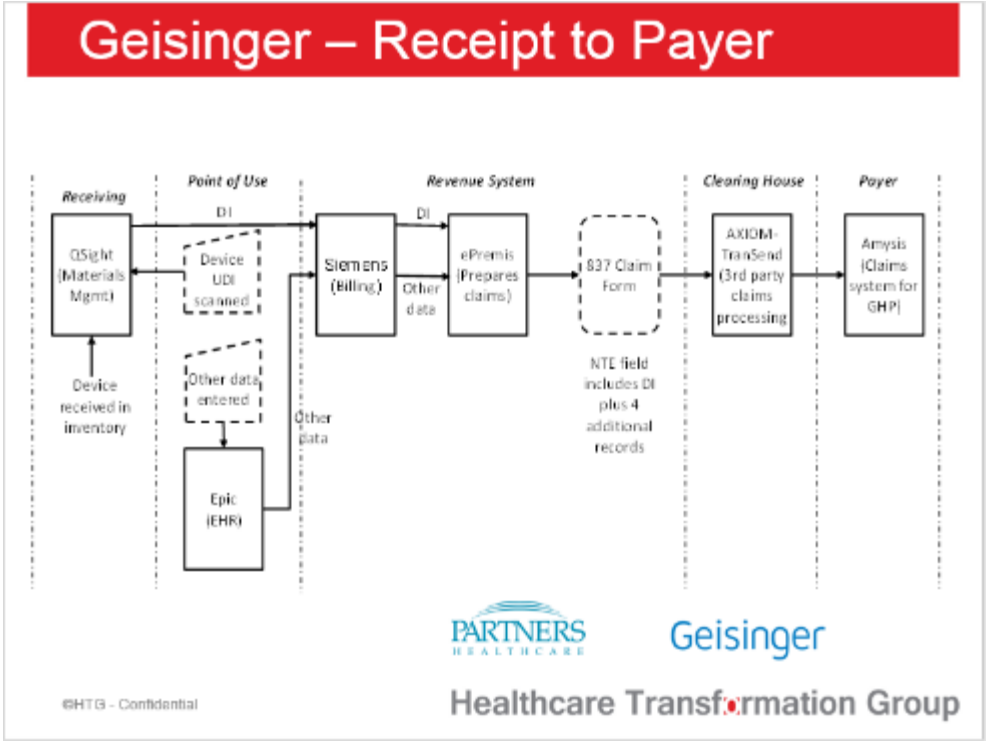


Kevin Capatch – Geisinger

Questions

- What is Geisinger's experience with accessing data and integrating into internal systems?
  - No Single Source, and no validated Source of Truth
- Are you using it in the supply chain / logistics or is it more about clinical, medical outcomes, or recalls?
  - Using in Contract Management and Item Master
  - Using in Purchasing and EDI
  - Pilots in research and claims from QSight
- Since GUDID only provides certain data for medical devices, where do you get the rest of the data you need.
  - Back Door, Side Door & Front Door

Kevin Capatch – Geisinger



Kevin Capatch – Geisinger

What's Next

- Stop data burying!
- Nobody speaks UPC!
- We have not even engaged the healthcare consumer yet!

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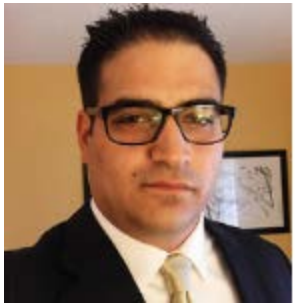

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