The DoD/VA pilot as proof of principle

- putting standards and infrastructure in place

Col Chris Harrington, Deputy PM DHSS

Washington, DC

April 4-6 2011

Need For Data Synchronization:

In DoD supply chain Bad data is causing:

- Dirty Item Masters
- Accounts Payable mismatches
- EDI kick outs and rejections
- Wasted clinicians time
- Non-contract pricing
- Inaccurate rebates
- Returns & credits for wrong items
- Bringing substitutes into the item master

DoD/VA GDSN Pilots

- Phase I: Identify the problem through analysis
  - (4/05 – 3/07)
- Phase II: Education and Testing with Industry
  - (4/07 – 3/08)
- Phase III: Putting Standards to Use
  - (4/08 – 3/11)

DoD/VA Data Synchronization Pilot Program Phase I

- Proof of Principle for Industry
- Manufacturer as source of data
    - 23 manufacturers and 2 prime distributors submitted data
- Central Data Repository (Product Data Bank)
    - Data Disconnects, Packaging levels, Audit Tool certification
    - Feedback to Partners

Example of Findings – DoD/VA Pilot Phase I

Type of Problem	Mfr	Dist	GPO	Provider
Missing Middle Packaging Levels	15-20%	1-4%	20-25%	15-25%
Hard “Packaging Quantity” Errors	1%	1%	2%	2-5%
Unit of Measure Confusion/Misuse	2-6%	1-3%	2-5%	Unknown
Missing Packaging—not middle level	3-8%	3-8%	3-7%	5%
Manufacturer Name Problems	n/a	2-5%	1-4%	30%
Obsolete Products	1-4%	2-5%	1-8%	5-15%
Missing Product Brand Names	2-5%	5-10%	5-10%	20-25%
Incomplete Item Descriptions	5-15%	3-12%	5-15%	10-20%
Wrong Customer Unit Prices	Unknown	1-2%	n/a	1-2%
Customer Paid More Than Lowest Contract Price	n/a	Unknown	n/a	3-6%

Errors increase closest to the customer!

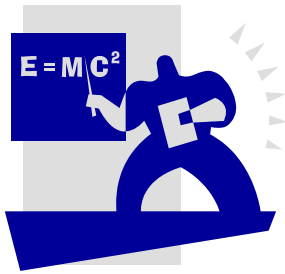
Example Results after Data Synchronization

	Becton Dickinson Before / After	DoD Before / After
Missing Middle Levels of Pkging	2% <1%	20-25% 2-5%
Hard "Packaging Quantity" Errors	<1% 0	2% <1%
Unit of Measure Confusion/Misuse	2% 1%	2-5% 1-2%
Missing Packaging—not Middle Level	1% <1%	3-7% 1-3%
Manufacturer Name Problems	NA	1-4% <1%
Obsolete Products	0%	1-8% <1%
Missing Product Brand Names	0%	5-10% 1-3%
Incomplete Item Descriptions	0%	5-15% 3-5%

DoD Lessons Learned

- Cleaning and standardizing in-house data is not enough.
  - Very expensive to constantly cleanse data – not the answer
  - Adopt standards
    - Products and packaging are defined differently depending on the author
    - Highly efficient, fast moving industries utilize standards as their baseline
  - Adoption of an industry PDU is the way to achieve quality medical product data for the entire healthcare community

- Synchronizing and accessing data from central utility:
  - Reduces bad data
  - Reduces costs
  - Increases operational efficiencies



DOD Data Synchronization Value Proposition Example:

- Data Sync application tools identified
  - Savings opportunities
    - Better contract price available
    - **Saved $40M so far at 80+ hospitals**
  - Opportunities to increase eCommerce
    - Available from eCommerce sources
    - **Moved $25M to eCommerce sources**

- Created robust DoD & VA Med Surg product data bank of 1.7 million + records
  - Accurate master records for 93% of DoD buys: $322M
  - Joint DoD & VA access to wealth of pricing, packaging, product ID information

Unique Device Identification

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 was signed into law. This act includes language related to the establishment of a Unique Device Identification System. This new system when implemented will require:

- the label of a device to bear a unique identifier, unless an alternative location is specified by FDA or unless an exception is made for a particular device or group of devices.
- the unique identifier to be able to identify the device through distribution and use
- the unique identifier to include the lot or serial number if specified by FDA

FDA will shortly begin developing draft regulations to implement these requirements. Interested stakeholders may wish to subscribe to Email updates for Unique Device identification to be notified as they become available.

Related Documents

- Information about the October 25, 2006 public meeting on Unique Device Identification
- August 9, 2006 Public Notice that requested comments on Unique Device Identification
- Comments Received from the August 9, 2006 Public Notice on Unique Device Identification
- Presentations
- ERG Final Report: Unique Identification for Medical Devices (March 22, 2006)
- The Food and Drug Law Institute / CDRH Report on Meeting to Discuss Unique Device Identification (April 14-15, 2005)
- ECRI / FDA White Paper: Automatic Identification of Medical Devices (August 17, 2005)
- The Food and Drug Law Institute / CDRH Report on Meeting to Discuss Unique Device Identification (October 27, 2005)

Contact Us

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1350 Piccard Dr., Rockville, MD 20850
Phone: 240–276–3400
e-mail: CDRHUDI@fda.hhs.gov

http://www.fda.gov/cdrh/ocd/udi/

Industry PDU… Try a Existing Venue

- **Criteria**
  - Unique product registry for validated basic information
  - Capable of transmitting Healthcare specific attributes
  - Governance mechanism to set standards and govern operability
  - Global reach and partnership
- **Existing commercial solution GDSN**
  - Eliminates major unknowns for transition to Industry PDU
  - Established systems network platform for sharing synchronized data used by major US industries, e.g. Wal-Mart, Lowe's, etc
  - Facilitates implementation of RFID and potential use of GLNs
  - Many major healthcare mfrs already active participants in GDSN for retail

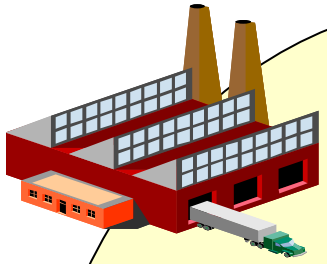
DoD/VA GDSN Pilot II Goals

(April 2007 – March 2008)

The Phase II pilot was designed to answer the following questions:

- Does the GDSN data set meet the needs of the healthcare industry for standardized data?
  - Can the GDSN be used as the “data standard definition” for healthcare?
  - Can healthcare specific fields be added in a timely manner?
- How difficult is it for manufacturers to load product data into GDSN?
- Will hospital MMIS, GPO and distributors be able to store and use GDSN provided data?

DoD/VA GDSN Pilot Phase II Execution & Participants



Manufacturers (BD, Sage)

GDSN

On Boarding Partner (Ontuet)

Global Registry

1SYNC Data Pool

On Boarding Partner (Ontuet)

GPO (Premier)

Hospital (Baptist / Lawson)

Provider Data Receipt

- Premier receives data via GDSN
- Distributes to Baptist into Lawson

Manufacturer Loading

- Sample items from mfrs
- ***Documentation of Challenges and Lessons Learned***

BD

SAGE PRODUCTS INC

GS1

1SYNC

ONTUET

PREMIER

LAWSON

Baptist Health South Florida

What We Learned in Phase II

Manufacturer:

- Have data, just not in one place – need an internal product data strategy
- Need for an Industry-wide product data strategy
- Global impact on decisions

GPO:

- Can consume GDSN data with minor changes to current system
- Minor enhancements required to deliver GDSN data using existing delivery system
- Well positioned to provide standards based integration approaches beyond current delivery mechanism

Software Provider:

- Internal business systems have many of the fields, technology and processes to get started with data synchronization
- Long term, they will need to be further adapted for new processes driven by the GDSN
- Processes exist for managing GDSN communications outside of ERP

Hospital:

- Can use data for spend analyses
- Project significant savings in reconciliation of GPO and distributor item files

Initial Pilot Report

Pilot Report
https://dmmonline.dscp.dla.mil/datasynchronization/dodpilots.asp

Press Release
http://www.prnewswire.com/cgi-bin/stories.pl?ACCT=ind_focus.story&STORY=/www/story/11-15-2007/0004706890&EDATE=THU+Nov+15+2007,+02:52+PM

DoD and VA GDSN Pilot Phase III
April 08 – March 11

- Continue expansion to supply chain participants
  - Manufacturers, distributors, GPO, MMIS and providers
  - Add new members and expand current participant goals
  - Identification and recruitment of additional data users
- Welcome additional GDSN technology providers
  - Educate technology providers to Healthcare requirements
  - Provide opportunities for technology providers to lend services for GDSN testing by Pilot participants
- Cooperate with GS1 US and GS1 Healthcare to assure:
  - Coordination of goal setting and avoidance of content redundancy
  - Aggregated education needs of pilot participants are met by GS1 US
  - Planning for participation of DoD Pilot in the GS1 Healthcare global pilot
- DoD Pilot Team specific goals
  - Respond to participant requests for assistance
  - Survey government systems for safety related attribute requirements

DoD Healthcare GDSN Pilot Phase II

Manufacturers

BD
SAGE PRODUCTS INC
KCI
GOJO
COOK
Baxter
Kimberly-Clark
3M
MEDLINE
CardinalHealth

Distributors

CardinalHealth
Owens & Minor
SutureExpress

Providers

Baptist Health South Florida
MayoClinic.com Tools for healthier lives
UNIVERSITY HEALTH CARE SYSTEM
ProMedica HEALTH SYSTEM
NORTON HEALTHCARE
BOSTON MEDICAL CENTER EXCEPTIONAL CARE. WITHOUT EXCEPTION.
MERCY SISTERS OF MERCY HEALTH SYSTEM
ASCENSION HEALTH
Atlantic Health
Kettering
DukeHealth
St. Alexius PrimeCare
JOHNS HOPKINS INSTITUTIONS SHARED SERVICES
ORLANDO REGIONAL HEALTHCARE
SENTARA

On Boarding Partner
ONTUET

On Boarding Partner
ONTUET

Mfg Retail Crosswalk

GDSN Global Registry
GS1
Data Pool
1SYNC

GPOs

Amerinet
PREMIER

MMIS

Caduceus Systems
LAWSON
McKESSON
Empowering Healthcare

Expectations of Participants

- Executive sponsorship
- Commitment to stay engaged
  - Single POC, regular attendance, responsiveness
  - Resources assigned to accomplish tasking
- Willingness to share
  - Weekly updates become part of pilot record
- Baseline, Goals and Reporting
  - High level “before” visual
  - Hypothesis/expected learning – metrics
  - High level – “after” visual (proposed and final)
  - Execution
  - Weekly progress updates
- Lessons learned reporting

Resource Requirements

- Key contacts – situational:
  - item manager, buyer, contracting, IT/database/software solution partner/consultant, business analyst
- Chart data flow – current and pilot proposed
  - Identify technology gaps, if any
- Establish Pilot goals and Metrics
- Initial and Ongoing Updates to Working Group

Weekly Update Meetings

- Thursdays at 3:00 PM ET
  - Via web conference and dial in
  - 60 minutes or less
  - “Around the Horn” participant status updates
    - Project tasks and target dates
    - Lessons learned
  - Healthcare Industry actions update
  - Data Sync updates from other industries
  - Guest speakers
    - GS1 on data governance
    - Technology partners on enablement options and process
    - Updates from parallel initiatives
      - Medi-Cal, USDA, FDA, Foodservice, etc…
  - Minutes and slide distribution

Provider Benefits

- By participating in the DoD sponsored GDSN industry pilot, providers have gained:
  - A understanding of how to utilize GTINs to identify products
  - An understanding of GDSN product data attributes
  - Use of the GDSN process to receive validated product data and exchange synchronization messaging with trading partners
  - The ability to compare existing item master data with GDSN approved data
  - Active participation in the industry pilot and the opportunity to share/learn from other participants
  - Consensus that unrelated providers share the same data issues
  - Access to validated manufacturer product data (from participating manufacturers)

First Steps for Providers

New Item Data Flow

- Our model for learning how to assist you in the pilot and to bring you up to baseline with the other participants is to have you walk through your "new item add" process steps. Once we understand that process we can help you to create pilot goals, tasks and timeline.

- If you have materials we can review beforehand it would be helpful:
  - high level flow chart of the item add process
  - what are your require product attributes, we can review (some or all):
  - spreadsheets you ask your vendors to complete
  - screen shots of your intranet site for adding data
  - screen shots of MMIS fields you use
  - work instructions for "data add" procedure

- After we understand your "add" process we help to prepare slides (including data flow and pilot goals) for an introduction of your organization to the pilot on one of the Thursday calls.

Participant Sample Presentations

DukeHealth

Duke Medicine conceptually integrates the Duke University Health System, the Duke University School of Medicine, and the Duke University School of Nursing.

It is the combination of research, clinical care, and education that takes place through the efforts of our faculty, staff, students, and trainees at many different sites throughout our region and worldwide.

As a world-class academic and health care system, Duke Medicine strives to transform medicine and health locally and globally through innovative scientific research, rapid translation of breakthrough discoveries, educating future clinical and scientific leaders, advocating and practicing evidence-based medicine to improve community health, and leading efforts to eliminate health inequalities.

Cary, NC
Chapel Hill, NC
Clayton, NC
Concord, NC
Creedmoor, NC
Danville, VA
Durham, NC
Fayetteville, NC
Fort Bragg, NC
Greensboro, NC
Henderson, NC
Hillsborough, NC
Laurinburg, NC
Louisburg, NC
Lumberton, NC
Mebane, NC
Morrisville, NC
Oxford, NC
Pittsboro, NC
Raleigh, NC
Roanoke Rapids, NC
Roxboro, NC
Sanford, NC
Smithfield, NC
Wake Forest, NC
Whiteville, NC
Winston-Salem, NC

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Duke University and
Duke University Health System
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jane.pleasants@duke.edu

Duke University Goals

- Data Fields Gap Analysis
  - Chart current data flow and fields
  - Compare current needs to Work Group recommendations
  - Review GS1 data set and field governance process
- Project potential “after” data flow with standardized data
  - Subscribe to pilot items in flat file format
    - Assess publish, subscribe and approve model
  - Study current validation model vs. “after” dataflow
    - Will current data cleansing process be impacted
    - Impact on “procure to pay” internal audit findings

Duke University Goals

- Assess SAP capabilities and/or gaps
  - Research SAP interaction with GDSN or data pools, if any
  - Engage SAP to determine flexibility or support for industry fields
    - Patient safety, dimensions, storage requirements others…
    - Understand GTIN support in SAP – can it be “key” field
  - Determine impact on clinical item catalog
    - Items used in OR, but not in master
      - 24 hour turn requirement
- Research GDSN pricing functionality
  - Review GS1 List Price attributes
  - Review pricing functionality currently used in retail

Duke University Health

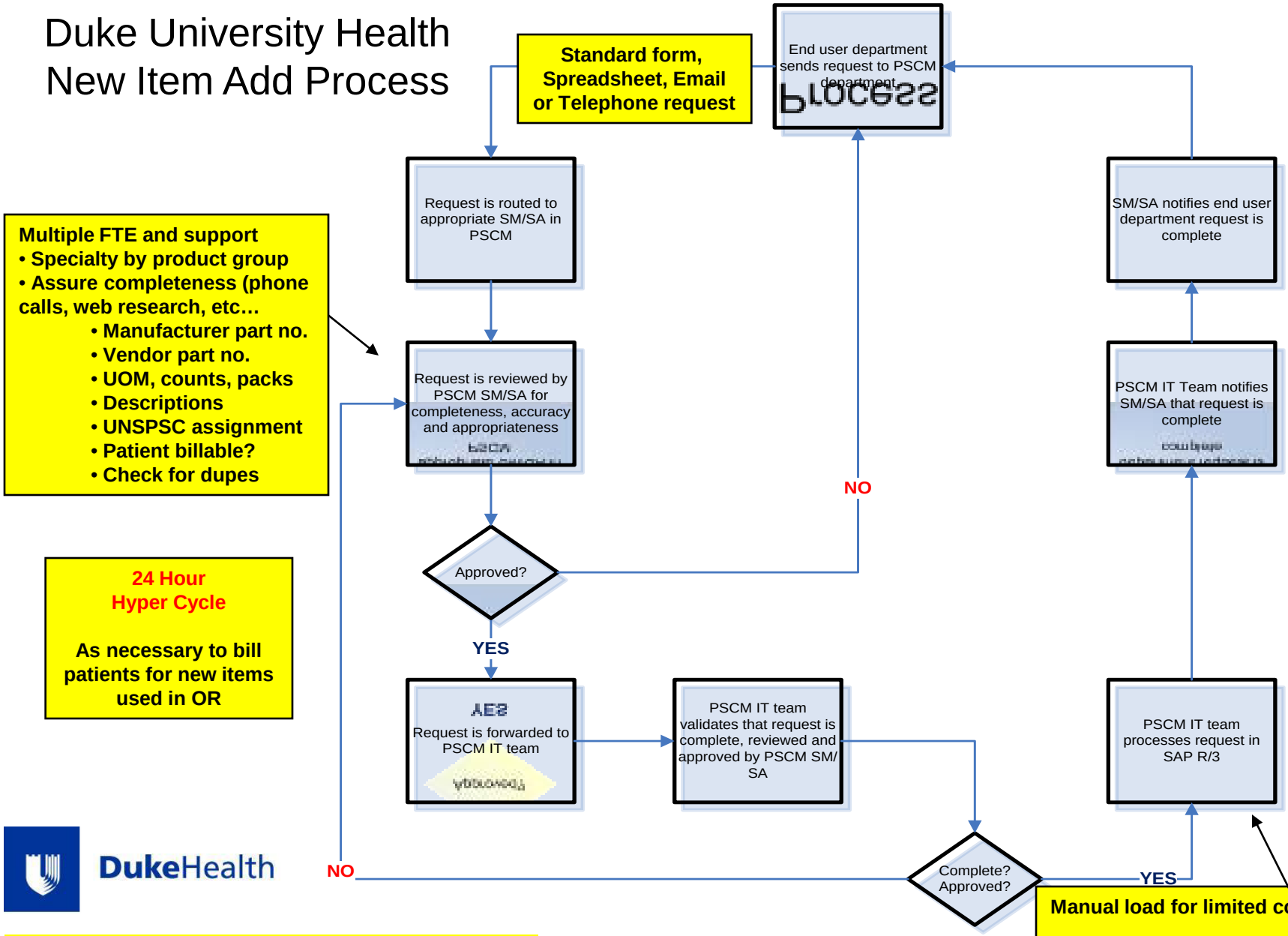
Healthcare Data Fields Analysis

	A	B	C	D
1	Common Field Name Highlighted in grey if required on Duke Spreadsheet or Form	GDSN Required (Core 27)	Healthcare Required	Duke Specific observations
2	**ITEM ID and Ownership**			
3	GTIN	Yes	Yes	Available in SAP - not used
4	Unit Descriptor	Yes	Yes	Required and used in SAP
5	Target Market Country Code	Yes	Yes	n/a
6	Manufacturer Name	Yes	Yes	Required and used in SAP
7	Manufacturer GLN	Yes	Yes	IDs are used in SAP - currently sequential
8	Brand Owner GLN	Yes	Yes	IDs are used in SAP - currently sequential
9	Alternate Trade Item ID Type	No	Yes	Manufacturer and Vendor Item number both
10	Alternate Trade Item Value		Yes	Manufacturer and Vendor Item number both
11	**Item Classification**			
12	GPC Code	Yes	Yes	n/a
13	Additional Classification	No	Optional	
14	Additional Classification		Optional	UNSPSC is assigned by Analyst team
15	**Item Descriptions**			
16	Brand Name (35)	Yes	Yes	Field available in SAP - not used
17	Functional Name (35)	Yes	Yes	Field available in SAP - not used
18	Short Description (30)	No	Optional	
19	Medium Description (1-40)	No	Required	40 character SAP description
20	Medium Description (41-350)	No	Optional	SAP will hold, not searchable
21	Long Description (1,000)	No	Optional	SAP will hold, not searchable
22	**Packaging**			
23	Height	Yes	Yes	Field available in SAP - not used
24	Height UOM	Yes	Yes	Field available in SAP - not used
25	Width	Yes	Yes	Field available in SAP - not used
26	Width UOM	Yes	Yes	Field available in SAP - not used
27	Depth	Yes	Yes	Field available in SAP - not used
28	Depth UOM	Yes	Yes	Field available in SAP - not used
29	Net Content	No	Yes	Required for UOM fields
30	Net Content UOM	No	Yes	Required for UOM fields
31	Gross Weight	No	Yes	Field available in SAP - not used
32	Gross Weight UOM	No	Yes	Field available in SAP - not used
33	Consumer Unit	Yes	Yes	Would assist to populate UOM fields
34	Orderable Unit	Yes	Yes	Would assist to populate UOM fields
35	Invoice Unit	Yes	Yes	Would assist to populate UOM fields
36	Shipping Unit	Yes	Yes	Would assist to populate UOM fields
37	Item Base Unit	Yes	Yes	Would assist to populate UOM fields
38	Item Variable Unit	Yes	Yes	n/a today - perhaps with pharma

	A	B	C	D
1	Common Field Name Highlighted in grey if required on Duke Spreadsheet or Form	GDSN Required (Core 27)	Healthcare Required	Duke Specific observations
39	**Package Markings**			
40	Package Marked with Bar	No	Optional	Not currently stored - can add SAP data fields
41	Packaging Marked with Batch	Yes	Yes	Not currently stored - can add SAP data fields
42	Package Marking - Latex	No	Optional	Not currently stored - can add SAP data fields
43	Package Marking - Sterile	No	Future	Not currently stored - can add SAP data fields
44	**Heirarchy Information**			
45	Parent GTIN	No	Yes	Would assist to populate UOM fields
46	Child Quantity	No	Yes	Would assist to populate UOM fields
47	Child GTIN	No	Yes	Would assist to populate UOM fields
48	**Dates**			
49	Availability Start Date	No	Optional	
50	Effective Date	No	Optional	
51	Publication Date	No	System	

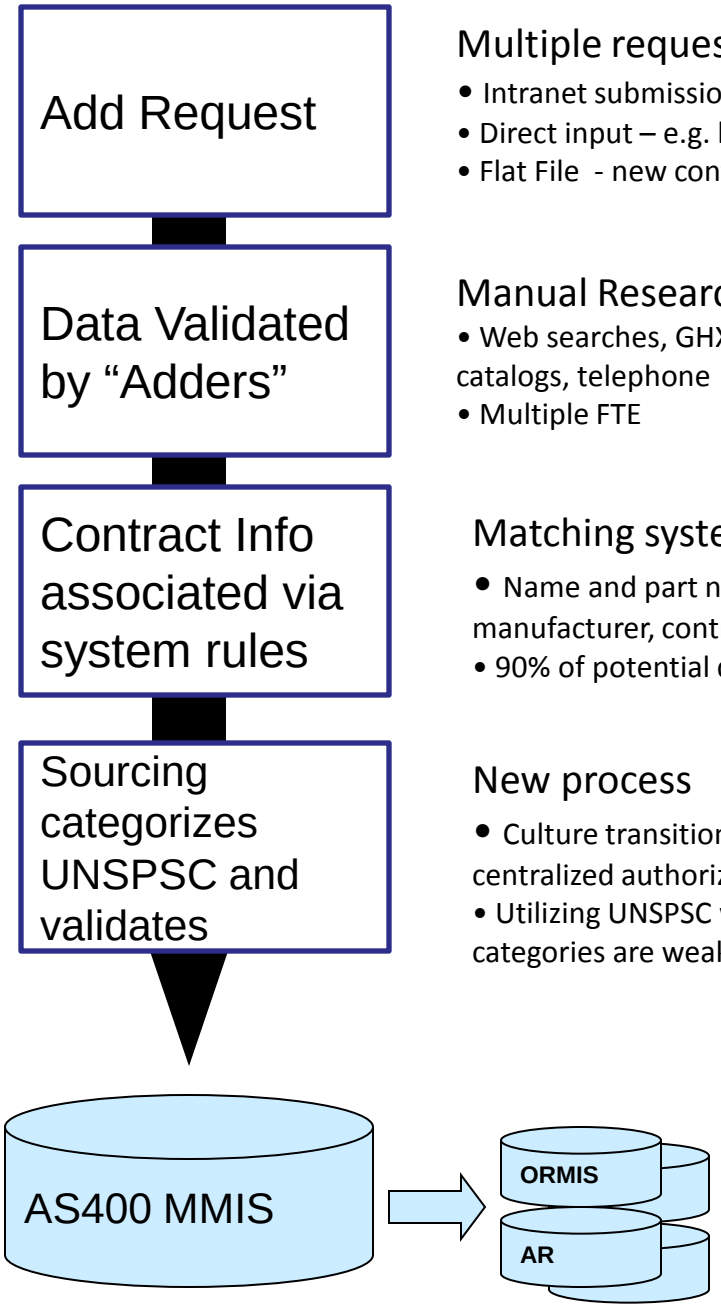
DukeHealth

Duke University Health
New Item Add Process



DukeHealth

PSCM = Procurement and Supply Chain Management
SM = Sourcing Manager
SA = Sourcing Analyst



Multiple dependent systems

Multiple requestors and formats

- Intranet submission with workflow
- Direct input – e.g. big consignment agreement
- Flat File - new contract, direct import to MMIS

Manual Research

- Web searches, GHX data, product packaging, catalogs, telephone
- Multiple FTE

Matching system process

- Name and part number associations align manufacturer, contract and manufacturer data
- 90% of potential dupes removed by rules

New process

- Culture transitioning to more “standards” approach with centralized authorization
- Utilizing UNSPSC with some customization where sub-categories are weaker

Intermountain Healthcare | Healing for life

New Item Add Process

New Item Requests
- End Users
- Sourcing Council
- Local Sites

Local Review
- Info gathering

Submit Request Online
- 30 buyers can submit
- Intranet application for workflow
- Bulk requests on spreadsheets
- Full descriptions

Data Management
- Centralized review
- 75,000+ master items
- 2 FTE
- Standardize descriptions
- De-duplication
- Price verification, loading
- Packaging string creation
- Add supply and billing codes
- Update requests

Quarterly scripts
- **Duplicate search**
- **Status updates (A/I)**
- **Expense code clean up**

Corrections updated manually

MMIS

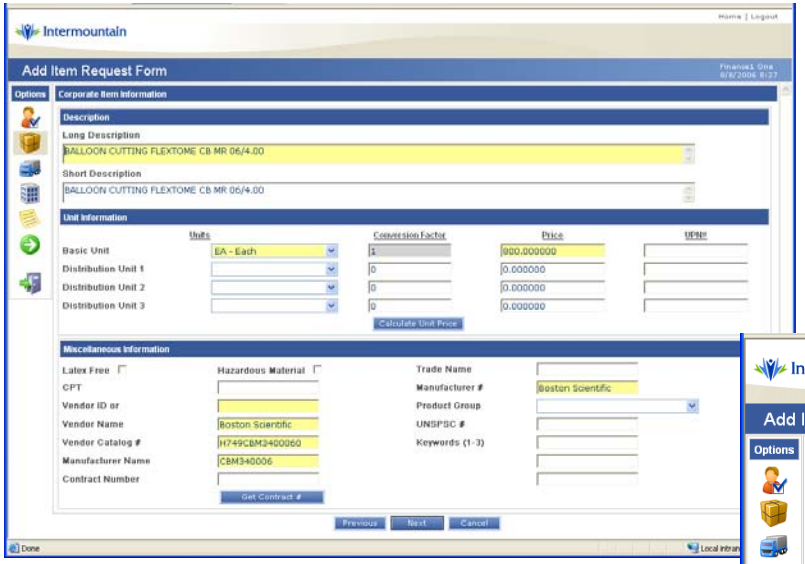
- **Manual load and maintenance**
- **Import capabilities for large files**

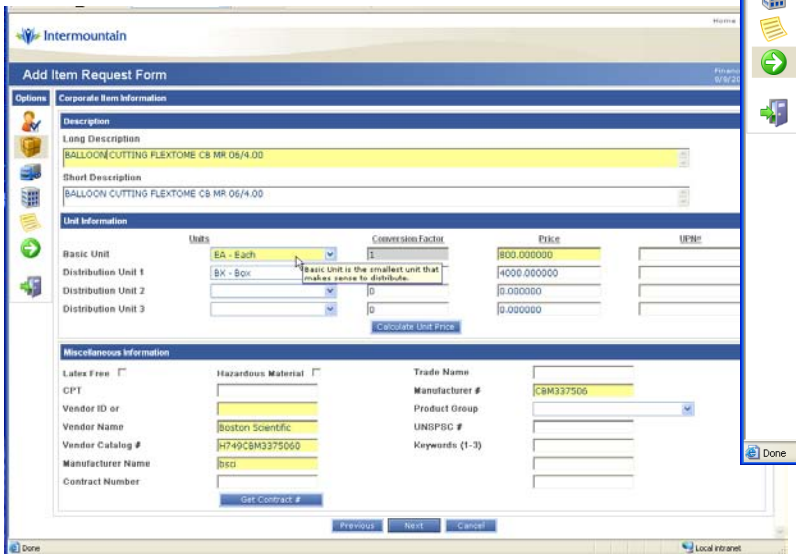
Enterprise MM Tool

- **MMIS fields / web form**
- **Workflow and status**
- **Attachments**
- **Contract linking**
- **Vendor linking**
- **Update capabilities**

Ministry Health Care

Intranet New Item Add Screen Samples



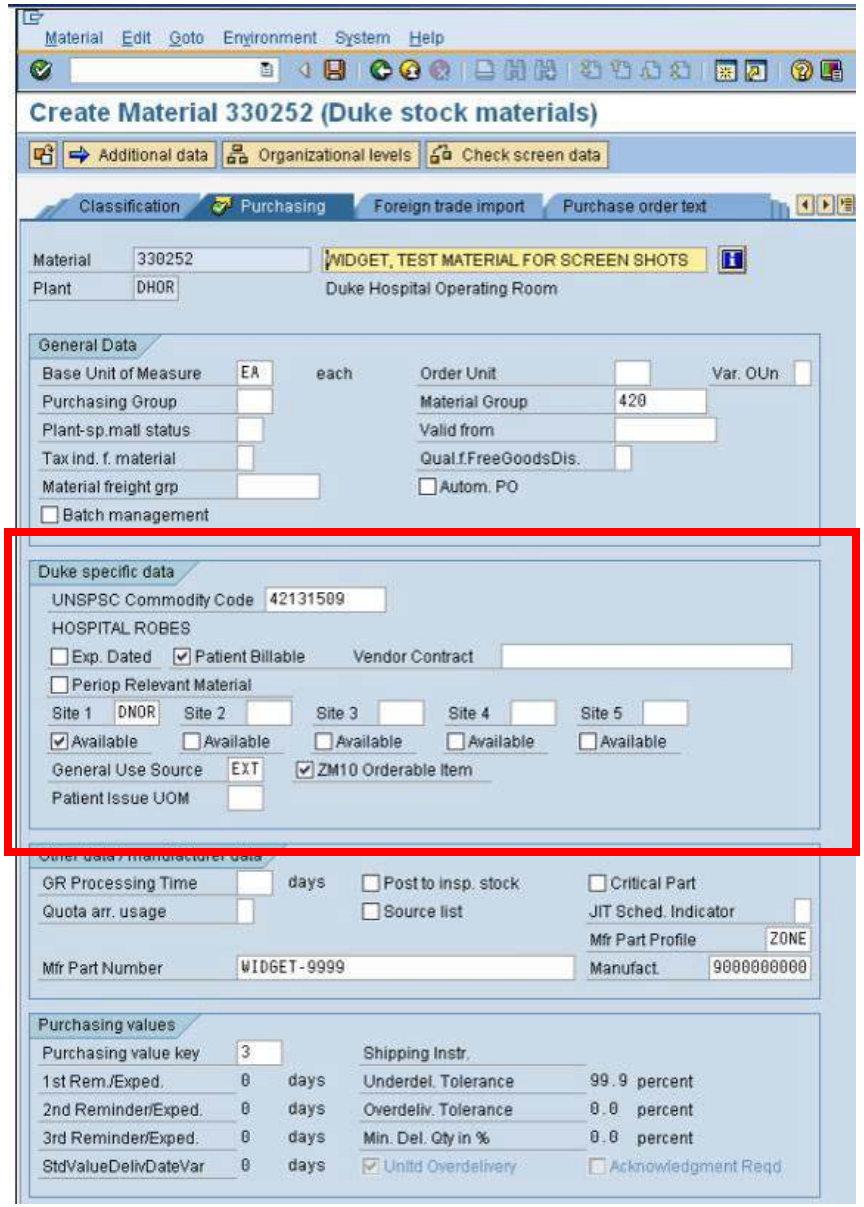


- Standardized inputs (dropdown values)
- Workflow and escalation for approvals
- Built in conversions to calculate prices and quantities between UOM

Intermountain Healthcare | Healing for life

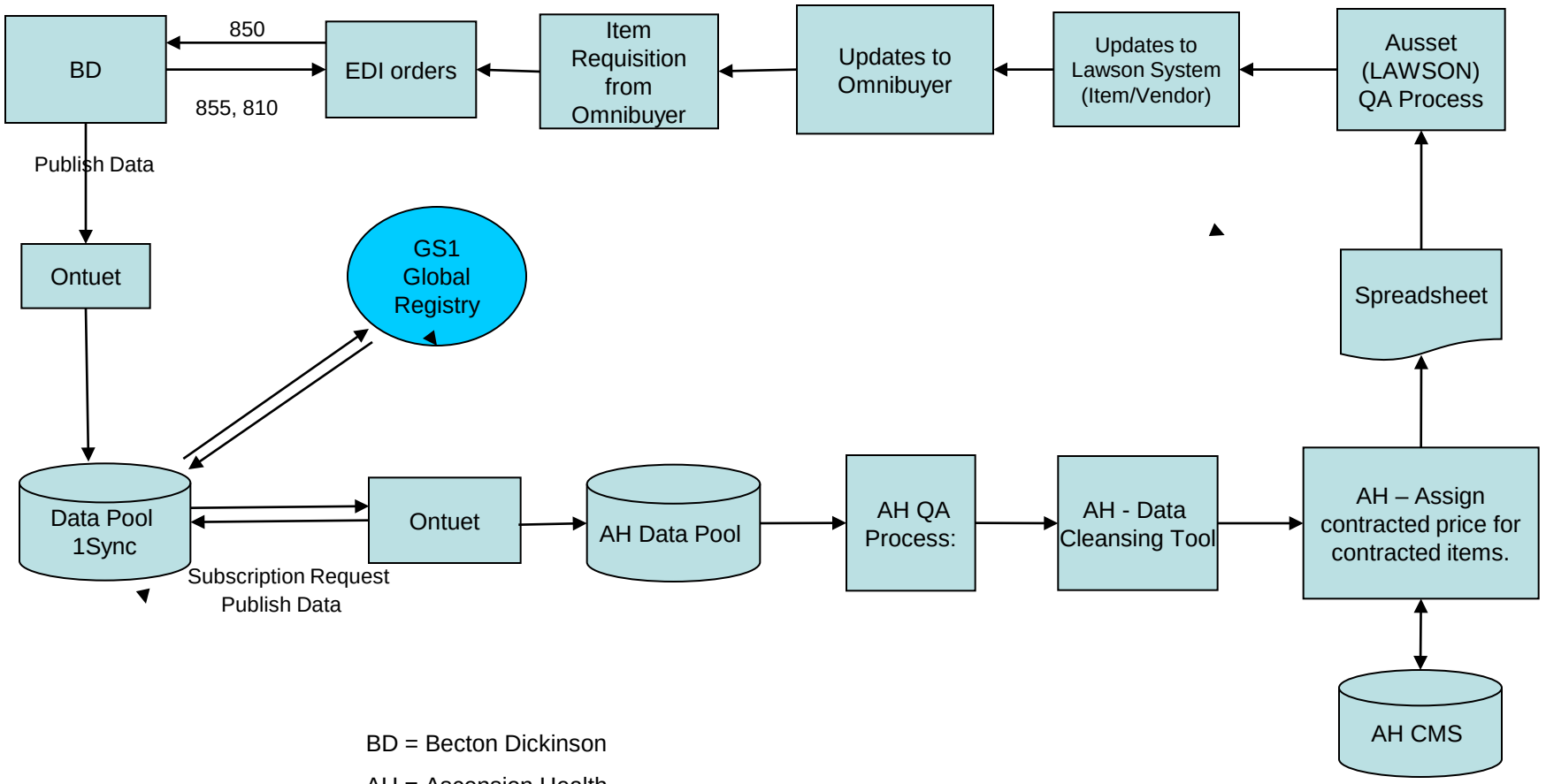
Duke University Update

- Data Fields Analysis completed
  - Work Group recommended set contains more values than currently required by Duke today
  - SAP contains placeholders for many of the Healthcare fields
  - Duke has the existing capability to expand our item master to store additional attributes
    - No SAP assistance required to add new fields
    - Any added fields are maintained through upgrades
    - Potential home for Safety attributes



DukeHealth

BD GLN/GTIN Pilot



BD = Becton Dickinson

AH = Ascension Health

AUSSET = Seton Healthcare Network (Austin, TX) running Lawson

CMS = Contract Management System

Provider Project Template

- Not all participants were required to take all pilot steps
- Kick Off, Gap Analysis and Data Flow were required activities
- Many participants moved from initial pilot steps into GS1 sponsored implementation activities


A GS1 Healthcare US™ Success Story

Seton Family of Hospitals and BD Use GS1 Standards and Processes to Reduce EDI Errors in Pursuit of "Perfect Orders"

- New Provider Ramping Template
  - KickOff Meeting
    - DoD/VA Data Sync Project Background
    - FDA UDI Status and Background
    - Industry Activity Background
    - GS1 and Data Pool Overview
    - Synchronization process overview
    - DMMONLINE education materials
  - Establish Participant scope
    - Gap Analysis - Required
      - Gather current attributes and requirements
      - Identify "local" definitions and/or workarounds
      - Compare to standard definitions and identify gaps
      - Report findings and gather lessons
    - Data Flow - Required
      - Chart "new item add" process
      - Consider current and "after standards" scenarios
    - eProfile (MMIS, infrastructure, EDI capabilities, centralized item mgmt or remote etc…)
    - MMIS requirements discussion (possible tasking)
    - Participant requested tasking - Optional
    - Task List and timeline
  - Receive available GTIN data
    - Data pool no-cost pilot contract
    - Pilot manufacturers forward/publish available GTIN item data
    - Provider internal tasking (if any) upon analysis
  - GTIN in Transactions Study and/or testing (optional)
    - Identify current EDI methodology
    - Review current structure for standards support (4010 version, other…)
    - Engage EDI provider to review industry proposed format
    - Revisit MMIS discussion - research possible short term workaround
    - Gap analysis results
    - Draft implementation tasks, resources and timelines (short/long term)
    - Trading partner pairing
    - Execution and Testing (if desired/applicable)
  - Document Lessons Learned
    - Interim reports to Pilot Work Group (ongoing)

Considering a Pilot?
A few recommendations…

- Design a safe and open forum for education and testing
- Allow otherwise unrelated participants to recognize that they share similar data management issues with their peers
- Require that participants have executive sponsorship, initial briefings should include senior leader(s)
- Minimize tasking requirements for those desiring to “get on the same page” but lacking dedicated resources
- Monitor standardization activities inside and outside healthcare
- Develop materials that allow participants to make the case to internal leadership and subsequent implementation teams
- Highlight first mover progress, lessons learned and ROI
- Identify the availability of standardized manufacturer data

DoD/VA GDSN Pilot III Participants

Manufacturers

BD
SAGE PRODUCTS INC
KCI
GOJO
COOK
Baxter
Kimberly-Clark
3M
MEDLINE
CardinalHealth
propper
ARJOHUNTLEIGH
AVID MEDICAL
inverness medical innovations
JERO Medical Equipment & Supplies Inc.

Technology

GDSN Registry

GS1

Data Pool

1 SYNC

Distributors

CardinalHealth
Owens & Minor
SutureExpress

Payer

MEDI-CAL

GPO

PREMIER
Amerinet
Novation

Providers

Baptist Health South Florida
MayoClinic.com Tools for healthier lives
UNIVERSITY HEALTH CARE SYSTEM
ProMedica HEALTH SYSTEM
NORTON HEALTHCARE
BOSTON MEDICAL CENTER EXCEPTIONAL CARE. WITHOUT EXCEPTION.
MERCY SISTERS OF MERCY HEALTH SYSTEM
ASCENSION HEALTH
Atlantic Health
Kettering
DukeHealth
St. Alexius PrimeCare
JOHNS HOPKINS INSTITUTIONS SHARED SERVICES
ORLANDO HEALTH
SENTARA
Novant HEALTH
Intermountain Healthcare
YALE NEW HAVEN HEALTH
UKHealthCare
GEISINGER
PARTNERS HEALTHCARE
CATHOLIC HEALTH EAST
UNIVERSITY of VIRGINIA HEALTH SYSTEM
ALLINA Hospitals & Clinics
The Medical Center of Central Georgia
SPECTRUM HEALTH
Hannibal Regional Hospital
MINISTRY HEALTH CARE
PINNACLEHEALTH
Hunterdon Healthcare

MMIS

LAWSON
McKESSON
EHS
Caduceus Systems

Questions

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