



HIMSS¹⁹ CHAMPIONS OF HEALTH UNITE

Global Conference & Exhibition
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Using Data to Generate Evidence Which Drives Value

Session SC3, February 11, 2019

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Relationships with Industry

James E. Tcheng, MD

- Fees for non-CME services received directly from a commercial interest or their agents: GE Healthcare
- Ownership interest (stocks, stock options or other ownership interest excluding diversified mutual funds): International Guidelines Central, LivMor
- Data Safety Monitoring Board: AstraZeneca



Learning Objectives

- Establish the strategic importance of using data captured across the point of use and its ability to solve the cost/quality equation
- Identify ways to disseminate data so that it guides and informs clinical practice
- Review the technologies needed to create, maintain, and support robust data capture
- Examine the challenge and opportunities with data governance across enterprises



Topics

- At the intersection of cost, quality and outcomes:
 - Aligned hospital administration, supply chain, physicians
 - Data, data, data
- Given the strategic importance of data
 - Challenge 1: high quality data
 - Challenge 2: workflow integrated data capture at point of use
- Complex systems theory
- Data management logistics
 - What are the goals?
 - What data is needed?
 - Why not wait for “interoperability” to solve this?
 - What is best practice for capture of high quality data?
- Who are external drivers?
 - FDA (UDI), NESTcc



Data and Health Research

A New Concept in Medicine?



“Chronic diseases can be studied, but not by the methods of the past. If one wishes to create useful data ... computer technology must be exploited.”

— *Eugene Stead, MD (ca. 1965)*

- Led to the concept of the “*computerized textbook of medicine*”
- Foundation of the Duke Databank for Cardiovascular Diseases (→DCRI)
- Spurred a generation of clinical and quantitative researchers



Is Healthcare Changing for the Better ...

Envisioned

EHR “Meaningful Use”
Usability and productivity
Patient engagement

Effective clinical care
Population health
Bending healthcare cost curve
Better provider work life

Torrent of real-world data
Big (clinical) data analytics
Leveraged RCTs via registries

Reality

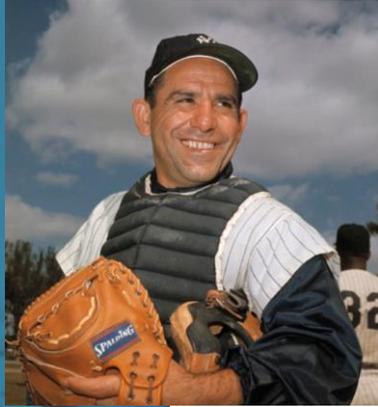
EHR meaningless burden
Death by clicking
AVS drivel

CDS trivial pursuit
Resource consumption focus
Cost control and penalties
NOT!

Puddles of document exchange
Small transactions data
20th century paradigms



Aspiration

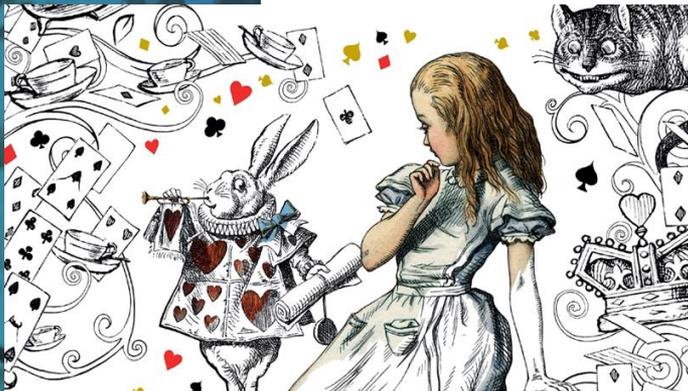


*If you don't know where you are going,
chances are you will end up somewhere else.*

Yogi Berra

*If you don't know where you are going,
any road will take you there.*

Lewis Carroll



Is Healthcare Changing for the Better ...

What Should the Common Denominator Be?



Clinical documentation
Registry reporting
Quality and performance
Supply chain
Device safety, surveillance
Clinical research
RWD → RWE

Computational constructs:
CDS, AI, machine learning, etc.



The Importance of Data Quality

$$\int_{i=0}^{\infty} \textit{garbage} = \textit{garbage}$$

D. Fridsma, 2018



Swivel Chair Interoperability



American College of Cardiology - National Cardiovascular Data Registry: CathPCI Operational Environment

- >90% US PCI procedures, process and quality focus
- Relies on clinical documentation and “swivel chair” interoperability (i.e., little structured reporting)
- NCDR data dictionary: clinical / operational focus, not data standards (primarily name of concept, allowed values)
- No authoritative process to follow for developing data elements as HIT standards (& no single repository)
- No consistent instrument for technical consumers (HIT vendors, db developers): data elements, data capture instruments, workflow engineering
- \$10 million+ book of business → \$500 million+ site expenditure (2000 sites, 2+ FTEs per site)



2018 Map of the Complexity Sciences

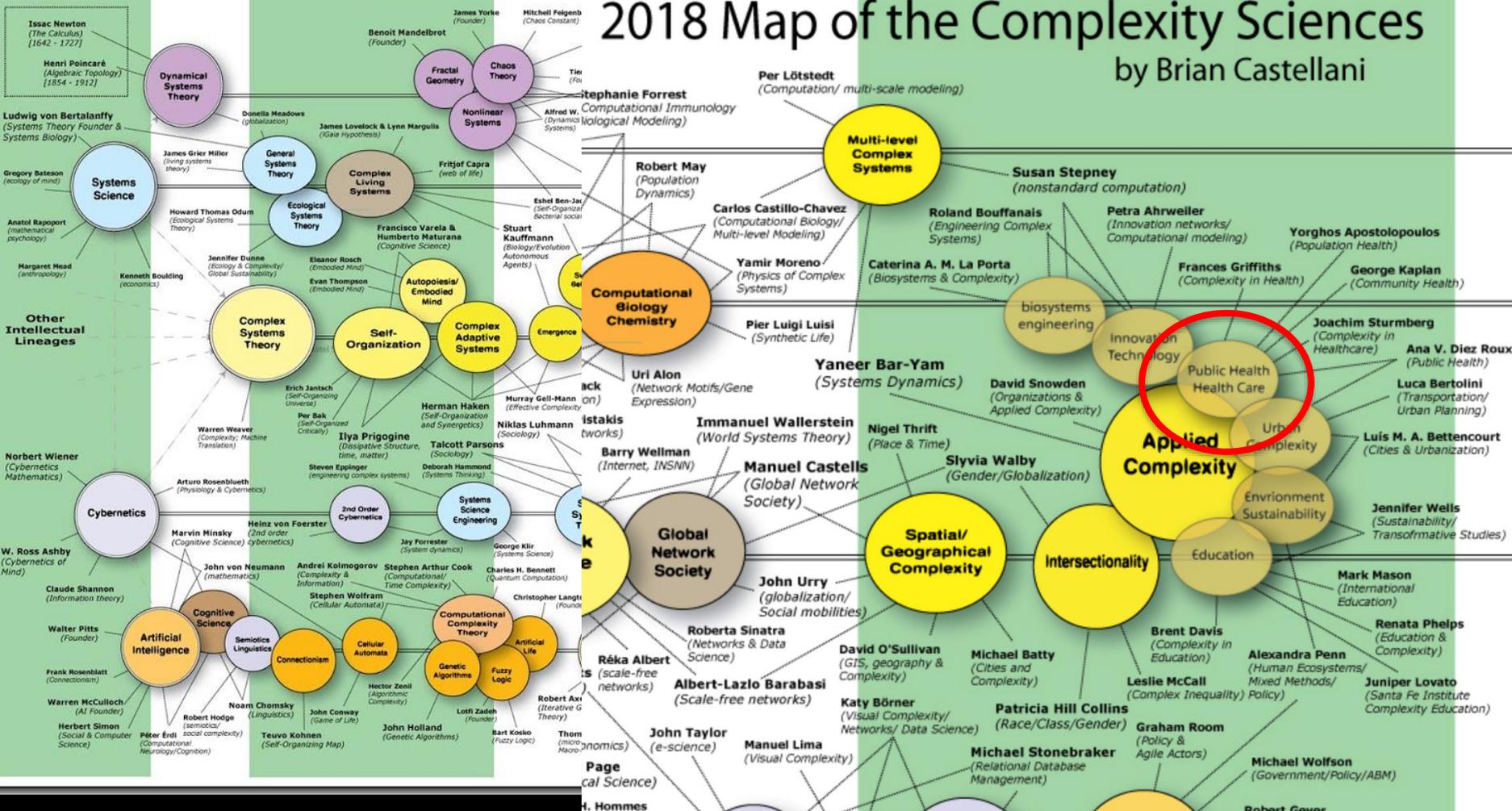
by Brian Castellani

1940-1950s

1960's

1970's

1980's





Key Healthcare Targets

- Clinical care: data as a medical partner
 - X Clinical documentation focused on care (not billing)
 - X Engineered data capture via care processes
 - X Outcomes-based (not just systems / processes)
 - X Incorporate patient-reported information, f/u
 - X Clinical decision support, pre-authorization support, reduction in variability, revenue recovery
- Research: changing the RCT paradigm
 - X Observational / CE studies, pragmatic trials
- Regulatory: changing the evidence paradigm
 - X RWD → RWE (not just adverse events / recalls)
 - X Pharmacovigilance, device surveillance



Excellence & Mediocrity



“A society which scorns excellence in plumbing simply because it is plumbing, but rewards mediocre philosophy simply because it is philosophy, will soon become a society in which neither its pipes nor its theories will hold water.”

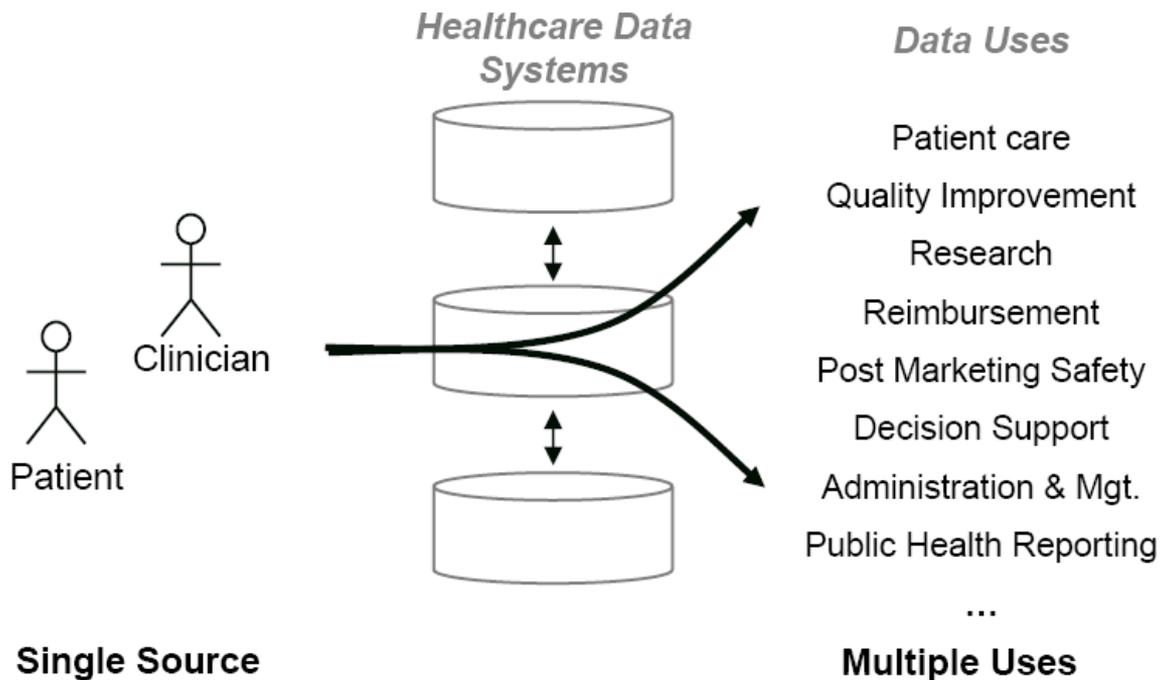
John W. Gardner (1961)

HEW Secretary under Lyndon Johnson

Engineer of the Great Society (Medicare, PBS)



Exchange, Use, and Reuse of Data Requires Shared Data Definitions, Including Semantics



What is Required to Share Data?

- What: conceptual clinical definitions (vocabulary)
- When, where: interfaces (forms) to capture specific data at point of care by individuals closest to the data
- How:
 - physical layer (data capture and storage, native data interoperability)
 - communication layer (syntactic, semantic interoperability)
 - common / standard format (data modeling)
 - bindings to controlled terminologies (SNOMED-CT, LOINC, RxNorm)

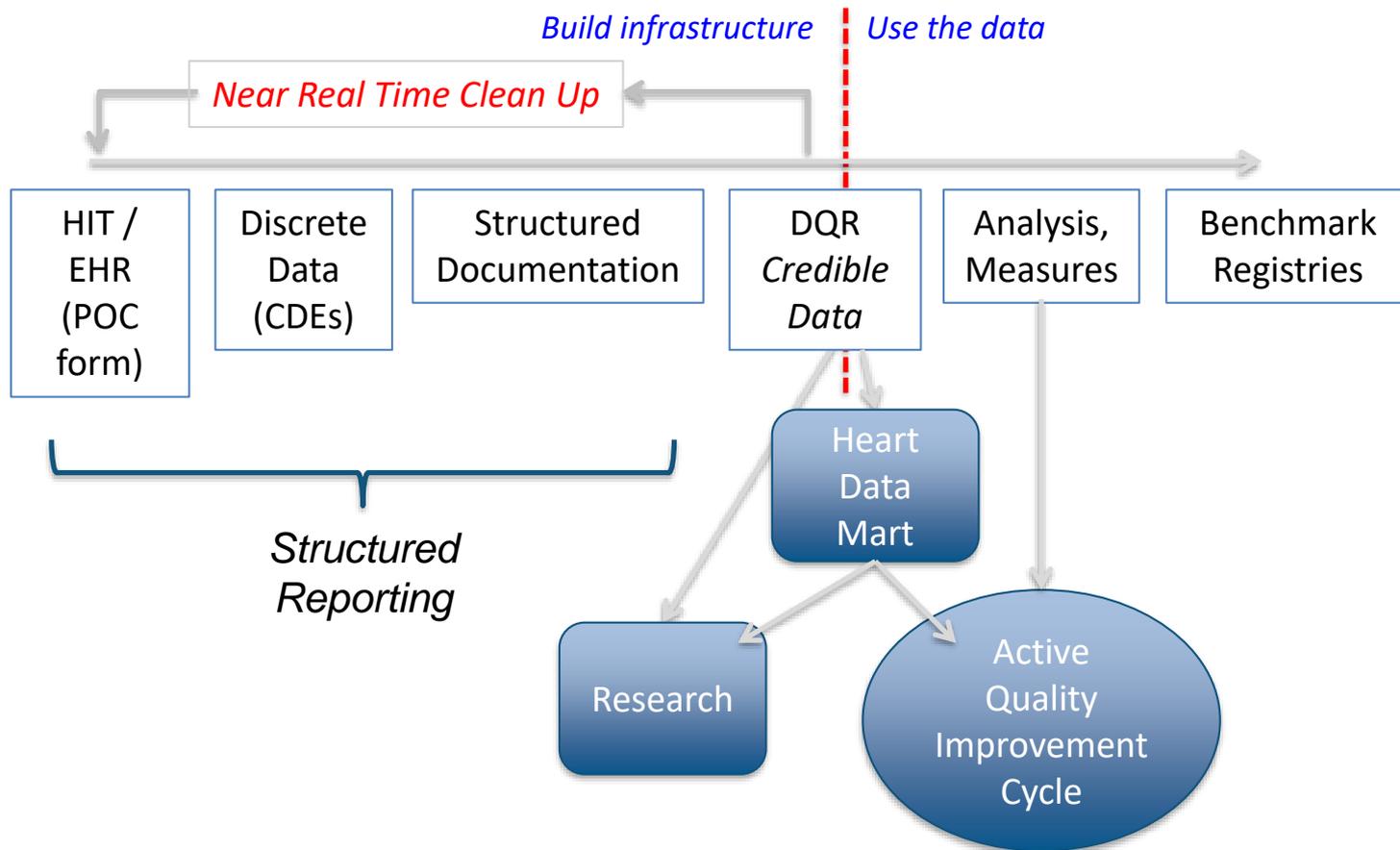


Data Destinations: Multiple Masters



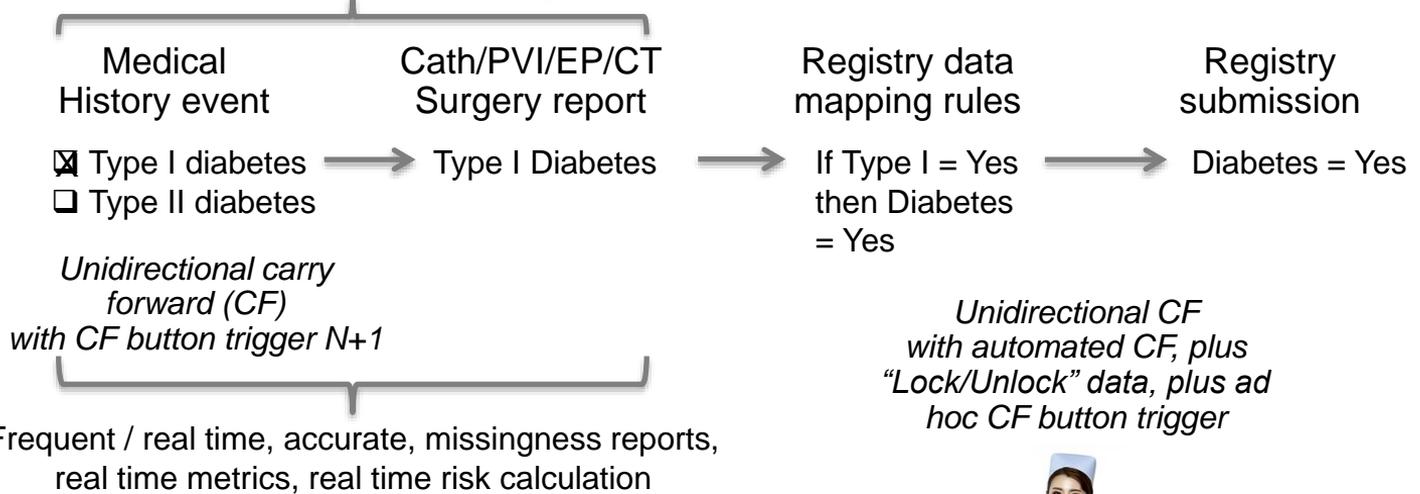
... who are time-challenged, short-staffed, over-burdened ...

Duke Heart Center - Dataflow End State



Concurrent Data Acquisition Model and Data Flow Into Registries

Clinical data collected during case



Cath Lab / Surgery Staff



Registry Nurse

- Data quality
- Performance improvement

What is Structured Reporting?

- Explicit clinical data captured by the person closest to that data, integrated into clinical workflow (e.g. MA, tech, RN, pt)
- Informatics formalisms: universal, well-defined common data elements; data model that parallels (i.e., is representational of) clinical care model
- Data compiled by the computer to produce majority of report content; MD validates the data, contributes only cognitive assessment and recommendations
- Output: the *structured report*
- ROI: ↑ data quality /quantity, ↓ redundancy / repetition, time to final reports, FTE requirements → augmented knowledge, revenue recovery, financial gains



How Is Structured Reporting Done?

HEALTH POLICY STATEMENT

ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for the Cardiac Catheterization Laboratory



A Report of the American College of Cardiology Clinical Quality Committee

Developed in Collaboration With the American Association for Critical-Care Nurses, Asian Pacific Society of Cardiology, Canadian Cardiovascular Society, Health Level Seven International, Inter-American Society of Cardiology, Integrating the Healthcare Enterprise, Society of Thoracic Surgeons, and Society for Vascular Surgery

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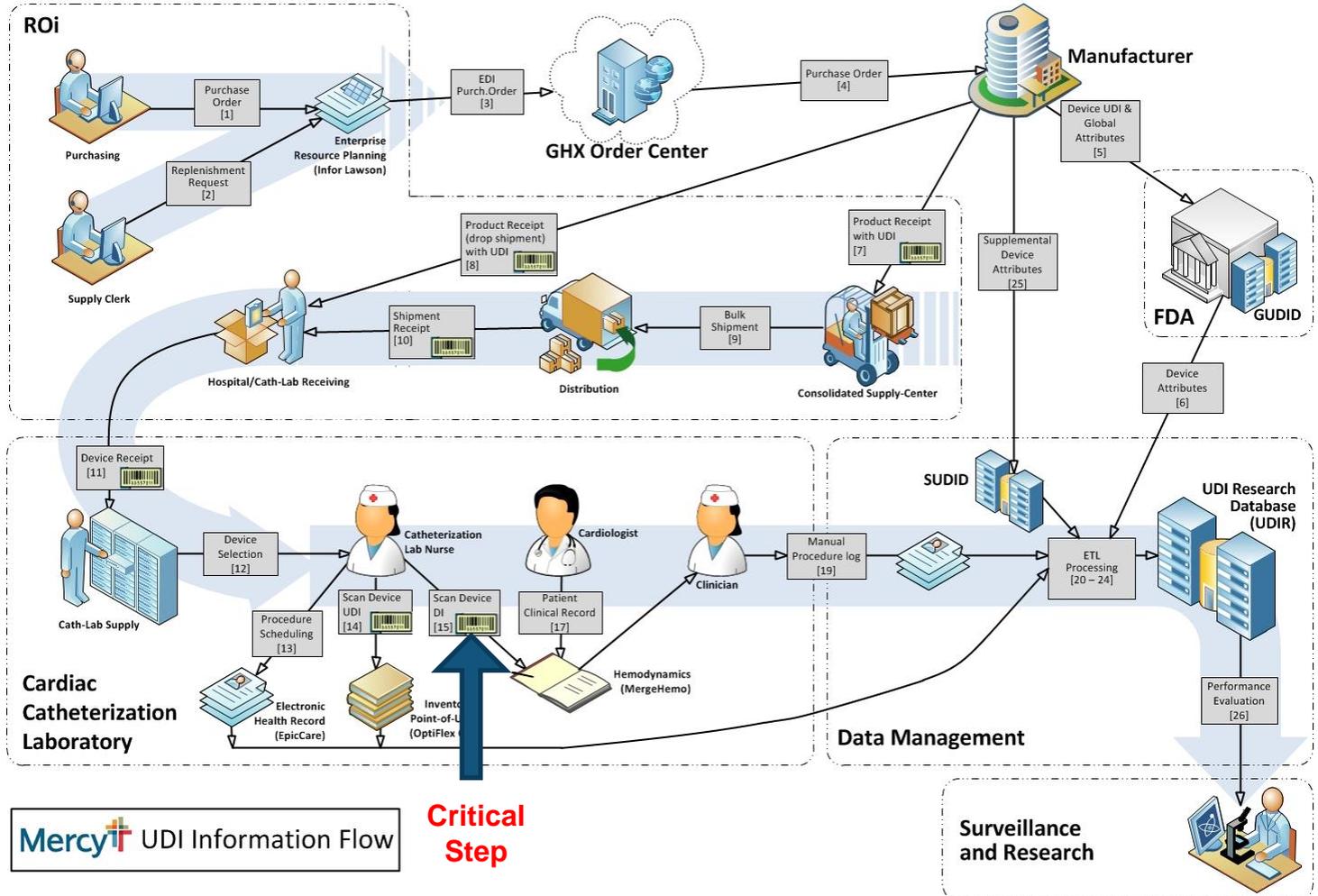
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- Engineered, best-practice workflows
- Just in time, context specific, high usability, point of care data capture
- Data persistence
- Lots of business rules
- Optimized IT form factors

In other words ...

- Command of who does what when, where, and how

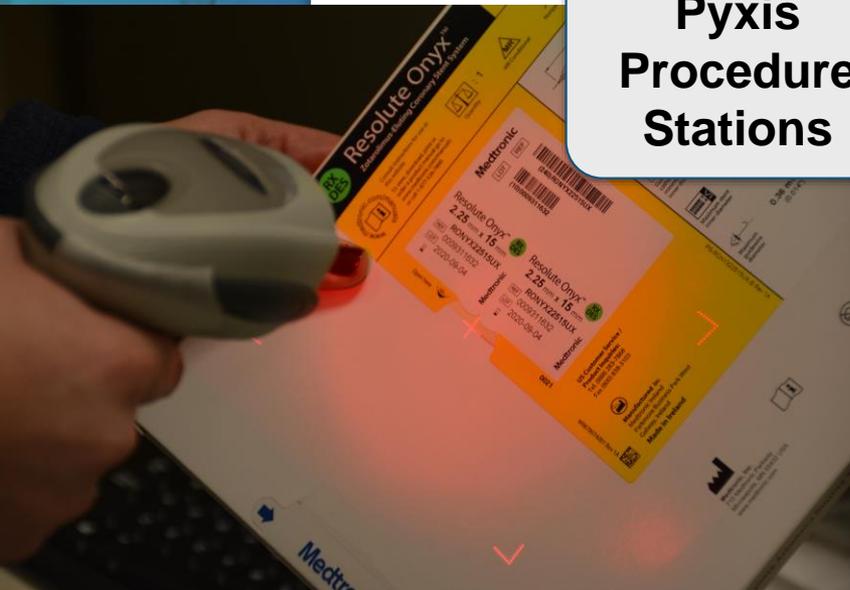
Device (UDI) + Clinical Data Integration



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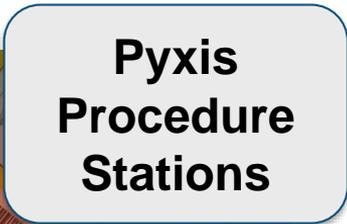
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Orders ORM
Pt data
Accession, case #
Procedure data

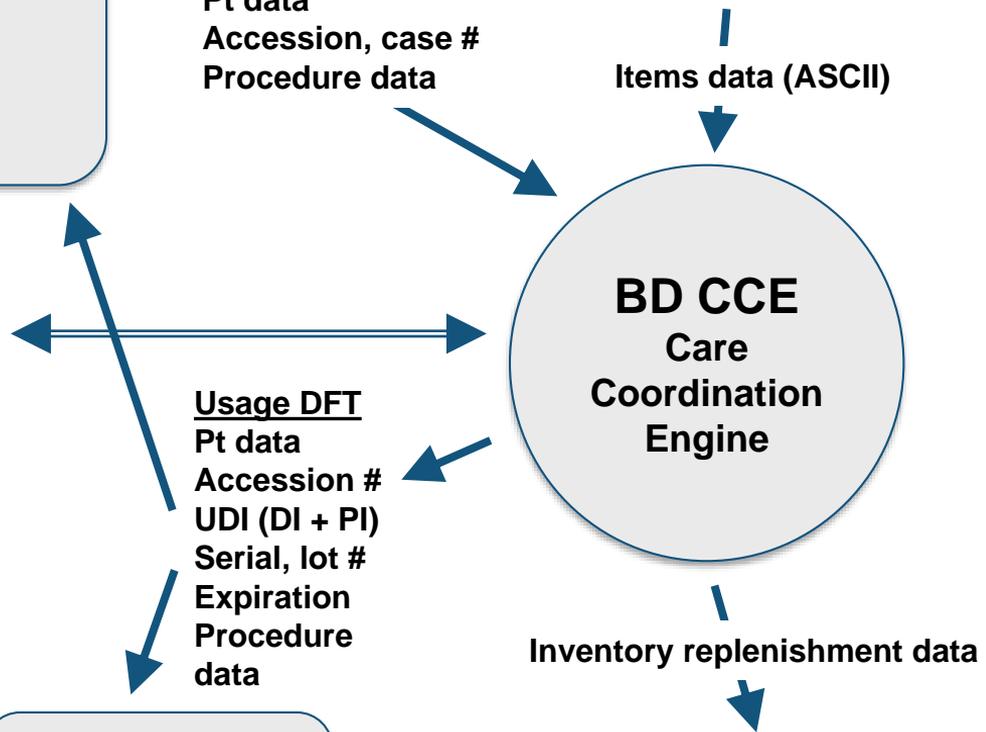
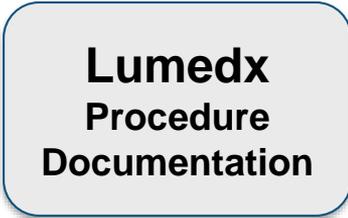


Items data (ASCII)



Usage DFT
Pt data
Accession #
UDI (DI + PI)
Serial, lot #
Expiration
Procedure
data

Inventory replenishment data



What Does UDI Enable?

- Standardized device description → procedure report
 - no more MD recall, transcription errors
- Inventory management (lower PAR levels → >\$1m savings / yr - Mercy Cath Lab)
- Device use attribution (e.g., waste, failure to deploy)
- Consignment device management
- UDI to the EHR (exported to the UDI device table)
- Device explants (e.g., CIED) – closing the loop
- Administrative reporting (e.g., device usage reports)
- Adverse event reporting (e.g., FDA MedWatch)



How Important is it to Identify an Implant?

Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Pepperidge Farm® Announces Voluntary Recall of Four Varieties of Goldfish® Crackers

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For Immediate Release

July 23, 2018

Contact

Consumers

Customer Service
 ☎ 800-679-1791

Media

Bethridge Toovell
 ✉
Bethridge_Toovell@PepperidgeFarm.com
 ☎ 203-846-7136

Announcement

[View Product Photos](#)

Pepperidge Farm has been notified by one of its ingredient suppliers that whey powder in a seasoning that is applied to four varieties of crackers has been the subject of a recall by the whey powder manufacturer due to the potential presence of *Salmonella*. Pepperidge Farm initiated an investigation and, out of an abundance of

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Consumers - Decisions Within Days

Company Announcement

When a company announces a recall, market withdrawal, or safety announcement as a public service. FDA does not endorse either the

Pepperidge Farm® Announces of Four Varieties of Goldfish®

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For Immediate Release

July 23, 2018

Contact

Consumers

Customer Service
800-679-1791

Announcement

[View Product Photos](#)

Pepperidge Farm has been notified by a supplier that a whey powder in a seasoning that is applied to subject of a recall by the whey powder manufacturer due to the potential presence of *Salmonella*. Pepperidge Farm initiated an investigation and, out of an abundance of caution, is voluntarily recalling select varieties of Goldfish crackers.

From: Walmart.com Recalls - WMA1807231@walmart.com

Date: Wed, Jul 25, 2018 at 12:19 AM

Subject: Pepperidge Farm Recalls Varieties of Goldfish Crackers

Dear Valued Walmart Customer:

Pepperidge Farm has been notified by one of its ingredient suppliers that a whey powder in a seasoning that is applied to some varieties of crackers has been the subject of a recall by the whey powder manufacturer due to the potential presence of *Salmonella*. Pepperidge Farm initiated an investigation and, out of an abundance of caution, is voluntarily recalling select varieties of Goldfish crackers.

Pepperidge Farm has asked us to recall the products listed below with the corresponding Best by Dates. Our records reflect that you may have purchased one or more of the items listed below.

Description	UPC	Sell By Dates	Product Images
Pepperidge Farm® Goldfish® Flavor Blasted® Ktra Cheddar Crackers, 6.6 oz. Bag	1410008548	WO 11/25/18	
		WO 12/2/18	
		WO 12/9/18	
		WO 12/16/18	
		WO 1/20/19	
		RU 12/30/18	

Your prompt action to this notice is strongly encouraged. If the affected product is still in your possession, we request that you do not consume it, discard it, and go to any Walmart store for a full refund. At Walmart, we adhere to strict quality assurance controls and work with our suppliers to ensure that we provide you with quality products. The supplier is cooperating fully with the U.S. Food and Drug Administration (FDA) to resolve the issue.

Pepperidge Farm recommends consumers with any questions or concerns about this recall visit www.pepperidgefarm.com/GoldfishUpdate or contact 1-800-679-1791.

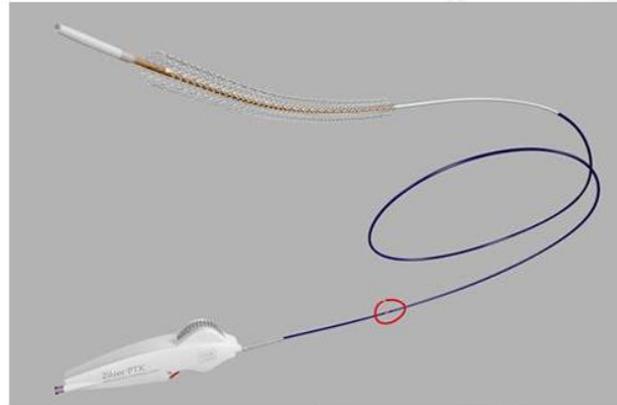
Consumers with additional questions may also contact the Walmart Customer Care Center through the contact form at: <http://help.walmart.com/app/grocery>.

We apologize for any inconvenience and look forward to meeting your needs in the future.



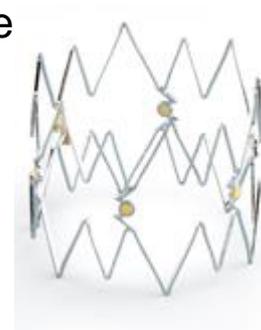


Registry Assessment of Peripheral Interventional Devices (RAPID)



Registry Assessment of Peripheral Interventional Devices (RAPID)

- The MDEpiNet RAPID project is designed to advance the foundational elements of the approach for the evaluation of medical devices used to treat and manage peripheral artery disease.
- RAPID is an archetype of the total product lifecycle (TPLC) ecosystem.
- It is one of a series of projects initiated to advance and demonstrate the interoperable flow of data across electronic health information systems.
- Is fundamental to the basis of the development of the National Evaluation System for Health Technology (NEST).
- A demonstration project of MDIC/NESTcc, a public-private partnership.



UDI in RAPID: Improve Decision Making with Better UDI Data

GUDID/Informatics Workgroup Phase III

1. Objective

- a) To improve UDI capture/utilization and broaden its impact
- b) Demonstration Project
 - Use findings and partnerships built in Phase I and Phase II to form a partner-based quality improvement study of UDI workflow
 - Develop process to capture RWE from selected data partners for worldwide regulatory support of device TPLC

2. Methodology

- Clarifying structured data device parameters to be assigned by manufacturers to improve quality of clinically relevant size and device categorization in GUDID
- Assessing existing workflows at NESTcc data partners who are committed and show high level of UDI adoption maturity

UDI in RAPID: Improve Decision Making with Better UDI Data

Methodology (cont'd)

- Assisting implementation of the core RAPID clinical data elements (including UDI) into EHR or other point of care systems
- Exploring mechanism for transfer of data into a PAD registry
- Evaluating impact on data partner workflows and reductions in data capture, data transfer, and feedback to improve value of UDI to multi-stakeholders across the PAD lifecycle
- **Expected NEST impact:** facilitate development of UDI workflow processes in NEST partners that could be leveraged by other healthcare systems, as well as evidence generation processes that could be utilized across the medical device industry



Summary

- All segments must work in concert toward common goal: data driving the cost, quality and outcomes equation
 - Manufacturers: discrete data
 - Supply chain: integration into clinical care
 - HIT: solutions enabling engineered, best practice clinical workflows
 - FDA: UDI, supplemental device attributes
 - Clinical: structured reporting
 - Professional societies: leadership, coordination
 - Healthcare systems: vision, implementation
 - Healthcare: data interoperability, not documents
- Contact: james.tcheng@duke.edu

