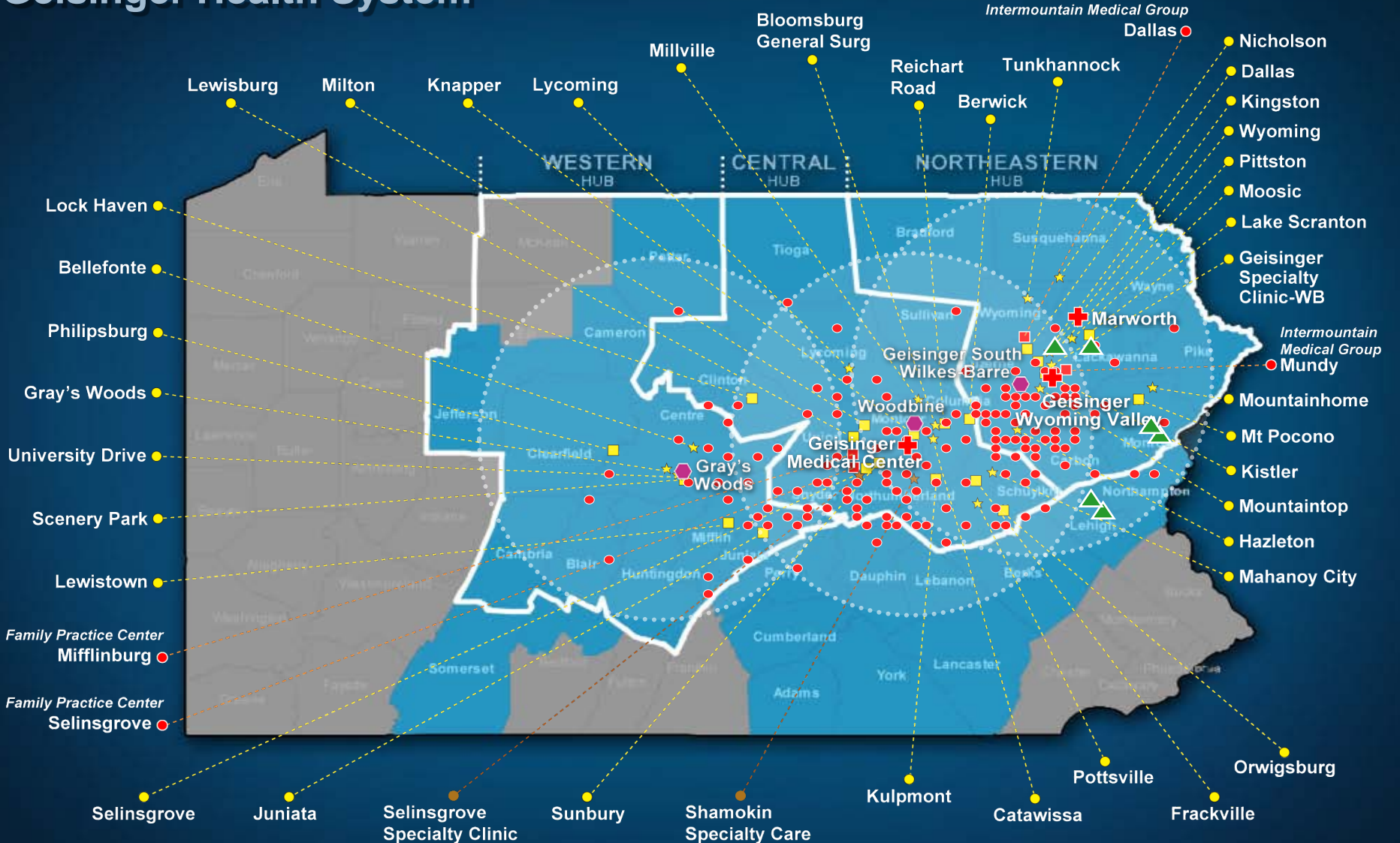


UDI Driven Improvements for Patient Safety

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Vice President, Supply Chain Services
Geisinger Health System

Geisinger Health System

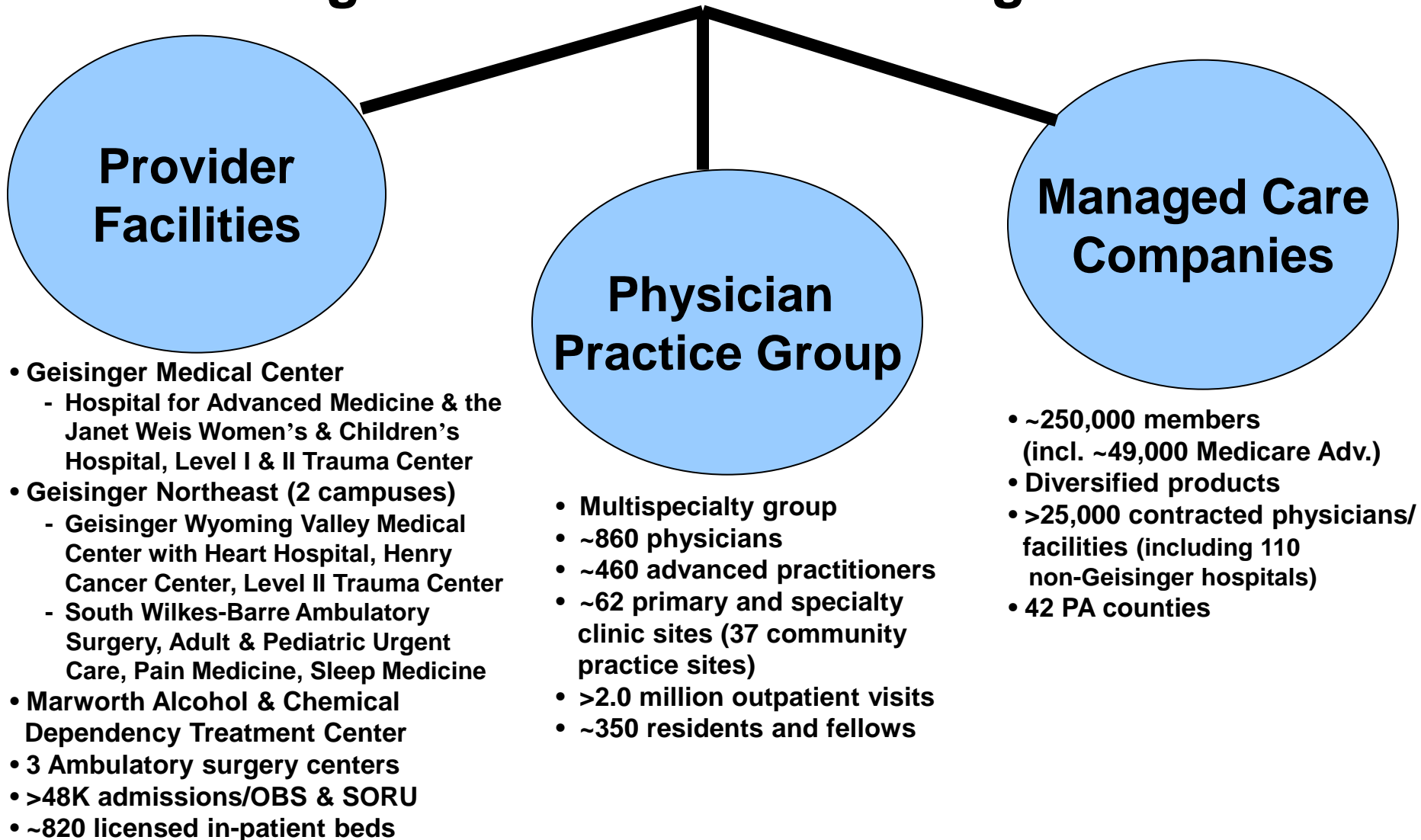


Last updated 11/12/09

- Geisinger ProvenHealth Navigator Sites
- + Geisinger Inpatient Facilities
- ▲ Careworks Convenient Healthcare
- Contracted ProvenHealth Navigator Sites
- ◆ Ambulatory Care Facility
- Geisinger Health System Hub and Spoke Market Area
- ★ Geisinger Medical Groups
- Geisinger Health Plan Service Area
- ★ Geisinger Specialty Clinics
- Non-Geisinger Physicians With EHR

Geisinger Health System

An Integrated Health Service Organization



Electronic Health Record (EHR)

- > \$130M invested (hardware, software, manpower, training)
- IT Operating costs: ~4.4% of annual revenue of > \$2.3B
- Fully-integrated EHR: 37 community practice sites; 2 hospitals; 2 EDs; 6 Careworks Retail-based and worksite clinics
 - Acute and chronic care management
 - Optimized transitions of care
- Networked PHR - ~155,000 active users (33% of ongoing patients)
 - Patient self-service (self-scheduling, kiosks)
 - Home monitoring integrated with Medical Home
- “Outreach EHR” - 2,600 non-Geisinger physician users
 - Regional image distribution
- Active Regional Health-Information Exchange (KeyHIE)
 - 11 hospitals, 90+ practices, 400,000 patients consented
- Keystone Beacon Community
 - HIT-enabled, Community-wide care coordination in 5 rural counties

We need to provide the highest **quality**,
safest care

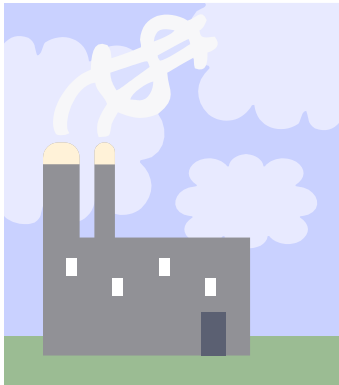
- as **efficiently** as possible across the continuum
- for **lower cost** per outcome.

Targets for the Geisinger Transformation

- Unjustified variation-Need to measure and monitor effectiveness of care
- Fragmentation of care-giving-Need common language to share information
- Perverse payment incentives-need cost effectiveness, efficiency and ability to document quality performance outcomes
 - ↑ Units of work
 - Outcome irrelevant
- Patient as passive recipient of care, not active participant-Systems need to start with the patient

WHAT ARE WE TRYING TO ACCOMPLISH?

APPLICATION OF DATA STANDARDS ACROSS THE ENTIRE HEALTHCARE SUPPLY CHAIN



From Finished Goods



Through Marketing,
Sales and Distribution



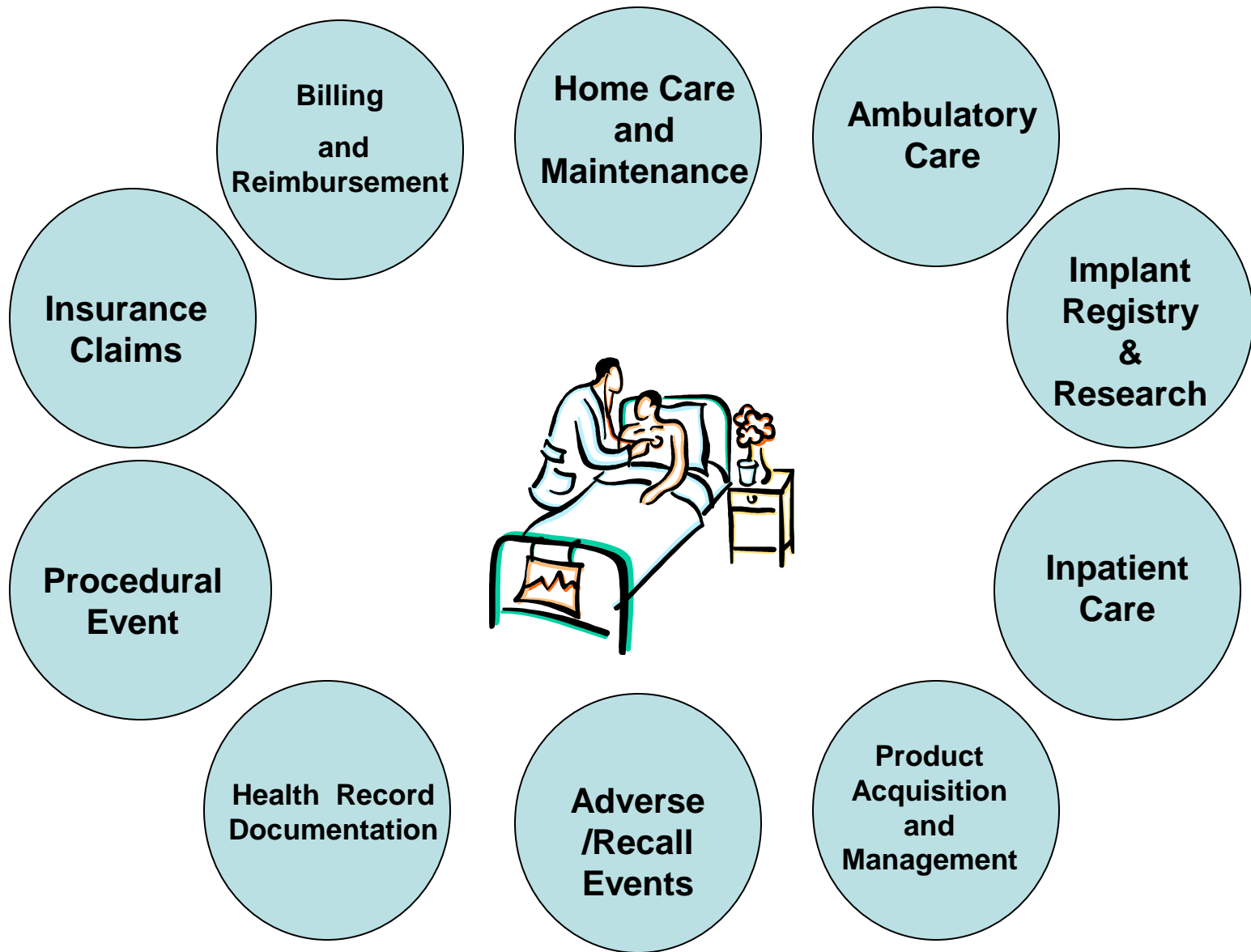
To Product Use

Challenges in the Healthcare Supply Chain

- Counterfeiting-counterfeit drugs sales
 - FDA no luck in implementing a national system to fight counterfeit drugs
 - WHO estimates that counterfeit drugs make up less than 1% of the nation's drug supply
 - In California would mean that up to 3 million RX's per year could be filled with counterfeit product
- Medication Errors
 - At least 19 deaths in US linked to heparin contamination
 - California delayed in legislation that would require manufacturers and retail pharmacies to create an electronic system to record a drug's journey from factory to patient (2011) (e-pedigree)
- Supply Chain Efficiency
 - administrative costs reported to constitute 30-40% of US healthcare costs
- Regulatory Evolutions
 - Pedigree Legislation
 - FDA UDI proposed regulations (20??)
- Data Integrity
 - Data is a corporate asset and can provide a competitive advantage
 - Needs to be clean, complete, accurate and timely
- Medical Device Recalls (more than 700 recalls issued in US in 2008, including more than 100 Class 1 recalls (dangerous or defective products that could cause serious harm or death)) and Device Correction notices

Main goal of a UDI System is to improve Patient Safety by:

- facilitating traceability of devices
- enhancing the identification of devices in case of adverse events
- assisting in the event of a field safety correction
- possibly facilitating the reduction of medical errors



Procedural Event



Application: **GTIN** and **UDI**

- Accurate product identification
- Accurate and complete documentation
- Automated documentation (bar code scanning)
- Device “reprocessing”/tracking

Inpatient Care

Application: **GLN, GTIN** and **UDI**;
Product Serialization)



- **Bedside Identification** of drug, device or supply (barcoding, etc)
- Safety: **Error prevention**
- Increased ability to **track product performance**; tie to clinical outcomes data
- Increased ability for “**remote**” device **programming** (e.g. IV pumps)
- **Attribute** assignments: latex, etc.
- **Bedside recording** of information – “Point-of-Use” data capture (IV Pumps, etc.)
- **Asset Tracking**



Electronic Health Record Documentation and Database Links



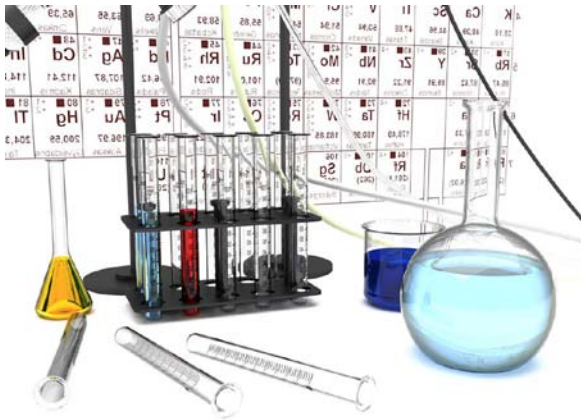
Application: **GTIN** and or **UDI**

- **Documentation of Primary and Secondary Device information; Consistent documentation**
- **Searchable, Retrievable and Comparable data**
- **“Shareable” information; Interoperability**
- **Allow linkage of disparate databases; UDI = the “key”**
- **Documentation of allergic reaction to devices with automated warnings**
- **Documentation of MRI-incompatible implants/devices**

Implant Registry and Research

Application: **GTIN** or **UDI**

- Ability to have **consistent documentation**
- **Searchable and Retrievable** Information
- Base for **Comparative Effectiveness Research**
- Base for “State and National” databases
- Increased efficiency for **recall process**
- Ability to have accurate patient records for **remote treatment** (e.g. hemophiliacs, implantable devices)



Billing and Reimbursement



Application: **GTIN** and **UDI**

- **Billing accuracy and consistency**
- ? Better **understood** or match to use?
- **Eliminate** need for **separate codes** for reimbursement purposes?
- **Improved accounting** for the cost of care (bundled payment)



Insurance Claims



Health Insurance

Application: GTIN and UDI

- **Accurate** and **consistent** data transmission
- **Streamlined** processing
- Data **trending** and research



Home Care and Maintenance



Application: GTIN or UDI (?GLN)

- **Remote Device** Use, Monitoring and Communication
- **ePedigree**
- **Product Identification** and **Education**
- **Recall** handling
- Extension of e-prescribing and health records for **recording** patient **allergic reactions**, **device incompatibility** and **auto notification** if issue detected



Ambulatory Care

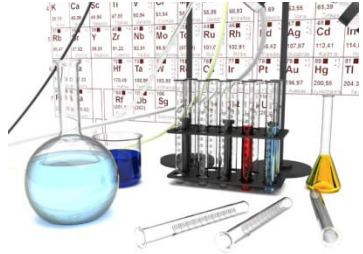


Application: GTIN and UDI

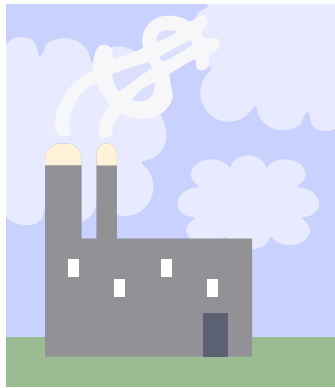
- **Asset tracking**
- **Electronic Health Record Communication**
- **Automated communication** of device/implant incompatibility or patient allergic reactions
- **Regional databases** for Patient Management (Ventricular Assist Devices, Hemophiliacs)



Product Acquisition and Management



Application: GLN, GTIN, UDI, GDSN



- Disaster Supply Management
- Increased Visibility throughout the Supply Chain

- Chain of Custody: Track and Trace (epedigree, counterfeit and diversion prevention)

- “Perfect Order” communications: Right product, right place, right price
- Ease of Identification, Storage and Distribution
- Effective and Efficient Recall Handling
- Effective BackOrder Management



Adverse/Recall Events



- Application: **GLN, GTIN** and **UDI**
- More rapid **Identification** of drug, device or supply
- Assistance with “**user error**” **identification**
- **Ability to pull** affected items quickly
- **Ability to identify** affected **patients** quickly
- Increased ability to **track product performance**
- Facilitation of **field service corrective actions**
- **Greater completeness and accuracy** in **reporting** and **aggregation** of related **reports; analysis and issue identification and resolution**
- More accurate **target communication** of alerts, recalls or corrective action
- Protection of **public health**



Provider Standards Needs

- GS1 Standards chosen for proven success in other industries, flexibility and international capabilities –**We need ONE standard**
- Currently, **no common product identifiers** yielding multiple inefficiencies and fragmented systems. Providers recognize the potential of having a solid base (**common vocabulary**) in data collection and management. –Education in the Provider “world” still needed.
- Technology **solution providers** need to partner to support database needs-However, a technology solution is not necessary to see the benefits of deploying Standards.
- **Manufacturers** need to recognize a supply chain that ends at the patient bedside or Point-of-Use We need to collaborate across this total supply chain.
- **Information maintenance** and **access** needs to be **efficient and “real time.”**
- We have the opportunity to create an infrastructure that will be **mutually beneficial- We need to all engage together to build efficient and effective systems that will support the care we all desire and deserve.**

Current Standards-Based Supply Chain Activity at Geisinger

- Electronic Health Record: Building Supply Chain Connections
 - Operating Room
 - Future: Interventional Radiology, Cardiac Cath and Nursing Units
- Warehouse Inventory Management: bar code scanning
- Establishment of GTIN's within database for transaction exchange
- Exploring RFID/RTLS technology for asset management
- Testing of Chain of Custody methods in Pharmacy; Bedside Bar Code Scanning Preparation
- Current need to tie Charge Master to Item Master and in the future include standards for billing purposes
- Transactional EDI and EFax utilizing GLN information

What are we doing to move forward?

- Involved in Standards development through GS1 and FDA efforts
- Helping to educate our peers
- Engaging our biomedical support
- Working with manufacturers, distributors and technology solution providers to develop, test and utilize the Standards

What is Needed to Realize the True Benefit of UDI?

- All stakeholders, from manufacturer through to healthcare providers need to use the globally harmonized UDI system.
- Education of all users along the supply chain.
- An international approach will make the medical device market more secure for all stakeholders (health authorities, hospitals, manufacturers, distributors, etc.).
- Electronically readable labeling with security or encryption features.

We don't need Standards, do we?



<p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p> <p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p>	<p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p> <p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p>	<p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p> <p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p>	<p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p> <p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p>	<p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p> <p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p>	<p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p> <p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p>	<p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p> <p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p>	<p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p> <p>Pedea 5 mg/ml</p> <p>UK, IE, MT, NL, BE, DE, AT, FR, ES, PT, GR, CY, NO, SE, DK, FI</p>
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- The package has:**
- 6 machine readable codes (5 bar codes, 1 data matrix).
 - 17 flags (UK, Ireland, Malta, Netherlands, Belgium, Germany, Austria, France, Spain, Portugal, Greece, Cyprus, Norway, Sweden, Denmark, Iceland, Finland) (not Italy)
 - 12 different language texts (English, French and German are used in more than one country).

