The Canadian Healthcare Data Standards Project
Who is Alberta Health Services

• A single provincial health service replacing 13 health units across the province

• Nine regional health units
• Alberta Cancer Board
• Alberta Alcohol and Drug Abuse Commission
• Alberta Mental Health Board
• EMS
Procurement and Quality of Care

- **Acceptability**: CPSM engages with clinical stakeholders in relation to strategy development, prioritization, standardization, and procurement decisions, allowing for overall value to AHS as well as meaningful outcomes. A strong partnership with internal and external groups leads to ongoing engagement with patients, staff, and communities to guide and support anticipatory planning. CPSM is making engagement a core component of our business model.

- **Accessibility**: CPSM, in collaboration with stakeholders, must ensure that all services are delivered to meet local needs in a timely manner without interrupting delivery of care. Additionally, CPSM must facilitate movement of patients across the continuum of care. Services are provided at 354 locations across the province and include the provision of supplies to sites, management of warehouses, local engagement, and transportation etc.

- **Appropriateness**: Adapting services to local needs is included within CPSM’s operational and strategic planning through engagement. This ensures that services are complimentary to the work of other stakeholders and are relevant to current needs and issues. Shared understanding of business models and processes provide value to invested parties. By mitigating and avoiding barriers, we focus on optimizing service levels, and maximizing customer satisfaction.

- **Effectiveness**: Innovation of current programs and partnerships with professional bodies/industry experts is at the forefront of exploring and evaluating options to achieve desirable outcomes. Technology is leveraged to increase effectiveness of processes and Key Performance Indicators (KPIs) are utilized to measure progress and for on-going continuous improvement.

- **Efficiency**: With escalating costs of health care, how we spend our scarce resources is extremely important so as to get the best quality product and services for the greatest value. From 2009, CPSM has achieved cost reduction and will continue to focus on efficiency by balancing value for money considerations. Since people are our most important resource and carry out these functions on a daily basis, it is vital that we provide them with appropriate training, tools, and education as they deliver services.

- **Safety**: CPSM supports safety in patient care by ensuring that the quality of products and services are always maintained as a priority in any procurement. Established standards and monitoring provide day-to-day assurance of safety throughout the delivery of all services.
Why Initiate this Project

• Healthcare Providers have been talking about data standards for a long time
• AHS has a data warehouse, integrated ERP, has been reporting on supply chain metrics for a few years and now would like to use the data for clinical purposes
• Resource utilization in data cleansing will always take away valuable resources from doing the tasks we should be focused on
• Influencing quality through procurement will be a challenge as end to end tracking of devices, innovation, etc. will be difficult (as it is in AHS) which influences activities such as recalls, device issues tracking
• Our functions are data dependent and data is foundational to our ability to deliver savings, influence sustainability of health systems and ensure we are contributing to the quality agenda
• This project IS NOT JUST ABOUT THE GTIN but all the other attributes as you heard earlier
• This is a precursor project to the implementation of a CIS in Alberta with the output from this activity feeding into the CIS
The Potential Outcomes….

- **Where**
  - bedside scanning would confirm that a patient gets the right product at the right place at the right time
  - patient records capture the product and lot number of the device (based on the class of device)
  - you can identify the exact location where the product was delivered to based on a standardized GLN
  - products are accurately and quickly recalled from every point in the supply chain
  - we can support standardization of products, reduce variation, promote safety and contribute to the creation of a sustainable health system
  - manufacturers can monitor real-time demands and adapt production accordingly
  - the product attributes enhance the patient experience a
  - AHS can comply with future legislative requirements to track devices using UDI
A Collaborative Model

- Different organizations have tried different approaches to get standards data – contract and RFP language, downloading GTIN’s through GDSN portals, ECCNET, etc.
- This is a complex problem that requires significant planning and collaboration with the vendors as well as internally with our own staff to ensure everyone is on board.
- There was strong support for this initiative in AHS as there was a strong commitment from our Executive Team, Ministry, and Quality Health Improvement area to focus on device safety and reporting of device-related issues given the interdependency to the CIS implementation.
- AHS wanted to use a model where all key stakeholders could participate in the development and implementation of a strategy that would work for all parties as this is a complex undertaking both for providers and vendors.
- As a result, AHS entered into a partnership with GHX, eight suppliers, and MEDEC to embark on this journey.
- AHS also was in this for the long haul – we understood that success was not going to come overnight and that we needed to be prepared to support all our partners through this journey of discovery.
Medical Device Industry & Healthcare Provider Readiness
Key Background Information

Medical Device Industry
Key Background Information

Medical Device Industry

1. Scope of Medical Devices Identification:
   1. Number of Medical Devices requiring unique identifiers
   2. Annual number of changes, updates and new devices resulting in required changes in data attributes

2. FDA database (GUDID) requirements that has resulted in the Medical Device companies compiling “Unique Identification” data on each unique product …… Moving in the right direction

3. Impact of Medical Device Companies creating systems and processes for organizing, collecting, validating and maintaining data for GUDID
Number of Medical Devices (Class 2, 3 & 4)

- There are approximately 1,000,000 devices that require their own Unique Device Identifier (UDI) by Regulatory Authority.
- Regulatory Authorities undertake two types of approvals regarding Medical Devices:
  - Amendments: 6% of Devices undergo incremental changes annually.
  - New applications: # of new product approvals equal 5% of base annually.
- As a result, approximately **100,000 UDI’s** may need to be created or updated by manufacturers annually.
- For the manufacturer, this means a Global process that corporate offices must oversee and local markets implement.
FDA Global Unique Device Identification Database

- FDA is established a UDI system to adequately identify medical devices through their distribution and use.
- Required that the label of most devices will include a UDI in human- and machine-readable form.
- 55 attributes under six categories: Identification, Labeler, Regulatory, Packaging, Production control and Characteristics
- The system was phased in over a two year period (Sept 2014 to September 2016)
- Follow ISO standards ….. Issuing format can be HIBCC, GS1, ICCBA – or HL7 (loaded through portal into GUDID
- It is believed that UDI implementation will improve patient safety, modernize device post market surveillance, and facilitate medical device innovation.
## GUDID & The Medical Device Industry

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<tr>
<th><strong>GUDID</strong></th>
<th><strong>THE INDUSTRY</strong></th>
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<tr>
<td>When completed, the GUDID will mean that approximately 55 X 1,000,000 data fields will be filled</td>
<td>Built Organizational capacity and capability to organize, collect and validate data. Also, has been requiring a high degree of organizational IT and systems focus.</td>
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<td>Over 100,000 new or amended UDI’s yearly</td>
<td>Require systems and capacity to maintain the data.</td>
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<td>Data format follows ISO standards</td>
<td>Data entered via HL7, GS1, HIBCC or CCBBA.</td>
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<td>55 “attributes” or data points for each UDI</td>
<td>Align with at least 10 GDSN attributes (including identifier), but not necessarily in the GS1 system (depending on company).</td>
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Supply Chain Standards Readiness in Healthcare

1. Medical Device Industry Readiness
2. Readiness at the Interface between Industry and Provider ..... “Standards Reality in Healthcare”
3. AHS Data Standards project
The Supplier Market and GDSN

• Globally and in Canada the Medical Device industry is committed to Unique Device Identifiers (UDI), Electronic supply chain data communication, GS1 standards and GDSN interoperability adoption.

• Currently:
  – Regulatory FDA GUDID requirements are the primary focus of the industry
  – Suppliers largely “choosing” GS1 as their standard, but “Readiness” for communication of GDSN supply chain data is variable.
  – Requests to publish will require sufficient lead-time to format and publish …. Depending on the company
  – Multinational organizations “primary teams” that develop and implement the operational plans for supply chain electronic communication are based internationally….same process as GUDID….. So international core teams and Canadian implementation team
The Supplier Market and GDSN

- The industry is in an active stage of adoption, but operational integration into internal processes is still generally in development
  - Conversations regarding the “work” to publicize Electronic Supply Chain data creates a belief that it is “plug and play”
  - In essence the implementation of this type of process requires considerable **planning** and effort/ resource allocation …… lead time.
Standards Reality in Healthcare

• Throughout North America, GS1 utilization is very low in the healthcare industry
  – A very immature model without wide scale industry adoption or coordination
    • Essentially no integration with legacy systems …… Updates and/ or new systems required
  – Limited use of GLNs by suppliers and providers
    • Often assigned, but not actively utilized, published or communicated
  – Nearly zero % use of GTINs in healthcare e-commerce between providers & suppliers
    • Less than 5% through GHX transactions; true integration to internal systems unknown
  – Providers Beginning to “request” data from suppliers, yet have little plans for utilization
    • No regulatory pressure to use
  – SSO / GPOs interested in GTIN / GLN data
    • Contracting, Admin fees, etc.
  – Varying perceptions of use, timing, value and ability to “consume” the new data attributes into operations
  – Providers generally know they “want” the data, but not sure how / what to do with it
AHS Standards Initiative Overview
The Overall AHS Data Journey

• AHS is undertaking the following as part of its data journey in addition to the data standards project:
  – Nomenclature
  – Purchasing Categories (UNSPSC) – 2nd round of implementation
  – UOM, UOP, UOI standardization
  – Item Mapping to Purchasing Categories
  – Purchasing Category mapping to MIS Chart of Accounts
  – Sourcing Categories aligned to Purchasing Categories
  – Sourcing Plans aligned to Sourcing Categories
  – Overall Business Architecture
  – Preferred List of Medical Devices (“Formulary”)
  – Data Mining to Site and Cost Centre Level
Overall Concept

- Collaborative initiative to accelerate data pool adoption at AHS
- Establish an agreed approach and model for data pools and GS1 use in e-commerce, clinical standards and reporting
- Rapid involvement of potential stakeholders to maintain momentum
- Provide vendors with time to gain support from global offices for the AHS project
- Definition of process, systems, data capabilities and planned utilization of data pool data
- Proof of concept, refinement, expanded roll out
- Develop a Provincial Item Registry which would become the foundation for the Clinical Information System to use for tracking and charting
- Develop a Provincial Location Registry that can be used for purposes beyond supply chain – identification of buildings, utilization in tracking infrastructure maintenance, etc.
Initiative Participants

- Alberta Health Services/MEDEC (co-sponsors)
- GHX (Data Pool Process, Transaction Partner and overall Project Management)
- Baxter Corporation
- Canadian Hospital Specialties (CHS)
- Cardinal Health Canada
- Cook (Canada) Inc.
- Medtronic
- Johnson & Johnson Medical Products, Inc.
- Zimmer Biomet
# Participant Roles

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<th>Roles</th>
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<th>MEDEC</th>
<th>GHX</th>
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AHS GDSN Vision

• Create an end to end Global Data Standards solution for Alberta Health Services (AHS) that:
  – Provides data synch opportunities via the GDSN network
  – Use a collaborative outreach effort for supplier adoption
  – Allow for new data attributes to be utilized within technology systems and e-Commerce transactions
  – Create value to patients and clinical activities
  – Creates community awareness of the AHS model to the Canadian marketplace
  – The end result – a “Provincial Item Repository” with cleansed data that can then be utilized by clinical systems
Initiative Approach

**Recruit Partners**
- Identified key stakeholders; solicited interest and participation.
- Gathered market intelligence.
- Collected partner intelligence and GS1 / GDSN experience.

**Develop Charter**
- Defined scope, assumptions and critical success factors.
- Developed business case scenarios.
- Collaboratively finalized goals and project plan.

**Initiate Plan**
- Created required / optional data attribute requirements.
- Established process, expectations and tentative timelines.
- Phase one focus on standards leadership.

**Proof of Concept**
- Collected attributes for sub-set of supplier products.
- Analyzed content, format and GDSN load schedule.
- Defined AHS data receipt and consumption model.

**Refine and Expand**
- Refine approach as required.
- Expand scale on products.
- Utilize pub / sub via GDSN.

Current Status
AHS Initiative Focus Areas

• GDSN Standards Leadership
  – Collaborate with supplier stakeholders to define data attributes, processes and pub/sub using GDSN

• E-Commerce Transactional Leadership
  – Actively utilize GTIN/GLN attributes in e-commerce transactions

• Operational Leadership
  – Map and define how data will be used in a major provider organization
Current Status / Lessons Learned
Submission analytics

• Over 90% of “mandatory” fields provided by supplier partners
  – 100% of conditional mandatory
  – 32% of optional fields
  – 75% of “AHS Highly Desired”

• Format of Data submission (alpha, numeric, characters)
  – Compliant with GDSN standards

• Content accuracy of data
  – Compliant with GDSN standards

• Overall strong performance
Observations / Lessons Learned

• **Industry Interest**
  – Canadian stakeholders (provider, supplier, distributor, industry groups, other) have recognized the value and are participating
    • Participating stakeholders are committed to the effort
  – Other organizations in the Canadian market are taking notice and considering similar, possibly competing, efforts
  – Organizations outside of the AHS sponsored initiative have informally inquired about status and possible participation
Observations / Lessons Learner

- **Model Creation**
  - Alignment around the overall concept was rapidly achieved with stakeholders
  - Specifics around publication/subscription process and timing cannot be established until data acquisition is complete
  - Provider (AHS) data consumption process definition should have been initiated earlier in the process
  - More proactive communication through the process is desired
Observations / lessons learned

• **Challenges Encountered**
  – Data attribute acquisition more challenging than anticipated
    • Fewer mandatory attributes during proof of concept preferred
    • Suppliers would prefer more assistance during data collection
    • There are still too much room for interpretation/variations of what information should be provided.
  – Time required to accurately capture and populate attributes was underestimated
  – More frequently (formally) scheduled & attended status meetings may have expedited the initial effort
Summary of Lessons Learned

– “Proving the Hypothesis”
  • Even with committed participants, the effort…
    – Requires more time than expected
    – Data collection & management presents large challenges
    – Stakeholder internal process clarity

– Beyond the data, the exercise is valuable
  • Learn the process, challenges and pathway
  • Critical to future clinical integration
Questions?