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Leading Healthcare Organisations set their sights on standards implementation

Established in 2005, and with more than 500 experts in various standards development working groups and more than 10,000 contact hours, GS1 Healthcare, the global Healthcare user group, is now leading the sector into a new era of Healthcare-wide implementation of global supply chain standards. These will address security and efficiency concerns in the Healthcare supply chain, including medication errors, counterfeiting and product recalls.

From 16-18 June 2009, more than 250 participants from over 20 countries attended the global GS1 Healthcare Conference in Washington DC (USA) where more than 30 industry experts outlined the progress made so far, with global standards and provided an outlook towards future standards development and implementation. The webcast of the plenary sessions attracted over 1,000 viewers; all videos are available at: www.gs1.org/healthcare/news_events/160609/

The conference was opened by Dr Daniel Schultz, Director of the Center for Devices and Radiological Health (CDRH) at the American Food & Drug Administration (FDA), who spoke about the important need to start implementing solutions to increase supply chain security, in particular, Unique Device Identification (UDI). See page 5 for the latest developments on UDI.



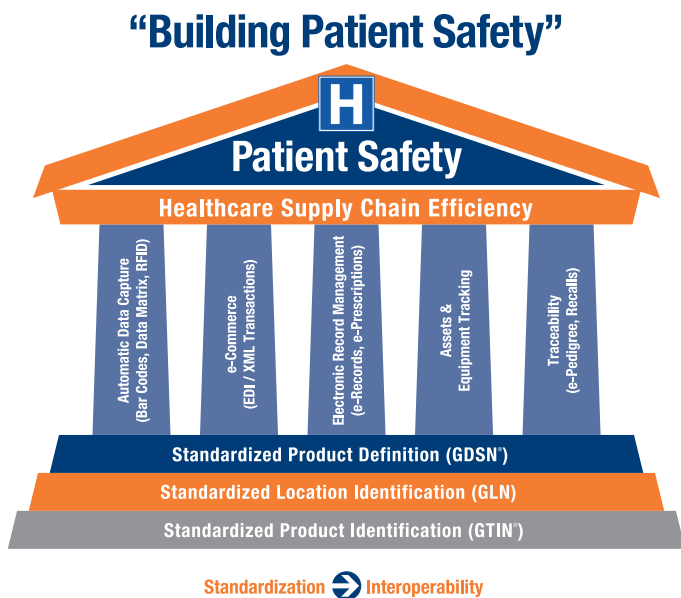
This newsletter also includes a special feature on 'GS1 Standards at work in the U.S.', following the model for 'Building Patient Safety' put forward by GS1 Healthcare US. Read more starting on page 2.



SPECIAL FEATURE: GS1 STANDARDS AT WORK IN U.S. HEALTHCARE

Building Patient Safety

More than one year after its launch, the GS1 Healthcare US™ industry group has gained members from hospitals, associations, group purchasing organizations and suppliers that, in aggregate, reach almost 90% of all U.S. hospitals.



GS1 Healthcare US has created a model for 'Building Patient Safety', with the ultimate goals to improve patient safety and increase supply chain efficiency. This requires a strong foundation building on standards: Global Trade Item Number (GTIN), Global Location Number (GLN) and Global Data Synchronisation Network (GDSN) constitute the foundation of a robust supply chain.

The 'pillars' in the model represent the Healthcare applications necessary to achieve patient safety and supply chain efficiency:

- Automatic Data Capture
- E-Commerce
- Electronic Record Management
- Assets & Equipment Tracking
- Traceability

J&J committed to GTIN



GS1 Healthcare US put forward a voluntary US Healthcare implementation path, envisioning adoption of GTIN by US Healthcare by 2012. In a first phase, the GS1 Healthcare US Product Identification Team is promoting awareness, as well as identifying and resolving issues associated with adoption and implementation. "At J&J, pharmaceuticals and consumer Healthcare bar codes are already GS1 compliant," said Ed

Dzwil, Manager of Package Technology, GPSG, J&J and co-chair of the work group, "Migration of J&J's medical devices and diagnostics companies to GS1 Standards is in process. We continue to be involved in the various GS1 work groups to contribute to these groups and stay informed."

Mayo Clinic and Cardinal Health implement GLN

The voluntary implementation path targets 2010 for GLN implementation in US Healthcare. Mayo Clinic and Cardinal Health are among the first organisations in Healthcare to implement GLNs in supply chain transactions. Their collaborative project has demonstrated that the GLN could be implemented swiftly and easily, requiring only weeks, as opposed to months or years.

The more supply chain partners adopt GS1 Standards, the greater the benefits for the entire industry

"We have started with our largest and most trusted trading partners," said Joe Dudas, Director of Informatics, Mayo Clinic, "Converting to EDI has allowed us early success without significant investment. For example, price accuracy improves with location identification accuracy: Mayo Clinic / Cardinal Health price accuracy is now 99.5%; all other suppliers average 95%. The more supply chain partners adopt GS1 Standards, the greater the benefits for the entire industry."

Mayo Clinic and Cardinal Health have developed a white paper to serve as a guide to help other providers and suppliers to rapidly implement and immediately realise the benefits that the usage of GLN can bring to the healthcare industry.

[Click here to download the case study.](#)



DoD and Kimberly-Clark getting ready to leverage the GDSN



"Billions of dollars are lost each year due to information inefficiencies, impacting the entire Healthcare industry," said Kathleen Garvin, Program Manager, DoD Data Synchronization, Program Manager, DMLSS-DLA, U.S. Department of Defense (DoD), "DoD is relying on the commercially based supply chain,

but Healthcare supply chain data are broken." The Product Data Utility (PDU) project, initiated in 2005, has proven that data synchronisation works and has already realised more than US\$36 million in savings to date. However, it was an interim solution, and not sustainable long term. "The DoD GDSN Pilot has taught us that good data leads to the desire for more good data," said Garvin, "A hospital has saved 50% in spend analysis match time; a Group Purchasing Organisation (GPO) streamlined two processes, with an estimated potential for US\$250,000 annual savings." "As a supplier, if you are publishing information for a customer, it needs to be in a format that is understandable.

We have to populate the GDSN to a point where it is usable for providers.

Another big thing for us is data upkeep; the information needs to remain accurate as customers will start relying on that information," said Roy Ludvigsen, Associate Director, Supply Chain, Kimberly-Clark Corp., "In a first step, we looked at compliance: at the packaging level going to the distributor, we have 85% of GTINs available; at the box level, typically going to providers, it was much lower. As a supplier, we were in our own little world of delivering cases to our distributors, but we should think about our providers and how their systems operate," said Ludvigsen, "We have to populate the GDSN to a point where it is usable for providers. We will review and modify product descriptions for accuracy and standards conformance, develop online descriptions for all SKUs and review and correct sales units of measure. For us, the benefit of GDSN is having great data in one place."



Fifteen years of Bar Code Medication Administration at VA

In 1994, the U.S. Department of Veteran Affairs (VA) was one of the first Healthcare organisations to develop Bar Code Medication Administration (BCMA) technology to improve patient safety. After a successful pilot in Topeka VA Medical Center, the department rolled out BCMA to



all VA Medical Centers, totalling 60,000 beds, between 1999 and 2003. Since its inception, 1.3 billion medications have been scanned, or 678,000 medications each day. "Bar code quality assurance is critical," said Chris Tucker, Director, Bar Code Resource Office, Veterans Health Administration, "2.8 million bar

codes have been observed since the 2006 Bar Code Quality Directive; overall scan success has significantly improved from 94.8% in 2006 to 99% today." Monitored areas include manufacturer packaging, pharmacy re-labelling and automated packaging. "Looking back, we have always lacked universal bar code standardisation for Healthcare," concluded Tucker, "Standardised product identification, based on GTINs, should be the next step."

Pursuit of perfect orders BD, Sentara and Seton



"Strategic Marketplace Initiative (SMI) members have identified transactional inefficiencies as a major industry challenge," said Dennis Orthman, Project Director, Strategic Marketplace Initiative, "Widely recognised issues include poor EDI utilisation and poor identification of products and

pricing." Achieving perfect orders will greatly improve operational effectiveness and reduce cost, but data standards are needed to enable perfect orders. The Sentara (a not-for-profit Health partner - operates more than 100 care giving sites in the USA including 7 acute care hospitals with a total of 1,728 beds) and the Becton Dickinson (BD) Beta Test addressed some primary challenges, including the difficulty in sharing and synchronising data on pricing, contracts, location and item master, the inability to consistently process electronic orders without manual intervention and the process on validating discrepancies and denials. "About 75% of Sentara's orders were electronic," concluded Orthmann, "The pursuit of the perfect orders pilot allowed Sentara to decrease the number of electronic purchase orders and the number of errors, resulting in improved operational effectiveness."

Ascension Health recognised that using GS1 Standards would improve supply chain efficiency.

In another pilot with BD and Ascension Health (USA's largest Catholic and largest non-profit health system, serving patients through a network of hospitals and related health facilities), Seton Family of Hospitals (member of Ascension Health) began purchasing BD products using GS1 Standards in September 2008. In past transactions between the Seton Family of Hospitals

and BD, both parties were identified with proprietary numbers: Seton Family of Hospitals with a BD-assigned SAP "Ship to" number and BD with a Seton-assigned item master "Supplier" number. For products, the Seton Family of Hospitals was creating new proprietary product numbers for BD products using ID numbers from GPOs, distributors or BD catalogues and price lists. Assigning proprietary numbers, which do not translate across the supply chain, is a common practice of the Healthcare industry. In addition, current data cleansing processes require significant resources. Incorrect data can create a variety of errors that result in costly rework. Ascension Health recognised that using GS1 data standards would improve supply chain efficiency. Both trading partners could quickly realise substantial benefits, including no more Unit of Measure EDI errors, no more confusion on errors on ship-to locations, no synchronisation work-around processes, and one source for accurate product data. "BD already has experience using GTINs and GLNs with our retail customers, and we want to move towards using standards with all of our Healthcare customers, distributors and GPOs. Complete adoption of data standards in Healthcare will dramatically improve the industry's efficiency levels and reduce rework", concluded Dennis Black, Director of E-Business, BD.

[To view the case study click here.](#)

GS1 and Electronic Health Records

"Despite large industry awareness, we haven't seen wide adoption EHR over the last 10 years. Only 1% of the hospitals and 13% of physicians are using a fully implemented EHR; 43% of hospitals and 13% of physicians are using a partially implemented EHR", said Mary Beth Lang, Senior Vice President, Business Analytics/President Diagnostix, Amerinet. "The top barriers to EHR acquisition and implementation are the concerns regarding information standards, coding sets, funding, physician usage and interoperability."



There is an opportunity to link GS1 Standards to EHR and HIE.

The American Recovery and Reinvestment Act freed up US\$19 billion for Healthcare Information Technology (HIT). "There is an opportunity to link GS1 Standards to Electronic Health Records (EHR) and Health Information Exchange (HIE)", concluded Lang, "We are finding that only 30 out of 1,000 data fields are being used. Physicians don't have all the information. It is taking physicians seven times longer to document an episode of care; so they are going to other areas of data to reduce that time; they are also looking for better product information. For example, standardised product identification will allow effective documented treatments in the EHR; which

drugs have been administered, which medical devices have been applied, and so on. Our initiatives will be enablers for EHR."

Assets and Equipment Tracking at UK HealthCare

"We've experienced in the University of Kentucky (UK) HealthCare a lot of equipment hoarding, requiring staff to start looking for equipment anywhere where they think they can possibly find it. Another challenge was recalls and event reporting. Last, but not least, we had rental expenses of US\$400,000 just for IV pumps, which we actually shouldn't pay as there are sufficient IV pumps available." said Jean Sargent, Director, Supply Chain, UK HealthCare "Basically, we didn't know what was actually being used, or what was stashed. That is why we started to work with the rental company to use RFID to track equipment. We are talking 'vision' and 'visibility' here," said Sargent. "We are starting to tag 2,600 pieces of equipment, as well as start implementation of staff tracking and possibly patient tracking. Our aim is to eliminate rental equipment, and the associated cost and to bring a ROI on investment. Part of the ROI that is more difficult to quantify is: what is the outcome for the patient if there is a delay in care because we don't have the equipment available?"



Tracking serialised products at McKesson and J&J

"International legislative and regulatory agencies have concerns about the pharmaceutical supply chain's ability to effectively protect products", said Ron Bone, Senior Vice President, Distribution Support, McKesson, "A single weak link in the supply chain means we all fail. We need to have our electronic systems capture and validate the information, and provide actionable information to the staff."



A single weak link in the supply chain means we all fail.

As wholesalers, our greatest priority is the security of the supply chain." Wholesalers gather the required data on the inbound shipment from the manufacturer – the critical new data element that was not available before is a unique serial number at the lowest unit of sale. Wholesalers also need to verify the electronic information received from the manufacturer, against the physical product; a new process of quarantining mismatching product is yet to be developed. It is also

not clear yet what the ramifications will be to availability of drugs if a 100% match is not achieved. Wholesalers will then have to pick units of products for the providers and retailers by serial numbers and commission a tote, which connects the serialised units inside the tote with a serial number on the tote, to enable a quick check at the pharmacy. But what are the ramifications at the pharmacy site if this process has errors that need to be resolved before the product can be dispensed?

"To achieve compliance, with serialisation requirements, manufacturers will not only have to serialise products, but also ensure accuracy of the serial number," said Michael Rose, Vice President Supply Chain Visibility, J&J, "That also means 100% readability of bar codes or RFID tags. The manufacturer will retain a database of valid serial numbers." This will have a broad operational impact in complex manufacturing environments. Other key considerations include evolving technology, limited practical experience, GMP compliance and coordination with external manufacturers as well as downstream supply chain stakeholders. Defining industry wide interoperability will be key.

GPOs and Healthcare providers endorse GS1 Standards

"We're taking this leadership position now because it is time to implement GS1 Standards in Healthcare if we hope to reduce the overall cost of Healthcare, significantly increase supply chain efficiency and improve patient safety," said Curtis Rooney, President of the Health Industry Group Purchasing Association (HIGPA). "GPOs stand ready to help their hospitals and, supplier partners make Healthcare better today!" HIGPA is a broad-based trade association that represents 16 group purchasing organisations, including for-profit and not-for-profit corporations, purchasing groups, associations, multi-hospital systems and healthcare provider alliances.



This endorsement follows earlier announcements by the Association for Healthcare Resource & Materials Management (AHRMM) of the American Hospital Association (AHA), Strategic Marketplace Initiative (SMI), including thirty-two leading Healthcare providers, the University HealthSystem Consortium (UHC), an alliance of 103 academic medical centers and 219 of their affiliated hospitals, and more.

For more information go to:
www.gs1us.org/healthcare

GOVERNMENT AND REGULATORY ACTIVITIES

Unique Device Identification (UDI): Getting ready



"I want a system in place that allows us to track medical devices that are being used on patients," said Dr Daniel Schultz, Director CDRH, FDA, "That doesn't seem so difficult. In fact, it is not surprising that we are looking for such a system; what is surprising to me is the fact that it is taking us so long to get there. I'm very

encouraged to see all the people here that will help us to get from here to there... The reality is the time to get this done is here, is now; we need to get it moving...

Even better than a system that works in the US is a system that works worldwide.

In order for us to be able to evaluate safety, to track problems, to take corrective actions, we do not only need to know which product, we need to know which one exactly, which version, which lot number, ... all the things that Unique Device Identification (UDI) will be able to give us. We have looked at areas where we can make improvements; the truth of the matter is that the

day that a product goes to market is only the beginning of the story; that is when we need to apply our greatest effort to make sure that those products are doing what they need to do in helping patients. We need UDI for that. FDA is currently drafting regulations that will allow us to get there. The question is not if, not when, but how. It is going to happen, it will be mandated, but we want to do it the right way, not overly burdensome to industry and recognising the many differences in technologies that we regulate... Even better than a system that works in the US is a system that works worldwide. It makes sense for us to have a single, global system, if we can get there. We have tried in the past not just to move forward just as the FDA in the US, but we've tried to engage with as many people around the world to get to a single, global system for UDI."

FDA envisions four distinct steps to establish a Unique Device Identification (UDI) System:

- Develop a standardised system for unique device identifiers
- Place the UDI in human readable and/or machine readable form on a device and/or its label
- Create and maintain the UDI database
- Adoption and implementation

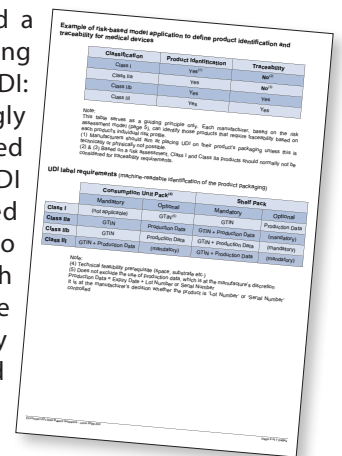
“Our goal is to start small and ramp up over time, as well as learn what the issues are,” said Jay Crowley, Senior Advisor for Patient Safety - Center of Devices and Radiological Health, FDA. Technology issues (bar codes, direct part marking, RFID), distributor and hospital uptake and use, integration issues (MMIS-Clinical) all need to be addressed.



and on supply chain management: smaller production lots, additional costs for warehousing, additional administration efforts, etc. Dr. Lukan acclaimed the GHTF for addressing the UDI initiative in an ad hoc working group. “Eucomed and B.Braun believe in global standards and endorse GS1 Standards, recommending its step-by-step implementation. But the best standards won’t be beneficial if they are not used across the entire supply chain; Healthcare providers need to get ready to use these global standards,” concluded Dr. Lukan. “More importantly, let’s keep it simple! It is better to start at a lower level in an appropriate timeline than to wait for the perfect solution.”

Eucomed and B.Braun believe in global standards and endorse GS1 Standards.

Eucomed has recently issued a guidance document advocating a risk-based approach to UDI: Eucomed not only strongly advocates a standardised approach with regard to UDI product identification based on global standards, but also believes a risk-based approach is needed to evaluate the actual risk to patient safety and the risks associated with counterfeiting and reimbursement fraud, especially if serialisation is considered as a requirement, for specific classes or types of products.



To view the guidance document click here.

Manufacturers should get ready... to comply with UDI requirements.

“Manufacturers should get ready for changes to their devices and processes to comply with UDI requirements”, said Jeff Secunda, Vice President Technology and Regulatory Affairs, AdvaMed. “The code and mark parts are well understood, but the database on the other hand is where the rubber meets the road; you can have a code and a mark, but those are meaningless without a database to provide the information to the person using that information. The database needs to have clear ownership and governance. Access to the database is very important; we want this to be a public database, however regulatory bodies have specific needs in order to protect the public, which may require additional information that is not, and should not be, publicly available. Another key objective is to minimise the reporting of manufacturers to multiple databases.”

“The Ad Hoc working group of the Global Harmonization Task Force is an important means to confront different approaches and definitions worldwide,” said Rodolphe Muñoz, DG Enterprise & Industry, European Commission and member of the GHTF Ad Hoc Working Group, “We need to ensure global compatibility and

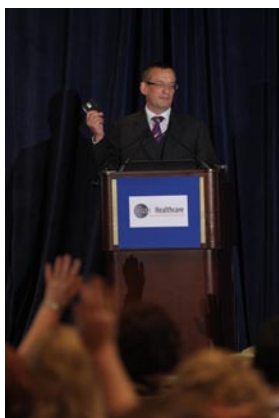


define a minimum dataset needed for an effective global market surveillance. The task force will address the compatibility with the US FDA UDI mechanism and with other regional regulatory frameworks, and eventually propose the implementation of the UDI system into the GHTF model”.

The task force has developed draft recommendations, to be finalised by early November 2009, including for example the usage of currently available globally accepted device auto-identification standards for manufacturers to create the UDI code. The UDI system should also be implemented according to the risk of the device... and allow sufficient implementation time frames to allow manufacturers to comply with the requirements. The Unique Device Identification Database (UDID), currently under development by the FDA, should be established with a global and compatible perspective, so that this UDID can be used globally or a data exchange network, to other existing or emerging regional UDI-database, can be established.

“We are at a crossroads for UDI: although it is challenging to develop a global approach, such a global approach is very important,” concluded Muñoz.

Dr. Meinrad Lukan, Member of the Management Board of B.Braun Melsungen AG and Member of the Board of Eucomed, emphasised the importance of this global approach: “Healthcare is a global business where supply chain partners exchange goods and information. Global standards are key success factors for process improvements”. Country-specific Auto-ID regulations have a major impact on product assortment



Securing the pharma supply chain



"Globalisation has created unique challenges to supply chain security," said Ilisa Bernstein, Director of Pharmacy Affairs, US FDA, "To increase product integrity, we need

to consider the lifecycle of the product and existing, new and emerging technologies for track and trace." Challenges presented by globalisation include more foreign facilities supplying the US, increasing the volume of imported products and greater complexity in supply chains.

...the FDA needs to develop a serialisation standard by March 2010.

FDA started the Secure Supply Chain Pilot Program (published in the Federal Register on 15 January 2009). "Incomplete information about supply chains, including who is involved, increased its vulnerability." said Bernstein. "An anti-counterfeiting strategy must be a multi-layered approach to secure product and packaging, movement of drugs and business transactions." A pedigree documenting each sale or transaction of the product will help to secure the movement of drugs through the supply chain. As per the Food and Drug Administration Amendments Act of 2007, the FDA needs to develop a serialisation standard by March 2010. The Standardised Numerical Identifier (SNI) draft guidance proposes a serialised identifier for prescription drugs consisting of the National Drug Code (NDC), compatible with the GTIN, and a unique 8 digit serial number. It does not include a recommendation for a data carrier. Forty-four comments were submitted to this draft guidance, also from PhRMA, the Pharmaceutical Research and Manufacturers of America. Many comments suggested making the SNI compatible with a serialised GTIN.

"We need a systems approach as there is no single magic bullet," said Dr. Alan Goldhammer, Vice-President of Scientific and Regulatory Affairs, PhRMA. Referring to their 2005 white paper, PhRMA advocates that all prescription drugs should contain a machine-readable serial number, including the company identifier, at pallet, case and item level. The machine-readable code can include bar codes or RFID tags. Electronic authentication should focus initially on the end-user dispensing site, but is not intended to exclude other supply chain participants.

FDA is also involved in the GS1 Healthcare work groups developing Global Traceability Standards for Healthcare, as well as in the GS1 Healthcare US work groups driving the implementation of GS1 Standards. "We need to move forward on developing and implementing

identification, track and trace, validation, and authentication standards," concluded Bernstein, "We need to continue aggressive enforcement strategies based on risk and find ways to leverage resources and trusted partners".

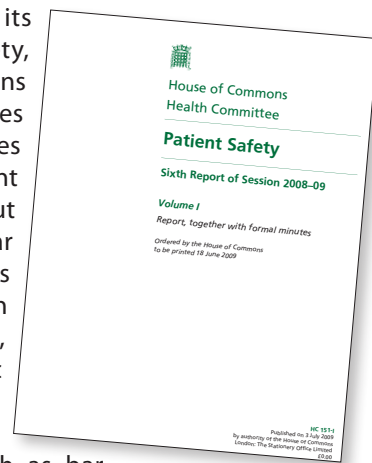
UK: House of Commons backs GS1 Standards for patient safety

In a report concluding its inquiry into patient safety, the House of Commons Health Committee argues that "several technologies could make significant improvements to care, but are being introduced far too slowly." It highlights automated decision support systems, including electronic prescribing, Automatic Identification and Data

Capture technology, such as bar coding and other tracking systems for blood, drugs and other assets, and electronic patient records. The report presses the Department of Health to make further progress with getting GS1 standards adopted for AIDC technology in England.

[Click here to view the full report \(HTML\)](#)

[Click here to view the full report \(PDF\)](#)



Canadian Healthcare Supply Chain Standards Project



"The mission of the Canadian Supply Chain Project is to speed the adoption of a common system of supply chain standards in Healthcare in order to improve patient safety, cost efficiency and staff productivity. Ultimately we will ensure all Healthcare trading partners are able to operate in an e-driven

global supply chain reality," said David Loukras, Project Lead, Supply Chain, British Columbia Health Authority Shared Services Vancouver, Canada. The Canadian Institute for Health Information and Canada Health Infoway estimate that, out of the 2.5 million people who are admitted into hospital every year in Canada, between 9,000 and 24,000 people died as a result of preventable adverse events; 20-30% of supply chain administrators' time is spent fixing data errors; up to 70% of hospital orders contain an error that require manual intervention. "Global supply chain standards are recognised as necessary to truly affect change," concluded Loukras, "We have government support right now, both in participation and from significant funding from almost every province in the country."

Making Health IT work

"The basic assumption is that investment in Health IT will save money through efficiencies, and improve the quality of care delivered," said Vish Sankaran, Program Director, Federal Health Architecture, Office of the National Coordinator (ONC) for Health Information Technology, Department of Health and Human Services. "In the last four years, ONC worked with Federal, States and the private sector to harmonise interoperable standards, create Health IT certification for functionality, security, and interoperability, and launch the Nationwide Health Information Network.



The tipping point for phase 2 is now at hand." In February 2009, President Obama stated: "We'll be on our way to computerising all of America's medical records, which won't just eliminate inefficiencies, save billions of dollars and create tens of thousands of jobs – but will save lives by reducing deadly medical errors." The American Recovery and Reinvestment Act of 2009 appropriates US\$2 billion to the Office of the National Coordinator for Health IT (ONC). To achieve the President's goal, the adoption of electronic health records needs to be stimulated through financial incentives and incentives to use EHRs to improve quality and efficiency. "The Federal Health Architecture ultimately aims to ensure the secure exchange of interoperable health information," concluded Sankaran, "For this transformation to succeed, all of us must participate."

NEWS FROM AROUND THE WORLD

USA: "The Bar Code Evangelist"

"Communication errors in our hospitals are costly. We have for example many problems with sound-alikes and look-alikes. Think about the adult and the baby dose of Heparin that look alike; the Dennis Quaid twins got the adult dose and nearly bled out; 6 babies in Indianapolis unfortunately did," said Mark Neuenschwander, Barcode-enable Point of Care (BPOC) Advocate, "The American Society of Health-System Pharmacists (ASHP) did a patient survey in 2004 and discovered that the number one fear of patients going into the hospital is 'will they give me the wrong medications?'



but only 2% of those errors get intercepted, while 50% of the remaining errors get intercepted. Electronic Medication Administration Record (eMAR) systems provide the means for better communication between the caregiver, pharmacy and physician. The systems are there to assist them, not to replace them. An accurate eMAR is invaluable for physicians; caregivers need this safety net. Physicians today think that Computerised Physician Order Entry (CPOE) is the answer, but no CPOE can heal the mis-documentation at the point of care. BPOC systems are interface tools between physicians and EHR that help ensure that those critical records are reliably populated and faithfully relied upon at the point of care. But the efficacy of BPOC depends on the accuracy of packaging and labelling. I encourage hospitals to get as many medications as possible with original source marking, which is possible today in the U.S. thanks to the FDA 2006 Rule. I commend GS1 and the user community for helping to make the FDA Rule a reality and paving the way."

We need to apply BPOC for a safer medication-use process.

And it is not an unfounded fear. One out of five medication administrations is in error in our hospitals; 500,000 adverse drug events that cause extended stay, that cause grief to families, that cause injury to individuals and that cost money to hospitals. About 7,000 lives lost each year to medication errors alone in the U.S. We need to apply BPOC for a safer medication-use process. But any system implemented should be as safe or safer than the system it is replacing, and any system should be as efficient or more efficient than the system it is replacing. We should be making it easier for caregivers to do their job and to do it right. Those two axioms don't always play well together... In the first place, we need to address the 'sweet spot' in the medication-use process: 38% of medication errors happen in the last step, administering the medication,

Canada: ISMP Canada and CPSI endorse GS1 Standards

The Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI) jointly endorsed the adoption of the GS1 Standards for automated identification (e.g., bar coding) of pharmaceutical products in Canada, after a thorough analysis of existing standards.



On January 24, 2008, a stakeholder invitational roundtable, co-chaired by ISMP Canada and CPSI was convened in Ottawa to discuss and seek pharmaceutical manufacturer consensus on voluntary guidelines for

the use of bar codes to label medications at the unit-of-use packaging level. The project is being guided by an Implementation Advisory Committee, co-chaired by ISMP Canada and CPSI and currently comprising representatives of Canada Health Infoway, Canada's Research-Based Pharmaceutical Companies, Canadian Association of Chain Drug Stores, Canadian Association for Pharmacy Distribution Management, Canadian Generic Pharmaceutical Association, Canadian Society of Hospital Pharmacists, Group Purchasing Organisation Alliance (currently includes Approvisionnement-Montréal, HealthPRO, and Medbuy) and the Public Health Agency of Canada. By proactively and cooperatively reaching agreement on the standards to be implemented, the Healthcare system can move toward the implementation of bar coding to enhance safety checks during medication use processes such as compounding, dispensing and administration, as well as benefiting from enhanced efficiencies along the entire medication supply chain.

Ireland: Traceability at St James Hospital

The National Centre for Hereditary Coagulation Disorders (NCHCD), located at St James's Hospital, Dublin, manages patients with inherited and acquired bleeding disorders (approximately 2,000 patients with haemophilia). "Patients became infected with Hepatitis C and HIV due to contaminated blood products; lacking bar codes, we didn't know where the medication was, so even after the recall, people still got infected," said Feargal McGroarty, St James's Hospital, "The European Union subsequently issued a Directive in 2002 that all blood should be tracked from donor to recipient. We decided to redesign our service, building the service around the patient. Bar codes allow us to accurately identifying patients, locations and medications uniquely in real-time, thus ensuring 100% track and trace of all medication and validating cold chain delivery. We have implemented unique GS1 bar codes, bar code scanning within the hospital and at home, electronic patient records and linking all the information."



Once you standardise data entry into EPR, then you get complete and accurate reporting.

The system has been deployed at three centres, including the St. James's Hospital. Over 75% of patients receive products at home – a dedicated transport company ensures quality of product using validated scheduled cold chain delivery. All movement is confirmed using hand held scanners. "Once you standardise data entry into EPR, then you get complete and accurate reporting. We have electronic access to key clinical information out of hours via summary screen. With the hospital product

tracking system, we have 100% visibility of all stock within the hospital, detailed reports on stock movement /issued/wastage, and reduced errors by providing an electronic check on product versus prescription before issue", concluded McGroarty, "A real winner was cold chain delivery. Since this service started, all products are verifiably delivered between 2° to 5° Celsius. Product wastage was reduced from €90,216 to zero in the immediate year post service implementation. €5 million worth of medication stock has been removed from the supply chain. The big thing here is that we can do a recall of all medication within 10 minutes!"

Canada: Vaccine Project Cost-benefit analysis

"In Canada, all of the work on identification of vaccine products began with a statement from the National Advisory Committee on Immunization in 1999 recommending the implementation of bar codes be incorporated in vaccine labelling to improve immunisation record keeping and inventory management," said Rob Van Exan, Vice-chair, Vaccine Industry Committee (VIC) and Director of Immunization Policy, Sanofi Pasteur. The Canadian Automatic Identification of Vaccine Products (AIVP) working group, formed in 2007, provides leadership, overall guidance and direction for the development and implementation of bar codes in Canada, consistent with global standards.



The benefit/cost ratio was astounding, ranging from 8.2 to 1 and 4.0 to 1 for the different options.

An important achievement of the work group so far is a cost-benefit analysis, quantifying the costs (including scanner purchasing, database configuration, bar code printing, etc.) and the benefits (including time savings, improved immunisation record completeness and accuracy, improved supply chain management, etc.). Different options were considered, with a stepwise progression to the end vision of having a 2D bar code on the primary package (including GTIN, lot number and expiry date), a bar code on the secondary package (with the same information) and two peel-off labels. "The benefit/cost ratio was astounding, ranging from 8.2 to 1 and 4.0 to 1 for the different options. The Net Present Value ranged from CDN\$797 to 919 for the different options. The implementation of AIVP thus yields significant value to the Canadian society. Another important outcome of the analysis was that the costs of adding peel-off labels were substantial, while the additional benefits were small. There were also non-quantifiable benefits, including improved patient care and improved data sharing between stakeholders," said Van Exan, "Building this model also helped us to reach consensus amongst all stakeholders and generated

strong support for implementation of bar codes on vaccines in Canada". AIVP has now established three working groups (Communication, State of Readiness and Implementation) to work towards implementing global standards for bar coding on primary and secondary packaging of vaccine products.

UK: 'Coding for Success' in the English NHS

The key principle of the National Health Service (NHS) is free Healthcare at the point of use. One million, two hundred thousand staff, make it the 3rd largest employer in the world, providing one million treatments every 36 hours. "Effective information is very much recognised in the English NHS as a requirement for effective Healthcare service; a high amount of information flow between various parties," said Rachel Hodson-Gibbons, NHS, "Lots of different, independent systems operate within the English NHS. In our 400 provider units, we have 7 pharmacy systems, and we pull data from those in a central data-warehousing unit. We have for example 130 different descriptions of Bleomycin, which could easily be resolved with one product code."

Effective information is very much recognised in the English NHS as a requirement for effective Healthcare service.

The Department of Health issued a policy guidance to use GS1 coding to support the application of AIDC technologies (Coding for Success – February 2007). The Department of Health funds membership of GS1, for NHS hospitals– for the use of GS1 coding within NHS organisations. "There are many benefits for procurement from common coding standards: interoperability of systems and processes, robust processes and compliance and improved Healthcare provision", said Hodson-Gibbons, "There is currently a lack of ownership throughout many of the trusts and everybody is working in a different direction. The idea is to have everybody with a common strategy, a common direction and a common specification of requirements. Common standards, and obviously GS1 GTINs are the basis and interoperability between systems is needed. Essential is core data management; the GDSN is something very important to us in that area."



Leeds Teaching Hospital, the largest trust in the NHS with 3,000 beds, embarked upon an eEnablement strategy

several years ago. "The case for coding is compelling; Standards ensure consistent outputs," said Chris Slater, Head of Supplies, Leeds Teaching Hospitals and chair of the National eEnablement Programme. "e-Enablement coding & classification standards include GS1 Standards such as GTIN and Global Data Synchronisation." One project in their Catheter Labs, introducing computerised inventory management through bar code scanning, generated remarkable results. "We were able to reduce stock by approximately GB£900,000 over twelve months; nursing time was freed up to concentrate on patient care and clinical tasks; and as orders were streamlined through IT systems, we could reduce weekly orders from 10 to 2."

Standards ensure consistent outputs.

Another inventory control project in Orthopaedics revealed over GP£400,000 of 'consignment' stock found to belong to the Trust. Without bar codes, there was no method of identifying products. "Absolute key to this is to have accurate master data and the adoption of global standards," concluded Slater.

In February 2007, NHS Connecting for Health (CFH) entered into an agreement with GS1 UK, an international standards body for Auto Identification and Data Capture (AIDC) technologies, for the provision of AIDC codes to the NHS. "We needed someone at the table from every facet of Healthcare, so that we can make things happen across the whole NHS supply chain. We have assembled a core project team to gain the greatest support and influence within the Healthcare sector," said Neil Lawrence, AIDC Manager, Technology Office, NHS Connecting for Health, "Over 200 hospitals and trusts have already signed up to the programme. We also see continued media coverage of the programme and other countries, including Canada and the Netherlands, launching similar programmes."



EU: BRIDGE pharmaceutical traceability project concludes

"We have managed to successfully pilot the implementation of a supply chain traceability system for pharma products in a real life operational environment," said Henri Barthel, Project Coordinator BRIDGE. Nine supply chain end users tested an easy-to-use, robust system for product authentication, recalls, inventory management and financial reconciliation. One years' pharmacy stock from nineteen product lines from; Actavis, Athlone, and Sandoz were successfully tracked using GS1 DataMatrix (2D) bar codes and GS1 EPCglobal RFID tags up to the hospital pharmacy.



"Inline production equipment installation has proven to be a complex, precise and resource intensive operation," concluded Barthel, "But supply chain wide traceability has also proven to be feasible if you ensure good planning & resourcing, user commitment (senior level) and prioritisation, and easy to use, intuitive, robust user systems and processes based on trading partner collaboration."

For more information on this project go to:
www.bridgewp6.eu

Japan: Durable 2D marking of steel instruments



In 2006, JAMEI (Japan Association of Medical Equipment Industries) published a guideline for the marking of 2D bar codes on steel instruments, to incorporate GTIN and serial number in a very limited and small space. "Although we published this guideline, there was no technical specification and it was uncertain that all the symbols indicated on the market products could actually be readable with a laser scanner," said Akio Murata, JAMEI, "So we decided to conduct a pilot test to make sure what kind of marking method is best for steel instruments, in terms of marking pattern and bar code size." Ageing tests, using the salt spray test, were conducted after laser marking the instruments. "White patterns turned out to be much more durable against rust: the rate of readable symbols with a white pattern is 83%, that of a black pattern only 8%," concluded Murata, "Bar code readers should be able to read 2mm to 5mm symbols." 2D bar codes on surgical instruments have

been used at Osaka University Hospital for two years without any reading failures. "Ongoing development of the technology will further widen the range of instruments, particularly for neurosurgery and eye surgery instruments," said Ryuichiro Azuma, Sakura Seiki.

USA: The Global Data Synchronisation value proposition: A retail perspective

Wegmans Food Markets, a US\$5 billion food retailer in the U.S. with 73 stores, already started synchronising master data through GDSN in 2003. "Our consumers expect innovation, unique products, services, freshness and social awareness. Leveraging information is a competitive Supply Chain advantage," said Kathy Welch, Wegmans Food Markets, "High quality, synchronised information is foundational to a productive trading relationship and enables business growth." Today, Wegmans is synchronising mandatory attributes, including GTIN, dimensions, gross case weight and net content, as well as some other attributes. "For Merchandising and Sales, accurate and synchronised data will eliminate many manual processes in the item setup and maintenance process," said Welch, "For Logistics and Distribution, synchronised and accurate volume and weight data will enable an efficient and shared supply chain; and for Store Operations, it will improve efficiency and the customer shopping experience."

Tremendous supply chain value can be achieved in making data accurate.

Their suppliers also benefit from data synchronisation: "One supplier corrected a weight error on a top selling item and saved US\$2.5 million in transportation costs for one product line; another supplier will increase administrative productivity by 59,000 hours annually by reducing inspection time of each order by just 5 minutes," said Welch, "Tremendous supply chain value can be achieved in making data accurate, but it is not about technology, but about business process improvements."



GS1 HEALTHCARE UPDATE

GS1 Healthcare elects new leadership team

The global GS1 Healthcare user group announced their newly elected leadership team to lead the sector into a new era of Healthcare-wide implementation of standardised supply chain solutions. The GS1 Healthcare Leadership Team embodies representation of key stakeholders in the Healthcare supply chain worldwide, including leading Healthcare organisations.

GS1 Healthcare Leadership Team voting members:

Abbott Laboratories	Mike Wallace (co-chair)
Alcon Laboratories	Grant Hodgkins
Baxter	Nathan Habeck
B.Braun	Volker Zeinar
Covidien	Kevin Mulligan
GlaxoSmithKline	Grant Courtney
Johnson & Johnson	Tom Werthwine
McKesson	Ron Bone
Medtronic	Jackie Elkin
Novartis	Scott Cameron
Novation	Dennis Byer
Pfizer	Tim Marsh (co-chair)
Premier	Joe Pleasant
R. Ballanger Hospital	Frédérique Frémont
Smiths Medical	Jim Willmott

GS1 Healthcare presents its 2009/2010 Reference Book



GS1 Healthcare presents the first edition of the GS1 Healthcare Reference Book, a compendium of information on global standards in the Healthcare supply chain; adoption initiatives, lessons learnt from implementation projects, regulatory developments and more. Experts from different countries and different backgrounds share their perspectives on, and experiences with, supply chain projects, patient safety initiatives and regulations.

[Click here to view the GS1 Healthcare Reference Book](#)

GDSN Implementation Initiative off to a flying start



In May 2009, GS1 Healthcare announced a GDSN Implementation Initiative to accelerate adoption and implementation of global data synchronisation in Healthcare. In a little more than a month, 18 participants have got this initiative off to a flying start: seven suppliers and eleven

demand participants have registered their GLN in the Global Registry of the GDSN; 580 GTINs were loaded in the Global Registry; 275 subscriptions (requests from the data recipients to receive the registered information). "We have focused on implementation and metrics for today, not theoretical discussions of 'what would be nice to have,'" said Grant Hodgkins, Manager, Strategy/Standards/Processes, Global Supply Chain at Alcon Laboratories, "We started with a limited scope in order to minimise the re-work required during the learning process, but we will expand as we move forward." "We can learn from each other; providers should work with their suppliers, distributors, and group purchasing organisation to stay on track with standards implementation," said Joe Pleasant, Chief Information Officer and Senior Vice President, Premier, "The bottom line is that we can only be successful by working together, keeping it simple, getting some successes, and building from there...".



Supplier participants include: Abbott, Alcon, BARD, B.Braun, Baxter, BD and Linde.

Demand participants include: Amerinet, Aurora Healthcare, De Kroyft-Metz, Novation, Premier, UK Healthcare, University Healthcare, University of Mississippi Medical Center, Waldo County General Hospital and Walgreens.

GDSN-certified data pools used were: 1SYNC, GHX, and SA2.

To join, contact: [Peter Alvarez](mailto:peter.alvarez@gs1.org) at peter.alvarez@gs1.org

Join the new Patient & Caregiver Identification Work Group

The development and adoption of standardised identification of patients and caregivers will have huge benefits to patient care. GS1 Healthcare has initiated a work group in the Global Standards Management Process (GSMP) to develop global standards for the unique identification of patients and caregivers. In its kick-off conference call on 7 July 2009, the work group has already defined a common understanding of the challenges to be met. The work group will now start gathering patient and caregiver identification requirements, requiring as much expertise input as possible. If you work in a hospital or have eHealth expertise, we ask you to become involved in this work group.



Professor Christian Lovis of the University Hospitals of Geneva (Switzerland) is co-chairing this work group. This work group is in collaboration with ICCBBA, the standards development organisation for blood, tissues and cellular therapy products.

To join, contact: [Christian Hay](mailto:christian.hay@gs1.org) at christian.hay@gs1.org or [Tania Snioch](mailto:tsnioch@gs1au.org) at tsnioch@gs1au.org

GS1 Healthcare - A neutral and trusted source

GS1 Healthcare is a recognised, open and neutral source for regulatory bodies and other governmental authorities seeking input and direction for global standards in Healthcare for patient safety, supply chain security & efficiency, traceability and accurate data synchronisation. The GS1 Healthcare Public Policy Work Team leads this effort and develops collective input and feedback of GS1 Healthcare. The work team has recently published two public policy fact sheets with recommendations and standards perspective on important issues:

- [Combating counterfeiting through product authentication and traceability - 'Global standards enable anti-counterfeiting technologies'](#)
- [Reducing Medication Errors - Ensuring the '5](#)

patient rights' - *'The right product for the right patient at the right time in the right dose through the right route'*

The work team also maintains an overview of the increasing global regulatory requirements on AIDC, Data Synchronisation and Traceability and other important Directives and Guidelines from stakeholder groups. A requirements database and country dossiers have been developed and will be continuously updated and maintained.

Jackie Elkin, Sr. Regulatory & Quality Compliance Manager, Medtronic, and Scott Cameron, Head of Global Application Solution Centre for Supply Chain and Sales & Distribution, Novartis Pharma AG, are co-chairing this work team.

To join, contact: [Ulrike Kreysa](mailto:ulrike.kreysa@gs1.org) at ulrike.kreysa@gs1.org

Data exchange standards

"The FDA Data Standards Council, chartered in 2001, manages health and regulatory data exchange and terminology standards for the FDA, and works with other standards setting organisations to adopt existing standards when available," said Randy Levin, Director for Health and Regulatory Standards, FDA, "We focus on using standards from HL7 as our basis for data exchange standards." The HL7 Reference Information Model represents Healthcare domain information and data, detailing clinical events, their results and their context. HL7 messages are derived from the Reference Information Model, providing the semantic (meaning) and lexical (vocabulary) connections between the information carried in the fields of HL7 messages. "In one of the exchange standards, Structured Product Labelling, there are places where GS1 Standards are a code set that you can store into the Structured Product Labelling. We can carry that information and use that so that it can be linked together."



Patient focused quality oversight

"We need to have some cross-fertilisation between the work of ISQua and GS1," said John Helfrick, Immediate Past President, International Society for Quality in Health Care and Senior Consultant, Partners Harvard Medical International. "ISQua accredits the accreditors, such as the Joint Commission International (JCI) and the Australian Council on Healthcare Standards (ACHS) in Australia; we have standards, we evaluate the



standards of the accreditors and their process.” The International Society of Quality in Healthcare (ISQua) is an independent, not-for-profit, global organisation driving continual improvement in the quality and safety of Healthcare worldwide. ISQua’s programmes include accreditation, indicators, publications and education. “A Harvard Medical Practice Study in the early 1990s indicated a rate of 3.7% of adverse events, almost 20% of those were adverse drug events” said Helfrick, “If we wanted to reduce those medical errors, we needed to know what was happening and why it was happening. A ‘no harm, no foul’ approach allowed us to start tracking what was happening and why. Root causes included communication, training and patient assessment. Joint Commission International developed the International Patient Safety Goals, including identifying patients correctly, improving effective communication, improving safety of high-alert medications, and ensuring correct-procedure and correct-patient surgery. We see an opportunity here for ISQua and GS1 to work together,” concluded Helfrick, “I’m convinced that standards-based accreditation in Healthcare drives improvement and that is where there are synergies between ISQua and GS1.”

GS1 Healthcare welcomes participation from solution providers

The GS1 Healthcare Leadership Team invites solution providers to participate in the standards development work groups. As focus and work efforts are shifting towards implementation and adoption activities, all solution providers are encouraged to join us and help shape the future of Healthcare.

[To view the announcement click here](#)

For more information or to join contact:
[Gwen Lurie at gwen.lurie@gs1.org](mailto:gwen.lurie@gs1.org)

DATES FOR YOUR DIARY

Global GS1 Healthcare Conferences

- 6-8 October 2009 in Hong Kong – co-hosted by Hong Kong Food & Health Bureau, Hong Kong Hospital Authorities and GS1 Hong Kong

[For further conference details click here](#)



- 16-18 March 2010 in Sao Paulo, Brazil - Hosted by GS1 Brazil



GS1 Healthcare at other international events

- 19-22 July 2009 - AHRMM09 Annual Conference & Exhibition, Tampa Convention Center, Tampa, FL
www.ahrmm.org/ahrmm_app/conference/annualconf09/index.jsp
- 7-8 September 2009 - 4th Annual Pharmaceutical Anti-Counterfeiting Strategies, London, UK
www.visiongain.com/Conference.aspx?cid=173
- 20-21 October 2009 – UDI Conference, Hilton Orlando Bonnet Creek, Orlando, FL
www.udiconference.com
- 20-21 October 2009 - End to End: Pharma Logistics & Security, Hotel Le Plaza, Brussels, Belgium
- 27-28 October 2009 – Labelling and Packaging Compliance for Medical Devices & IVDs, Hilton Olympia, London, UK
www.informa-ls.com/labelling



To relive the GS1 Healthcare Conference in Washington [click here](#)
GS1 Healthcare newsletters can be downloaded from the 'News & Events' section at: www.gs1.org/healthcare



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