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GS1 HUG - The Business Case for Global Healthcare Data Standards

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The global language of business

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Summary of the Business Case

- The rationale for adopting Global Data Standards in the Healthcare Industry includes:
  - Humanitarian reasons – Death and illness resulting from medication errors and counterfeiting
  - Provides common data for tracking all healthcare items through the supply chain from manufacturer to patient
  - Standards would provide:
    - Clear, documented, common language for interoperability among all sectors of the supply chain
    - Higher degree of inventory visibility and order management efficiency

The Supply Chain and Pharmaocoeconomics

- Healthcare supply chains lack transparency:
  - Modalities have developed to get products from manufacturers to customers through various routes
  - Research has shown as many as 17 transfers in the process (Lara, 2005)
  - Tracing products through these permutations is often impossible or requires significant effort
  - Healthcare must balance innovation and access, provide response to an ever increasing list of conditions and regulations while generating financial returns
    - Differential pricing is a leading technique for balancing these market drivers

Arbitrage & Parallel Trade

- Arbitrage is the opportunity to buy for a low price in one market and sell for a high price in another
  - "…arbitrage is the nemesis of differential pricing" (Outterson, 2004)
- Where arbitrage involves intellectual property *and* the product crosses international borders, it is called parallel trade or grey market
- Grey market or parallel trade *can* be legal!
- The encouragement of free trade between countries in the EU has fostered a thriving legal parallel trade
- Can Parallel Trade pose threats to patient safety and/or public health?
  - With 140 million packages traded in the EU in 2005, there is potential for exploitation of the system for illegal activities and mistakes

Does parallel trade and lack of transparency pose a threat?

"... parallel traders open 140 million packets of drugs, remove their contents and repackage them. But these parallel profiteers are in the moneymaking business, not the safety business. . . ., mistakes happen. . . . ., new labels incorrectly state the dosage strength; the new label says the box contains tablets, but inside are capsules; the expiration date and batch numbers on the medicine boxes don't match the actual batch and dates of expiration of the medicines inside; and patient information materials are often in the wrong language or are out of date." (Pitts 2006)

Illicit Activities and the Need for Standardization

- A multi-echelon supply chain that lacks transparency in an environment of parallel trade and differential pricing presents great opportunities for those with illicit intentions
- Fines for diversion and counterfeiting are less severe than for selling illegal drugs (like cocaine and heroin) or running guns, and this attracts the efforts of organized crime
  - Ways criminals arbitrage illegally
    - Diversion of charitable product into high priced markets
    - Purchase, and then resale, of products from “closed door” pharmacies of small institutions (nursing homes, hospices, AIDS clinics, etc)
    - Diversion or theft of devices and drugs from hospital supplies
    - Cash to Medicaid patients for their items
    - Corrupt employees of healthcare companies who acquire products illegally
    - Illegal arbitrage also likely serves as a gateway to counterfeiting

Arbitrage as a Gateway to Counterfeiting

"Counterfeiting dispenses with the need to collect the product in far-flung locations, repackage it, and transport it back to the OECD markets. Counterfeiting can be produced in market at very modest cost, more cheaply perhaps than obtaining diversions in low-income countries." (Outterson 2004)

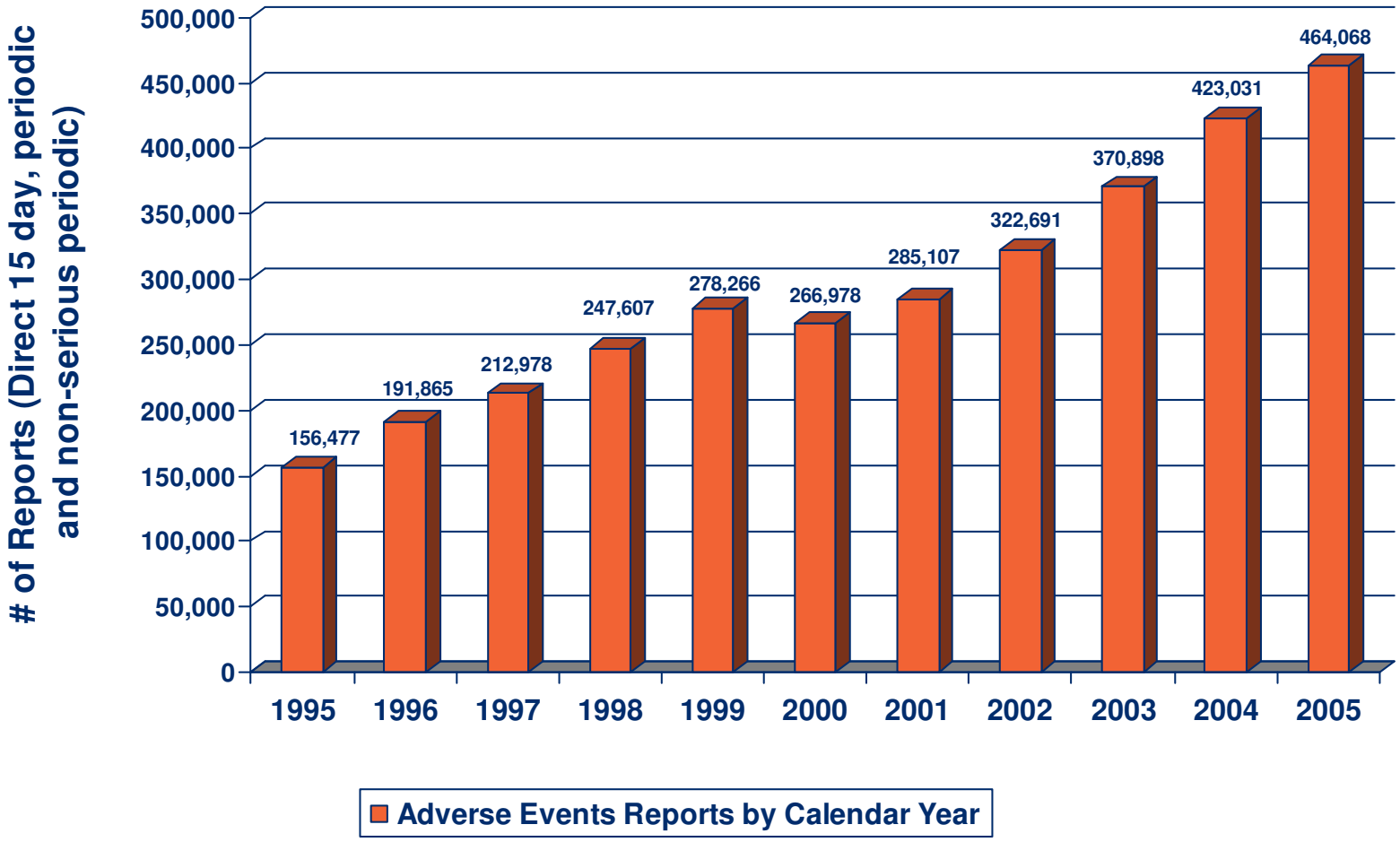
Impact of Illegal Arbitrage and Counterfeiting

- No one is quite sure of the magnitude of illegal arbitrage and counterfeiting with the healthcare supply chain
- However – the absence of universally accepted definitions and standards:
  - “makes information exchange between countries very difficult, limits the ability to understand the true extent of the problem at a global level, and hinders the development of global strategies to combat the problem.” (World Health Organization 2006)

Lack of definitions

- PhRMA testimony before the US House Committee on Ways and Means:
  - Wording of the laws governing counterfeit drugs in China creates a situation where Chinese officials are "hamstrung by excessive evidentiary requirements." (Ritter, February 15, 2007)

Rise in Adverse Drug Events (ADE) Reported to US FDA



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News clips and headlines

- **How a drug mix-up that killed 3 babies happened**
- **Trail of human errors reveals fragile system that is 'depressingly normal'- Associated Press- September 22, 2006**
- **See these links for details**
  - http://www.channel3000.com/news/9508296/detail.html
  - http://www.theindychannel.com/video/9909155/index.html
  - http://www.theindychannel.com/video/9891886/index.html

Healthcare Patient Rights

"5 Rights" for Pharmaceutical Products	"8 Rights" for Medical Devices	27 "Never Should Happens" from the Minnesota (US) Department of Health
1. Right patient 2. Right drug 3. Right dose 4. Right route 5. Right time	1. Right device 2. Right location 3. Right time 4. Right condition 5. Right procedure 6. Right anatomic unit 7. Right patient 8. Right user	1. Surgery on the wrong body part 2. Surgery on the wrong patient 3. Wrong surgical procedure performed on a patient 4. Object left in patient after surgery 5. Death of a patient, who had been generally healthy, during immediately after surgery for a localized problem 6. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics 7. Patient death or serious disability associated with the misuse or malfunction of a device 8. Patient death or serious disability with intravascular air embolism 9. Infant discharged to the wrong person 10. Patient death or serious disability associated with patient disappearing for more than four hours 11. Patient suicide or attempted suicide resulting in serious disability 12. Patient death or serious disability associated with a medication error 13. Patient death or serious disability associated with transfusion of blood or blood products of the wrong type 14. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy 15. Patient death or serious disability associated with the onset of hypoglycemia, a drop in blood sugar 16. Patient death or disability associated with failure to id and treat hyperbilirubinemia, a blood abnormality, in newborns 17. Severe pressure ulcers acquired in the hospital 18. Patient death or serious disability due to spinal manipulative therapy 19. Patient death or serious disability associated with an electric shock 20. Incident where designated oxygen or other gas delivered contains the wrong gas or is contaminated by toxic substances 21. Patient death or serious disability associated with a burn incurred in the hospital 22. Patient death associated with a fall suffered in the hospital 23. Patient death or serious disability associated with the use of restraints or bedrails 24. Care ordered or provided by someone impersonating a physician, nurse, pharmacist, or licensed healthcare provider 25. Abduction of a patient 26. Sexual assault on a patient 27. Death or significant injury of a patient or staff member resulting from a physical assault in the hospital

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Similar Gaps in the Error Reporting Arena

"In carrying out this study the IOM committee identified enormous gaps in the knowledge base with regard to medication errors. Current methods for generating and communicating information about medications are inadequate and contribute to the incidence of errors. Likewise, incidence rates of medication errors in many care settings, the costs of such errors, and the efficacy of prevention strategies are not well-understood."

Institute of Medicine of the National Academies, 2006

Ways Auto ID can Benefit the Healthcare Supply Chain

- Order processing and transmittal
- Inventory control
- Bills of lading and ownership documentation (electronic pedigree)
- Information for regulators and customs agents
- Computerized Physician Order Entry (CPOE) systems
- Effective utilization of devices and other supplies
- Accurate tracking of reprocessed equipment
- Improved patient use validation (5 rights, 8 rights and 27 “never should happen” events)
- Recall activation and control of the reverse chain
- Billing and reimbursement
- Public health emergency response
- Evidence for prosecution and chain of custody

Conclusions

- There are many **different healthcare products and supply chains,** each with their own intricacies and nuances
- These products are distributed throughout the world using supply chains that contain **multiple hand offs** and many times **do not have accurate documentation** regarding where items have been or how they were handled.
- Politics and law play roles in encouraging much of what happens. Some impact in positive ways, other times **loopholes are created** and **penalties are weak**. This serves to encourage those with illicit intentions.
- **Differential pricing**, which balances the juxtaposed goals of access and innovation, in the current supply chain creates an environment where **dysfunctional arbitrage** is possible. This is a **gateway to counterfeiting**
  - People are **dying from counterfeit** healthcare products
  - Even when those with ill-intentions do not interfere with the supply chain, there is ample opportunity for mistakes
    - Mistakes occur throughout the supply chain
    - People are **dying from mistakes**
- These problems occur in the **developed world and the developing world**

Call to those in the system

- Auto ID should be expanded into all elements of healthcare, from manufacturer to patient
- The data requirements should be standardized
- Auto ID should be interoperable with all computer driven systems
- Standardization should occur in an open, transparent consensus driven fashion
- Standards should be written so that they do not become technical barriers to trade, in violation of the WTO Technical Barriers to Trade Agreement

Call to those in the System

- Lack of consistent terminology is a major stumbling block
- Various definitions and reporting systems make it impossible to precisely quantify the magnitude or costs associated with illicit activities and medication errors as they relate to patient safety
- Various definitions create loopholes in the laws, which allow offenses to go unpunished in some countries
- Various definitions make meaningful conversations regarding proposed strategies and solutions difficult
- Various definitions make it hard to measure the impact of solutions implemented to improve patient safety
- Consistent definitions are the logical first step in standards writing

Conclusions

Supply chain partners should be free to adopt the technology that best suits their processes.

Whether identification codes are conveyed by human readable characters, bar codes or radio frequency will be based on available technology and economic justification,

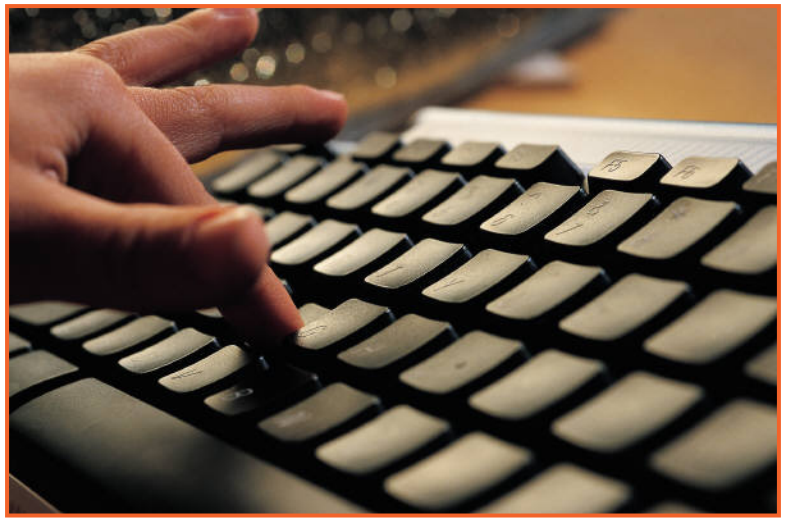
Interoperability must be ensured by adopting data standards and definitions that can be used throughout the world.

Conclusions

All players in the legitimate system, from manufacturer to patient, need information regarding the identity and the condition of the product. Some of the players make the products, some ship them, some buy them, some prescribe them, some dispense them, some administer them.

Whether it be a drug, device, biologic or diagnostic, all seemingly unrelated entities in the healthcare matrix, at the end of this chain is the patient who receives the treatment – and for the patient, patient safety is paramount.

Questions -> GS1 website



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