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Business Case for a Global Healthcare Data Standard

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The global language of business

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Are Global Standards Desirable?

YES

Are Global Standards Necessary?

YES

Here's why…

Expert Opinion: American Red Cross

- Interview: O. Keith Helferich, Subject Matter Expert for RFID, American Red Cross, 1/15/2007
  - American Red Cross Logistics Manager at Oklahoma City Bombing and NYC 9/11/01

- Red Cross is concerned with blood-related products, prescription pharmaceuticals, general first aid supplies, emergency food and water, and even emergency equipment and consumer staples (tents, blankets, etc.)

- Dr Helferich made the following observations during our interview with him:

Expert Opinion: American Red Cross

- Automatic Identification is a process
- The process can be served by a number of technologies
- The process works best when it is standardized
  - Interoperable for ongoing, integrated supply chain partners
  - Interoperable for emergency crisis situations
    - E.g. 9/11 Blood shipments to Mid-Town Manhattan, and Oklahoma City Bombing

World Regulators Agree on this Concept

- Counterfeit = Adulteration

  "…counterfeit products may include products,
  - with correct ingredients
  - with wrong ingredients
  - without active ingredients
  - with fake packaging."
  - Source: WHO General information on counterfeit medicines

- This matches closely the definition of adulterated drug in the U.S. Food, Drug and Cosmetic Act of 1938, as amended, Section 501

Examples of Other Nations

- Similar views on Counterfeit as Adulteration

Nigeria	United Kingdom	Australia
Pakistan	China	Argentina
Philippines	Russia	Mexico

WHO Comments on Counterfeiting

"There is no simple solution or remedy that can be applied to eliminate counterfeit medicines nor can the problem be solved by an individual company or government. The problem has reached a global dimension and needs a global approach." (WHO.int)

http://www.who.int/medicines/servies/counterfeit/overview/en/index1.html

Counterfeit Drugs are Adulterated Drugs

- Counterfeit Drugs in 6 Categories
  - Without active ingredients: 32%
  - Incorrect amount or active ingredients: 20%
  - Wrong ingredients: 21%
  - Correct amount of ingredient but false packaging 16%
  - Copies of original product 1%
  - High levels of contamination 9%
- Source: WHO General Information on counterfeit medicines
  - 46 Drug reports received from 20 countries

Patient Safety

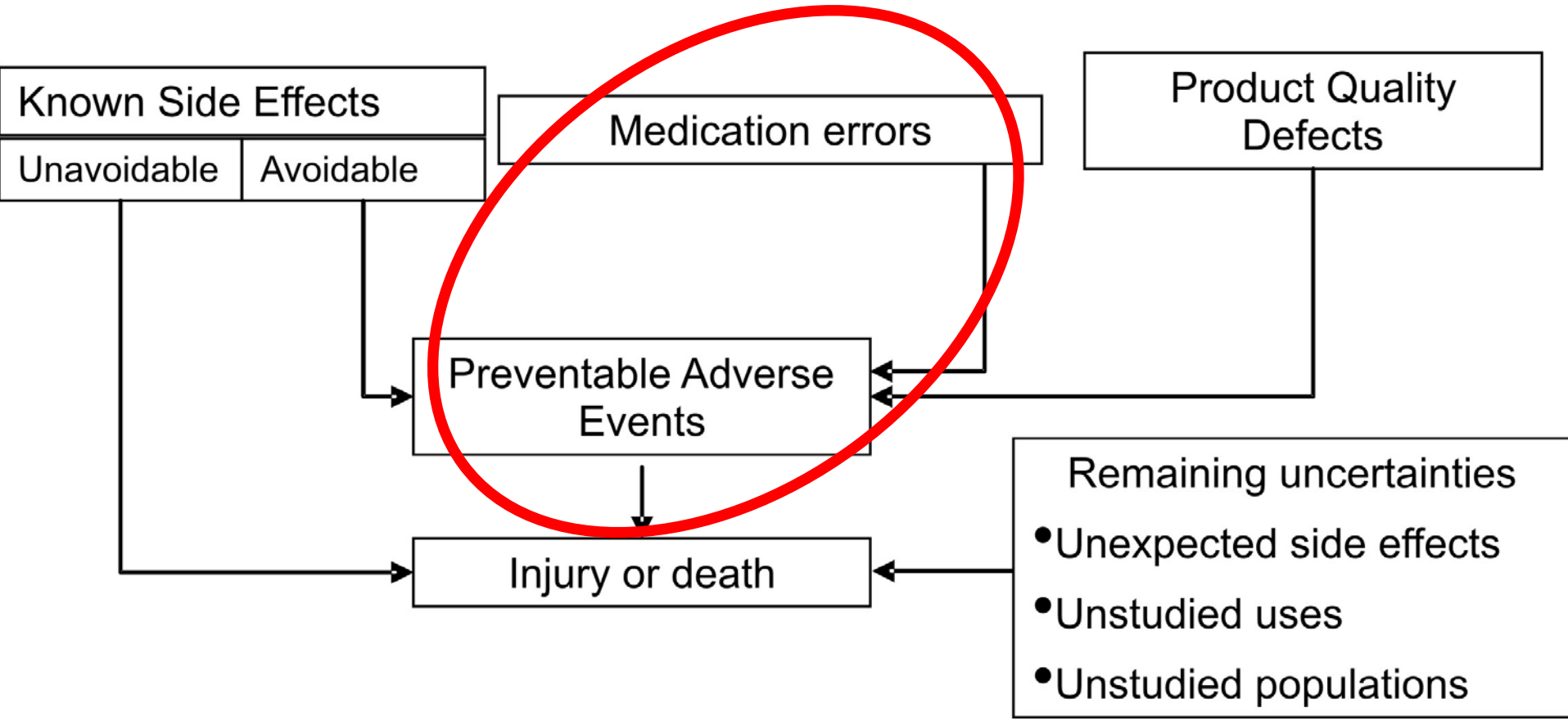
- Five Rights for Drugs
  - 1. Right patient
  - 2. Right drug
  - 3. Right dose
  - 4. Right route
  - 5. Right time

Patient Safety

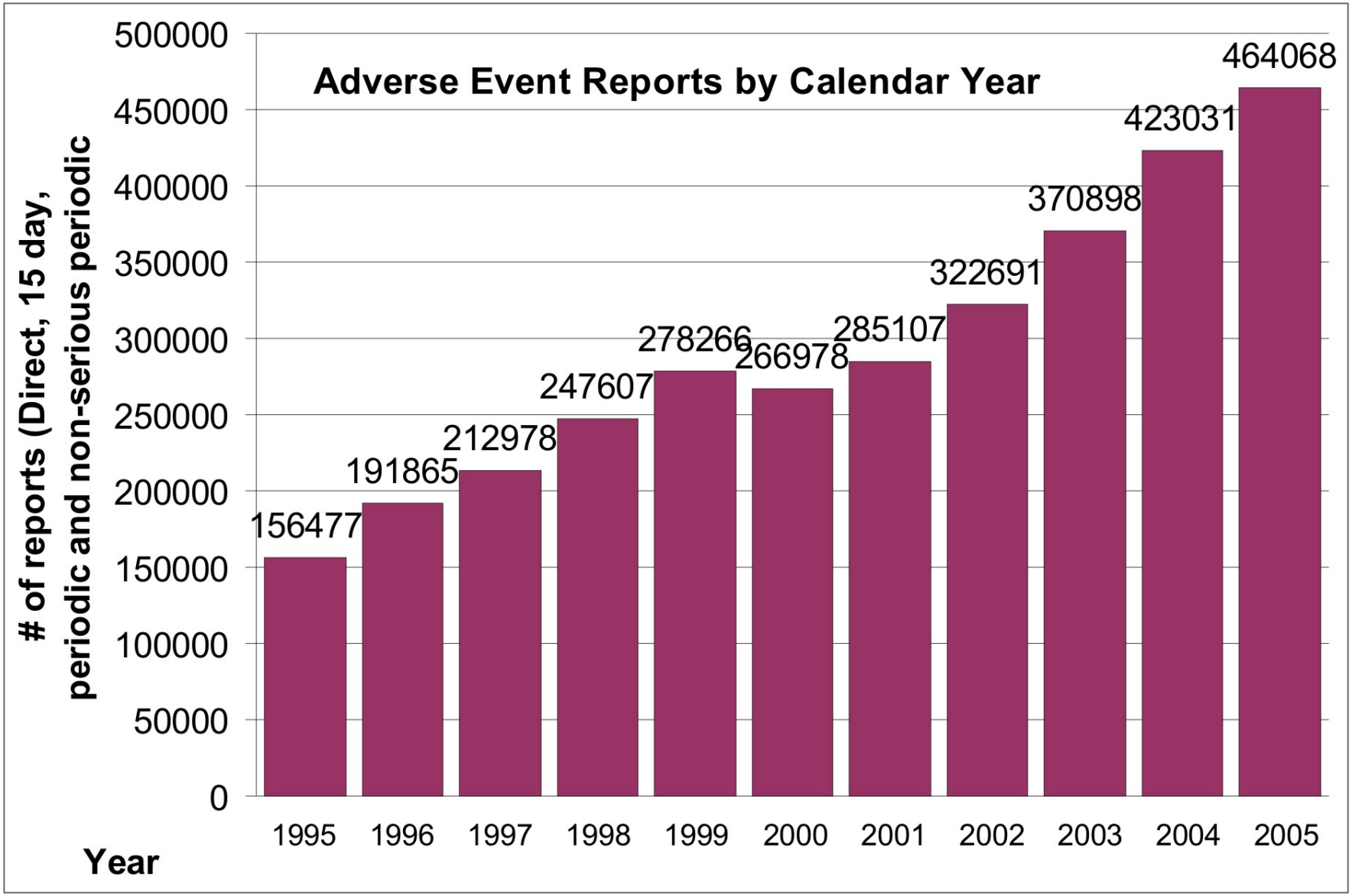
- Eight Rights for Medical Devices
  - 1. Right device
  - 2. Right location
  - 3. Right time
  - 4. Right condition
  - 5. Right procedure
  - 6. Right anatomic unit
  - 7. Right patient
  - 8. Right user

Sources of Risk from Medicine

(Source- 2005 CDER Report to the Nation)



Rise in ADEs Reported to FDA (US)



A Case Study on Medication Errors

- Medication Error – Barcoding at the Bedside
- Northern Michigan (US) Hospital – Petoskey Study
- Reference: Nursing Management. CHICAGO: May 2003. Vol. 34. Iss. 5. Pg. 36.
- In U.S. over 7,000 deaths per year from medication errors:
  - Prescription
  - Transcription
  - Processing
  - Administration of Medication

- Most errors occur in prescriber ordering (39%) and at patient bedside (38%)

A Case Study on Medication Errors

- This study utilized “Barcode Enabled Point-of-Care” (BPOC)
  - Utilized BPOC software readers at bedside, etc
  - Hospital barcoded documents, medications, personnel.

- Findings:
  - Late dose >60 minutes after target
    - 20% of doses violated this late dose rule
    - The hospital redefined late dose to: grace period +/- 120 minutes from target
  - Omitted doses
    - Constituted the majority of 40,000 errors reported in Med MARx (USP)
    - Were 30% of medication errors reported in 36 hospitals in Atlanta and Denver

A Case Study on Medication Errors

- Study Conclusion
  - In this study barcode use reduce omitted dose by 22% in this hospital
  - Overall, in the 9 month period prevented 1300 medication errors of:
    - Wrong dose
    - Wrong drug
    - Discontinued order

American Red Cross Interview

- A global standardization focus takes technologies (i.e., barcode, RFID) out of the equation
- This focuses on the need for true worldwide standards
- It leads to interoperability

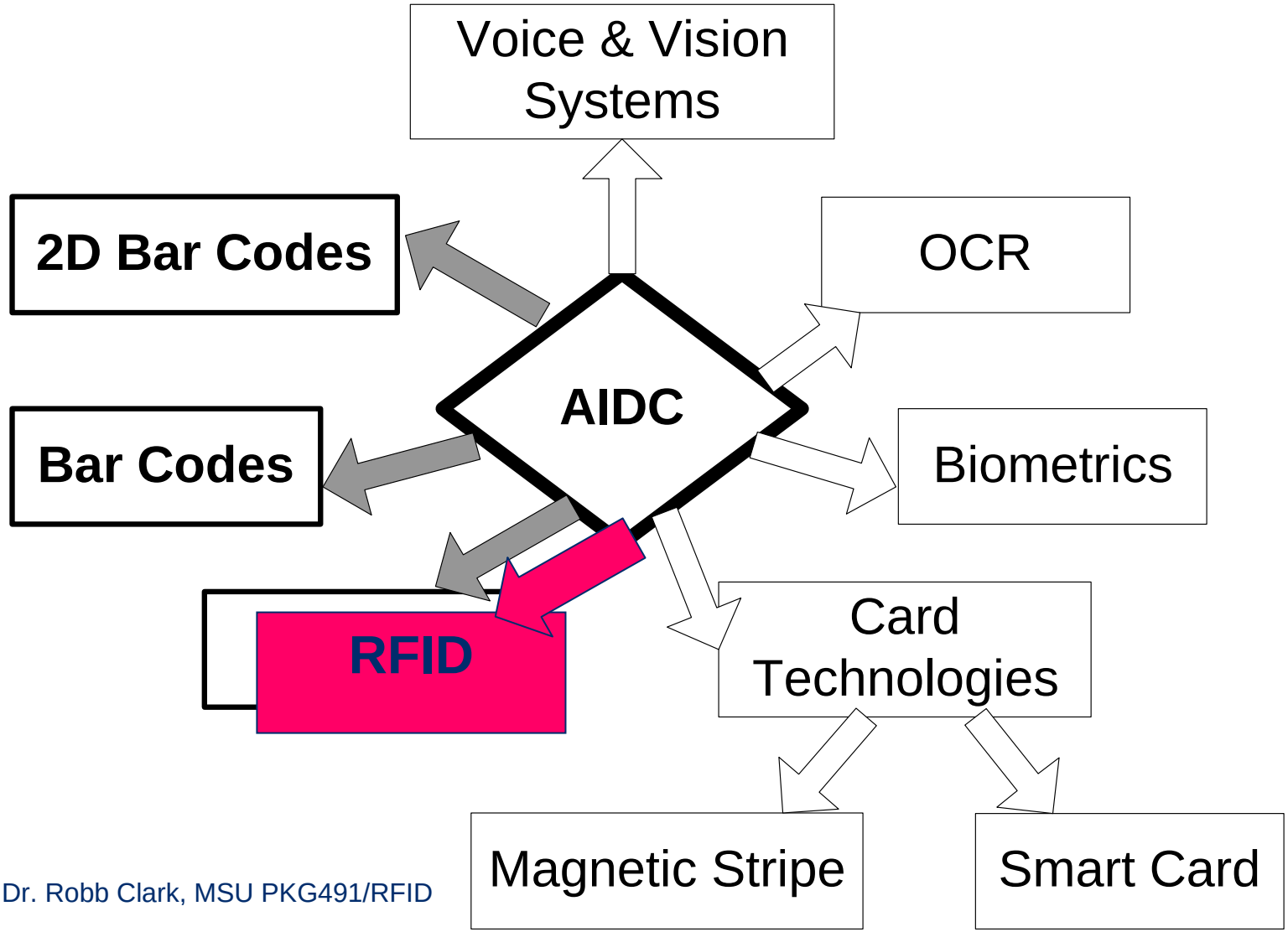
American Red Cross Interview

- Emergency Crisis Management concern:
  - Product identification and authentication during a crisis where product needs to move quickly to and from a variety of inventory sources
  - Traceability and authentication to prepare for potential emergencies, such as Avian Flu – e.g. Tamiflu counterfeits
- General Inventory Management concern:
  - coordination between systems and sources
- Case Study: Blood Shipped to NYC 9/11 – multiple inventory points could ship and immediately be used by emergency workers

Global Standardization Focus

- Takes technology (barcode, RFID) out of the equation
- Focuses on need for standardization worldwide
- Leads to interoperability

Auto Identification and Data Capture



From: Dr. Robb Clark, MSU PKG491/RFID

Government Regulators Call for Standardization, Some Examples

- UK's NHB Purchasing and Supply Agency recommends EAN/ UCC standards
- California Senate Bill 1476, Section 63 calls for:
  - Electronic pedigree
  - Interoperable electronic system
    - Track-and-trace
    - Unique identification
    - Standardized nonproprietary format and architecture used by manufacturers, wholesalers, and pharmacies
- US FDA Counterfeit Drug Task Force Report: 2006 Update

Benefits of Global Healthcare Data Standard

- Reduction of errors in all systems
  - Correct identification of;
    - Patients
    - Medication
    - Caregiver
    - Type of care
  - Interoperability among systems and technologies
    - Information easily, quickly, and accurately available where needed in the system
  - Updating information is made fast and accurate across all systems, worldwide
  - Allow scanning in
    - Supply chain
    - Pharmacy
    - Robotic dispensing machines
    - Patient bedside
    - Clinician at bedside
  - Fast response by health care services

Cost-Benefit Table

Source: FDA proposed rule for requiring barcodes on hospital packages

Estimated Impacts of the Proposed Rule (in Millions of Dollars) Over a 20-Year Period at 7% Discount Rate Source- Proposed Rule (21 CFR 201, 606 and 610, March 14, 2003)					
Impacts	Regulatory Costs	Anticipated Hospital Costs[1]	Societal Benefits[2]	Potential Hospital Efficiences[3]	Net Benefits (benefits minus costs)[4]
Present Value	$53.1	$7,204.30	$41,381.30	$4783.30-$7643.00	$34,123.90
Annualized	$5.1	$680.00	$3,906.10	$451.40-$721.50	$3221.00

[1]Costs due to voluntary accelerated purchase and utilization of bar coding systems.
[2]Benefits to public health to avoidance of adverse drug events.
[3]Potential efficiencies in reports, records, inventory and other hospital activities.
[4]Net benefits include only public health benefits of increased patient safety.

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