

An Industry and Standards perspective on FDA's Unique Device Identifier NPR

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Elliot Sloane's bio-brief

or, "30+ years of the Healthcare and Information Technology wars"



- **Vice President, ECRI - 1975-1990, CIO & CTO**
 - Medical technology research, testing, and education; medical device nomenclature; standards directories; product evaluations; forensic/accident investigations
 - Part of the team that originally developed the UMDNS, ECRI's Problem Reporting Network
- **Vice President, MEDIQ/PRN - 1990-2000, COO & CTO**

Medical device & drug distribution, service, rental, and manufacturing

 - Registered medical device manufacturer, drug distributor, and repair company
 - Owned and serviced 500,000 life-support devices rented to hospitals nationwide, 24x7
- **Faculty, Department of Decision and Information Technologies, Villanova University, since 2000 (*In 12-step CE and MIS Recovery Program...*)**

Teaching, research and publishing in databases, decision support, healthcare technology assessment and management, telecommunications, and health informatics.

 - Healthcare Information Standards Panel member for US National Healthcare Information Infrastructure and Network (NHII/NHIN)
 - Co-chair of the HIMSS IHE Strategic Development Committee
 - Senior Member, IEEE; Board of Directors, IEEE Engineering in Medicine and Biology Society; sponsor of IEEE x11073 series of medical device interoperability standards.
 - Past President, American College of Clinical Engineering
 - Founding Board Member, ACCE Healthcare Technology Foundation

Reality check #1: Medical devices can and do kill and injure patients.



- Though fortunately not too common, the FDA and ECRI databases clearly document the LONG history of serious failures, as well as product abuses.
 - I investigated my first medical device death for ECRI in 1976, and have confronted the issue non-stop since then.
 - In 1992, a ventilator owned, overhauled, and serviced by MEDIQ was involved in 3 patient deaths by fire in NYC (turned out to be a defective humidifier – not MEDIQ's – on a different ventilator not owned by MEDIQ).
 - Properly identifying each device and accessory – to the serial/lot number involved is a critical part of such investigations.

The glass is way more than half full:

Thanks in part to technology, US life expectancy and quality of life continues to rise, though we're only #19 worldwide...

Reality check #2: At least 30% of all healthcare is occurring outside hospital walls already!



- Personal home care
- Nursing homes
- Assisted living centers
- Durable medical device rental firms
- Home medical care agencies
- Visiting nurses

Government, employers, and insurers are working very quickly to shift primary care decision to the individual – and their pocketbook – as quickly as possible!

By 2000, nearly HALF of MEDIQ's \$500 Million annual medical equipment rentals (IV Pumps, Ventilators, etc) were for non-hospital use!

It is informative to see the wide array of healthcare technologies the public can buy at AMAZON.com RIGHT NOW!

This screenshot shows the Amazon.com search results for the keyword "defibrillator". The page displays several product listings, including:

- PHILIPS HeartStart OnSite DEFIBRILLATOR AED "SPECIAL PRICE!" by Philips Medical Systems**: Price: \$1,499.00, Special Price: \$1,075.00.
- Philips OnSite Defibrillator with Slim Carrying Case AED by Philips Medical Systems**: Price: \$1,499.00, Special Price: \$1,075.00.
- Automated External Defibrillator (AED) by Heartline with FREE soft carry case by Medtronic**.

The search results are organized into sections: "Showing All Results", "Narrow or Expand Results", "Expand Your Results", "Narrow by Category", "Narrow by Brand", and "Narrow by Price". The page also includes navigation links for "Health & Personal Care" and "Medical Equipment & Supplies".

This screenshot shows the Amazon.com product page for the "Welch Allyn Vital Signs Monitor with NIBP Only, includes Pulse Rate and MAP (Model 53000-E1)".

Product Details:

- Price:** \$1,384.25
- List Price:** \$1,598.00
- You Save:** \$213.75 (13%)
- Availability:** Usually ships in 1-2 weeks. Ships from and sold by General Medical.

Product Features:

- Other products by Welch Allyn
- Quantity: 1
- Add to Shopping List
- Add to Wish List
- Add to Wedding Registry

The page also includes a "Product Features" section and a "See larger image" link. The bottom of the page shows the Amazon.com search results for "Vital Signs Monitor", displaying various models and their prices.

There are some “full out” medical devices there, too!



The top screenshot shows the Amazon.com product page for the **NPB-40 Handheld Pulse Oximeter by NELLCOR-ONE OF A KIND!**. The price is \$399.00. The product description states: "Description The NPB-40 Handheld Pulse Oximeter is both compact and portable. Product Features Durable unit is simple and small & indications for usage intended for noninvasive spot-check over time. The Nellcor NPB-40 includes One Reusable Adult Finger C...".

The bottom screenshot shows the Amazon.com product page for the **BURDICK Atria 3000 ECG EKG MACHINE 12 LEAD ECG**. The price is \$3,100.00. The product description states: "Description Combines the flexibility of a traditional ECG with the efficiency of a PC. For those physicians looking for advanced communications and storage features, but prefer a traditional ECG, Burdick's ATRIA™ 3000 ECG with advanced communications systems combines the best of both worlds. It also allows physicians to combine ECGs from both traditional and PC-based products into a single workflow. Advanced communications protocols allow for wireless data transmission & make test results via PDFs Export files to Electronic Medical Records (EMR). Saves money by printing test results to plain paper printer sends results to your network for unlimited storage Modern meets FDA requirements Communications include: Ethernet, IEEE 802.11 and IEEE 1394 wireless, USB, Bluetooth, VGA...".

Don't forget medical supplies and accessories, either...



The screenshot shows a search results page on Amazon.com for medical supplies. The search results are displayed in a grid format, showing various items such as gloves, bandages, and other medical accessories. The page includes filters for price, brand, and other attributes. The search results are sorted by relevance.

Something to ponder:



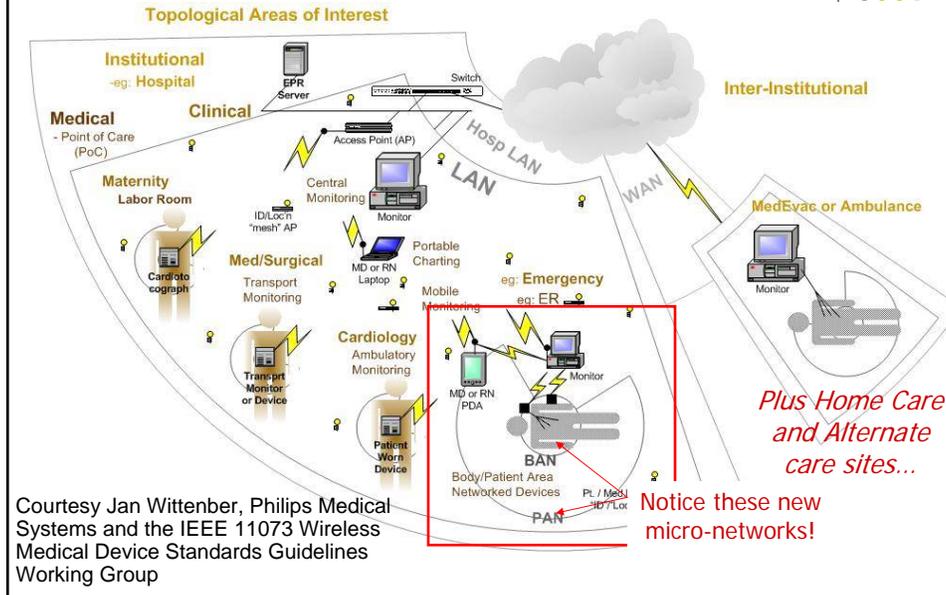
- How are medical device updates, recalls, calibration, repairs, preventive maintenance, etc. ensured if so much technology is diffused outside the hospital?
 - *Possible solution: an electronic UDI that makes the devices discoverable any time they are connected to a data network...*

Reality check #3: 1/3 of every healthcare dollar is wasted!



- Documented in the 2005 joint report of the Institute of Medicine and the National Academies of Engineering “Building a Better Delivery System: A New Engineering/Health Partnership”
 - These experts’ key conclusions include:
 - Process automation tools from other industries **MUST** be adapted and adopted to healthcare **NOW**
 - Wireless medical devices must be deployed as quickly and widely as possible to provide healthcare at the point – and time – of actual need.

Reality check #4: Wireless medical devices are proliferating rapidly!



Virtually all wireless (and wired) medical devices are now using IEEE-standard data links.



- Wireless
 - “Wi-Fi” (IEEE 802.11 a/b/g)
 - “Blue Tooth” (IEEE 802.15.1)
 - “Zigbee” (IEEE 802.15.4)
 - “Wi-Max” (IEEE 802.11.n)
- Wired
 - “Ethernet” (IEEE 802.3)
 - “Firewire” (IEEE 1394)
 - “USB” (Intel and IEEE 1667draft)

ALL of these IEEE standards require at least 1, if not more, Unique Device Identifiers, and Plug-and-Play capability requires device-specific feature/model identification to ensure reliable and automatic interfacing.

Reality check #4:



- A National Healthcare Information Infrastructure is finally slowly but steadily taking shape.
 - By vote of the Healthcare Technology Standards Panel on October 20, 2006, a electronic standards and process framework was approved.
 - Allows creating the first National Electronic Health Records by sharing data electronically between computer systems;
 - Aggregates key laboratory results and other clinical data – especially for chronic care and biosurveillance/public health – in a electronic standardized format; and
 - Enables Consumer Empowerment by making clinical data available directly to consumers so they can make better decisions.

The general basis for the NHIN is industry standards...



- Using the HIMSS/RSNA/ACC frameworks (www.ihe.net) and many other industry data standards:
 - DICOM, LOINC, HL-7, ASTM, IEEE, etc
- Basic medical device IHE processes are already under way (www.ACCEnet.org/IHE), and they are based on the IEEE 11073.x data communication standards.
- Medical device electronic interoperability is on the recommended priority list for 2007 HITSP goals.

All of the medical device NHIN tasks will require at least:



- A single UDI for each device so that wired and wireless networks can keep the data streams separate AND so those data streams can be reliably matched with the correct patient!
- Until a framework of national UDIs is provided, manual data entry and/or local, transient identifiers will have to be used, which will solely feed the EHR. NO other device tracking, recall, or problem identification will be feasible.

Here are my quick, hard won lessons and recommendations from the healthcare and other industries...





Voice of Experience 1:

1. Manual data entry from clinical devices is not sustainable, nor is it acceptable to gain the required results from Electronic Health Records
 - Industry standards of 2% error rates for data entry professionals – let alone patients, families, nurses, and physicians – will destroy EHR utility
 - Not only are the error rates unacceptable, but it will be impossible to assure IF and WHEN data will be entered, defeating the opportunity for timely and accurate healthcare decisions.



Recommendations for Issue 1?

- A Unique Device Identifier (UDI) is needed for each unique piece of medical technology.
 - Since electronic logging directly to an HER will take years to fully deploy, human readable formats are needed as well.
 - **VOICE OF WISDOM 1:** Add a simple, easily calculated check digit to each UDI to prevent erroneous manual entry (NIST can supply algorithms.)
 - Wish we'd done that when we started ECRI's UMDNS!
 - **VOICE OF WISDOM 2:** Provide a common, layperson English description of each device with the UDI.
 - Consider imbedding and displaying a check-digitated UDI descriptor code (full UMDNS) alongside each UDI.



Voice of Experience 2:

- Wireless medical device deployment is inevitable, desirable, and necessary
 - They will use commercial interfaces from the general computer and telecommunications field for cost, reliability, and security reasons.
 - For both in-hospital and the ever-growing out-of-hospital care, Plug-and-play system convenience and reliability will be required



Recommendations for Issue 2?

- A UDI will not be enough to meet these challenges and opportunities
 - **VOICE OF WISDOM 3:** In addition to the UDI, each device must be assigned a permanent, clear, and accurate electronic (i.e., digital format) product classification, manufacturer, and model identifier.
 - **VOICE OF WISDOM 4:** These electronic codes must be assigned by a permanent government or independent agency that cannot be influenced or delayed by industry or other parties.
 - **VOICE OF WISDOM 5:** Each of these fields must be printed in human-readable form, too, and therefore **MUST** have a check digit to prevent errors.

Thank you!

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