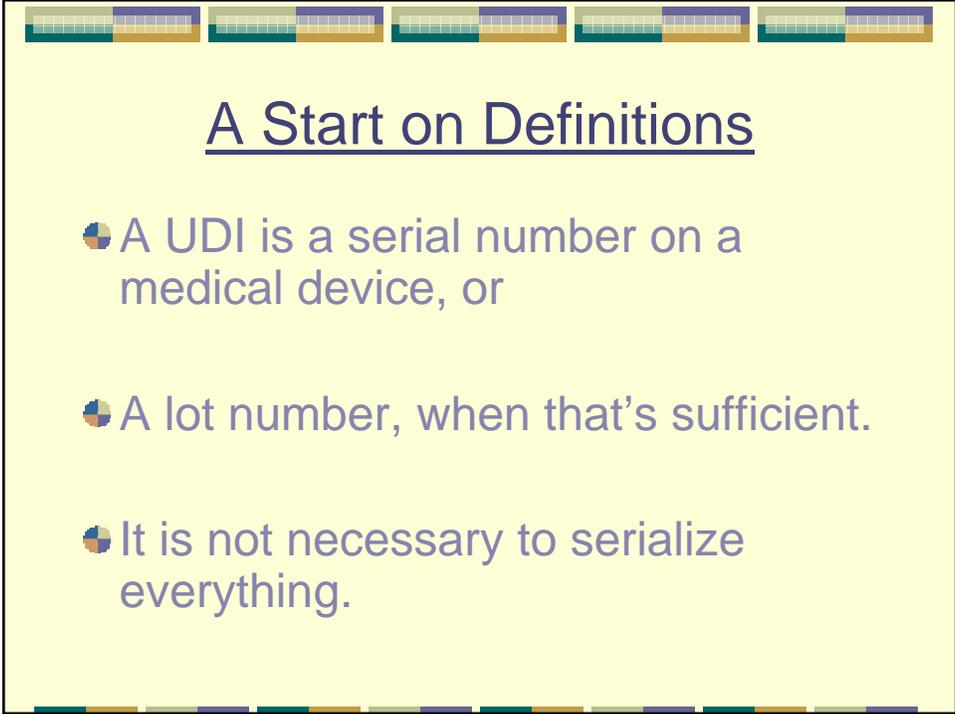


# THE BENEFITS AND COSTS OF A UNIQUE DEVICE IDENTIFICATION SYSTEM

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## A Start on Definitions

- A UDI is a serial number on a medical device, or
- A lot number, when that's sufficient.
- It is not necessary to serialize everything.

## For Preliminary Estimates:

- We've focused on incremental costs for the lowest level of existing labeling
- In conversations thus far, some variations in the assumptions used

## What are the public health and patient safety benefits?

- Better ID of devices in adverse events
- More rapid, more accurate recalls
- Enhanced capability for post-market surveillance

## Achieving public health benefits

- Facilitate hospital device ID and locator systems
- Facilitate ID of specific model information
- Facilitate comparisons of effectiveness

## Estimated Recall Savings

Cost Element	Hospitals, by Number of Beds						Total
	<50	50-99	100-199	200-299	300-399	400+	
No. of Hospitals	1,292	1,031	1,168	624	349	428	4,892
No. Hrs. Saved (000)	10	46	124	122	104	321	726
Savings/Hosp. (\$)	\$359	\$2,122	\$5,086	\$9,391	\$14,219	\$35,942	--
Total Savings (\$millions)	<b>\$0.5</b>	<b>\$2.2</b>	<b>\$5.9</b>	<b>\$5.9</b>	<b>\$5.0</b>	<b>\$15.4</b>	<b>\$34.8</b>

## Needs for Hospital Infrastructure Development

- Capture UDI on incoming devices
- Capture UDI of devices used in patient care
- Locate devices in the hospital (e.g., internal GPS)

## Potential Hospital Costs of UDI

(\$ millions)

Costs	Hospitals, by Number of Beds						Total/ Avg.
	<50	50-99	100-199	200-299	300-399	400+	
Investment	\$102	\$157	\$312	\$265	\$201	\$371	\$1,408
1 <sup>st</sup> Year Training	\$15	\$38	\$92	\$90	\$73	\$168	\$476
Recurring	\$33	\$56	\$116	\$100	\$78	\$151	\$533
Total Annualized	\$50	\$83	\$173	\$151	\$117	\$228	\$801
Avg. Cost/Hosp. (\$000/Year)	\$38	\$81	\$148	\$242	\$334	\$532	\$164

## Hospital Costs of Developing eHR Functionality (\$ million)

Item	No. of Hospitals/Costs per Hospital			Total No./Costs
	<300 Beds	300+ Beds	Avg. Cost	
Hospitals to Add eHR	3,675	639	--	4,313
eHR Capital Cost	\$9.4	\$29.5	\$12.4	\$53,316
UDI Capital Cost	\$0.3	\$1.0	\$0.4	\$1,883
Annualized Cost: eHR	\$2.3	\$7.4	\$3.1	\$13,329
Annualized Cost: UDI	\$0.1	\$0.4	\$0.2	\$801.4

## Cost Components for Device Manufacturing—Internal

- Internal planning
- Online barcode (or other) printing
- Relabeling
- IT integration

## Small and Large Manufacturer Challenges

- Small firms add printing
- For some large firms, costs in millions
- IT system development
- Lengthy implementation times

## Preliminary Manufacturer Costs for ~6,000 Establishments (\$million)

<b>Cost Item</b>	<b>Total Cost</b>
Administration and Planning	\$63.0
Equipment and Other Investments	\$172.3
Relabeling	\$191.8
Total Investment Costs (exc. IT)	\$427.0
Recurring Costs	\$42.7
<b>Annualized Total (exc. IT)</b>	<b>\$103.5</b>

## Initial IT Integration Costs (\$ Millions)

<b>Cost Item</b>	<b>Total</b>
Initial IT Integration Costs	\$246.0 - \$2,713.0

## Cost Components for Industry Infrastructure

- Standard-setting for UDI protocols
- Product data utility
- Training and communication for users



## Still Collecting Information

- Care to offer your estimate?
- What aspects of implementation are potentially disruptive?