



Survey of nearly 1,000 hospital professionals backs need for UDI Safety Institute Device Recall Survey

On October 20, 2006, a “device recall survey” was sent via e-mail to the subscribers of Premier Inc.’s Safety Institute *Safety Share* newsletter. The survey was part of Premier’s effort to gather information on the current methods used in healthcare settings to record and track information on medical devices.

It was noted in the request for participation that the information gathered in the survey would be shared with the FDA as additional insight into how a unique device identification (UDI) system may improve patient safety by facilitating device recalls and improving medical device adverse event reporting.

Survey findings

1. More than 80 percent of respondents stated that a national UDI system would enhance patient safety.
2. The most common method used to record information on a patient record regarding an implanted medical device is transfer of a product label into the patient’s record (60 percent).
3. When recalls occur, nearly all hospitals are conducting manual searches of records or logs to identify patients who received a recalled device or product.

Respondent characteristics

A total of 948 individuals responded to the survey. Respondents were asked to select a job type that best represented their responsibilities. These are the job types reported by respondents:

Table 1

Job type	Number of respondents
Administration	175
Infection control	172
Materials management	149
Risk management	120
Nursing	111
Quality services	111
Surgery/OR	93
Clinical support	81
Safety	74
Pharmacy	32
Facility/environment	27
Regulatory compliance	27
Physician/medical	25
TOTAL	948

Table 2

1. To the best of your knowledge, which methods or system (s) do you currently use to record information in the patient record on the medical devices that are implanted in a patient? Check all that apply:	
• Handwrittten recording of the device in patient record	51.1%
• Transfer of text label provided by the medical device company into the patient record	60.1%
• Transfer of a bar coded label (or other device identifier) from the device into the patient record.	40.8%
• Don't know	19.6%
• Other	8.7%
2. Do you have a system or database, beyond the individual patient record, to track or record medical devices that are implanted in a patient?	
• Yes	46.2
• No	20.8%
• Don't know or not applicable	33%
3. Which of the following systems do you use to label patient care equipment or medical devices (e.g., IV pumps) for the purpose of locating or tracking them. Check all that apply:	
• Manual method (e.g., handwritten or text label)	65.8%
• Electronic method (e.g., bar coding)	28%
• Radiofrequency identification (RFID)	2.8%
• Don't know or not applicable	15.4%
• Other	6.1%

Table 2 (continued)

4. When there is a recall of a medical device, either implanted or patient care-related device, what method do you currently use to track or locate the device and/or the patient? Check all that apply:	
• Manual review of patient record	42%
• Manual review of logs	58.4%
• Electronic retrieval of information	40.5%
• Don't know or not applicable	16.2%
• Other	5.6%
5. To what degree do you believe that having a unique device identifier system would enhance patient safety by improving your current process for recording device information and tracking recalls?	
• None	2.3%
• Minimal	6.8%
• Somewhat	27.7%
• Greatly	52.7
• Don't know or not applicable	10.7
6. Are you currently establishing your own identifier for products once they are received and before they are distributed to patients?	
• Yes	28.7%
• No	32.2%
• Don't know or not applicable	39.1%