

Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 3:12 PM
To: Butler, Jennie C
Subject: FW: The Statement of the National Alliance for Health Information Technology

-----Original Message-----

From: John Combes [mailto:JCOMBES@Haponline.org]
Sent: Friday, July 12, 2002 9:47 AM
To: grossm@cdcr.fda.gov
Subject: The Statement of the National Alliance for Health Information Technology

Hi Mary, Per my voice mail This is the person NAHIT would like to present our statement on July 26:
Tim Zoph
Vice President of Information Services/CIO
Northwestern Memorial Hospital
251 E. Huron, Feinberg 3-710
Chicago, IL 60622
312-926-3040
e-mail:tzoph@nmh.org

Please let me know where you would like us to send NAHIT's statement. Hopefully we can touch base today if you can tell me a best time to call. John
P.S. I will be presenting separate information from the AHA on the panel in the morning.

02N- 0204

APE 155

Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 3:11 PM
To: Butler, Jennie C
Subject: FW: Summary for Speaking at FDA Bar Code Meeting



FDA Public Hearing
on Bar Code



Exhibit A Bar code
flow in PPT

-----Original Message-----

From: JRedenius@HIMSS.ORG [mailto:JRedenius@HIMSS.ORG]
Sent: Friday, July 12, 2002 9:34 AM
To: grossm@cdcr.fda.gov
Cc: JSensmeier@himss.org; csmith@himss.org
Subject: Summary for Speaking at FDA Bar Code Meeting

Good Morning Mary,

I emailed you earlier this week to register Carla Smith, Executive Vice President for the Healthcare Information and Management Systems Society (HIMSS), to speak at the July 26 FDA meeting on bar coding. Please find a summary of Ms. Smith's presentation attached. I have also attached a power point presentation. I will call you a little later today to make sure that you have received everything you need to ensure that Ms. Smith is register to speak at the meeting. Thank you.

See attached file: FDA Public Hearing on Bar Coding July 26 2002 -
(s.doc) (See attached file: Exhibit A Bar code flow in PPT.ppt)

Best regards,

Jill

Jill Redenius
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Advancing the best use of information and management systems for the betterment of human health.

02N-0204

APÉ 155

Summary of Presentation by Carla Smith, Executive Vice President of The Healthcare Information and Management Systems Society (HIMSS)

Docket Number 02N-0204

FDA Public Meeting – Bar Code Label Requirements for Human Drug Products, July 26, 2002

The Healthcare Information and Management Systems Society (HIMSS) provides leadership in healthcare for the management of technology, information, and change through member services, education and networking opportunities, and publications. Members are kept abreast of the latest industry information and research, as well as legislative and policy issues. Based in Chicago with an office in Ann Arbor, Mich, HIMSS has 39 chapters and more than 13,000 individual members working in healthcare organizations throughout the world. Individual members include healthcare professionals in hospitals, corporate healthcare systems, clinical practice groups, HIT supplier organizations, healthcare consulting firms, and government settings in professional levels ranging from senior staff to CIOs and CEOs. HIMSS also serves over 80 corporate members, which include suppliers and consultants in the health information and management systems industry.

HIMSS strongly supports industry cooperation in achieving viable point-of-care, unit-of-use bar coding to reduce medical errors and improve productivity. HIMSS members represent all aspects of the supply chain impacted by unit-of-use bar code technology. By means of the advocacy process as implemented by the Advocacy Committee, HIMSS is working to accelerate adoption of bar coding at the point of care through initiatives in the following areas:

- Publication of a White Paper on Bar Coding for Patient Safety and other related articles in a variety of HIMSS publication venues.
- Formation of a Supply Chain Special Interest Group. This group provides a forum within HIMSS to create, share, review and advocate for information and management systems issues related to the healthcare supply chain from manufacture to point of use and disposal. This forum focuses on issues that add value to patient care through greater efficiency and cost savings as well as patient safety.
- Formation of a Bar Coding Task Force whose mandate by HIMSS Board of Directors is to facilitate industry cooperation in achieving viable point-of care, unit-of-use bar coding to reduce medical errors and improve productivity.
- Development of a flow chart describing the effect of bar code technology on the continuum of care (see exhibit A)

- Development of a HIMSS position statement on point-of-care unit-of-use bar coding technology which follows:

Position Statement

With the goal of moving towards a fully electronic record keeping system, the Healthcare Information and Management Systems Society (HIMSS) advocates the comprehensive use of standards-based¹ bar coding technology in the healthcare environment. The Society recognizes the significant benefits this technology can bring forward in the following areas:

- Patient registration and/or admission processes
- Patient safety, clinical care delivery, and patient tracking
- Product/supply logistics and material management coordination
- Patient accounting and billing

Methodology

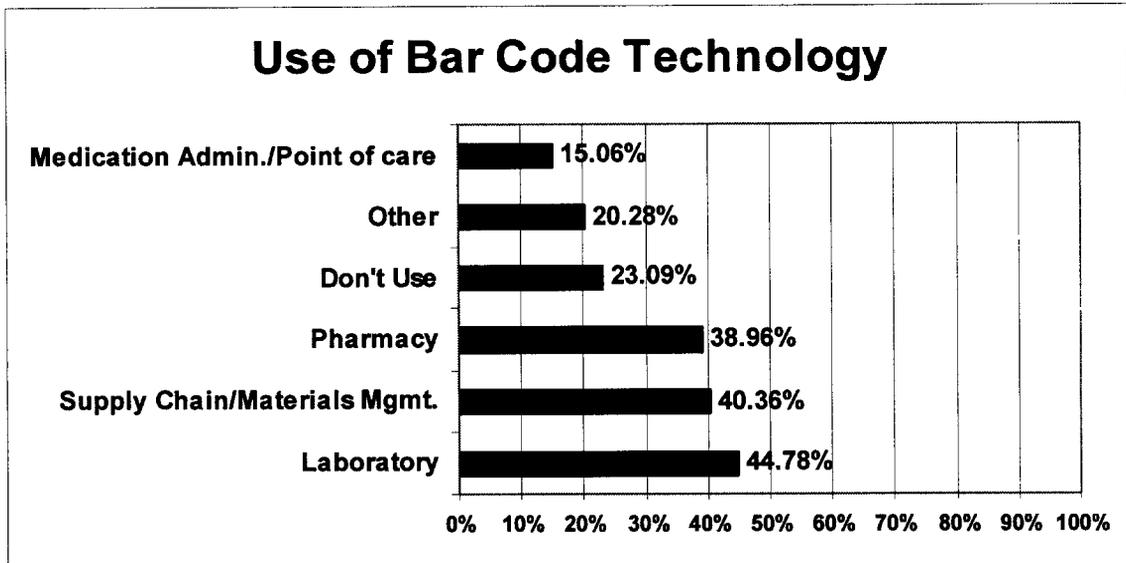
- Improvements in the patient registration and/or admission processes can be achieved by use of bar codes on patient:
 - forms
 - labels and wrist bands
 - records (including face sheets)
- Improvements in patient safety, clinical care delivery, and patient tracking can be achieved by use of:
 - bar codes on unit-of-use medications
 - bar codes on medical devices
 - bar codes on medical/surgical supplies
 - bar codes to identify care givers, clinicians and patients
 - bar codes on order requisitions, test results, and patient charts/medical records
 - bar coding scanners at the point of care
- Improvements in product, supply, and material management coordination can be achieved by use of bar codes on:
 - unit-of-use items for inventory control/tracking
 - bulk items to assist in materials tracking and logistics
 - tracking of reusable/refurbished equipment and supplies, product recalls, and warnings
- Improvement in patient accounting and billing can be achieved by use of bar codes on:

¹ HIMSS endorses the bar coding standards of UCC/EAN and the HIBC Supplier Labeling Standard and Provider Standard.

- supply items to capture charges
- patient statements for identification of remittance advice

Current Statistics

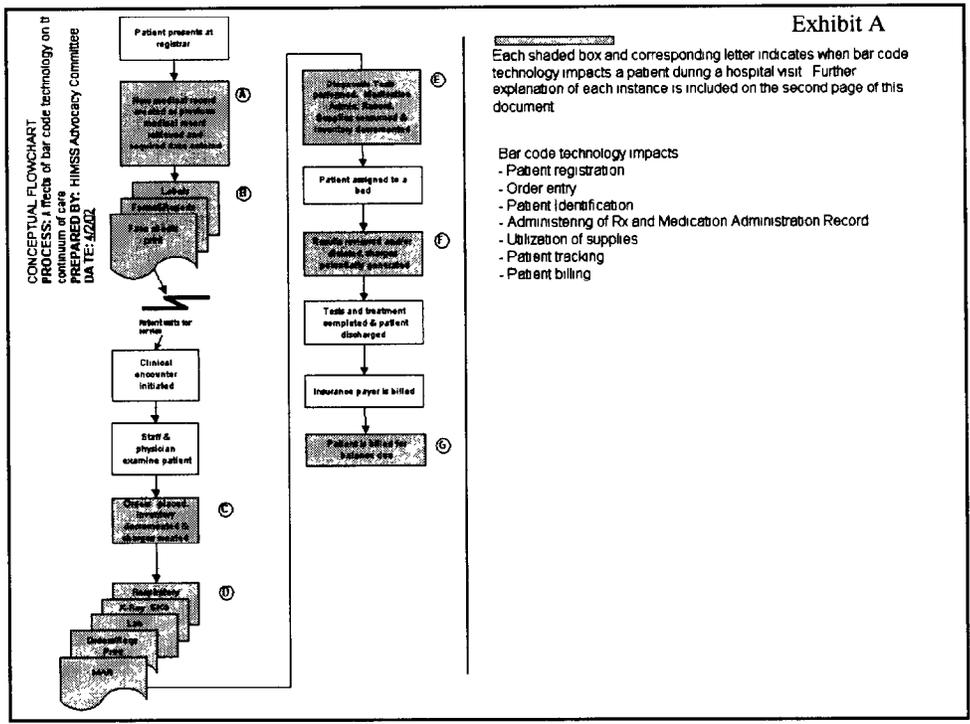
Nearly 77 percent of the 619 respondents of the HIMSS 2002 Hot Topics survey reported that their organization uses bar coding technology. The survey, conducted at the 2002 Annual HIMSS Conference and Exhibition in January, addressed key topics influencing the healthcare IT industry, including the issue of patient safety. The two areas in which bar coding was reported to be most prevalent are laboratory (45 percent) and Supply chain/materials management (40 percent). However, only 15 percent of respondents indicated that their organization uses bar coding technology for medication administration at the point of care.



Final Statement

HIMSS strongly supports industry cooperation in achieving viable point-of-care, unit-of-use bar coding to reduce medical errors and improve productivity, and stands ready to work with the industry towards its implementation. HIMSS recognizes that implementation of comprehensive use of standards-based bar coding technology is dependent upon multiple components, including organizational readiness and the existing IT infrastructure. A healthcare organization may choose to start at any point in this methodology and still achieve significant benefits. To assist organizations with assessing readiness and understanding the complexities of implementing this technology, HIMSS has developed a compendium of materials, which are available at:

<http://www.himss.org/ASP/advocacy.asp>.



- (A) Once a patient presents for admission, bar code technology may be utilized to scan a patient ID card previously issued by the healthcare system assisting in the elimination of duplicate medical record creation
- (B) Labels (for patient arm bands and misc forms), insurance forms and face sheets are generated upon registration and contain a patient identifying bar code
- (C) When orders are placed, the patient wrist band is scanned to ensure that orders are entered for the correct patient and on the correct account
- (D) Order requisitions are printed in various departments for the diagnostic tests ordered. Medication Administration Records (MAR) may be updated as meds are administered. Each item or med has an identifying bar code so that patient & clinician matching/tracking can be automated
- (E) As tests are performed, supplies are consumed (gauze, needles, dye, prep materials). These items should be scanned before utilizing them, thereby assisting in tracking of inventory and charge creation. MAR may also be updated again
- (F) Bar codes should be placed on charts, films, lab reports, and specimens to facilitate proper patient identification for dictation and results delivery
- (G) Bar codes should be placed on the remittance portion of the patient bill to increase accuracy when posting patient payments in the patient accounting department