ISBT 128 Labels for CT

Implementation: System Design, Development, Changes, and Challenges: Part Deux

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Dartmouth-Hitchcock
WORKSHOP OBJECTIVES

- Provide information regarding global implementation of ISBT 128 Labeling for CT Products
- Identify areas of global discussion which influence decisions regarding a formal implementation date
- Review updates to the ISBT 128 Standard
- Familiarize the attendee with product code selection through product scenario exercises
- Discuss specific questions regarding system operation and labeling applications
- Review an ongoing implementation process to include system design, development, changes, and challenges
A cellular therapy facility will share their experience of ISBT 128 Labeling System design, development and implementation with the audience. Specific components for discussion will include software updates and improvements, label format changes, label examples and implementation target timelines and outcomes. System and Implementation challenges will also be addressed.
First – An Apology!
Dartmouth-Hitchcock

– 396 inpatient bed capacity tertiary care center

– Level 1 Trauma Center

Norris Cotton Cancer Center

– NCI Designated Comprehensive Cancer Center

– Inpatient Oncology Care unit – 28 beds, 9 designated for BMT patients
Implementation process

Intro to ISBT128
- Outline project timeline
- Review terminology
- Map-up the process, identify correct S codes

Software
- Select ISBT128 compliant software
- Select stand-alone vs. mainframe

Validation
- Validation of the software/printers
- Validation of the labels stock/content
- Implement the system

Z. Szczepiorkowski 2009
Implementation process

- **Intro to ISBT128**
  - Outline project timeline
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Z. Szczepiorkowski 2009
Outline Project Timeline

• Jan 2007 – ISBT Implementation Plan drawn up.
  – Team members drafted, roles defined
    Medical Director of Transfusion Medicine
    LIS Specialist for Transfusion Medicine
    Transfusion Medicine Safety Officer
    Transfusion Medicine Supervisor
    Blood Donor Program Asst Supervisor
    Cellular Therapy Specialist
Outline Project Timeline

• Plan called for implementation of ISBT 128 labeling in all DHMC locations concurrent with upgrade to Cerner Millennium LIS.
  – “The Conversion of the Cellular Therapy Center to ISBT 128 will occur concurrently with the full ISBT implementation in other Transfusion Medicine Service Sections”
Outline Project Timeline

• ISBT 128 for blood products has been now mandatory for almost a year.

• Our Blood Bank Software was initially able to only accept ISBT128 labeled blood products but eventually (June 2008) was upgraded to generate ISBT128 labels for blood products.

• Subsequently, our Blood Donor Program moved to ISBT128 labels (October 2008) with a new release of its software.
Outline Project Timeline

• May 2010 – Full ISBT 128 implementation in the CTC is still pending...

What happened?
Being part of a traditional lab is a blessing and curse.
• If you are lucky, you get swept along with everyone for improvements.
• If you are unlucky, you struggle to fit your products into their systems.
Outline Project Timeline

ISBT 128 (Blood Bank)

ISBT 128 (BDP)
- Blood products (number / label)
- Cellular Therapy Products (number)

ISBT 128 (CTC)
- Terminology
  - Number
  - Full label
Review Terminology

Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions
For Use with Product Description Code Database Version 3.37
May 2010
Map up the Process, Identify correct S codes

• Codes selected 5/2009 to validate:
  • S1129, S1177, S1186, S1183, S1181, S1167, S1166, S1194, S1196, S1297, S1298, S1134, S1219, S1221, S1188, S1179, S1185, S1299, S1301, S1302

• Codes still applicable from those selected:
  • S1129, S1177, S1186, S1183, S1181, S1167, S1166, S1194, S1196, S1297, S1298, S1134, S1219, S1221, S1188, S1179, S1185, S1299, S1301, S1302
Map up the Process, Identify correct S codes

• Try to weed out the obvious codes that won’t apply, e.g.
  – 3rd party components
  – Other additives
  – Concentration of DMSO (5% or 10%)
  – Storage temperature (-150°C or -120°C)
  – Products you don’t use (MSCs, Pooled Products)
Implementation process

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Select ISBT 128 Compliant Software

- Stand alone or LIS integrated label printing
- Vendors listed on ICCBBA website.
- Evaluated 2 and went with Digi-trax
- HemaTrax CT v.2 coming out soon – we are a beta test site
Select ISBT 128 Compliant Software

- Vendors listed on ICCBBA website for Cellular Therapy Labeling
  - Chek-Lab, Inc.
  - Computype, Inc. **
  - Data2 Corporation
  - Digi-Trax Corporation**
  - HealthCare Products International, Inc.
  - Inlog International S.A.S.
  - Mediware Information Systems, Inc.
  - Medservice Sp. z o.o.
  - Niceware International, LLC
  - Pall Medical
  - Shamrock Scientific Specialty Systems, Inc.
  - Zebra Technologies Corporation

**Exhibitors**
## Stand alone vs. primary system

<table>
<thead>
<tr>
<th>Manufacturer A</th>
<th>Manufacturer X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large Blood Bank Software Company</td>
<td>Stand alone label making company</td>
</tr>
<tr>
<td>Significant Delays in Introduction of S codes (not yet available)</td>
<td>Willing to work with the laboratory (beta site)</td>
</tr>
<tr>
<td>Future updates (likely in July 2009) will have S codes as part of the release</td>
<td>Responsive to identified issues during the implementation process</td>
</tr>
<tr>
<td>Recently dropped blood donor program module</td>
<td></td>
</tr>
</tbody>
</table>
HemaTrax v.2 Changes

• Added a tabbed interface instead of switching from form to form.
• Selecting labels is now done through a dropdown menu.
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Validation of the Software/Printers

• Validation plan drafted 5/2009
Validation of the Label Stock/Content

- Storage for 1 week in a liquid nitrogen freezer (Label A)
- Storage for 1 week in the 37°C CO₂ incubator (Label B)
- After 30 minutes in a 37°C water bath (Label C)
- Storage for 48 hours at 1-6°C (Label D)
- Storage for 24 hours at 22-24°C (Label E)
Validation of the Label
Stock/Content
## Validation of the Label Stock/Content Results

### Label Stock Validation for Manufacturer X-CT ISBT Labeling System

<table>
<thead>
<tr>
<th></th>
<th>Label A</th>
<th>Label B</th>
<th>Label C</th>
<th>Label D</th>
<th>Label E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the label firmly attached to the bag with no evidence of peeling?</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Is all of the handwritten information clearly visible on the bag?</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Is all of the handwritten information present in a non-smudged condition?</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>No</td>
</tr>
<tr>
<td>Is there any evidence of portions of the written information flaking off the label?</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>No</td>
</tr>
<tr>
<td>If you run your finger over the handwriting does it remain clear and unaltered without evidence of smudging or flaking?</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>No</td>
</tr>
<tr>
<td>Is all the printed information on the label present in a non-smudged condition?</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Is there any evidence of any of the printed information flaking off the label?</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>If you run your finger over the printed information does it remain clear and unaltered without evidence of smudging or flaking?</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Can the following barcode be read correctly?</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>DIN</td>
<td>W13830860162200</td>
<td>W13830860162200</td>
<td>W13830860162200</td>
<td>W13830860162200</td>
<td>W13830860162200</td>
</tr>
<tr>
<td>ABORh Type</td>
<td>8600</td>
<td>8600</td>
<td>8600</td>
<td>8600</td>
<td>800</td>
</tr>
<tr>
<td>Product code (HPC, Apheresis with Citrate at RT)</td>
<td>&lt;S1129100</td>
<td>&lt;S1129100</td>
<td>&lt;S1129100</td>
<td>&lt;S1129100</td>
<td>&lt;S1129100</td>
</tr>
</tbody>
</table>
Cerner Millennium v.18 has cellular therapy terminology. We were set to implement upgrade and the lab postponed it. Without the upgrade – we can’t implement ISBT 128 labeling.
Implement the System

- CT labs not required to print ISBT labels – yet
- ISBT terminology is required by FACT and AABB
- >350 Codes already generated for CT products – users have the ability to request new codes
Small Cell Therapy Group Survey

1. Are you using ISBT 128 labels for cellular therapy products? NO
2. Which Vendor did you choose? DIGITRAX
3. Any specific reasons why you went with one company over another? BLOOD BANK PREFERENCE AND WHAT WAS AVAILABLE TO WORK WITH OUR LIS
4. Which label sizes do you use? BB USES THE 4 x 4. I HAVE 4x4 AND 1.5x1.5 LABELS IN WAITING. I HAVE NOT FOUND VIAL LABELS YET
5. Do you use the label for cryovials? NO
6. How did you validate the labels? VISUAL CONFIRMATION WITH A REQUIRED DATA CHECKLIST (IN BB)
7. Did you discover any major issues during validation of the system? THERE ARE A TON OF ISBT CATEGORIES FOR CELLS. IT WAS HARD TO NARROW DOWN TO WHAT I WILL BE USING
1. Are your labels tied in with a Laboratory information system? If so, which one and what version are you running? YES WE ARE ON SUNQUEST 6.4

2. Do you use label verification with your LIS? IT IS NOT INTEGRATED WITH SUNQUEST YET. OUR DIGITRAX IS FREE STANDING

3. If you aren't using ISBT 128 labels yet - what is the reason? IT TOOK SO LONG FOR ICCBBA TO PUBLISH THE LIST OF CT PRODUCTS THAT OUR CONTRACT WITH DIGITRAX EXPIRED FOR CELL THERAPY. WE ARE NOW WAITING A BUDGET RENEWAL OF THIS COST. NOT SURE HOW LONG BEFORE WE MAY BE APPROVED IN THIS CURRENT ECONOMIC CLIMATE. ALSO, WE ARE NO LONGER AN NMDP COLLECTION SITE SO SHIPPING PRODUCTS IS NOT AN ISSUE WHICH WAS PARTIALLY SUPPORTING MY REQUEST FOR THE SYSTEM.

4. Is there anything in particular you would like addressed in the ISCT presentation? WHAT ISSUES ARE HOLDING UP THE NATIONAL ARC FROM GOING FORWARD?
Helpful Links

• Small Cell Therapy Lab – Google Group
  – http://groups.google.com/group/small-cell-therapy-lab

• ICCBBA Cellular Therapy Home Page
  – http://iccbba.org/cellulartherapy_home.html
Thanks!

• Zbigniew “Ziggy” M Szczepiorkowski, MD, PhD, FCAP
• Miriam Fogg Leach, MSAI, MT(ASCP)SBB, BSIS,QLI
• Jeff Dragoo, Sales Engineer, Digi-Trax Corporation