Implementation of ISBT128 in a medium size cellular therapy product processing laboratory – thoughts, challenges and personal experience

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Q: Who should be on my implementation team?

A: ISBT 128 will affect many departments in the facility. The staff involved with administration of the product will need to know where to find specific information located on the new label.

The laboratory personnel will need to be familiar with product codes when performing modifications.

The Accounting Department will need to understand the products that they will be billing.

Medical records personnel will also be affected.

A recognized Team Leader should be chosen to spearhead the project.
As previously mentioned it is not required by any of the accrediting organizations.

The terminology is, however, required by AABB, FACT-JACIE; Netcord; NMDP; and provided in the Circular of Information.

So, how one can be compelled to go to the next step…
ISBT128 Cellular Therapy
Our story…

- ISBT 128 for blood products has been now mandatory for almost a year.
- Our Blood Bank Software was initially able to 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…
Analyze your process first...

Example:

HPC, Apheresis
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
## 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>
Manufacture X and challenges…

YOU ONLY LIVE TWICE…
Resolution of initial problems with Manufacturer X...

After the first viewing of the software “...I must say that I am extremely disappointed in this software; I was excited about it due to the excellent experience we had with both the Manufacturer X server and stand-alone systems. However, I cannot say that this software is up to the prior Manufacturer X standard...”

This was followed by a lengthy list of limitations...
Resolution of initial problems with Manufacturer X...a week later...

“...Thank you for the responses. It would have been very helpful, and less frustrating, if this information had been known before I started testing...”

And a few days later...” ..I am about ready to start the validation of these labels...”

This was a definitely mutually enriching experience for us and the engineers from the Manufacturer X.
And finally...

“All sounds good! The S codes we will be using are:

S1129, S1177, S1186, S1183, S1181, S1167, S1166, S1194, S1196, S1297, S1298, S1134, S1219, S1221, S1188, S1179, S1185, S1299, S1301, S1302

We will be using the 3x2 label with the face perf, the 1.5x.75 cryo vial label and the 3x2 base label…”
Implementation process

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Manufacturer X

SOFTWARE PRESENTATION
Initial screen...
Product code selection

[Image of a software interface with highlighted product codes and blood type fields.]

- Product Code: S1380
- Enter DIN Barcode: Facility ID W138, Number 25
- Select Facility: Collection Facility, Processing Facility
- Special Message: Plasma reduced
- Expiration Date/Time: GMT
- Donor ID, Date of Birth, MRN, Date of Birth are also visible on the interface.

Circled areas highlight the product codes and other relevant fields for selection.
Scanning of the number, ABO type...
Insert patient’s name…
(a computer challenging for that…)
Donor/Recipient Name: MacDonald-Szczepiakowski, Jane
MRN: 590000000-9
Date of Birth: 10/16/1966

For Autologous Use Only
MacDonald-Szczepiakowski
Donor #: 0000000
Date of Birth: 10/16/1966
Facility selection…
Split product (division)
Areas to improve…

The good news is that the new version of the software will be available within next 7-10 days…
Examples of labels
Implementation process

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Validation
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- Validation of the labels stock/content
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First, the stock labels needed to be validated under the following conditions:

- 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 (labels) cont’d

1. Is the label firmly attached to the bag with no evidence of peeling?
2. Is all handwritten information clearly visible on the bag?
3. Is all handwritten information present in a non-smudged condition?
4. Is there any evidence of portions of the written information flaking off the label?
5. If you run your finger over the handwriting does it remain clear and unaltered without evidence of smudging or flaking?
6. Is all the printed information on the label present in a non-smudged condition?
7. Is there any evidence of any of the printed information flaking off the label?
8. If you run your finger over the printed information does it remain clear and unaltered without evidence of smudging or flaking?
9. Can the following barcode be read correctly?
10. DIN ; ABO Rh type; Product Code
### Final results…

<table>
<thead>
<tr>
<th>Label Stock Validation for Manufacturer X-CT ISBT Labeling System</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Label A</strong></td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td><strong>Is the label firmly attached to the bag with no evidence of peeling?</strong></td>
</tr>
<tr>
<td><strong>Is all of the handwritten information clearly visible on the bag?</strong></td>
</tr>
<tr>
<td><strong>Is all of the handwritten information present in a non-smudged condition?</strong></td>
</tr>
<tr>
<td><strong>Is there any evidence of portions of the written information flaking off the label?</strong></td>
</tr>
<tr>
<td><strong>If you run your finger over the handwriting does it remain clear and unaltered without evidence of smudging or flaking?</strong></td>
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</tr>
<tr>
<td><strong>Can the following barcode be read correctly?</strong></td>
</tr>
<tr>
<td><strong>DIN</strong></td>
</tr>
<tr>
<td><strong>ABORh Type</strong></td>
</tr>
<tr>
<td><strong>Product code</strong></td>
</tr>
</tbody>
</table>
Label validation

Tag label

Main Label/Tag Label
The second part of label validation is associated with computer/software validation. This will be performed once the final version of the software is available and all three printers are available.
Validation (software)

- We have postponed software validation to second version of the software from “manufacturer X”
- It seemed critical that the software will have some if not all shortcomings eliminated prior to the full validation.
- We expect it to be accomplished within next 2 months.
Splitting products – example where ISBT implementation experience is necessary

1. Receive a product HPC, Apheresis
2. Use ISBT 128 initial split modification option to add AO division characters
3. Use ISBT 128 additional split option to make an aliquot Aa to infuse and reduce the volume of AO appropriately
4. Remainder of AO
   - Use the make new ISBT 128 product option to make TC, Apheresis product from remaining HPC, Apheresis (AO)
   - Use the freeze option to freeze the TC, Apheresis made above
   - Use the thaw option to thaw the product when ready to infuse
5. Infuse Aa
6. Issue to the patient
Cost analysis of introduction of CT ISBT128 in the cell processing laboratory

<table>
<thead>
<tr>
<th>Item</th>
<th>COST /TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printers (ZEBRA-CT-GX43-E)*</td>
<td>$ 3000.00</td>
</tr>
<tr>
<td>Stock labels</td>
<td></td>
</tr>
<tr>
<td>CT-44 -G</td>
<td>$115.00</td>
</tr>
<tr>
<td>CT-232-FOLD-G 3x2 (4600)</td>
<td>$147.00</td>
</tr>
<tr>
<td>CT-15x75-G cryo vial (3000)</td>
<td>$50.00</td>
</tr>
<tr>
<td>Selection of codes</td>
<td>1-4 weeks</td>
</tr>
<tr>
<td>Interface build (if necessary)</td>
<td>1-4 weeks</td>
</tr>
<tr>
<td>Software validation</td>
<td>2-3 months</td>
</tr>
<tr>
<td>Label validation</td>
<td>1-4 weeks</td>
</tr>
</tbody>
</table>

*depending on the number of label sizes used; we have selected 3 for ease of operation
Summary

- Plan appropriately for the extent and experience of IT Specialist involvement. Do not underestimate the complexities of the system…
- Establish relationship with software manufacturer
- Map up your processes and consider changes in your products to adequately select “S” codes.
- Validate your labels and software
- Consider the overall costs [e.g. technologists time; IT time; validation time (software and labels); stock labels; printers; client computers, if necessary etc]