

## ISBT 128

ACL-IL  
TRANSFUSION  
SERVICES

## OBJECTIVES

At the end of this presentation the employee shall

- Be familiar with the differences between ISBT 128 labeling and Code-A-Bar labeling.
- Be familiar with , but not fully trained, on the procedure modifications that will accompany the implementation of ISBT 128 at ACL

## What is ISBT 128?

- International Standards for Blood Transfusion
- 128 system for labeling

## What will happen?

- On April 28, 2008, LifeSource is expected to convert operations from Code-A-Bar to ISBT 128.
- On that date forward, all products collected and prepared will be labeled differently than in the past.

## What does this mean for ACL?

- ISBT 128 utilizes different bar code language and different bar code translations.
- By the date that LifeSource begins labeling with ISBT 128 labels, ACL needs to have AML ready to accept the new bar codes and staff trained on how to read the new bar codes and trained on changes to the computer system needed.

## Why not leave things alone?

- First, it is FDA mandated that all licensed blood collection facilities implement ISBT 128 by May 1, 2008 or get waiver.
- Second, it is CAP and AABB mandated that all agencies receiving blood products be able to incorporate ISBT 128 labeling into its systems by the implementation date of its blood supplier.

### Why not leave things alone (cont)?

- There are many benefits to implementing ISBT 128 that we do not have under the present system.

No duplication of BUI numbers anywhere in the world

- Currently each center is free to develop its own blood unit identification (BUI) system. This means that there are many duplicate BUI numbers.
- Incorporated into the ISBT 128 BUI numbering system are collection facility and year collected identifiers. Since each collection facility gets a unique identifier, there will be no duplication of BUI numbers for 100 years.

### Why not leave things alone (cont)?

- There are many benefits to implementing ISBT 128 that we do not have under the present system.

Quicker notification of defective product

- Resource sharing among blood centers is very common. Since blood transfused in Chicago, may have been collected in New York but sent to Chicago from Los Angeles, notification of a defective product back to the supplier can be time consuming.
- Because the BUI number incorporates the collection facility one can determine which center to notify from the BUI number instead of notifying middlemen, etc.

Not realized benefit immediately

### Why not leave things alone (cont)?

- There are many benefits to implementing ISBT 128 that we do not have under the present system.

Brings to world one bar code language for and one product coding for blood banks

- Currently, each country is free to develop its own bar code language for blood product labeling. In addition, each country is free to establish its own product codes. The result is an inability to communicate globally.
- ISBT 128 has been chosen by the blood banking community as the bar code language and product code nomenclature of choice and brings all of the participating world into one network. With an ever increasing global market, especially for plasma, enhanced communication is essential.

### Why not leave things alone (cont)?

- There are many benefits to implementing ISBT 128 that we do not have under the present system.

Brings to world one label format for blood products.

- Currently, each country is free to develop its own format for labeling of blood components. For example, in the US, the blood type is found in the right hand upper corner of the blood product label. It is not found there in Japan.
- ISBT 128 labeling formats have been chosen by the blood banking community as the format of choice and brings all of the participating world into one format. A person in Japan will now be able to recognize the way essentials of a US blood product label without additional training and vice versa.

### Cut to the chase!

- All of this is fine and good but what I want to know is HOW does this affect ME, in MY job?
- What other CHANGES can I expect?

### What can YOU expect?

- First, almost of the work is complete and there is very little that you will have to do. In fact, most of the changes will be invisible to you.

## What can YOU expect?

- The members of the ACL ISBT implementation committee are:

John A. Giandelone  
Sandra Bartkowiak  
Chiu Tse  
Marilyn Bristow  
Randy Milstagle  
Teri Hoel  
LeAnn Deptula  
Rogene Gall

## What can YOU expect?

- The ACL ISBT Implementation team has been working very hard to make certain the transition is as seamless as possible.

**BUT**

## What can YOU expect?

- One of the first things you will notice is that the labels will not have multiple colors.
  - Group O labels are black and white, not blue and white.
  - Group A labels are black and white not yellow and white.
  - Group B labels are black and white not pink and white.
- In other words all of the label will be in black and white.

## What can YOU expect?

**IF YOU RELIED ON COLORS TO HELP PICK BLOOD TYPE YOU WILL NOT BE ABLE TO DO THAT ANY MORE. YOU ARE FORCED TO READ LABELS MORE CLOSELY.**

*OH, the humanity!!!!*

## What can YOU expect?

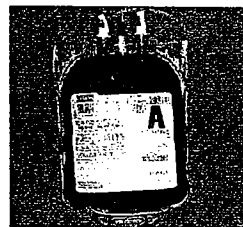
- The second thing you will notice is that things on the label are not necessarily in the same place it was before.

*Hey!!! Who Moved the Cheese?*

You will have to **UNLEARN** the automatic motions you have used in entering and issuing units and **LEARN** new automatic motions.

*Adult education at its finest!!!!*

## What can YOU Expect?



- This should look familiar to all of us.

• *OOOH, Pretty!*

**What can YOU Expect?**

- TA DA, the label of the future. Notice the monochromatic color scheme, the tiny writing, and more bar codes than ever before.
- *Pretty darn simple if you ask me.*

**What can YOU expect?**

- The biggest and most aggravating thing that you can expect is that the BUI goes from 7 to 13 digits.
  - This means that you have 13 digits to write on your logs every time you irradiate a unit.
  - This means that you have 13 digits to check every time you issue a unit.
  - This means that you have 13 digits to check every time you want to allocate a unit.

**What can YOU expect?**

*ARE YOU KIDDING ME?*

**What can YOU expect?**

- Sorry, but this is fact.
- Here's something interesting though!
  - Remember earlier I said the collection facility and date were incorporated into the BUI number. Well, it is in the first six digits. This means that for a few year every blood component received from LifeSource and collected by LifeSource will have the same exact first six digits. There will be no change until the following year and then it will stay the same for another full year and so on.

**What can YOU expect?**

- See that's not so bad. Since the first six digits are the same for all of the units they are not that important. So then, to make matters easy let's just put into our records the first six digits (default) and then we only have to record the last seven like we do now. Boy, that would make things much easier.

**What can YOU expect?**

**Yeah, Right!**

**Think Again!**

*Have you lost your mind?*

**In other words:**

What can YOU expect?

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**NEVER!**

What can YOU expect?

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**REVIEW  
TIME!**

What can YOU expect?

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**Yeah, Right!**  
Think Again!  
*Have you lost your mind?*  
In other words:

What can YOU expect?

---

**NEVER!**

What can YOU expect?

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One of the major advantages of ISBT to an importing blood center (like LifeSource) is that the blood center will not need to assign the imported unit a separate number, since with ISBT there is no way to duplicate a number.  
Therefore, re-numbering by LifeSource will go away.  
Therefore, not all blood components shipped to us from LifeSource will start with the LifeSource digits.

What can YOU expect?

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The first six digits will be assigned and may be very similar (one of two digits difference). It would be very easy to miss the digit difference if we allowed a default.  
Always take care when recording.  
Bar code the unit number whenever possible.

What can YOU expect?

To assist you in assuring that you record all 13 digits, forms that require manual recording of the blood unit number are being revised so that the area for recording the blood unit number is broken down into 13 spaces.

What can YOU expect?

When we rollout the new forms, whenever possible the space to record the BUI number will look like this. If you miss or add a digit it will be easy to see.

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What can YOU expect?

The next thing you will notice is that all of the product codes are changed. More than ever, scanning bar codes is essential. You cannot manually enter product codes. If you manually enter a product code and make a mistake, the person behind you trying to scan will have difficulty.

What can YOU expect?

All of the new product codes have been entered into AML and are tied to the correct AML codes. Entering blood products is the same as always (with some exceptions) as long as you scan.

What can YOU expect?

In Code-A-Bar, the product codes are all numeric. The product code for autologous, directed, and allogeneic are all the same. Autologous, directed and allogeneic are not part of the product code.

What can YOU expect?

In ISBT, the product codes are alpha numeric. The product code for autologous, directed, and allogeneic are all different (different alpha portion). Autologous, directed and allogeneic are part of the product code.

What can YOU expect?

Instead of differentiating autologous and directed units by looking for special labels, you need to differentiate by product code. The ABO label on an autologous unit is the same as for an allogeneic unit.

What can YOU expect?

Therefore, it is more likely that an autologous unit can be placed on the same shelf as with allogeneic units. Since the autologous unit will look more like an allogeneic unit, it can be easier to issue an autologous unit inappropriately.

What can YOU expect?

**UNLESS**

What can YOU expect?

You ALWAYS, ALWAYS, ALWAYS, issue blood through the computer and pay attention to the messages. If you do not issue blood through the computer, because units all look alike, you increase the risk of incorrectly issuing a wrong unit.

What can YOU expect?

**IF YOU CHOOSE TO BYPASS THE COMPUTER TO ISSUE A UNIT YOU DO SO AT YOUR OWN PERIL AND JEOPARDIZE YOUR EMPLOYMENT.**

Doing so constitutes a serious error.

What can YOU expect?

Because there is no set implementation date for ISBT conversions, for the next year (perhaps longer) you will continue to see some products with Code-A – Bar labeling and some products with ISBT labeling.

What can YOU expect?

Red blood cells collected before the conversion date will not be re-labeled with ISBT labeling.  
Frozen products collected before the conversion date will not be re-labeled with ISBT labeling.

What can YOU expect?

So, for some time to come, you can expect an inventory of blood products that have some products labeled as with Code-A-Bar and some with ISBT labels.  
As a matter of fact....

What can YOU expect?

Because we are using Sunquest, ACL-IL will re-label components it prepares with Code-A-Bar labels, even if the mother unit is labeled with ISBT labels (until further notice).

What can YOU expect?

Originally, the intention was to purchase printers that will give real time component labels whenever you modify a component in BCP. This is still the eventual goal for ACL. However...

What can YOU expect?

Sunquest has not fixed all its glitches to allow this to happen for all functions AND Sunquest has not yet decided on what printers will be tied to the program AND These printers are very expensive, SO We decided to wait to implement the real-time printing of labels until all of the fixes are in and Sunquest has completed the programing.

What can YOU expect?

All of the bar code readers that are used in blood bank will be replaced with bar code readers that concurrently read Code-A-Bar and ISBT (no need to toggle).  
Validation is complete and ordered.

## What can YOU expect?

So, quick review of what we have covered so far:

- All units look alike (exercise care and always use computer)
- BUI number is longer
- Mixed inventory of blood product
- AML set up for ISBT, BUT

## What can YOU expect?

Since Sunquest is not completely ready we need to modify a few procedures (work-arounds).

The rest of this presentation will be spent on discussing the work-arounds.

Complete training on the work-arounds will take place at the different sites, this will be an overview.

## What can YOU expect?

Before we discuss the work-arounds, are there any questions regarding the material that has been presented so far?

## Work arounds

The work-arounds include:

1. Implementing a label recheck procedure
2. Use of Code-A-Bar labels
3. Segregating blood products upon receipt from supplier and before BPE.
4. Different supplier for aliquots and divided units.

## Work arounds

### Label Recheck

A new SOP will be implemented that will require a label check **ANYTIME** a product is modified in BPE.

Once implemented, this procedure is **REQUIRED** and will remain as permanent procedure.

## Work arounds

### Label re-check

1. Physically modify the product.
2. Modify in BPE.
3. Go to label recheck program (in AML)
4. Perform label recheck function.
5. AML will check new product label against information in AML and accept or issue warning/message.
6. Correct/continue as indicated

**Work arounds**

Label re-check

1. Irradiation
2. Aliquoting
3. Dividing
4. Pooling
5. Washing
6. Does not affect thawing

**Work arounds**

Use of Code-A-Bar labels

When you create or modify a component a new product code is assigned to the product. All new labels will be Code-A-Bar labels. All existing labels will not be changed.

**Work arounds**

Use of Code-A-Bar labels

This means that on a particular product, you can have some Code-A-Bar and some ISBT labels.

irradiated products

**Work arounds**

Use of Code-A-Bar labels

This means that on some product, you can have all Code-A-Bar labels even though the original product had all ISBT labels.

- Aliquots
- Pooled
- Washed

**Work arounds**

Use of Code-A-Bar labels

AML has been validated to assure that using different labels on products does not affect the information stored for the product.

ACL-IL is not FDA licensed and therefore this mix is allowed, (not so for FDA licensed blood suppliers).

Temporary fix, will be modified with Sunquest makes final fixes (as mentioned earlier)

**Work arounds**

Segregating components upon receipt

This is a major change that will be implemented.

Sunquest is not yet able to recognize the bar code for 2<sup>nd</sup> and 3<sup>rd</sup> products collected by apheresis techniques.

Therefore:

**Work arounds**

**Segregating components upon receipt**

Sunquest does not allow bar code entry of apheresis red cells (2<sup>nd</sup> unit) and single donor platelets (2<sup>nd</sup> and 3<sup>rd</sup> units) and apheresis plasma (not used in ACL-IL at this time)

In order to scan units into inventory Code-A-Bar labeling is required. HOWEVER:

**Work arounds**

**Segregating components upon receipt**

Life Source is prohibited from labeling a product with Code-A-Bar labeling once converted.

Thus our work-around as follows:

**Work arounds**

**Segregating components upon receipt**

1. When red cells are received, review the product codes and segregate the product codes that represent the 2<sup>nd</sup> unit of a double red cell.

SOP will contain list of affected product codes and product descriptions

**Work arounds**

**Segregating components upon receipt**

2. Red blood cells that are not the 2<sup>nd</sup> unit of a double red blood cell may be entered as normal.
3. Attach a manila tag containing the Code-A-Bar label to the 2<sup>nd</sup> unit of the double red blood cell before entering into BPE.

**Work arounds**

**Segregating components upon receipt**

4. When entering the product into BPE, use the Code-A-Bar label to enter the product code, not the product code on the component.
5. Keep the manila tag attached to the unit unless returned to the blood center.

**Work arounds**

**Segregating components upon receipt**

6. When entering product code information into AML, use bar code on manilla tag, not on product. This includes issue to the floor.
  1. If the unit is made into another component the new component code will apply and the manila tag is to be removed. For example, if irradiated, an irradiated product code is fixed to the product over the original

**Work arounds**

Segregating components upon receipt  
The 2<sup>nd</sup> and third units of platelets work the same way as red blood cells.

**Work arounds**

Segregating components upon receipt  
The reason we do not apply the Code-A-Bar product code over the original product code initially is because this would make the product non-returnable.

**Work arounds**

Segregating components upon receipt  
The reason we can apply the Code-A-Bar product code over the original product code following component prep is because the act of making the new component not returnable as well as making it a new product.

**Work arounds**

Segregating components upon receipt  
Before we move on to the next and final work-around are there any questions on the first three?

**Work arounds**

Aliquoting/dividing  
ISBT does not recognize unit numbers with slashes.  
Sunquest still generates slash numbers for aliquots.  
Thus the conflict.

**Work arounds**

Aliquoting/dividing  
When an aliquot is made it is important to use the same BUI number as the mother unit.  
When preparing an aliquot in BCP, AML retains the original product code and modifies the BUI with a slash. In ISBT the BUI remains unaffected and the product is differentiated using a new product code.

**Work arounds**

Aliquoting/dividing

Until this is fixed the work-around we cannot use BCP to make aliquots The work-around is as follows:

1. Physically make the aliquot.
2. Label the product with the same unit number as the mother unit, the appropriate product code, (unit 1, 2, 3, etc) and ACL-IL as the supplier (labels will be provided)

**Work arounds**

Aliquoting/dividing

3. Enter the aliquot into BPE.
4. Attach note to mother unit indicating volume removed and volume remaining.

**Work arounds**

Aliquoting/dividing

Special Notes:

Units entered with ACL as the supplier will not be required to have the ABO recheck testing performed. However, you are required to answer a new test that states you have reviewed the testing on the mother unit and that all testing required to issue the mother unit is completed.

**Work arounds**

Aliquoting/dividing

Special Notes:

Before you make an aliquot, you will need to review the history and choose the next aliquot product code. If two aliquots have already been made, you should choose aliquot number three.

**Work arounds**

Aliquoting/dividing

Special Notes:

The reason we cannot assign an ACL Code-A-Bar number is because this would not allow us to trace the unit if needed in an error free manner.

**Work arounds**

Aliquoting/dividing

Special Notes:

Another way to get around this is to have the blood center provide us with a mother unit and aliquots already labeled. We are investigating this. Problems include:

By law, aliquots must be made, labels cannot be attached to empty aliquot bags.

Aliquot amount needed may not match aliquot volume prepared by blood center.

[Handwritten ID]

**Work arounds**

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Aliquoting/dividing  
 Special Notes:  
 Aliquots **REQUIRE** label recheck.

[Handwritten ID]

**Work arounds**

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Are there any questions regarding the work-arounds.

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**Summary**

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Item	Tasks
Receive red blood cells from LifeSource	Review product codes Segregate units Attach manilla tag where applicable

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**Summary**

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Item	Tasks
Enter red cells into AML	Access BPE Manilla tag, product code from tag No manilla tag, product code from unit

[Handwritten ID]

**Summary**

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Item	Tasks
Irradiate red cells	Perform irradiation Attach new product code to unit label. Remove manilla tag where applicable Update BCP Perform label recheck

[Handwritten ID]

**Summary**

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Item	Tasks
Aliquot red blood cells	Review AML data and assure mother unit satisfactory Prepare and label aliquot (no manilla tag) Enter aliquot into AML (ACL supplier) Update mother unit record Perform label recheck on aliquot

Summary

Item	Tasks
Issue red blood cells	Access BPI Use product code on manilla tag if applicable Issue with manilla tag attached if applicable

Summary

Item	Tasks
Return red blood cells to supplier	Access AML Use product code on manilla tag if applicable Remove manilla tag attached if applicable

**ISBT 128 TRAINING**

- I certify that I have attended the ISBT overview training. All of my questions have been answered. Additional questions should be forwarded to my supervisor. I understand training on applicable procedures mentioned in this presentation is forthcoming prior to implementation.
- Print name: \_\_\_\_\_ Site: \_\_\_\_\_
- Signature: \_\_\_\_\_ Date: \_\_\_\_\_
- Presenter signature: \_\_\_\_\_ Date: \_\_\_\_\_