

Butler, Jennie C

From: Gross, Mary
Sent: Friday, August 09, 2002 3:10 PM
To: Butler, Jennie C
Subject: FW: Slide presentation-barcode



FDA Meeting July
26 2000 ppt



Chronology pdf

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

From: Edwin A Steane, PhD [mailto:esteane@iccbba.com]
Sent: Friday, July 12, 2002 7:44 AM
To: GrossM@cder.fda.gov
Subject: Slide presentation

Mary:

Here is my slide presentation. There was one minor error in the chronology I sent previously (caught by a very sharp-eyed reader), so I'm sending the corrected version.

Ed

02N-0204

TS 30

Bar Code Label Requirement for Human Drug Products

FDA Meeting, July 26 2002

**Edwin A Steane, PhD
Executive Director
ICCBBA, Inc, York, PA**

What is ICCBBA, Inc?

**A not-for-profit independent organization,
incorporated in the Commonwealth of
Virginia, established to support, maintain
and extend *ISBT 128***

[<http://www.iccbba.com>]

What Is *ISBT 128*?

An internationally agreed-upon collection of data structures and their associated rules of use for data capture, labeling, process control, electronic data interchange and data management in transfusion medicine and transplantation

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More

***ISBT 128* data structures are designed to be technology independent; when used as bar codes, data identifiers have been registered so the bar code is uniquely recognized as a blood, stem cells or tissue product**

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We Would Like to Make Four Points

Point One

FDA should mandate the *use* of machine-readable data in therapeutic settings wherever possible

Point Two

The goal should be the elimination of data entry through the keyboard, by handwritten records, *etc*, to the greatest extent possible

Point Three

Emphasis should be placed on the standardization of data structures, not the technology to be used in capturing the data

Point Four

The information on a label should be that important to the end-user and should also be encoded, specifically including product identification and lot number

Build on Successful Models

- ◆ **Consumer electronics: model number, serial number**
- ◆ **Blood components: donation identification number, product code**
- ◆ **Retail sales: universal product code**
- ◆ **Automobile identification**

Standard Data Structure for Patient Identification

Not difficult; no need for hospitals to change their current numbering system; all that is needed is a standard “container” into which the number can be placed

Bar Coding of Whole Blood and Blood Components: An Historical Perspective and Present Status

Edwin A Steane, PhD
Executive Director, ICCBBA, Inc

ABC Codabar: the Old Standard

- In 1975, the American Blood Commission (now defunct), with the aid of a generous contract from the National Heart, Lung and Blood Institute, established the Committee for Commonality in Blood Banking Automation (CCBBA). Preliminary labeling guidelines for simplified labeling and bar coding of whole blood and blood components were adopted in January 1975 and became reality when the American Red Cross began using what came to be known as *ABC Codabar* somewhere around 1980. A preliminary committee report¹, dated August 29 1977, was transmitted to the ABC. This was followed by the publication of the full committee report (in seven (7) volumes²) by the ABC, with publication and distribution supported by a grant from the Henry J Kaiser Family Foundation.
- In 1985 the Food and Drug Administration (FDA) formally recognized *ABC Codabar*.³
- A 1989 revision⁴, published in draft format, was never formally recognized by the FDA, but became the *de facto* standard.
- Since no formal mechanism was established to maintain and extend *ABC Codabar*, many organization added functionality to meet their needs, but these additions could not be interpreted by other organizations.
- This was particularly true with respect to product coding, and as a result the American Association of Blood Banks (AABB) created a new Commonality Committee to “fix the problems.”
- Another group, the Working Party on Automation & Data Processing (WPADP) of the

¹ Report of the Committee For Commonality In Blood Banking Automation (CCBBA), August 29, 1977.

² Committee for Commonality in Blood Banking Automation, Final Report, 1977.
Volume I - Executive Summary.
Volume II - The CCBBA Labeling System & Code Assignments for Blood Products
Volume III - ABC Symbol
Volume IV - Application of ABC Symbol
Volume V - Results of CCBBA Field Tests
Volume VI - Dimensions & Print Specification for CCBBA Labels
Volume VII - Record of CCBBA Meetings & Proceedings of Wind-Up Meeting

³ Guideline for the Uniform Labeling of Blood and Blood Components, FDA in cooperation with ABC, August 1985.

⁴ Guidelines for the Uniform Labeling of Blood and Blood Components, American Association of Blood Banks, American Red Cross, & Council of Community Blood Centers in cooperation with ABC & FDA, DRAFT, August, 1989.

International Society of Blood Transfusion (ISBT) published a status report⁵ on *Automation & Data Processing in Blood Banking* in 1981. There was also an official report⁶ in the ISBT journal *Vox Sanguinis* published that same year.

- The ISBT WPADP continued to meet sporadically, and in 1989 began work on a new standard to replace *ABC Codabar*.
- When it was decided that *ABC Codabar* could not be “fixed,” the AABB Commonality Committee was folded into the AABB Information Systems Committee and began assisting in the development of the new ISBT WPADP standard.

ISBT 128: the New Standard

1989

- At a meeting of the ISBT WPADP in The Netherlands, Markus Fessler (Switzerland) and Bruce Wray (USA) jointly proposed changing the symbology used in labeling blood products from CODABAR to Code 128.
- In the USA, the merged AABB Commonality and Information Systems Committee and the American Red Cross (ARC) Labeling Issues Task Force propose that a permanent office be established to maintain and extend any new standard so that it would not again fall into disrepair, as occurred with *ABC Codabar*. With this proviso, AABB and ARC agree to fund at least one representative to work with the ISBT WPADP on developing a new standard based on Code 128.

1990 through 1993

- At meetings of the ISBT WPADP in Germany, France and Canada work continues on the development of the new standard, now called *ISBT 128*.
- Data identifiers proposed for *ISBT 128* bar codes are officially approved by the appropriate governing bodies and reserved for use in transfusion medicine.
- To speed up development, the ISBT WPADP agrees to hold a second meeting each year in conjunction with the AABB Annual Meeting.

1993

- AABB establishes an *ad hoc* committee to discuss the establishment of a permanent maintenance office and formally commit funds to the project.
- A draft business plan for the Council for Commonality in Blood Banking Automation (CoCBA) is prepared by the *ad hoc* committee and formally approved by AABB and ARC.
- The US Department of Defense commits to the new standard and issues a contract for services with the new office.

⁵ Automation & Data Processing in Blood Banking: a Status Report. October 1981.

⁶ Brodheim, E and Moore, BPL: Automation and Data Processing. *Vox Sang* 40: 129-244, 1981.

1994

- Baxter Healthcare, Deerfield, IL, USA provides a three-year grant to assist in the establishment of the office.
- AABB and ARC each appoint two persons and jointly appoint one more to form a five-member Board of Directors for the new office.
- In July, the ISBT Council approves the *ISBT 128* standard⁷ and agrees in principle to form the International Council for Commonality in Blood Banking Automation (ICCBBA) by adding members to the CoCBBA Board of Directors.
- The CoCBBA Board of Directors advertises for an appoint an Executive Director for the office, and the office opens on October 5 1994 in space rented from the AABB. The ISBT Council names three more persons to the Board of Directors of the CoCBBA, commits funds to the project, and ICCBBA becomes an official entity. The full Board of Directors holds its first meeting in November.

1995

- The ICCBBA Board of Directors meets in February, writes bylaws, establishes a budget, and prepares Articles of Incorporation for the subsequent incorporation of ICCBBA in the Commonwealth of Virginia.
- The ISBT Council formally cedes ownership of *ISBT 128* to ICCBBA, Inc.
- In March, the Blood Products Advisory Committee of the FDA votes to recommend the use of *ISBT 128* in the US according to a timetable presented by ICCBBA, Inc.
- ICCBBA, Inc applies for and receives not-for-profit status from the US Internal Revenue Service.
- Registration and license (user) fees are established at an ICCBBA, Inc Board of Directors meeting held at the AABB Annual Meeting in New Orleans.

1996

- ICCBBA, Inc Board of Directors establishes policies for release of ICCBBA, Inc-owned materials.
- Draft 4 of the US Industry Consensus Standard distributed. Discussed at a public meeting in Washington, DC, USA in December.

1997

- Version 1.0.0 of the US Industry Consensus Standard⁸ submitted to the FDA for review and comment. Version 1.1.0 was published for comment in the Federal Register. Acceptance was received and a guidance document published in the Federal Register in June 2000.

⁷ *ISBT 128: Bar Code Symbology and Application Specification for Labeling of Whole Blood and Blood Components*, draft 8.1, ISBT WPADP

⁸ *United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128*, Version 1.0.0, July 1996, ICCBBA, Inc

Keeping This Chronology Up-to-Date

In 1997, 1999 and 2001 ICCBBA, Inc published bi-annual reports. These are available to licensed users of *ISBT 128* in the Licensees Only section of the ICCBBA, Inc Website

(<http://www.iccbba.com>). Representatives of organizations not implementing *ISBT 128* may request electronic copies by sending an E-mail to iccbba@iccbba.com. Please indicate your affiliation and your organization's specific interest in your requesting message. Interested individuals may request electronic copies minus the financial statements by sending a similar E-mail. Financial reports are, as required by law, available for inspection at the ICCBBA, Inc office in Nashville, TN, USA. Should you wish to review the financial reports please send an E-mail requesting an appointment and suggesting possible dates to iccbba@iccbba.com.

All current documentation and code database tables for *ISBT 128* are maintained on the ICCBBA, Inc Website. The *Application Specification* is available for purchase. Other documentation, including the extension of *ISBT 128* to include hematopoietic progenitor cells (including cord blood cells) and other tissues, and the associated code database tables are available only to registered and licensed users.

ICCBBA, Inc maintains three Advisory Groups to assist in the maintenance and extension of *ISBT 128*. These are:

The Americas Technical
Advisory Group
Chairman: **Suzanne Butch**
(butchs@umich.edu)

the Middle East and Europe
Technical Advisory Group
Chairman: **Paul Ashford**
(paul.ashford@wbs.wales.nhs.uk)

and a Plasma Technical Advisory
Group
Chairman: **Wayne Barnett**

Please contact the appropriate chairman at the E-mail address listed for details about membership, liaison or observer status. Attendance as an observer at Technical Advisory Group Meetings is by invitation of the chairman only.

The current officers and members of the ICCBBA, Inc Board of Directors are:

Jukka Koistinen, Chairman
Helsinki, Finland
Charles Wallas, Vice-
Chairman
Chapel Hill, NC, USA
Louise Smith, Secretary
Los Angeles, CA, USA
Michael Fuller, Treasurer
Sacramento, CA, USA

Francine Décary
Montreal, Québec, Canada
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St Petersburg, FL, USA
Donald Fipps
Rosslyn, VA, USA

Wolfgang Mayr
Vienna, Austria
Michael Stanton
McLean, VA, USA
Richard Thomas
Berkeley, CA, USA

The most recently published report on the implementation of *ISBT 128* appeared in 2001 in *Transfusion Today*.⁹ For convenience, Table 1 from this paper, showing the status of world wide implementation of *ISBT 128* as of May 2001, is reproduced below.

TABLE 1 CURRENT STATUS OF IMPLEMENTATION OF *ISBT 128* (MAY 2001)

Austria	Plasma fractionator registered and licensed; rest of country by 2003.
Belarus	Registered facilities.
Belgium	Implementation in Flemish- and French-speaking parts proceeding.
Denmark	Ten percent of units labeled with <i>ISBT 128</i> , including international product codes. It is estimated that the figure will be approximately 50% at the end of the year.
Estonia	<i>ISBT 128</i> fully implemented with the exception of international product codes.
Eire	Will proceed to <i>ISBT 128</i> after implementation of new software this year.
Finland	Fully <i>ISBT 128</i> , including international product codes.
France	No plans to implement <i>ISBT 128</i> .
Germany	No plans to implement <i>ISBT 128</i> .
Iceland	Will implement fully in spring 2002, including international product codes.
Netherlands	<i>ISBT 128</i> fully implemented with the exception of international product codes.
Norway	Started. 60% will have fully implemented by the end of the year, including international product codes.
Portugal	Used in one institution (5% of collections). By the end of the year 33% of collections could be <i>ISBT 128</i> labeled.
Russia	Implemented in Ekaterinburg.
Slovenia	Registered facilities.
Spain	Registered facilities.
Sweden	Started. Fully implemented by the end of the year, including international product codes.
Switzerland	Full implementation planned for January 1, 2003.
Turkey	Used in one institution (1% of collections), but Red Crescent (50% of collections) is interested.
UK	Fully implemented donation number and blood group codes. Other codes to follow.
Egypt	Centers registered; implementation beginning soon.
Jordan	Centers registered; implementation beginning soon.
Kuwait	Centers registered; implementation beginning soon.
Oman	Centers registered; no information on implementation plans.
Canada	Committed to <i>ISBT 128</i> . Implementation date not yet set. Centers registered in Quebec. Canadian Blood Services registered for remainder of Canada.
USA	Committed to <i>ISBT 128</i> . Some implementation underway (Chicago, Mayo Clinic, Department of Defense); others early next year; some have not yet set date.
China	Shanghai and Wuhan registered and licensed; major software developer registered and licensed; no further information.
Hong Kong	Implementation to begin soon.
Australia	Committed to <i>ISBT 128</i> ; using Donation Identification Number for donor testing, but not yet for labeling; implementation plans progressing.

⁹ Georgsen, J, Ashford, P, Steane, E: *Status of Implementation of ISBT 128*. *Transfusion Today*, No 48, 3-5, September 2001.