



Cord Blood Bank Informatics



CBB Informatics Overview

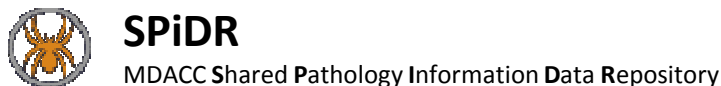
i **Cord Blood Information System (CBiS)**

- | Developed internally
- | Label Generation and Tracking
- | Donor Data Collection
- | Processing Data Collection
- | Testing/Reference Lab Data Collection

CBB Informatics Overview

- i Data for each cord blood unit is directly entered into and/or electronically transferred into CBiS from several different sources
- i Once all of the data is contained within the CBiS application and has been reviewed and approved, it is electronically transferred to the NMDP via Cord Link

OmniForm 5.0
Donor Questionnaire/Data Collection



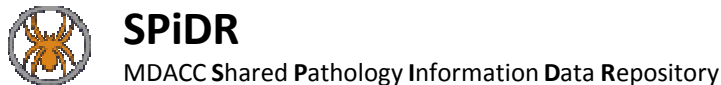
CBiS



Donor Data Collection

- i Cord donor and collection data is collected on laptop or tablet PCs utilizing a custom donor questionnaire developed using an off-the-shelf form building program called *OmniForms 5.0*

OmniForm 5.0
Donor Questionnaire/Data Collection



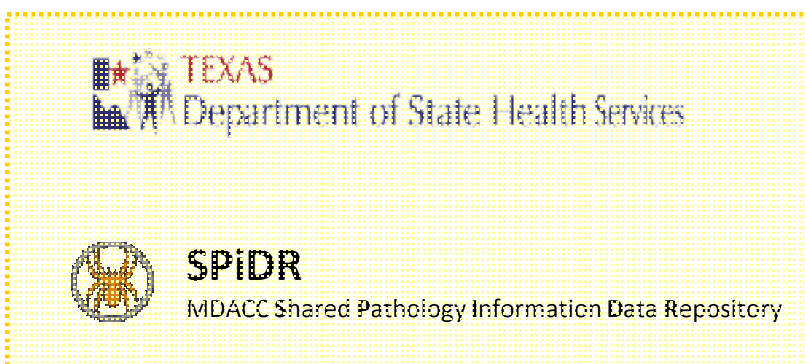
CBiS



Laboratory Informatics Integration

- i The M.D. Anderson Cord Blood Bank is currently importing all reference laboratory testing performed on both the cord and maternal samples
- i Improves efficiency while limiting data entry errors.

OmniForm 5.0
Donor Questionnaire/Data Collection



CBiS





Laboratory Informatics Integration

- i FTP file import from Texas Department of State Health Services (DSHS)
 - | Hemoglobinopathy Screening
- i DSHS generates an excel spreadsheet of HgB Screening results
- i Spreadsheet is secured by DSHS and then transferred to a secure folder on the MDACC FTP server.
- i We have developed and validated a service that checks the folder for new files and imports that data into our database.



Laboratory Informatics Integration

- i Institutional Web Service (SPIDR)
 - | Maternal Infectious Disease
 - | Maternal ABO/Rh
 - | Cord ABO/Rh
 - | Cord Microbiology

- i We developed and validated an interface that uses SOA (service oriented architecture) to communicate between the institutional pathology data repository and CBiS.

Laboratory Informatics Integration

- i The SPiDR data is interfaced directly into the CBiS application via an embedded web browser

The screenshot displays the Microsoft Access interface for the Cord Blood Information System (CBiS). The main window shows the patient ID 006185 and a table of clinical activities. The table is highlighted with a red border.

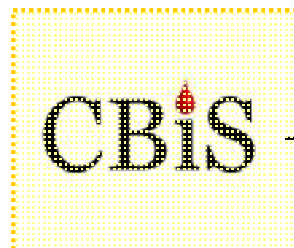
TEST NAME	REFERENCE RANGE	STATUS	REMARKS
ABO Rh	FOOTNOTE	F O POS	
CMV	F QNS	F NEGATIVE	
HBsAb	F QNS	F NON REAC	
HBsAb - QI			
HBsAg	F QNS	F NON REAC	
HCV Ab	F QNS	F NON REAC	
HIV1/2 NAT	F QNS	F NON REAC	
HIV 1 WB			
HIV 1/2 Ab	F QNS	F NON REAC	
HIV 2 ELA			
HIV NAT			
HIV 1/2 Ab	F QNS	F NON REAC	
HSA + TP			
MICRO			

Additional information visible in the interface includes the patient's status as 'Checked Into Lab (JMWILSON 10/01/2007 10:34)', the last comment as 'None', and a sidebar with navigation options like 'CREATE BARCODES', 'CORD UNIT CHECK-IN', 'DONOR & CORD DATA', 'CLINICAL ACTIVITIES', 'REPORTS & ANALYSIS', and 'LAB PROCESSING'. A disclaimer at the bottom states: 'Confidential - This system is intended for authorized users only. Report any suspected unauthorized activity to the Information Security Department at 713-745-3000. © 2005 M.D. Anderson Cord Blood Bank. All Rights Reserved.'

Laboratory Informatics Input

- i All other data is captured directly into CBiS.

OmniForm 5.0
Donor Questionnaire/Data Collection



Laboratory Informatics Input

- i Lab processing data is captured in 'real-time' in CBIS.

The screenshot displays the CBIS (Cord Blood Information System) interface. The window title is "CBIS - [Main Menu - Cord Blood Information System (CBIS)]". The user is logged in as JNWILSON on July 29, 2009, 09:34. The interface shows a search for Cord ID 019513, with a status of "Processing In Lab (SCRIPAN 07/29/2009 08:30)". The unit ID is 019513, and the maternal ID is MO19513. The interface is divided into several sections:

- LAB PROCESSING**: This section is currently active and contains sub-sections for "Processing & Cryopreservation", "Cord Blood Samples", "Maternal Samples", "Colony Forming Unit Assay", and "Flow & Specimen".
- UNIT LABEL INFORMATION AND VERIFICATION**: This section includes fields for "Collected At:" (The Methodist Hospital), "Collection Date:", "Bag Used:", "Time (24hr):", "Anticoagulant (ml):" (CPD), and "Total Volume on Label (ml):" (153). It also has checkboxes for "Bag label complete and unit # on bag matches database and transport list:" and "The condition and appearance of the bag was acceptable upon receipt:". A "Verify" button is present.
- PRE-PROCESS CALCULATIONS**: This section includes fields for "Unit Total Weight (g):", "Collection bag tare wt (g):", "Actual Unit Volume (ml):", "Unit total weight - col. bag tare wt.", "Actual CB Volume (ml):", "Actual unit vol - anticoagulant vol", and checkboxes for "Actual CB Volume \geq ml: Process Unit" and "Barcode labels printed and verified".

At the bottom left, there is a disclaimer: "Confidential - This system is intended for authorized users only. Report any suspected unauthorized activity to the Information Security Department at 713-745-9000. © 2005 M.D. Anderson Cord Blood Bank. All Rights Reserved."



Laboratory Informatics Interaction

- i The MDACC Cord Blood Bank transfers all cord data to the NMDP as XML using CordLink.
- i Once a record has been approved for upload, the XML document is created, based upon the document definition provided by the NMDP

```
<xdoc>
  <import_cbu>
    <ctr_code>173</ctr_code>
    <row>
      <abo_bld_typ>O</abo_bld_typ>
      <addtv_vol_pre_prcsng>35.0</addtv_vol_pre_prcsng>
      <baby_alc_gt_1500>U</baby_alc_gt_1500>
      <bact_cult_sts>N</bact_cult_sts>
      <b_dte>2009-06-12 18:06:00</b_dte>
      <cbb_lcl_registry_sts>AV</cbb_lcl_registry_sts>
      <cbb_val_protocol_used>N3</cbb_val_protocol_used>
      <cbu_prcsng_protocol_used>1.3</cbu_prcsng_protocol_used>
      <cbu_serum_aliquots_avail>0</cbu_serum_aliquots_avail>
      <cbu_vol_frzn>25.0</cbu_vol_frzn>
      <cbu_vol_pre_prcsng>84.8</cbu_vol_pre_prcsng>
      <cbu_vol_start_prcsng>119.8</cbu_vol_start_prcsng>
    </row>
  </import_cbu>
</xdoc>
```



CBB Informatics Change Management

- i Very rarely are the set of requirements for an informatics solution set into stone. Over time change is necessary for numerous reasons including:
 - l New internal process
 - l Evolution of existing process
 - l New regulatory requirements
 - l New technology



CBB Informatics Change Management

- i Change Management Process
 - | Provide a system for a change to be proposed
 - | Provide a system for technical review/risk analysis of the proposed change
 - | Provide a system for review of the change prior to implementation
 - | Provide notification to the user base once a change has been implemented



Cord Blood Bank Validation

- i All pieces of the MDACC CBiS application currently in production have been validated.
- i The application has been developed and validated in a 'modular' fashion adding pieces that interact, but typically address a specific issue on their own. The reasons for modular development are:
 - l Shorter timeframe for bringing a solution from development to production.
 - l Easier to address a smaller set of requirements
 - l Easier to validate a piece of the whole



Validation Process

- i The level of validation required is based upon the risk analysis performed in the change management process.
- i Use case analysis
 - l Each scenario where a user will interact with the interface being validated is defined
 - l The validation process is tailored for testing the application as it was intended to be utilized.



Validation Process

- i Test script generation based upon use case analysis.
 - l Test scripts are written to capture the following:
 - i Defined action
 - i Time of action
 - i Expected result
 - l User Interface
 - i Information is displayed properly
 - l Database
 - i Data is stored properly
 - i Audit trail is written
 - l Sometimes, more than one test script will have to be generated to adequately test an update.




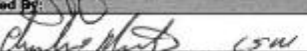
Validation Process

- i Test script execution
 - | Results are documented for both application/ user interface
 - | Any results not meeting the 'expected' result are reviewed and documented
 - i Error in script definition
 - i Error in script execution
 - i Error in application
 - | If an unexpected result is observed, the problem must be resolved and the script must be executed again to confirm that the issue observed has been resolved

Validation Process

i Test script (example)

Step	Description of Action	Expected Result	Result Observed
1	Cord Selection		
1.1	Identify Cord Unit ID and Cord Unit Collection Date and Time	Cord ID: 006200	Collection Date and Time: 11/5/2007 10:18am
1.2	Identify Maternal Sample Collection Date and Time	Maternal Sample Collection Date and Time: 11/4/2007 12:00pm	
2	Manual Data Entry		
2.1	Select the Cord ID from Step 1 using the CBIS user interface. Select the 'Clinical Activities' button from the menu. This will display the 'Enter and View Test Results' tab.	No Data Displayed in the 'Possible Reasons for Cord Blood Unit Rejection' list List of Initial Reactive/Non-Reactive Tests Displays the following tests: HBsAg, HbCAb, HCV Ab, HIV 1/2 Ab, HTLV I/II Ab, RPR, CMV, HCV/HIV NAT, WNV NAT, T. cruzi Ab	Result (Pass/Fail): PASS Result (Pass/Fail): PASS Screen Shot Attached: <input checked="" type="checkbox"/> Yes / No
2.2	Double Check that the 'Sample Collected On' combo box contains the Maternal Sample Collection Date and Time input in Step 1.2.	Maternal Sample Collection Date and Time: 11/4/2007 12:00pm	Maternal Sample Collection Date and Time: 11/4/2007 12:00
2.3	Select all available tests from the list and click the 'Non-Reactive' button	List will update the tests listed with: Result: 'NON REAC' Sample Collected On: '11/4/2007 12:00' Created By: 'JMWILSON' List of Possible Reasons for Cord Blood Unit Rejection will be updated with: Not all test results have been verified Testing detail display will be updated to display the Data Entry Tech and Data Entry Date and Time for the records with corrected/changed data	Result (Pass/Fail): PASS Screen Shot Attached: <input checked="" type="checkbox"/> Yes / No Update Date and Time: 11/8/2007 16:500 Result (Pass/Fail): PASS Screen Shot(s) Attached: <input checked="" type="checkbox"/> Yes / No
2.4	Print the updated results from the Lab Data Storage Database to show that data was inserted successfully. Compare the data against the expected data outlined in Data Table 1	Expected Data: Data should exactly match the data outlined in Data Table 1	Result (Pass/Fail): PASS

Performed By:  JMWILSON	Date: 11/5/2007 / 11/14/2007
Verified By:  CHARLES WHITE CSW	Date: 08/25/08



Validation Process

- i Validation Summary
 - | Summary Report:
 - i Summary of the testing procedure
 - i Issues observed
 - | All validation summaries must require review and signature of at least two individuals including one supervisor who was not involved in the testing process

Validation Process

i Validation Summary (example)



Validation of CBiS Manual Lab Data Entry

Overview:

The following validation tests conclude that the updated CBiS application in conjunction with a centralized departmental lab data repository is capable of properly capturing, verifying, and displaying lab data that is manually entered into the database by trained CBB staff. The validation involved the input of multiple lab results from multiple time points and multiple sources from 6 different cord blood units. The data was defined in test script documents and then input into the CBiS application. Upon completion of data entry, the screen output was compared against the manually entered lab result data defined in the test scripts for consistency and accuracy.

Validation Database Used: CB@RISTSSIT, SCTLD@RISTSSIT

Cord Blood Units Utilized: 006200, 006201, 006202, 006203, 006204, 006205

Main Issues or Comments: No unexpected results occurred during testing. All data displayed post manual entry exactly reflected the data defined in each test script for each cord.

Summary

The manual lab data entry process can repeatedly, reliably, and accurately capture lab data results manually entered through the updated CBiS application.

Supporting Documentation:

1. Hard copy of manual data entry test script for maternal initial reactive/non-reactive test results section including screenshots and database printouts
2. Hard copy of manual data update test script for maternal initial reactive/non-reactive test results section including screenshots and database printouts
3. Hard copy of manual data entry test script for other initial test results section including screenshots and database printouts
4. Hard copy of manual data update test script for other initial test results section including screenshots and database printouts
5. Hard copy of manual data entry test script for additional test results section including screenshots and database printouts
6. Hard copy of manual data update test script for additional test results section including screenshots and database printouts
7. Documentation of old and updated code for each object updated in the CBiS application

Testing Performed By:  Date: 12/17/2007

Results Validated By:  Date: 12/20/2007

Reviewed By:  Date: 02/25/08

Validation Process

