Moving Towards the Vision: Integrating the Cancer Registry into Clinical Research

Joyce C. Niland, Ph.D.
Chair, Division of Information Sciences
City of Hope National Medical Center
“Given the changes we are experiencing in medicine, the threats to the viability of the registry profession, and the potential opportunities for the future, the characteristics of successful cancer registrars most likely will include:

• flexibility, adaptability, ability to be proactive, assertiveness,
• willingness to learn new things
• willingness to collaborate and work in partnerships
• and an entrepreneurial outlook.”

*D.S. Miller, MD, MPH, Journal of Registry Management, 26:2, 1999*
Outline:

- City of Hope National Medical Center
  - IAIMS at COH
  - Cancer Registry
  - Clinical Trials Data
  - Outcomes Research

- Integrating the Registry into Clinical Research
  - Analysis of Data Flow
  - Re-engineering of Workflow

- Future Plans
City of Hope National Medical Center

- Began as 2 tents in the desert as a TB sanatorium in 1913
- Established as a hospital, moved to cancer emphasis ~ 1950s
- Now designated by NCI as a Comprehensive Cancer Center
State-of-the-art care to patients with cancer & other life-threatening diseases
- 200 beds, 110 MDs
- 2700 cancer patients/year

First of 5 endowed Beckman Research Institutes in the nation
- Leading edge research into causes, prevention, and cure of such diseases
- 154 research scientists
- $45 million in grants
3 Operational Systems for Cancer Patient Data at COH

- Cancer Registry: CNext
- Clinical Trials: BITS
- Outcomes Research: NCCN
Ultimate Goals for Integrated Information Systems

- Capture highest quality data one time at the source of origin
- Share data electronically as appropriate and as needed
- Create information out of data in near real time, with quality control “up front”
- Apply tools to create knowledge out of the information
Challenges in Data Integration

- Operational systems were created to meet different functional needs of an institution

- Clinical research systems are developed independently over time ("silos" approach)
  - Systems, rules, processes, and vocabularies for data collection vary
  - Standards for patient data collection are needed

- Semantic/conceptual barriers pose substantial challenges to database interconnectivity
  - Leads to the requirement for "metadata"
CNExt:
State Developed
Cancer Registry
Software System
### CONFIDENTIAL REPORT OF NEOPLASM

**DIAGNOSIS:** Lymph Nodes R Supraclav

**DATE:** 06/13/1998

**CITY OF HOPE:**

**FIRST SEEN:** 11/21/2001

**ACCESSION NO.:** 20010123800

**DOC NO.:** 05/07/2002

**PHYS.:**

- **ATTENDING:** SPIELBERGER, R MD 0015022
- **REFERRING:** SPIELBERGER, R MD 0015022
- **SURGEON:** RAUBITSCHEK, A MD 0013427

**TUMOR MARKER:**

- **NOT APPLICABLE**

**STAGING:**

- **STAGE:** DISTANT MET
- **POS. HISTOL:**

**RACE:** WHITE

**PLACE OF BIRTH:** UNKNOWN

**PLACE OF DIAGNOSIS:** Kaiser San Diego

**HOSPITAL REFERRED FROM:** KAISER SUNSET

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<th>REASON</th>
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**SUM SURGERY:**

- **DATE NON CA:** 06/18/1998
- **NON CA DIR:** 02/00
- **RECONSTRUCT SRS:** 0/0

**LABORATORY TESTS:** 7/10/01 HIV Neg.

**DIAGNOSTIC PROCEDURES:**

- **PATHOLOGIST (GROSS & MICRO):** S01-6419
- **PATHOLOGIST:** S016419

**REMARKS:**

- **OHT. IX. CHM.:**
- **RAD.:**

**FOLLICULAR LYMPHOMA**

**CONFIDENTIAL**

**DATE PAT CONF.:** 02/28/2002

**VITAL STAT.:** ALIVE

**DATE L TUM ST:** 02/28/2002

**TIM STAT.:** FREE

**TYPE LAST PULP:** READMISSION

**TYPE LAST TUMFUP:** READMISSION

**CONFIDENTIAL REPORT OF NEOPLASM**

**CNEvT Software**

**Public Health Institute**
E-Path:
Automated Case Finding

ISIS-Registrar:
Electronic Path Reports
### PATHOLOGY REPORT

<table>
<thead>
<tr>
<th>Report Identification</th>
<th>Patient Information</th>
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<td>Institution: CCO</td>
<td>Chart/MRN: 452616</td>
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<td>Pathology ID: 97.52532</td>
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<tr>
<td>Pathologist: LAFARGA, A</td>
<td>Ethnicity:</td>
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</table>

### DIAGNOSIS

A. SEGMENT OF SIGMOID COLON, WELL DIFFERENTIATED ADENOCARCINOMA INFILTRATING FULL THICKNESS OF THE BOWEL WALL AND FOCALLY THE SEROSA.

ALL THE MESENTERIC LYMPH NODES ARE FREE OF METASTATIC TUMOR.

TUBULAR ADENOMA.

ADENOMATOUS POLYP.

B. PROXIMAL AND DISTAL RINGS OF ANASTOMOSIS, FREE OF TUMOR.

/Un

### Clinical History

Not available on the requisition.
BITS:
Biostatistics Information Tracking System
Clinical Trials at City of Hope

- Approximately 350 open trials at City of Hope
  - Over 150 treatment trials open to accrual

- Sponsorship of protocols:
  - ~1/3 National Cooperative Groups
  - ~1/3 Pharmaceutical Sponsors
  - ~1/3 Intramural Trials

- Developed centralized in-house data repository / data collection application in 1989:
  - BITS: Biostatistics Information Tracking System
AUTOLOGOUS BMT
DATA COLLECTION FORM:
Hodgkin's Disease & Non-Hodgkin's Lymphoma

Missing value codes for fill-in blanks: -8=N/A and -9=missing or unknown
Please do not use missing value codes in date fields.

Date Form Completed: 6/12/02
Completed By: Mudra Nathwani

A. DEMOGRAPHICS
First Name: ____________ MI: - Last Name: ____________

Treating MD: Molina

Medical Record Number: [Redacted] Protocol Number: 55555

B. PATHOLOGY AT DIAGNOSIS

Date of Diagnosis: 1/19/01 Missing ☐ (-9)

Diagnosis:
- Hodgkin's Disease [□ (4)]
- Composite HD & NHL [□ (10)]
- Non-Hodgkin's Lymphoma [X (3)]
- Missing [□ (-9)]
- N/A [□ (-8)]

Other Specify________ [□ (99)]

Date of Biopsy: 1/19/01 Missing ☐ (-9)

Site: Clavicle

Hodgkin's Disease:
- Lymphocyte predominance [□ (1)]
- Nodular sclerosis [□ (2)]
- Mixed cellularity [□ (3)]
- Lymphocyte depletion [□ (4)]
- Other Specify________ [□ (99)]

Non-Hodgkin's Lymphoma:
- Low grade [□ (5)] Specify: E (Mantle cell)
- Intermediate grade [X (6)] Specify: E (Mantle cell)
- High grade [□ (7)] Specify:
- Other [□ (99)] Specify:
- Missing [□ (-9)]
BITS II

“Son of BITS” *

*Caution: speak slowly & enunciate very clearly
**Patient Diagnosis Entry**

**Identifying Information**
- Medical Record No: 91-11-56-B
- DX Sequence No: 1
- Name: Duck, Kozmo
- Date of DX: 12/04/1989

**Primary Diagnosis**
- **Primary Site**: C42 - BONE MARROW
- **Histology**: 9861 - ACUTE MYELOID LEUKEMIA
- **Behavior Code**: ...  
- **Differentiation Code**: AML

**Prior Diagnosis**

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<tr>
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<th>Histology</th>
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<tr>
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</tr>
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</table>

**Concurrent Primary Diagnosis**

- Revised by: AJINENZ
- Revised on: 03/30/1999
Enhancements to BITS II

- Migrating from AREV to MS SQL Server 7.0
- Web-browser application for direct data entry from local or remote sites
  - Allow direct data entry from multiple sites
- Developing additional electronic interfaces
  - IRB database system, HLA data, cytogenetics
- Re-engineering of data collection to include Cancer Registry and outcomes staff
Internet-based Data System:
The NCCN Outcomes Research Database
NCCN Outcomes Research Data System

- Alliance of 20 national cancer centers
- Experts developed evidence-based clinical guidelines
Primary Treatment

Stage I, IIA, IIB

- Lumpectomy, level I, II axillary dissection\(^b\) and radiotherapy (preferred)\(^a\)
- Total mastectomy with level I, II axillary dissection ± reconstruction

- Premenopausal + 1-3 positive nodes
- Tumor > 5cm or margins positive
- Premenopausal + 0 positive nodes + tumor ≤ 5cm + margins negative
- Postmenopausal + < 4 positive nodes + tumor ≤ 5cm + margins negative

- ≥ 4 positive nodes
- Consider postchemotherapy RT to chest wall + SCV area (category 3; controversy is “consider” vs “should”); consider internal mammary irradiation (category 3; controversy is no RT vs “consider”)
- Postchemotherapy RT to chest wall + SCV area
- No RT

\(^a\) See Relative Contraindications to Breast Conserving Surgery (BINV-19)
\(^b\) See Axillary Dissection (BINV-20)

No RT
NCCN Outcomes Research Data System

- Alliance of 20 national cancer centers
- Experts developed evidence-based clinical guidelines
- Conducting research to measure treatment patterns and outcomes
- COH serves as Data Coordinating Center
- Created an Internet-based data system, deployed nationwide for past 5 years

Use of Tamoxifen in Patients with DCIS* Within 180 Days of Diagnosis

Tamoxifen time trend is statistically significant controlling for center (p <0.0001)

* DCIS: Ductal Carcinoma in Situ
Demographics

Record Complete: 1=Yes

Date of Birth: 01/20/1956 (mm/dd/yyyy)

Racial Background: 4=American Indian, Aleutian, Eskimo

Other race type: 

Spanish/Hispanic Origin: 1=Non-Spanish/Non-Hispanic

Gender: 1=Female

Cause of Death, ICD Code: 
Structure of Clinical Data Systems within the Division of Information Sciences

Cancer Registrars

CNET2

All Cancer Patients at City of Hope

Demos

Accession

Diagnosis

Treatment

Outcomes

Follow-up

NCCN

Treated Patients with Major Cancers

Past Hx

Presentation

Treatment

Clinical Trials

Outcomes

Follow-up

Outcomes Data Managers

BITS

Protocol Data

Past Hx

On-Study

Treatment

Toxicity

Outcomes

Follow-up

Clinical Research Associates
Future Clinical Data Systems within the Division of Information Sciences

- Protocol Data
- Patients with Disease
- Presentation Demos Diagnosis
- Past History
- Protocol (Standard or Clinical Trial)
- Treatment
- Toxicity
- Outcomes
- Long-Term Follow-up
How Do We Get There from Here?

The Analysis......
A Case Study:

Shared Data for Non-Hodgkin's Lymphoma (NHL) Patients
Intersecting Data Collection for NHL Patients

NCCN:
More Common
NHL Histologies

BITS:
All NHL BMT Recipients
# Reporting Requirements

**Cancer Registry:**  
State of California Department of Health Services  
American College of Surgeons  
SEER

**NCCN:**  
Disease-specific Executive Committee

**BITS:**  
COH Investigators  
Study Sponsor  
National Cancer Institute
<table>
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<tr>
<th>Inclusion Criterion:</th>
<th>Cancer Registry</th>
<th>NCCN Outcomes</th>
<th>BITS Clinical Trials</th>
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<tbody>
<tr>
<td>Histology</td>
<td>Any</td>
<td>Common only</td>
<td>Any</td>
</tr>
<tr>
<td>Age</td>
<td>Any</td>
<td>&gt; 18 years</td>
<td>&gt; 18 years</td>
</tr>
<tr>
<td>Prior Cancer</td>
<td>No exclusion, all recorded</td>
<td>No concurrent cancer</td>
<td>No previous cancer</td>
</tr>
<tr>
<td>Prior Treatment</td>
<td>Analytic &amp; non-analytic</td>
<td>Primary rx at institution</td>
<td>Any (record all prior rx)</td>
</tr>
<tr>
<td>Current Treatment</td>
<td>Any</td>
<td>Any</td>
<td>BMT</td>
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# Processes & Timing of Data Collection

<table>
<thead>
<tr>
<th>Organization</th>
<th>Timing of Data Collection</th>
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<tbody>
<tr>
<td><strong>Cancer Registry:</strong></td>
<td>Data collection starts after completion of 1st treatment course. Treatment prior to presentation requested, not required. No consent required.</td>
</tr>
<tr>
<td><strong>NCCN:</strong></td>
<td>Data collection starts after consent. Treatment prior to presentation and outside treatment requested. Consent required prior to data collection.</td>
</tr>
<tr>
<td><strong>BITS:</strong></td>
<td>Data collection starts 100 days post-BMT. All treatments and relapses prior to presentation to COH must be recorded. Outside treatment required from physician offices or hospitals. Consent required.</td>
</tr>
<tr>
<td>Data Element</td>
<td>Cancer Registry</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Name</td>
<td>✔</td>
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<tr>
<td>Medical Rec #</td>
<td>✔</td>
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<tr>
<td>DOB</td>
<td>✔</td>
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<tr>
<td>Gender</td>
<td>✔</td>
</tr>
<tr>
<td>Race</td>
<td>Very Detailed</td>
</tr>
<tr>
<td>Hisp Origin</td>
<td>✔</td>
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<tr>
<td>Diagnosis</td>
<td>Clinical</td>
</tr>
<tr>
<td>Disease /</td>
<td>Follow</td>
</tr>
<tr>
<td>Vital Status</td>
<td>Annually</td>
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</table>

* After 1 year post-BMT annual follow-up done through COH
Long-term Followup Office
### Entity-Attribute-Value (EAV) Map

<table>
<thead>
<tr>
<th>Super Type Entity</th>
<th>Sub Type Entity</th>
<th>Attribute (Data Element)</th>
<th>Description</th>
<th>Domain</th>
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<tbody>
<tr>
<td>Person</td>
<td>Patient</td>
<td>Gender</td>
<td>Patients</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>NCCN</td>
</tr>
</tbody>
</table>

### System Data Dictionary

**CNET**

**Technical Directory:**
This area describes the field format, length, storage, etc.

**Business Directory:**
This area defines the element from the user’s perspective.

### Domain Value Map

<table>
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# NHL Treatment and Complication Data

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<th>BITS Clinical Trials</th>
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<tbody>
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<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Chemo End Date</td>
<td>Text</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Drugs Rec’d</td>
<td>Single vs.</td>
<td>Coded</td>
<td>Coded</td>
</tr>
<tr>
<td></td>
<td>Multiple</td>
<td></td>
<td></td>
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<td>Chemosensivity</td>
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<td>✔️</td>
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<tr>
<td>Rx Complications</td>
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<td>10 Major</td>
<td>Detailed CTC</td>
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* After 1 year post-BMT annual follow-up done through COH Long-term Followup Office
Re-engineering of Workflow

Developing a system in which Cancer Registrars, Outcomes Data Managers and Clinical Research Associates combine efforts to eliminate redundant data, share data collection efforts
**Assumptions:**
- Bone Marrow Transplant Patient is when a patient has been accessed and a schedule generated

**Tasks:**
- Clean-up in BITS of the diagnosis record and retrospective data collection, summary diagnosis, table relational structure, reports
Staging of Data Integration Across Data Systems

- Initial Presentation
  - Diagnosis and Staging

- Long Term Follow-up
  - Relapse and Survival

- General Case Reviews
1. Diagnosis and Staging

- Change timing of CTR case review
  - CRA contacts assigned CTR when patient to go on clinical trial
  - Accept Cancer Registry diagnosis information as most accurate for all cancers
- Process created for rectification of disagreements
  - Provides additional quality assurance of data
- Fields added to track method of diagnosis
  - Different rules by reporting requirements
- Non-cancer diagnoses handled by CRA
2. Follow-up Data

- Phase in Cancer Registry collection of follow-up data, beginning with patients on national cooperative group studies
  - death and relapse only
  - contact outside sources for more detail
    - including some toxicity data
  - bring follow-up to within 12 months minimum
- CRAs continue to follow other patients
- Phase in additional Cancer Registry follow-up now that this segment is successful
3. Sharing of Case Reviews

- Initiator of case shares completed data
  - Generally NCCN or BITS data completed first
  - Central registration of cases to determine if data already abstracted for a given patient
  - Online view-only access to each data system

- Subsequent data abstractors utilize information collected to date
  - Saves time, must be mindful of differences in definitions, timing, context
  - Provides additional quality assurance
  - Process for resolving discrepancies
Issues and Findings to Date

• Most granular data should precede others
• Need to be continually mindful of differences in definitions, context of data collection
  – Accurate metadata!
• Improved accuracy achieved in many cases
  – Price is delays in collection, timing issues
• Able to bring CT follow-up into compliance through assistance by Registry staff
• Has led to improved communication and data flow between the 2 areas
  – Physical joint relocation of staff offices a plus
Future Plans

Based on lessons learned through this process:

• Provide electronic data exchange among CNext, BITS, and NCCN systems
  – No redundant data entry
  – Requires ability to add user-defined builds
  – Ideal is to import electronic files into CNET

• Explore enhancement of data sharing e.g. via coded treatment data for all modalities

• Develop Web application interface for data collection

• Include systems as operational data ‘feed’ into research data warehouse

• Lessons learned are informing our model for “Fully Integrated Research Standards & Tech”
Prediction for the Future of Tumor Registrars...

Outcomes Research Associates of the Future!
Thanks to my collaborators….

Ina Ervin, Cancer Program Coordinator
Janet Nikowitz, Outcomes Research Coordinator
Joycelynne Palmer, Sr. Systems Analyst
Geri Connie, CTR, Outcomes Data Manager
Mudra Nathwani, Clinical Research Associate
QUESTIONS?
Transition from Today…

**Today**
- Automated
- WEB
- FAX
- Paper

**12-24 Mo**
- Automated
- WEB
- FAX
- Paper

**5 Years**
- Automated
- WEB
- FAX
- Paper
Our Ultimate IAIMS Integration Project:
Research Data Warehouse
Obstacles to Data Warehousing for Research

- Semantic/conceptual barriers pose the most substantial challenges to database interconnectivity

- Standards for patient data are needed
  - Data collection methods, taxonomies, level of comprehensiveness, granularity, and knowledge representation schema

- Leads to the requirement for “metadata”, including unique concept identifiers and mapping tools
### Operational Systems:

<table>
<thead>
<tr>
<th>System</th>
<th>A2K</th>
<th>OACIS</th>
<th>CNET</th>
<th>BITS</th>
<th>NCCN</th>
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<td>Propr-1</td>
<td>ACOS</td>
<td>Propr-1</td>
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<td>SNOMED*</td>
<td>ICD-0*</td>
<td>ICD-9, NCI</td>
<td>ROADS</td>
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<td>(Text)</td>
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*In the UMLS*

<--- - - -Vocabulary- - -->
### Operational Systems:

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<td>(Text)</td>
<td>Propr-3</td>
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<td>(Text)</td>
<td>ACOS</td>
<td>Propr-6</td>
<td>ACOS</td>
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</tbody>
</table>

*-In the UMLS

**Unified clinical research system**
Metadata Are Critical!

- **Data about the data:**
  - What data are available?
  - Who is responsible for it? (“data stewards”)
  - Where is it stored? In what format? etc

- **Technical Directory:**
  - Field name, format (character/numeric), length....

- **Business Directory:**
  - Definition of data field, how is it collected, what is the context, where is it used, .....
IAIMS: Integrated Advanced Information Management Systems
Integrated Advanced Information Management System (IAIMS) Program

- Founded by the National Library of Medicine in 1984 to facilitate and fund information systems and integration.

- Goals:
  - Manage medical knowledge more effectively.
  - Provide for a system of comprehensive and convenient information access.

- City of Hope funded by IAIMS program:
  - Phase I Planning Grant: 1996-1998
  - Phase II Implementation Grant: 1998-2003
Biostatistics Information Tracking System (BITS)

CPRMC / IRB

Accession Logs

Reports (NCI)

Protocol Data

Patient Data

Mainframe