

An Update on i2b2 and Registries at CCHMC

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Overview

- i2b2 (non-registry)
 - Background
 - Current projects
 - De-identified
 - QI
- Registries
 - Clinical registries @ CCHMC
 - Epic-based
 - i2b2
- Question & answers

What is i2b2?

- i2b2 = Informatics for Integrating Biology & the Bedside
- National Center for Biomedical Computing (NCBC)
 - Funded by NIH to develop national computational infrastructure for biomedical computing
 - Centered at Partners HealthCare in Boston
- Open-source warehouse architecture
 - Based on Research Patient Data Registry developed at Massachusetts General Hospital (MGH)
 - Geared toward identification and analysis of patient cohorts.

What is i2b2? (cont'd)

- Adoption/Evaluation
 - Over half of CTSA's
 - International – Europe, Asia
 - Pharma
- Development
 - i2b2 1.0 – driven by i2b2 team
 - i2b2 2.0 – community driven
 - CCHMC code now publicly available
 - Used by collaborators at Children's Boston
 - Recombinant Data Corp.

De-identified i2b2

- Use case
 - Cohort identification
 - How many patients meet criteria X, Y and Z?*
 - Preparation for research, grant submissions, etc.
- Functionality
 - Obfuscated aggregate counts
 - Workflow to request elevated access (coming soon)
 - De-identified: “Automated” access - similar to Data Use Agreement
 - Chart Review (through workbench)
 - Extracts (TBD)
 - Identified: Still submit through IRB

De-identified i2b2 – Data

- Available now
 - Demographics
 - Diagnoses
 - Problem List
 - Encounter
 - Discharge
 - Medication Orders
 - Procedures
 - Lab Results
- Coming soon
 - Flowsheets
 - Medical & Surgical History
 - Notes (Progress, Admission, etc.) (de-identified)
 - Pathology & Surgical Reports (de-identified)

CCHMC i2b2 workbench

The screenshot displays the CCHMC i2b2 workbench interface, which is used for building and executing clinical queries. The interface is divided into several sections:

- Navigate Terms / Find Terms:** A search bar contains the text "Toxic Effect Of Lead And Its". Below it is a tree view of the Epic Ontology, with "Demographics" expanded to show "Age" categories. The "07-09 years old" category is currently selected.
- Query Tool:** This section contains three query groups, each with a "Dates", "Clear", and "Exclude (x)" button.
 - Group 1:** Contains a tree view with "04-06 years old" expanded, showing sub-categories "04 years", "05 years", "06 years", "07-09 years old", "07 years", "08 years", and "09 years".
 - Group 2:** Contains a single term "Male".
 - Group 3:** Contains a tree view with "Toxic Effect Of Lead And Its C" expanded, showing terms like "Blue Line Gum(984.9AA)", "Blue Line Of Gum(984.9B)", "Blue Line On Gingivae(984.9C)", "Blue Line On Gums(984.9D)", "Burton'S Line(984.9C)", "Burton'S Lines(984.9AD)", "Chronic Lead Nephropathy", and "Galic. Deusschire Mee(984.9B)".Vertical "AND" labels are positioned between the groups, and a large "OR" label is centered between the first and second groups. Each group has a "Drag terms here" label at the bottom.

Below the query tool is a large blue button labeled "Run Query".

At the bottom of the interface, there are two sections:

- Previous Queries:** A box with a question mark icon and the text "Drop here to display saved query results".
- Query Results:** A box displaying "Patient Count: 186 (+/-3)".

Other Functionality

- Auto Suggest
 - Current: simple text matching
 - Future: semantic filtering (“spinal tap” = lumbar puncture)
- XML Filtering
 - Search for problem list vs. encounter diagnosis
- Age at Event
 - Find patients who had observation occur at, before, or after a given age
- Chart Review (next slide)
 - Must request access
 - Only for single cohort, limited time frame

The screenshot displays a search interface with the following components:

- Search Bar:** Contains the text "Toxic Effect Of Lead And It" with a magnifying glass icon.
- Search Results:** A list of three items:
 - Toxic Effect Of Lead And Its Compounds (Including Fumes)
 - Toxic Effect Of Lead And Its Compounds (Including Fumes)(984.9AL)
 - Toxic Effect Of Lead And Its Compounds(984.9Z)
- Constrain by diagnoses:** A sub-window titled "Blue Line Gum(984.9AA)" with instructions: "Select the filter group. In each filter group, you can choose from a series of diagnoses filters pertinent to that group. The filters work within the context of the filter group, and a patient is considered a match if 'any' of the filter group's match. If no filters are defined within a given filter group, then that group's match criteria will be ignored. Only configure the filters that meet your cohort criteria; irrelevant filters will be ignored."
 - Buttons: ProblemList, EncounterDx, DischargeDx
 - Table with columns: Chronic?, Class Of Problem?, Problem caused in hospital?, Priority?, Status?

| Chronic? | Class Of Problem? | Problem caused in hospital? | Priority? | Status? |
|----------|-------------------|-----------------------------|-----------|----------|
| N | Stage 2 | N | Low | Active |
| Y | Acute | Y | Medium | Deleted |
| | Chronic | | High | Resolved |
| | Temporary | | | |
| | End Stage | | | |
| | Stage 1 | | | |
| | Minor | | | |
 - Buttons: Save, Reset
- Age At Event:** A sub-window titled "Blue Line Gum(984.9AA)" with fields:
 - Operator: --choose--
 - Unit: Year(s)
 - Age: [text input field]
 - Buttons: Apply, Cancel

Chart Review

Choose Patient

Show

| | | | | | | |
|----------|-----|------------|------------|--------------------|----------|----------------|
| i2b2 ID: | Sex | Birth Date | Death Date | Race | Religion | City/State/Zip |
| 4153722 | F | 2007-03-12 | | White or Caucasian | BAPTIST | 41051 |

Lab Tests Medications Diagnosis Encounters

Encounter Filter (click encounter to display encounter details)

| # | Start | End | Location | In/Out |
|------------|------------|-----|----------|--------|
| 1014340667 | 2010-09-16 | | | |
| 1014340668 | 2010-09-16 | | | |

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Diagnosis

| Start Date | End Date | Diagnosis | Type | Status | Class | Primary? | Chronic? |
|------------|----------|----------------------------------|-----------|---------|-------|----------|----------|
| 2010-09-16 | | Nevus(216.9EZ) | NN | | | No | No |
| 2010-09-16 | | Accommodative Esotropia(378.35A) | NNDeleted | Deleted | | No | No |
| 2010-09-16 | | Accommodative Esotropia(378.35A) | NN | | | No | No |
| 2010-09-16 | | Accommodative Esotropia(378.35A) | NN | | | No | No |
| 2010-09-16 | | Aphakia(379.31) | NN | | | No | No |

Medications

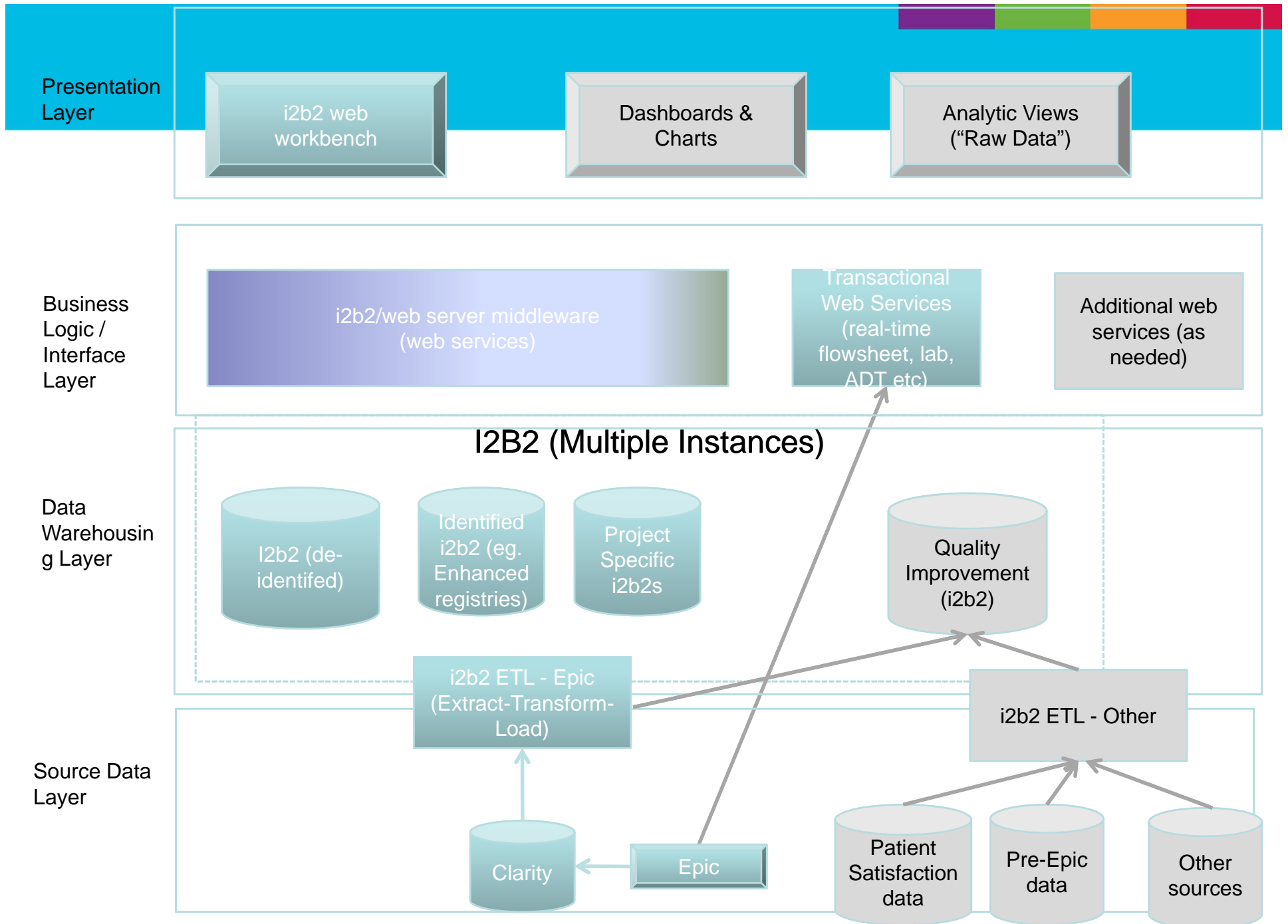
| Order Date | Medication | Value | Form | Route | Strength |
|------------|-------------------------------|-------|-----------|---------------|-----------|
| 2010-09-16 | Influenza Virus Vaccine Split | | Injection | Intramuscular | |
| 2010-09-16 | Levothyroxine Sodium | | | Oral | |
| 2010-09-16 | Psyllium | | Cap | Oral | 0.52 GM |
| 2010-09-16 | Acetaminophen-Codeine | | Tab | Oral | 300-30 MG |
| 2010-09-16 | Allopurinol | | Tab | Oral | 300 MG |

De-identified i2b2 – Access

- Available to anyone with CCHMC login
- <http://i2b2.cchmc.org> for access information
- Instructions and training opportunities coming soon
- Feedback & suggestions for additional functionality are appreciated

Performance Measurement and Reporting System (QI i2b2)

- Collaborative effort of BMI, IS, and Anderson Center
- Main goals:
 - Automated calculation of outcome measures, other metrics (actual i2b2 part)
 - Standardized “look and feel” of dashboards and control charts
 - Data entry system for manual values
- Wiki to store data definitions – common metadata
- Prototype Example – Periop noon time cases that start on time



NoonTimeCases - Wiki

MEASUREMENT

Percentage of mid-day perioperative cases starting on time.

Description and Rationale

This measure is an indicator of the timeliness of services provided to patients as well as a measure of how effective morning cases were so that we can expect the day to end on time. This measure is for cases at Main and Liberty campuses. They are analyzed and reported separately.

Population Definition (Inclusions/Exclusions)

Only Periop cases scheduled mid-day are used for this measure.

Exclusions:

- add-ons
- cancelled cases
- CCU Cases
- ICU Cases
- RCNIC Cases
- CT scans
- MRIs
- Interventional Radiology
- Cath Lab
- Weekends

Cases that are considered bad data are also excluded as follows:

- If a case occurred over 12 hours before it was scheduled or more than 12 hours after it was scheduled it is excluded.
- If a case's actual room duration is ≤ 0 or > 18 hours, it is excluded
- If a case's scheduled room duration is ≤ 0 or > 18 hours, it is excluded

Data Source(s)

Prior to July, 2008: Centricity Perioperative Management System (CPM) relational database

After July, 2008: EPIC

Sampling and Data Collection Plan

All cases are included. Data are collected and entered into the CPM and EPIC systems by Perioperative personnel.

Detail

This measure shall be further analyzed based on the following:

- Case was on time
- Location (campus and room)
- Day of the week
- Scheduled Service
- Primary Surgeon
- Count of Actual Procedures in a Case

NoonTimeCases – i2b2

Navigate Terms Find Terms

Query Tool

New Query Add Group

1 Dates Clear Exclude (x)

NoonTime Cases on time- Yes/No

OR AND

Drag terms here

Previous Queries ?

Drop here to display saved query results

Query Results

Patient Count: 3209 (+/-3)


| On Time? | Room? | Location? | Role? | Prov Name? |
|----------|--------|------------------------------|----------------------|-----------------------|
| 0 | L OR06 | LIBERTY PERIOP SVCS LOCATION | Fellow | BROMWICH, MATTHEW A. |
| 1 | OR14 | MAIN PERIOP SVCS | Assisting | BUCUVALAS, JOHN C. |
| | OR24 | | Co-Primary | EGHTESADY, PIROOZ |
| | OR25 | | Resident - Assisting | FYE, WILLIAM M. |
| | OR19 | | Primary | GAMMON, STEVEN R. |
| | OR22 | | Resident - Observing | GREINER, JENNIFER L. |
| | L OR08 | | | JAMES, JEANNE M. |
| | OR21 | | | KESSELRING, AUDREY A. |
| | L OR07 | | | KOCH, BERNADETTE L. |
| | OR04 | | | KOCOSHIS, SAMUEL A. |

| Service? | Proc Name? |
|------------------|--|
| Anesthesiology | ABCESS I & D |
| Cardiology | ABD. SCAR REVISION |
| Cardiothoracic | ADENOIDECTOMY |
| Colorectal | ADENOIDECTOMY W/ MYRINGOTOMY & INSERT PET |
| Dental | ALVEOLAR CLEFT CLOSURE W/ BONE GRAFT |
| Fetal Surgery | ANAL BOTOX INJECTION - W/ FELLOW |
| Gastroenterology | ANKLE ARTHRODESIS |
| General Surgery | ANKLE ARTHROSCOPY W/ DRILLING OCD LESION & INT. FIXATION |
| Gynecology | ANKLE BONE BX |
| Hematology | ANKLE HARDWARE REMOVAL |

| Sched Casetime? | Sched Roomintime? | Sched Setuptime? | Sched Dayofweek? |
|-----------------|-------------------|------------------|------------------|
| | | | Friday |
| | | | Monday |
| | | | Thursday |
| | | | Tuesday |
| | | | Wednesday |



Registries @ CCHMC



Registries - A Definition

A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined **scientific, clinical, or policy** purpose(s).

---User's guide to registries
evaluating patient outcomes,

AHRQ, 2009

Background on Clinical Registries @ CCHMC

- Numerous “home-grown” registries/clinical databases pre-dating the ambulatory EHR (~2000-2005)
 - Headache db
 - CF/JRA registries
 - Liver portal db
- Docsite
 - Selected in 2005
 - Meant to “bridge the gap” prior to EpicCare implementation



Clinical Registries – Core functions

1. Define patient cohort
2. Track individual and population metrics (both process and outcome)
3. Produce operational and analytical reports

Clinical Registries – Challenges

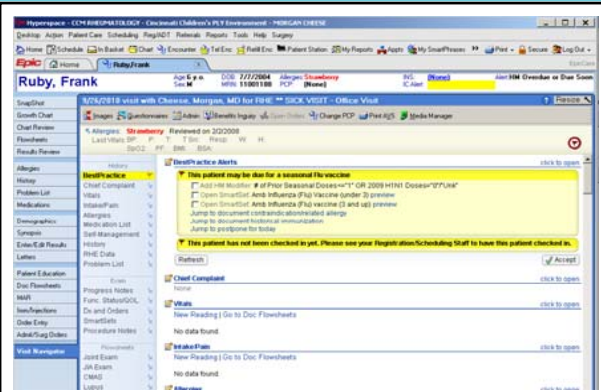
- Defining the patient cohort
 - Hand-curation vs. rule-based classification
 - If rule fails:
 - Change the workflow to collect better data?
 - Define a different rule?
- What are the rules around inclusion/exclusion and re-inclusion?

Epic Based Registries

- New functionality (to be installed at CCHMC in Feb 2011)
- Designed to support tracking and reporting for chronic disease
- Embedded in the front-end application

Epic Based Registries

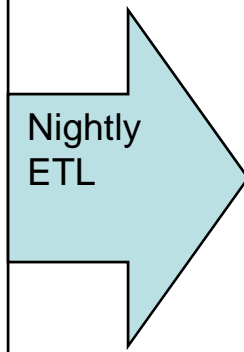
- Requires that division be live on Epiccare
- Intended **primarily** for clinical functions
(connection to research possible)



Epic Chronicles



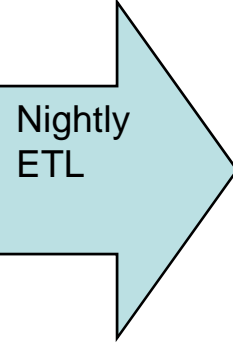
Epic Chronicles



Epic Clarity

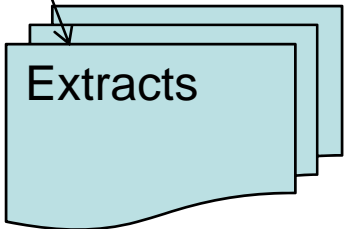
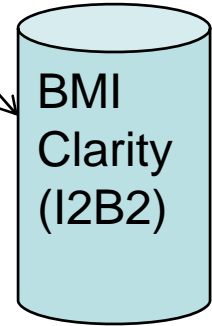
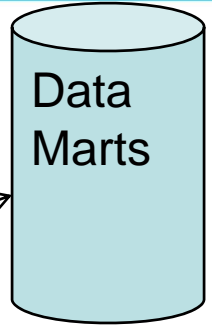
Epic Chronicles

The screenshot shows a patient record for Ruby, Frank. The interface includes a navigation menu on the left with categories like Alerts, Demographics, and Patient Education. The main content area displays a 'Health Alerts' section with a highlighted alert: 'This patient may be due for a seasonal flu vaccine'. Below this, there are sections for 'Chart Complaint', 'Vitals', and 'Orders'.

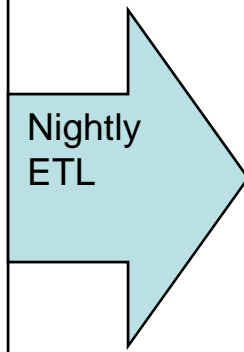


Epic Clarity

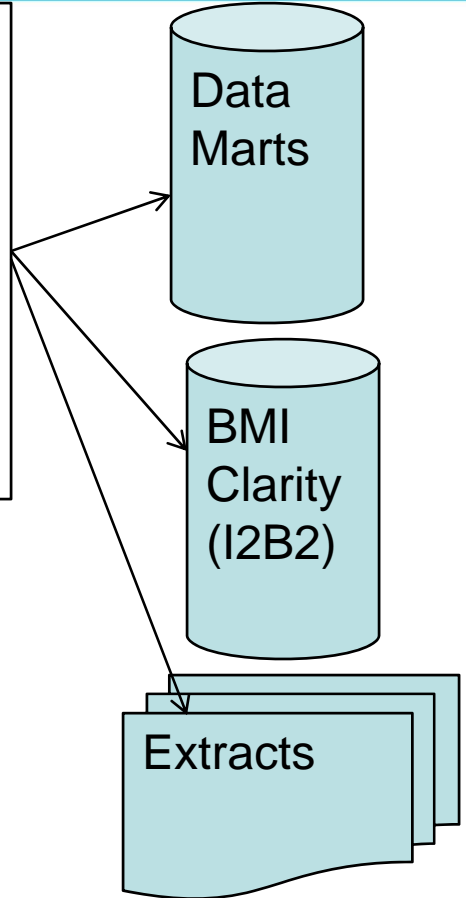
The screenshot shows a data interface with a search bar and a table of data. The table has columns for 'Title', 'Last Run', and 'Owner'. The table is currently empty, displaying 'No data to display'.



Epic Chronicles

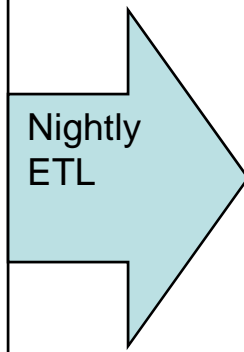


Epic Clarity



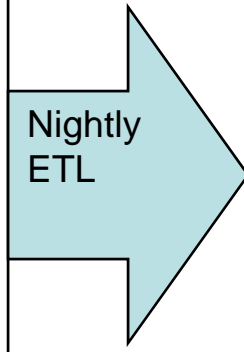
Registry Editor

Epic Chronicles

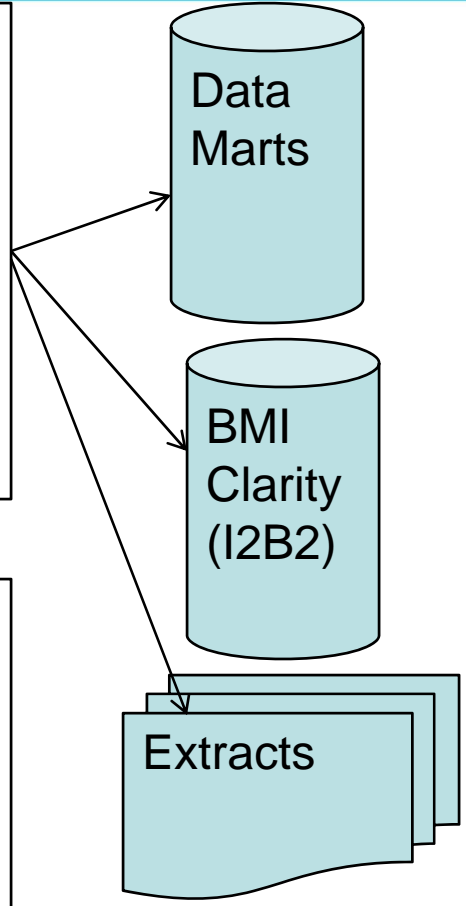


Epic Clarity

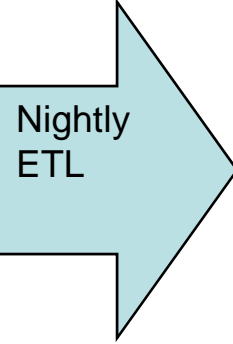
Registry Editor



Epic Clarity



Epic Chronicles

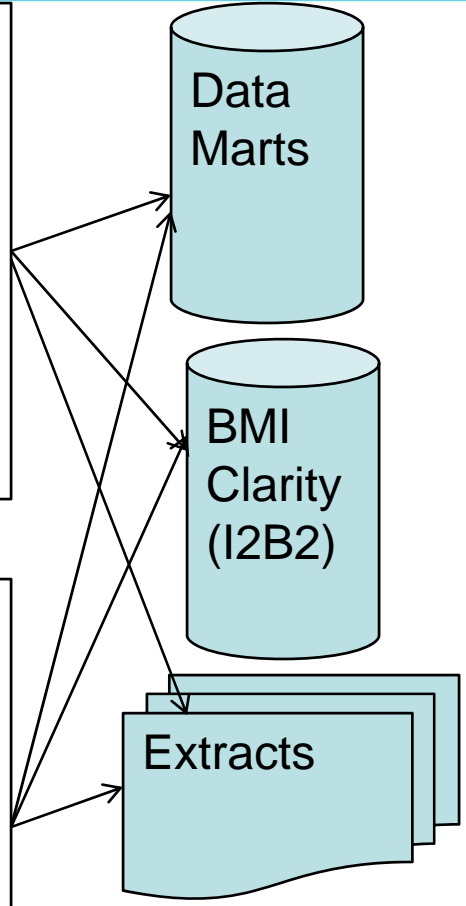


Epic Clarity

Registry Editor



Epic Clarity

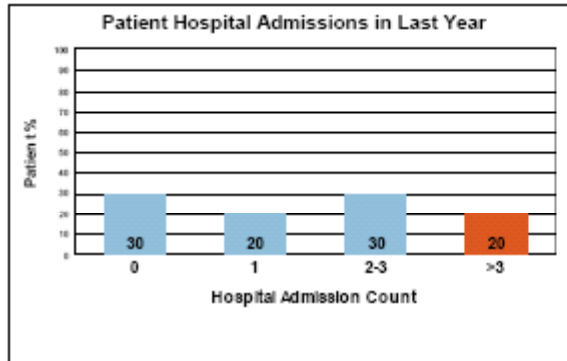


Patients with Asthma

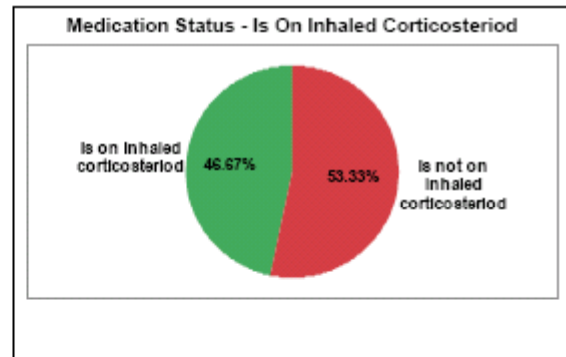
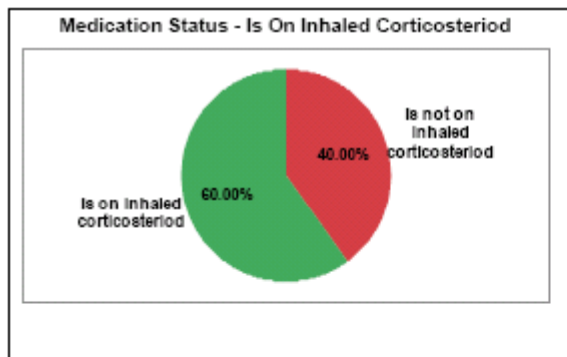
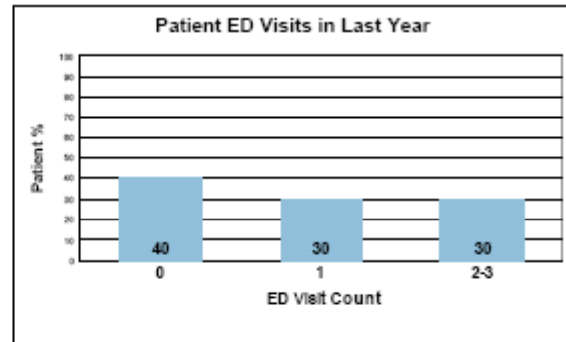
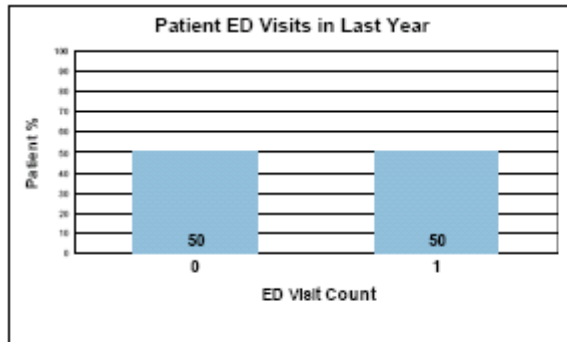
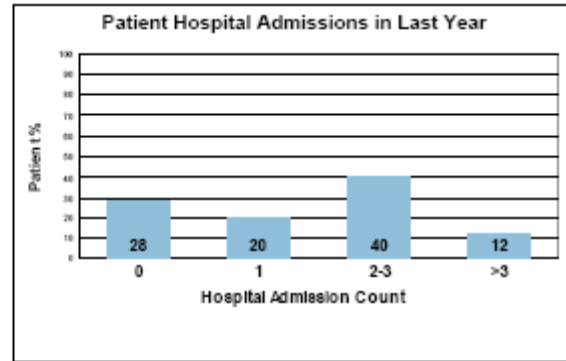
PCP: Juarez, Christina



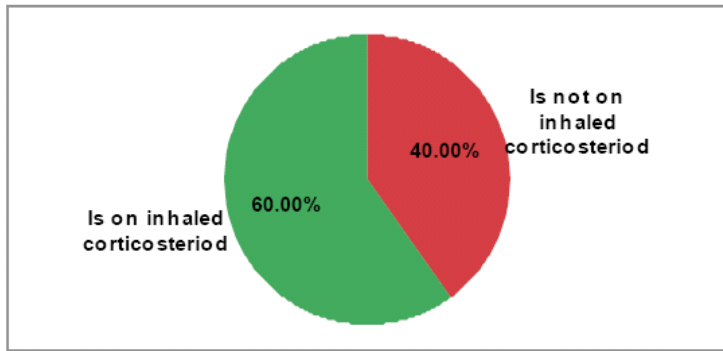
My Patients



All Patients



Medication Status - Is On Inhaled Corticosteroid



Drill down

Is on inhaled corticosteroid

| Patient Name | Patient MRN | Sex | Age |
|--------------------------------------|----------------------------------|----------------------------------|------|
| ALMOND, JANE | 3101393 | F | 38 |
| General Health | Current Medication Status | Comorbidities (last yr) | |
| Height: 5' 8" | On Antihistamines: Y | Has Sinusitis: | Y |
| Weight (lb): 157.50 | On Inhaled Corticosteroids: Y | Has Allergic Rhinitis: | Y |
| Tobacco Usage (last yr): Passive | On Antibody Inhibitors: Y | Has GERD: | N |
| | On Leukotriene Modifiers: Y | Has OSA: | Y |
| | On Methylxanthines: N | Has Anxiety: | N |
| | On Mast Cell Stabilizers: N | | |
| | On Inhaled Steroid Comb.: N | | |
| Office Visit (last 3 yrs) | On Inhaled Beta-Agonists: Y | Test Results (last 3 yrs) | |
| Date: 06/12/2007 | | FVC (L): | 2 |
| Provider: Juarez,Christin a | | FEV1 (L): | 1 |
| Specialty Visits (last 3 yrs) | Immunization Status | FEV1/FVC: | 0.72 |
| Allergy: 04/30/2007 | Flu Vacc (last yr): N | | |
| Pulmonology: 11/24/2007 | Pneum Vacc: N | | |
| Patient Name | Patient MRN | Sex | Age |
| RICKERT, CLAIRE | 3101404 | F | 52 |
| General Health | Current Medication Status | Comorbidities (last yr) | |
| Height: 5' 4" | On Antihistamines: Y | Has Sinusitis: | N |
| Weight (lb): 141.44 | On Inhaled Corticosteroids: Y | Has Allergic Rhinitis: | N |
| Tobacco Usage (last yr): Never | On Antibody Inhibitors: Y | Has GERD: | Y |
| | On Leukotriene Modifiers: N | Has OSA: | Y |
| | On Methylxanthines: Y | Has Anxiety: | N |

Epic Based Registries

- Consistencies via embedding definition in the front-end
- Identical patient lists in Chronicles as well as Clarity
- Epic development futures
- “Easy” setup for inclusion criteria & metrics



Epic Based Registries

- Piloting in 3rd quarter of FY11
- Roll-out plan to be developed after pilot

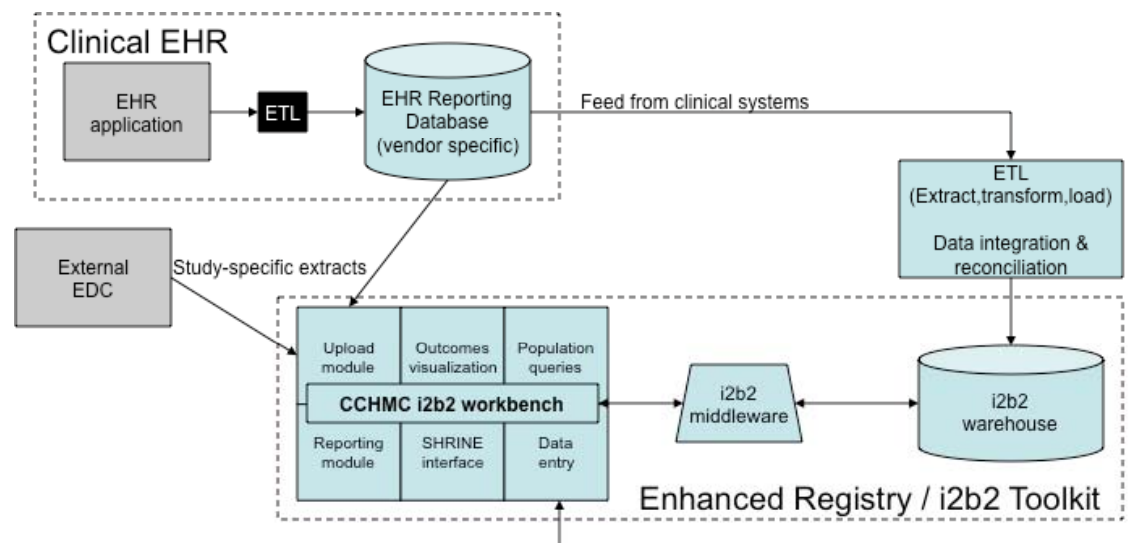


i2b2-based research registries

- **Strengths of i2b2**
 - Integrate data from multiple sources
 - Identify patient cohorts
- **Registries and research databases**
 - Revolve around cohort queries (patient & population management, adherence to guidelines, etc.)
 - Desire to populate with data from medical record (without double data entry)

i2b2 Enhanced Registries

- Intent: primary data collection occurs in the EHR
 - Reduce the need for double data entry
 - Leverage Epic registry data/definitions
- Multiple entry routes
 - Direct data entry
 - File upload
 - Direct EHR feed



i2b2 Registries – Other Functionality

- Data validation and exception reports
- “Annotation” of EHR data
- Outcomes visualization (site vs. network)
- Standing reports, ad hoc (eventually)
- “Raw” access, data extracts
- i2b2 query tool for ad hoc questions

Support for multi-center registries

- SHRINE federated query platform allows for distributed queries
- Several possible models:
 - Each site submits data to a central i2b2 node
 - Each site has their own i2b2 node, communicates via federated queries
 - Hybrid model – mix of central, local i2b2s

Challenges

- EHR vs. registry “visit”
 - “Static” variables may have multiple entries (race, date of diagnosis)
 - Data is stored all over the EHR, complicating extraction/classification
- Data issues
 - Completeness
 - Quality
 - Correctness
- Multi-site challenges
 - Standardizing EHR build(s)
 - Aims of network vs. aims of single site
 - Definition of outcomes
 - Ability to make changes to EHR
 - Support of technologies

i2b2 Registries

- Liver Transplant – internal pilot
 - EHR-based data collection
 - Migration of historical data
- Eosinophilic esophagitis
 - EHR-based data collection
 - 5 sites submit to central node
- Rheumatology (CARRA)
 - Sites enter data in DCRI-hosted EDC system
 - Data for each site stored in separate i2b2 (60 total)
 - Communicate via distributed queries
- ImproveCareNow (coming soon)
 - EHR-based data collection
 - Mix of central, local i2b2s

Web-based forms

Data Entry | **Form Designer**

Choose Study: **Liver Registry**

Name: _____ Alias: _____

Reason for change? _____

Previous Value: _____

Change Patient

Apply Changes **Cancel**

Liver Registry

Patient Information | Clinical Information | Research

Patient Information

- Demographics
- Contact Info
- + Care Giver Info
- Insurance Info
- Provider Info
- Allergies
- Immunizations

Patient Demographics

| | | |
|--------------------|--|---|
| MRN | | E |
| First Name | | E |
| Middle Name | | E |
| Last Name | | E |
| Alias | | E |
| Birth Date | | E |
| Age | | E |
| Race | | E |
| Ethnicity | | E |
| Gender | | E |
| Citizenship Status | | E |

Submit **Validate**

Liver Registry

Patient Information | **Clinical Information** | Research

Clinical Information

- Tracking/Score
- Referral
- + Evaluation
- + Listing
- Pre-Transplant
- + Transplant
- Outside Admissions
- Rejection
- Exit

Evaluation Information

| Evaluation(s) | Evaluation | Vitals |
|---------------|--|----------------------|
| ✕ | Evaluation Date : View | View |
| ✕ | Evaluation Date : View | View |

Submit **Validate**

Evaluation Information

| Add [Evaluation] | ✕ | ✕ **New** |
|-------------------------|----------------------|----------------------|
| Evaluation Date | <input type="text"/> | <input type="text"/> |
| Team Discussion Date | <input type="text"/> | <input type="text"/> |
| Team Discussion Outcome | <input type="text"/> | <input type="text"/> |
| Deferral Reason | <input type="text"/> | <input type="text"/> |
| Organs Evaluated | <input type="text"/> | <input type="text"/> |
| Primary Liver Disease | <input type="text"/> | <input type="text"/> |
| Secondary Liver Disease | <input type="text"/> | <input type="text"/> |
| Evaluation Surgeon | <input type="text"/> | <input type="text"/> |

Reports

Liver Outcomes Report

Liver Transplantation and Recovery

Measure

Calculation

Graft or Organ Survival at 90 Days: % of liver graft or organs living 90 days after transplant procedure 96.77%

Patient Survival at 90 Days: % of patients living 90 days after their transplant procedure 100%

General Information and Demographics

Measure

Calculation

Technical - Variant Donors: Number of patients transplanted with an organ from a living related donor, reduced-size liver, or split liver 1

Number of Transplants: Total number of potential Liver transplant procedures 45

Median Wait Time for Liver Transplant: Number of days a child waited for a liver transplant 59.5 Days

Patients under Age 2: % of patients under age 2 awaiting liver transplant 22.22%

Deaths while on Waiting List: % of patients who died while on the waiting list for a liver 0.00%

Complications Within 90 Days

Measure

Calculation

Biliary Complications: Number of patients experiencing complications caused by problems with bile (the waste product of the liver) 3

Vascular Complications: Number of patient experiencing complications from the clotting or bleeding of blood vessels 0

Rejections: Number of patients experiencing complications from how the body's immune system reacts to the new organ 0

After Liver Transplant

Measure

Calculation

Percent of patients who have been re-transplanted 16.66%

Patient Survival at 2 years: % of patients living three after their transplant procedure 100%

For more information/updates:

- <http://i2b2.cchmc.org>
- Now available:
 - Registry “playground”
 - Re-release of de-identified warehouse
- Check site for access/usage instructions
- Watch for information on additional demos and training
- Please provide feedback, suggestions for improvement



QUESTIONS?