



Fred Hutchinson Cancer Research Center  
University of Washington  
Children's Hospital & Regional Medical Center

# Research Access to Clinical Data

BRIITE Conference

Fred Hutchinson Cancer Research Center

September 11, 2003

Bill Lober, MD

University of Washington



# Not an Oncologist

- Electrical/Computer Engineering
- Boarded in Emergency Medicine
- Faculty in Biomedical and Health Informatics
  - Public Health Informatics
    - Bioterrorism Surveillance
    - Integration of PH Reporting Systems
  - Clinical Informatics
    - Clinical Data Interfaces for Research Systems
    - “Specialty” clinical and research infrastructure
  - Enterprise CIS @ UW Medicine



# Bob's goal

- Look at “IT in an R01 setting”
- How clinical data access is affected by:
  - Funding/Organizational goals
  - Security/Auth/Authz
  - Distribution and dissemination
  - Data representation/management
- Develop a framework to facilitate working group discussions



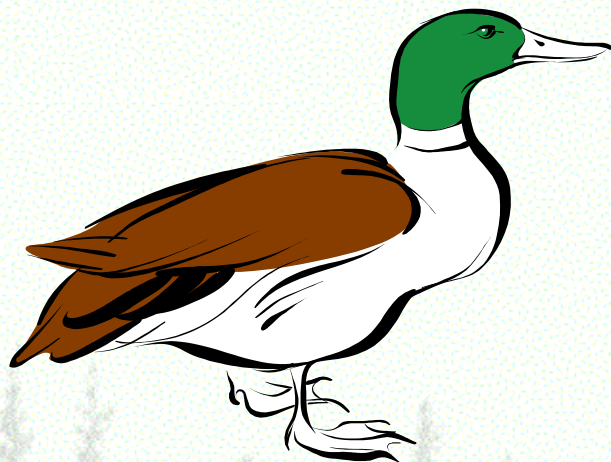
# Bob's questions

- What issues control/limit/promote research use of clinical data?
- Why is it so darn hard to figure out?
- We spend so much \$\$ on these clinical systems, why aren't research apps just the icing on the cake...?



# My talk

- Issues in using clinical data
- Organize issues into framework
- Succumb(ed) to pessimism
- Raise difficult issues
  - and then



Duck...



# Issues

- What data?
- What uses for it?
- What is hard?
- Research is different, right?



# What data are we talking about?

- Demographics
- Labs
- Structured
- Unstructured...
  - Clinic Notes, Path Reports, Images...



**University of Washington Medical Center**  
**PATIENT F. TEST U6999999 Female Age: 53**  
 Provider lober [10-Sep-2003 21:31:57](#)  
 NW A0016999999  
 CHMC ATEST1  
**UWPN MR# N1065140**

<a href="#">Select New Patient</a>	<a href="#">User Config</a>	<a href="#">Health Links</a>	<a href="#">Medcon</a>	<a href="#">UWPN Epic-Web</a>	<a href="#">Help</a>	<a href="#">Clinical Info Matrix</a>	<a href="#">Email Feed-back</a>	<a href="#">Log Off lober</a>	
<a href="#">Demographics</a>	<a href="#">Problems</a>	<a href="#">Medications</a>	<a href="#">Allergies</a>	<a href="#">Providers</a>	<a href="#">Lab</a>	<a href="#">Visits</a>	<a href="#">Transcripts</a>	<a href="#">Radiology</a>	<a href="#">Pathology</a>
<a href="#">Cardiology</a>	<a href="#">Reminders</a>	<a href="#">Immuniz</a>	<a href="#">Procedures</a>	<a href="#">Findings</a>	<a href="#">Perinatal</a>	<a href="#">Summarize</a>	<a href="#">CHIP</a>		

**i** Ethnomed - site contains info about cultural beliefs and medical issues pertinent to the health care of recent immigrants to Seattle.  
**i** Culture Clues(tm) serves as a tool to improve clinician's understanding of their patients' and families' perspective of their health care experience.

### Patient Demographics

<b>Age:</b> 53 years	<b>Language:</b> unavailable
<b>Born:</b> 01-apr-1950	<b>Race:</b> Black
<b>SSN:</b> 000-64-0027	<b>Home phone:</b> (206) 111-1111
<b>Occupation:</b> RETIRED	<b>Work phone:</b> (206) 598-7775

1015 BLOWHOLE COURT  
 ELECTRIC CITY, WA 99123 9218

**Medicaid Pic Number:** CL042683PEEKB2  
**Medicare Number:** 123456789A

**Mother's Maiden Name:** HAROLDSON  
**Father's Name:** unavailable

**internal PCP - PETER TARCZYHORNOCH**  
**internal PCP - DOUGLAS PAAUW**

**Next of kin:**  
 JOHN DOE

**Patient ID at External Hospitals:**  
 A0016999999 at Northwest Hospital  
 ATEST1 at Children's Hospital



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immunoblot, please contact Community Services at (206) 598-6066 to direct questions about further evaluation.			
<b>Blood Gas Panel 1, ART</b> Jul 29, 2003 18:15 Final			
Specimen Description	Arterial		unavailable
RX (O2) L	Not done L		unavailable
FI (O2) %	100 %		unavailable
PEEP (Pos End Expir Pres)	5		unavailable
pH, ART	7.35		7.35-7.45
pCO2, ART	* 60 mm Hg		33-48
CERNER TESTING, CALLED TO VIRTUAL FLOOR			
pO2, ART	* 120 mm Hg		70-95
Bicarbonate, WBLD	24 mEq/L		24-31
O2 Saturation, ART	* 90 %		95-99
Base Excess of Blood, ART	* 5.2 mEq/L		0.0-3.0
Base Deficit of Blood, ART	1.1 mEq/L		0.0-2.0
Sodium, WBLD	* 135 mEq/L		136-145
Potassium, WBLD	* 3.6 mEq/L		3.7-5.2
Calcium (Ionized), WBLD	1.22 mmol/L		1.18-1.38
Glucose, WBLD	* 150 mg/dL		62-125
<b>Glucose</b> Jul 29, 2003 17:10 Final			
Specimen Type: Jackson Pratt			
Glucose	40 mg/dL		unavailable
<b>Protein (Total), FLD</b> Jul 29, 2003 17:10 Final			
Specimen Type: Jackson Pratt			
Protein (Total), FLD	2 g/dL		unavailable
<b>Cell Count, Body Fluid</b> Jul 29, 2003 17:00 Final			
Specimen Type: Pleural Fluid			
Body Fluid Specimen Type	Pleural Fluid		unavailable
Body Fluid RBC	100 CELLS/uL		unavailable
Body Fluid WBC	50 CELLS/uL		unavailable

[Healthlinks Drug Resources](#) **Current Outpatient Medications** Summary by Date [Antibiotic Comparisons Chart](#)

Submit Reset

ref. lib.	Last Actv Dt	Start Dt	<a href="#">Current D/CExt Med</a>	Medication Name, Strength, Form <small>click for detail</small>	Sig	Refls Cnt	Refls Left	Prescriber	Location or Phone
<a href="#">1</a>	19-aug-03	19-aug-03	<input type="checkbox"/>	<a href="#">Trimethoprim\Polymy (Oph) Sol</a>	see <a href="#">detail</a>	0	0	Uh Pharmacy	USTR
<a href="#">1</a>	13-aug-03	13-aug-03	<input type="checkbox"/>	<a href="#">Aspirin 600Mg Sup</a>	see <a href="#">detail</a>	0	0	Uh Pharmacy	USTR
<a href="#">1</a>	13-aug-03	13-aug-03	<input type="checkbox"/>	<a href="#">Docusate 10Mg\MI Liq</a>	see <a href="#">detail</a>	0	0	Uh Pharmacy	USTR
<a href="#">1</a>	14-jul-03	01-jul-03	<input type="checkbox"/>	<a href="#">Sildenafil 50Mg Tab</a>	1TQD	0	0	Uh Pharmacy	UAMB
<a href="#">1</a>	01-jul-03	01-jul-03	<input type="checkbox"/>	<a href="#">Sildenafil 25Mg Tab</a>	1TQD	0	0	Uh Pharmacy	UAMB
<a href="#">1</a>	26-jun-03	26-jun-03	<input type="checkbox"/>	<a href="#">Aldesleuk.(18Mu\MI) 22Mu Sdv Inj</a>	see <a href="#">detail</a>	0	0	Uh Pharmacy	USTR
<a href="#">1</a>	25-jun-03	25-jun-03	<input type="checkbox"/>	<a href="#">Carboplatin 50Mg Inj</a>	RTS	0	0	Uh Pharmacy	USTR
<a href="#">1</a>	25-jun-03	25-jun-03	<input type="checkbox"/>	<a href="#">Tacrolimus 0.03% Oin</a>	RTS	2	2	Uh Pharmacy	USTR
<a href="#">1</a>	22-may-03	27-mar-03	<input type="checkbox"/>	<a href="#">Sulfapyridine 500Mg Tab</a>	see <a href="#">detail</a>	5	5	Uh Pharmacy	USTR
<a href="#">1</a>	19-may-03	19-may-03	<input type="checkbox"/> <input type="checkbox"/>	<a href="#">Beclometh (Qvar) 40Mcg Inh</a>	TEST			Harris Baden	XTRN
<a href="#">1</a>	06-may-03	06-jan-03	<input type="checkbox"/>	<a href="#">Amoxicillin 500Mg Cap</a>	1CTID	0	0	Uh Pharmacy	UAMB
<a href="#">1</a>	27-feb-03	27-feb-03	<input type="checkbox"/>	<a href="#">Botulinum Tox A-Hcp 1Unit\Ea Inj</a>	see <a href="#">detail</a>	0	0	Uh Pharmacy	UINP
<a href="#">1</a>	25-feb-03	25-feb-03	<input type="checkbox"/>	<a href="#">Dn-101(Calcitriol) 15Mcg Cap</a>	see <a href="#">detail</a>	0	0	Celestia Higano	UIDS
<a href="#">1</a>	19-feb-03	19-feb-03	<input type="checkbox"/>	<a href="#">Propofol 10Mg\MI Inj</a>	see <a href="#">detail</a>	0	0	Uh Pharmacy	UINP
<a href="#">1</a>	12-feb-03	12-feb-03	<input type="checkbox"/>	<a href="#">Selenium 40Mcg\MI Inj</a>	see <a href="#">detail</a>	0	0	Uh Pharmacy	SELU
<a href="#">1</a>	12-feb-03	12-feb-03	<input type="checkbox"/>	<a href="#">Valacyclovir 500Mg Or Plcb Tab</a>	see <a href="#">detail</a>	0	0	William Nichols	UIDS
<a href="#">1</a>	30-jan-03	30-jan-03	<input type="checkbox"/>	<a href="#">Dmethylphenidate/ Plcbo Tab</a>	see <a href="#">detail</a>	0	0	Julie Gralow	UIDS
<a href="#">1</a>	28-jan-03	28-jan-03	<input type="checkbox"/>	<a href="#">Bupropion *Sr* Study Tab</a>	1TBID	0	0	Scott Lee	UIDS
<a href="#">1</a>	17-jan-03	13-nov-00	<input type="checkbox"/>	<a href="#">Investigational Drg Study Mis</a>	see <a href="#">detail</a>	3	3	Moira Aitken	UIDS
<a href="#">1</a>	08-jan-03	08-jan-03	<input type="checkbox"/>	<a href="#">Erlotinib Study Tab</a>	see <a href="#">detail</a>	100	100	Robert Livingston	UIDS
<a href="#">1</a>	06-jan-03	06-may-03	<input type="checkbox"/>	<a href="#">Amoxicillin 250Mg Cap</a>	1CTID	0	0	Uh Pharmacy	UAMB
<a href="#">1</a>	12-dec-02	12-dec-02	<input type="checkbox"/>	<a href="#">Dolasetron 20Mg\MI Inj</a>	see <a href="#">detail</a>	0	0	Uh Pharmacy	USTR
<a href="#">1</a>	22-nov-02	22-nov-02	<input type="checkbox"/> <input type="checkbox"/>	<a href="#">Coal Tar\Menthol W\Cond Lotn</a>	see <a href="#">detail</a>	15	15	Harris Baden	XTRN
<a href="#">1</a>	22-nov-02	24-may-02	<input type="checkbox"/> <input type="checkbox"/>	<a href="#">Idarubicin (1Mg\MI) 5Mg\Ea Inj</a>	UAD	0	0	Uh Pharmacy	XTRN
<a href="#">1</a>	20-nov-02	20-nov-02	<input type="checkbox"/>	<a href="#">Docusate 100Mg Cap</a>	see <a href="#">detail</a>	0	0	Kate Chan	USTR
<a href="#">1</a>	10-oct-02	07-oct-02	<input type="checkbox"/>	<a href="#">Doxycycline 100Mg Cap</a>	1CQD	0	0	Uh Pharmacy	USTR
<a href="#">1</a>	09-oct-02	07-oct-02	<input type="checkbox"/>	<a href="#">Amoxicillin 500Mgdud Cap</a>	1CTID	0	0	Uh Pharmacy	USTR

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Address <https://mindscape.mcis.washington.edu/main/uwmc/mindscapeFrameset.html> Go Links >>

### Problem List

[Major](#)   [Minor](#)   [All](#)   [Add a Problem](#)   [Update Major Problems](#)

ref. lib.	Problem Description click  for detail; click descr to edit	Onset Date ~ approx	Last Dx Date	Episode Number	Status
<a href="#">i</a>	<a href="#">SCHIZOPHRENIA UNSPECIF</a> I see dead people....	~ 01-jun-2002	22-nov-2002	2	Active
<a href="#">i</a>	<a href="#">PRINZMETAL ANGINA</a> teste	~ 01-nov-2002	06-nov-2002	1	Active
<a href="#">i</a>	<a href="#">SYST RHEUM ARTHRITIS NE</a>	24-sep-2002	24-sep-2002	unreported	Active
<a href="#">i</a> <b>USW</b>	<a href="#">HTN, ESSEN, BENIGN</a>	~ 01-jul-2002	23-jul-2002	unreported	Active
<a href="#">i</a>	<a href="#">LBP</a>	~ 01-jul-2002	23-jul-2002	unreported	Active
<a href="#">i</a>	<a href="#">CEREBRAL ARTERITIS</a>	25-feb-2002	25-feb-2002	unreported	Active
<a href="#">i</a>	<a href="#">FX LUMBAR VERTEBRA-CLOS</a>	25-feb-2002	25-feb-2002	unreported	Active
<a href="#">i</a>	<a href="#">TOXIC ENCEPHALOPATHY</a>	~ 01-jun-2000	25-feb-2002	unreported	Active
<a href="#">i</a>	<a href="#">OTHER BREAST DISORDERS</a>	~ 01-feb-2002	05-feb-2002	unreported	Active
<a href="#">i</a>	<a href="#">RENAL ARTERY ANEURYSM</a>	13-jan-2002	13-jan-2002	unreported	Active
<a href="#">i</a>	<a href="#">ARRHYTHMIA</a> Onset of SVT 1998	~ 01-sep-2001	24-sep-2001	1	Active
<a href="#">i</a>	<a href="#">COLON CA</a>	~ 01-sep-2001	24-sep-2001	unreported	Active

Done Internet

**University of Washington Medical Center**  
**PATIENT F. TEST U6999999 Female Age: 53**  
 Provider lober 10-Sep-2003 21:43:34  
 NW A0016999999  
 CHMC ATEST1  
**UWPN MR# N1065140**

<a href="#">Select New Patient</a>	<a href="#">User Config</a>	<a href="#">Health Links</a>	<a href="#">Medcon</a>	<a href="#">UWPN Epic-Web</a>	<a href="#">Help</a>	<a href="#">Clinical Info Matrix</a>	<a href="#">Email Feed-back</a>	<a href="#">Log Off lober</a>	
<a href="#">Demographics</a>	<a href="#">Problems</a>	<a href="#">Medications</a>	<a href="#">Allergies</a>	<a href="#">Providers</a>	<a href="#">Lab</a>	<a href="#">Visits</a>	<a href="#">Transcripts</a>	<a href="#">Radiology</a>	<a href="#">Pathology</a>
<a href="#">Cardiology</a>	<a href="#">Reminders</a>	<a href="#">Immuniz</a>	<a href="#">Procedures</a>	<a href="#">Findings</a>	<a href="#">Perinatal</a>	<a href="#">Summarize</a>	<a href="#">CHIP</a>		

**ALERT! History of Harm/Violence**

**PATIENT HAS REMINDERS DUE** [see them](#)

**Transcripts**

[Refresh](#)

Click ▶ below to filter by Type, Clinic, Status, Author, or Authenticator.

Service Date	Dictate Date	Type (click to view)	Clinic	Status (click for dtl)	Author; Authenticator
31-dec-2003	08-sep-2003	<a href="#">Admit Note</a>		<a href="#">Authenticated</a>	Tan, Emilie Tan, Emilie
10-sep-2003	10-sep-2003	<a href="#">Nursing Record/Note</a>		<a href="#">Unauthenticated</a>	Walden, Blake C Walden, Blake C
10-sep-2003		<a href="#">Pathology Report</a>		<a href="#">Authenticated</a>	Chou,MD, David
10-sep-2003	10-sep-2003	<a href="#">Clinic Note</a>	3-Gen Int Med	<a href="#">Transcribed</a>	Lingbloom, Heather
10-sep-2003	10-sep-2003	<a href="#">Clinic Note</a>	3-Endocrine	<a href="#">Transcribed</a>	Test, Position2
09-sep-2003		<a href="#">Lft Ht Cath Retro</a>		<a href="#">Authenticated</a>	Chou,MD, David
07-sep-2003	07-sep-2003	<a href="#">In Error</a>	3-Gen Int Med	<a href="#">In Error</a>	PositionTest, PDS Imaging PositionTest, PDS Imaging
07-sep-2003	07-sep-2003	<a href="#">In Error</a>		<a href="#">In Error</a>	Tan, Emilie Tan, Emilie
06-sep-2003	06-sep-2003	<a href="#">Clinic Note</a>		<a href="#">Authenticated</a>	Reilly, Dominic Francis

<b>University of Washington Medical Center</b> <b>PATIENT F. TEST U6999999 Female Age: 53</b> Provider Iolber <a href="#">10-Sep-2003 21:45:33</a> NW A0016999999 CHMC ATEST1 <b>UWPN MR# N1065140</b>				<a href="#">Select New Patient</a>	<a href="#">User Config</a>	<a href="#">Health Links</a>	<a href="#">Medcon</a>	<a href="#">UWPN Epic-Web</a>	<a href="#">Help</a>	<a href="#">Clinical Info Matrix</a>	<a href="#">Email Feed-back</a>	<a href="#">Log Off Iolber</a>
<a href="#">Demographics</a>	<a href="#">Problems</a>	<a href="#">Medications</a>	<a href="#">Allergies</a>	<a href="#">Providers</a>	<a href="#">Lab</a>	<a href="#">Visits</a>	<a href="#">Transcripts</a>	<a href="#">Radiology</a>	<a href="#">Pathology</a>			
<a href="#">Cardiology</a>	<a href="#">Reminders</a>	<a href="#">Immuniz</a>	<a href="#">Procedures</a>	<a href="#">Findings</a>	<a href="#">Perinatal</a>	<a href="#">Summarize</a>	<a href="#">ChIP</a>					

**ALERT! History of Harm/Violence**

**PATIENT HAS REMINDERS DUE** [see them](#)

**CLINIC NOTE**

**PAIN CENTER**

**IDENTIFICATION:** Mrs. Doe is a 46-year-old female, previously seen by myself on 7/17/98.

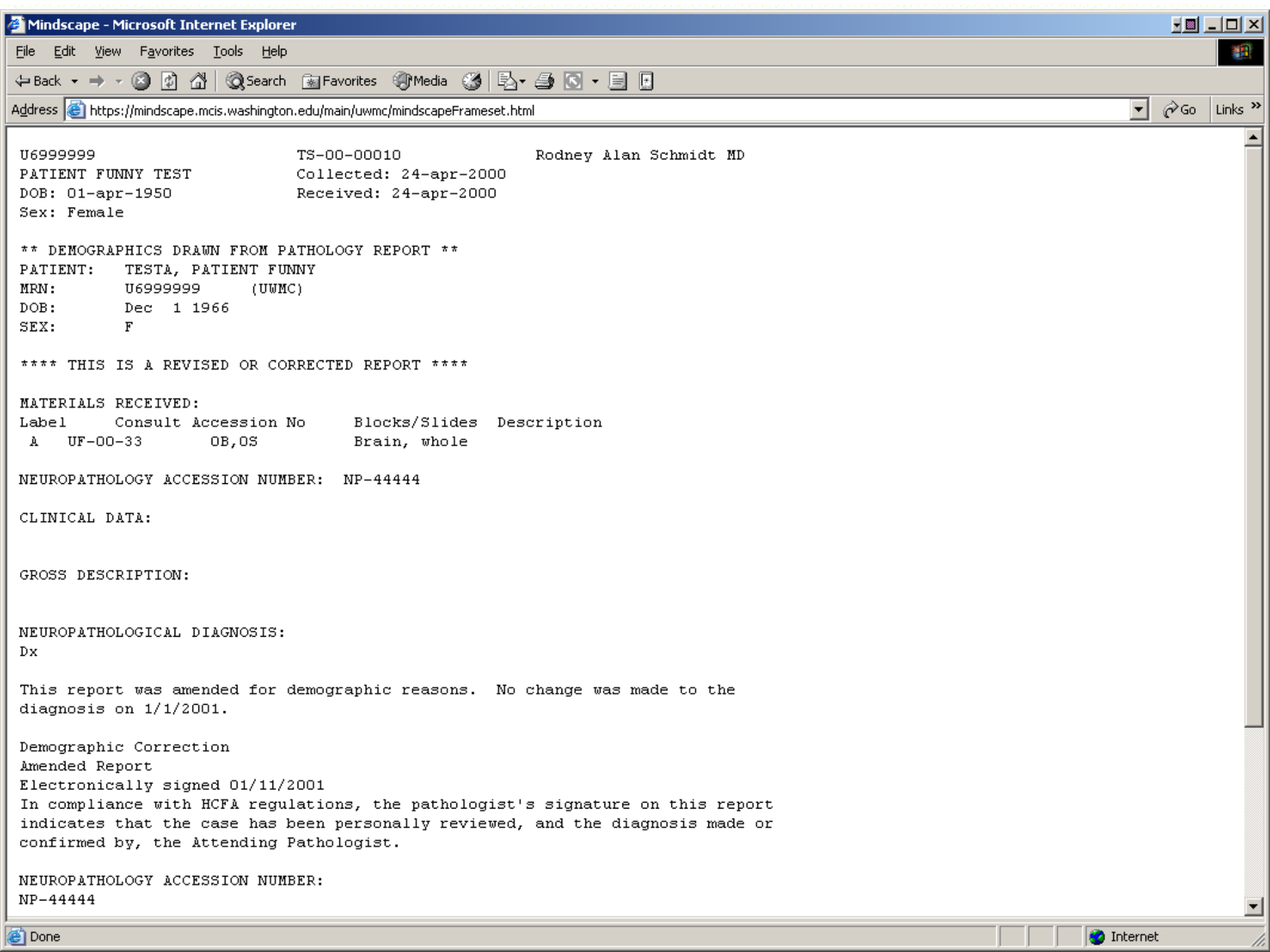
**SUBJECTIVE:** The patient has returned complaining of symptoms of menopause and to follow up on her lab examinations. She has been complaining of hot flashes since this summer, as well as increasing irritability and difficulty with sleep.

**OBJECTIVE:** Blood pressure 104/80. Pulse 72. Physical examination was deferred, except for pelvic, which shows normal external genitalia, normal vaginal mucosa without lesions. No cervical discharge. A repeat Pap was done.

**LABORATORY DATA:** Laboratories done 7/98, Pap was negative, but showed no endocervical cells. Her labs dated 12/14/98, showed FSH of 127, post menopausal is greater than 30 million IU/ml.

**ASSESSMENT/PLAN:**

1. I discussed hormone replacement with Mrs. Doe. She has no history of breast cancer and is willing to undergo the slight increase in breast cancer risk. She has no family history or personal history of thromboembolic disease. She is interested in the benefits, including decreasing her symptoms, her cardiovascular benefits, as well as osteoporosis. She understands that she might have some spotting and may require further intervention in the future. We have discussed various modalities and she prefers to be on a continuous Premarin/Provera combination, as she has not had a hysterectomy in the past. We will consider cyclic if this is not sufficient in the future.



U6999999 TS-00-00010 Rodney Alan Schmidt MD  
PATIENT FUNNY TEST Collected: 24-apr-2000  
DOB: 01-apr-1950 Received: 24-apr-2000  
Sex: Female

\*\* DEMOGRAPHICS DRAWN FROM PATHOLOGY REPORT \*\*

PATIENT: TESTA, PATIENT FUNNY  
MRN: U6999999 (UWMC)  
DOB: Dec 1 1966  
SEX: F

\*\*\*\* THIS IS A REVISED OR CORRECTED REPORT \*\*\*\*

MATERIALS RECEIVED:

Label	Consult	Accession No	Blocks/Slides	Description
A	UF-00-33	OB,OS		Brain, whole

NEUROPATHOLOGY ACCESSION NUMBER: NP-44444

CLINICAL DATA:

GROSS DESCRIPTION:

NEUROPATHOLOGICAL DIAGNOSIS:

Dx

This report was amended for demographic reasons. No change was made to the diagnosis on 1/1/2001.

Demographic Correction

Amended Report

Electronically signed 01/11/2001

In compliance with HCFA regulations, the pathologist's signature on this report indicates that the case has been personally reviewed, and the diagnosis made or confirmed by, the Attending Pathologist.

NEUROPATHOLOGY ACCESSION NUMBER:

NP-44444



University of Washington Medical Center  
PATIENT F. TEST U6999999 Female Age: 53  
Provider lober 10-Sep-2003 21:40:44  
NW A0016999999  
CHMC ATEST1  
**UWPN MR# N1065140**

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<a href="#">Cardiology</a>	<a href="#">Reminders</a>	<a href="#">Immuniz</a>	<a href="#">Procedures</a>	<a href="#">Findings</a>	<a href="#">Perinatal</a>	<a href="#">Summarize</a>	<a href="#">ChIP</a>		

- EKG**
- [Echocardiography](#)
- [Cardiac Cath](#)

Zztest, Pt. I.

ID:006999999

22-OCT-1996 09:11:00

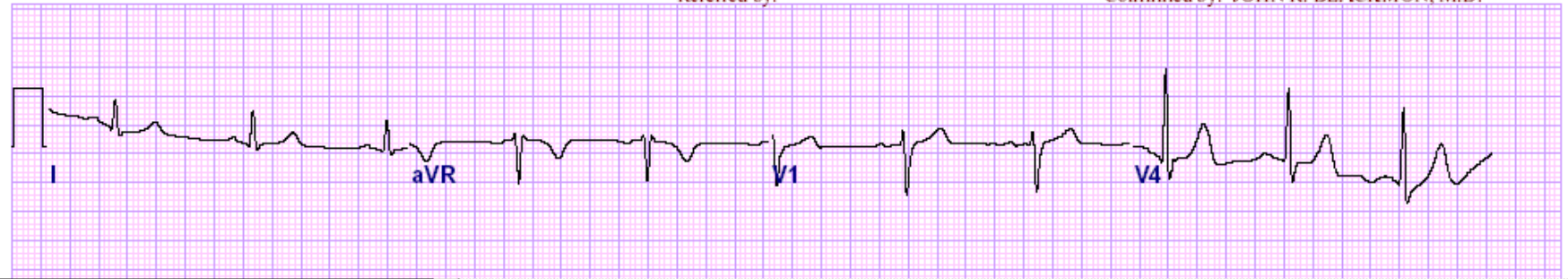
UW MEDICAL CENTER

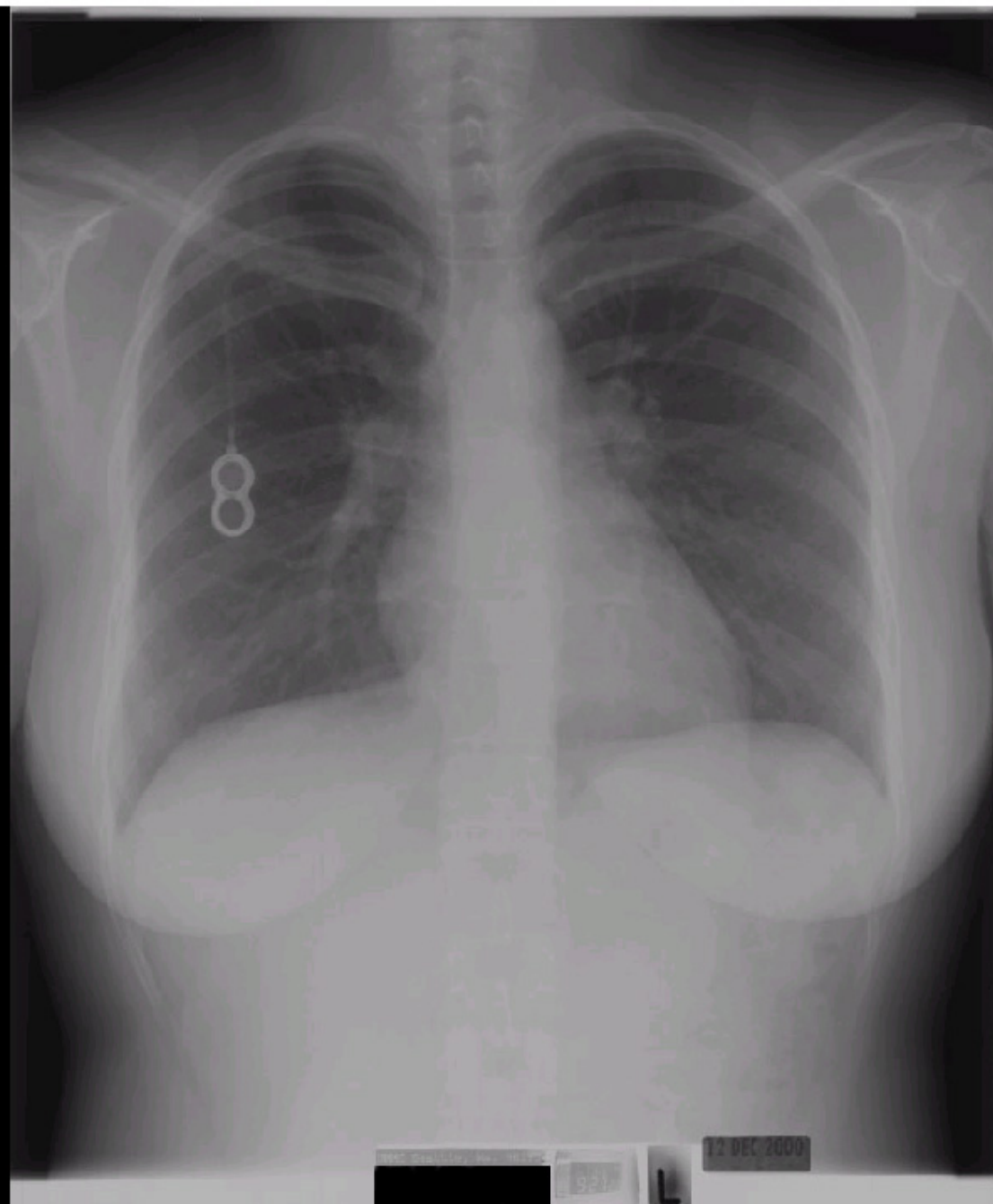
66 yr  
Male Caucasian  
Loc:3  
Vent. rate 67 BPM  
PR interval 168 ms  
QRS duration 100 ms  
QT/QTc 408/431 ms  
P-R-T axes 32 58 65

*NORMAL SINUS RHYTHM  
WITHIN NORMAL LIMITS  
NO PREVIOUS ECGS AVAILABLE*

Referred by:

Confirmed by: JOHN R. BLACKMON, M.D.







# What uses does it have?

- Identify Patients
- Link Patients
- Outcomes Data
- Treatment Data
- Enrollment
- Patient Care?



# What is difficult?

- Data Access
- Privacy
- Data Model
- Meaning
- Timeliness
- Linking research results



# Research is different, right?

- Timeliness of data
- Patient identified data
- ...



# Timeliness

- No
  - Retrospective analysis
- Yes
  - Patient Enrollment
  - Experiment/Lab Management Systems



# Patient Identification

- No
  - De-identified specimens
- Yes
  - Short term linkages to integrate data
  - Link across studies, across lifetimes
  - Familial studies
  - Re-identify tissue from banks?
  - ... just how good an identifier is DNA...?



# Research Systems are different, right?

- Purpose built
- Small user community
- ...



# Built for the right purpose?

- Clinical Systems
  - Origins in financial accounting/billing
  - Episodes based on billable encounters
  - Track patients across episodes/sites (hard)
- Research Systems
  - Organize data from experiments/studies
  - Episodes based on funded studies
  - Track patients across studies (hard)



# Purpose: Research Only?

- Research systems
  - Clinical uses?
    - Disease Specific Views
    - Diabetes system
  - Clinician/Researchers
    - GI Path
  - Research Group Information Systems
    - GI Path







**Main**

[Home](#) | [Help](#) | [Logout](#)

**General User Access**

- |  |                                   |
|--|-----------------------------------|
| <a href="#">Enter/Edit Patient</a>       | <a href="#">Specimen Search</a>   |
| <a href="#">Visit/Procedure/Specimen</a> | <a href="#">Specimen Checkout</a> |
| <a href="#">Edit Specimen</a>            | <a href="#">Specimen Check in</a> |
| <a href="#">Print Reports</a>            | <a href="#">Experiments</a>       |

**For Administrators**

- |   |                                 |
|---|---------------------------------|
| <a href="#">Enter/Edit Storage Location</a> | <a href="#">Enter/Edit User</a> |
| <a href="#">Enter/Edit Dx Codes</a>         |                                 |

# GI-PATH *system*

- Select Patient
- Patient Information**
- Patient Identifiers
- Study Enrollment

[Home](#) | [Help](#) | [Logout](#)

**John Doe**  
Study ID: 456213

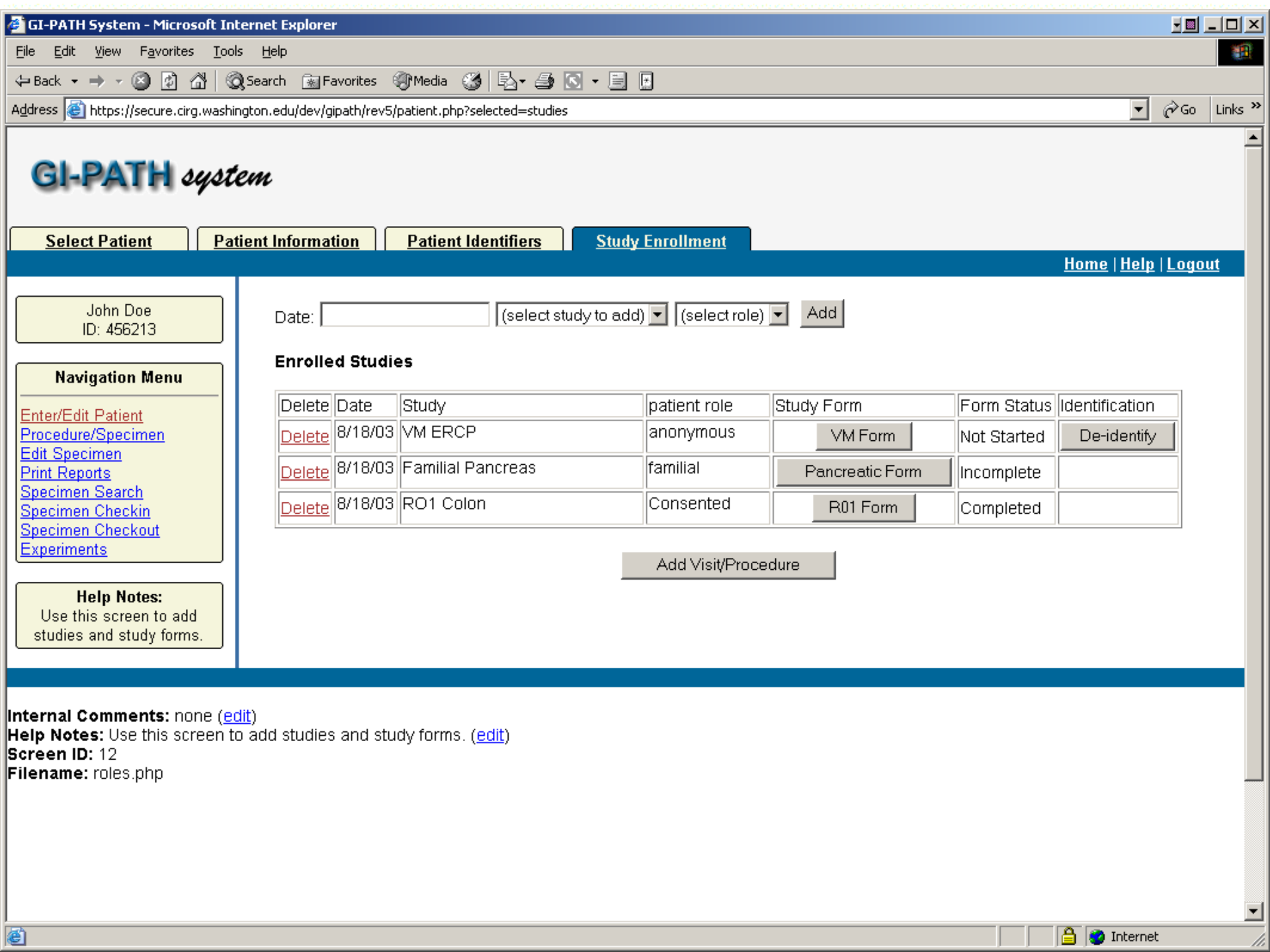
- Navigation Menu**
- [Enter/Edit Patient](#)
  - [Procedure/Specimen](#)
  - [Edit Specimen](#)
  - [Print Reports](#)
  - [Specimen Search](#)
  - [Specimen Checkin](#)
  - [Specimen Checkout](#)
  - [Experiments](#)

**Help Notes:**  
Use this screen to edit information about an existing patient.

Name:	<input type="text"/>	Study ID:	<input type="text"/>
Sex:	<input checked="" type="radio"/> M <input type="radio"/> F	Date of Birth:	<input type="text"/>
Referring MD:	<input type="text"/>	Follow up:	<input checked="" type="radio"/> Yes <input type="radio"/> No
MD Recommendation:	<input type="text"/>	Return Date:	<input type="text"/>

Save Cancel

**Internal Comments:** blah blah ([edit](#))  
**Help Notes:** Use this screen to edit information about an existing patient. ([edit](#))  
**Screen ID:** 11  
**Filename:** patient2.php



# GI-PATH system

- Select Patient
- Patient Information
- Patient Identifiers
- Study Enrollment**

[Home](#) | [Help](#) | [Logout](#)

John Doe  
ID: 456213

Date:  (select study to add)  (select role)  Add

- Navigation Menu**
- [Enter/Edit Patient](#)
  - [Procedure/Specimen](#)
  - [Edit Specimen](#)
  - [Print Reports](#)
  - [Specimen Search](#)
  - [Specimen Checkin](#)
  - [Specimen Checkout](#)
  - [Experiments](#)

### Enrolled Studies

Delete	Date	Study	patient role	Study Form	Form Status	Identification
<a href="#">Delete</a>	8/18/03	VM ERCP	anonymous	<input type="button" value="VM Form"/>	Not Started	<input type="button" value="De-identify"/>
<a href="#">Delete</a>	8/18/03	Familial Pancreas	familial	<input type="button" value="Pancreatic Form"/>	Incomplete	
<a href="#">Delete</a>	8/18/03	RO1 Colon	Consented	<input type="button" value="R01 Form"/>	Completed	

**Help Notes:**  
Use this screen to add studies and study forms.

**Internal Comments:** none ([edit](#))  
**Help Notes:** Use this screen to add studies and study forms. ([edit](#))  
**Screen ID:** 12  
**Filename:** roles.php



# Pancreatic Disease Data Collection Form

## Demographic and Lifestyle data

**Patient Age:**  years

**Birth Place:** City  State  Country

**Marital Status:**  Never Married  Married  Widow(er)  Separated  Divorced

**Race:**  White  Ashkenazi Jew  Black  Asian  Hispanic  Other

**Height:**  feet  inches (OR  cm)

**Current Weight:**  lbs (OR  kg)

**Weight Prior to Pancreatic Cancer:**  lbs (OR  kg)

**Education:**  Grade School  Junior School  High School  Technical  College

**Tobacco:**  Never Use  Current User  Ex-user *If Ex-user Cessation Date*

**Tobacco Type and Amount:**  Cigarettes <= 1 pack/day  Cigarettes > 1 pack/day  Cigars  Pipe  
 Chewing Tobacco

**Alcohol:**  Never drink  Drink less than 1 drink/day  Drink approximately one drink/day  
 Drink 2 or more drinks/day  Former Drinker *Number of Drinks*

**Coffee:**  Never Drink coffee  1 cup or less/day  2-5 cups/day  6 or more cups/day

**Type of Coffee:**  Regular  Decaffeinated  Espresso

# Clinical Data in Research Systems

- Avoid double entry
- Link with clinical system for updates
- Links back to clinical system?
- Patient self reported data
  - Common in clinical research
  - Soon in lab research?



# Patient self reported data

- Biomedical research
  - Cells and molecules
  - Test tubes and culture dishes
- People:
  - Large aggregates of cells
  - Capable of answering questionnaires
  - Contributing “clinical data” to research



# Quality of Life Survey

DEMO VERSION

ENTER Unumber

VIEW Patient Names and Unumbers

ordered by Last Name  ordered by Unumber



CANCEL



SUBMIT

# Quality of Life Survey

DEMO VERSION

\* U. number  Visit Number

First Name

Last Name

Patient's Age

GENDER  male  female

Today's Date: September 11, 2003

**BEGIN** 



Cancer Quality of Life Survey - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites Media Print Mail Stop

Address [http://www.cirg.washington.edu/cancerQOLDemo/process\\_form.php](http://www.cirg.washington.edu/cancerQOLDemo/process_form.php) Go Links >>

## Quality of Life Survey

DEMO VERSION (database entries will not be saved)

### What is this project all about?

We are developing better and more efficient ways to provide care to our patients. We are asking you to answer a quality of life/symptom questionnaire on this computer. We will go over this information with you when you are done and use it to plan ongoing care for you while you are receiving treatment.

We are also asking your permission to put your answers to the questions into a research database. The next screen will give you information you will need to decide if you give your permission for your answers to be used in the research database. If you do not want your answers to appear in the research database, your answers will only be in the clinical care database.

**NEXT** 

Cancer Quality of Life Survey - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites Media Print Mail Stop

Address <http://www.cirg.washington.edu/cancerQOLDemo/intro2.php> Go Links

## Quality of Life Survey

DEMO VERSION (database entries will not be saved)

### How the database works?

Your answers will be electronically recorded in a secure clinical database that is used for your ongoing care. The computer will graph your answers. The nurse or doctor will go over this graph with you and then it will be placed in your radiation care notebook.

We would also like to use your answers in a secure research database. If you give permission, we will electronically record your answers in the research database. Your answers will be grouped with those of other patients with cancer. We hope that the results of this project will help us better care for patients with a diagnosis of cancer. Your name will not appear in the research database and all other pieces of information that could identify you will be automatically removed from the displayed data.

### Are there any risks for this project?

Some people feel that providing information for research is an invasion of privacy. Some of the questions asked on the screen may make you uncomfortable or upset. You don't have to answer every question, just skip past those questions if you wish.

 **BACK**

**NEXT** 

DEMO VERSION

**Please select one:**

- I give permission for my answers to be in the research database table and also used by the nurses for my care in the clinic.
- I give permission for my answers to be used by the nurses only for my care in the clinic.
- I do not want to use the computer to answer any questions.

 **BACK**

**NEXT** 

12

DEMO VERSION

Think about what each statement says, then select the one statement that most closely indicates how you have been feeling during the past week including today.

### NAUSEA

- I seldom if ever have nausea
- I have nausea once in a while
- I have nausea fairly often
- I have nausea half the time at least
- I have nausea almost continually

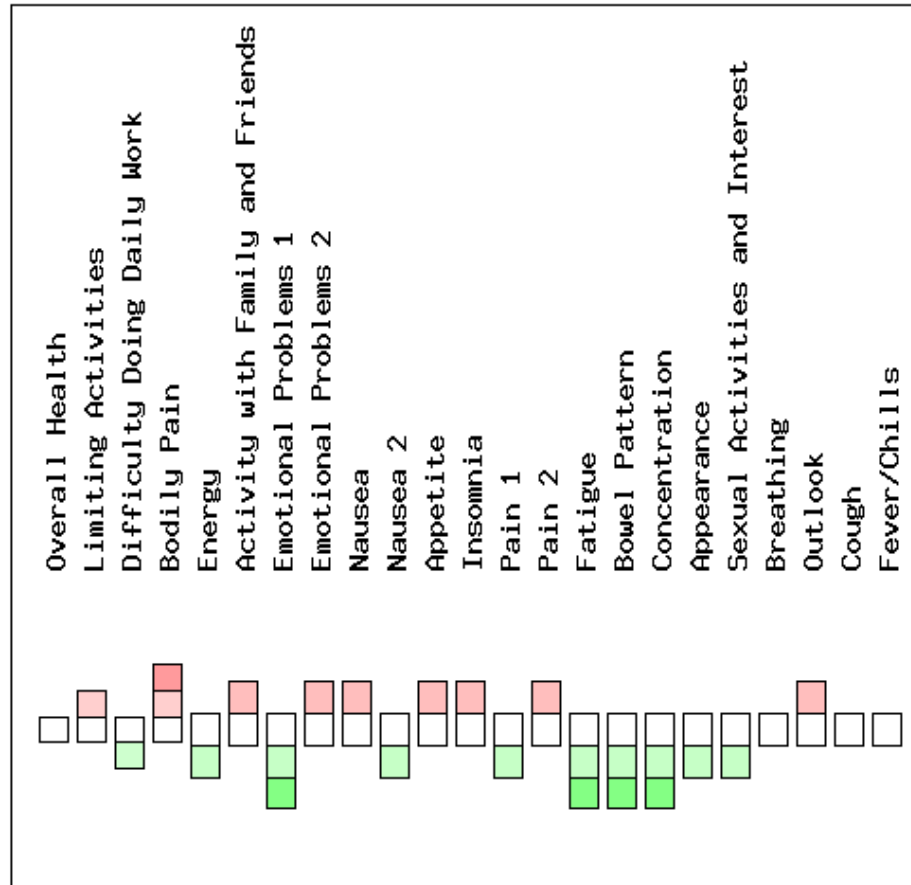
 BACK

NEXT 



09/11/2003

Bodily Pain -
Activity with Family and Friends -
Emotional Problems 2 -
Nausea - Half the time
Appetite - Force myself
Insomnia - Regularly
Pain 2 - Very intense
Outlook -
Limiting Activities -
Overall Health -
Breathing -
Cough -
Fever/Chills -
Difficulty Doing Daily Work -
Energy -
Nausea 2 - Mild
Pain 1 - Occasionally
Appearance - Occasionally
Sexual Activities and Interest - Some
Emotional Problems 1 -
Fatigue - Seldom
Bowel Pattern - Normal
Concentration - Never



Responses above (red scale), below (green scale), or on the threshold value (white).

Patient Name: TESTA, PATIENT

Age: 55

# Quality of Life Study

- Research data about a person
- Session response clinically useful
- Population responses are research
  
- What about longitudinal individual responses?
- Will this type of data be integrated with genome data...



# Purpose Built?

- Research systems
  - Clinical uses?
  - Clinician/Researchers
  - Research Lab Management Systems
- Clinical systems use for research
  - Outcomes research
  - Population research



# Unique to Research

- Tissue/specimen tracking
- Anonymous patient/specimens
- Distance from patients
- Different device/machine interfaces





# Central Questions

How are research and clinical systems the same? Different?

Clinical data should flow to researchers, but are their data that should flow back to clinical systems?



# Revisit: What is difficult?

- Data Access
- Privacy
- Data Model
- Meaning
- Timeliness
- Linking research results



# Data Access

- Institutional boundaries
- Multiple sites in an organization
  - Technical and organizational barriers
- Multiple sides of an organization



# Seattle Cancer Care Alliance

- Fred Hutch
- UW Medicine
  - UW Medical Center
  - School of Medicine
  - Harborview Hospital
  - UW Medicine Neighborhood Clinics (UWPN)
- Children's Hospital
- SELU Clinic Building



# Cancer Research Consortium

- Fred Hutch
- UW Medicine
  - UW Medical Center
  - School of Medicine
  - Harborview Hospital
  - UW Medicine Neighborhood Clinics (UWPN)
- Children's Hospital
- SELU Clinic Building
- \* Disclaimer: I could be wrong...



# Keeping Score

- 2 major cancer organizations
  - large overlap
  - parts of some entities excluded
- 4 Medical Records units (helpful)
- 3 IRBs (reciprocity)
- 3 IT groups (friendly, knowledgable)
- Large herd of Cats  
(with independent funding!)...  
(and advanced degrees!)...



# Data Access

- Organizational Agreements
  - Intended use
  - Privacy safeguards
  - Security
  
- But, with whom?



# Privacy

- HIPAA Privacy regulations
- Patient Data
  - Protected Health Information
  - De-identified
  - Limited Data Set
- Accounting of Disclosures





# Protected Health Information

- Relates to the past, present, or future physical or mental health or condition of an individual; or
- Relates to the provision of health care to an individual; or
- Relates to the past, present, or future payment for the provision of health care to an individual; and
- Identifies the individual; or with respect to which there is a reasonable basis to believe the information can be used to identify the individual.



# Limited Data Set requires

- Excluding direct identifiers for patient, relatives, employers, or household members
- Data sharing agreement
  - Establish permitted uses of data
  - Establish recipients of data
  - Establish no use or further disclosure beyond data user agreement
  - Appropriate safeguards, transitive property, etc....



# Limited Data Set excludes

- 1) Names;
- 2) Postal address information, other than town or city, State, and zip code;
- 3) Telephone numbers;
- 4) Fax numbers;
- 5) Electronic mail addresses;
- 6) Social security numbers;
- 7) Medical record numbers;
- 8) Health plan beneficiary numbers;
- 9) Account numbers;
- 10) Certificate/license numbers;
- 11) Vehicle identifiers and serial numbers, including license plate numbers;
- 12) Device identifiers and serial numbers;
- 13) Web Universal Resource Locators (URLs);
- 14) Internet Protocol (IP) address numbers;
- 15) Biometric identifiers, including finger and voice prints; and
- 16) Full face photographic images and any comparable images.



# De-identified

- 1) all LDS data elements, *plus...*
- 2) geography smaller than state, or 3 digit zip (if > 20K people)
- 3) all elements of dates except year (birth, admit, d/c, death, and age > 89 yrs.)
- 4) any other unique identifying number, characteristic, or code (sequence data?!)



# De-identified

OR – a demonstrated “very small” risk of re-identification by expert using generally accepted methods.

May assign re-identification number

Ref: [https://know1.mcis.washington.edu/manuals/amc\\_privacyPolicy/](https://know1.mcis.washington.edu/manuals/amc_privacyPolicy/)



# Accounting of Disclosures

- Patient has right to receive an accounting of when PHI disclosed outside of
  - Treatment, Payment, or Operations
  - LDS disclosures (data use agreement)



# Revisit #2: What is difficult?

- **Data Access**
- **Privacy**
- Data Model
- Meaning
- **Timeliness**
- **Linking research results**



# Data Model

- Common clinical model
  - Visit oriented
  - Patient-centric
- Common research model
  - Study oriented
  - Specimen-centric
  - Subset view of patient





# Data Model

- Interesting research data
  - Pedigrees
  - Specimens, incl. anonymous
  - Tumor/Dz registry links
  - Sequences/expression data, etc.
  - Next year's research tests



# Missing from Clinical and Research

- Lifetime view
  - + family, population
- Common data model
- Comprehensive view



# Different Representations?

- Operational, stable
  - Fixed model
  - Relational tables
  - Event driven
- Adaptable, dynamic
  - Extensible
  - Entity-Attribute-Value model?
  - Graph/Network model?



# Master Patient Index

- Clinical
  - Multi-system deterministic matching
  - Multi-institutional, maybe
- Research
  - Multi-institutional
  - Probabilistic matching



# Data Integration

- Vendor C – “buy from us”
- HL7 messaging
- HL7 RIM
  - eHealth initiative, HL7 EMR ballot
- Distributed Queries/Multiple Schemas
  - Mediated schema
  - PTP discoverable schemas



# Meaning

- Syntax
  - Message structure
  - Granularity
  - HL7 Reference Information Model?
- Semantics
  - Vocabularies
  - SNOMED?



# Interfacing

- Event Driven
  - HL7 messaging
- Query Driven
  - Reporting
  - “Research”



# Timeliness

- Real Time
  - “clinical”
- Near Real Time
  - BT surveillance
- ~~Research~~ Retrospective Time
  - Study data analysis





# Research Time?

- When do researchers care about real time?
  - Patient enrollment
  - Clinical decision making
  - Experiment/lab management systems



# Revisit #3: What is difficult?

- Data Access
- Privacy
- Data Model
- Meaning
- Timeliness
- Linking research results



# Why? - Structural Challenges

- Centralized support, decentralized activity
- Different needs for overlapping data
- Different meanings of same data
- Different performance issues with aggregate vs. individual queries
- Uniform security and privacy concerns

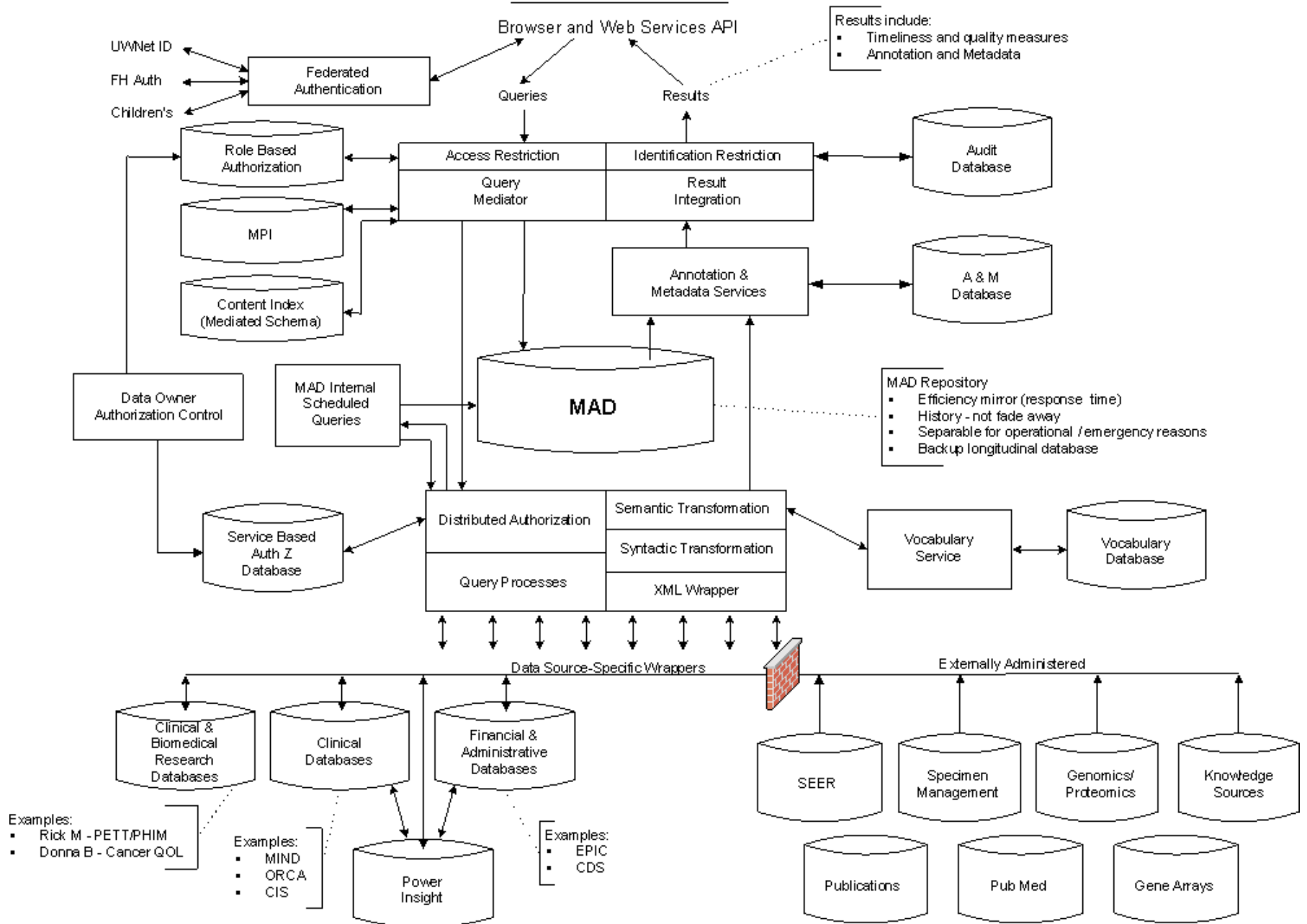


# Approach – Central Services?

- Authentication/Authorization/Auditing
- Master Person Index, De-identification
- Individual/aggregate query support
- Query/Result Annotation
- Extensible, secure storage
- Protocol/Guideline support
- ...



# Users



# Questions

???

