Patient Reported Outcomes (PRO)
Infrastructure Workshop
November 19-20, 2013 | Atlanta, GA

Research Use of PRO data from EHRs

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Professor of Surgery
Chair, myQuest Steering Committee, D-H
Physician Lead, Patient Reported Measures, TDI

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VISION

The Spine Center at Dartmouth-Hitchcock 1998

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Many Programs See Value in PRMs

Department	Condition/Population
Ortho	Hip/Knee/Shoulder
Plastics	Hand/Breast
Spine Clinic	Spine Diagnoses
Pain Clinic	Pain
Hem/Onc	Breast/Head & Neck/Neuro Onc/Prostate
Psychiatry	Sleep Disorders/Depression/Anxiety
OB/GYN	UroGynecology/Post Partum Depression
Rehab	Functional Restoration Program
Neurology	Epilepsy/Multiple Sclerosis
Primary Care	Primary Care Annual Visits
Surgery/Anesth	Pre-Admission Testing
Vascular	Aneurysm, Carotid Disease, Varicose Veins

Practical Issues

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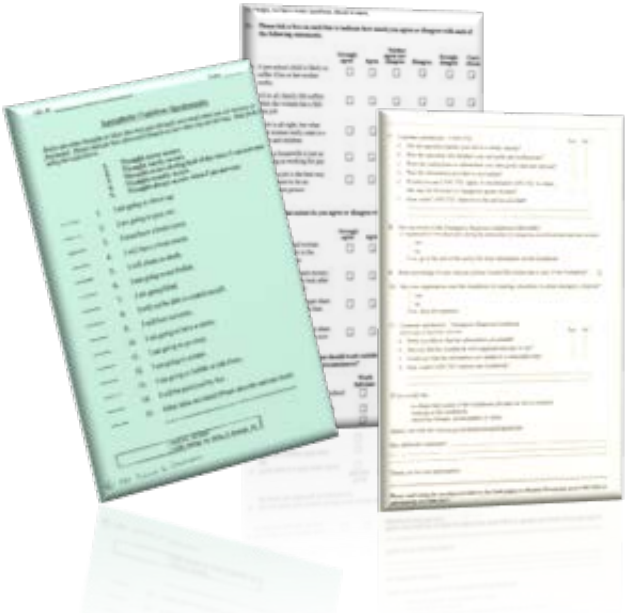
Selecting the right questions requires broad consensus from providers and patients



- 1–2 local champions does not result in high quality, evidence-based Q with a high degree of buy in.
- Consider respondent burden

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Where is the patient reported measure?

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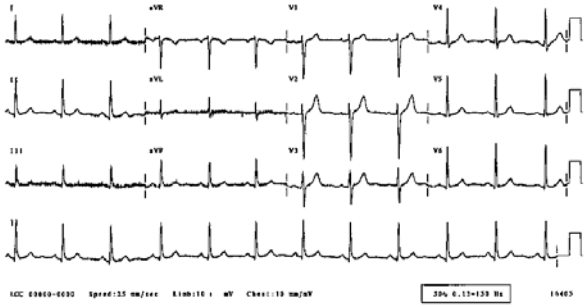
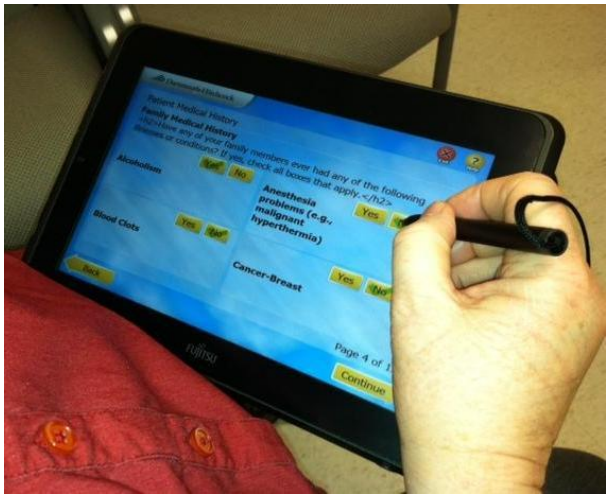
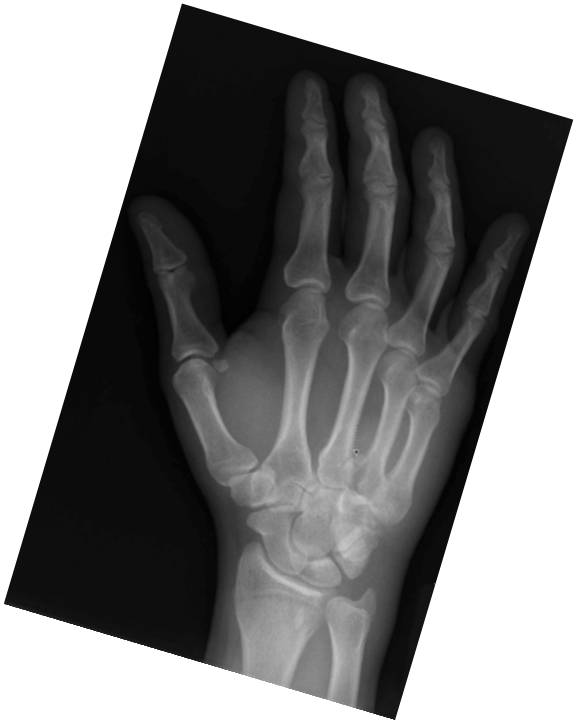
Envision seamless integration of PROs into practice







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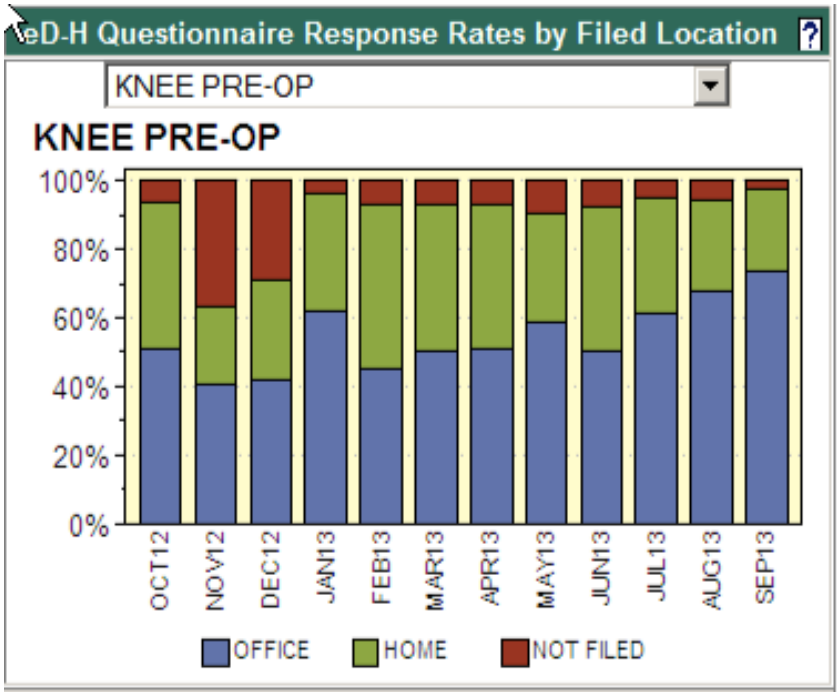
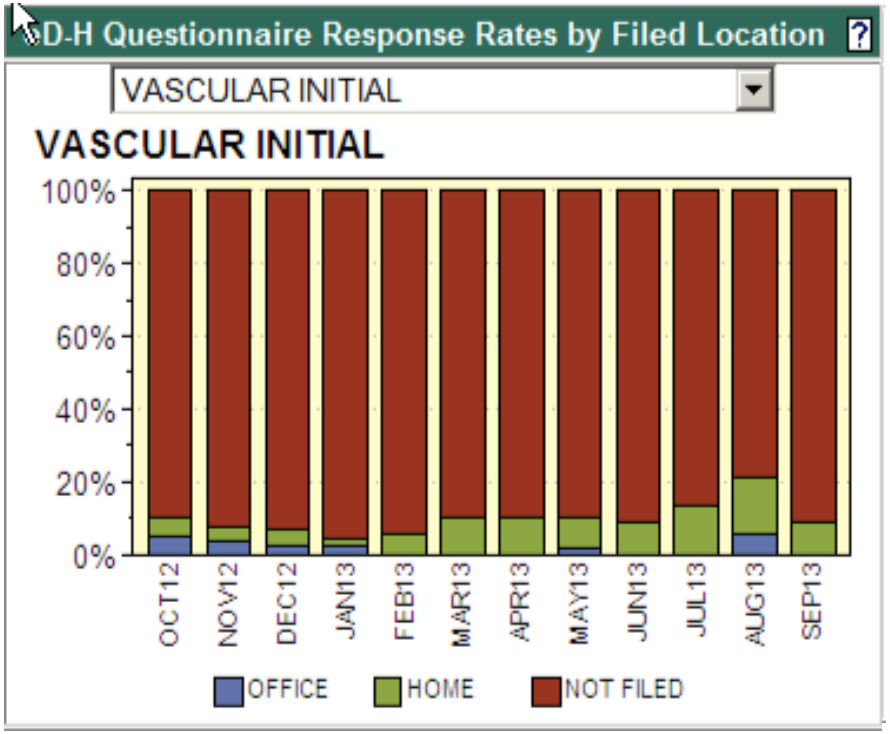
Questionnaire Completion Rates: Process Measure





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Exit Survey

Did you fill out an electronic health questionnaire for your visit today?

[ ] Yes [ ] No

(if you check "No" you do not need to answer any other questions.)

Did anyone thank you for filling out the questionnaire during your visit?

[ ] Yes [ ] No

Did anyone show you or talk to you about the results from the electronic questionnaire during your visit?

[ ] Yes [ ] No

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Incorporation into the clinical encounter

Building

Queuing/Ordering

Patient Interfaces

Clinical Team Use

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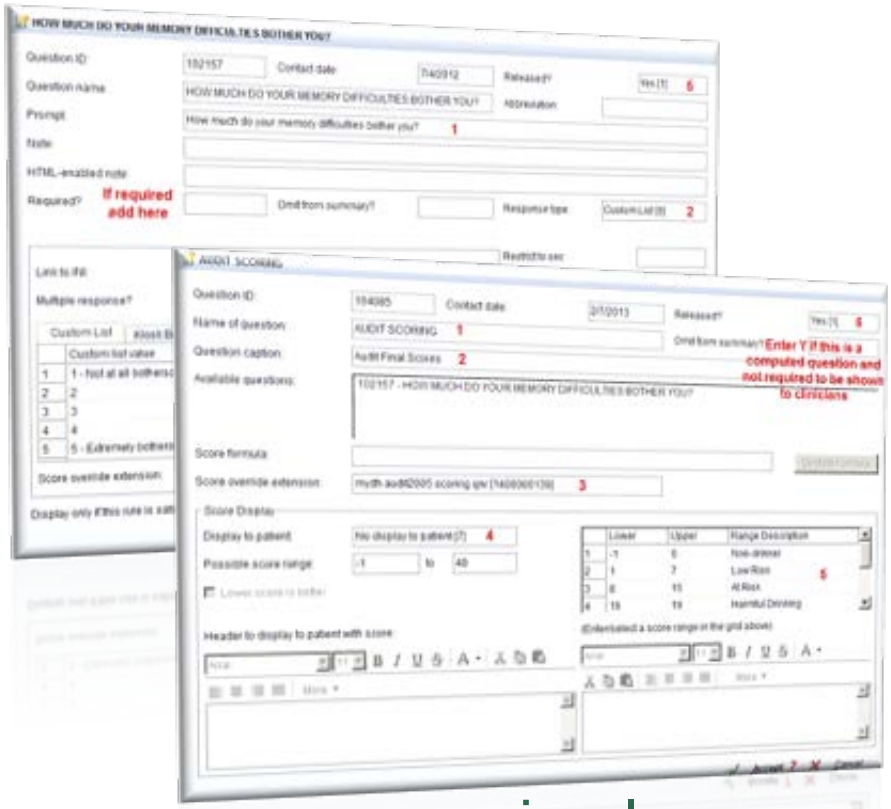
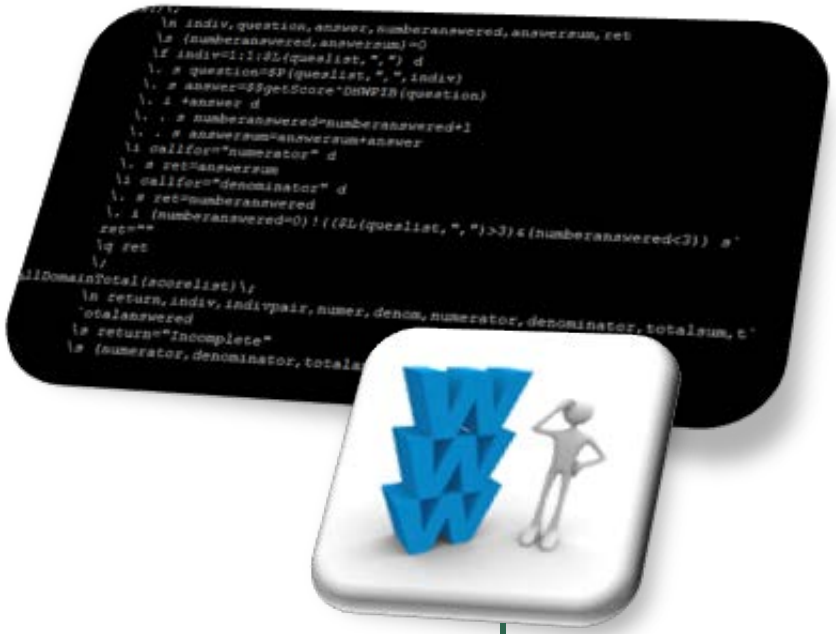
Built it and they will use it .....not



simple

complicated



complex

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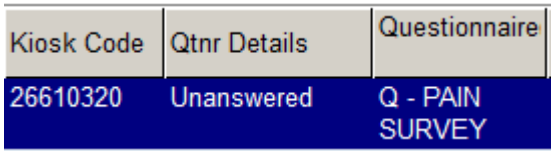
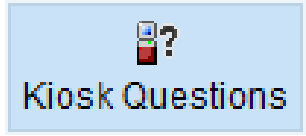
Questionnaire Queuing in EPIC

- Initiated with Appointment



- Sent as Secure Patient Message

- Added on-the-fly as Kiosk Questionnaire



- *Order as a pre-defined series (future)*

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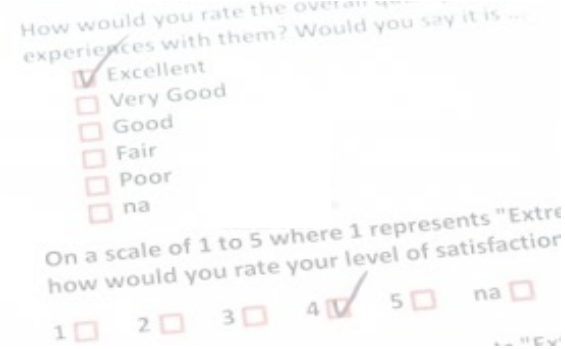
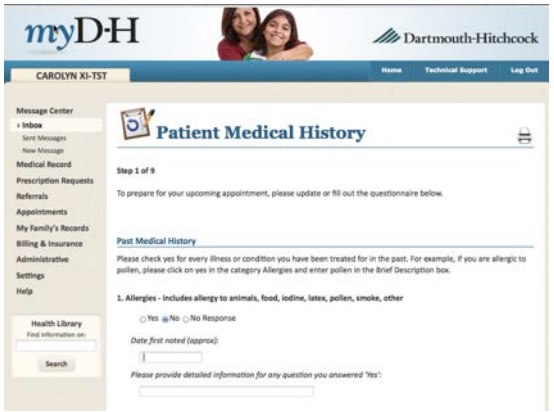
Patients need multiple options for Q completion





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Example of Multimedia

To help you to make an informed decision about colon cancer screening, please choose one of the following radio buttons:

- ○ Link to detailed written information on my computer now
- ◉ Watch a 30 minute video streaming on my computer now
- ○ No, thanks- I already know enough to make the decision
- ○ No, thanks- prefer my doctor makes this decision for me, or not interested

< Back | Continue > | Save a

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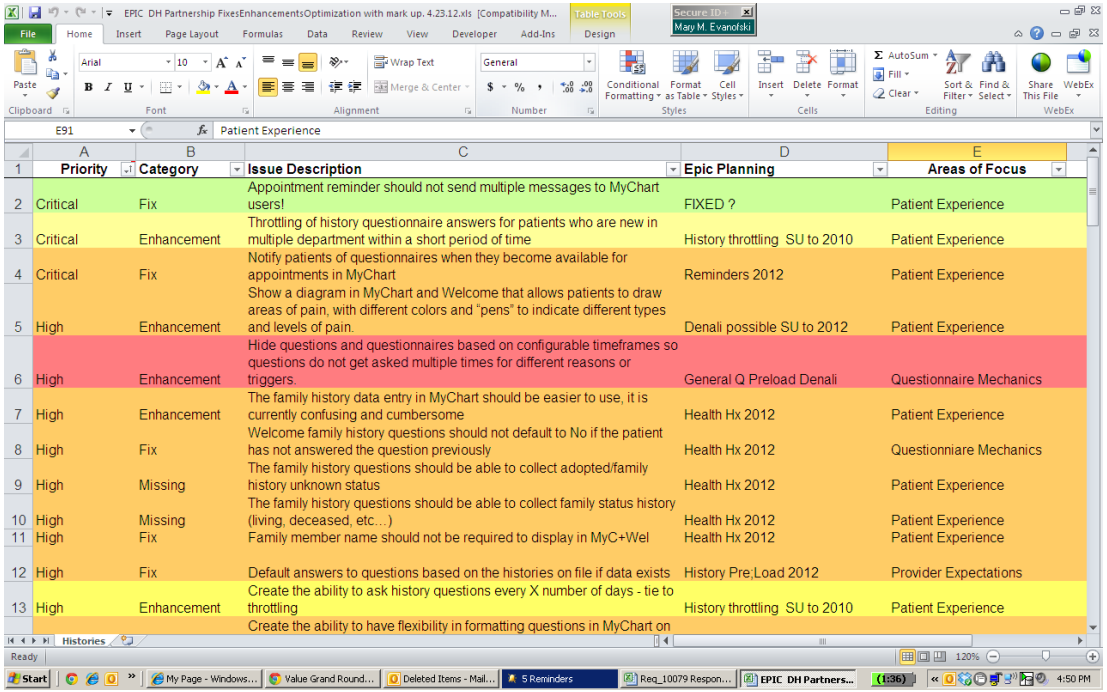
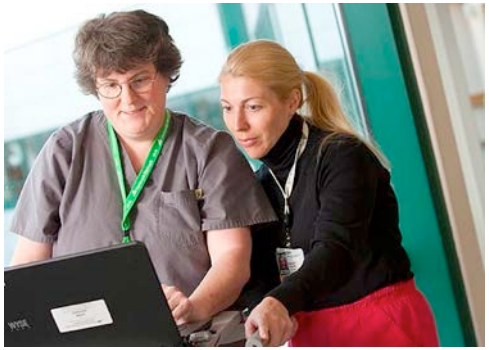
Engaging patients in co-design improves usability

- Volunteers testing design interface
- Capture and track recommendations

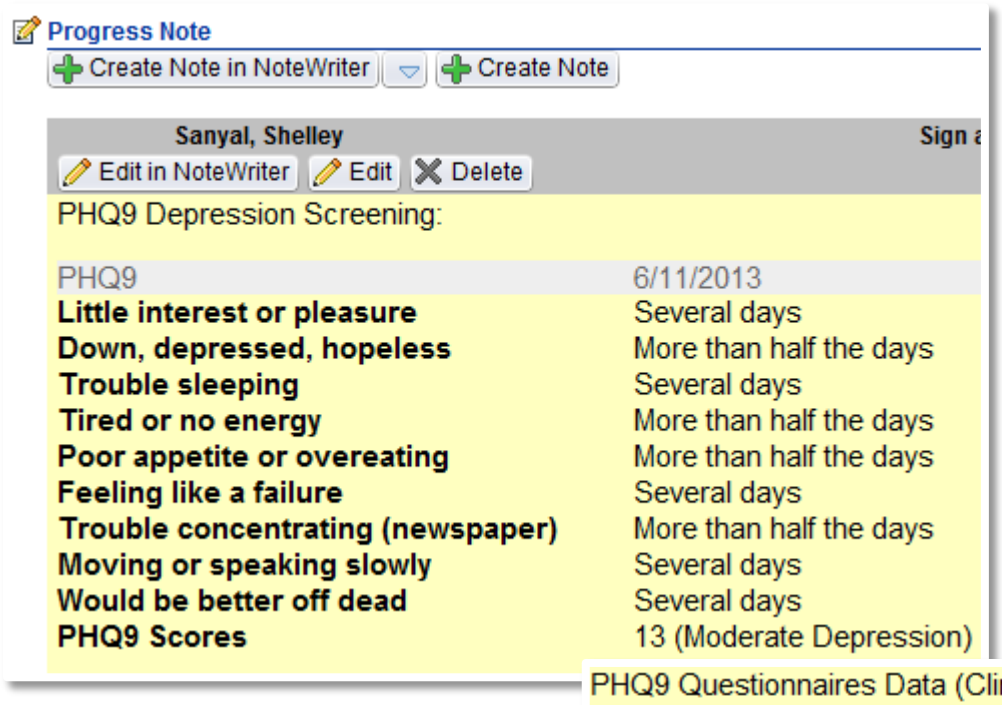


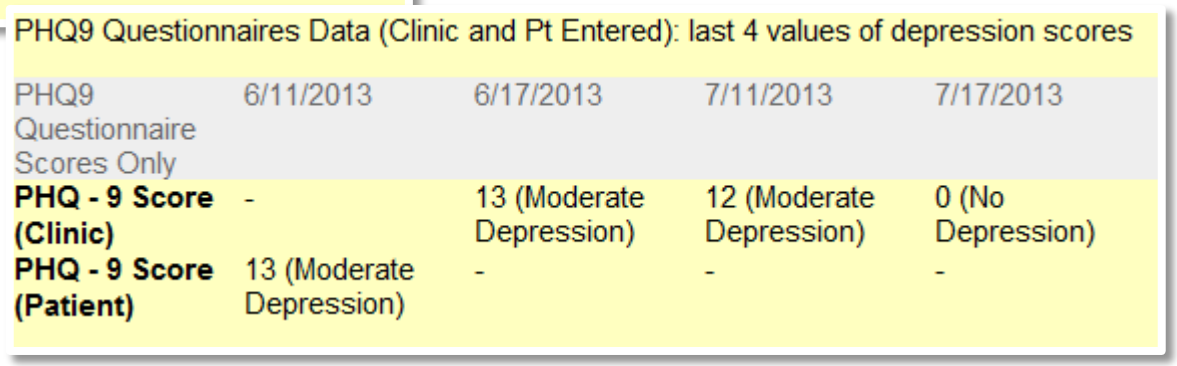
	Priority	Category	Issue Description	Epic Planning	Areas of Focus
2	Critical	Fix	Appointment reminder should not send multiple messages to MyChart users!	FIXED ?	Patient Experience
3	Critical	Enhancement	Throttling of history questionnaire answers for patients who are new in multiple department within a short period of time	History throttling SU to 2010	Patient Experience
4	Critical	Fix	Notify patients of questionnaires when they become available for appointments in MyChart	Reminders 2012	Patient Experience
5	High	Enhancement	Show a diagram in MyChart and Welcome that allows patients to draw areas of pain, with different colors and "pens" to indicate different types and levels of pain.	Denali possible SU to 2012	Patient Experience
6	High	Enhancement	Hide questions and questionnaires based on configurable timeframes so questions do not get asked multiple times for different reasons or triggers.	General Q Preload Denali	Questionnaire Mechanics
7	High	Enhancement	The family history data entry in MyChart should be easier to use, it is currently confusing and cumbersome	Health Hx 2012	Patient Experience
8	High	Fix	Welcome family history questions should not default to No if the patient has not answered the question previously	Health Hx 2012	Questionniare Mechanics
9	High	Missing	The family history questions should be able to collect adopted/family history unknown status	Health Hx 2012	Patient Experience
10	High	Missing	The family history questions should be able to collect family status history (living, deceased, etc…)	Health Hx 2012	Patient Experience
11	High	Fix	Family member name should not be required to display in MyC+Wel	Health Hx 2012	Patient Experience
12	High	Fix	Default answers to questions based on the histories on file if data exists	History Pre;Load 2012	Provider Expectations
13	High	Enhancement	Create the ability to ask history questions every X number of days - tie to throttling	History throttling SU to 2010	Patient Experience
			Create the ability to have flexibility in formatting questions in MyChart on		

Frontline Team needs Training



Questionnaire .phrases

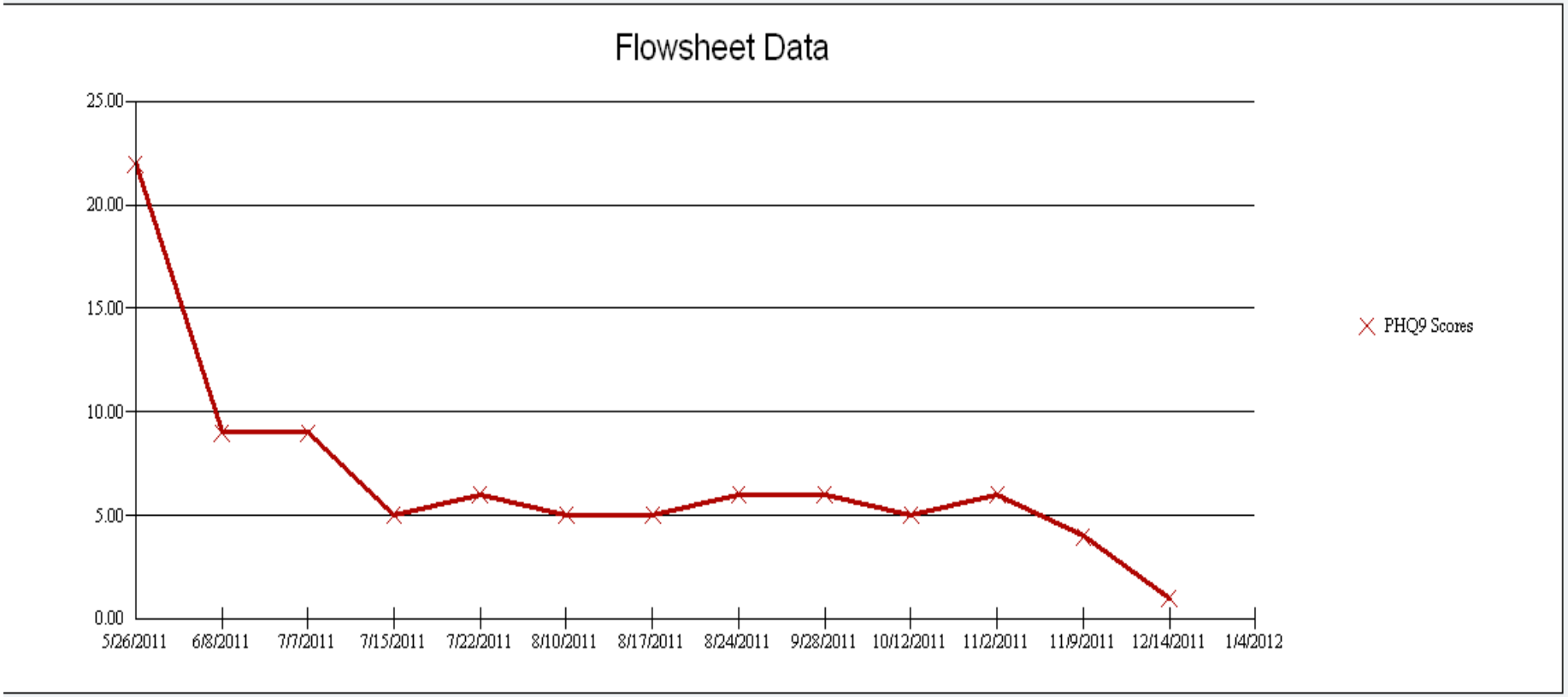




Select Flowsheets to View

PHQ 9 DEPRESSION SCREENING [294]

Load More



Bar Chart | Line Graph | Refresh | Print Graph | Show Flowsheet

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Patient Data Displays?

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My Own Health Report (MOHR) Project

Russell E. Glasgow, PhD.
University of Colorado School of Medicine

…on Behalf of the MOHR Investigator Group

Funded by NCI, AHRQ, and OBSSR

Purpose

To test the feasibility of assessing and providing feedback on 10 key health behavior, mental health risk, and substance abuse factors in diverse primary care settings.

Krist, A. H., et al. Designing a valid randomized pragmatic primary care implementation trial…MOHR) project. *Implement Sci, 2013 Jun 25;8*:73

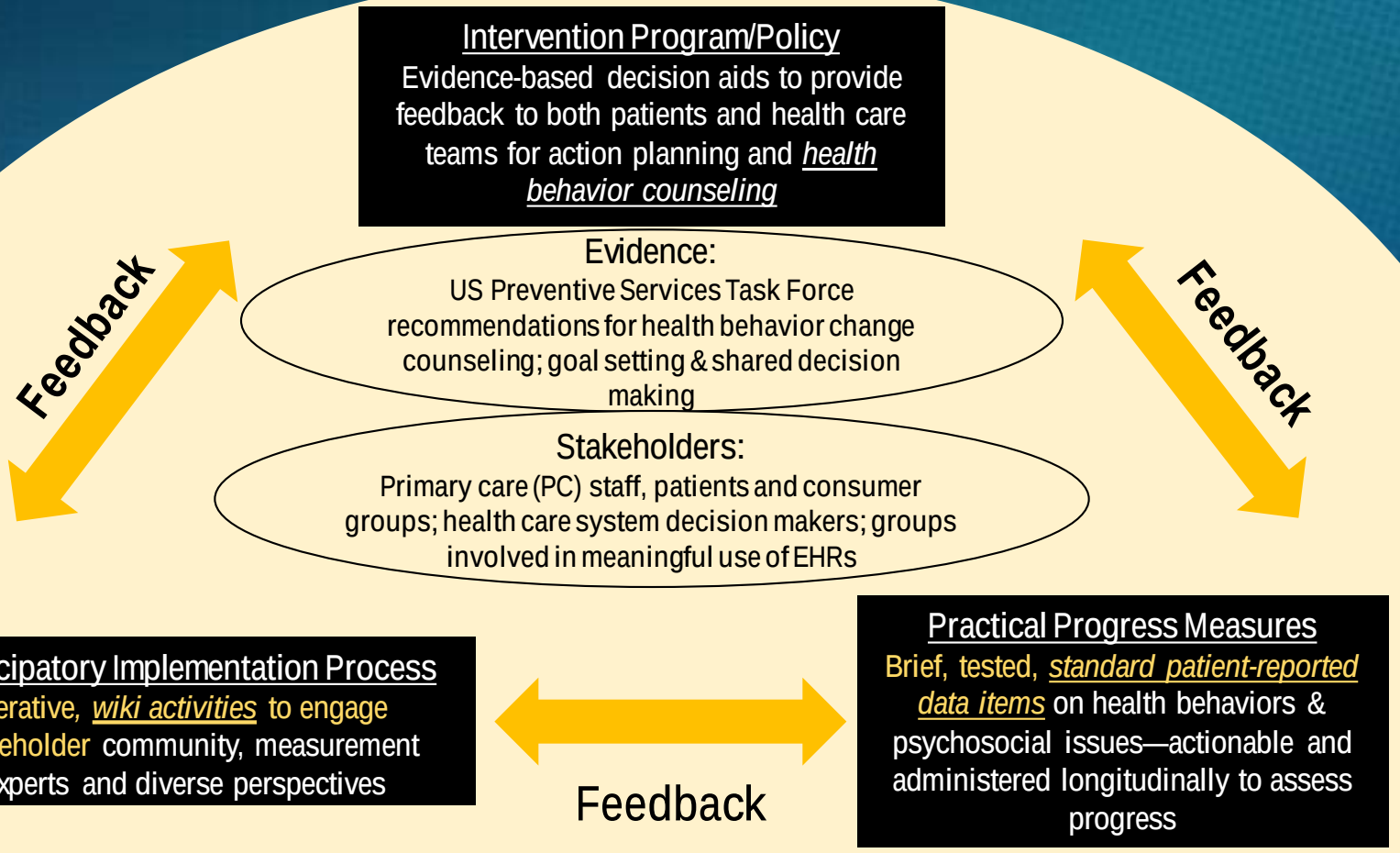
Rationale for MOHR

- Behavioral and mental health issues account for large share of preventable deaths, disability, and health care costs
- Patient report and health behaviors are not routinely assessed or part of the medical record
- Logically impossible to be patient centered if do not assess and respond to patient reports and preferences
- Practices need help and structure to do this—that does not interfere with their other goals

What's Different about This Example?

- In primary care—need to address *many* things
- PR items asked had to be actionable and broadly applicable (as well as valid, reliable, and exceedingly brief)
- Intent was to use items for both clinical (individual and panel) and research purposes
- Needed to provide immediate summary feedback to patient/family and primary care team
- myownhealthreport.org in public domain

Evidence Integration Triangle (EIT)—A Patient-centered Care Example



Multi-Level Context

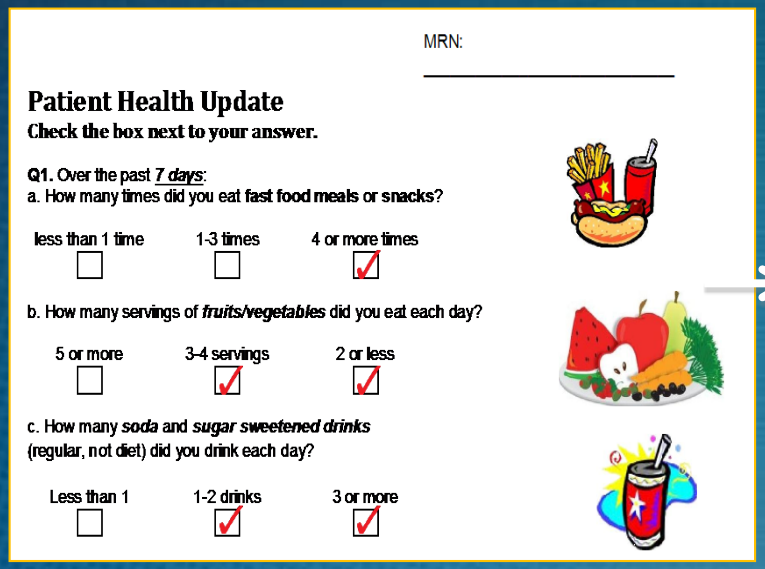
- **Dramatic increase in use of EHR**
- **Primary Care Medical Home**
- **CMS funding for annual wellness exams**
- **Meaningful use of EHR requirements**

Glasgow RE, et al. An evidence integration triangle…*Am J Prev Med* 2012;42(6):646-654.

MOHR Measures for Adult Primary Care

Domain	Final Measure (Source)
1. Overall Health Status	1 item: BRFSS Questionnaire
2. Eating Patterns	3 items: Modified from Starting the Conversation (STC) [Adapted from Paxton AE et al. *Am J Prev Med* 2011;40(1):67-71]
3. Physical Activity	2 items: The Exercise Vital Sign [Sallis R. *Br J Sports Med* 2011;45(6):473-474]
4. Stress	1 item: Distress Thermometer [Roth AJ, et al. *Cancer* 1998;15(82):1904-1908]
5. Anxiety and Depression	4 items: Patient Health Questionnaire—Depression & Anxiety (PHQ-4) [Kroenke K, et al. *Psychosomatics* 2009;50(6):613-621]
6. Sleep	2 items: a. Adapted from BRFSS b. Neuro-QOL [Item PQSLP04]
7. Smoking/Tobacco Use	2 items: Tobacco Use Screener [Adapted from YRBSS Questionnaire]
8. Risky Drinking	1 item: Alcohol Use Screener [Smith et al. *J Gen Int Med* 2009;24(7):783-788]
9. Substance Abuse	1 item: NIDA Quick Screen [Smith PC et al. *Arch Int Med* 2010;170(13):1155-1160]
10. Demographics	9 items: Sex, date of birth, race, ethnicity, English fluency, occupation, household income, marital status, education, address, insurance status, veteran's status. Multiple sources including: Census Bureau, IOM, and *National Health Interview Survey (NHIS)*

My Own Health Report (MOHR)
Web-based Assessment and Feedback Tool



MRN: _____

Patient Health Update

Check the box next to your answer.

Q1. Over the past *7 days*:

a. How many times did you eat **fast food meals or snacks**?

less than 1 time	1-3 times	4 or more times
☐	☐	☑

b. How many servings of ***fruits/vegetables*** did you eat each day?

5 or more	3-4 servings	2 or less
☐	☑	☑

c. How many ***soda*** and ***sugar sweetened drinks*** (regular, not diet) did you drink each day?

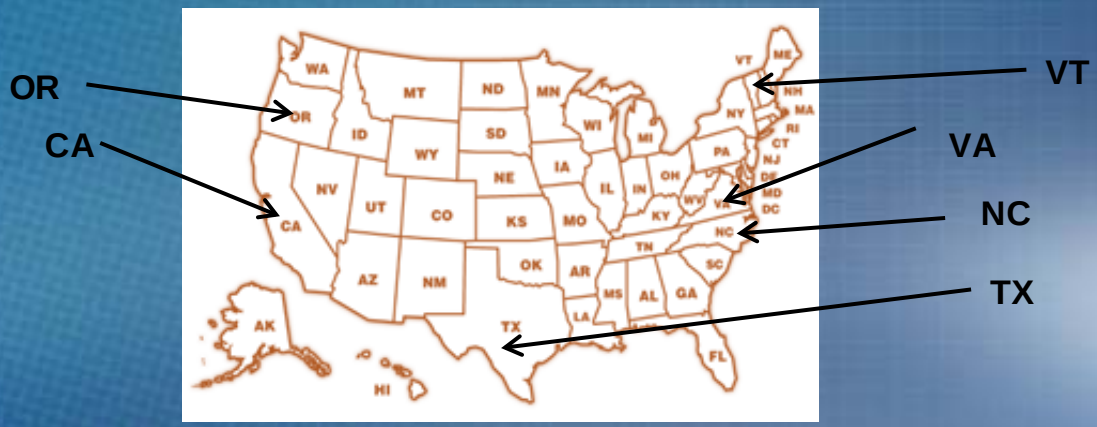
Less than 1	1-2 drinks	3 or more
☐	☑	☑

- Database of text messages and triggers
- Summary display and printout for patient and family
- Action Plan printout
- Summary display and printout for health care team
- Report data stored in database
- Research analysis

Krist A, et al. Designing a valid pragmatic primary care implementation trial…*Implement Sci* , 2013, 8:73

MOHR Project—Key Points

- **Cluster randomized trial** of 9 clinic pairs, staggered early and late intervention
- Approximately half of clinics community health centers, others AHRQ-type PBRN clinics
- Designing for flexibility and adoption—e.g., varying levels of clinic integration of EHRs, different levels and modalities of decision aids
- **WHAT is delivered**—e.g., automated assessment tool, feedback, goal setting materials, follow-up are **STANDARD**
- **HOW this is delivered is customized** to setting
- Study goal = Sustainable, routine use of intervention



MOHR Key Outcomes

- Primary Outcome = Percent and representativeness of patients who have a personalized action plan set ('meaningful use')
- Secondary Outcomes = Percent who receive follow-up contacts; improvement on health behaviors and mental health issues; costs and resources required; adaptations made
- Note: At this point not integrated into the diverse EHRs

MOHR: Current Status

- Completing intervention phase
- Different cultures in PBRNs and community health (safety net providers for low income and uninsured) centers
- This trial will be fast, inexpensive, implementation informative…and not definitive
- Key focus is implementation: reach, equity and 'fit' in diverse settings are central.

MOHR: Lessons Learned to Date

- Each clinic, population, and IRB is different
- Key to pragmatic study success is balancing fidelity (to evidence-based principles not static protocol) with context-sensitive adaptation
- Context Changes—and needs repeated, multi-method assessment
- Patients have multiple needs—average of over 6 areas
- Cost, resource, and time issues are central
- Importance of flexibility for researchers and clinics—e.g., to fit local flow, priorities, modality and timing preferences

For More Information on MOHR

Alex Krist, Virginia Commonwealth University
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myownhealthreport.org

Suzanne Heurtin-Roberts
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Russ Glasgow, University of Colorado
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For info on training, materials, etc.:
healthpolicy.ucla.edu/mohr

Other Data Collected in MOHR

- Cost
  - Collected 2x in early intervention sites
- Clinic Context
  - Collected 3x pre-, mid-, post-intervention, qualitative template
- Project Context
  - Collected once, end of project, open-ended survey of key project stakeholders (e.g., researchers, funders)
- Post-Implementation Interview
  - Group interview, clinic staff

Future Pragmatic Needs and Opportunities: Keys to Advance Translation in MOHR and in General

- Health equity impacts—along multiple dimensions of RE-AIM
- Context—key factors that may moderate results, measurement
- Scalability—potential to impact large numbers
- Sustainability
- Patient / citizen / consumer and community perspective and engagement throughout
- Multi-level interactions, especially between policy and practice

Cleveland Clinic

PRO, EMR and research : the Cleveland Clinic experience

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Department of Neurosurgery
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November 20, 2013

Knowledge Program

Background

- Originated 2007 as a collaboration between Neurological Institute, Imaging Institute and Information Technology Division at Cleveland Clinic
- Disease Outcome Integration

Neurological Institute:

- 15 disease based Centers of Specialty
- Clinics Main Campus & 15 Ambulatory Health Centers
- 154,944 ambulatory visits 2010

2007 -- Spine Center and KP – New strategy needed

Need patient centered outcomes

Need efficient data entry

Need efficient workflow

- high volume center, multiple providers at multiple locations

What health status measures do we use?

- Faculty polled and …
  - MOS-36, ODI, NDI, Euroqol, VAS, PHQ-9, PDI

What happened?

Forms not completed – too long

Forms not completed – slowed down clinic too much

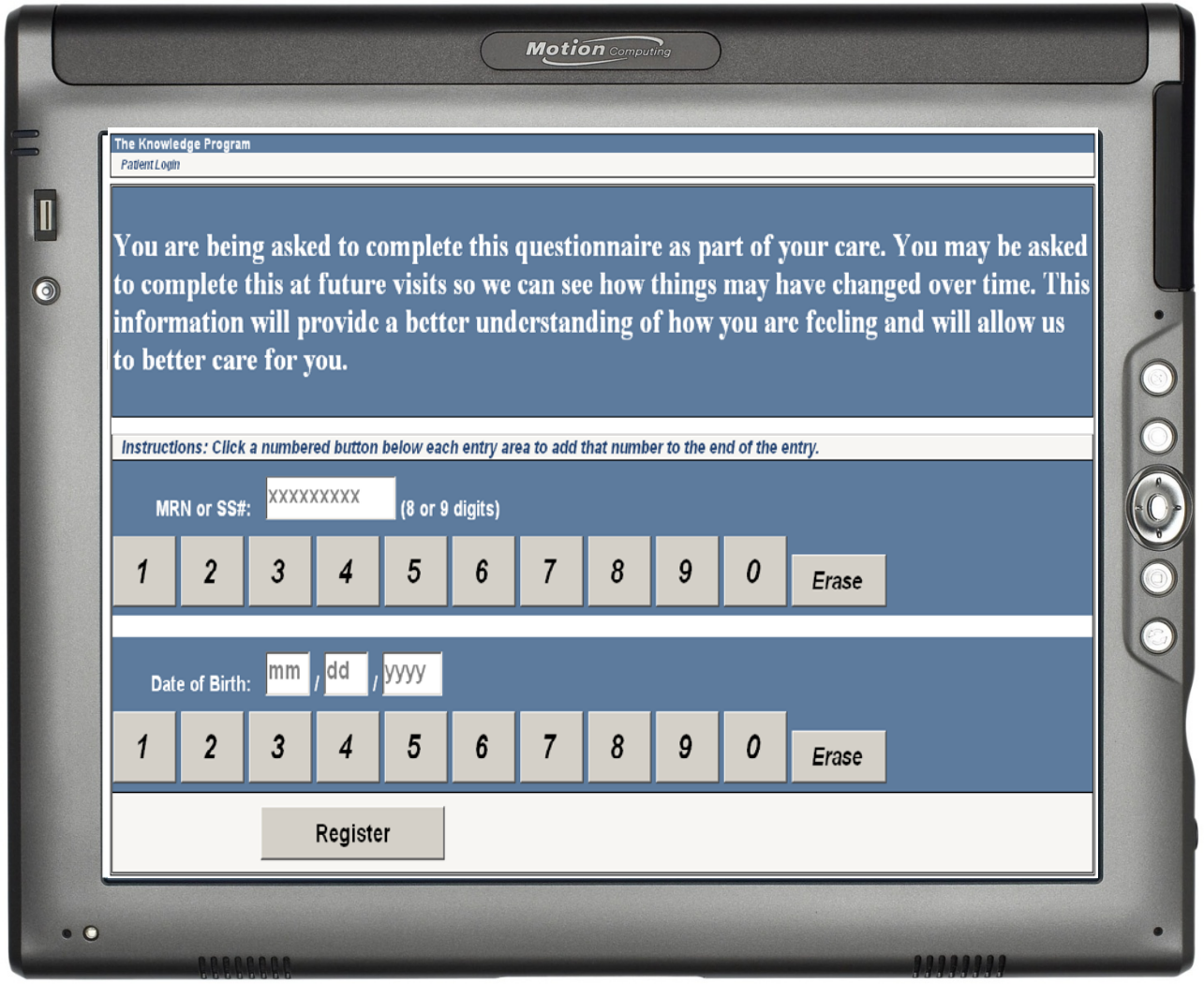
Forms not completed – not available at remote locations

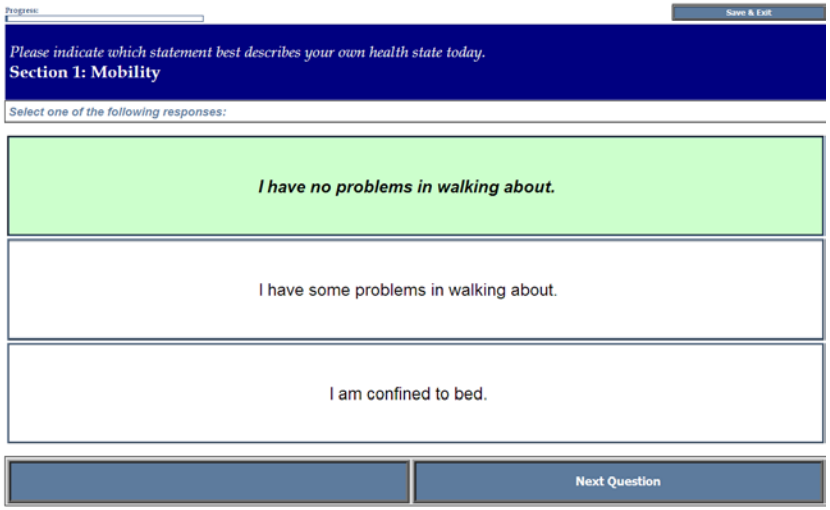
Spine Center and KP -- where are we now?

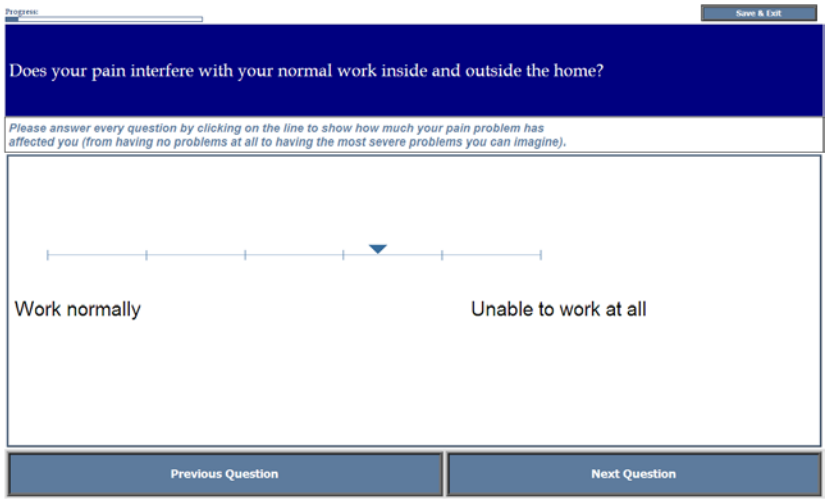
Changed strategy for outcome measures

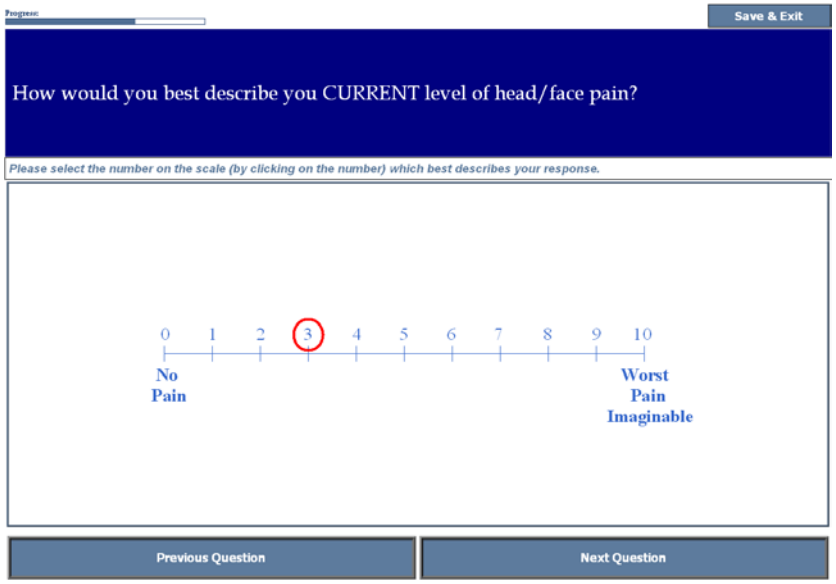
- Broke with tradition – MOS-36 / ODI / NDI/ PDI dumped
- Rational design of outcome measures to cover multiple domains
  - EuroQol
  - Patient Disability Questionnaire
  - PHQ-9
  - VAS
  - Work status
  - Personality inventory
  - (JOA)

Tablet Entry

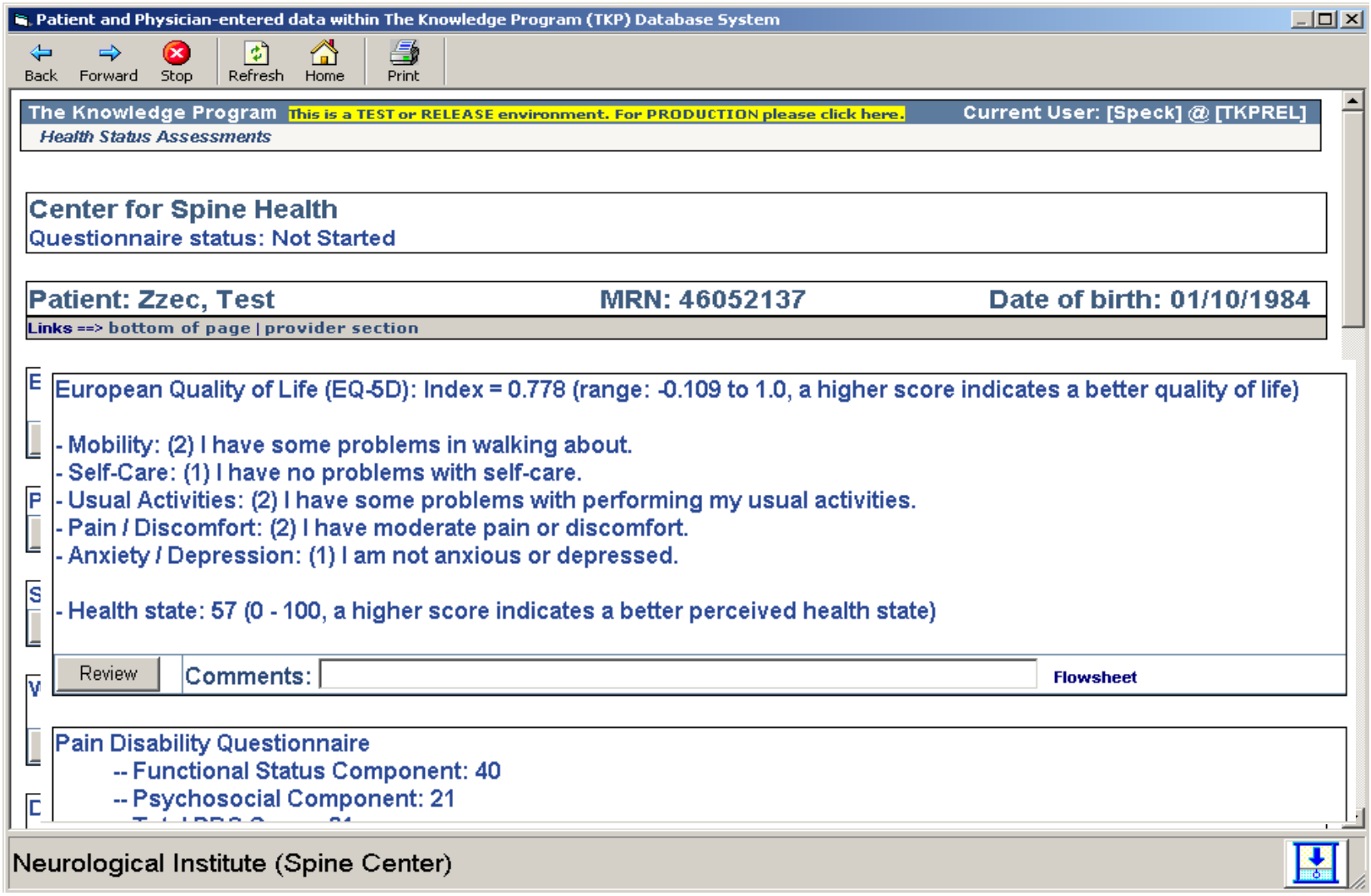



Progress:
Save & Exit
Please indicate which statement best describes your own health state today.
Section 1: Mobility
Select one of the following responses:
I have no problems in walking about.
I have some problems in walking about.
I am confined to bed.
Next Question

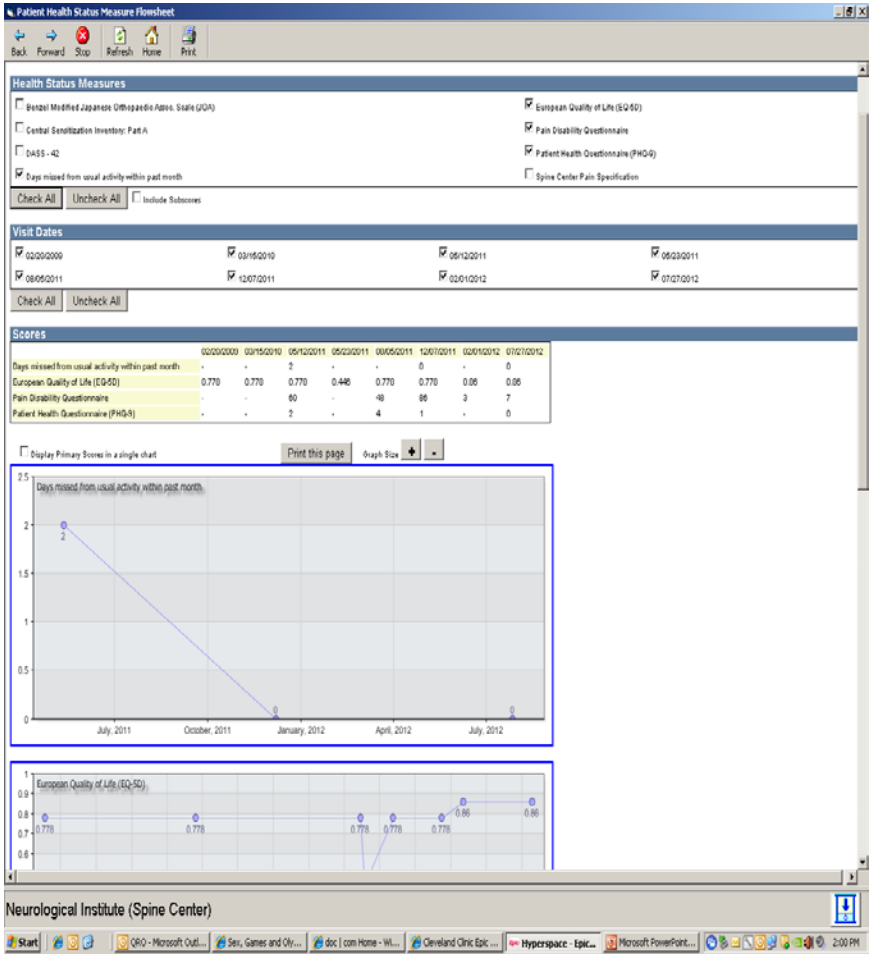

Progress:
Save & Exit
Does your pain interfere with your normal work inside and outside the home?
Please answer every question by clicking on the line to show how much your pain problem has affected you (from having no problems at all to having the most severe problems you can imagine).
Work normally
Unable to work at all
Previous Question
Next Question

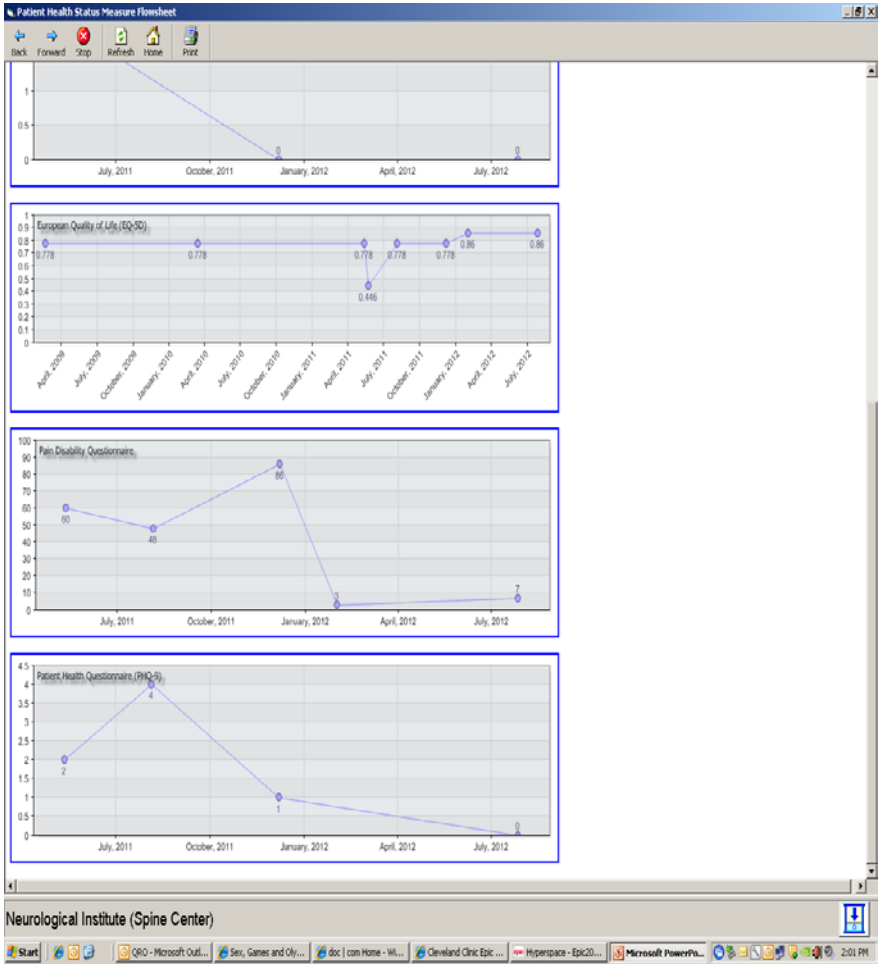

Progress:
Save & Exit
How would you best describe you CURRENT level of head/face pain?
Please select the number on the scale (by clicking on the number) which best describes your response.
0 1 2 3 4 5 6 7 8 9 10
No Pain
Worst Pain Imaginable
Previous Question
Next Question

Physician workflow

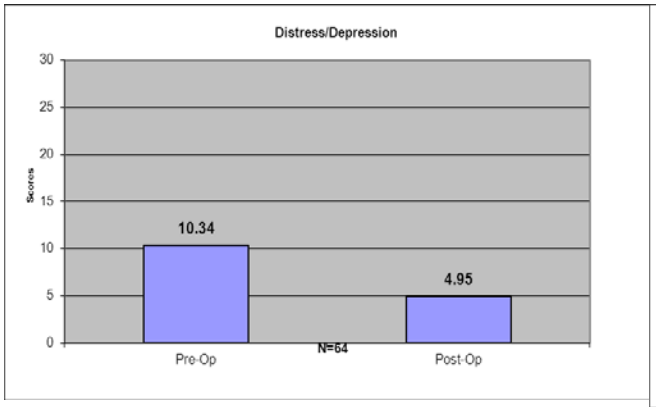


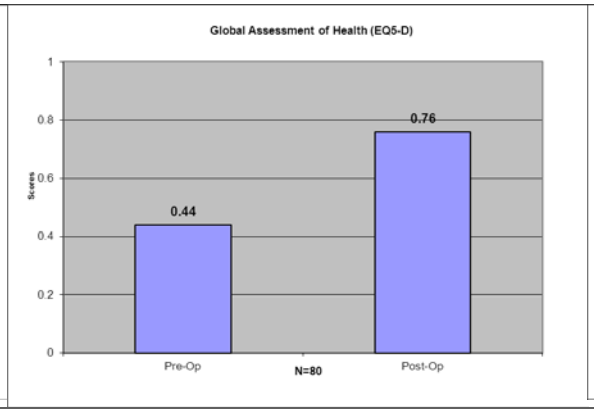
Real Patient –s/p TLIF 12/12/11

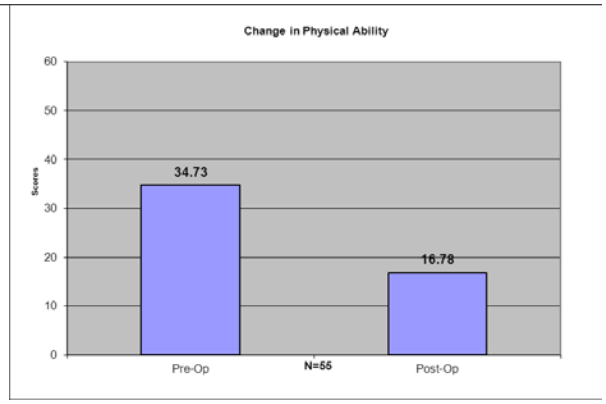


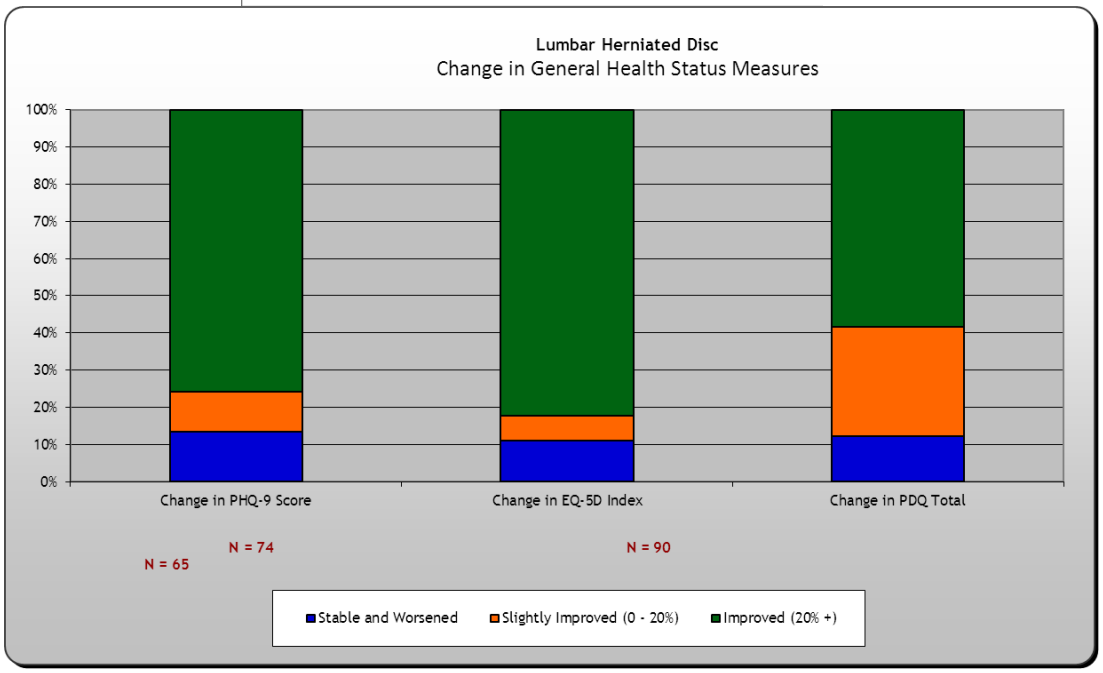


Knowledge Program Outcomes

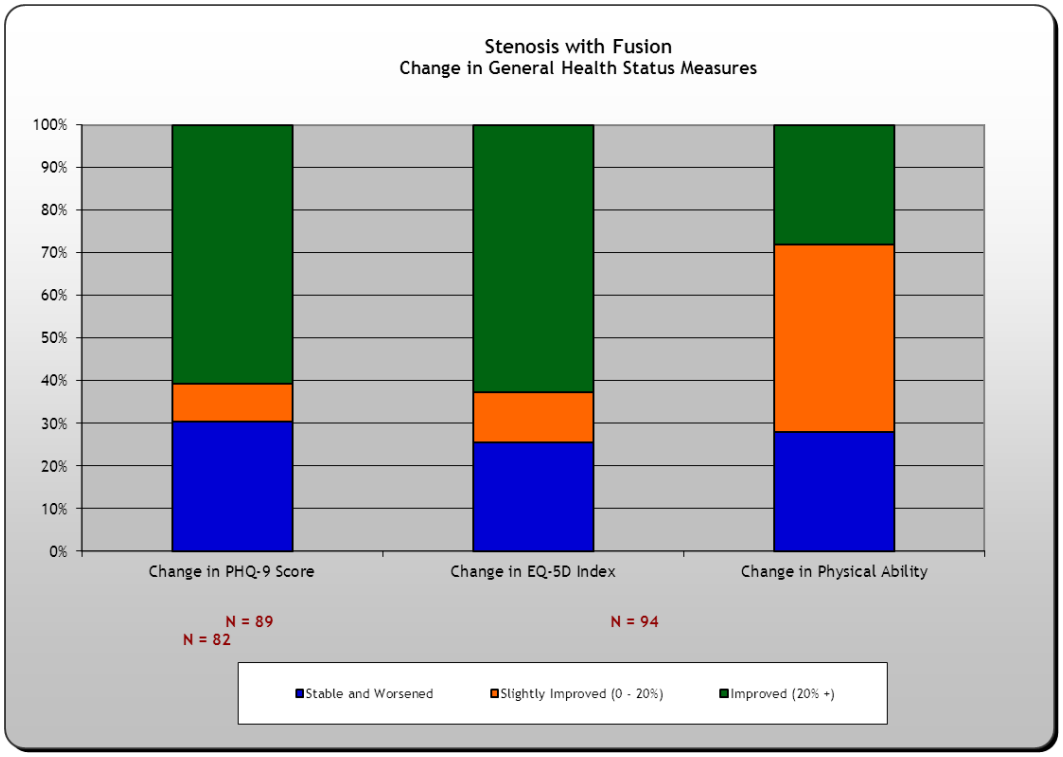


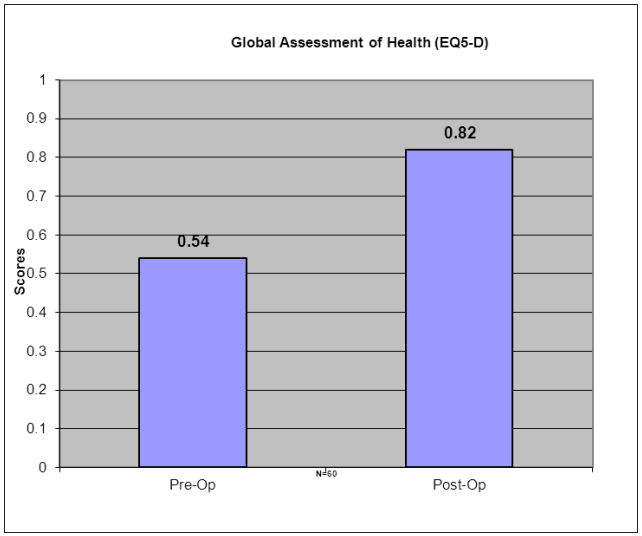


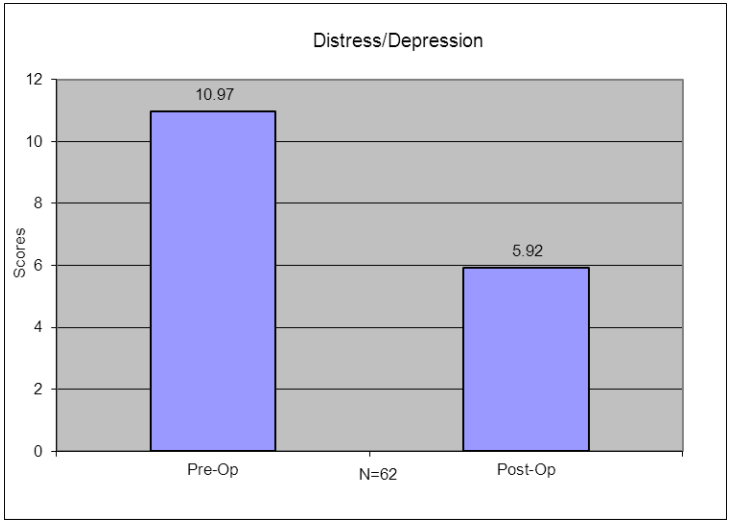




Knowledge Program Outcomes







Current Studies:

Comparative effectiveness of TLIF vs PLF in degenerative spondylolisthesis

Comparative effectiveness of ACDF vs cervical foraminotomy

Does improvement in mJOA scores after surgery for cervical myelopathy correlate with improvement in quality of life scores?

Does obesity have an effect on outcomes in patients undergoing spinal fusion for degenerative spondylolisthesis

- Fellow: Dhaliwal

Cost of surgery vs outcome

- Resident: Rosenbaum

Cell salvage vs blood transfusion – effects on cost and outcomes

- Resident: Rosenbaum

Effect of microdiscectomy on depression scores in patients with radiculopathy

- Fellow: Anderson

What have we learned?

KP extremely powerful tool for research

Important to have a well designed battery of outcomes instruments

Need to keep questionnaires as short as possible

Frustrations:

- Incomplete data sets!
  - Sub-optimal completion rate
  - Inconsistent follow-up
  - Length of follow-up
- Efficiency of data extraction / searches
- No “gold standard” for outcomes measures / cost analysis
  - Commonly used spine measures are long
  - Up hill battle to change “standard” measures
- Difficulty obtaining long term follow-up (financial pressures)

Future?

Decouple PRO from clinical encounter

Standardize follow-up across practice

Refine measures (PROMIS)?

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The Cleveland Clinic
The Arnold and Sydell Miller Family Pavilion

THANK YOU

PCORI: PRO Infrastructure Workshop

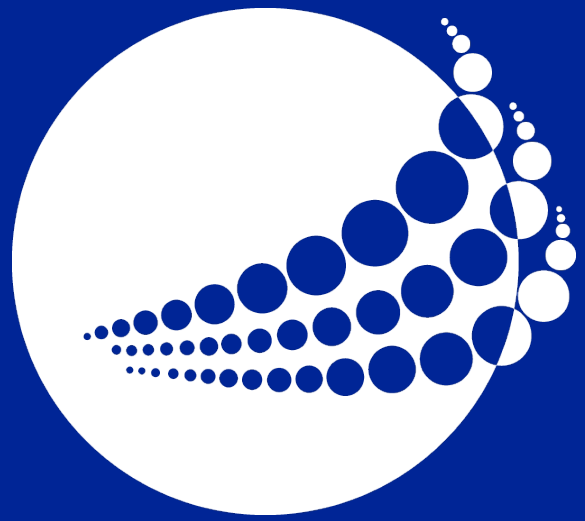
Research and Clinical Uses of EMRs and PROs

November 2013

Marc L. Berger, M.D.

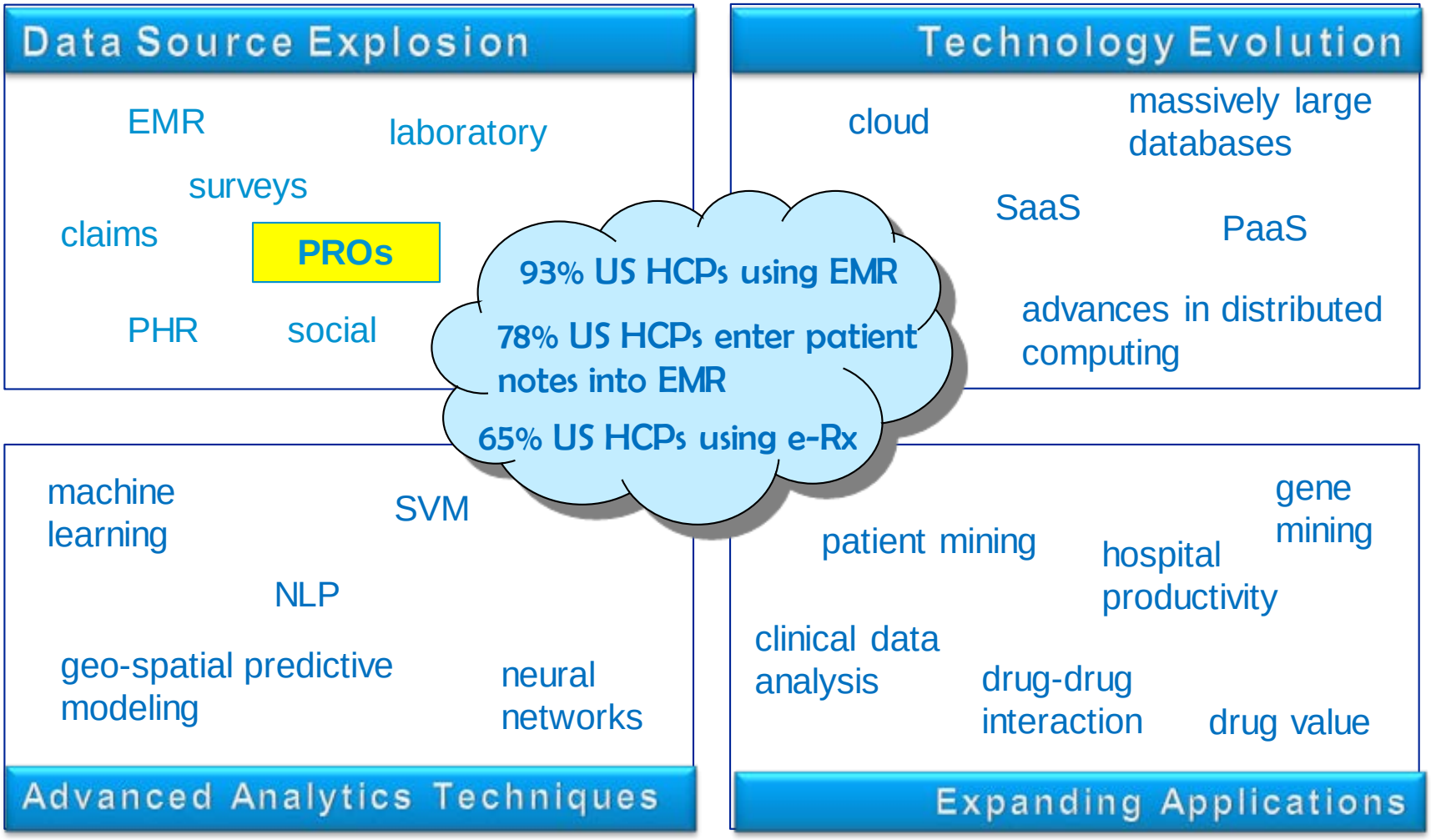
Vice President

RW DnA



Enhancing Real World Insights Together

Current Landscape



: http://newsroom.accenture.com/news/emr-and-hie-use-increases-among-us-doctors-accenture-annual-survey-finds.htm

What is Real World Data?

Real World Data is healthcare data used for decision making that is not collected in conventional randomized controlled trials (RCTs)

Sources of Real World Data:

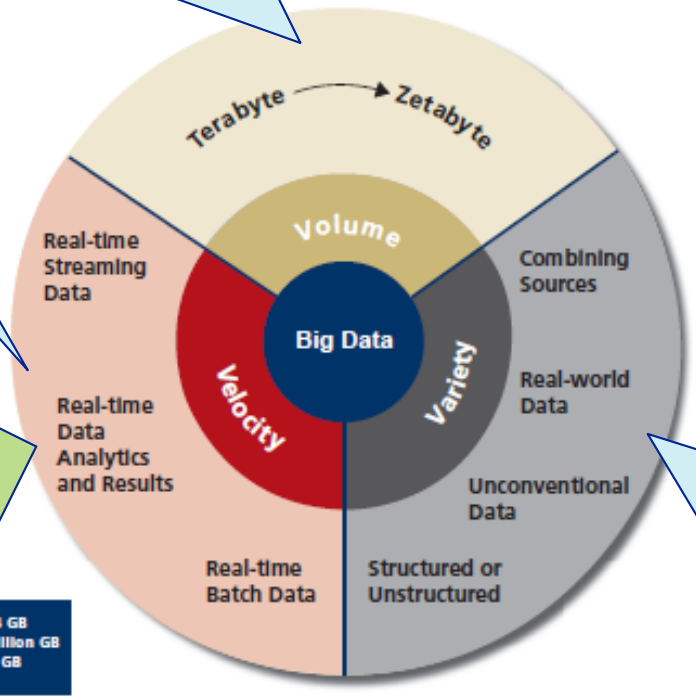
Databases	• Cross-sectional and longitudinal databases which essentially provide retrospective data but increasingly offer the opportunity to have prospective add-ins.
Surveys	• Primarily for epidemiological information.
Pt Reported Measurements	
EMRs	• Used to reflect particular insights in patient management.
Cohort studies	• What most people would understand by real life studies.
Pragmatic clinical trials	• Simple experimental trials, where efforts are however made to mimic a real life situation as much as possible.
Registries	• Analyzing all patients treated at a particular center for a particular condition on a continuous basis.

- "Using Real-World Data for Coverage and Payment Decisions: The ISPOR Real-World Data Task Force Report," Value in Health, Volume 10, November 5, 2007.
- Annemans, L., Aristides, M., Kubin, M. "Real-Life Data: A Growing Need," ISPOR Connections 2007.

Real World Data is Big Data

Genomic
Imaging
EMR Unstructured Notes

Sensors and Health Monitoring Devices



Learning Healthcare System

1 Terabyte = 1024 GB
1 Petabyte = 1 million GB
1 Zetabyte = 10^{12} GB

Claims, Laboratory
EMR, PHR
Surveys: Health Risk Assessments, Health Status Assessments
Pt Reported Outcomes
Revealed Pt Behaviors and Preferences (ex. Purchasing Habits, Google Trend)

Adapted from: Zikopoulos PC, Eaton C, deRoos D, Deutsch T, Lapis G. *Understanding Big Data. New York: McGraw Hill; 2012*

Typical RW Studies and Analyses

Research & Analysis

- Natural Hx of Disease
- Treatment Patterns
- Burden of Illness
- Response to Treatment
- Adherence/Persistence
- Comparative Effectiveness
  - Individual Treatments
  - Systems of Care
- Health Care Resource Use
- Cost-Effectiveness
- Predictive Modeling
  - Tx Choice, Brand Choice
  - Disease Progression – Pt Heterogeneity
  - Response to Therapy – Pt Heterogeneity

Clinical Care

- Assess Quality of Care
  - Support Quality Improvement Efforts
  - Compare outcomes among providers & centers
- Assess Cost of Care
  - Manage HC expenditures
  - Compare costs among providers & centers
- Identify patients for specific interventions
  - Disease / Care Management
    - Patient Heterogeneity
  - Screening
- Risk Estimation and Management
  - Benefit Design, Contracting

Who Can Respond to Treatment?

Identifying Patient Characteristics Related to Heterogeneity of Treatment Effects

Sherrie H. Kaplan, PhD, MPH, John Billimek, PhD, Dara H. Sorkin, PhD, Quyen Ngo-Metzger, MD, MPH, and Sheldon Greenfield, MD

Background: Interest in comparative effectiveness research and the rising number of negative or "small effect" trials have stimulated research into differential response to treatment among subgroups of patients.

Objective: To develop and test the Potential for Benefit Scale (PBS), a composite measure to identify subgroups of patients with differential potential for response to treatment, using diabetes as a model.

Design: Cross-sectional and longitudinal cohort study.

Subjects and Setting: Type 2 diabetes patients (n = 1361) were identified from 7 outpatient clinics serving a diverse population. Of these, 611 completed a 1-year follow-up.

Measures: To represent patients' health status, we used the Total Illness Burden Index, the Physical Function Index of the SF-36, the Center for Epidemiologic Studies Depression Scale, and the Diabetes Burden Scale. To represent personality characteristics related to health, we used the Provider-Dependent Health Care Orientation scale. We assessed the contribution of these measures to a composite scale of patients' potential for treatment response in terms of self-reported medication adherence and glycemic control.

Key Words: heterogeneity of treatment effects, comorbidity, diabetes

(*Med Care* 2010;48: S9–S16)

■ *If it were not for the great variability among individuals, medicine might as well be a science and not an art.*
—Sir William Osler, The Principles and Practice of Medicine 1892

Called "heterogeneity of treatment effects," the recognition that patients vary in response to treatment is not a new concept, as illustrated by the quote from Sir William Osler from 1892. However, the recent re-emergence of this concept in the clinical and statistical literature is a reflection of its sustained importance for clinical practice, clinical guidelines, and most importantly, for the design and conduct of clinical trials.[1–6] The need to understand and respond to patient variation in treatment response has been fueled by the convergence of 2 phenomena: (1) the rise in

Patient Reported Measurements and Other RWD may assist in assessing Patient Heterogeneity

Potential Data Sources

Claims, Lab →

HRA, HSA, TIBI, **PROs** Lab →

Pt Surveys →

Claims, HSA, HRA →

Survey, EHR →

Survey, HSA →

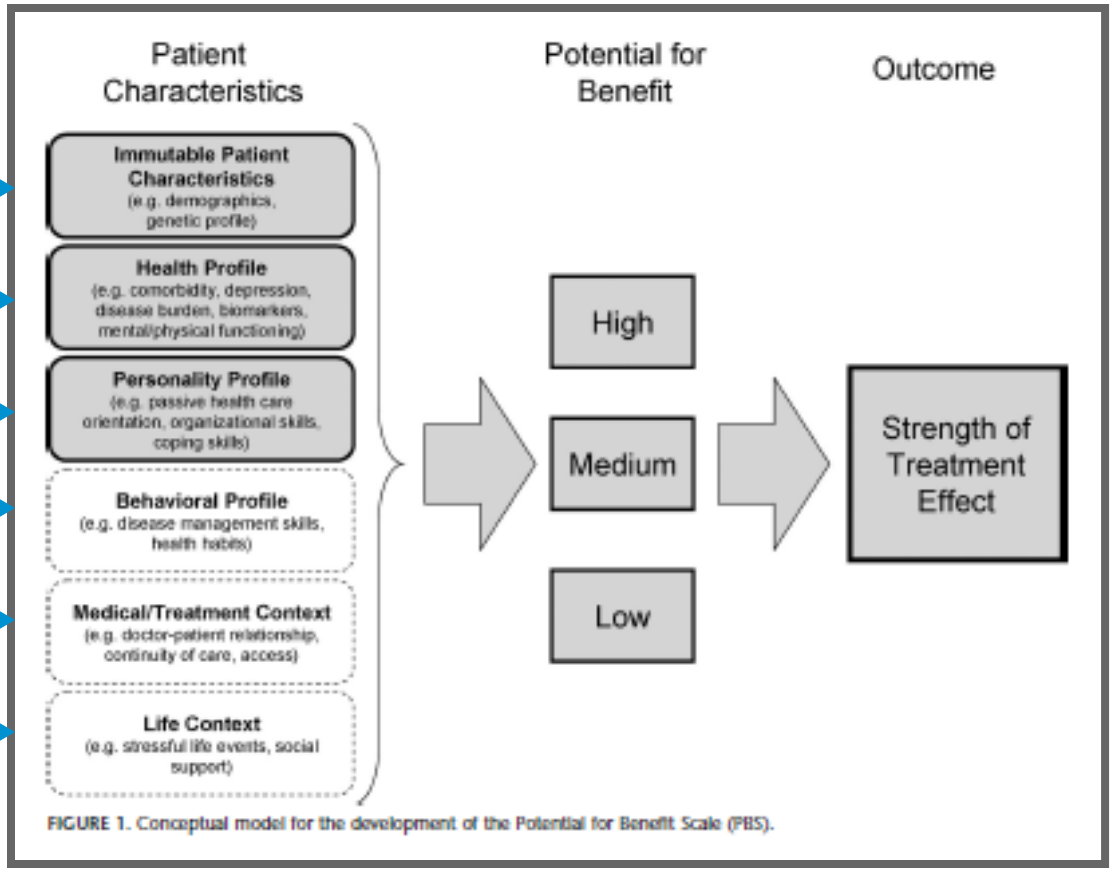


FIGURE 1. Conceptual model for the development of the Potential for Benefit Scale (PBS).

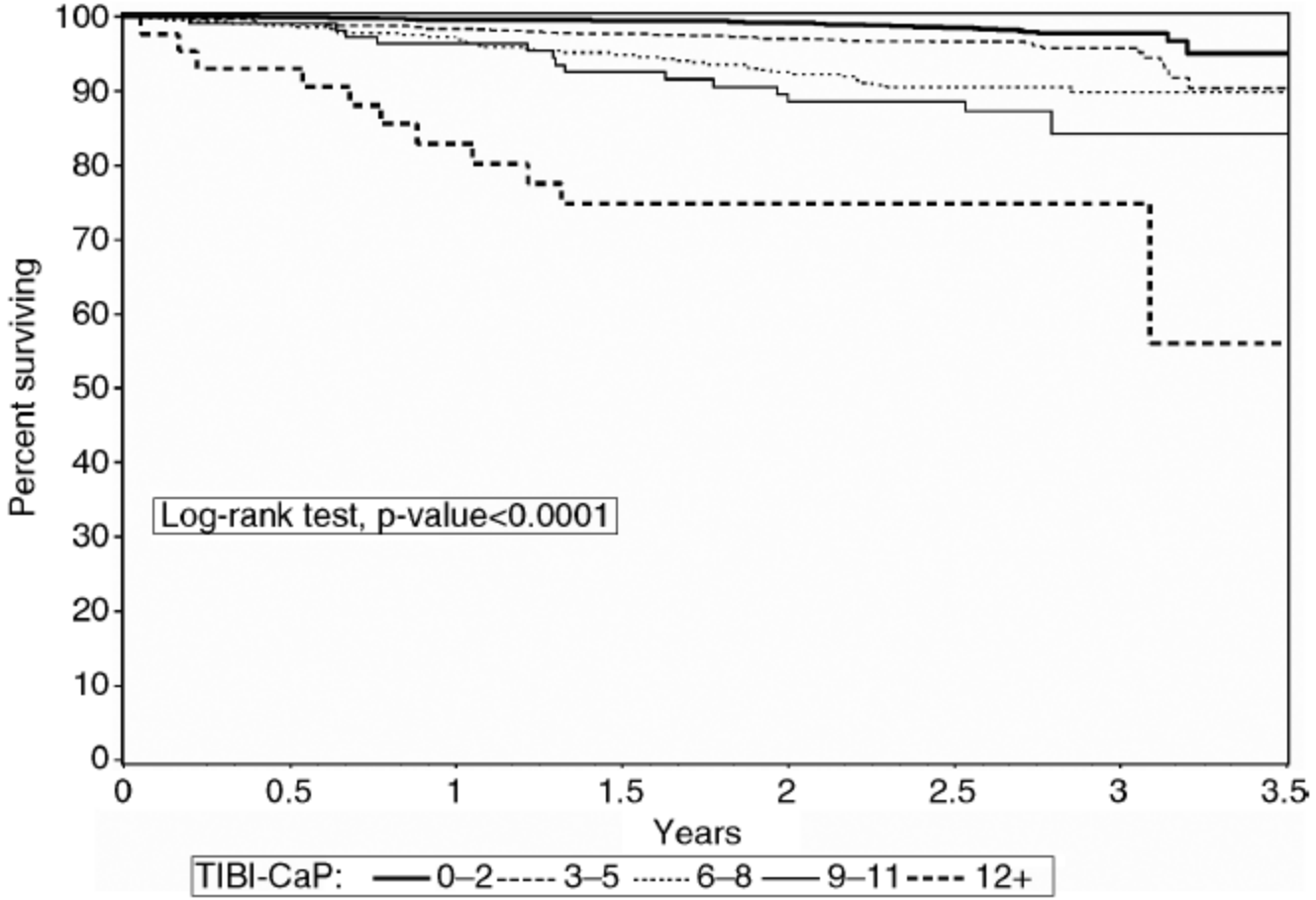
Other RWD →

Purchasing Habits
Internet Search
FICO Data
Travel Patterns

Modified from Kaplan et al Medical Care

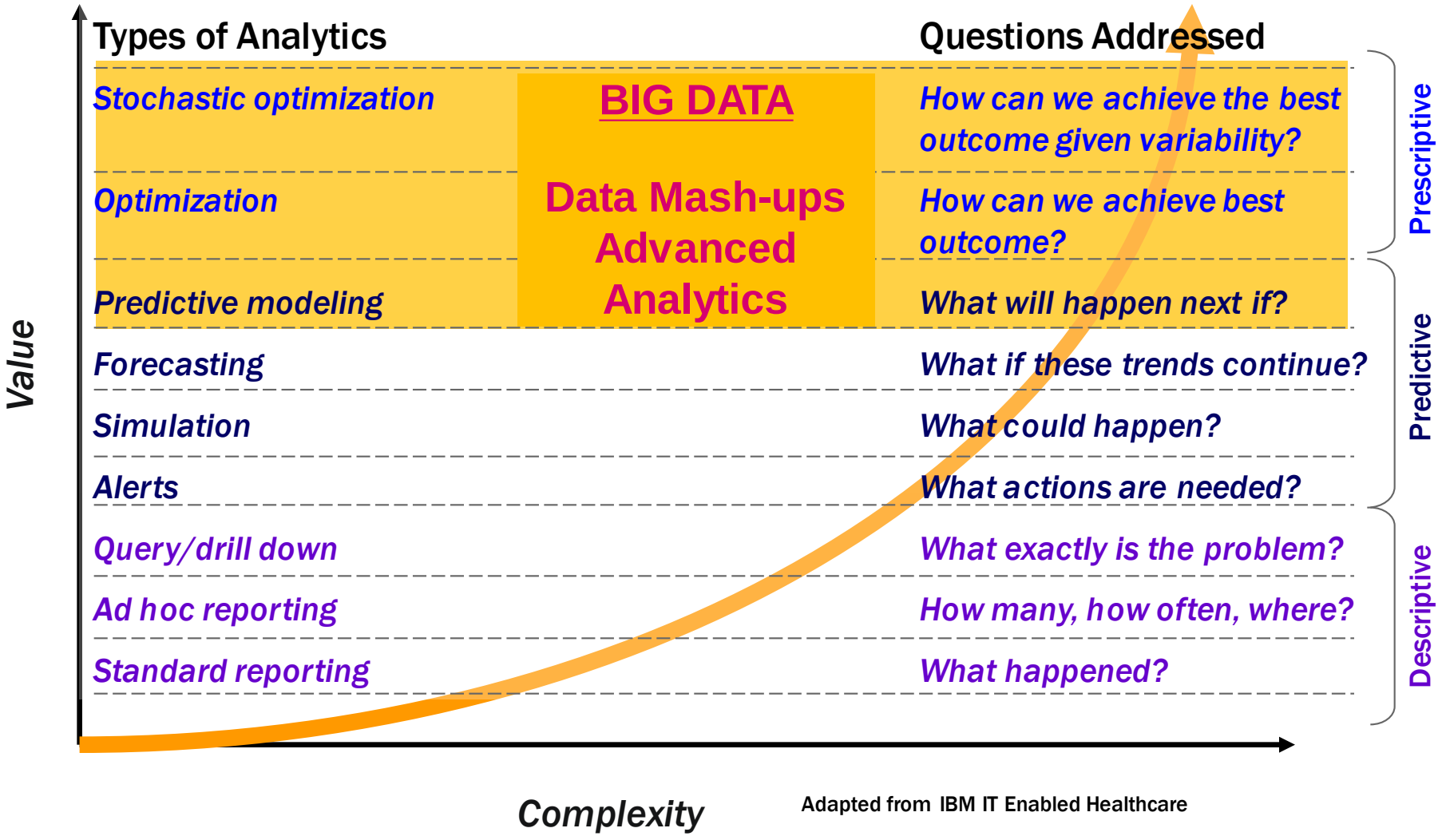
179 The Total Illness Burden Index

S. Greenfield · J. Billimek · S. H. Kaplan



* N = 135 deaths unrelated to prostate cancer

RW Research → Moving up in Value



Adapted from IBM IT Enabled Healthcare

Challenges

- Current EMRs are not designed to support research
  - Structured and Unstructured Data
  - Ease of data extraction to create analyzable data sets
- Use of Natural Language Processing to extract Patient Reported Measures from Unstructured Notes
  - Missing Data is a big problem
  - Loss of information as data is structured
- Embedding standardized Patient Reported Measures into Clinical Practice
  - Cleveland Clinic experience → Must make Clinician's job easier
    - 5 clicks for rehab
- Patient confidentiality, data ownership, and the opportunity for data integration / data mash-ups
  - Potential role of patient as true data owner

QUESTIONS?