Challenges and Opportunities to Creating a PRO Infrastructure for Purposes of Informing Clinical Care, Research, and Quality Improvement

Panel Presentation #4:

Integration of Research, Clinical Care, and Quality

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UNC Gillings School of Global Public Health

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

Can we collect “research quality, clinically-relevant”* PRO data in an efficient and safe way to inform clinical care, quality improvement, and CER / PCOR?

*Credit to Amy Abernethy, MD (Duke University) for terms.

1) What types of patient-reported data should we be collecting?

Will there be differences in what is needed for clinical care, quality improvement, or research?

Patient-Reported Data

- Symptoms / Review of Systems
- Functional Status
- General Health Perceptions
- Quality of Life
- Health Behaviors
- Medications
- Treatment Adherence
- Health History
- Family History
- Role in Decision Making
- Preferences / Values
- Insurance / Economic Burden
- Access to Resources / Barriers / Needs
- Satisfaction with Medical Care

Table 4 Recommended common data elements by domain

Domain	Final measure	Recommended frequency	Items
Eating patterns	Modified from starting the conversation (STC)[22]	Annual	Over the past 7 days: a. How many times a week did you eat fast food or snacks or pizza? b. How many servings of fruits/vegetables did you eat each day? c. How many soda and sugar sweetened drinks (regular, not diet) did you drink each day?
Physical activity	The exercise vital sign[23]	Annual	a. How many days of moderate to strenuous exercise, like a brisk walk, did you do in the last 7 days? b. On those days that you engage in moderate to strenuous exercise, how many minutes, on average, do you exercise at this level?
Risky drinking	Alcohol use screener[24]	Annual	How many times in the past year have you had X or more drinks in a day? (where X is 5 for men and 4 for women)
Smoking/tobacco use	Tobacco use screener[25]	Annual	Have you used tobacco in the last 30 days? Smoked cigarettes: Yes/No Smokeless tobacco product: Yes/No
Substance use	Drug use screener[26]	Annual	How many times in the past year have you used an illegal drug or used a prescription medication for non-medical reasons?
Anxiety and depression	PHQ-4[27]	Annual	Over the past 2 weeks have you been bothered by these problems? (Leichert scale: not at a several days, more days than not, nearly every day) a. Feeling nervous anxious, or on edge b. Not being able to stop or control worrying c. Feeling down, depressed, or hopeless d. Little interest or pleasure in doing things
Stress	Distress thermometer[28]	Annual	Please circle the number (0–10) that best describes how much distress you have been experiencing in the past week including today.
Demographics	Multiple sources[29]	Variable	9 items: Sex, date of birth, race, ethnicity, English fluency, occupation, household income, marital status, education, address, insurance status, veteran's status.
Sleep	Adapted BRFSS[25]; Neuro-QOL[30]	Annual	Do you snore or has anyone told you that you snore?In the past 7 days, I was sleepy during the daytime… never, rarely, sometimes, often, always

Estabrooks PA, Boyle M, Emmons KM, Glasgow RE, Hesse BW, Kaplan RM, Krist AH, Moser RP, Taylor MV. Harmonized patient-reported data elements in the electronic health record: supporting meaningful use by primary care action on health behaviors and key psychosocial factors. J Am Med Inform Assoc 2012;19:575-582.

2) What do we do about PRO domains where there exists multiple measures?

Do we seek consensus on one measure OR create cross-walks among measures?

PROsetta Stone®

Linking Patient-Reported Outcome Measures

PROMIS Depression

CES-D	PROMIS Depression and CES-D Linking Table	PROM
SF-36/Mental Health	PROMIS Depression and SF-36/Mental Health Linking Table	PROM
PHQ-9	PROMIS Depression and PHQ-9 Linking Table	PROM
Neuro-QOL Depression	PROMIS Depression and Neuro-QOL Depression Linking Table	PROM

PHQ-9 Score	PROMIS T-score	SE
0	37.4	6.4
1	42.7	5.3
2	45.9	4.8
3	48.3	4.7
4	50.5	4.3
5	52.5	4.0
6	54.2	3.8
7	55.8	3.7
8	57.2	3.6
9	58.6	3.5
10	59.9	3.4
11	61.1	3.3
12	62.3	3.3
13	63.5	3.2
14	64.7	3.2
15	65.8	3.2
16	66.9	3.2
17	68.0	3.1
18	69.2	3.2
19	70.3	3.2
20	71.5	3.2
21	72.7	3.3
22	74.0	3.4
23	75.3	3.5
24	76.7	3.6
25	78.3	3.7
26	80.0	3.8
27	82.3	3.8

PROMIS Depression and PHQ-9

Seung W. Choi, Tracy Podrabsky, Natalie McKinney, Benjamin D. Schalet, Karon F. Cook & David Cella

Department of Medical Social Sciences
Feinberg School of Medicine
Northwestern University

This research was supported by an NIH/National Cancer Institute grant PROSETTA STONE (1RC4CA157236-01, PI: David Cella). Authors acknowledge careful reviews, comments, and suggestions from Drs. Robert Brennan, Lawrence Hedges, Won-Chan Lee, and Nan Rothrock.

3) What should be the characteristics and psychometric properties of the patient-reported measures we use?

Does it matter depending on the purpose?

#	Attribute
1	Conceptual and Measurement Model
2	Reliability
3	Validity
3a	- Content Validity
3b	- Construct Validity
3c	- Responsiveness
4	Interpretability of Scores
5	Translations
6	Patient and Administrator Burden

Reeve BB, Wyrwich KW, Wu AW, Velikova G, Terwee CB, Snyder CF, Schwartz C, Revicki DA, Moinpour CM, McLeod LD, Lyons JC, Lenderking WR, Hinds PS, Hays RD, Greenhalgh J, Gershon R, Feeny D, Fayers PM, Cella D, Brundage M, Ahmed S, Aaronson NK, Butt Z; on behalf of the International Society for Quality of Life Research (ISOQOL). **ISOQOL recommends minimum standards for patient-reported outcome measures used in patient-centered outcomes and comparative effectiveness research**. Quality of Life Research. [epub ahead of print January 4, 2013] 1-11.

Table 4 Recommended common data elements by domain

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3) What should be the characteristics and psychometric properties of the patient-reported measures we use?

Does it matter depending on the purpose?

Screener for Clinical Care

In the past 7 days,	No pain										Worst Imaginable pain
How would you rate your pain on average?	0	1	2	3	4	5	6	7	8	9	10

In the past 7 days,					
My sleep quality was…	very good	good	fair	poor	very poor

In the past 7 days,					
I felt fatigued…	not at all	a little bit	some what	quite a bit	very much

In the past 7 days,					
I felt depressed…	never	rarely	some times	often	always

In the past 7 days,					
I felt anxious…	never	rarely	some times	often	always

Questionnaire for group-level research

In the past 7 days…	**Very poor**	**Poor**	**Fair**	**Good**	**Very good**
My sleep quality was	☐	☐	☐	☐	☐

In the past 7 days…	**Not at all**	**A little bit**	**Somewhat**	**Quite a bit**	**Very much**
My sleep was refreshing.	☐	☐	☐	☐	☐
I had a problem with my sleep	☐	☐	☐	☐	☐
I had difficulty falling asleep	☐	☐	☐	☐	☐

Questionnaire for individual-level research

In the past 7 days…	Very poor	Poor	Fair	Good	Very good
My sleep quality was.....	☐	☐	☐	☐	☐

In the past 7 days…	Not at all	A little bit	Somewhat	Quite a bit	Very much
My sleep was refreshing.....	☐	☐	☐	☐	☐
I had a problem with my sleep	☐	☐	☐	☐	☐
I had difficulty falling asleep	☐	☐	☐	☐	☐
My sleep was restless	☐	☐	☐	☐	☐
I tried hard to get to sleep.....	☐	☐	☐	☐	☐

PROMIS CAT-based measures with variable stopping rules

In the past 7 days,	No pain										Worst Imaginable pain
How would you rate your pain on average?	0	1	2	3	4	5	6	7	8	9	10

In the past 7 days,					
My sleep quality was…	very good	good	fair	poor	very poor

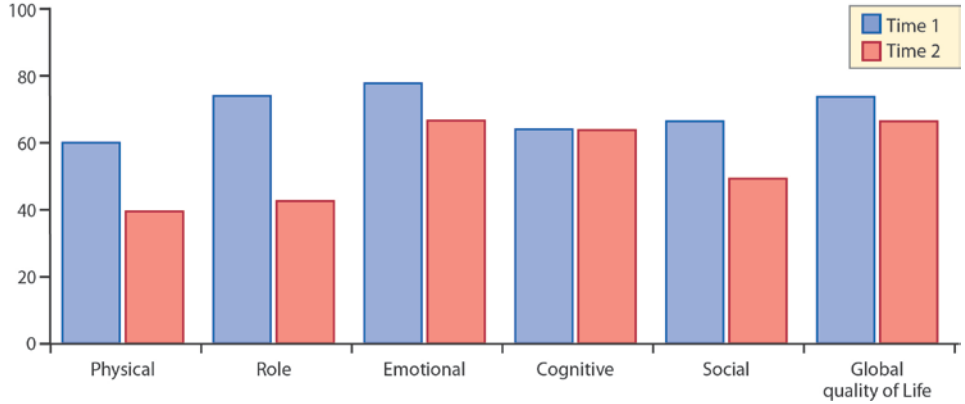
In the past 7 days,					
I felt fatigued…	not at all	a little bit	some what	quite a bit	very much

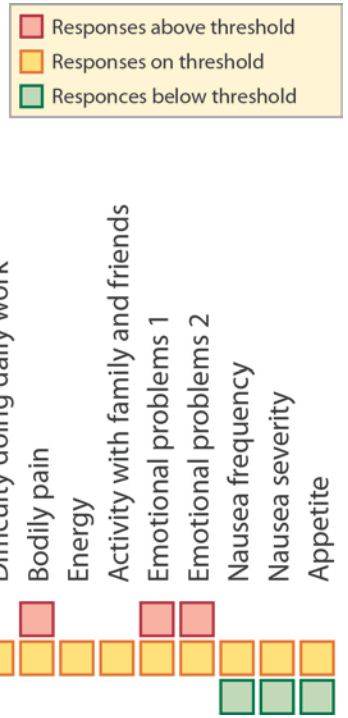
PROMIS CAT-based measures with variable stopping rules

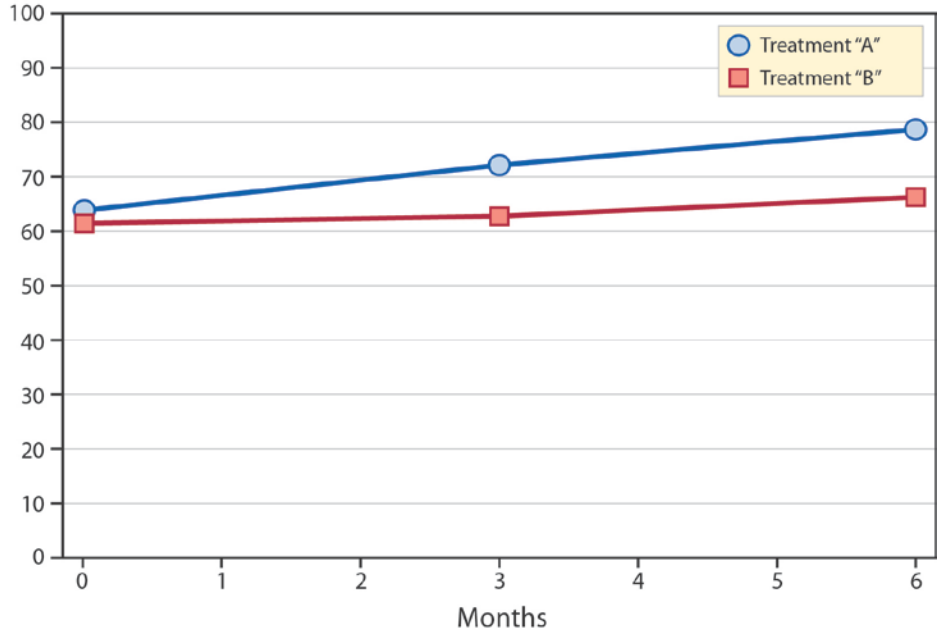
In the past 7 days,					
I felt depressed…	never	rarely	some times	often	always

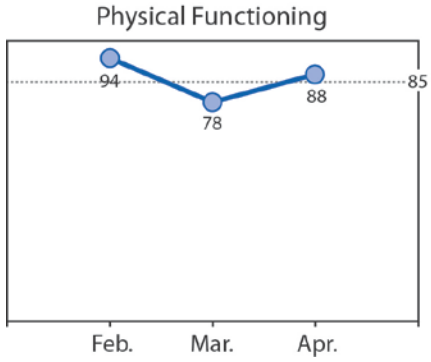
In the past 7 days,					
I felt worthless…	never	rarely	some times	often	always
In the past 7 days,					
I felt helpless…	never	rarely	some times	often	always
In the past 7 days,					
I felt hopeless…	never	rarely	some times	often	always

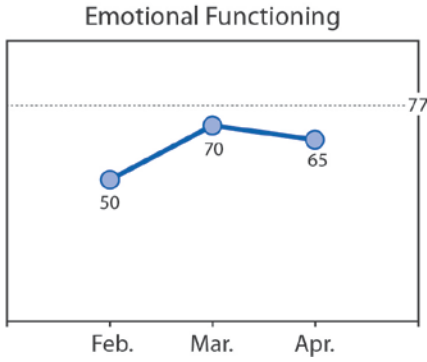
4) How do we present data to patients and doctors to maximize understanding?





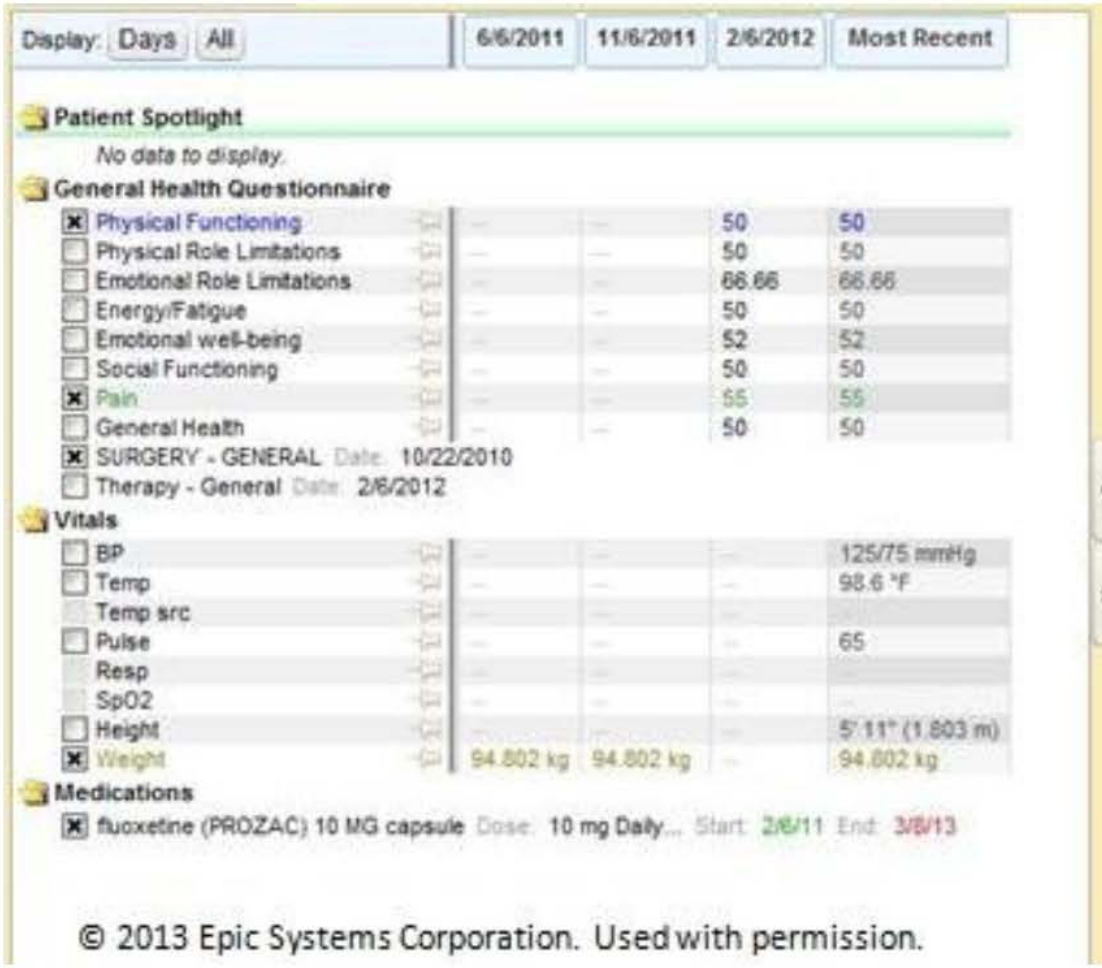




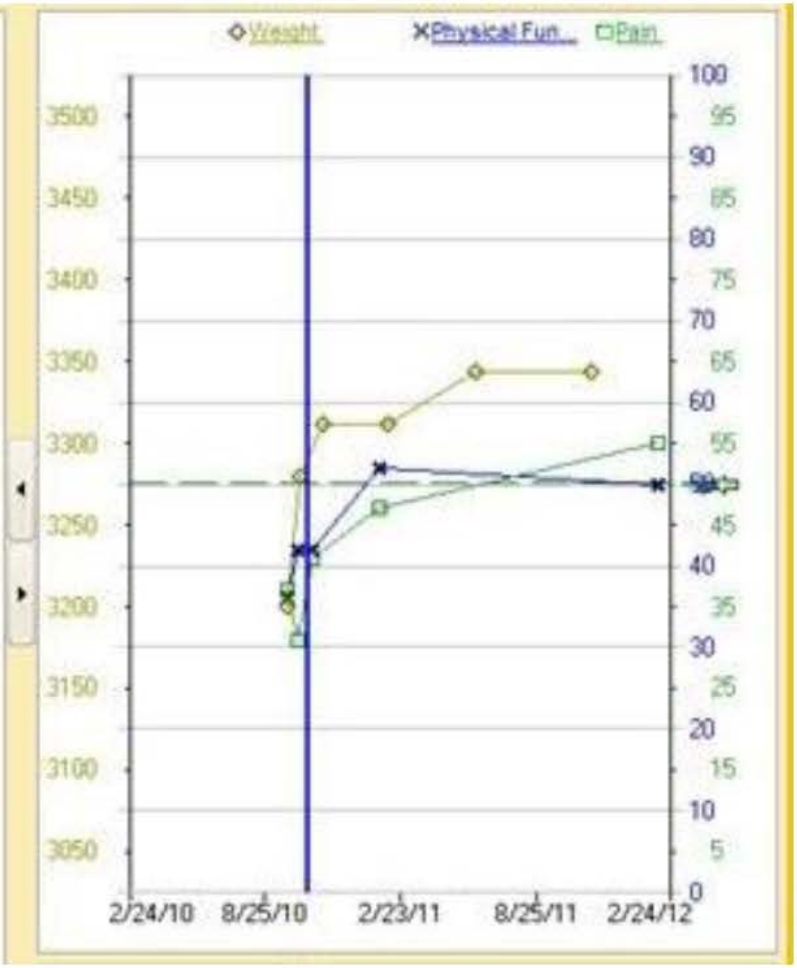


Coles T, Reeve B. Interpretation of Patient-Reported Outcome Results in Routine Clinical Oncology Practice: A Literature Review of Presentation Considerations. Poster presented at the 20th Annual ISOQOL Conference; October 9-12, 2013. Miami, FL.

Epic Systems Corporation: EpicCare longitudinal integration of PRO and clinical data



Display: Days All	6/6/2011	11/6/2011	2/6/2012	Most Recent
Patient Spotlight				
No data to display.				
General Health Questionnaire				
☒ Physical Functioning	--	--	50	50
☐ Physical Role Limitations	--	--	50	50
☐ Emotional Role Limitations	--	--	66.66	66.66
☐ Energy/Fatigue	--	--	50	50
☐ Emotional well-being	--	--	52	52
☐ Social Functioning	--	--	50	50
☒ Pain	--	--	55	55
☐ General Health	--	--	50	50
☒ SURGERY - GENERAL Date: 10/22/2010				
☐ Therapy - General Date: 2/6/2012				
Vitals				
☐ BP	--	--	--	125/75 mmHg
☐ Temp	--	--	--	98.6 °F
Temp src	--	--	--	
☐ Pulse	--	--	--	65
Resp	--	--	--	
SpO2	--	--	--	
☐ Height	--	--	--	5' 11" (1.803 m)
☒ Weight	94.802 kg	94.802 kg	--	94.802 kg
Medications				
☒ fluoxetine (PROZAC) 10 MG capsule Dose: 10 mg Daily... Start: 2/6/11 End: 3/8/13				



PCORI Funded Contract:

Presenting Patient-Reported Outcomes Data to Improve Patient and Clinician Understanding and Use

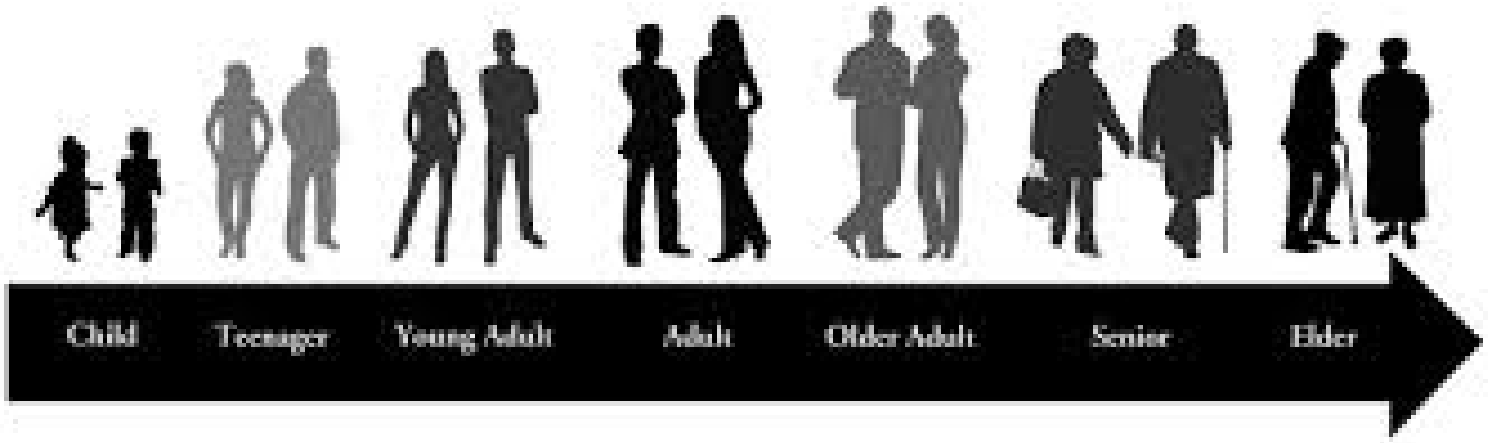
Claire Snyder, PhD (Johns Hopkins University), &
Michael Brundage, MD (Queens University)

5) To what extent are we willing to accept proxy data for individuals who may be too ill, too young, or have functional limitations that limit their ability to self-report?

6) How can we integrate patient-reported data with clinical and other data to inform decision making?

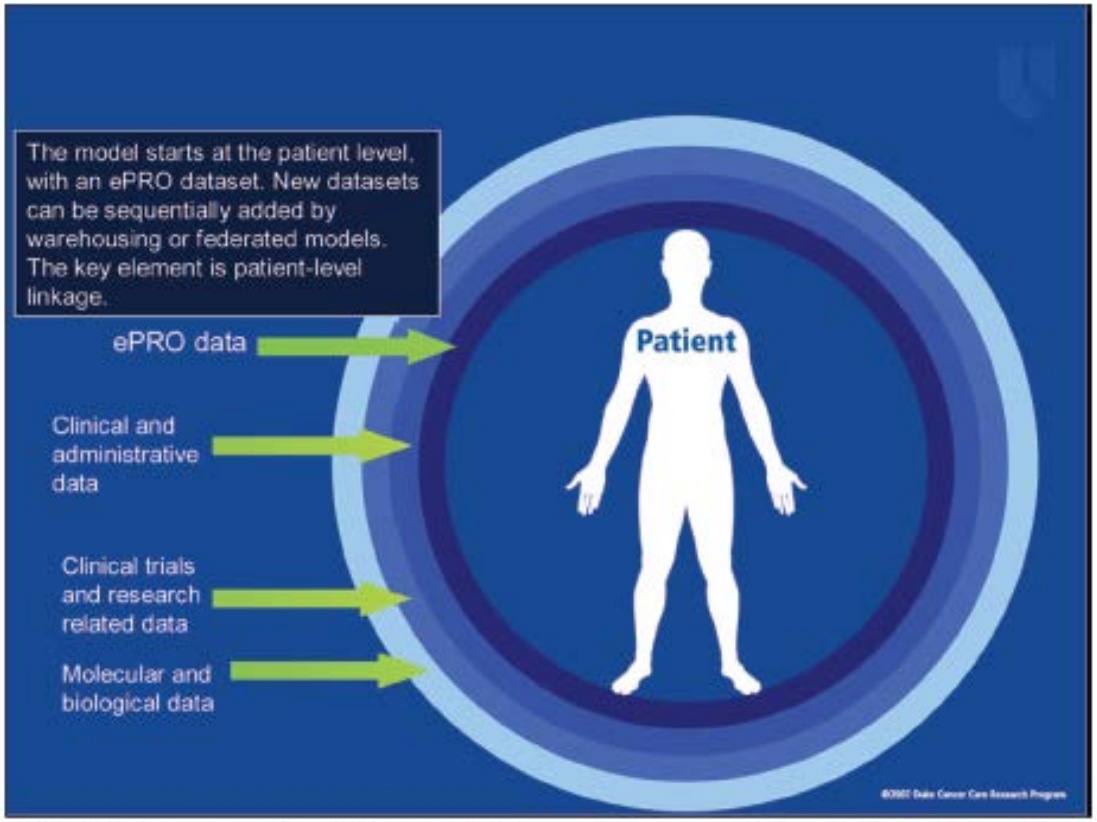
7) Does “one size fit all”? Should ALL patients at ALL clinical visits provide patient-reported data?

8) Can we have common metrics across the life span?



9) Are there opportunities to develop centralized PRO registries?

Rapid Learning Cancer Care System



Note: "Warehousing" refers to the central data repository approach (ie, a "data warehouse"), whereas "federated models" refer to approaches in which data residing in local databases are linked to one another through various means.

Abernethy et al. 2010 Medical Care.

MHRN Mental Health Research Network

GroupHealth

Using systematic outcome assessment for patient care, quality improvement, and research

Greg Simon – Group Health Research Institute
Group Health Cooperative Behavioral Health Service
Mental Health Research Network

MHRN Mental Health Research Network

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Outline

- How we got here
- Where we are
- Where we hope to go
- What might get in our way

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History of measurement-based care for depression

- Nationally
  - 1990s – Effectiveness trials of collaborative care (with routine outcome measurement a central element)
  - 2000s – Large-scale dissemination efforts (Diamond, IMPACT, VA Tides)
- At Group Health
  - 2001 – Guidelines recommend routine use of PHQ9 for depression visits in primary and specialty care
  - 2006 – PHQ9 flowsheet tools implemented in EMR
  - 2011 – BHS implements standard assessment program

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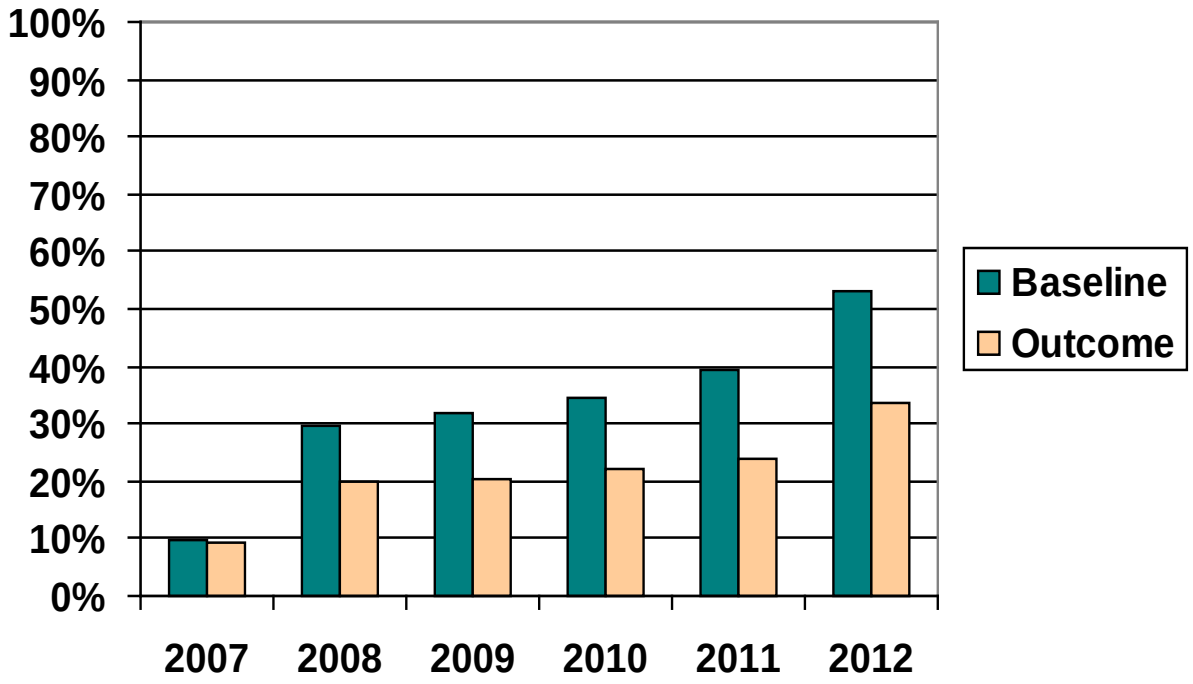
Proportion of primary care antidepressant treatment episodes with PHQ9 recorded in EMR



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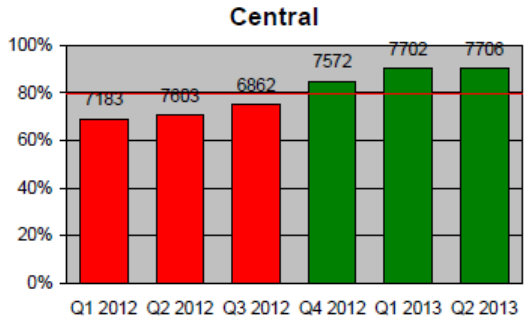
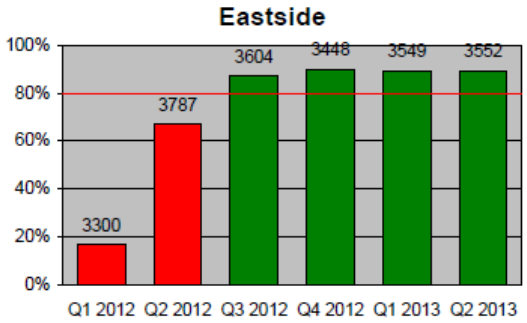
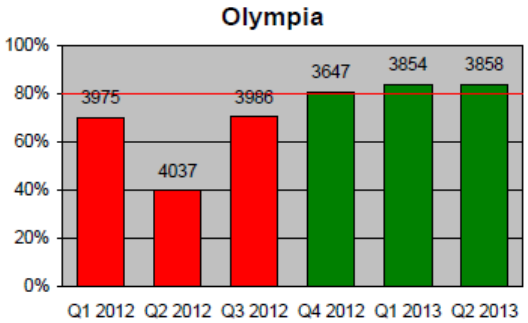
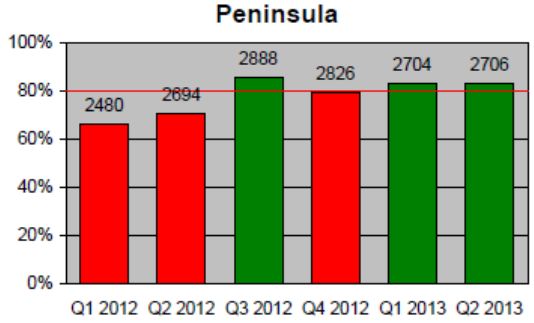
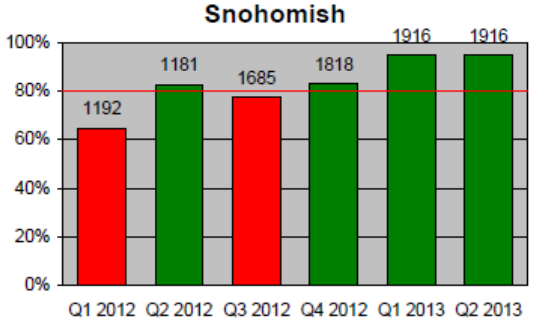
Compliance Rate of PHQ9 Documentation by Quarter

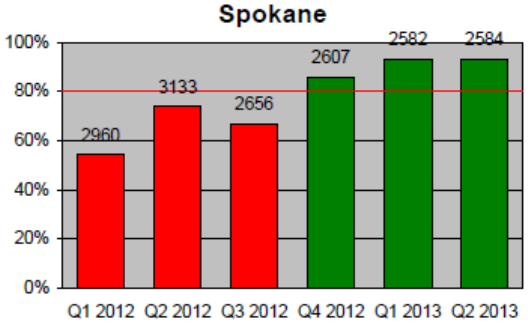


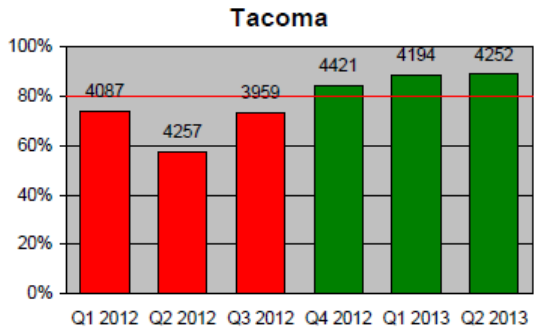


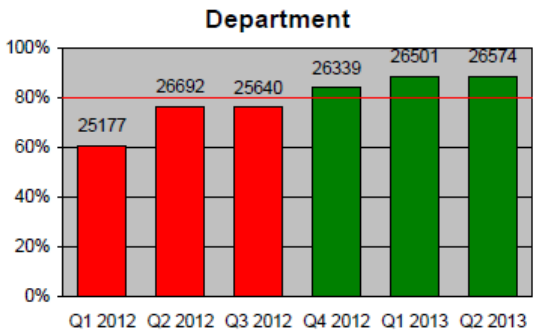












Target = 80%

- All visits, including group, count toward this measure.
- Patients >= 12 years old.

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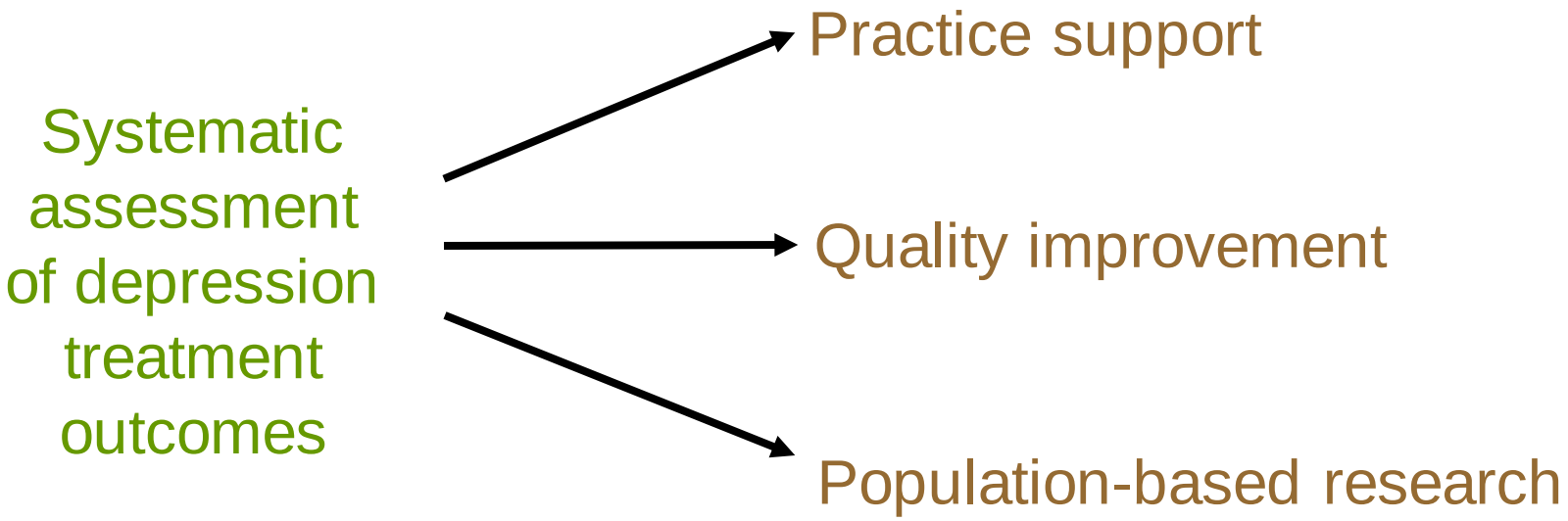
PRO data drive integration of research and practice



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The goal: a real learning healthcare system:

"Each patient care experience naturally reflects the best available evidence, and, in turn, adds seamlessly to learning what works best in different circumstances."

IOM Roundtable on Evidence-Based Medicine, 2008

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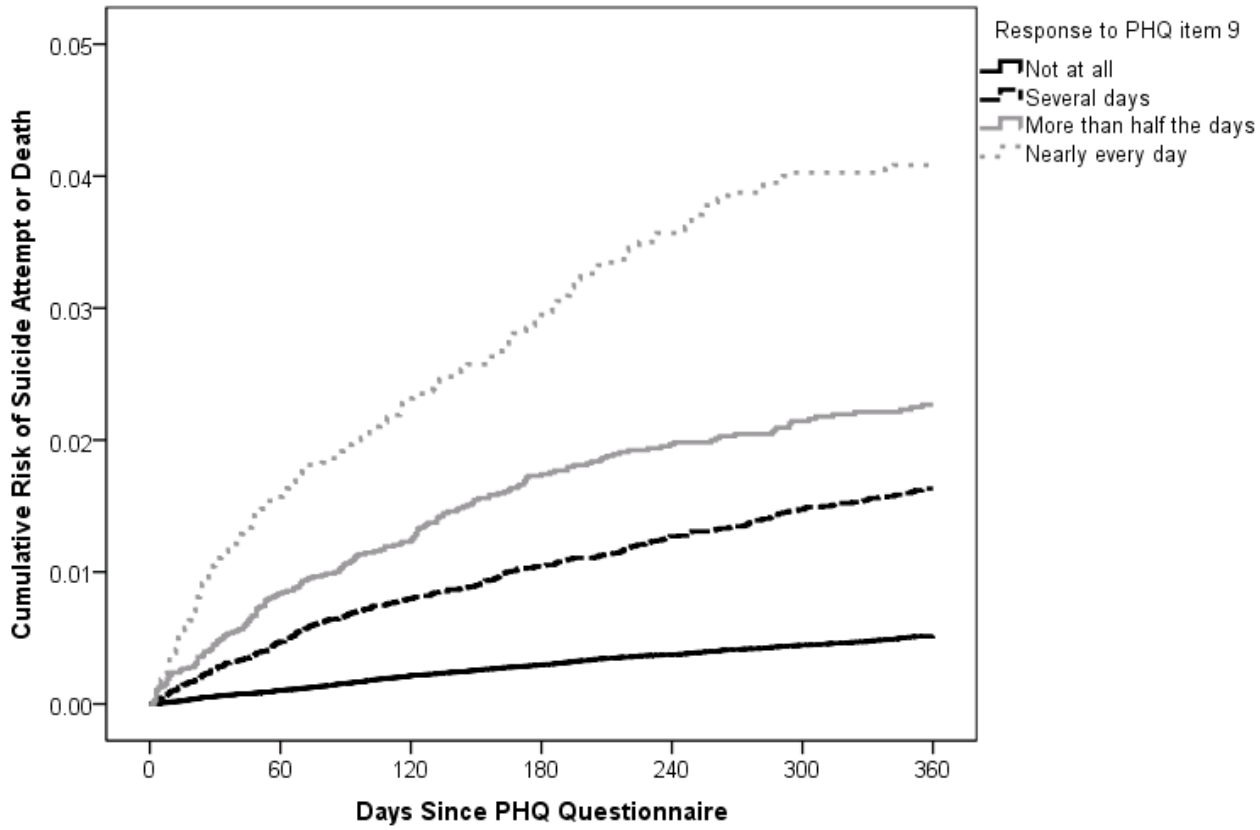
Example: prediction / prevention of suicide attempt

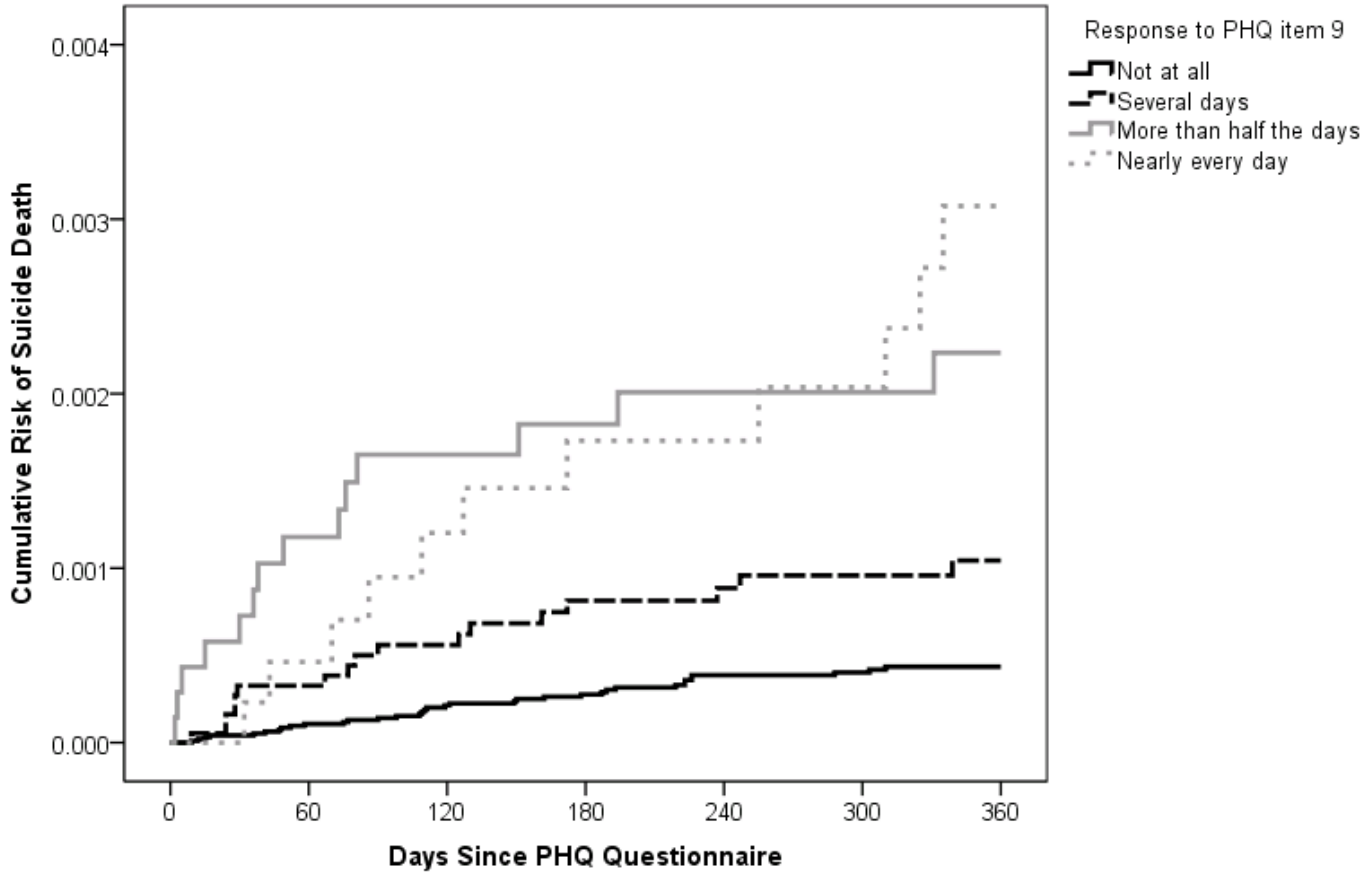
- From NIH: Prediction and prevention of suicide attempt identified as top DHHS/NIH priority in 2011.
- From health system leaders: Suicide risk identified as top safety priority for Group Health BHS.
- From clinicians: What are we supposed to do when people report thoughts of death or self-harm on PHQ?

So….Let's look!

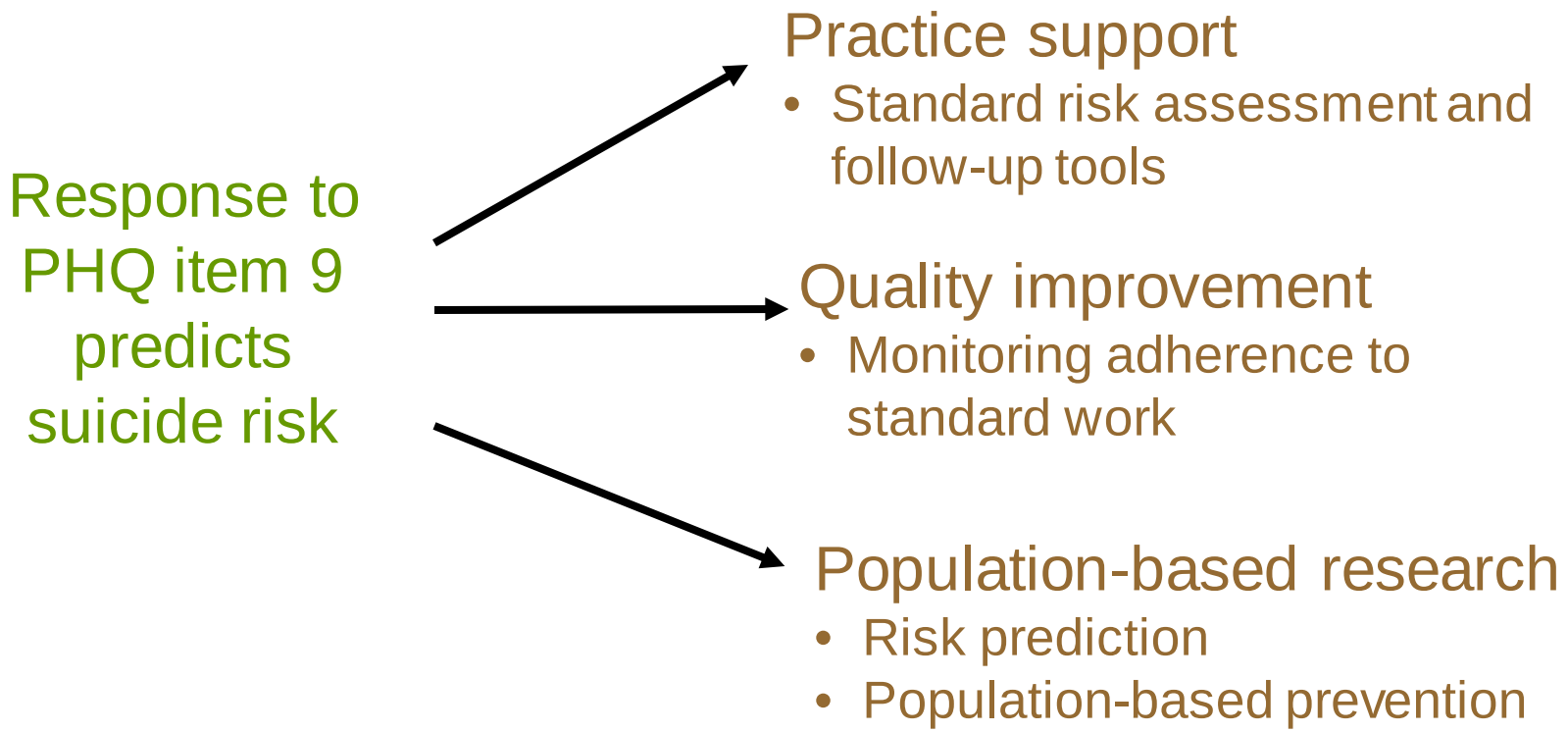
Risk of suicide attempt by score on PHQ item 9: "Thoughts of death or of hurting yourself in some way"



Risk of suicide death by score on PHQ item 9

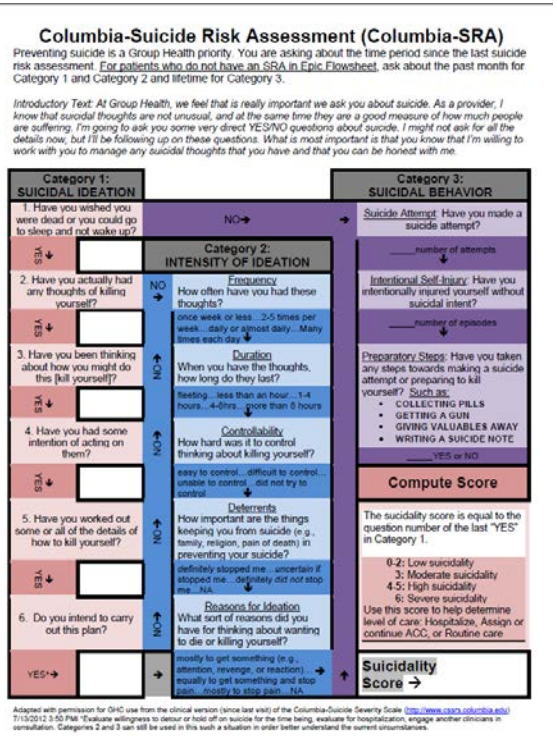


PRO data drive integration of research and practice



Practice support: Standard tools and processes for risk assessment and follow-up care

Structured assessment required if PHQ item 9 score <=2



Columbia-Suicide Risk Assessment (Columbia-SRA)

Preventing suicide is a Group Health priority. You are asking about the time period since the last suicide risk assessment. For patients who do not have an SRA in Epic Flowsheet, ask about the past month for Category 1 and Category 2 and lifetime for Category 3.

Introductory Text: At Group Health, we feel that is really important we ask you about suicide. As a provider, I know that suicidal thoughts are not unusual, and at the same time they are a good measure of how much people are suffering. I'm going to ask you some very direct YES/NO questions about suicide. I might not ask for all the details now, but I'll be following up on these questions. What is most important is that you know that I'm willing to work with you to manage any suicidal thoughts that you have and that you can be honest with me.

Category 1: SUICIDAL IDEATION

1. Have you wished you were dead or you could go to sleep and not wake up? → NO → Category 3
   - YES ↓
2. Have you actually had any thoughts of killing yourself? → NO → Category 3
   - YES ↓
3. Have you been thinking about how you might do this [kill yourself]? → NO → Category 3
   - YES ↓
4. Have you had some intention of acting on them? → NO → Category 3
   - YES ↓
5. Have you worked out some or all of the details of how to kill yourself? → NO → Category 3
   - YES ↓
6. Do you intend to carry out this plan? → NO → Category 3
   - YES* →

Category 2: INTENSITY OF IDEATION

- Frequency: How often have you had these thoughts? — once week or less…2-5 times per week…daily or almost daily…Many times each day
- Duration: When you have the thoughts, how long do they last? — fleeting…less than an hour…1-4 hours…4-8hrs…more than 8 hours
- Controllability: How hard was it to control thinking about killing yourself? — easy to control…difficult to control…unable to control…did not try to control
- Deterrents: How important are the things keeping you from suicide (e.g., family, religion, pain of death) in preventing your suicide? — definitely stopped me…uncertain if stopped me…definitely did not stop me…NA
- Reasons for Ideation: What sort of reasons did you have for thinking about wanting to die or killing yourself? — mostly to get something (e.g., attention, revenge, or reaction)… equally to get something and stop pain…mostly to stop pain…NA

Category 3: SUICIDAL BEHAVIOR

- Suicide Attempt: Have you made a suicide attempt? ____number of attempts
- Intentional Self-Injury: Have you intentionally injured yourself without suicidal intent? ____number of episodes
- Preparatory Steps: Have you taken any steps towards making a suicide attempt or preparing to kill yourself? Such as:
  - COLLECTING PILLS
  - GETTING A GUN
  - GIVING VALUABLES AWAY
  - WRITING A SUICIDE NOTE

  ____YES or NO

Compute Score

The sucidality score is equal to the question number of the last "YES" in Category 1.

0-2: Low suicidality
3: Moderate suicidality
4-5: High suicidality
6: Severe suicidality

Use this score to help determine level of care: Hospitalize, Assign or continue ACC, or Routine care

Suicidality Score →

Adapted with permission for GHC use from the clinical version (since last visit) of the Columbia-Suicide Severity Scale (http://www.cssrs.columbia.edu) 7/13/2012 3:50 PM. *Evaluate willingness to detour or hold off on suicide for the time being, evaluate for hospitalization, engage another clinicians in consultation. Categories 2 and 3 can still be used in this such a situation in order better understand the current circumstances.

Risk-specific follow-up protocol:

- Low: Routine follow-up
- Moderate: Create crisis plan
- High: Create crisis plan, refer to acute-care coordination path
- Severe: Consider hospitalization

Quality improvement: Monitoring and feedback regarding adherence to standard work

SRA Misses 08/2013

Pra Nbr	Pra Last Name	Fist Name	Csr Number	Encounter Date	PHQ-9 Question 9
043816	xxxxxx	xxxxxx	zzzzzz	08AUG2013 :15:00:00	2
043816	xxxxxx	xxxxxx	zzzzzz	13AUG2013 :16:30:00	2
043816	xxxxxx	xxxxxx	zzzzzz	16AUG2013 :11:00:00	2
043816	xxxxxx	xxxxxx	zzzzzz	23AUG2013 :11:00:00	3
043816	xxxxxx	xxxxxx	zzzzzz	23AUG2013 :11:30:00	2
043647	xxxxxx	xxxxxx	zzzzzz	06AUG2013 :17:00:00	2
043647	xxxxxx	xxxxxx	zzzzzz	13AUG2013 :16:00:00	3
043647	xxxxxx	xxxxxx	zzzzzz	23AUG2013 :16:30:00	3
025426	xxxxxx	xxxxxx	zzzzzz	15AUG2013 :11:00:00	3
025426	xxxxxx	xxxxxx	zzzzzz	22AUG2013 :11:00:00	3
001153	xxxxxx	xxxxxx	zzzzzz	26AUG2013 :16:00:00	2
002731	Simon	Gregory	zzzzzz	26AUG2013 :15:00:00	2
002359	xxxxxx	xxxxxx	zzzzzz	15AUG2013 :09:30:00	2
002359	xxxxxx	xxxxxx	zzzzzz	22AUG2013 :13:30:00	2
001996	xxxxxx	xxxxxx	zzzzzz	09AUG2013 :14:30:00	2
001996	xxxxxx	xxxxxx	zzzzzz	19AUG2013 :13:30:00	3

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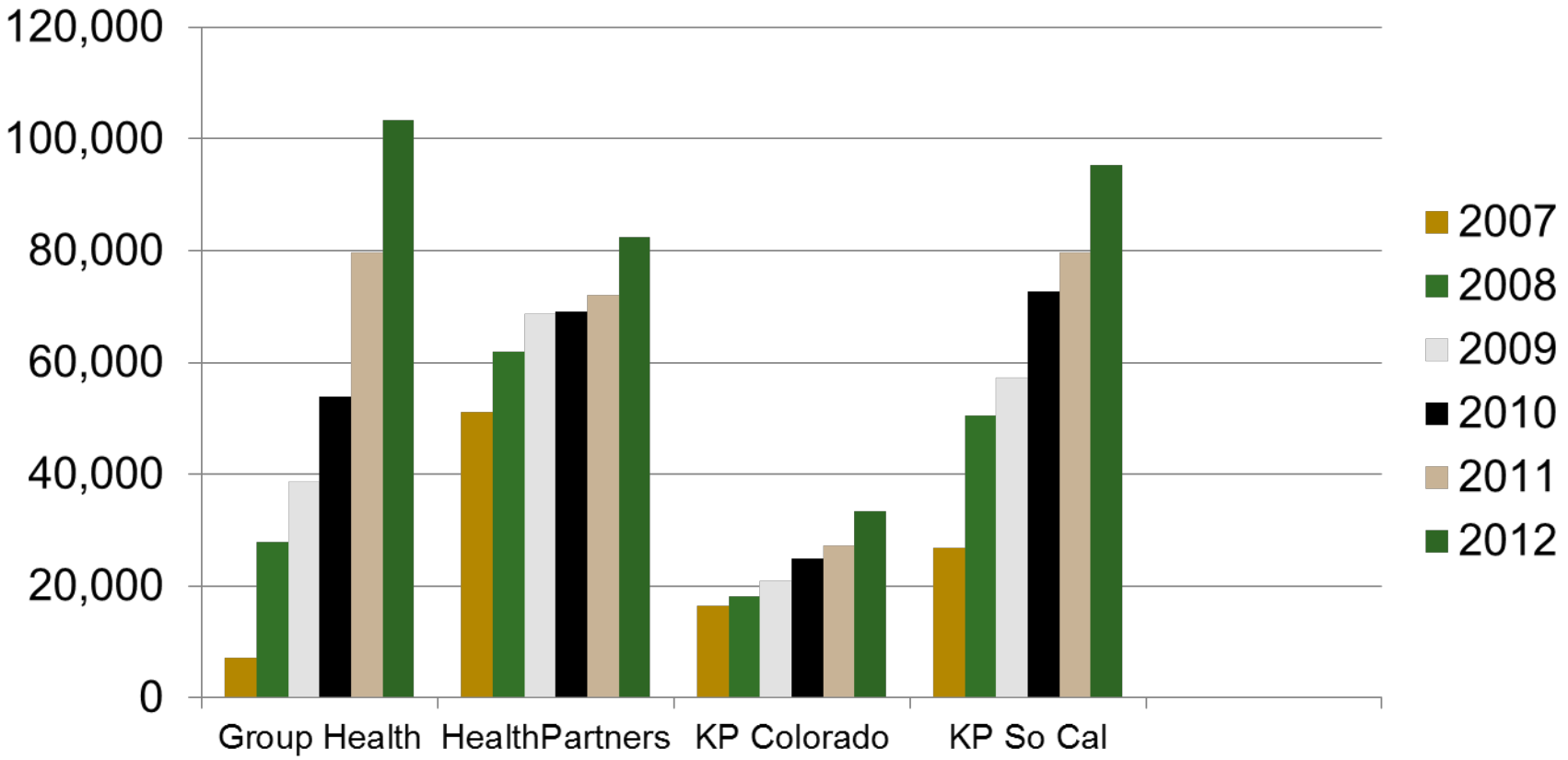
Use of PHQ9 across four health systems



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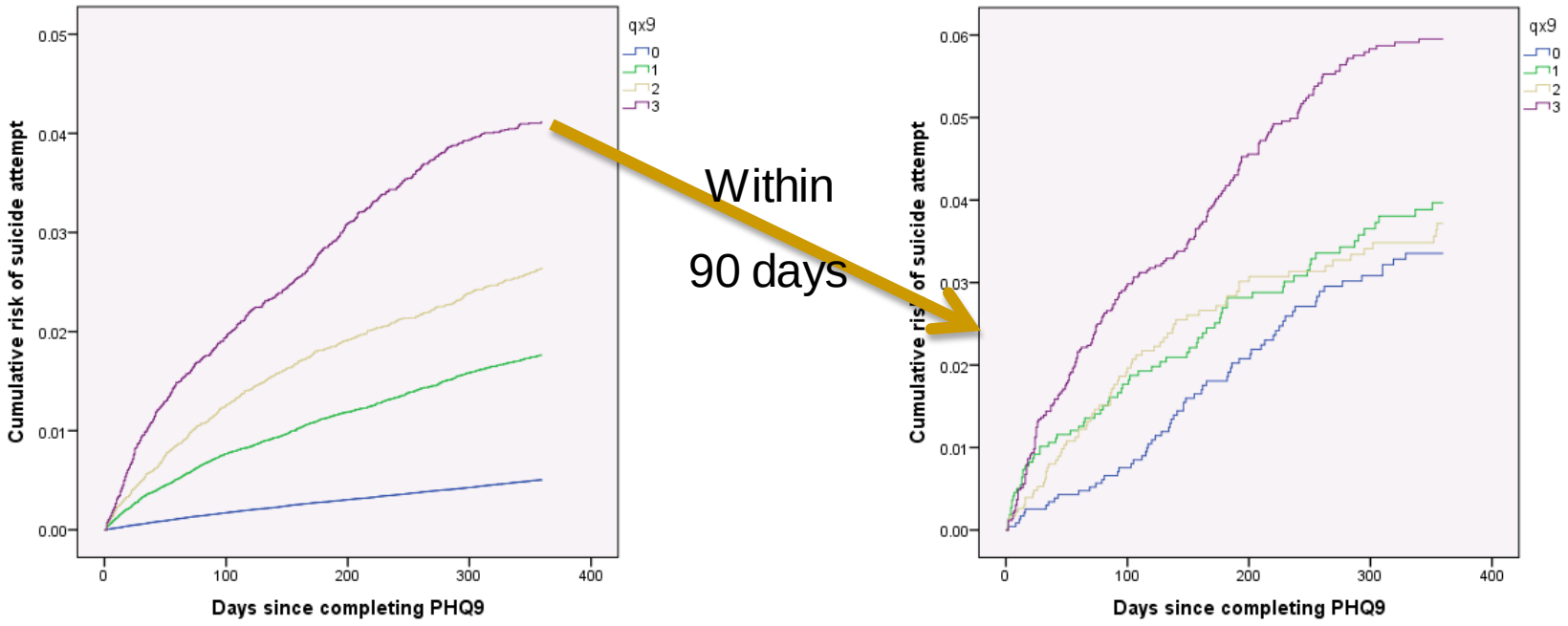
Epidemiologic Research: Separating the "Who?" and the "When?" in suicide risk prediction

- Link PRO, EHR, and claims data across four health systems (GHC, HealthPartners, KPCO, KPSC)
- 930,000 PHQ9 observations for 420,000 patients
- Examine risk associated with changes in self-reported suicidal ideation
- Example: What if suicidal ideation "resolves" within 90 days?

Epidemiologic Research: Separating the "Who?" and the "When?" in suicide risk prediction



Self-reported suicidal ideation is a good predictor of "who" – but not a very good predictor of "when"

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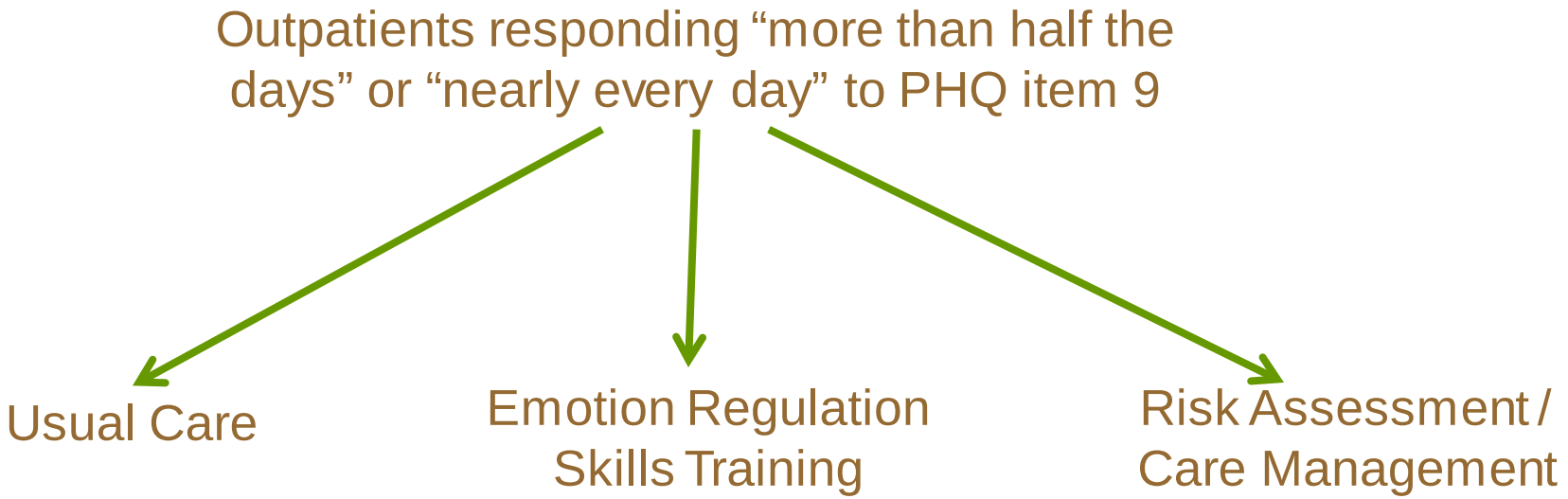
Intervention Research: Pragmatic trial of population-based selective prevention programs (funded by NIH Collaboratory)



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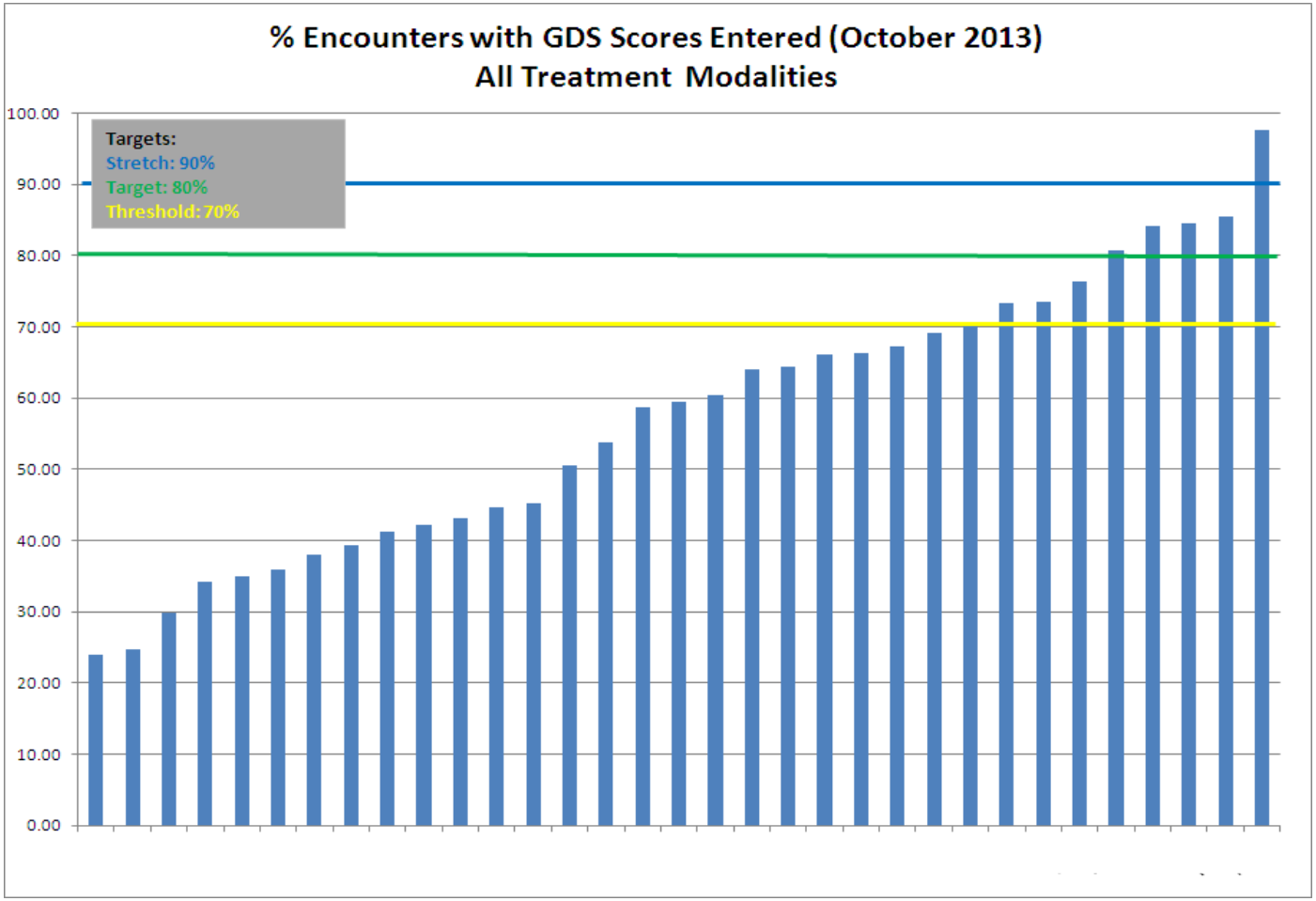
KAISER PERMANENTE®



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A learning healthcare system means:

- All experience contributes to evidence
- Evidence is truly based in experience
- It all happens continuously, in real time
- Clinical data = research data

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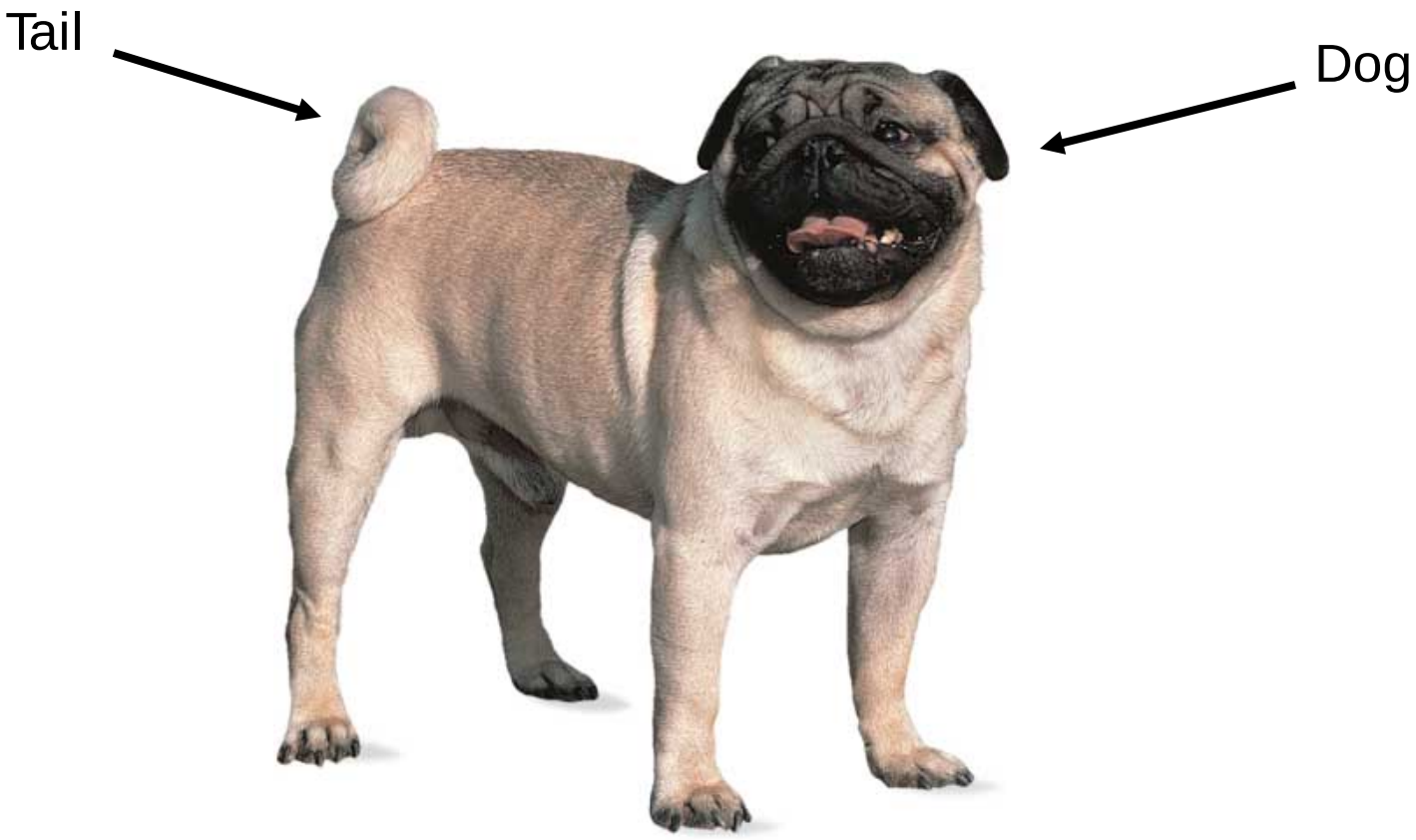
Two challenges:

- Improving data quality
- Building a culture of transparency and trust

These are cultural challenges, not technical ones.

Where is the real data quality problem?



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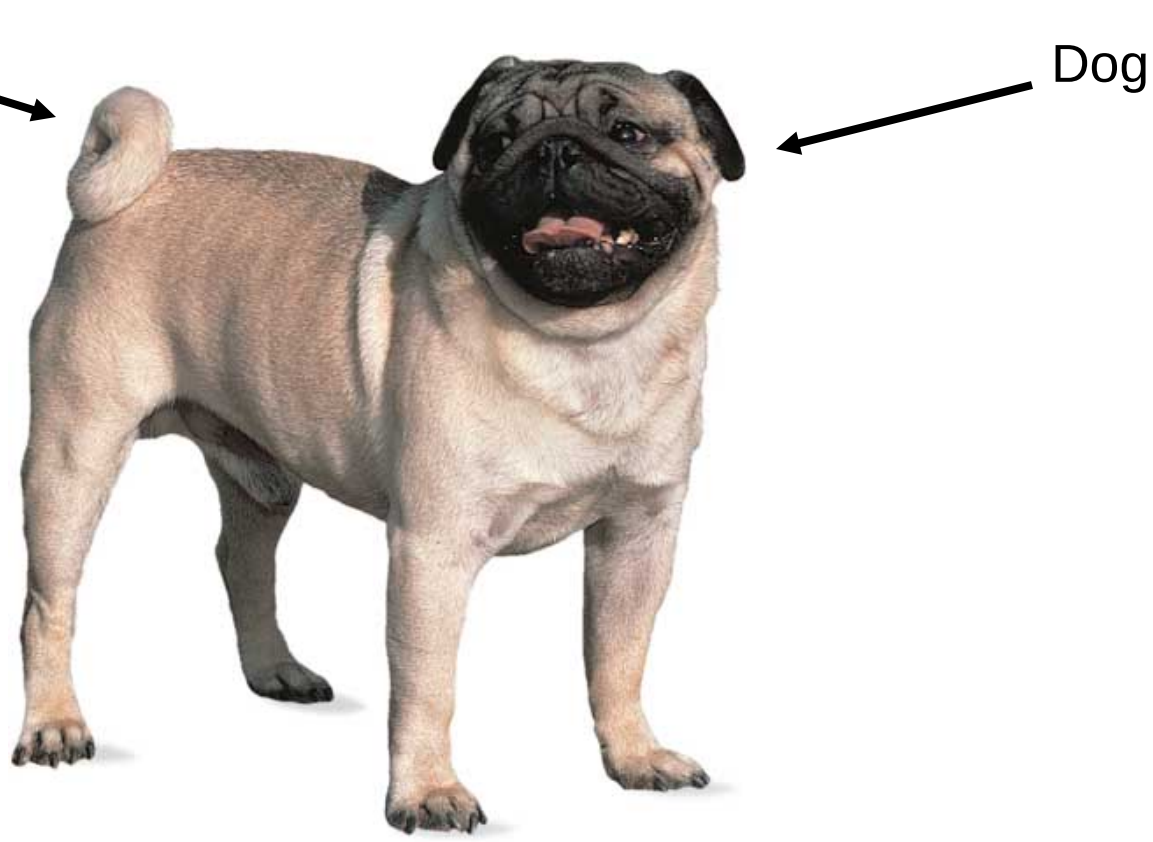
Where is the real data quality problem?

If the data aren't good enough for research,



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Where is the real data quality problem?

Tail

Dog

If the data aren't good enough for research,

…they certainly aren't good enough for taking care of patients.

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It's not about research data quality. It's about clinical data quality!

The tail's problem:	The dog's problem:
Unmeasured baseline covariates	Appropriate clinical assessments are either not performed or not recorded.
Residual confounding by indication	Reasons for treatment choices are not recorded – and may not be reasonable!
Informative censoring of outcomes	"Lost to follow-up" is too often the norm.

Our goal is to place systematic measurement at the center of health care quality. Research is just a side effect.

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When we say "sharing data", do patients and providers see…

Isaiah's Peaceable Kingdom…

…or Orwell's Big Brother?

Reasonable questions patients ask:

- Can I know who is looking at my information?
- Can I know what those people are thinking or deciding about me?
- How will I now how that my information helped other people?

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- Can I know who is looking at my information?
- Can I know what those people are thinking or deciding about me?
- How will I now how that my information helped other people?

Our traditional answer: Just trust us. You couldn't possibly understand it anyway.

Privacy protection for whom?

	We Want
Patients	√
Providers and health systems	?
Researchers	X

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Privacy protection for whom?

	We Want	We Have
Patients	√	?
Providers and health systems	?	√
Researchers	X	√

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Privacy protection for whom?

	We Want	We Have
Patients	√	?
Providers and health systems	?	√
Researchers	X	√

We want downstream transparency and upstream privacy.

The one-way mirror has been facing the wrong direction!