Do's and Don'ts of PRO Implementation

James H. Willig, MD, MSPH; University of Alabama at Birmingham
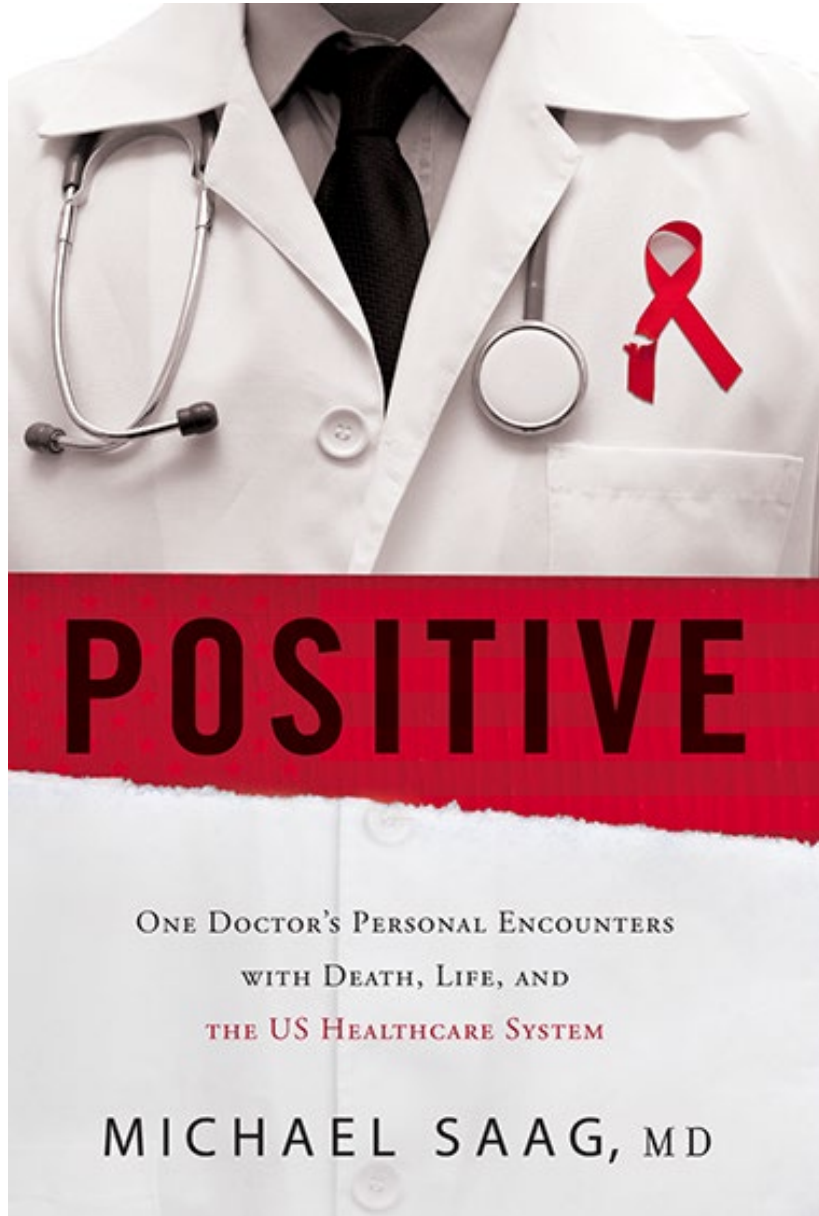
Alfredo Guzman, MEng; University of Alabama at Birmingham

Roadmap

- Setting
  - Why implement PROs? The innovation space.
  - The innovation space

- PROs
  - How not to do it…
  - Getting it to work!
  - Early research examples

- Lessons learned

- PROs growth
  - 1917 Clinic today (Clinical decision making; research; etc.)
  - Other partners

The UAB 1917 HIV/AIDS Clinic

- Why 1917 Clinic?

- Demographics
  - Started in 1988
  - Located in Birmingham, Alabama

- Currently over 3,300 clients
  - Multispecialty
  - Medical home

POSITIVE

ONE DOCTOR'S PERSONAL ENCOUNTERS
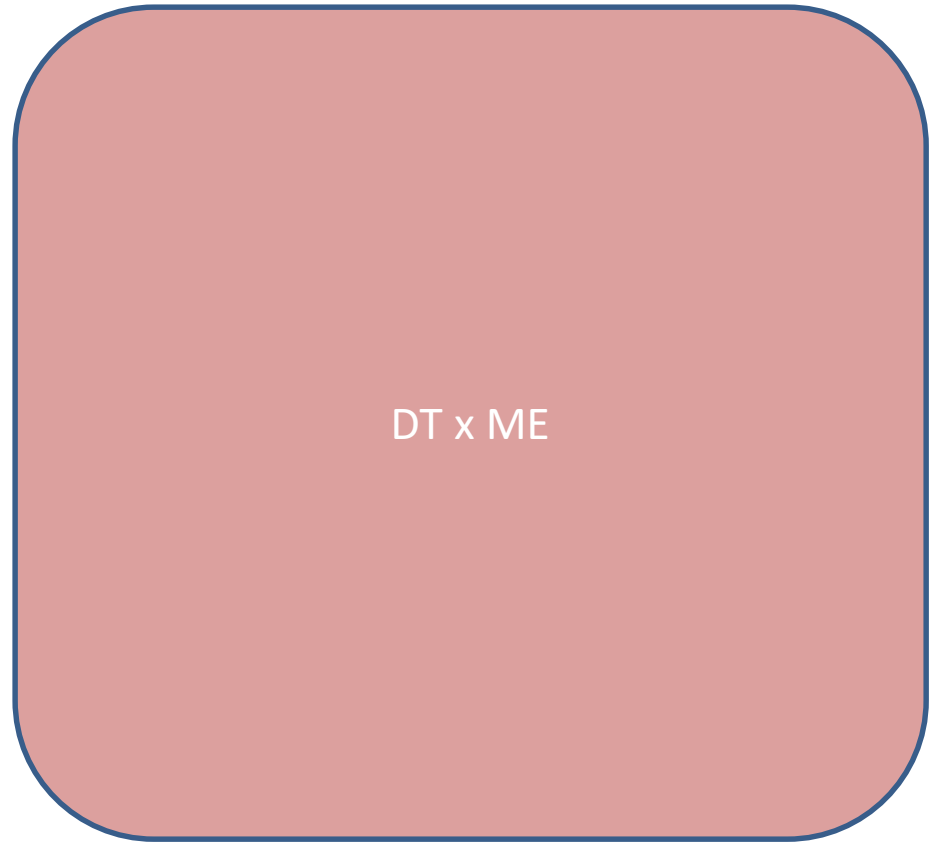WITH DEATH, LIFE, AND
THE US HEALTHCARE SYSTEM

MICHAEL SAAG, MD

The story of the
        1917 HIV/AIDS Clinic

	1988	**1995**	1999	**2004**	2008
Demographic	green	green	green	green	green
Therapeutic	orange	orange	orange	orange	orange
Concurrent Treatments		green	green	green	green
Clinical – HIV/AIDS events	orange	orange	orange	orange	orange
Clinical – Comorbidities		green	green	green	green
Laboratory – HIV associated	orange	orange	orange	orange	orange
Laboratory – General		green	green	green	green
Socioeconomic		orange	orange	orange	orange
Health services utilization			green	green	green
Adherence – Self report		orange	orange	orange	orange
Patient Reported Outcomes					green

10/1/2014: 14,420 PRO sessions

Innovation Area

Innovation area =

Methodological Expertise (ME)

Data Types (DT)

DT x ME

Factors associated with 30 day readmission in patients with CHF?
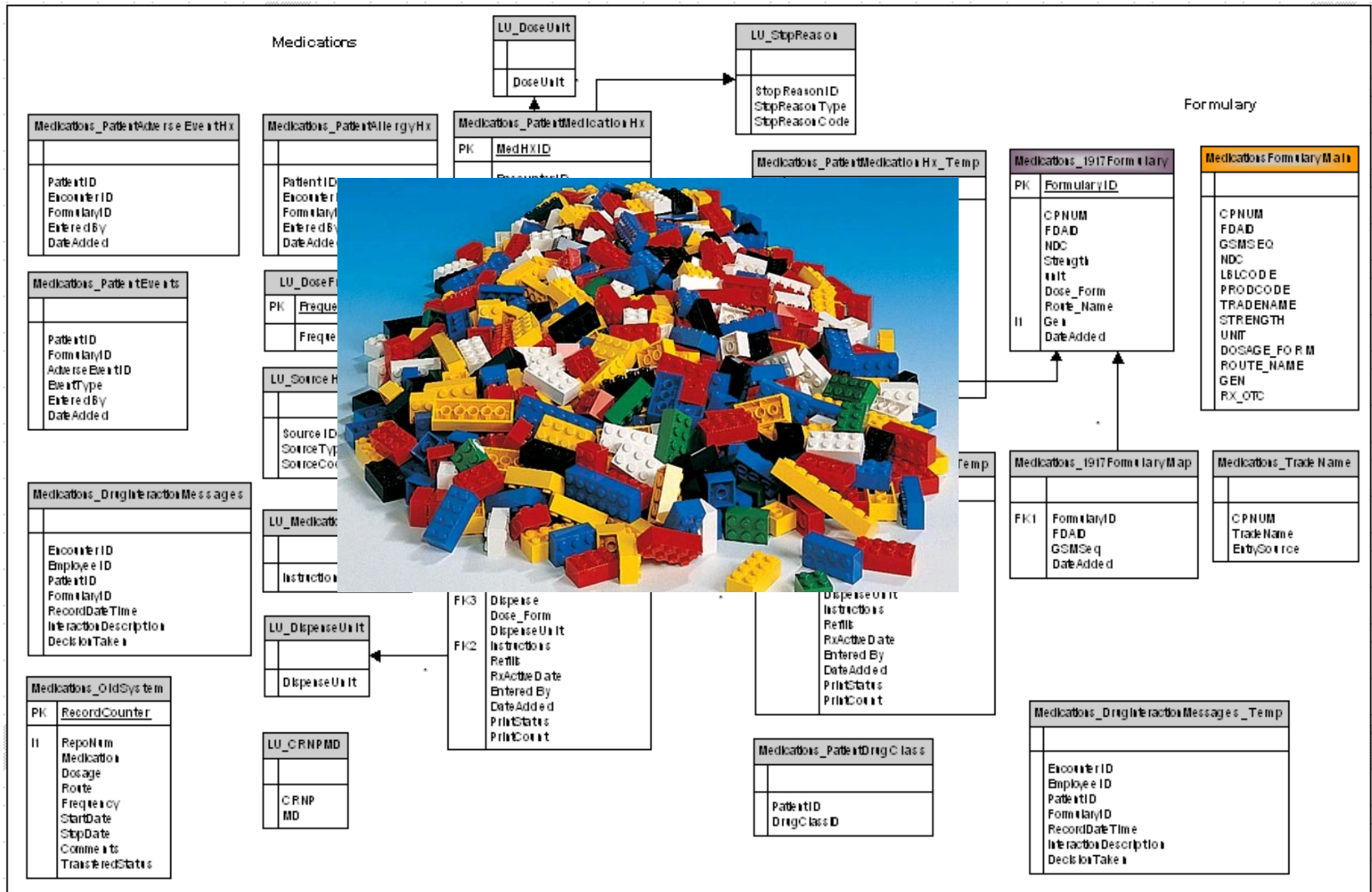
OR

LR

PH

Descriptive

Demo

Meds

Co-morbid

Labs

Dx

Logistic Regression

Admit

Demo | Labs | Meds | Dx | Admit | Co-morbid

Innovation Space

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(2004) PROs: Why did we do it?

- Benefits to researchers
  - Expansion of the innovation space – new variables, novel research
  - How to survive as a single site cohort in a multi-cohort world? Expand your innovation space! (speed boats vs. cruise ships)

How not to do it: August 2, 2004

- The Patient Information Questionnaire (PIQ) Episode

- What did we do wrong?
  - Long instruments – total time of administration 45 minutes
  - Single point of administration
  - Solely Researcher driven selection of instruments, minimal clinician or clinic leadership participation in logistics
  - Limited client/patient integration (keyboard and mouse, questions on screen/font size, etc.)

2007: Safety not guaranteed if you talked PROs…

- Carefully selected domains
  - Clinically relevant
  - The Golden Ratio? Aiding clinical decisions and aiding research (3:1)

- Carefully selected instruments
  - Easy to interpret results
  - Brevity at a premium (CAT)

- Front line level understanding of clinic workflow
  - Identification of "pockets of wait time"

PRO Implementation in high volume clinic setting
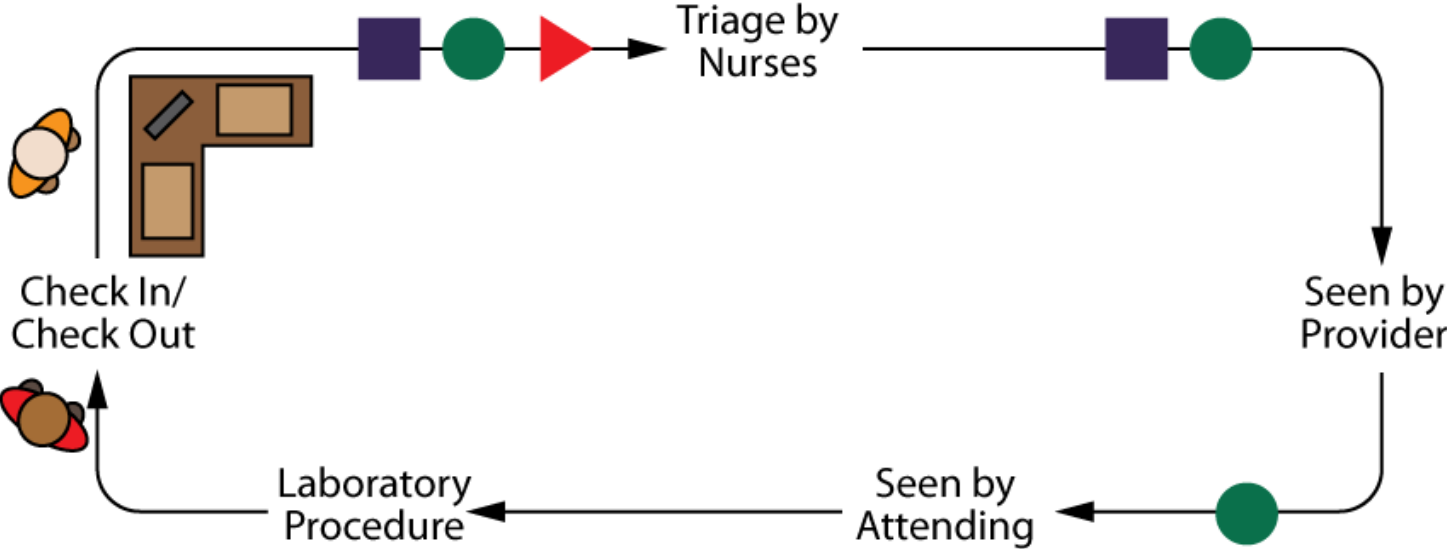
One person monitoring completion real time

MRN	First Name	Last Name	Birthdate	Earliest Answer	Recent Answer	Progress	Patient Page	Screening Report
				2014-09-11 11:32:13	2014-09-11 11:45:59		Go	Go
				2014-09-11 11:27:39	2014-09-11 11:41:48		Go	Go
				2014-09-11 11:19:31	2014-09-11 11:31:58		Go	Go
				2014-09-11 09:20:16	2014-09-11 10:02:44		Go	Go
				2014-09-11 07:58:03	2014-09-11 08:07:11		Go	Go
				2014-09-11 06:53:50	2014-09-11 06:55:46		Go	Go
				2014-09-11 06:46:49	2014-09-11 07:20:45		Go	Go
				2014-09-10 14:13:18	2014-09-10 14:20:07		Go	Go
				2014-09-10 11:51:36	2014-09-10 12:06:46		Go	Go
				2014-09-10 11:36:27	2014-09-10 11:36:27		Go	Go
				2014-09-10 09:53:51	2014-09-10 10:15:20		Go	Go
				2014-09-10 09:17:43	2014-09-10 10:01:44		Go	Go
				2014-09-10 09:01:23	2014-09-10 10:27:02		Go	Go
				2014-09-10 08:35:39	2014-09-10 09:02:09		Go	Go
				2014-09-10 08:11:21	2014-09-10 08:34:30		Go	Go
				2014-09-10 07:49:06	2014-09-10 08:04:09		Go	Go

Patient-Based Measures Provider Feedback

Patient-Based Measures Provider Feedback — Printed 9/11/2014

NAME   MRN   DOB

	9/11/2014 161 answers	3/6/2014 133 answers	9/5/2013 152 answers
Depression (PHQ-9)	0 No depression (0-4)	0 No depression (0-4)	0 No depression (0-4)
Suicide Ideation (PHQ-9) In Last 2 Weeks	0 Not at all	0 Not at all	0 Not at all
Tobacco Use	Previously smoked Less than half a pack a day	Currently Less than half a pack a day	Currently Less than half a pack a day
Alcohol Score	1 Not at-risk (AUDIT-C)	1 Not at-risk (AUDIT-C)	3 Not at-risk (AUDIT-C)
MINI Score	N/A	N/A	N/A
Substance Use (Past 3 months)	Marijuana	Marijuana	Marijuana
Antiretroviral Adherence (Past 4 weeks) Last missed	Excellent I never skip medications	Excellent I never skip medications	Excellent Within the last week
High-risk Behavior (Past 6 months)			
Anal sex condom use	All the time	All the time	All the time
Vaginal sex condom use	Never had vaginal sex	Never had vaginal sex	Never had vaginal sex
Sharing needles/injection equipment	Never used	Never used	Never used
Oral sex partners	1	1	1

(2008) PROs: Why did we do it?

- Enhance care
  - Dear provider, here's 5 minutes of your day back
  - And by the way, now you can do your job better (providing timely data at the decision making point of care)
  - Hey, we've enhanced care too (SI, IPV, etc.)!

- **Enhance Research**
  - **How to thrive as a single cohort in a multicohort world? Expand your innovation space (Cruise ships vs. Speed boats)**
 - Real time monitoring for study enrollment

- Sample Early Research Projects Using PRO data

Logistic Regression model: Outcome is self-reported SI – Yes.[1]

	Unadjusted	Adjusted
Age (per 10 years)	0.81 (0.69-0.96)	**0.74 (0.58-0.96)**
Depression (PHQ9)		
No Depression (0-4)	0.06 (0.02-0.16)	**0.08 (0.03-0.21)**
Mild (5-9)	1.0	1.0
Moderate (10-14)	3.89 (2.16-7.02)	**3.91 (2.12-7.22)**
Mod/Severe (15-19)	9.16 (4.85-17.31)	**9.08 (4.67-17.63)**
Severe (≥20)	21.70 (11.37-41.43)	**25.55 (12.73-51.30)**
Unknown	2.12 (0.23-19.86)	2.05 (0.20-21.64)
Substance Abuse		
Never	1.0	1.0
Yes – Historical	2.60 (1.73-3.90)	1.15 (0.66-1.98)
Yes – Current	6.32 (4.06-9.82)	**1.88 (1.03-3.44)**

1. Model also adjusted for: Gender, race, insurance, location, CD4, alcohol use.
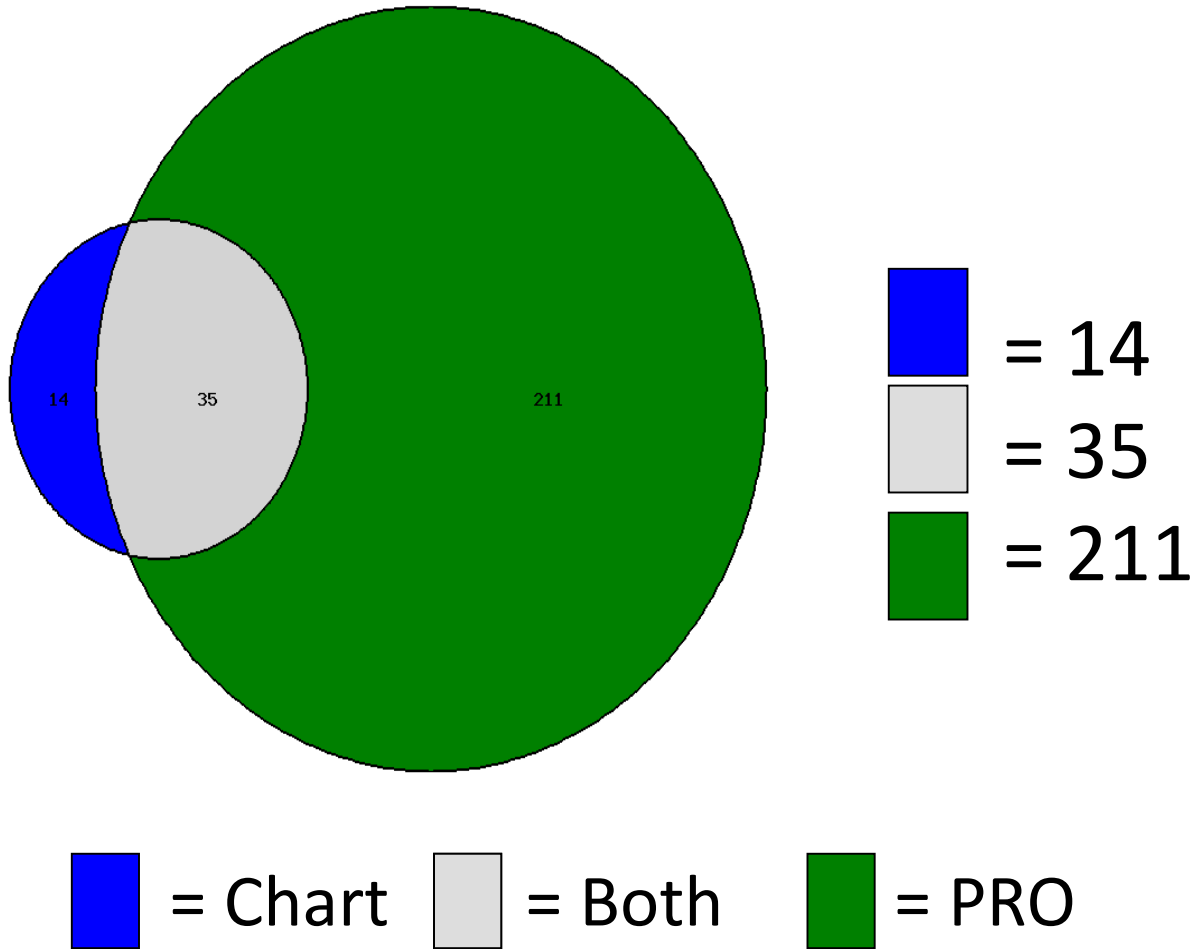2. Published in CID April 2010

Substance abuse = Current

= 73
= 26
= 19
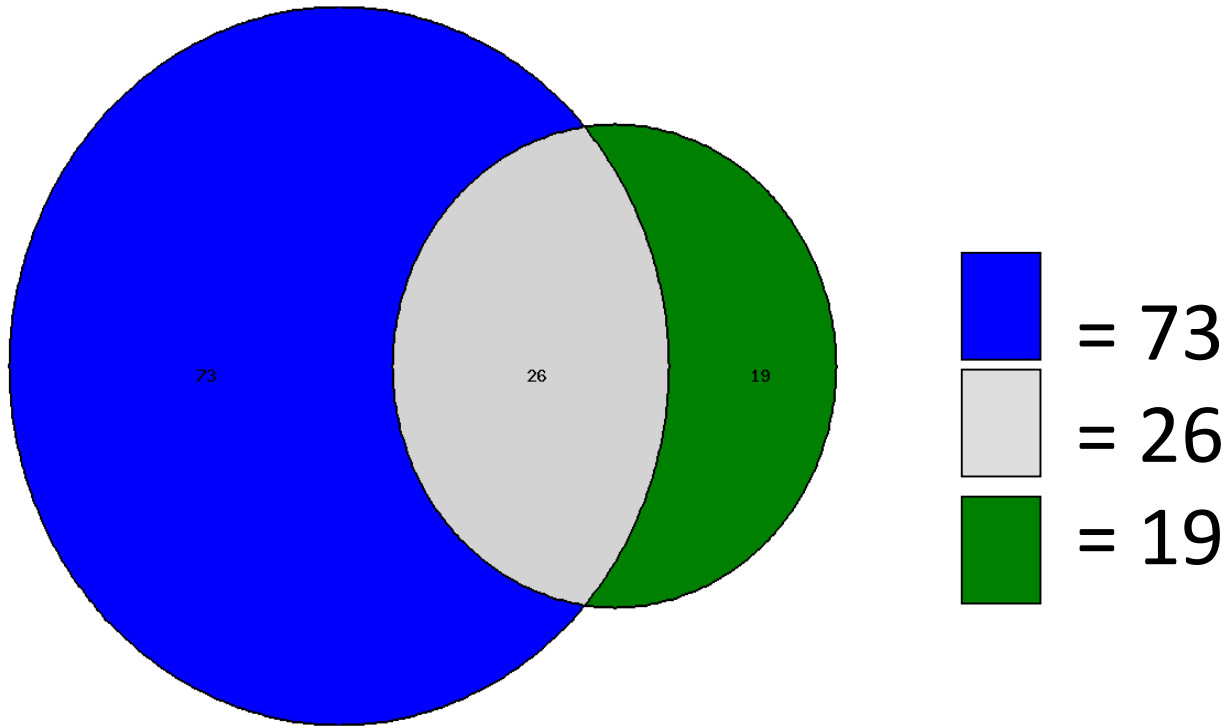
= Chart   = Both   = PRO

Substance abuse = Prior

14   35   211

■ = 14
□ = 35
■ = 211

■ = Chart   □ = Both   ■ = PRO

Logistic regression model of chart (provider entered) vs. self-reported (PRO) diagnoses in the prediction of poor adherence[1]

	Chart OR (95%CI)	PRO OR (95%CI)
Substance abuse[1]		
Never	1.0	**1.0**
Prior	0.85 (0.36-2.01)	**1.62 (1.01-2.61)**
Current	1.25 (0.70-2.21)	**2.78 (1.33-5.81)**
Depression[1] (yes vs. no)	0.93 (0.62-1.40)	**1.93 (1.12-3.33)**
Tobacco use		
Current	1.0	1.0
Prior	1.39 (0.60-3.23)	0.91 (0.51-1.62)
Never	1.55 (1.00-2.39)	0.91 (0.57-1.47)
Alcohol risk[1] (yes vs. no)	0.95 (0.49-1.86)	1.35 (0.78-2.36)
Black/other vs. white	**2.25 (1.46-3.46)**	**2.48 (1.59-3.86)**

1. Model also adjusted for: Age (per 10 years), gender, insurance, CD4, ART experience and viral load (>400 vs. < 400). Only the latter was significant.

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#1 Balance research and clinical imperatives

- 2004 imperative was data capture
  - We asked researchers alone for instrument recommendations

- Game theory and PRO selection
  - Tragedy of the commons situation: total time for all instruments overwhelms → Patient fatigue → Delays in care → Failed implementation

- Instrument selection must balance both the clinical and research viewpoints
  - Constant feedback from patients (end-users) necessary

#2: Brevity matters

- Weigh overall "time cost" of a panel, not individual instruments

- Compact instruments = easier implementation
  - Find a balance between desire for psychometric precision and brevity

- Computer adaptive testing is your friend

#3 Comprehensive stakeholder engagement

- Clinic staff buy-in
  - Access to in-depth workflow insights that facilitate implementation

- Patient/end-user buy-in
  - Perspective informs acceptable length and frequency of PRO administration

- Clinician buy-in
  - Enhance PRO utilization in point-of-care decision making
  - Prioritize instruments which impact point-of-care decisions
  - We suggest a clinical/research instrument ratio of 3 or 4:1

#4 Establish and assess metrics throughout

- Electronic monitoring of PRO completion in clinic with provision of assistance as needed
  - Literacy clues

- Continuously assess PRO completion rates by clients

- Continuously assess clinician utilization of data during encounters

- Continuously assess your panel
  - Be willing to renegotiate your instruments
  - Strive to balance multiple stakeholder perspectives

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PROs at 1917 Clinic Today

- Clinical benefits
  - Higher data quality? Decreased social desirability bias; patient updates status of "chronic diagnoses"
  - Clinical benefits (gain time, layer systems to enhance care: SI, IPV monitoring)

- Research benefits
  - All research endeavors benefit from new data type
  - Study recruitment

- Challenges
  - Implementation into existing workflow is paramount
  - Costs – but many alternatives to diminish cost

Outward Bound: Getting PROs to other Clinics

Settings	Instruments (questions)	Sessions
Social Services[1]	8 (n = 66)	2,185
Palliative[1]	5 (n = 42)	937
Signs & Symptoms[1]	1 (n = 20)	44,121
Viral Hepatitis[1]	6 (n = 55)	601
Supportive Care[2]	5 (n = 81)	777
Breast Health[2]	1 (n = 6)	102
iEngage[3]	R01	217
BA2C[3]		256
Pediatric Neurosurgery		*

(1) 1917 Clinic; (2) TKC; (3) Research

PRO Patient Reported Outcomes
Survey Web App

- Web based platform to implement the capture of patient reported outcomes in the care setting
  - PLCI grant collaboration

- Instrument library
  - Over 50 instruments programmed to date

- Practice specific "panels"

First question: Is your practice setting ready for PRO data capture?

Cincinnati Children's Hospital: PRO Readiness

Courtesy of: Esi Morgan De Witt, MD, MSCE

What is the desired outcome in using a PRO instrument? Why have you selected this outcome?

Have you used a PRO before? If so, this instrument? Describe how your process worked.

Do you need assistance in instrument exploration, validation and selection?

Do you have an instrument selected? If so which instrument and how was it selected?

Does the instrument measure the desired outcome for this patient population? If so, how?

Have you explored other instruments that might serve your purpose?

Instrument selection

Cincinnati Children's Hospital: PRO Readiness

Courtesy of: Esi Morgan De Witt, MD, MSCE

Does the team have QI/Data support? Do they meet regularly for improvement purposes?

Does this project have high priority divisional support to implement?

Is there consensus among clinicians to use the instrument results?
- **Use patient responses in clinic setting to make decisions**
- **Monitor and improve completion rates**
- **Monitor and adjust interventions as indicated**

Support: Informatics, Leadership and Clinicians

Cincinnati Children's Hospital: PRO Readiness

Courtesy of: Esi Morgan De Witt, MD, MSCE

Is the patient population homogenous?

Are there patients for whom the instrument is not appropriate? For example, are there age limitations?

Who will be completing the instrument (patient/parent/guardian)?

How long does it take to complete the instrument?

How will you identify these patients?

Adjustment to the population

PRO Implementation

- ## What is the goal?
  - Clinical, research, recruitment, etc.

- ## Analyze clinic workflow (site visit)
  - Where can we integrate capture with minimal disruption
  - How to feed results back to providers

- ## PRO issues
  - Selection, frequency, alerts, etc.

Viral Hepatitis Clinic

Depression

Anxiety

Alcohol

Substance

QOL

Fatigue

PRO Implementation
Selection of instruments
Sequence
Frequency

1917 Palliative Care Clinic
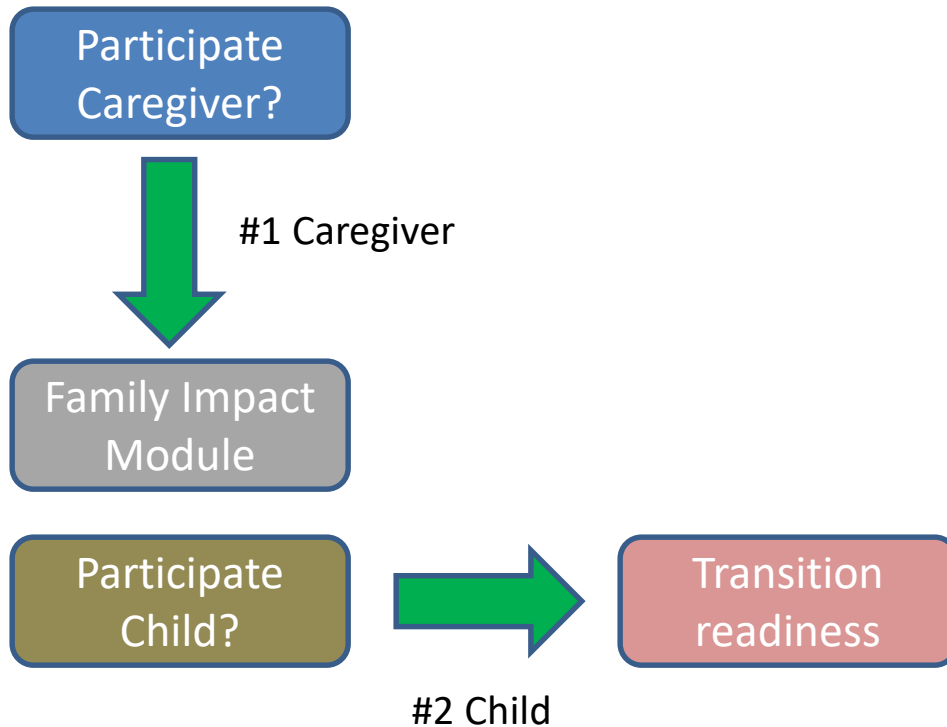
Symptoms

Improved Pain

n

Anxiety

QOL

Depression

PRO Implementation
Selection of instruments
Sequence
Internal logic
Frequency
Alerts

Notification Triggered
- Clinical: SI, IPV (starts clinic response protocol)
- Study enrollment

Pediatric Implementation #1 Spina Bifida

Participate Caregiver?

#1 Caregiver

Family Impact Module

Participate Child?

#2 Child

Transition readiness

PRO Implementation
Selection of instruments
Sequence
Internal logic
Frequency
Alerts
One session, multiple users

Next Partner Clinics
- Musculoskeletal
- Asthma

Next Steps

- Committee with HSIS Chaired by Jeff Curtis, MD
  - How to get PRO data into Impact?

- mHealth Assessment Service (MAS API)
  - 3 stages
    - Mpage with PRO results
    - PRO and PROMIS
    - Device data

- Capture PRO data in and outside Clinic settings
  - Study Buddy

Our failed 2004 PRO implementation provided key lessons that guided subsequent successful implementation in 2008 of ongoing data capture across multiple instruments in a high volume clinic setting.

What are **your** thoughts and concerns?

Thank you for your kind attention.

Thanks to the innumerable collaborators who have contributed to all this!