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DARTNet Guided Exploration of Linkages Between Existing Health Data, Patient Reported Outcomes and PBRN Research

Presented By:

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Moderated By:

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Agency for Healthcare Research and Quality

Sponsored by the AHRQ PBRN Resource Center
August 7, 2015

Agenda

- Welcome and introduction
- Presentations
- Q&A session with all presenters
- Instructions for obtaining your CME Certificate of Participation

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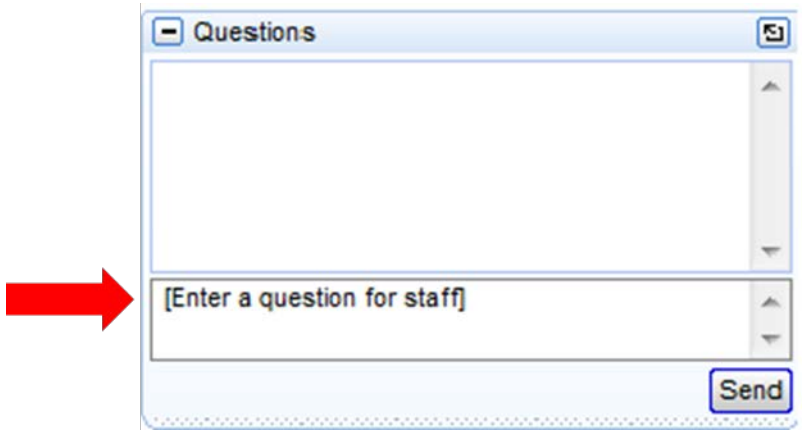

Today's Presenters

DARTNet Guided Exploration of Linkages Between Existing Health Data, Patient Reported Outcomes and PBRN Research

Wilson Pace, MD, FAAFP

Professor of Family Medicine, Green-Edelman Chair for Practice-based Research, University of Colorado Denver;
Director, American Academy of Family Physicians National Research Network;
Chief Executive Officer, DARTNet Institute

Chester Fox, MD, FAAFP, FNKS

Professor, University at Buffalo;
Director, Upstate New York Practice-based Research Network (UNYNET);
Research Director, AHRQ P30 Network of Networks Center of Excellence Grant

Linking PBRN Research and Electronic Health Data

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Disclosure Statement

Wilson D. Pace, MD, FAAFP

- Research Grants/Contacts: Sanofi US, Mallinkcrodt, Genova Diagnostics, Novo-Nordisk
- Stock: Pfizer, Novartis, GSK, Novo-Nordisk, Sanofi US, Merck, Abbvie
- No off label medication use will be discussed.

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Disclosure Statement

Chester Fox, MD, FAAFP

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- Stock/investments: Nothing to declare
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What Does Access to Existing Electronic Data Offer?

- Characterized patient populations
- Novel approaches to cluster randomization
- Advanced PBRN capabilities
  - More complete outcomes
  - Assess side effects
  - Assess negative consequences
- Temporal controls
- Further blurring of QI/Research

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Characterized Populations

- Atrial Fibrillation
  - Patient demographics
  - Cause/ co-morbidities
- Medications
  - Warfarin
  - New oral agents
  - No therapy
- Ancillary clinical data
- Significant outcomes

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Case Study

- Population – 850,000 Adult primary care patients
- A. Fib. Dx – 14,638
- On Warfarin – 8,598
- On newer oral anticoags – 1,570
- On both at some time – 750
- Plenty of patients to study, patients on both groups and many on no anti-coag.

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Feasibility Assessment

- Percent of population by age/gender with underlying condition(s)
- Percent with condition in each initial study cohort
- Observed complication rates (estimate)
- Calculate number of patients at population level required in “study practices”

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Pre-Research Use of Data

- Understand current prescribing practices
- Determine if any illogical practices are occurring or extent of variation
- Develop variable interventions based on baseline information
- Balance interventional cohorts at baseline

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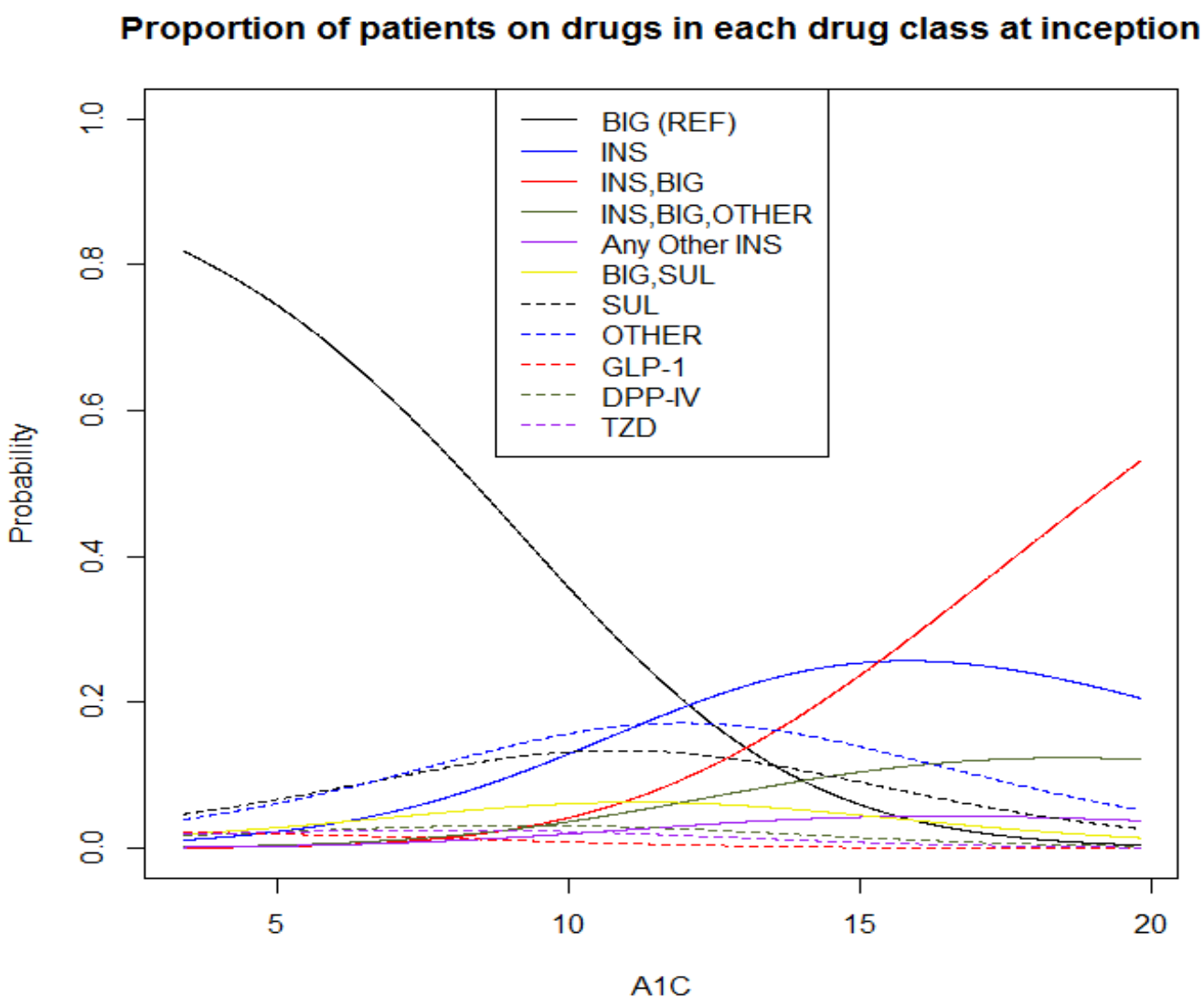
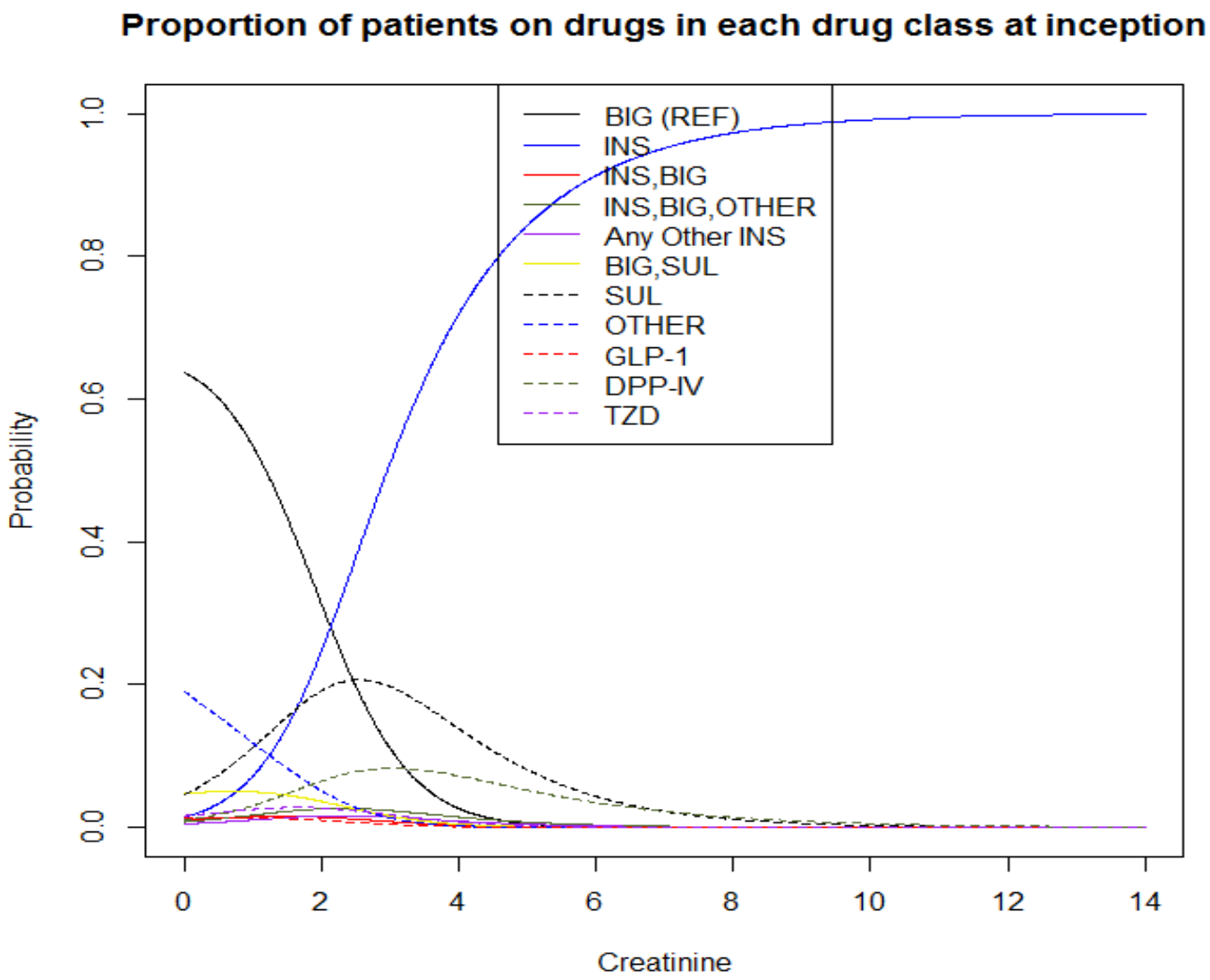


Initial T2DM Meds by A1c



Initial T2DM Meds by Cr

Data Leading the Way

- Research informed by local data
- Guide the study question
- Guide the study methods
- Guide the site selection
- Guide study assignment
- Guide implementation

- Changes the game!

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Enhanced PBRN Approaches

- Re-usable research laboratory
- Close working relationship between practicing clinicians and researchers
- Data collection methods that are non-disruptive or minimally disruptive to clinical care
- Point of care or near point of care data collection that can explore decision making at the patient level

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Taking Research to Scale

- Kidney Disease Outcomes Quality Initiative (KDOQI) are a mixture of evidence based information and expert opinion
- Reproducibility of efficacy studies has been variable
- No trials that look at impact of implementing the entire set of guidelines

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TRANSLATE-CKD

NIDDK –1R01DK090407-01 (Fox)

IMPROVING EVIDENCE-BASED PRIMARY CARE FORCHRONIC KIDNEY DISEASE

- Cluster randomized trial to implement KDOQI guidelines in 40 primary practices through clinical decision support versus full TRANSLATE model
- Tracking all outcomes through EHR and claims data
- Currently just over 28,000 patients with CKD in the study

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CKD Study Description: CRT Model

- Study objective: Test two approaches to improving care for stage 3 and 4 CKD patients in primary care practices
  - Control practices
    - Computer decision support (CDS) for CKD patients
  - Intervention practices
    - TRANSLATE action plan : 9 point action plan based on the CCM (includes CDS) plus practice facilitation
- Unit of randomization: practice
  - Three waves of implementation, each randomized separately

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Balancing Practices at Baseline

- Cluster randomized trials (CRT)
  - Unit of randomization is a group
  - Groups can be defined in a variety of ways
    - Geographic location (e.g. communities, counties, etc)
    - Organizational units (schools/classrooms, hospitals, medical practices)
- Why randomize clusters instead of individuals?
  - Intervention is at the level of the group
  - Potential contamination makes individual-level randomization problematic
  - Feasibility – convenience, economic considerations

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Common issues with CRTs

- Generally, the number of groups to be randomized is much smaller
- Heterogeneity among groups is a larger issue
- Simple, or even stratified randomization can result in study arms that are very different from each other
- Stratification can only deal with a limited number of variables

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What Does Big Data Bring?

- Randomization done using baseline practice performance and characteristics
- Able to balance multiple criteria at once even with small groups of practices
- Historical data allows tailoring of academic detailing to each site if needed
  - Focus on diagnosis if not many F/U tests done
  - Focus on screening if low
  - Focus on interventions if Dx data available

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Procedure for Covariate Constrained Randomization

- Baseline data on must be available
- All possible randomizations into study groups are generated
- A balance criterion (B), defined as the sum of squared differences between study groups on relevant standardized variables, is calculated for each randomization option
- Establish a criterion for maximum allowable difference between study groups which defines a set of “acceptable randomizations
- A single randomization is then chosen from the set of “acceptable randomizations”

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Randomization Variables - CKD

- Practice-level data
  - Structural and patient sociodemographic data
    - Obtained from practice survey
  - Clinical data
    - Baseline data for eligible patients obtained from EHR
    - Aggregated to the practice level
- Structural and sociodemographic data
  - # FTE clinicians, % African American, % Hispanic, % Medicaid or uninsured
- Clinical data
  - % of patients with HbA1c>9, % diabetic, % stage 4 CKD, % with systolic BP>130, % with systolic BP>140
  - Mean GFR, mean HbA1c, mean systolic BP

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Outcomes of "Worst" Randomization from Optimal Set*

Variable	Group 1	Group 2
FTE clinicians	(n) 3.9 (2.9)	3.6 (3.6)
African American race	(%) 2.2 (1.2)	3.7 (5.2)
Hispanic ethnicity	(%) 13.0 (3.6)	20.1 (2.1)
Medicaid/Uninsured	(%) 13.1 (8.2)	14.4 (9.4)
Diabetic	(%) 30.4 (11.6)	39.3 (23.3)
HbA1c >9	(%) 10.3 (8.9)	8.0 (6.2)
Stage 4 CKD	(%) 7.3 (3.8)	6.1 (5.3)
BP >130/80	(%) 55.4 (6.7)	60.1 (19.1)
BP >140/90	(%) 33.3 (6.5)	29.2 (15.4)
Mean HbA1c	7.0 (0.4)	7.0 (0.4)
Mean eGFR	48.4 (2.4)	50.4 (3.6)
Mean systolic BP	132.3 (3.0)	131.9 (4.6)

* No significant difference between any variable.

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Summary and Conclusions

- Covariate constrained randomization procedures are useful to achieve balance in CRTs
- Preliminary data on key variables is necessary
- Stratification can be incorporated
- Consider weighting
- Every study is different – it may not be possible to completely standardize SAS code

Dickinson LM, Beaty B, Fox C, Pace W, et. al. Pragmatic Cluster Randomized Trials Using Covariate Constrainted Randomization. JABFM; 2015:28 (in press)

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Blurring QI and Research - CKD

- All outcomes tracked by EHR data
- All interventions based on EHR data
- Clinicians entirely focused on delivery quality care to entire population at risk for or with CKD
- Both positive and negative outcomes can be tracked

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CKD – Positive Outcomes

- Intermediate outcomes
  - Increased screening
  - Improved diagnostic accuracy (less under AND over Dx)
  - Change in eGFR
  - Change in ACR
- Patient outcomes that matter
  - ESRD
  - Death – linkage to NDI

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CKD - Adverse Outcomes

- Adverse effects
  - Number of individuals who develop hyperkalemia
  - Rate of hip, forearm or clavicle fractures on and off ACE/ARB
  - Instances of acute renal failure

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Directed Collection of Data

- Not all studies can be performed through EHR data alone
- Clinician or patient decision making may be of interest
- Patient reported outcomes may be of interest
- Clinical data collection may need to be enhanced

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Moving Beyond Passive Data

- Information from clinicians or staff at or near the point of care (Classically a “Card Study”)
- Information from patients
- Informed by or additive to EHR data

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Card Studies

- Collection of patient-specific data at or near the point of care is a hallmark of PBRNs.
- “Card” studies were popularized by the Ambulatory Sentinel Practice Network
- “Card” studies have progressed in terms of the scope of data collected, the sources of data and the collection methods.
- For the Community Acquired-MRSA study, we integrated a “card” study with EHR data and incorporated the data collection into clinicians’ workflow

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Management of Patients with Skin and Soft Tissue Infections

AHRQ Contract # HHSA290 2007 10008

- Study goal: develop and test sustainable, guideline-consistent treatment strategies for CA-MRSA
- Data sources: EHR, Clinician Decision Making, Manual Chart Audit, Patient Outcomes (Specialty visit, ED visit, hospitalization) and Provider Evaluations
- All data sources linked for analysis

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Demonstrated ability to study /improve acute problems

- Tracked 100% of soft tissue infections
- 3112 SSTI cases observed during the pre-intervention period (12 months/ 28 practices)
- 1406 cases during the intervention (8 months/ 16 practices)
- Increased use of MRSA antibiotics
- No change in outcomes

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Provider Decision Making

- Interested in guideline related decisions
- Clinicians invited to evaluate certain SSTI cases via email
- Email links to internal website which displays patient information
- Internal website links to Online Evaluation
- Online Evaluation data linked back to de-identified EHR data

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Provider Evaluation Overview

- 16 different clinical scenarios for clinicians to evaluate via “card” study
  - Child (yes or no)
  - Culture done (yes or no)
  - Procedure done (yes or no)
  - Antibiotics prescribed (yes or no)
- Nightly data feed allowed patient and clinician sorting and avoided collecting information already in EHR

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Nuanced Decision Making

- Directed Chart Audit for antibiotic use post drainage
  - Procedures tracked
  - Antibiotics tracked
- Central chart audit for antibiotic indications following drainage
- Quickly able to collect data with single chart auditor across 16 practices in two states

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Patient Outcomes

- All patients called back at 2 weeks
  - Other physicians seen for SSTI
  - Additional procedures (outside system)
  - ED visits
  - Hospitalizations
- Claims data could be used
  - 30 to 90+ days behind
- Clearly demonstrated limited impact of guidelines

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Capturing Information from Patients

- Many conditions and care process studies require or can be enhanced with patient reported outcomes (PRO)
- Issues abound in trying this manually
  - Selecting patients
  - Collecting data without impact on practice
  - Linking PRO data to EHR data and perhaps clinician/staff data without requiring consent

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My Asthma AHRQ 1 R18 HS022689

- Evaluation of Patient Portals for MU-3
- Asthma classic illness where PROs are more important than physiologic measures
- Conducted in ePROS offices

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Selecting Patients

- EHR data queried and eligible patients recruited through mail, phone and at time of visits
- On-line system refined for data collection, education and feedback to clinicians
- Reminders based on time and pending appointments
- Data at end of study from on-line system linked to EHR data

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Data Collection and Feedback

- Conducted from patients homes with parents reporting for their children
- Immediate feedback to parent, educational videos available
- Immediate feedback to clinician if asthma in poor control

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Built on Existing System

MyAsthma Welcome **MyAsthmaTest2** ! [Log Out]

Home | Surveys | Help

Content in top region of page is customizeable

MyAsthma

MyAsthma is designed to help you and your pediatricians office manage your child's asthma care.

The first time you use MyAsthma you will fill out four surveys.

After that, MyAsthma will send you monthly automatic reminders to fill out just one survey, the Asthma Control Check-In survey.

Other MyAsthma Resources

Summary
A one page summary of your concerns, goals and monthly check-in results
Education
A collection of asthma patient education videos and hand outs

Available Surveys

Survey	Status
Parent Demographics	Complete
Asthma Concerns	Complete
Asthma Goals	Complete
Asthma Control Check-In	**Incomplete**

Click a hyperlink above to take a survey.

Surveys Taken Before

Rank	Module	Survey	Taken On	Completed?
3	Asthma Goals	Asthma Goals	7/8/2014	✓
2	Asthma Concerns	Concerns	7/8/2014	✓
1	Parent Demographics	Parent Demographics	7/8/2014	✓

Above is a list of surveys you have taken previously. Click on one of these surveys to view your previous answers and profile.

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Robust Data Collection and Reporting

MyAsthma

Welcome **KelliMyAsthma** ! [Log Out]

Home | Surveys | Help

1 of 1 | 100% | Find | Next

MyAsthma — Completed: **7/8/2014**

Practice:	Patient Name:	DOB:	MRN:
MyAsthma UCDenver Testers	**Kid, Test**	**5/2/2006**	**99997777**

Check-in Survey	**Goals** Edit goals...	**Concerns** Edit concerns...
You are not up to date.	Parent's goal: have child participate in sports	Steroids impacting growth: Definitely
Next check-in: August 08, 2014	Child's goal: play baseball	Cost of medication: Very Much
Last check-in: July 08, 2014		Taking too much medication: Very Much
		Impact on life: Moderately
		Medication dependency: Slightly
		Time to meet w/ doctor: Slightly
		Medication side effects: Not at all
		Time to manage medication: Not at all
		Other concerns: asdf

Check-in Survey Timeline

Good	Of concern	Major concern

	2014				
	2/12/2014	3/14/2014	6/5/2014	6/17/2014	7/8/2014
Asthma Control	Uncontrolled	Uncontrolled	Uncontrolled	Uncontrolled	Uncontrolled
Meeting Goals	Very Much	Slightly	Moderately	Moderately	Moderately
Managing Concerns	Definitely	Not at all	Not at all	Definitely	Very Much
Missed school/daycare	1 time	0	3 times	1 time	0
Steroid by mouth	5+ times	2 times	4 times	1 time	0
ED/Urgent Care visit	0	2 times	2 times	3 times	0
Hospital admission	4 times	1 time	1 time	2 times	0
Symptoms with play	All of the time	Most of the time	All of the time	A little of the time	Some of the time
Symptoms at night	Once or twice	2 or 3 nights a week	4 or more nights a week	Once a week	Once or twice
Needed albuterol	1 or 2 times per day	Once a week or less	Not at all	1 or 2 times per day	Once a week or less
Medication side effects	Yes	No	Yes	Yes	No
Taking Medications				More than half	

Multiple Paths to Data Collection

- In office tablet/browser based data collection
- Home based data collection
- Mobile enabled
- Multiple approaches to reminders
- Can incorporate EHR data

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Temporal Controls – Particularly Helpful in Quasi-Experimental Designs

- Implementation work may not have classic controls
- Practices agreeing to a study and randomized to a “control” state may “focus” on the area anyway or “standard of care” may include some intervention
- Control practices may drop out differentially

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Existing Data Again Required

- If data from multiple practices, unrelated to the study practices exist can create "temporal controls" using similar techniques to Covariate Constrained Randomization
- Classic propensity scoring approaches applied at the practice level can also be used

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Covariate Constrained Model

- Similar equation to randomization
- Select variables to include (must include outcome variables assessed at baseline)
- Random sub-sets of available practices created (typically have to limit the number of random options)
- Closest sets of practices selected (set calipers very tightly)
- Randomly select a set and use a control

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Propensity Scoring Approach

- Variable selection similar depending on propensity technique (high variable vs. DAG) – outcomes included
- Can use similar equation for practice scoring – others available
- After discarding outliers, match intervention to “temporal control” practice in same propensity score range (often quintiles)

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Model Differences

- Variable constrained approach creates similarities across the sites as a whole
- Propensity creates matching at quintile or some other group level
- Propensity typically requires a larger number of available “control” units to have sufficient practices in each group
- Many variations to consider and explore

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Research, CDS and ACO's

- Moderate Sized Multi-specialty ACO
  - ~250,000 total patients
  - ~40,000 Medicare patients
- Not meeting some immunization metrics
- Grant available through industry
  - Funds for ACO and research team
  - Enhanced CDS and standing orders
  - Novel feedback approach
  - Attempted to extend CDS to other specialists
  - Better integration of claims data

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Project Underway

- CDS improved – virtually 100% accurate
  - Vaccination refusals picked up
  - Standing orders variably accepted to date
  - Micro-team missed opportunities reports under development
  - Specialist CDS not implement at this time
- All immunizations tracked for negative or positive effects on other immunizations

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Multi-faceted Research

- Data mining for traditional OCER
  - Claims data critical
- Enhanced clinical data for OCER
- Information to inform studies
  - Eligibility criteria
  - Incidence and prevalence data
- Best practices research
- PBRN interventional trials

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Contact Information

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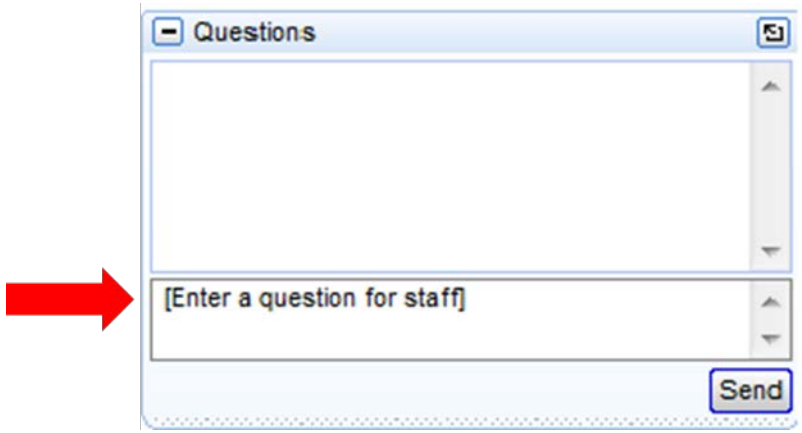

Obtaining CME Credit

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Upcoming Resources– Guide on PBRN-ACO Business Opportunities

- Practical Primer for Pursuing Business Opportunities between PBRNs and ACOs and Other Entities
- Guide objectives:
  - Acknowledge the capacity and experience of PBRNS to provide QI *training and services* to other entities
  - Encourage PBRNs to consider the *mix of research and QI expertise and services* offered to strengthen self-sustainability
  - Promote ACOs and other QI entities to *partner with PBRNs* to meeting increasing expectations for QI capabilities

Upcoming Events

Upcoming AHRQ PBRN Resource Center Webinars:

- **August 18, 2015, 12:30 – 2:00pm ET:** Adaptive Trial Design and Learning Evaluation
- **September 9, 1:30 – 3:00pm ET:** *Using Rapid-Cycle Research to Reach Goals: Awareness, Assessment, Adaptation, Acceleration*-A Guidance Document

Visit http://pbrn.ahrq.gov/events for webinar registration information and details on other upcoming PBRN-relevant events

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