U.S. Department of Health and Human Services

Agency for Healthcare Research and Quality
Advancing Excellence in Health Care • www.ahrq.gov

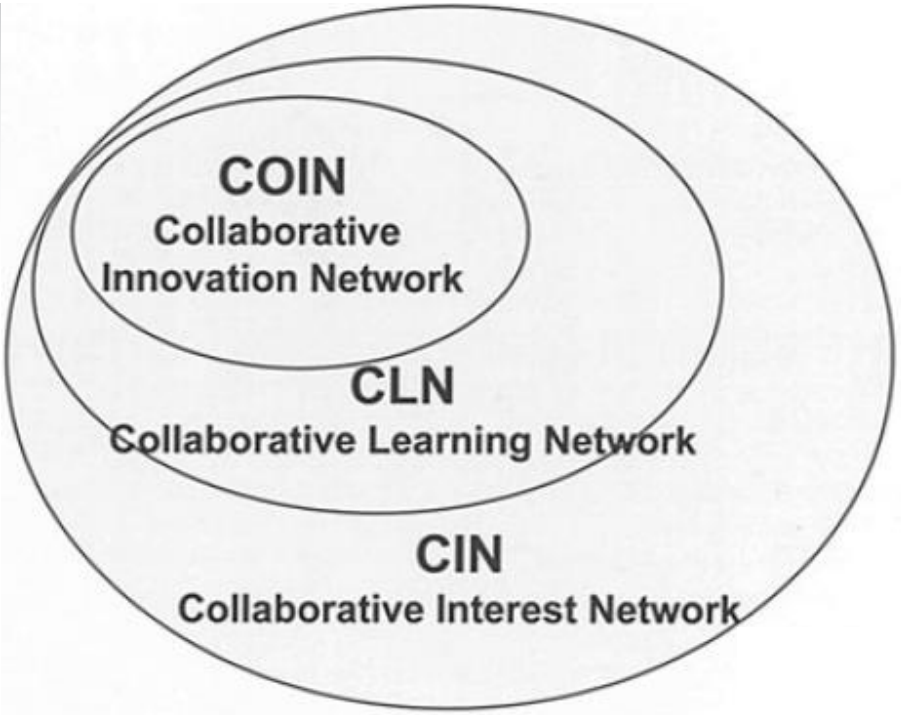
2014 NAPCRG PBRN Conference June 30, 2014

Improvement and Innovation Networks

The Intersection between Research and Quality Improvement

Lloyd Provost
Associates in Process Improvement
lprovost @apiweb.org

The Collaborative Knowledge Networks



Example:

Linux Creators

+

Linux Maintainers debian

+

Linux Users Slashdot

COINs are embedded into a multidimensional network of communities

Peter Gloor
MIT Center for Collective Intelligence

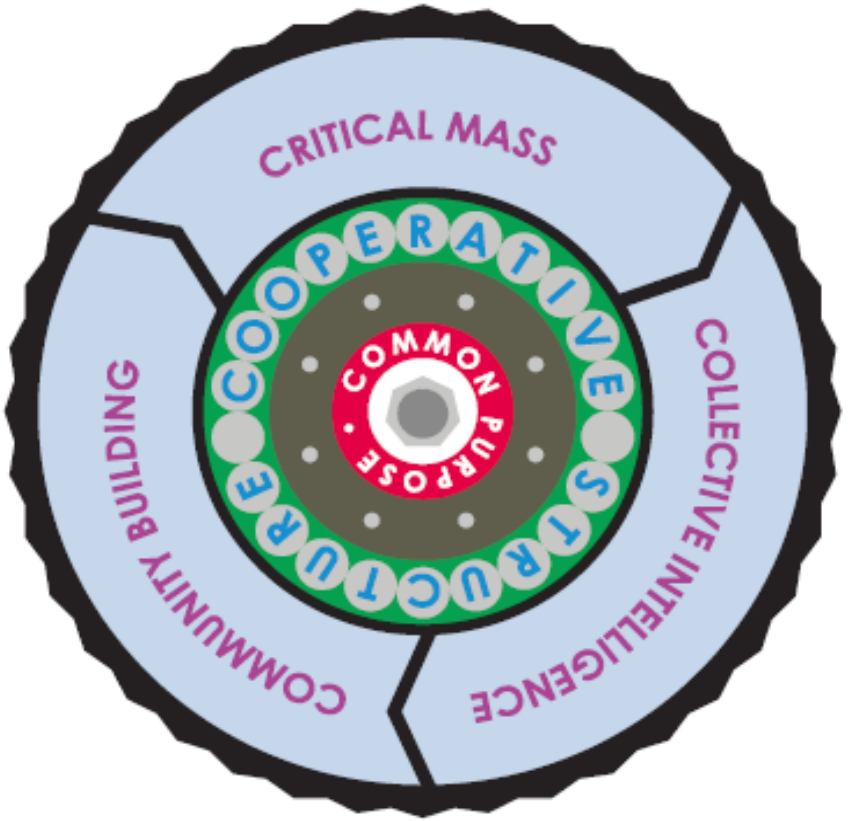
Effective networks for improvement

Developing and managing effective networks to support quality improvement in healthcare

The Health Foundation
Inspiring Improvement

Learning report

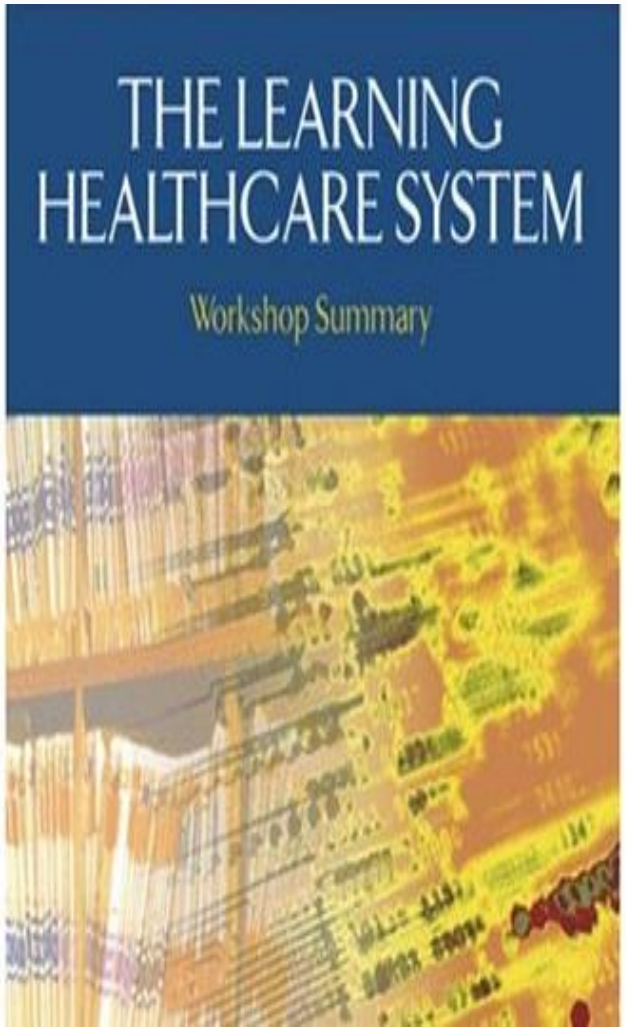
March 2014



http://www.health.org.uk/publications/effective-networks-for-improvement/

Learning Healthcare System

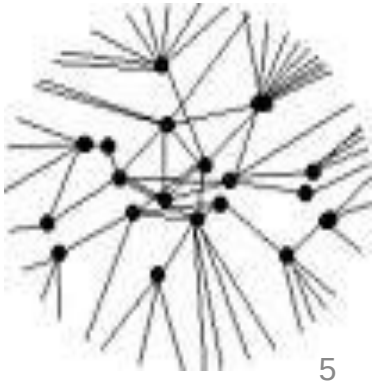
- Patients and providers work together to choose care based on best evidence
- Drive discovery as natural outgrowth of patient care
- Ensure innovation, quality, safety and value
- All in real-time



Components of a network-based Learning Health System*

- Focus on outcome
- Build community
- Effective use of technology
- Learning system

  System science, quality improvement, qualitative research, clinical research



ImproveCareNow is an Example of an Improvement Network

Purpose of ImproveCareNow (ICN):
Transform the health, care and costs for all children and adolescents with Crohn's disease and ulcerative colitis by building a sustainable collaborative chronic care network, enabling patients, families, clinicians and researchers to work together in a learning health care system to accelerate innovation, discovery and the application of new knowledge.

September 2012, first organized in 2005

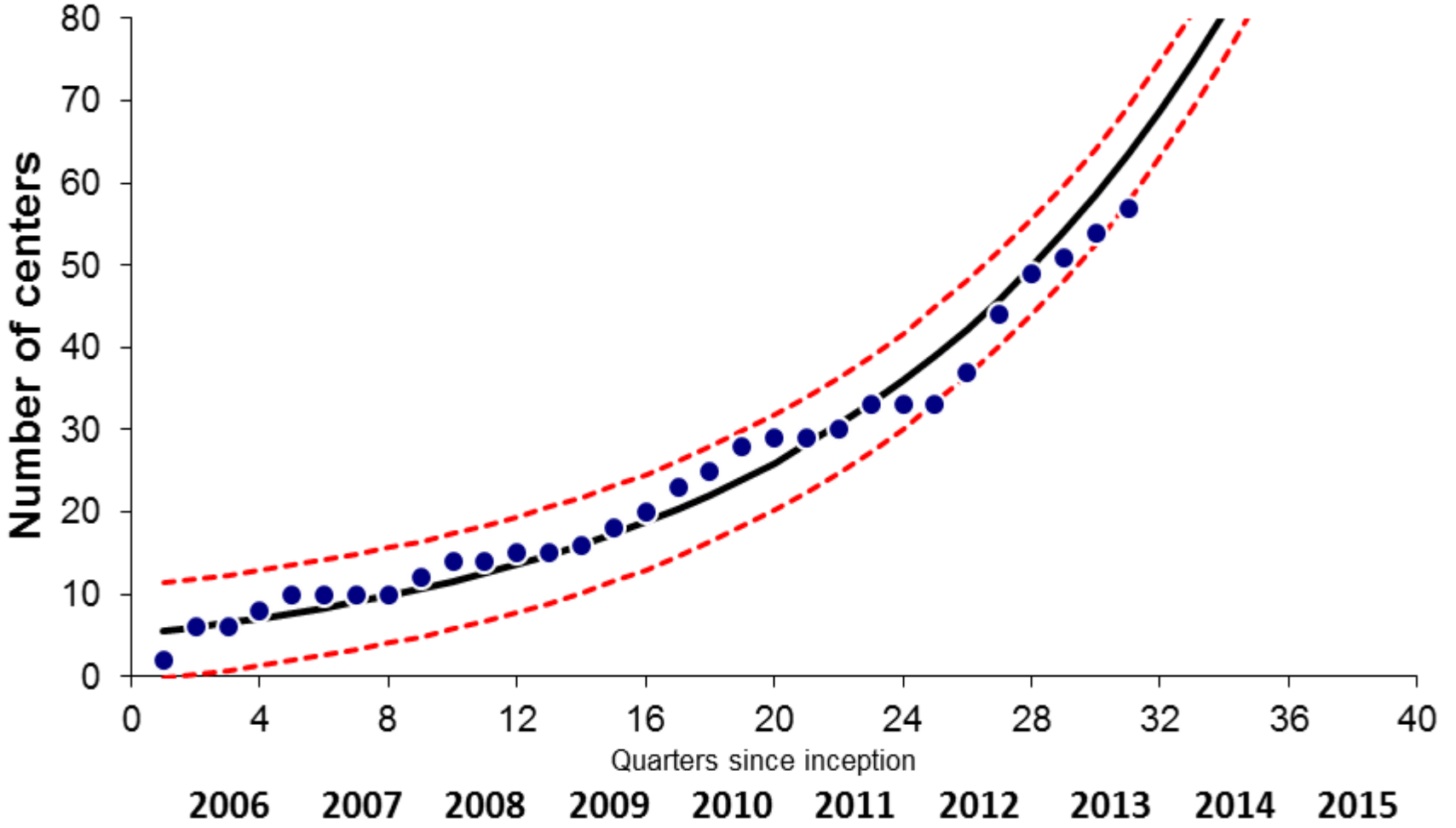
Richard Colletti, MD and Peter Margolis, MD, PhD. Supported by: NIH NIDDK R01DK085719, AHRQ R01HS020024, AHRQ U18HS016957, PCORI PPRN-1306-01754, ImproveCareNow Network Care Centers, CCHMC Learning Networks Program

The ImproveCareNow Story

- ImproveCareNow has **improved care and outcomes** for children **without new medications.**
- **Patients partnered** with researchers and providers **to innovate** within this Learning Health System.
- The network works continuously to **build a community** to motivate and support providers, researchers, and patients.
- Through a quality improvement network, ICN has **changed patients lives.**

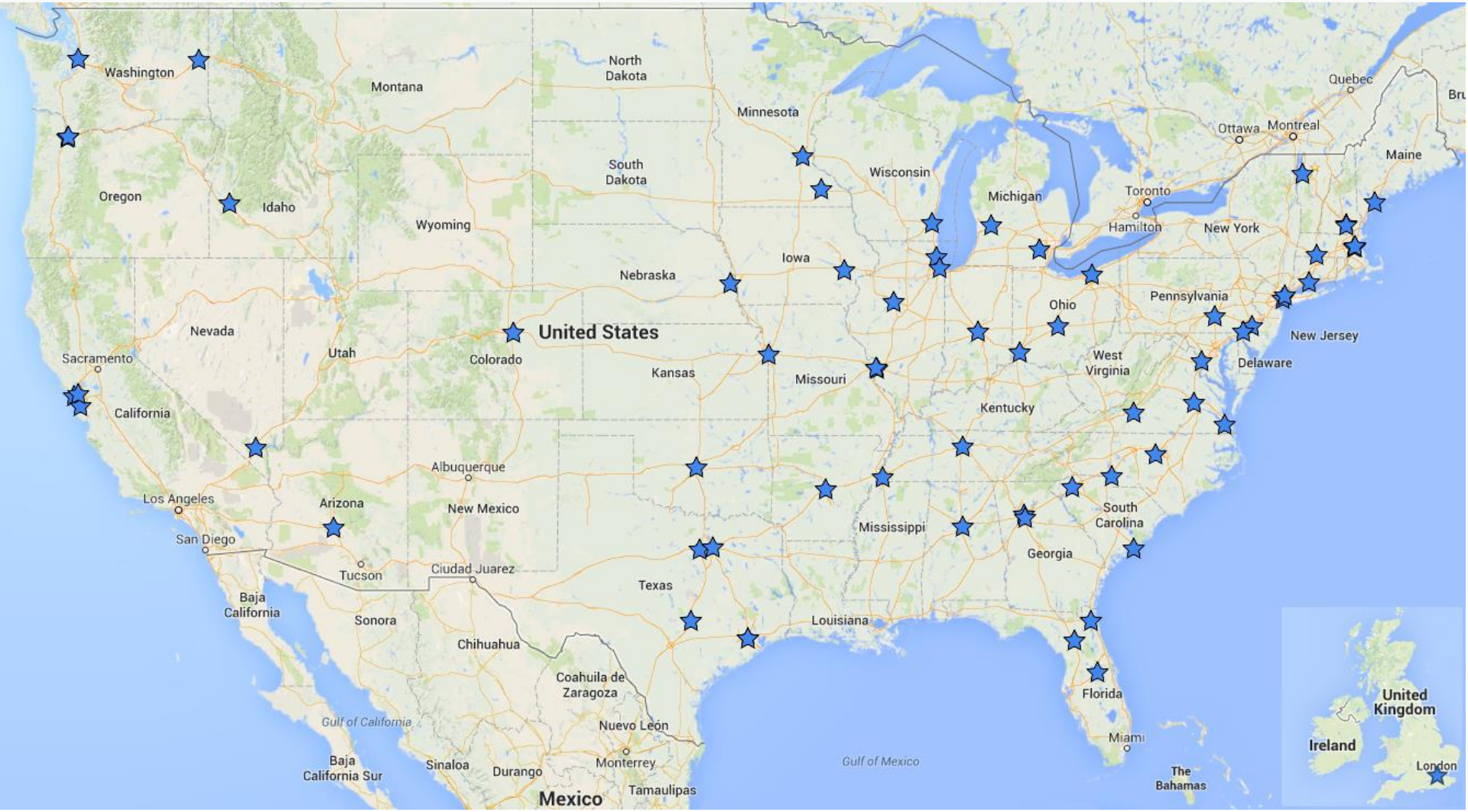
Number of centers in ICN

(Thru the 3rd quarter of 2013)



ImproveCareNow, 2014

Geographic Reach of ImproveCareNow Network, 2014



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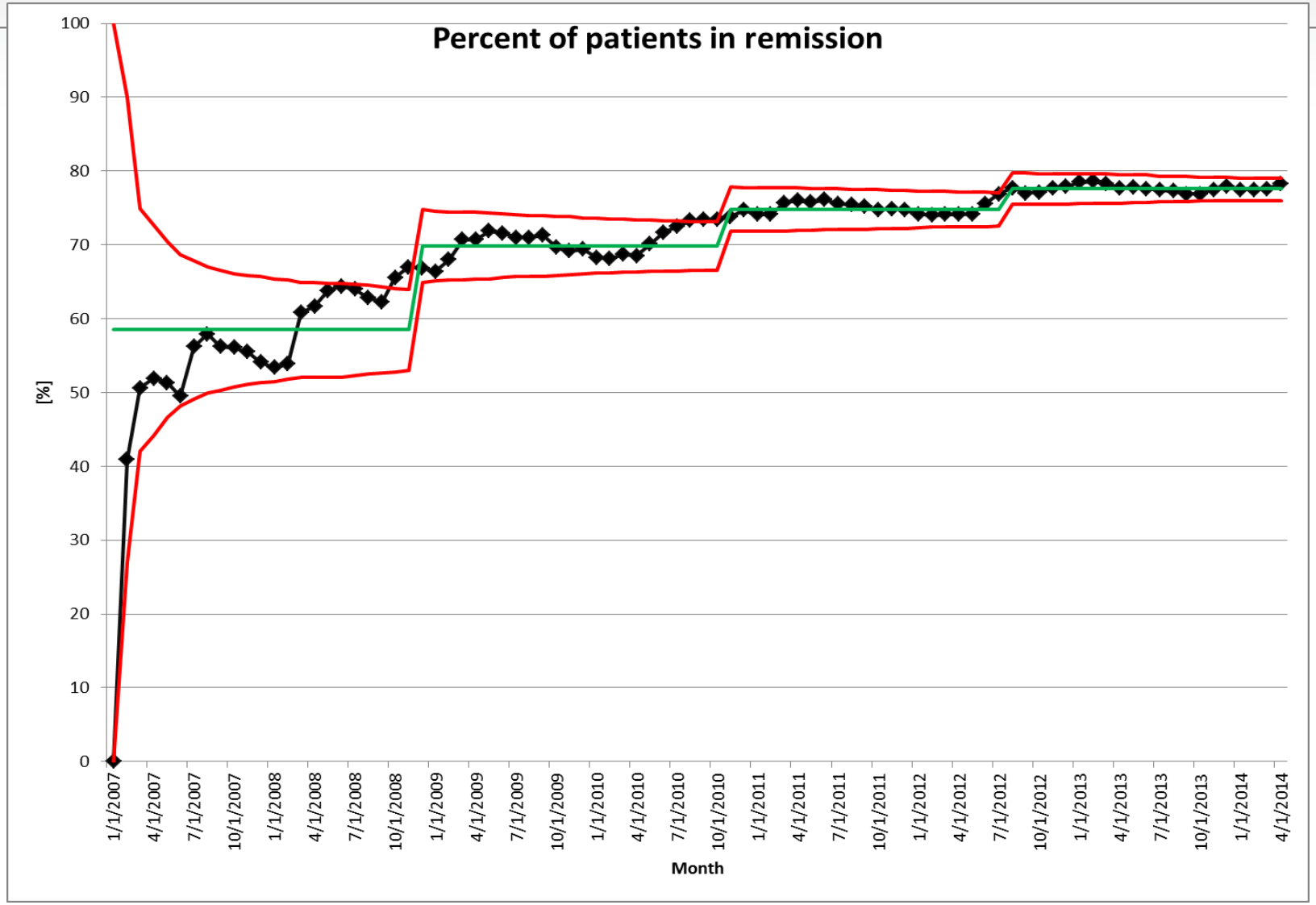
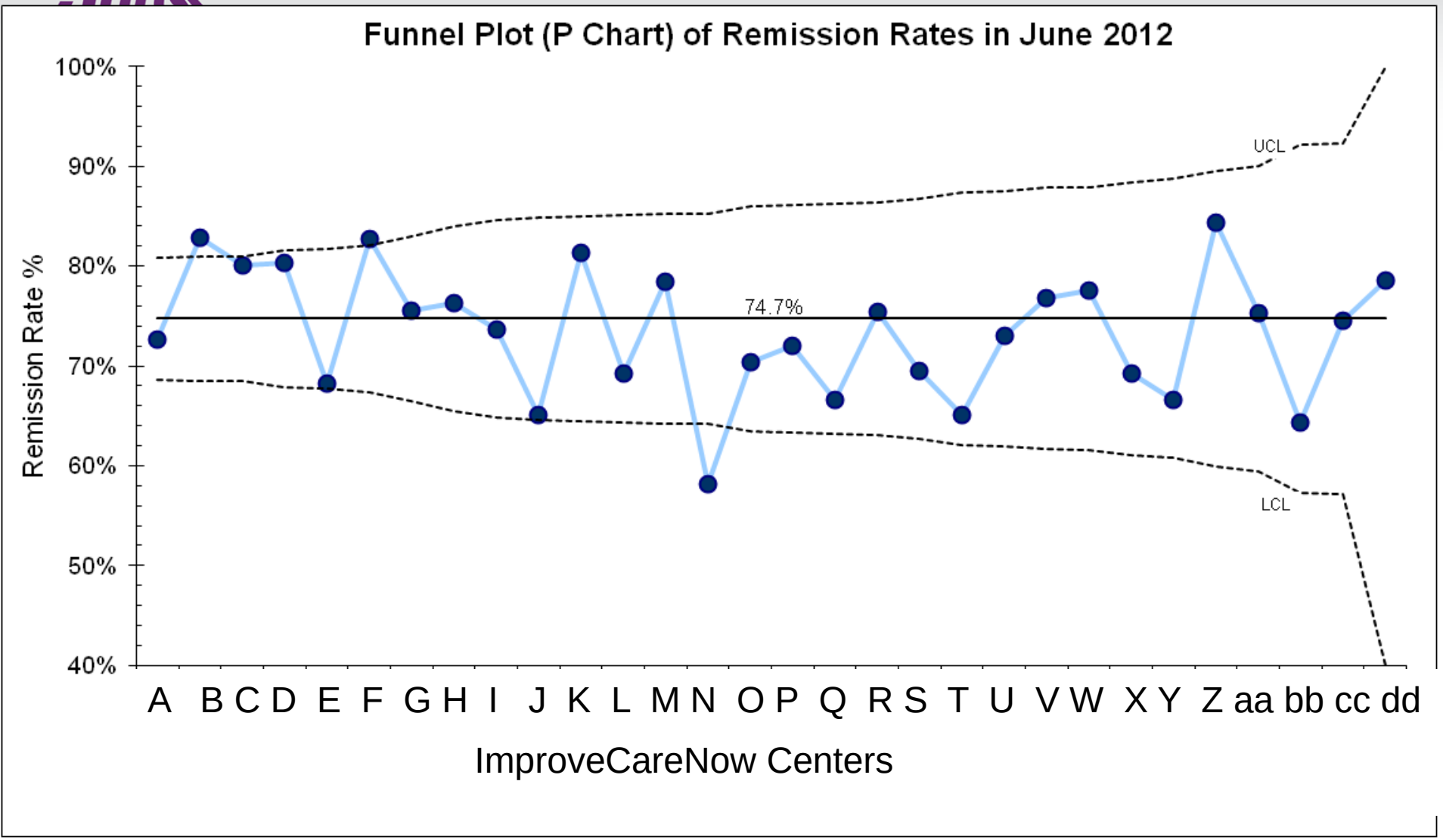
Aggregate Improvement in Outcomes



ImproveCareNow, 2014

Learning from Variation among Centers



ImproveCareNow, 2014

Some ICN Publications

ImproveCareNow: The Development of a Pediatric Inflammatory Bowel Disease Improvement Network

Wallace Crandall, MD,[1] Michael D. Kappelman, MD, MPH,[2] Richard B. Colletti, MD,[3] Ian Leibowitz, MD,[4] John E. Grunow, MD,[5] Sabina Ali, MD,[6] Howard I. Baron, MD,[7] James H. Berman, MD,[8] Brendan Boyle, MD,[1] Stanley Cohen, MD,[9] Fernando del Rosario, MD,[10] Lee A. Denson, MD,[11] Lynn Duffy, MD,[4] Mark J. Integlia, MD,[12] Sandra C. Kim, MD,[2] David Milov, MD,[10] Ashish S. Patel, MD,[13] Bess T. Schoen, MD,[9] Dorota Walkiewicz, MD,[14] and Peter Margolis, MD, PhD[15]

Inflamm Bowel Dis • Volume 17, Number 1, January 2011

Improved Outcomes in a Quality Improvement Collaborative for Pediatric Inflammatory Bowel Disease

Wallace V. Crandall, Peter A. Margolis, Michael D. Kappelman, Eileen C. King, Jesse M. Pratt, Brendan M. Boyle, Lynn F. Duffy, John E. Grunow, Sandra C. Kim, Ian Leibowitz, Bess T. Schoen, Richard B. Colletti and for the ImproveCareNow Collaborative

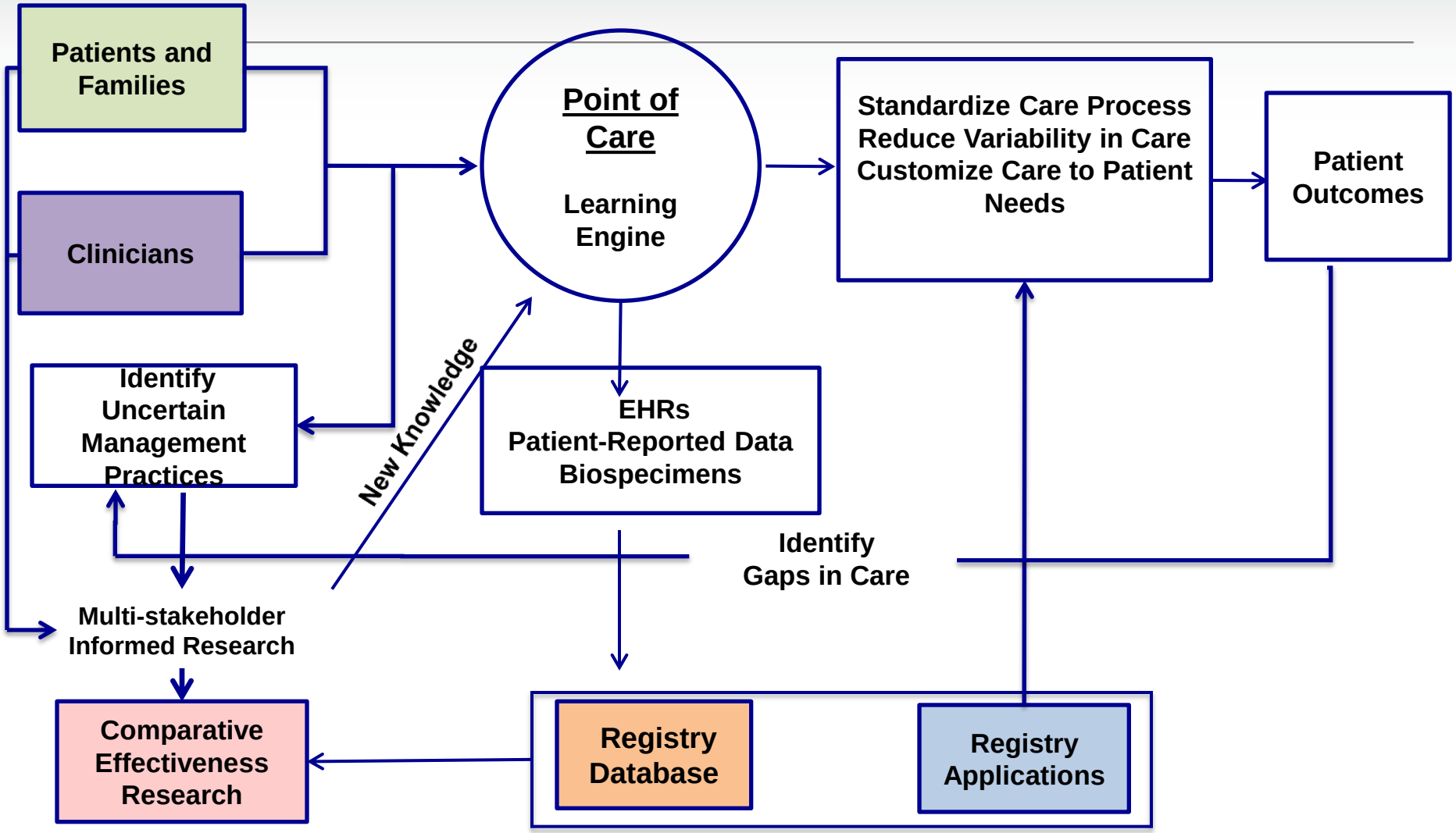
Pediatrics 2012;129;e1030; originally published online March 12, 2012;

Collaborative Chronic Care Networks (C3Ns) to Transform Chronic Illness Care

Peter A. Margolis, Laura E. Peterson and Michael Seid

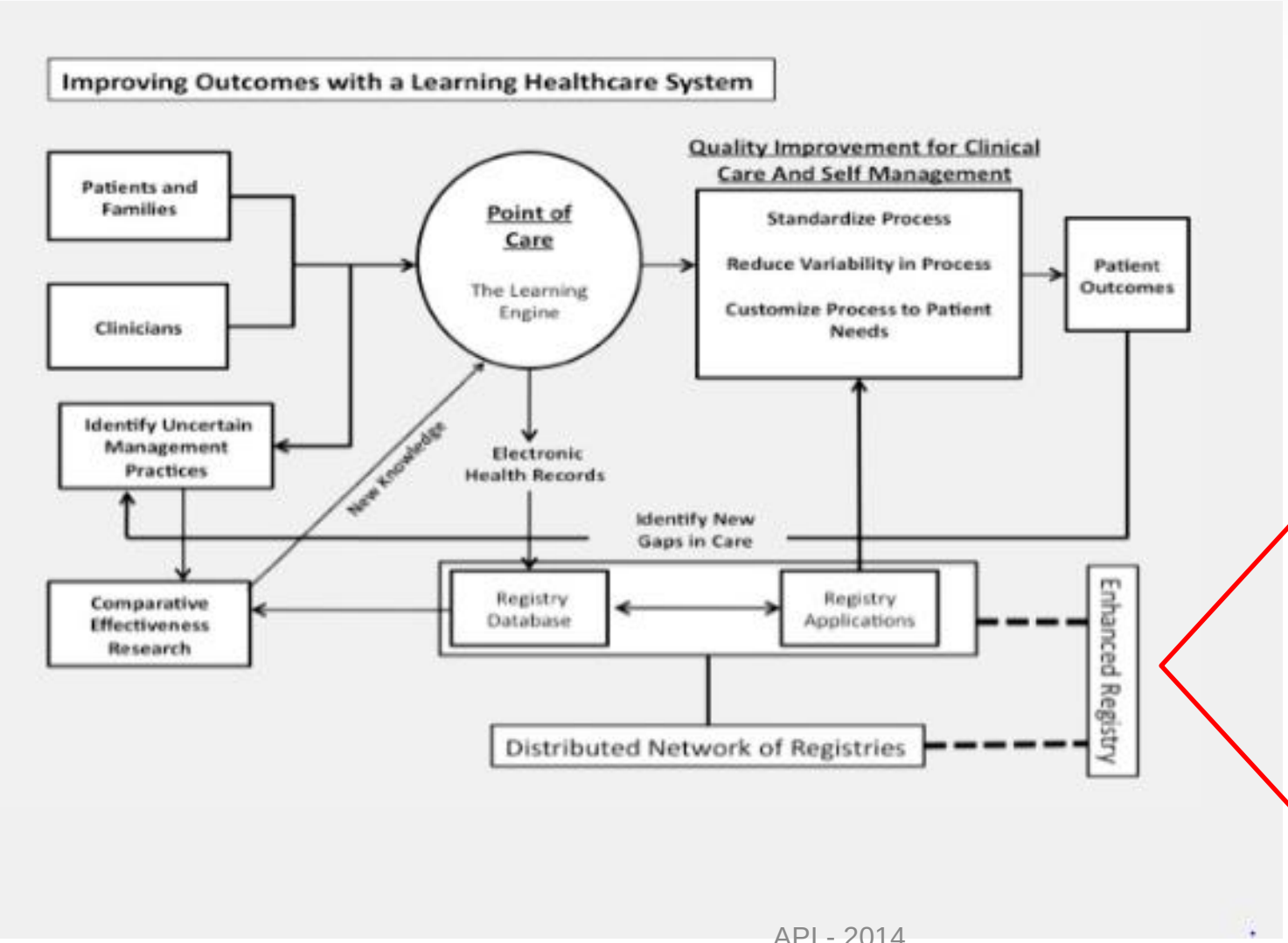
Pediatrics 2013;131;S219
DOI: 10.1542/peds.2012-3786J

Improving Outcomes with a Learning Health System



ImproveCareNow, 2014

The ICN2 Registry
Technology for real-time learning

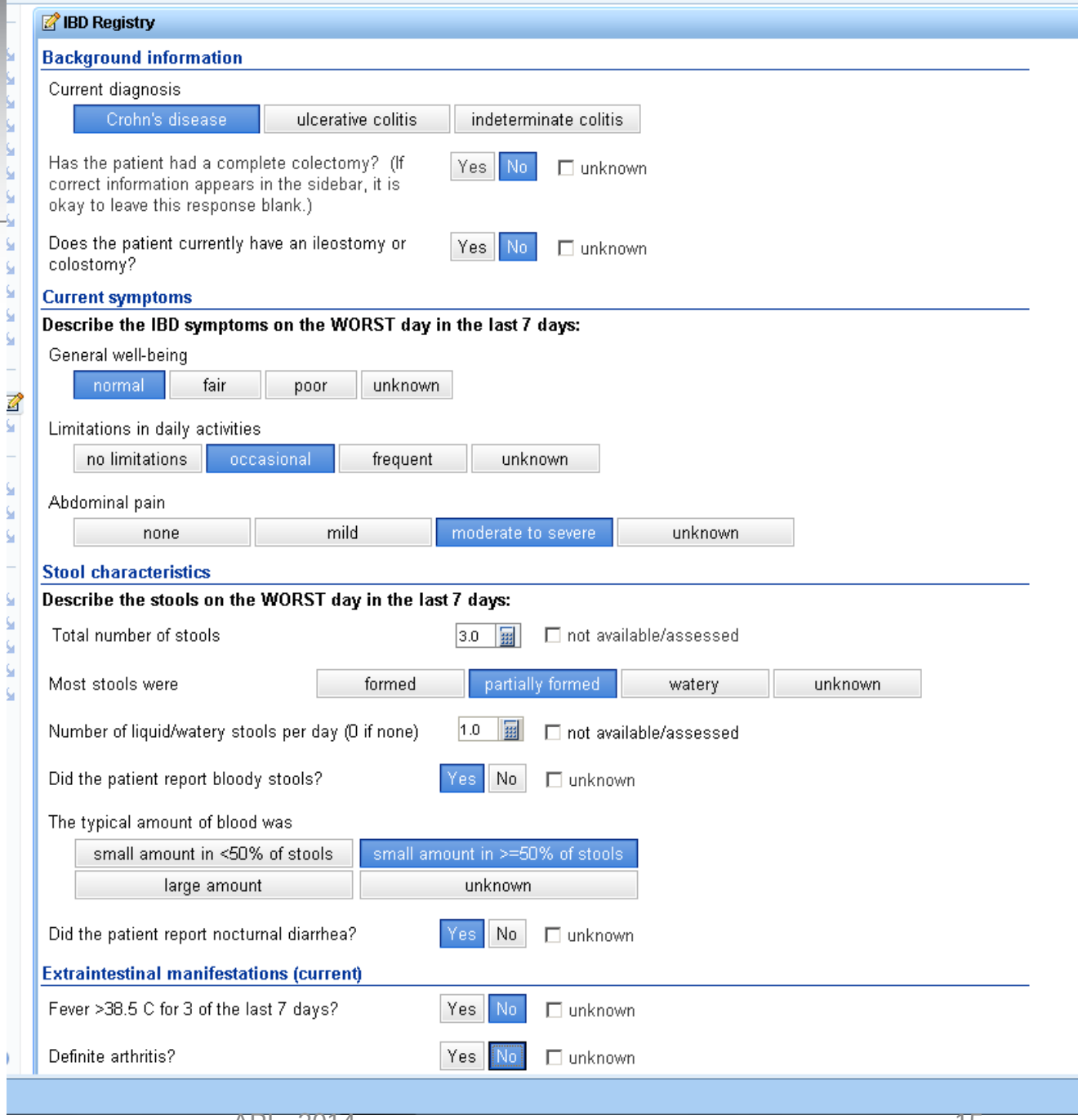


data on 14000 patients and 80000 patient visits. populated by EHR

ImproveCareNow, 2014

The ICN2 Registry

Data are entered in real time or close to real time during the visit and in many centers are being uploaded right from the electronic record. Visit records contain 80 variables describing that patient and their care.



Richard Colletti, M, Keith Marsolo, PhD

Registry: Management of Patient Population

ICN - Population Management Report

<-- Back to ICN Reports

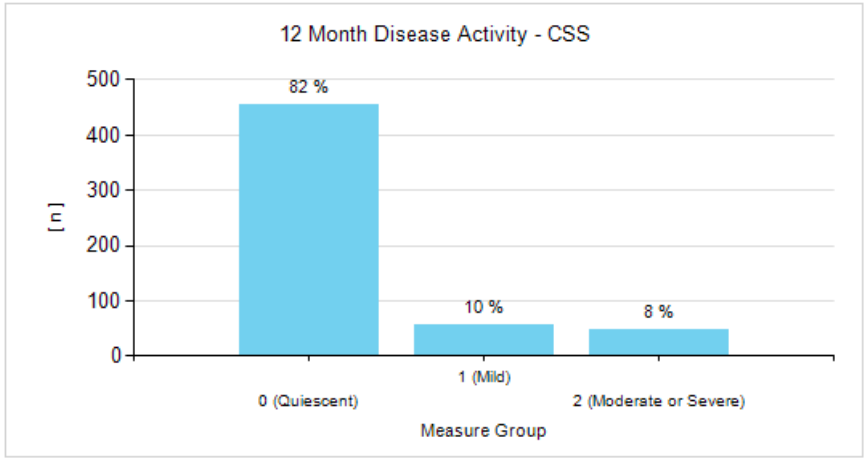
Data as of 11/26/2013

Nationwide Children's Hospital

DX: Crohns Disease,Indeterminate Colitis,Ulcerative Colitis

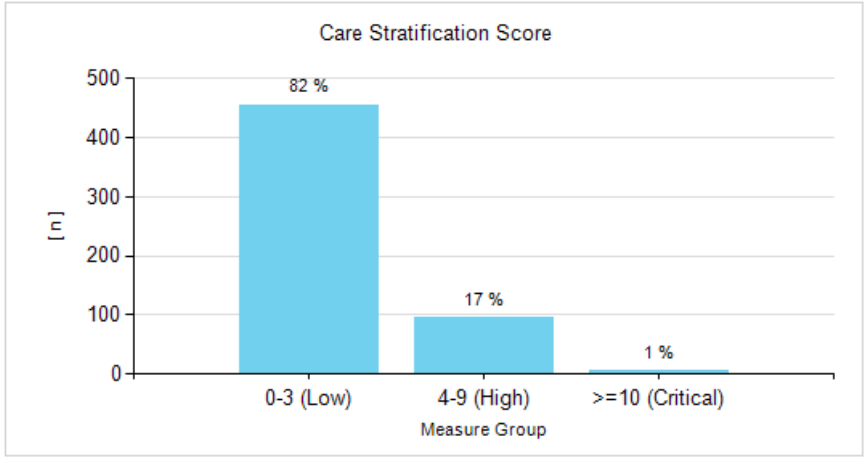
Care Stratification Score

Switch



	12 Month Disease Activity - CSS (n and %)
0 (Quiescent)	454
1 (Mild)	56
2 (Moderate or Severe)	47
Total	**557**

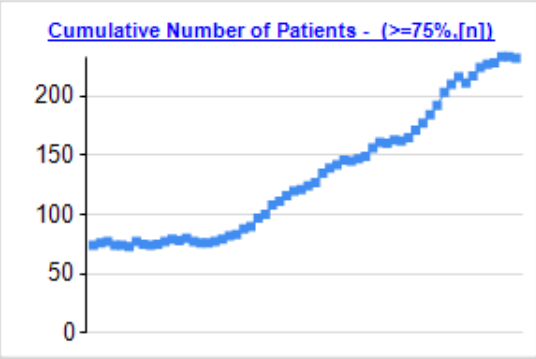
Switch

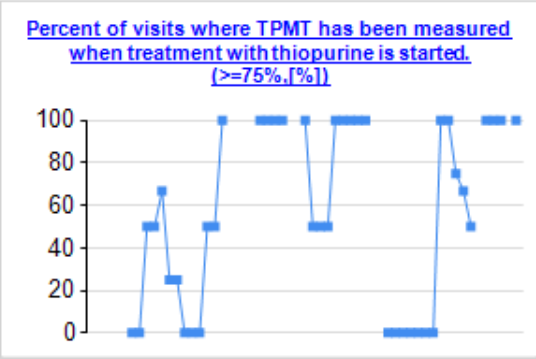


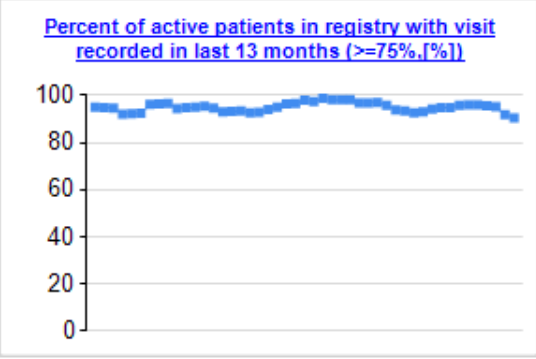
	Care Stratification Score (n and %)
0-3 (Low)	456
4-9 (High)	96
>=10 (Critical)	5
Total	**557**

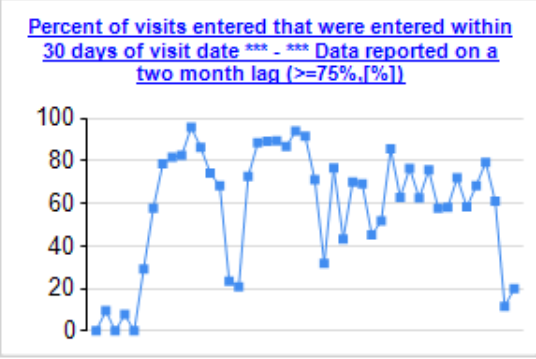
ImproveCareNow, 2014

Learning for Improvement (QI)
Care Center Performance Report









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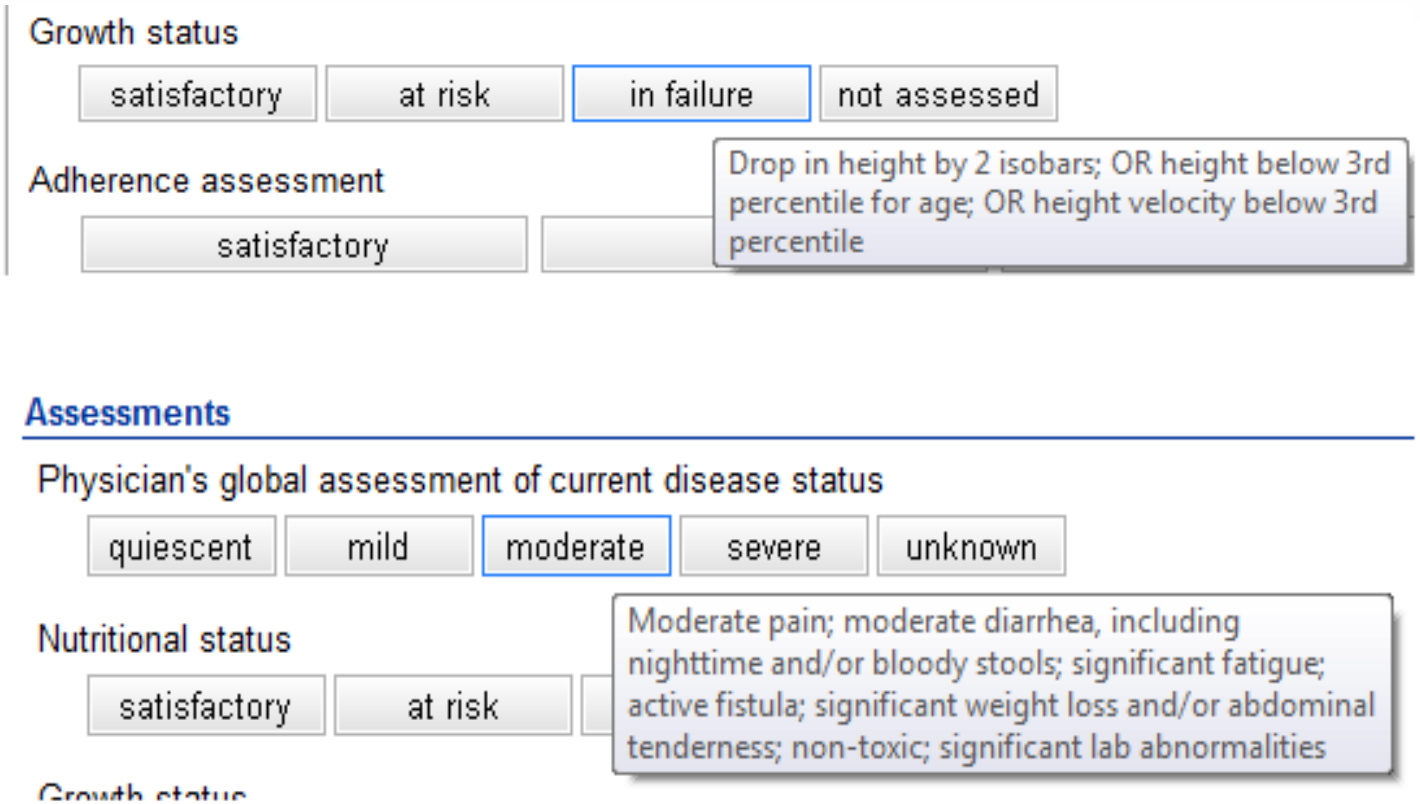
“Research Grade Data”



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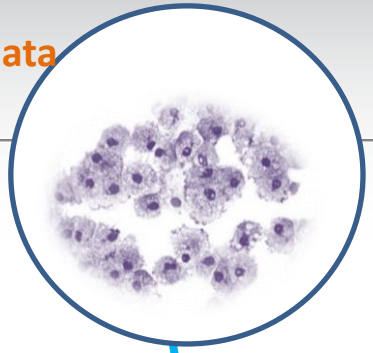
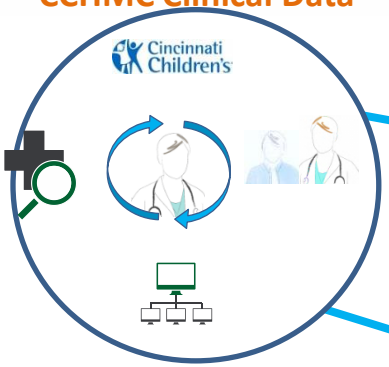
What kind of data does the Learning Health System have on Kyle?

Kyle's Biospecimen Data



Kyle's Other CCHMC Clinical Data



Kyle's Patient Reported Outcomes

Meet Kyle

Kyle is a 15 yo M h/o Crohn's Disease, penetrating phenotype x 5 years currently complaining of severe nausea.

Utilization Data

Registry data From Kyle's GI specialist

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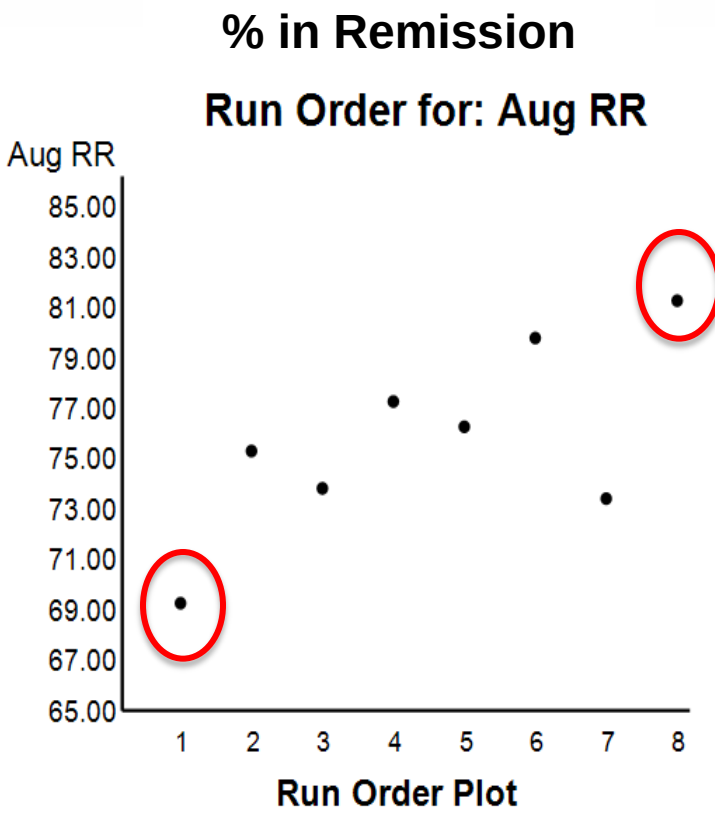
Care Center Level Studies

Treatment Combination	Pre-visit Planning	Population Management	Self-Management Support
Site 1	-	-	-
Site 2	+	-	-
Site 3	-	+	-
Site 4	-	-	+
Site 5	+	-	+
Site 6	-	+	+
Site 7	+	+	-
Site 8	+	+	+



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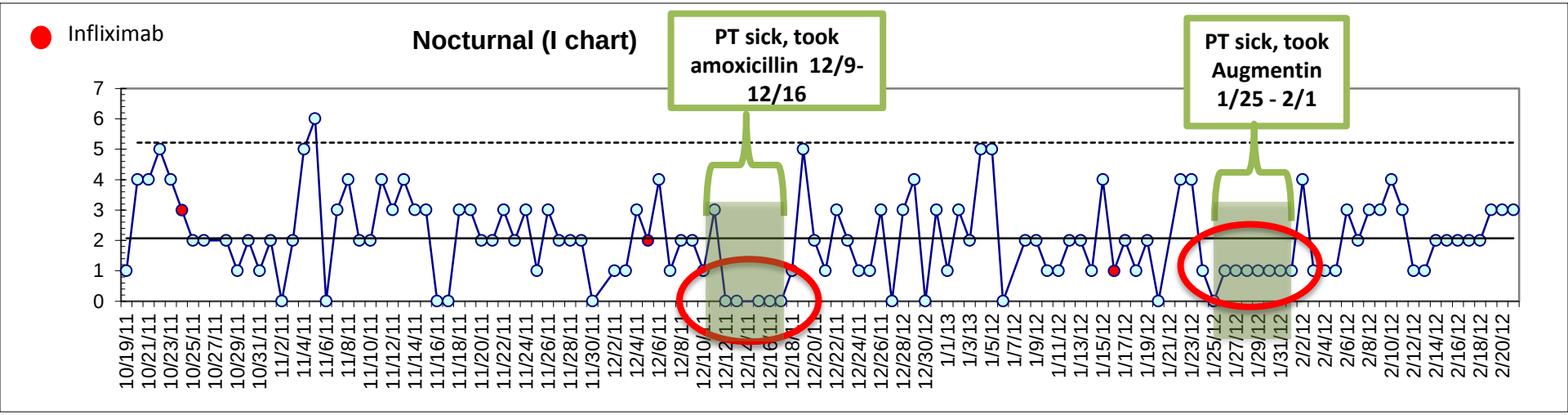
One Research area: Personalized Learning System

19 yr. old with Crohn's colitis
Colectomy with ileo-anal anastomosis (10 yrs)
Chronic diarrhea, nocturnal stools, fatigue, poor quality of life
Current medications: Infliximab & PRN imodium



Heather Kaplan, MD, MPH, Jeremy Adler, MD, MPH, Shehzad Saeed, MD, Ian Eslick, MS, Lloyd Provost, MS, Tom Nolan, PhD, Peter Margolis, MD, PhD

Traditional Research in IBD

The NEW ENGLAND JOURNAL of MEDICINE
N ENGL J MED 362;15 NEJM.ORG APRIL 15, 2010

ORIGINAL ARTICLE

Infliximab, Azathioprine, or Combination Therapy for Crohn's Disease

Jean Frédéric Colombel, M.D., William J. Sandborn, M.D., Walter Reinisch, M.D., Gerassimos J. Mantzaris, M.D., Ph.D., Asher Kornbluth, M.D., Daniel Rachmilewitz, M.D., Simon Lichtiger, M.D., Geert D'Haens, M.D., Ph.D., Robert H. Diamond, M.D., Delma L. Broussard, M.D., Kezhen L. Tang, Ph.D., C. Janneke van der Woude, M.D., Ph.D., and Paul Rutgeerts, M.D., Ph.D., for the SONIC Study Group*

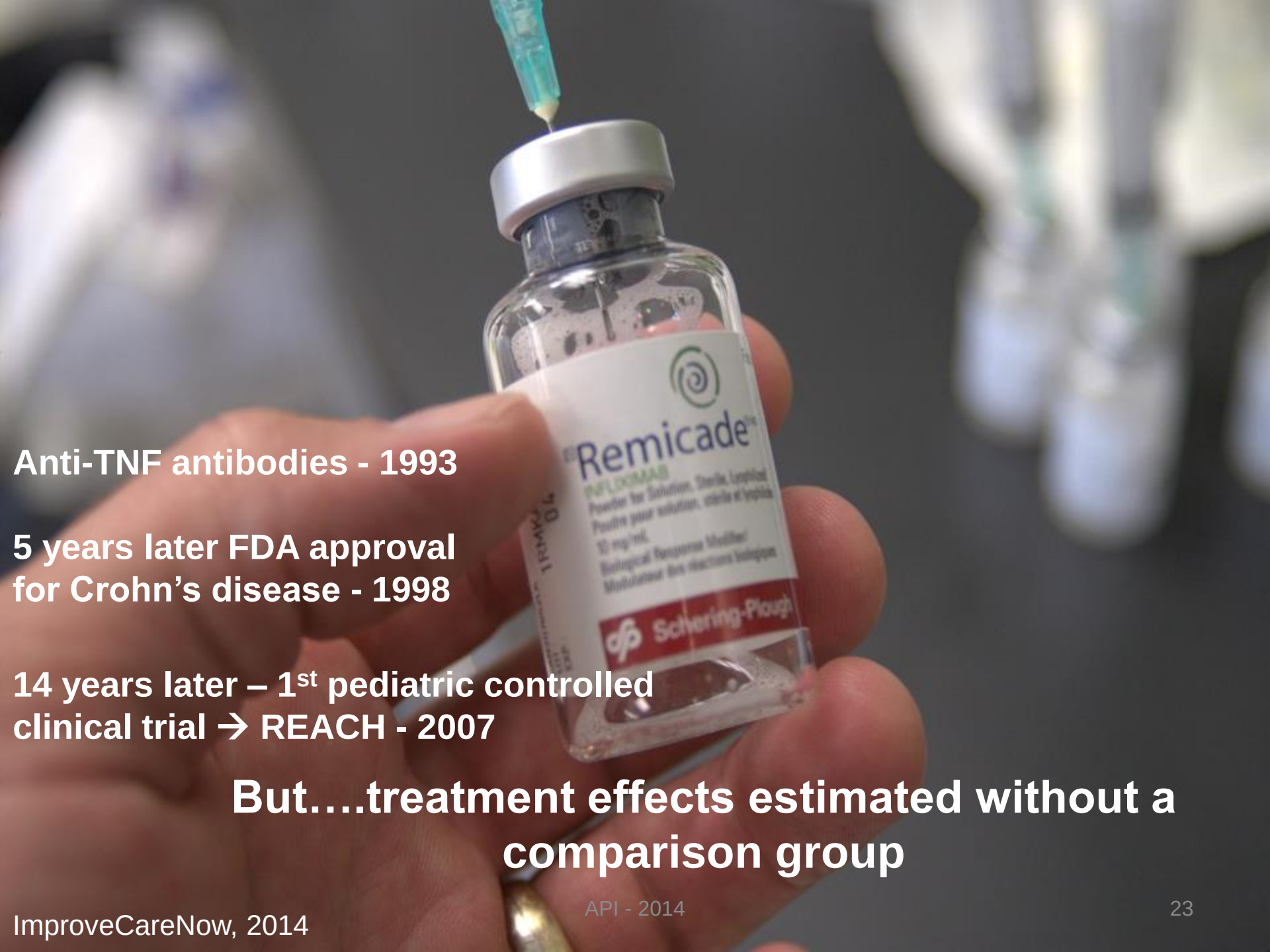
SONIC Study

Methods

In this randomized, double-blind trial, we evaluated the efficacy of infliximab monotherapy, azathioprine monotherapy, and the two drugs combined in 508 adults with moderate-to-severe Crohn's disease who had not undergone previous immunosuppressive or biologic therapy.

CONCLUSIONS

Patients with moderate-to-severe Crohn's disease who were treated with infliximab plus azathioprine or infliximab monotherapy were more likely to have a corticosteroid-free clinical remission than those receiving azathioprine monotherapy. (ClinicalTrials.gov number, NCT00094458.)



Anti-TNF antibodies - 1993

5 years later FDA approval for Crohn's disease - 1998

14 years later – 1st pediatric controlled clinical trial → REACH - 2007

But….treatment effects estimated without a comparison group

ImproveCareNow, 2014

Replicating the SONIC RCT using ICN Registry

PEDIATRICS Volume 134, Number 1, July 2014

Effectiveness of Anti-TNFα for Crohn Disease: Research in a Pediatric Learning Health System

AUTHORS: Christopher B. Forrest, MD, PhD,[a,b] Wallace V. Crandall, MD,[c] L. Charles Bailey, MD, PhD,[a,d] Peixin Zhang, PhD,[a] Marshall M. Joffe, MD, MPH, PhD,[d] Richard B. Colletti, MD,[e] Jeremy Adler, MD,[f] Howard I. Baron, MD,[g] James Berman, MD,[h] Fernando del Rosario, MD,[i] Andrew B. Grossman, MD,[j] Edward J. Hoffenberg, MD,[k] Esther J. Israel, MD,[l] Sandra C. Kim, MD,[c] Jenifer R. Lightdale, MD, MPH,[m] Peter A. Margolis, MD, PhD,[n] Keith Marsolo, PhD,[o,p] Devendra I. Mehta, MD, MS, MRCP,[q] David E. Milov, MD,[r] Ashish S. Patel, MD,[s,t] Jeanne Tung, MD,[u] and Michael D. Kappelman, MD, MPH[v]

WHAT THIS STUDY ADDS: Anti-TNFα therapy administered to children who have Crohn disease in routine practice settings was more effective than usual care at achieving clinical and corticosteroid-free remission. Using data from the ImproveCareNow learning health system for the purpose of observational research is feasible and produces valuable new knowledge.

This study provides evidence that anti- TNFa therapy given to pediatric patients who have moderate to severe CD in real-world settings is effective at achieving remission at rates comparable to single-group, open-label clinical trials, such as REACH,4 with pediatric patients and comparative controlled studies done with adults, such as SONIC.6

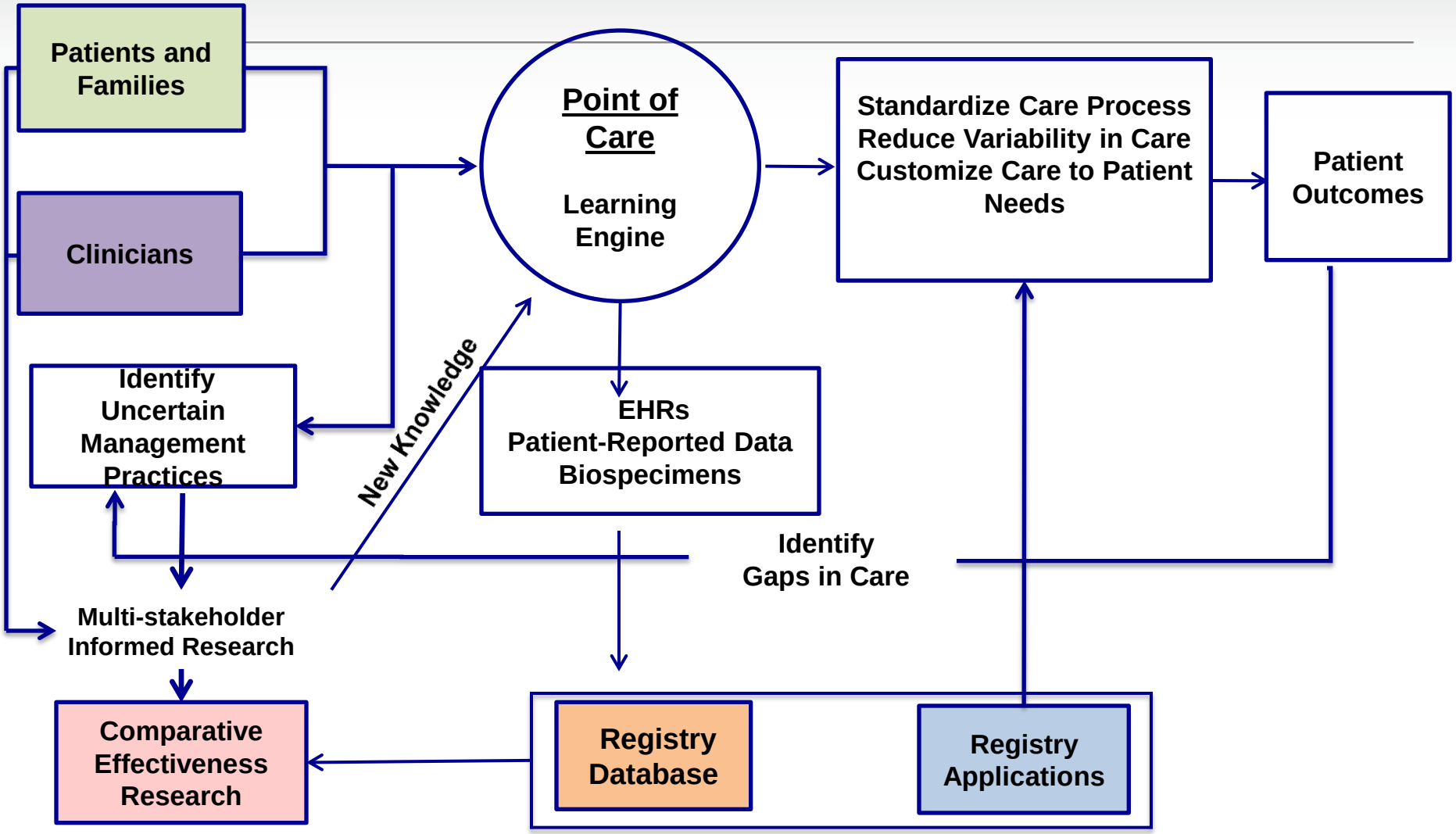
Replicating the SONIC RCT using ICN Registry

Applying REACH selection criteria to the ICN sample yielded an average of 75 initiator trials across the 100 replicates.

The approach we used in this study to examine observational registry data as a sequence of nonrandomized trials is a promising methodology that can be extended to other clinical questions.

The method allows generalization of likely benefits to patients as it avoids overly strict selection criteria that characterize explanatory clinical trials, which test efficacy and are not representative of real-world practice.

Improving Outcomes with a Learning Health System



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