

Making Good on the Promise of EHR for Research: The PCORnet Experience

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Scientific Evidence Underlying the ACC/AHA Clinical Practice Guidelines

Background: The ACC/AHA Clinical Practice Guidelines (CPGs) are developed by the American Heart Association (AHA) and American College of Cardiology (ACC) to provide evidence-based recommendations for the diagnosis and management of cardiovascular disease. The CPGs are developed through a rigorous process of evidence synthesis and expert consensus.

Objective: To provide the scientific evidence underlying the ACC/AHA CPGs and to assess the quality of the evidence used to develop the CPGs.

Data Sources and Study Selection: The CPGs are based on a systematic review of the literature. The search strategy was designed to identify all relevant studies published between 1990 and 2010. The search was conducted in MEDLINE, EMBASE, and Cochrane Database of Systematic Reviews. The search results were screened for relevance and quality.

Lack of high-quality evidence to inform patients, providers, payers, policy makers

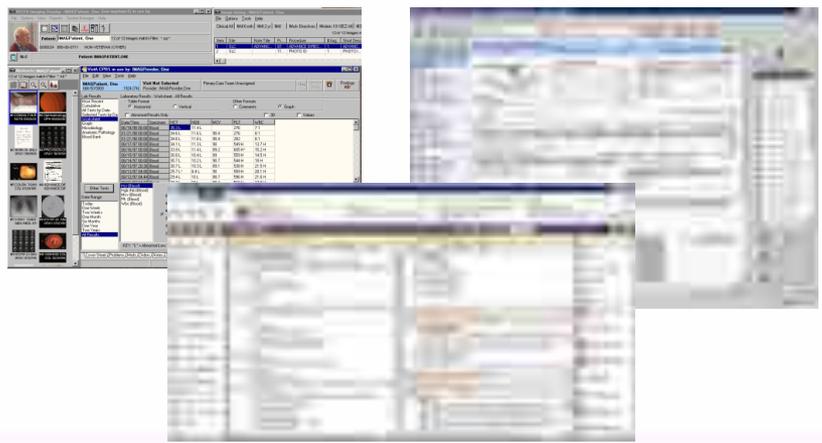
Inefficient clinical research system that favors disposable over reusable



...to a 5-fold increase in adoption of EHR



Hospital EHR adoption has increased more than nine-fold since 2008.



Henry, J., Pylpchuk, Y., Searcy T. & Patel V. (May 2016). Adoption of Electronic Health Record Systems among U.S. Non-Federal Acute Care Hospitals: 2008-2015. ONC Data Brief, no.35. Office of the National Coordinator for Health Information Technology: Washington DC.

Clinical trials have become less efficient...



Monthly Labor Review

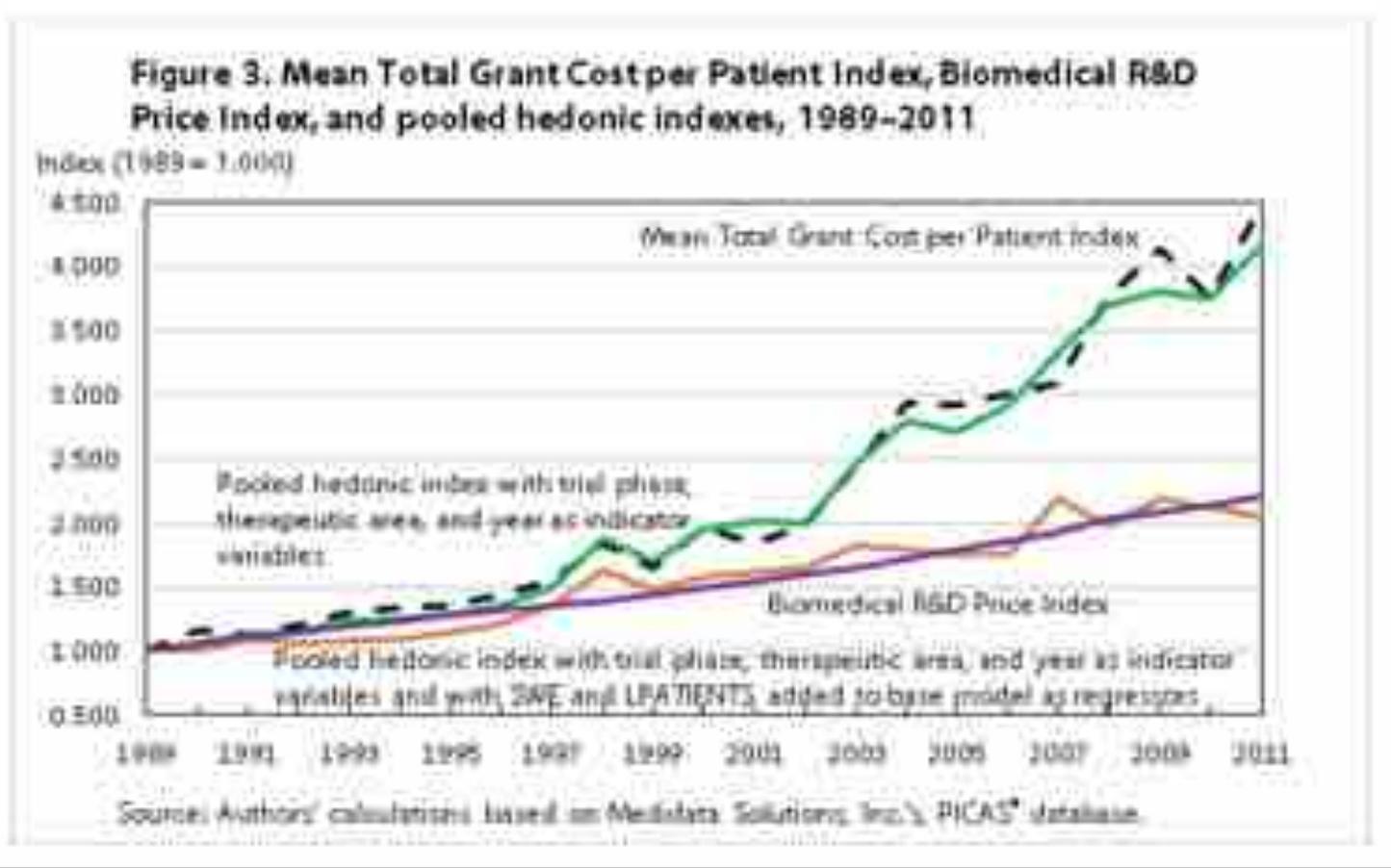
ARTICLE

JUNE 2014

Price indexes for clinical trial research: a feasibility study

A study using a large sample of agreements between sponsors of clinical trials and clinical investigators produces estimated historic price indexes for clinical trial research, an important component of biomedical research and development. Measured as total grant cost per patient, nominal prices grew by a factor of 4.5 between 1989 and 2011, while the U.S. National Institutes of Health Biomedical R&D Price Index, the only published source of information on trends in pricing in the biomedical research-and-development sector, rose only slightly more than twofold. After

...and more expensive.



The EHR isn't a ready-made solution

Standards are not standard

Health care is fragmented

Questionable fit for purpose

Standards are not standard

- 34 different result units for HbA1c

Diabetes and Hemoglobin (HbA1c) original result units?

%	% HIGH	% TL FOR	% HIGH
HMOGLOBIN	% High	% OF TOTAL	PERCENT
H	% High	% of High	Percent
% Hb	% NGSP	% of total	HbA1c
% HCT	% NGSP	% Hb	HbA1c
% AC	% TOTAL Hb	% NGSP	% A1C
HGBL	GDL	mmol/mol	mmol
% A1C	% A1c	% Hb	% Hb
NLL	% Hb		% Hb

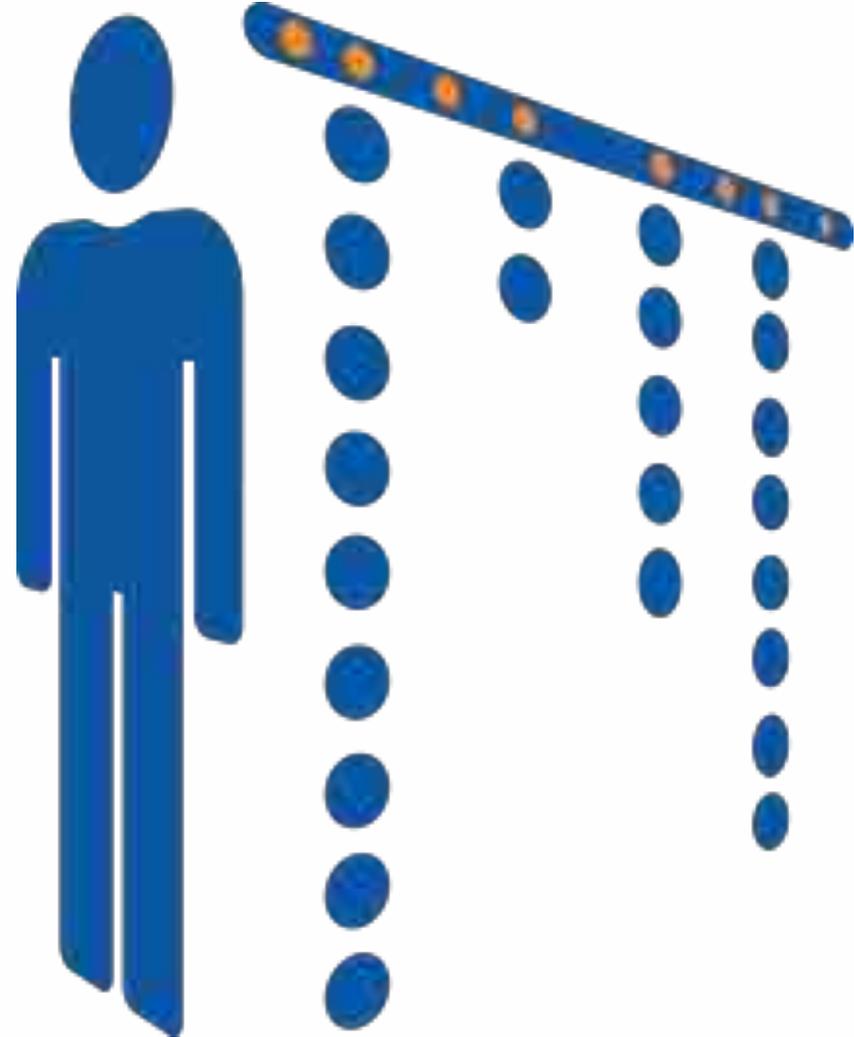
- 68 different result units for platelets

Platelet count original result units?

High	PL	THU	X10 ³
0	KCCMM	THOUMM	1000/L
100W	K/mm	thousand	X10 ³ /ML
CMH	KCC MM	thousand	X10 ³ /ML
CMH	KCCMM	THOUS	X10 ³ /ML
10 ³ /L	K/ML	THOUSCT MM	X10 ³ /L
10 ³ /ML	K/mL	THOUSMCL	X10 ³ /ML
10 ³ /ML	K/L	THOUSL	X10 ³
10 ³ /ML	K/L	THOUSL	X10 ³
10 ³ /ML	K/L	ThousL	X10 ³ /ML
10 ³ /ML	K/MM	THOUS	10 ³
10 ³ /ML	K/mm	THOUSAND	X10 ³ /ml
1000	L3	THOUSANDS	X10 ³ /L
10 ³	PLATELET CO	1	X10 ³
10 ³ /L	PCMM	X 10 ³ /L	K/L
10 ³ /L	PLUMM	X 10 ³ /L	K/L
CLMM	count	X10 ³	X10 ³

Healthcare is fragmented

Data from a single health system will be incomplete



Questionable fit for purpose



Ill-defined source population

Optimized for billing not research

PCORnet unites people, clinicians, and systems into a “community of research”



84 Datamarts
representing 102
health systems
and provider
groups

20
Patient-Powered Research
Networks (**PPRNs**)

+ 13
Clinical Data Research
Networks (**CDRNs**) =

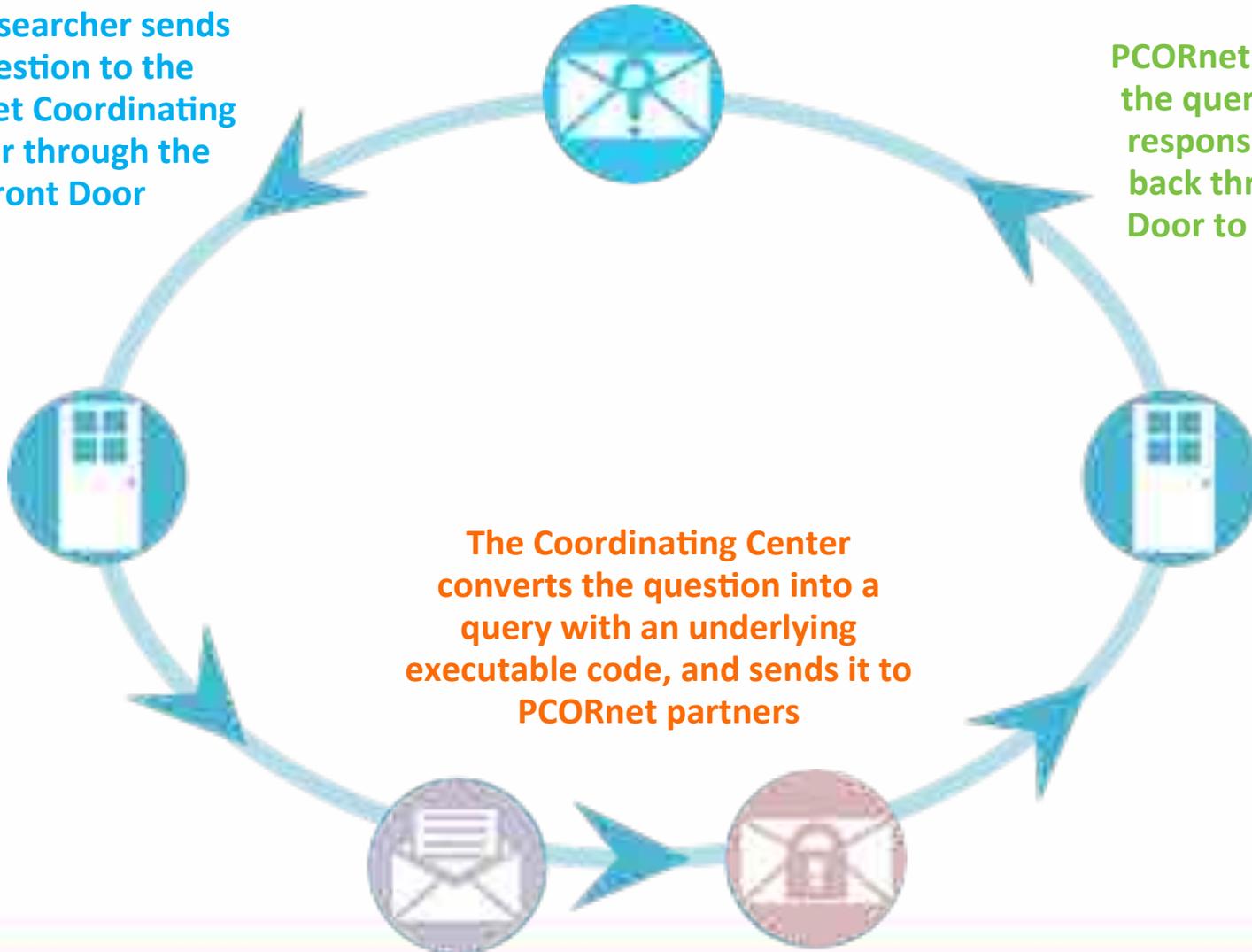
PCORnet
A national infrastructure
for people-centered
clinical research

PCORnet distributed research network

The Researcher sends a question to the PCORnet Coordinating Center through the Front Door

PCORnet partners review the query and provide a response, which is sent back through the Front Door to the Researcher

The Coordinating Center converts the question into a query with an underlying executable code, and sends it to PCORnet partners



Standards are not standard

Common data model with attention to quality

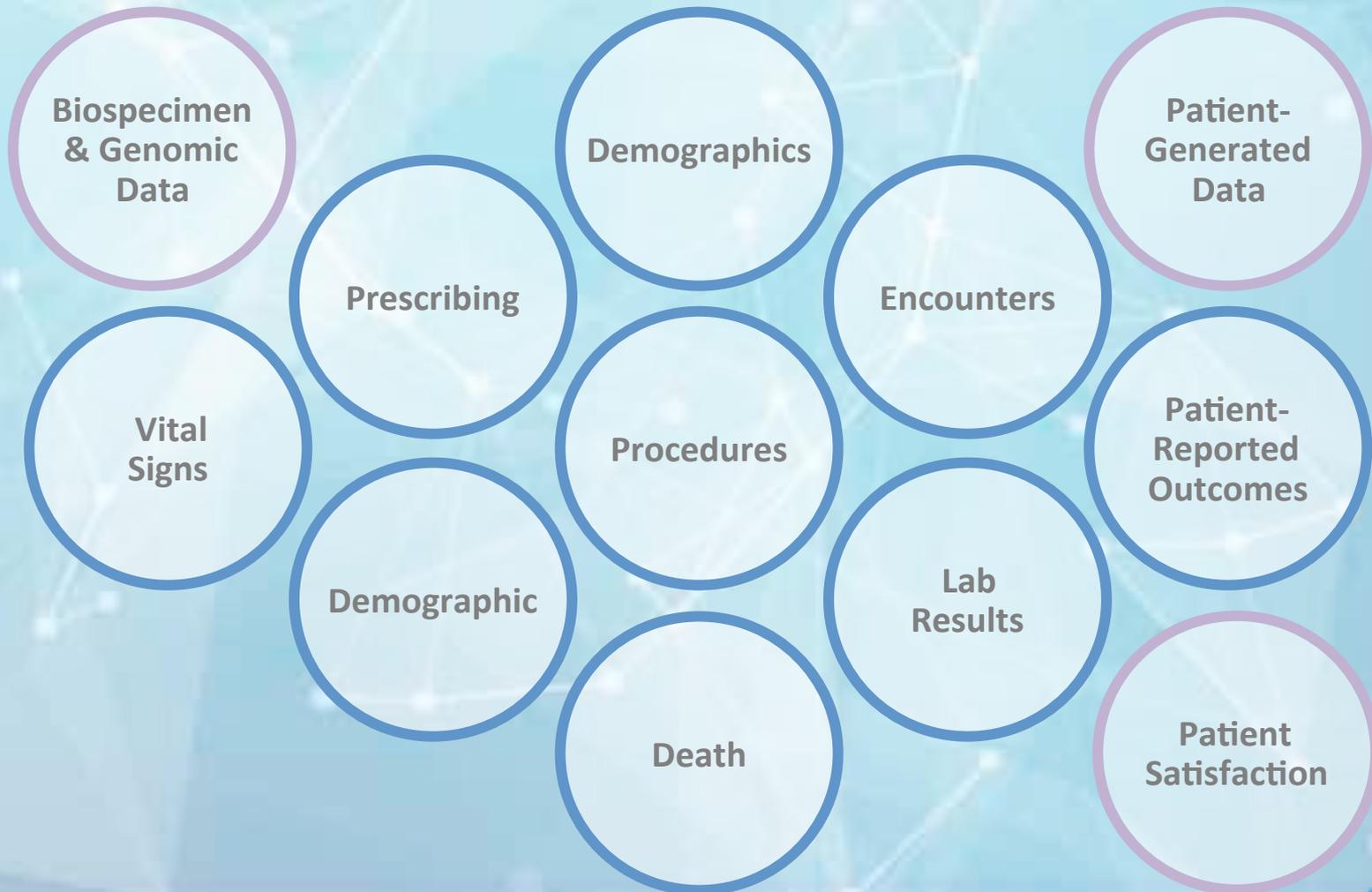
Health care is fragmented

Linkage with payer data

Questionable fit for purpose

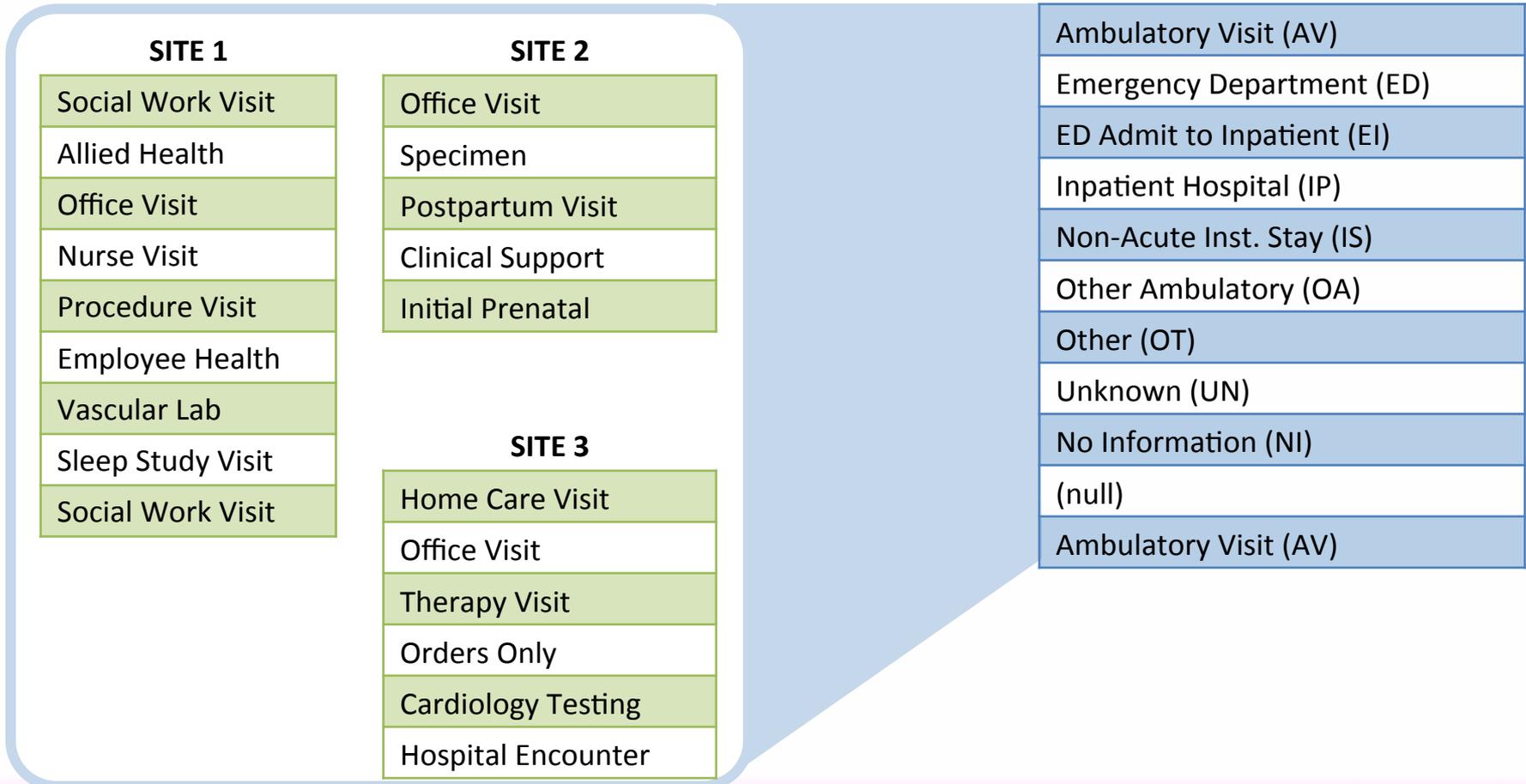
Learn by using

Standardization via a Common Data Model



Standardization via a Common Data Model

Same data are represented differently at different institutions
(e.g., *Type of Encounter*)



Attention to data quality

Data model conformance

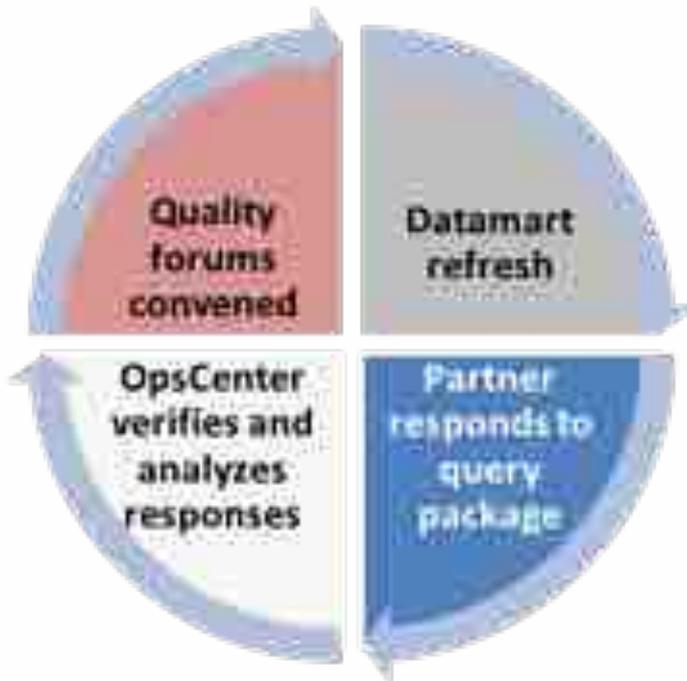
- Required tables are not present or populated
- Orphan patient IDs, encounter IDs
- Required fields have non-allowable values

Data plausibility

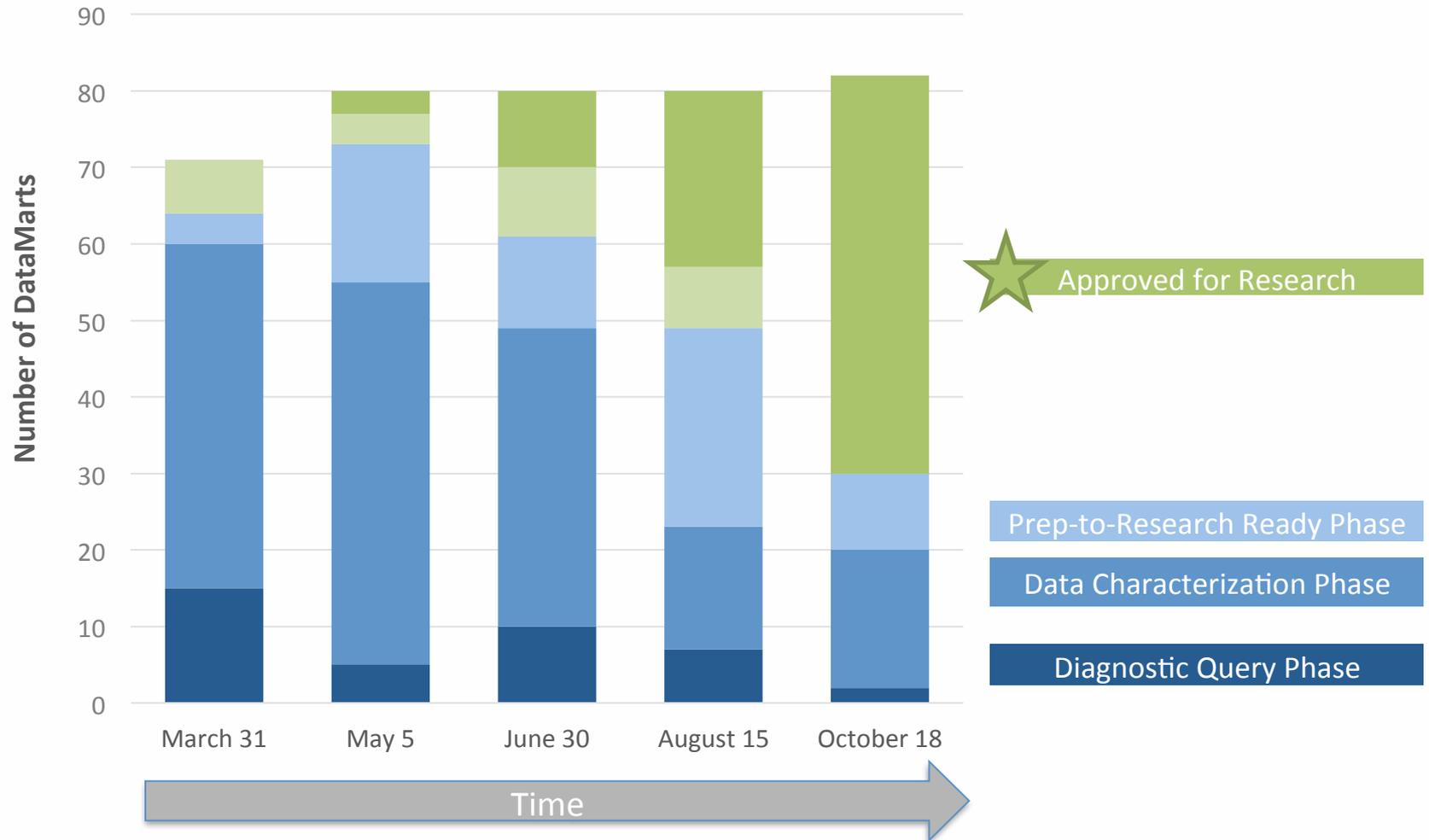
- Future or illogical dates
- Extreme values

Data completeness

- Diagnoses, procedures
- Missing or unknown values for key fields



Progress to date



A (Partial) Snapshot of PCORnet's Data: Query includes responses from 55 DataMarts in August 2016

Demographics	N=41,216,568	Percent	
Age			
0-20	11,361,889	27.6%	
21-44	11,589,633	28.1%	
45-64	10,951,968	26.6%	
65-74	4,156,901	10.1%	
75+	3,156,017	7.7%	
Sex			
Female	23,537,224	57.1%	
Male	17,667,683	42.9%	
Other/Missing	11,661	0.0%	
Race			
Black/African American	4,979,389	12.1%	
White	25,669,541	62.4%	
Other/Missing	10,537,665	25.6%	
Hispanic			
Yes	5,870,400	14.2%	2014 PCORnet Population: Individuals who had a medical encounter in 2014
No	23,357,500	61.5%	
Other/Missing	9,988,694	24.2%	

A Description of PCORnet Data by Conditions as of August 2016

	Respiratory Conditions	Selected malignancies	Myocardial Infarction	Stroke	Rheumatoid Arthritis	Ulcerative Colitis	Hypertension	Renal Disease	Influenza / Pneumonia
	N	N	N	N	N	N	N	N	N
Overall (N)	2,837,803	1,194,158	854,929	420,802	254,803	88,029	5,902,641	1,018,729	889,306
By Age Group									
01-20	897,610	85,884	1,118	15,008	13,169	6,547	57,550	34,164	264,345
21-44	518,969	103,066	13,216	24,103	36,215	26,501	184,777	60,287	143,363
45-64	666,583	433,554	109,787	115,742	101,877	30,822	2,403,695	252,738	168,304
65-74	370,315	354,411	301,606	101,197	58,300	18,902	1,490,122	271,067	83,006
75+	123,773	317,160	128,936	162,628	44,138	6,687	1,336,280	414,360	110,222
By Sex									
Female	1,585,123	611,348	123,253	218,727	132,348	46,130	3,120,007	499,206	448,800
Male	1,252,477	582,721	229,642	201,857	122,422	41,798	2,782,294	518,456	420,376
Other/Missing	180	49	118	14	111	110	318	38	18
By Race									
Black/African American	490,322	134,410	18,182	27,854	27,538	5,567	881,727	163,916	111,892
White	1,679,768	866,780	261,829	189,663	181,490	87,752	3,943,143	676,399	512,428
Other/Missing	667,713	192,962	54,918	68,273	45,770	14,693	1,070,798	178,404	144,988
By Hispanic									
Yes	438,600	98,893	11,688	17,864	28,271	8,325	628,810	109,525	138,825
No	1,643,487	921,715	322,230	277,809	170,566	58,431	3,781,713	627,740	506,441
Other/Missing	713,516	269,443	100,997	105,111	35,897	23,017	1,494,108	281,453	204,938

Linkage to address fragmentation



Trust



Data Use Agreement



Secure Process for
Sharing Identifiers
and Linking Data

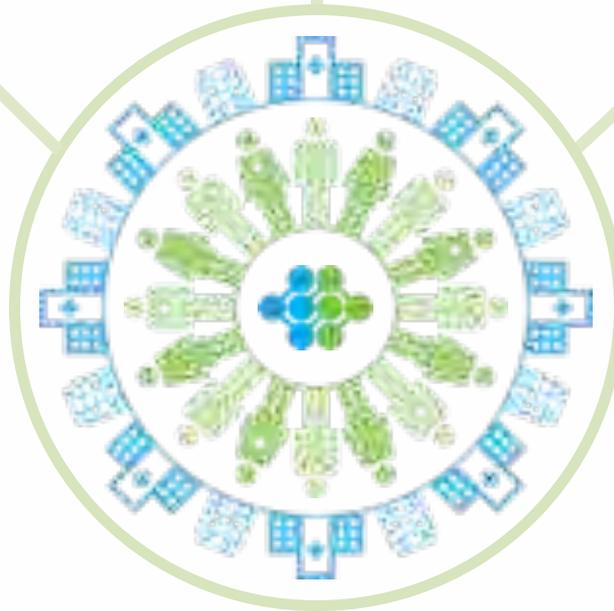


Data in a single
location

And we need them over and over again...

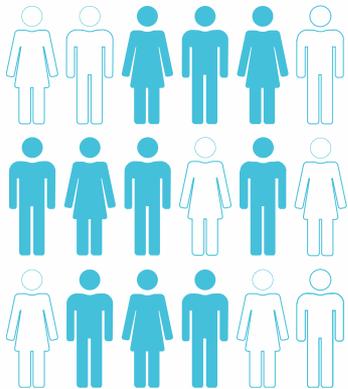


...in a very dynamic environment

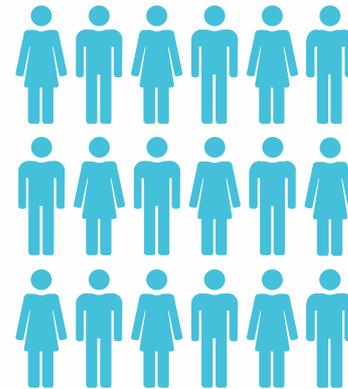


Learn by using...

Interventional studies



Observational studies





- High-dose vs. low-dose aspirin for secondary prevention of death, MI, and stroke.
- 7 CDRNs with planned enrollment of 20,000 participants
- \$850 per participant
- Patients involved in design, conduct, and dissemination
- Confirmatory screening and electronic informed consent via web portal
- Endpoint ascertainment via routine queries of the PCORnet CDM, participant contact via web portal, linkage, and call center.
- ~350 enrolled participants and counting



- High-dose trivalent influenza vaccine vs standard dose quadrivalent vaccine will reduce death and cardiopulmonary hospitalizations in high-risk CV patients
- “One shot deal”
- Randomization to 3-year strategy
- Followed up to 4 times/year
- 9300 participants across 4 networks (PCORnet, VA consortium, Midwest CTSA, Canada consortium)
- Event ascertainment via local study coordinators and EHR



- Assess the impact of antibiotic use in children under 2 on BMI and obesity at 5 and 10 years and growth trajectories to age 5
- 10 CDRNs with planned sample size of 600,000 children
- Parents and clinicians engaged to explore how best to put findings into everyday clinical practice.



- Assess 1-, 3-, and 5-year benefits (changes in weight, rates of remission and relapse of diabetes) and risks (major adverse events) of the 3 most common bariatric procedures
- 10 CDRNs with planned sample off 60,000 bariatric patients; more than 900 adolescents and more than 17,000 patients with diabetes.

Working to Make ~~Making~~ Good
on the Promise of EHR for
Research:
The PCORnet Experience

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