Regenstrief Institute

Better Care. Better Health.

AMIA 2018 Summit in CRI
CRI Year-In-Review

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Disclosures

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- **Corporate:** Signet Accel LLC (Co-Founder), Signet Innovations LLC (Advisor), Lifeomic LLC (Institutional Partnership)

Approach to this presentation

- Mixed approach to article identification:
  - Started with structured approach
    - (akin to ACP “update” sessions)
  - Augment with “what seemed interesting” approach
- Learned a lot from doing this last 7 years
  - Tracked manuscripts throughout the year
  - Intended to spread work out…

    …still worked down to the wire

- So, what was my approach…

Source of Content for Session

- Literature review:
  - Initial search by MESH terms:
    - "Biomedical Research"[Mesh] AND "Informatics"[Mesh] AND "2017/01/01"[PDat] : "2018/02/01"[Pdat]
    - Resulted in **473** articles
    - Limiting to English and Abstracts: **395**
  - Additional articles found via:
    - Recommendations from colleagues
    - Other keyword searches using terms like:
      - Clinical Trials, Clinical Research Informatics, Translational, Data Warehouse, Research Registries, Recruitment, Learning Health System
    - Yielding **435** total, from which **276** were CRI relevant
  - From those, I've selected **~53** representative papers that I'll present here (*briefly*)

Session caveats

- What this is not…
  - A systematic review of the literature
  - An exhaustive review

- What this is…
  - My best attempt at *briefly* covering *some* of the representative CRI literature from the past year
  - A snap-shot of excellent CRI activity over past year+
  - What I thought was particularly notable

Topics

- Grouped **53** articles into several CRI categories (admittedly, not *all* CRI areas)
  - Data Sharing, and Re-Use
  - CRI Methods and Approaches
  - Recruitment and Eligibility
  - Learning Health Systems & Delivery Science
  - PROs, SBDH, and Patient Perspectives
  - Ethics, Policy & Perspectives
- In each category, I'll highlight a few key articles and then given a quick(er) "shout out" to others
- Conclude with notable events from the past year

Apologies up front

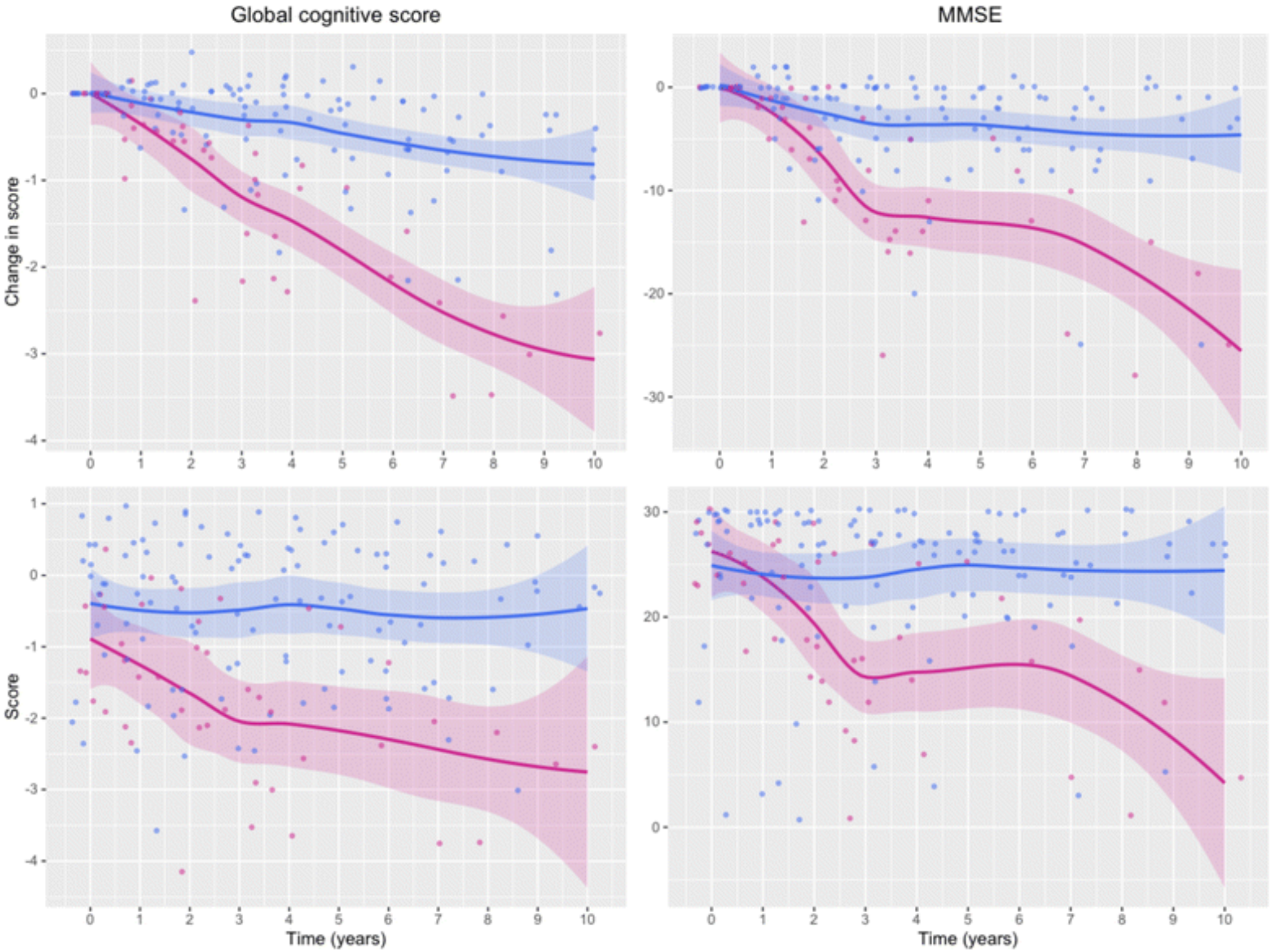
- I’m CERTAIN I’ve missed a lot of great work
- I’m REALLY SORRY about that

Data Sharing and Re-Use for Research

Evidence for benefit of statins to modify cognitive decline and risk in Alzheimer's disease

Geifman, N. et al. Alzheimer's Research & Therapy. 2017

- **Objective:** Statins posited to have role as AD Rx. Investigate possible protective and therapeutic effect of statins in AD through the analysis of datasets of integrated clinical trials, and prospective observational studies.
- **Methods:** Authors had access to unique database of the raw clinical research data from 18 studies from the Alzheimer's Disease Cooperative Study and the Alzheimer's Disease Neuroimaging Initiative conducted from 1993 to 2012.
  - The **integrated dataset** had demographics, cognitive assessments, ApoE genotyping, concomitant medications information and blood test data for a total of **4574 participants, and 25,164 encounters**.
  - With all this raw data, able to synthesize a big **"meta trial"**
- **Results:** Re-analysis of AD patient-level data from **failed** clinical trials suggested by trend that use of simvastatin may slow the progression of cognitive decline, and to a greater extent in ApoE4 homozygotes.


Global cognitive score
MMSE
Change in score
Score
Time (years)
Time (years)

Evidence for benefit of statins to modify cognitive decline and risk in Alzheimer's disease

Geifman, N. et al. Alzheimer's Research & Therapy. 2017

- **Conclusions:** These results indicate that the use of statins may benefit all AD patients with potentially greater therapeutic efficacy in those homozygous for ApoE4.
- **CRI Conclusion:** Combining clinical trial data enabled this study and findings heretofore elusive. Further evidence for need to sort out data sharing issues.

Stakeholders' views on data sharing in multicenter studies

Mazor KM, et al. Journal of Comparative Effectiveness Research. Aug 2017

- **Aim:** Understand stakeholders' views on data sharing in multicenter comparative effectiveness research studies and the value of privacy-protecting methods.
- **Materials & methods:** Semi-structured interviews with five US stakeholder groups.
- **Results:** 11 interviews, involving patients (n = 15), researchers (n = 10), Institutional Review Board and regulatory staff (n = 3), multicenter research governance experts (n = 2) and healthcare system leaders (n = 4).
  - Perceived **benefits and value** of research were strongest influences toward data sharing; **cost and security risks** were primary influences against sharing.
  - Privacy-protecting methods that share summary- level data were acknowledged as being appealing, but there were concerns about increased cost and potential loss of research validity.
- **Conclusion:** Stakeholders were open to data sharing in multicenter studies that offer value and minimize security risks.
- Main figure…

Stakeholders' views on data sharing in multicenter studies

Mazor KM, et al. Journal of Comparative Effectiveness Research. Aug 2017

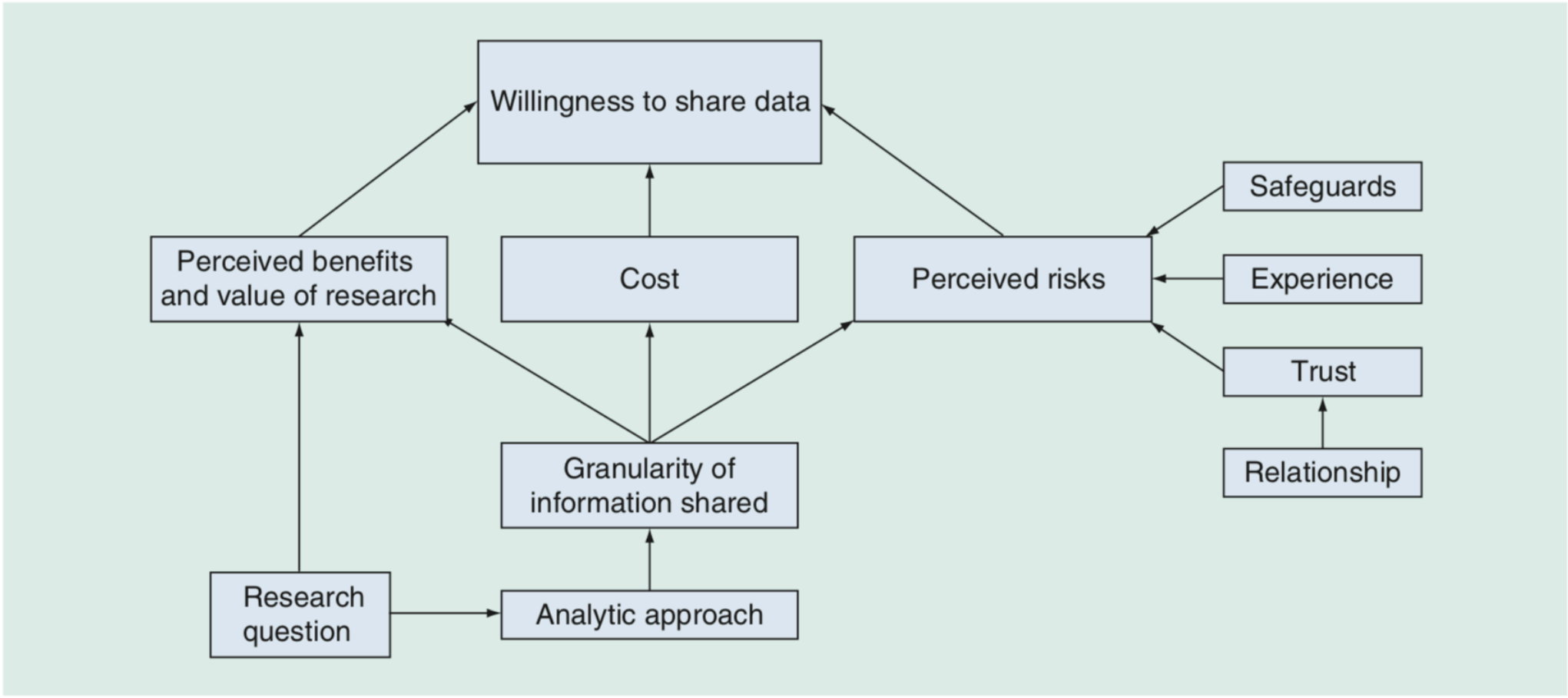


Figure 1. Major themes identified from the stakeholder interviews.

Data Authorship as an Incentive to Data Sharing.
Bierer, BE, et al. NEJM 2017

- *"No longer a hypothetical or occasional occurrence, the use of research data by persons other than those who originally gathered the data, termed "data sharing," is currently encouraged or mandated by parallel efforts in the legislature through the 21st Century Cures Act, biomedical journal leadership through the draft data-sharing policy of the International Committee of Medical Journal Editors, charitable foundations such as the Wellcome Trust and the Bill and Melinda Gates Foundation, and the National Institutes of Health (NIH) in its recent request for information on data management and sharing strategies."*

- "Data sharing" movement creates an obligation for the original investigators to make their curated data and associated metadata available to third parties.

- Despite this growing expectation/requirement, there is rarely academic recognition or reward for data sharing itself.

Data Authorship as an Incentive to Data Sharing.

Bierer, BE, et al. NEJM 2017

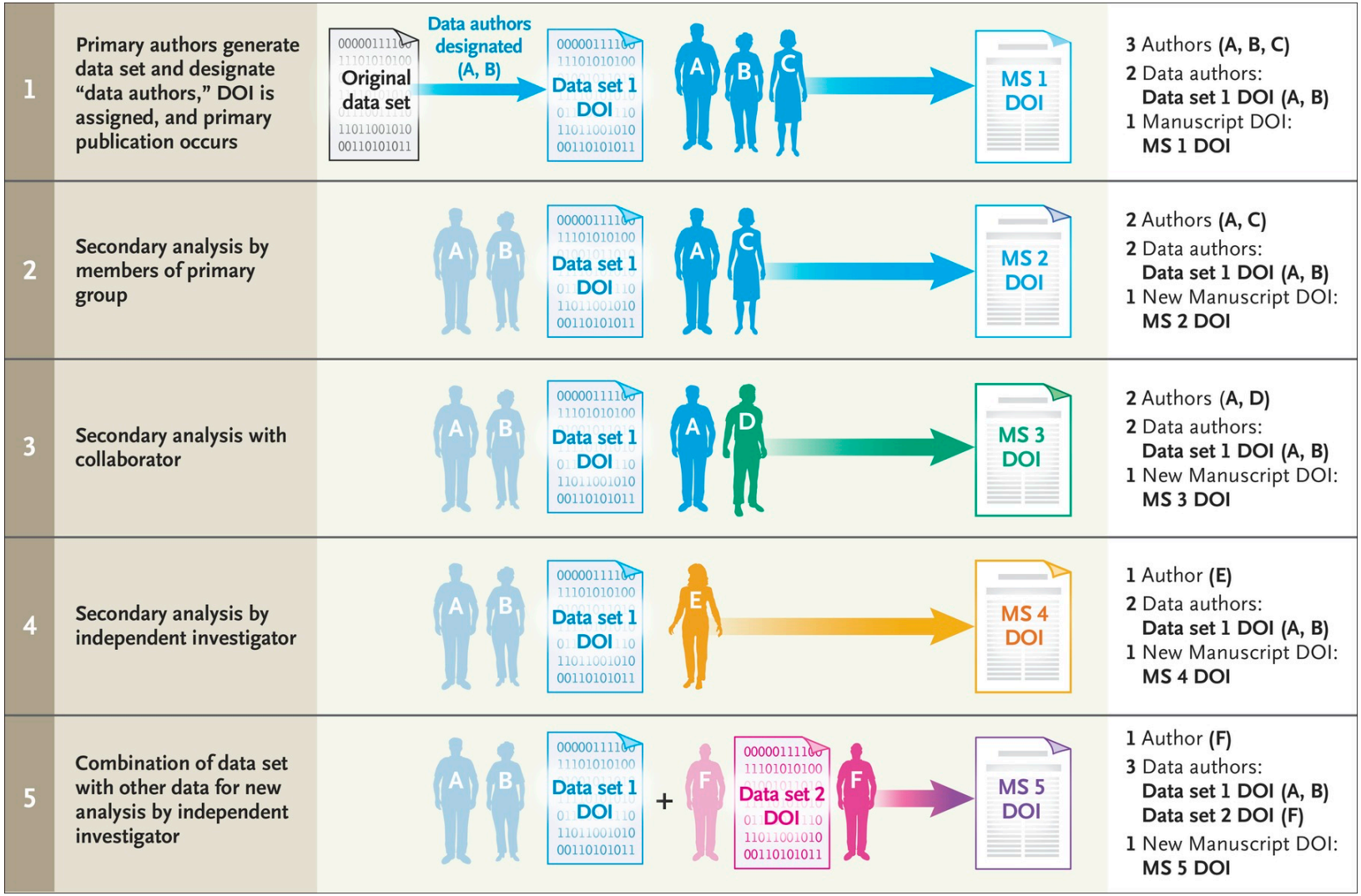


Figure 1. Credit for Data Sharing and Tracing the Data Set. Individual researcher (indicated by letters A through F) may be designated and credited as an author, a data author, or both, depending on contribution to the data & analysis in published work.

Data Authorship as an Incentive to Data Sharing. Bierer, BE, et al. NEJM 2017

- Suggestions: Data authors would need to be listed in the primary publication, on publication in data journals, or with direct citation from data repositories;
  - Cited in Medline as data authors;
  - be searchable in the National Library of Medicine and similar database resources (e.g., bioCADDIE).
  - Reflected on a person's curriculum vitae.
  - Academic institutions modify promotion criteria to recognize contributions
  - Instructions for the academic narrative, e.g. NIH biosketch, modified
  - The development of and methods for a "d-index" metric for data authors, similar to the "h-index" or "i10-Index" for authors,
  - Journal policies, peer review, and editorial practices evolve to include data authorship.
  - Granting agencies and foundations could consider data authorship, as well as contributions to data sharing generally, to be an element of review for further funding;
  - Monitor the subsequent use of data as an additional surrogate for importance, significance, and impact of the original, funded research.

A Data Quality Assessment Guideline for Electronic Health Record Data Reuse.

Weiskopf NG, et al. *eGEMS* 2017

- **Introduction:** Formulation, development, and initial expert review of 3x3 Data Quality Assessment (DQA), a dynamic, evidence-based guideline to enable electronic health record (EHR) data quality assessment and reporting for clinical research.

- **Methods:** Triangulation results from three studies:
  - Review of the literature on EHR data quality assessment,
  - Quantitative study of EHR data completeness, and a set of interviews with clinical researchers.
  - Review by a panel of EHR data quality experts.

- **Results:** Guideline embraces task-dependent nature of data quality and data quality assessment.
  - Three constructs of data quality: **complete, correct, and current** data.
  - Three primary dimensions of EHR data: **patients, variables, and time**.
  - Each of the nine operationalized constructs maps to a methodological recommendation for EHR data quality assessment.
  - Initial expert response to the framework was positive, but improvements are required.

- **Conclusions:** The initial version of 3x3 DQA promises to enable explicit guideline-based best practices for EHR data quality assessment and reporting.
  - Further work for operational use needed, but useful construct for many of us.

A Data Quality Assessment Guideline for Electronic Health Record Data Reuse.

Weiskopf NG, et al. *eGEMS* 2017

	A: COMPLETE	B: CORRECT	C: CURRENT
1: PATIENTS	**1A** There are sufficient data points for each patient.	**1B** The distribution of values is plausible across patients.	**1C** All data were recorded during the timeframe of interest.
2: VARIABLES	**2A** There are sufficient data points for each variable.	**2B** There is concordance between variables.	**2C** Variables were recorded in the desired order.
3: TIME	**3A** There are sufficient data points for each time.	**3B** The progression of data over time is plausible.	**3C** Data were recorded with the desired regularity over time.

Other notable papers in this (Sharing/Reuse) category:

- **Data Sharing from Clinical Trials — A Research Funder's Perspective.** Kiley R, et al. *NEJM* Nov 2017
  - Wellcome Trust, Medical Research Council, Cancer Research UK, Bill and Melinda Gates Foundation describe importance of sharing clinical trial data
- **A Conceptual Framework for Evaluating Data Suitability for Observational Studies. Shang N. et al.** *J Am Med Inform Assoc,* 2017.
  - Contributes a comprehensive framework for assessing the suitability of data for observational studies, even beyond data quality issues.

Other notable papers in this (Sharing/Reuse) category:

- **Association Between Androgen Deprivation Therapy and Risk of Dementia.** Nead KT, et al. *JAMA Oncology* 2017
  - Observational cohort study using 11 million largely unstructured clinical notes and reports, to find an association between use of androgen deprivation therapy and risk of dementia in a cohort of 9272 men. Increased absolute risk of dementia in those on androgen deprivation therapy was 4.4% at 5 years.
- **Observational cohort studies and the challenges of in silico experiments.** Walsh CG, Johnson KB. JAMA oncology. 2017
  - Commentary related to earlier article on androgen deprivation therapy and dementia – hilighting key challenges of secondary use
- **Data Sharing and Cardiology.** Pranammya, D. *Journal of the American College of Cardiology* 2017

Nationwide review of hormonally active adrenal tumors highlights high morbidity in pheochromocytoma

Parikh, PP. et al. Apr 2017. J. Surgical Research

- **Approach:** A retrospective review was performed using the **Nationwide Inpatient Sample** (2006-2011) to identify patients undergoing unilateral adrenalectomy for active tumors.
  - NIS developed as part of the Healthcare Cost and Utilization Project (HCUP) by AHRQ
- **Findings:** Patients with pheochromocytoma have high rates of preoperative comorbidities, postoperative cardiopulmonary complications, and longer and more costly stays
- **CRI Conclusion:** Rare disease research increasingly enabled by re-use of datasets, like those in HCUP family
- **My Conclusion:** I'm just a mild-mannered scientist again

CRI Methods and Approaches

A longitudinal analysis of data quality in a large pediatric data research network. Khare R, et al. JAMIA 2017

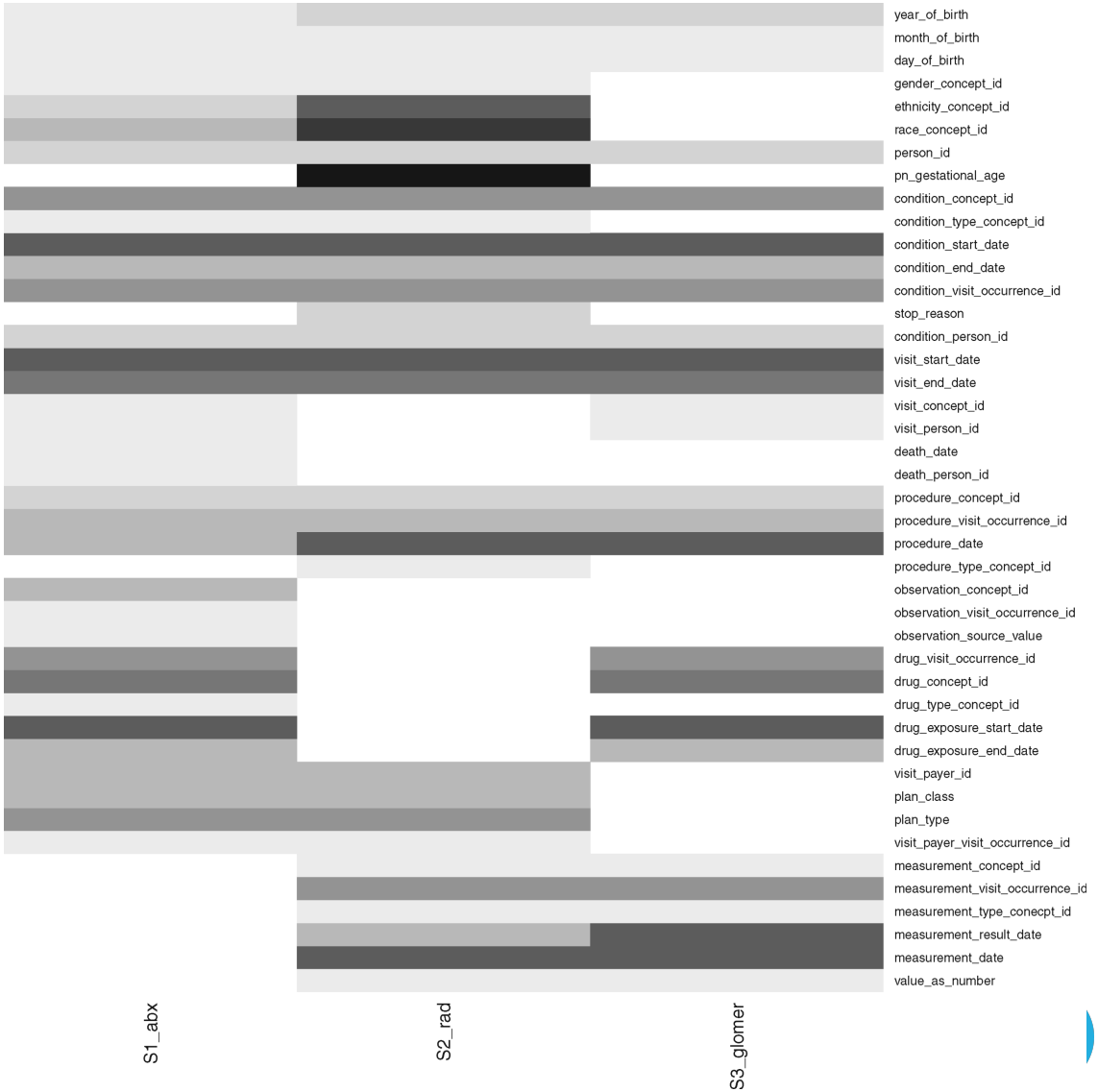
- **Objective:** Analysis of PCORI CDRN "PEDSnet" over initial 18-month startup, across 8 hospitals, to identify data quality issues.
- This study: empirical experience of studying data quality results over the course of building the digital infrastructure of PEDSnet.
- The data quality analyses report and interpret a range of data quality "issues," where an issue is an indication that the data could be inaccurate or difficult to use for some research purposes.

A longitudinal analysis of data quality in a large pediatric data research network. Khare R, et al. JAMIA 2017

- Typically we focused on 2 major causes of data issues: **systematic data errors** caused by programming errors, and **random data errors** (eg, inaccurate data transcription or typing errors).
- This work resulted in more granular causes (**10 precise causes**), motivated by real-world scenarios.
- To evaluate further, assessed quality against 3 scientific studies, created a "**heat-map**" of data quality issues across those studies…

A longitudinal analysis of data quality in a large pediatric data research network. Khare R, et al. JAMIA 2017

- **Figure 6.** Mapping of data quality to 3 scientific studies; lighter shades denote higher quality, white are data elements not relevant to that study.



A longitudinal analysis of data quality in a large pediatric data research network. Khare R, et al. JAMIA 2017

- Over time, trend of decreasing ETL (or fixable) issues, even with steadily increasing numbers of data quality checks and increasing awareness of inherent data issues.
  - With network evolution, less focus on ETL, more on norms in clinical pediatrics and research readiness.
  - Still, despite that trend, even at the end of the 9th data cycle, nearly 60 ETL issues still observed in network, owing to collective responsibility of sites (programming errors) and the PEDSnet DCC (ambiguity in ETL conventions).

- **CRI Conclusions:** Description from real-world experience of data quality assessments and approaches for others

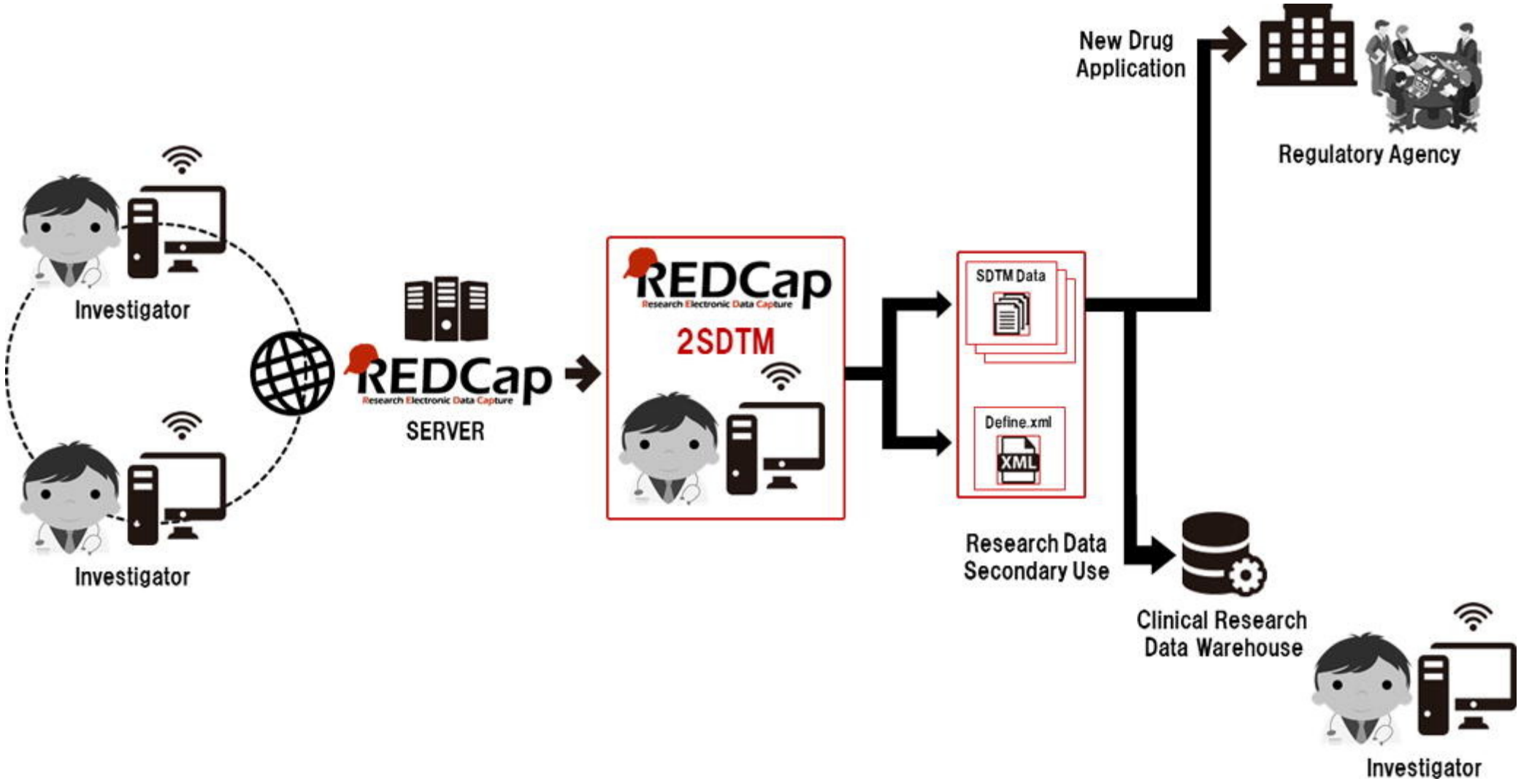
A pragmatic method for transforming clinical research data from the "REDCap" to Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM): Development and evaluation of REDCap2SDTM. Yamamoto K, et al. JBI 2017

- **Background:** The Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM)
  - Used for new drug application studies; also enabling secondary use
  - If Clinical Data Acquisition Standards Harmonization (CDASH) not used in set-up phase of a study, difficult to map SDTM format.
  - Most EDC systems don't export data in SDTM format;
  - To facilitate efficient reporting/secondary use of research data using SDTM, team developed approach to use with REDCap

A pragmatic method for transforming clinical research data from the "REDCap" to Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM): Development and evaluation of REDCap2SDTM. Yamamoto K, et al. JBI 2017

- **Approach:** Developed clinical trial to evaluate a tool called REDCap2SDTM
  - Tool maps information in the Field Annotation of REDCap to SDTM and executes data conversion, including when data must be pivoted to accommodate the SDTM format, dynamically, by parsing the mapping information using R.
- **Results:** Generated SDTM data and the define.xml file from REDCap using REDCap2SDTM.
- **Conclusions:** Leveraging common EDC system, dynamic approach to generating SDTM/XML without programming**,** rather than one-off for **each** clinical study. Could be helpful/reduce effort for new drug application AND secondary use for research **clinical** data collected with CDASH at the beginning of a study in non-standard format.

A pragmatic method for transforming clinical research data from the "REDCap" to Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM): Development and evaluation of REDCap2SDTM. Yamamoto K, et al. JBI 2017



MIMIC Code Repository: enabling reproducibility in critical care research. Johnson AE, et al. JAMIA 2017

- **Objective:** Lack of reproducibility in medical studies is a major issue.
  - Authors describe Medical Information Mart for Intensive Care (**MIMIC**) **Code Repository**, a centrallized code base for generating reproducible studies on an openly available critical care dataset.
- **Methods/Resource:** Code is provided to load the data into a relational structure, create extractions of the data, and reproduce entire analysis plans including research studies.

MIMIC Code Repository: enabling reproducibility in critical care research. Johnson AE, et al. JAMIA 2017

- **RESULTS:** Concepts extracted include severity of illness scores, comorbid status, administrative definitions of sepsis, physiologic criteria for sepsis, organ failure scores, treatment administration, and more. Executable documents are used for tutorials and reproduce published studies end-to-end, providing a template for future researchers to replicate. The **repository**'s issue tracker enables community discussion about the data and concepts, allowing users to collaboratively improve the resource.

Table 1. Concepts available in the repository

Category	Concepts
Severity of illness scores	APS III, SAPS, SAPS II, OASIS
Organ dysfunction scores	SOFA, qSOFA, LODS, SIRS, MELD, KDIGO, AKIN
Treatments	Continuous renal replacement therapy, intermittent hemodialysis, vasopressors, mechanical ventilation
Sepsis	Suspicion of infection, Angus et al. criteria, Martin et al. criteria, explicit ICD-9 coding of sepsis, *CMS sepsis criteria, CDC sepsis criteria*
Comorbid burden	Elixhauser et al. (AHRQ), Quan et al., *Charlson et al.*
First 24 h aggregates	Vital signs, laboratory values, blood gas values, urine output
Diagnosis groups	Certified Coding Specialist groups
Demographics	Weight, height, age, gender, *service type*
Hourly data	*Vasopressor doses, vital signs, laboratory values, blood gas values*
Fluid balance	*Total fluid intake, total fluid output*

MIMIC Code Repository: enabling reproducibility in critical care research. Johnson AE, et al. JAMIA 2017

- **DISCUSSION:** The centralized **repository** provides a platform for users of the data to interact directly with the data generators, facilitating greater understanding of the data.
  - Provides a location for the community to collaborate and share concepts and resources with other researchers
  - Consistent application of the same **code** for underlying concepts is a key step in ensuring that research studies on the **MIMIC** database are comparable and reproducible.
- **CONCLUSION:** By providing open source **code** alongside the freely accessible **MIMIC**-III database, this could enable end-to-end reproducible analysis of electronic health records.

Physicians' perception of alternative displays

Information Foraging Theory

"I think we finally mastered foraging theory."

Physicians' perception of alternative displays of clinical research evidence for clinical decision support–A study with case vignettes.

Slager SL, et al. JBI 2017

Coenzyme Q10, rosuvastatin, and clinical outcomes in heart failure: a pre-specified substudy of CORONA (controlled rosuvastatin multinational study in heart failure).

McMurray JJ, Dunselman P, Wedel H, Cleland JG, Lindberg M, Hjalmarson A, Kjekshus J, Waagstein F, Apetrei E, Barrios V, Böhm M, Kamenský G, Komajda M, Mareev V, Wikstrand J; CORONA Study Group.

J Am Coll Cardiol. 2010 Oct 5;56(15):1196-204. doi: 10.1016/j.jacc.2010.02.075.

PMID: **20883926** **Free Article**

Similar articles

Comparison of 80 versus 10 mg of atorvastatin on occurrence of cardiovascular events after the first event (from the Treating to New Targets [TNT] trial).

LaRosa JC, Deedwania PC, Shepherd J, Wenger NK, Greten H, DeMicco DA, Breazna A; TNT Investigators.

Am J Cardiol. 2010 Feb 1;105(3):283-7. doi: 10.1016/j.amjcard.2009.09.025. Epub 2009 Dec 22.

PMID: **20102935**

Similar articles

PubMed

Effect of rosuvastatin in patients with chronic heart failure (the GISSI-HF trial): a randomised, double-blind, placebo-controlled trial. ***Lancet.*** 2008. [Other funding]. [n=6975]. **Conclusions:** Rosuvastatin 10 mg daily did not affect clinical outcomes in patients with chronic heart failure of any cause, in whom the drug was safe. more

Effects of rosuvastatin on atrial fibrillation occurrence: ancillary results of the GISSI-HF trial. ***Eur. Heart J..*** 2009. [Other funding]. [n=6975]. **Conclusions:** This study shows that there is some evidence of a beneficial effect of rosuvastatin in terms of reduction of AF occurrence in patients with HF. Larger populations are needed to provide a definite answer to the question. ClinicalTrials.gov Identifier: NCT00336336. more

Summarized text

Effect of rosuvastatin in patients with chronic heart failure (the GISSI-HF trial): a randomized, double-blind, placebo-controlled trial. ***Lancet***. 2008.

Population	Primary Outcome	Study arm/results	Conclusion
Patients (>18yrs) with CHF of any cause, class II-IV, irrespective of cause and LVEF (n=6975)	Rosuvastatin 10mg (57%) vs. placebo (56%)	Clinical outcomes not affected by addition of 10mg rosuvastatin	57% vs 56% died or were admitted to hospital for cardiovascular reasons.

Effect of rosuvastatin on atrial fibrillation occurrence: ancillary results of the GISSI-HF trial. ***Eur. Heart. J***. 2009.

Patients (>18yrs) with CHF of any cause, class II-IV, irrespective of cause and LVEF (n=6975)	Occurrence of AF	Rosuvastatin 10mg (13.9%) vs. placebo (16%).	This study shows that there is some evidence of a beneficial effect of rosuvastatin in terms of reduction of AF occurrence in patients with HF.

Comparison of 80 versus 10 mg of atorvastatin on occurrence of cardiovascular events after the first event (from the Treating to New Targets (TNT) trial). ***Am. J. Cardiol***. 2010.

Patients (>=65) with stable CAD after their first cardiovascular event (n=5013)	Reduction in CV events	atorvastatin 80mg (22%) versus atorvastatin 10 mg (2.2%).	treatment with atorvastatin 80 mg continued to significantly decrease the risk of any cardiovascular event over time compared to atorvastatin 10 mg.

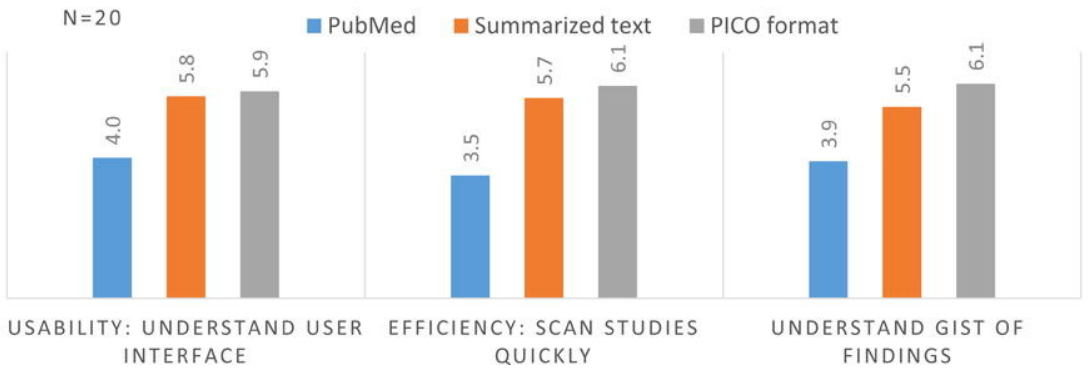
Coenzyme Q10, rosuvastatin, and clinical outcomes in heart failure: a pre-specified substudy of CORONA (controlled rosuvastatin multinational study in heart failure). ***J. Am. Coll. Cardiol***. 2010.

Patients (>=60) functional class II to IV heart failure (n=3.664)	Coenzyme Q10 level	Rosuvastatin 10mg vs. placebo.	Statin treatment reduced serum coenzyme Q10 concentration, but even in patients with a low starting coenzyme Q10, statin therapy was not associated with a significantly worse outcome.

Rosiglitazone evaluated for cardiovascular outcomes in oral agent combination therapy for type 2 diabetes (RECORD): a multicenter, randomized, open-label trial. ***Lancet***. 2009.

patients (40-75y) with type 2 diabetes on metformin or sulfonylurea monotherapy (n=4447)	Cardiovascular morbidity or mortality	rosiglitazone (n=2220) or to a combination of metformin and sulfonylurea (active control group, n=2227).	rosiglitazone does not increase the risk of overall cardiovascular morbidity or mortality compared with standard glucose-lowering drugs.

Tabular display in PICO format



Physicians' perception of alternative displays of clinical research evidence for clinical decision support–A study with case vignettes.

Slager SL, et al. JBI 2017

- **RESULTS:** Twenty physicians completed the study.
  - Table display rated higher than either text summary or PubMed's summary format
  - Usefulness ratings of seven pieces of information, i.e.
    - patient population, patient age range, sample size, study arm, primary outcome, results of primary outcome, and conclusion, were high
    - Study arm, primary outcome, and conclusion scored the highest (4.9, 4.85, and 4.85 respectively). Participants suggested additional details such as rate of adverse effects.

- **CONCLUSION:** Table format:
  - Reduced physicians' perceived cognitive effort
  - Physicians than the narrative summary or PubMed's summary format display.

- **CRI Conclusion:** Informs designs/approaches to translating evidence into practice for CDS and LHS efforts

Other notable papers in this (Methods/Approaches) category

- **Evidence Appraisal: A Scoping Review, Conceptual Framework, and Research Agenda.** Weng C. JAMIA 2017
  - Lit review to addresses key part of reproducibility and generalizability crisis, (68 themes, 10 categories), proposes a new research area for informatics community with a focus on informatics approaches to evidence appraisal
- **Dynamic-ETL: a hybrid approach for health data extraction, transformation and loading.** Ong TC, et al. BMC Med Inform Dec Making 2017
  - Excellent description of new approach to facilitating ETL from disparate sources to a common, prevailing data model

Other notable papers in this (Methods/Approaches) category

- **Identifying collaborative care teams through electronic medical record utilization patterns.** Chen Y, et al. *JAMIA*. 2017
  - Mining EHR utilization to explore patterns, useful method
- **Predicting inpatient clinical order patterns with probabilistic topic models vs conventional order sets**. Chen JH, et al. *JAMIA* 2017
  - An automated approach to detect thematic trends in patient care and generate decision support content. Research use cases as well.
- **Clinical code set engineering for reusing EHR data for research: a review.** Williams R, et al. *Journal of biomedical informatics*. 2017
  - Review of software tools that enable users to create, revise, extend, review and share code sets; recommendations for their design and implementation.
- **Comparison of EHR-based diagnosis documentation locations to a gold standard for risk stratification in patients with multiple chronic conditions.** Martin S, et al. *Appl. Clin. Informatics* 2017
  - Insights, lessons for leveraging, re-using data across sites for risk modeling

Participant Recruitment and Eligibility

rvey of practices for the use of electronic ealth records to support research recruitment

beid JS, Beskow LM, et al. Journ. Clinical and Translational Science. Sept. 2017

- For the Methods and Process AND Informatics Domain Task Force (DTF) of CTSA
- **Background:** A multidisciplinary workgroup examined current practices in the use of EHRs in recruitment and to propose future directions.
- **Methods:** Literature review. Surveyed consortium members regarding current practices. Over **98%** of the CTSA Consortium responded to the survey.

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beid JS, Beskow LM, et al. Journ. Clinical and Translational Science. Sept. 2017

- **Findings:** Related to EHR-based methods:
  - Brokered access to data warehouses (94%) and self-service query (92%) are widely implemented and used
  - Demand for EHR data for research use is high (88%)
  - When use of EHR data for recruitment is limited, it is often the result of logistical constraints and limitations on collaboration
  - Minority of institutions use EHR patient portals for research purposes (20%)
  - Electronic alerts targeting care providers and research teams about patients' eligibility are moderately implemented (45% and 48%, respectively); however, those targeting research teams seem to be higher demand (22% and 39%, respectively)

- Related to workflow and regulatory processes
  - A variety of direct patient engagement (e.g., registries of potential research subjects) are implemented at the majority of institutions
  - Many institutions provide a combination of self-service tools, data analysts and recruitment specialists

- Recruitment procedures (including cohort identification and contact) vary widely

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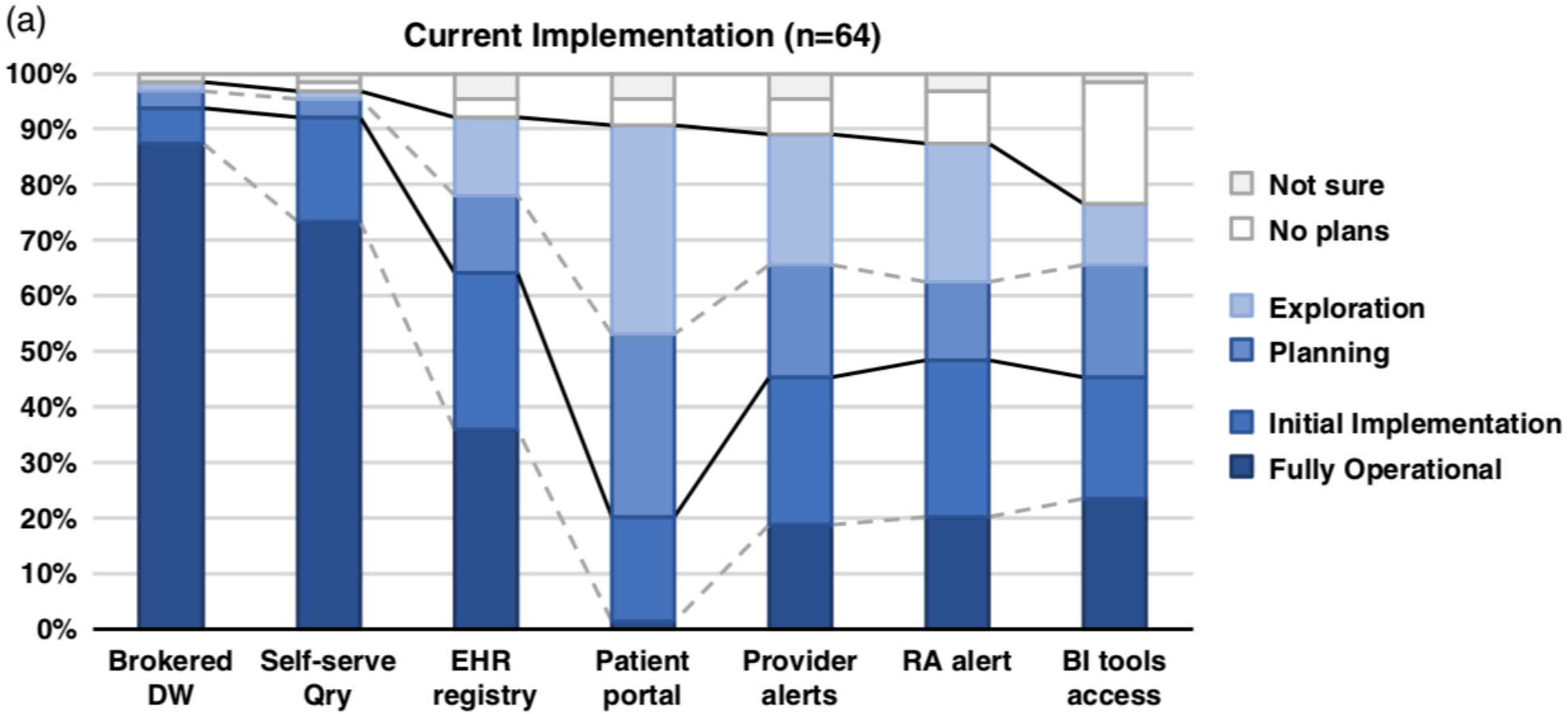

Fig. 1. Summary of responses to questions regarding methods of electronic health records (EHR)-based cohort identification and recruitment.

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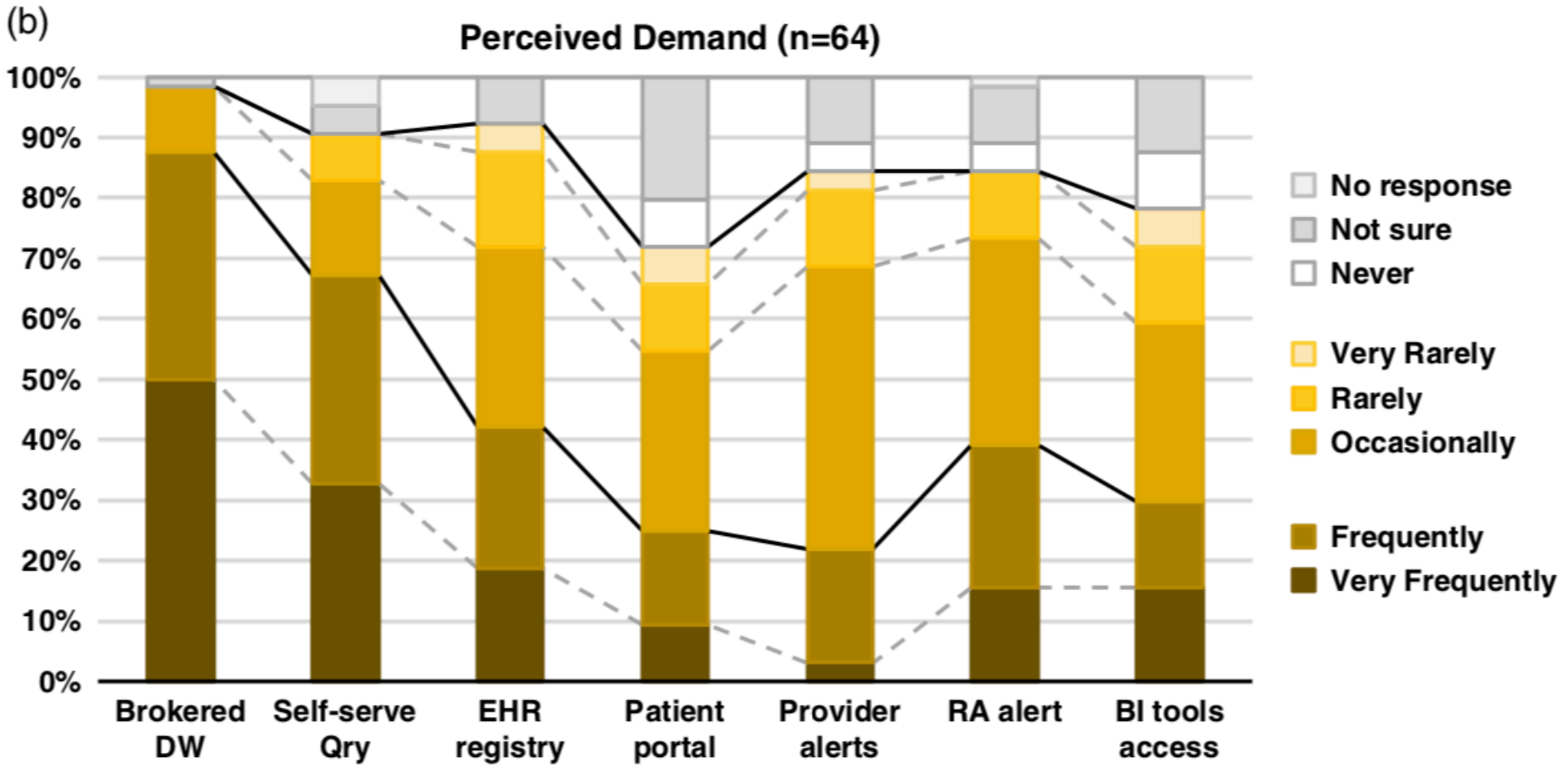

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beid JS, Beskow LM, et al. Journ. Clinical and Translational Science. Sept. 2017

- **Conclusions:**
  - Wide variation in implementation and approach,
  - Strong need for comparative research and development of best practices facilitate interinstitutional collaboration and multisite research
  - Useful insights into current use and demand for EHR-based recruitment approaches;
  - Adds to and updates existing/previous literature
  - Informs work of CTSA RIC effort among others

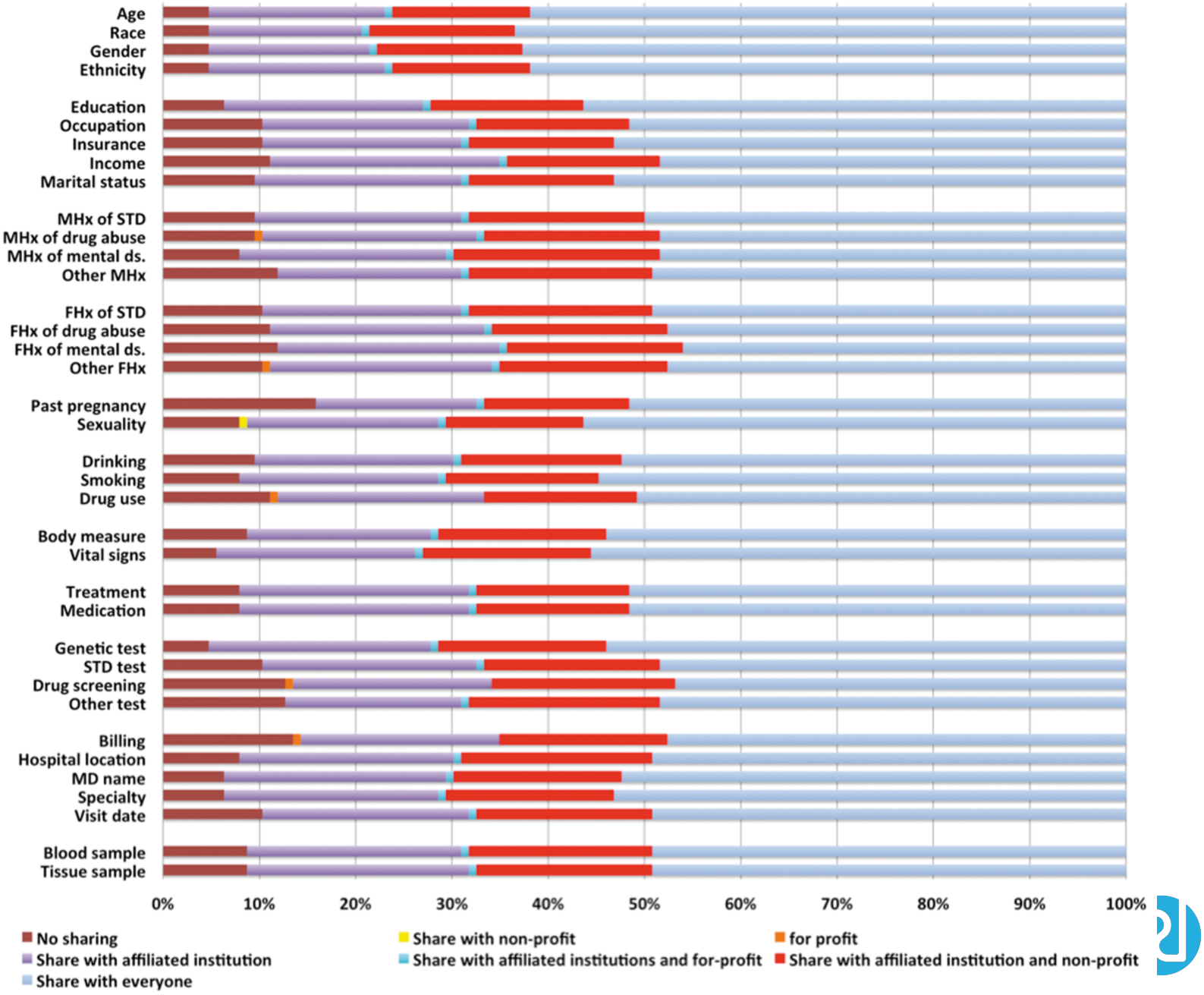
iCONCUR: informed consent for clinical data and bio-sample use for research.

Hyeoneui K, et al. JAMIA 2017

- **Approach:** A web-based, tiered informed consent tool called informed consent for clinical data and bio-sample use for research (iCONCUR)
  - Requests granular patient preferences for use of EHR data in research.
  - We piloted this tool in 4 outpatient clinics of an academic medical center.
- **Results:**
  - 126 patients (out of 1152) agreed to and accessed the website to indicate data category and data recipient.
  - The majority consented to share most of their data and specimens with researchers.
  - Willingness to share was greater among participants from an Human Immunodeficiency Virus (HIV) clinic than those from internal medicine clinics.
  - The number of items declined was higher for for-profit institution recipients.
  - Overall, participants were most willing to share demographics and body measurements and least willing to share family history and financial data.
  - Participants felt having granular choices for data sharing was appropriate, and liked being informed about who was using their data for what purposes, as well as about outcomes of the research.

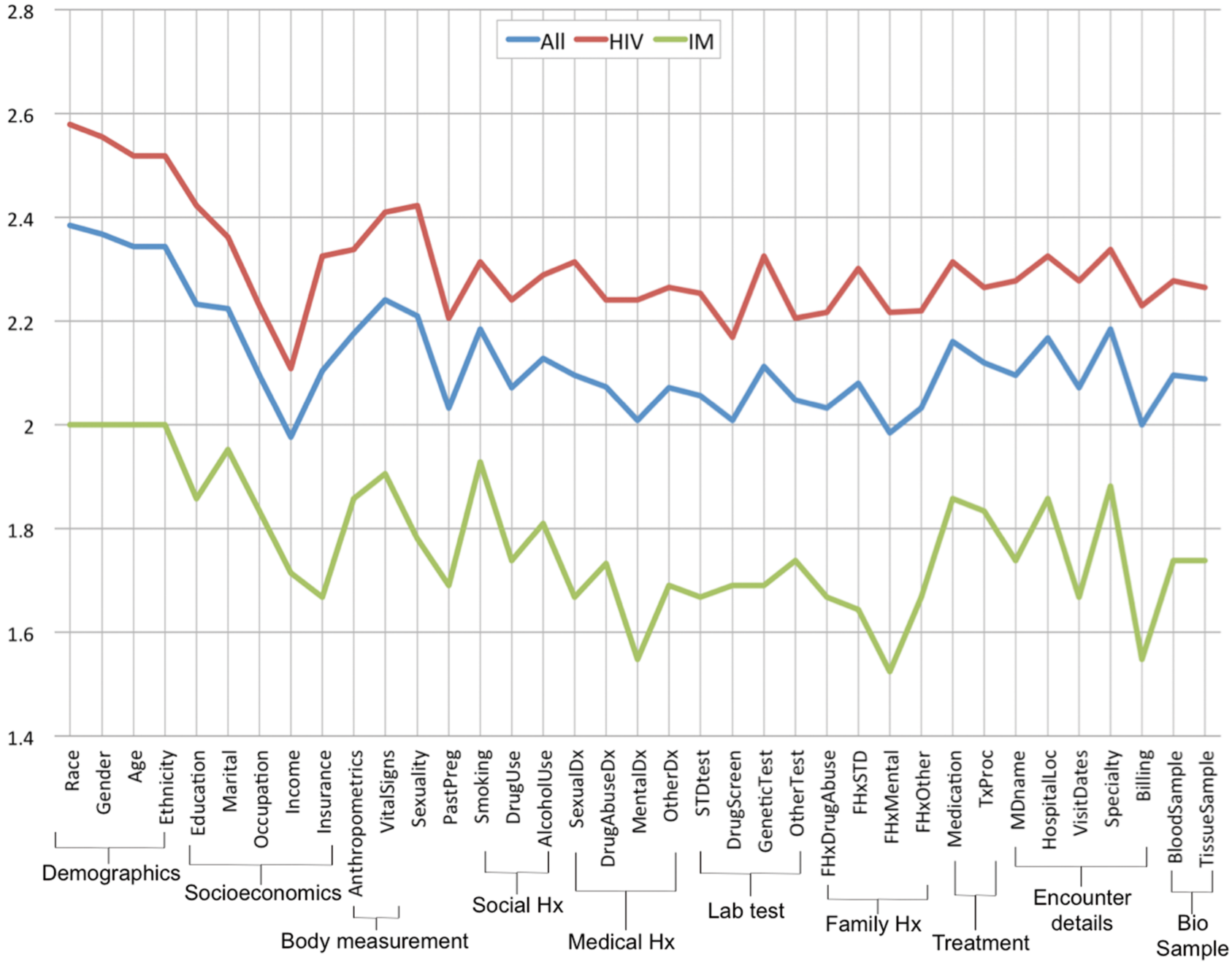
iCONCUR: informed consent for clinical data and bio-sample use for research.

Figure 1. Sharing preference by individual data item



iCONCUR: informed consent for clinical data and bio-sample use for research.

Figure 2. Mean willingness-to-share score by individual data item



iCONCUR: informed consent for clinical data and bio-sample use for research. Hyeoneui K, et al. JAMIA 2017

- **Conclusions:**
  - A tiered electronic informed consent system is feasible
  - Early finding indicates increases satisfaction, and does not significantly affect participation in research
  - Small sample participated, further study needed, but
  - Adds to literature on patient preferences, options for consent

Experience With Direct-to-Patient Recruitment for Enrollment Into a Clinical Trial in a Rare Disease: A Web-Based Study

Krischer, J., et al. (2017). J Med Internet Res

- **BACKGROUND:** VCRC of the RDCRN. Rare diseases require multicenter (center of excellence, CoE) engagement, with more complexity, cost, and regulatory requirements. Alternative recruitment strategies need to be tested against this standard model.
- **OBJECTIVES**: Test whether a Web-based direct recruitment approach (patient-centric, PC) using social marketing strategies provides a viable option to the CoE recruitment method.
- **METHODS:** PC recruitment and Web-based informed consent was compared with CoE recruitment for a randomized controlled trial (RCT) of continuing versus stopping low-dose prednisone for maintenance of remission of patients with granulomatosis with polyangiitis (GPA).

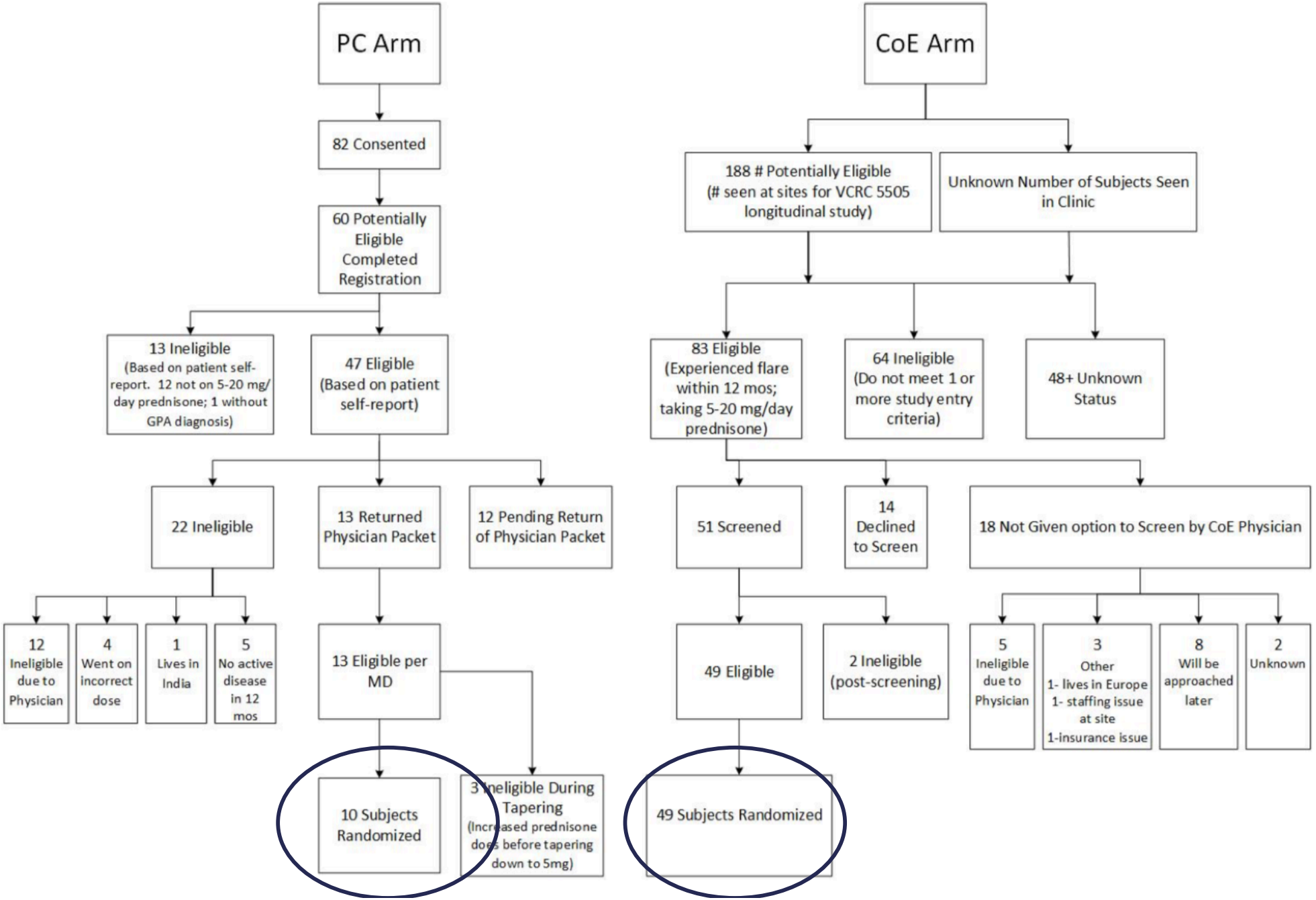
Experience With Direct-to-Patient Recruitment for Enrollment Into a Clinical Trial in a Rare Disease: A Web-Based Study

Krischer, J., et al. (2017). J Med Internet Res

- **RESULTS:**
  - The PC approach was **NOT** as successful as the CoE approach.
  - Enrollment of those confirmed eligible by their physician was 10 of 13 (77%) and 49 of 51 (96%) in the PC and CoE arms, respectively (P=.05).
  - The two approaches were not significantly different in terms of eligibility with 34% of potential participants in the CoE found to be ineligible as compared with 22% in the PC arm (P=.11) nor in provider acceptance, 22% versus 26% (P=.78).
  - There was no difference in the understanding of the trial as reflected in the knowledge surveys of individuals in the PC and CoE arms.

Experience With Direct-to-Patient Recruitment for Enrollment Into a Clinical Trial in a Rare Disease: A Web-Based Study

Figure 3. The Assessment of Prednisone in Remission (TAPIR) trial consort diagram.



Experience With Direct-to-Patient Recruitment for Enrollment Into a Clinical Trial in a Rare Disease: A Web-Based Study

Krischer, J., et al. (2017). J Med Internet Res

- **Their Conclusions:**
  - PC recruitment was substantially less successful than that achieved by the CoE approach.
  - However, the PC approach was good at confirming eligibility and was as acceptable to providers and as understandable to patients as the CoE approach.
  - The PC approach should be evaluated in other clinical settings to get a better sense of its potential.

- **My conclusions:**
  - PC not that bad… particularly for rare/complex condition.
  - This isn't an either/or proposition.
  - Seems could be a good adjunct. But, CoE approach is still key in certain settings

Other notable papers in this (Recruitment) category:

- **ElilE: An open-source information extraction system for clinical trial eligibility criteria.** Kang, T., et al. J Am Med Inform Assoc. Apr 2017
- **Leveraging the EHR4CR platform to support patient inclusion in academic studies: challenges and lessons learned.** Girardeau, Y., et al. (2017). BMC Med Res Methodol
- **Text Mining of the Electronic Health Record: An Information Extraction Approach for Automated Identification and Subphenotyping of HFpEF Patients for Clinical Trials.** Jonnalagadda, S. R., et al. (2017). J Cardiovasc Transl Res
- **A search algorithm for identifying likely users and non-users of marijuana from the free text of the electronic medical record.** Keyhani S, et al. PLoS One. 2018 Mar
  - Since we're in California ;)

Other notable papers in this (Recruitment) category:

- **A population-based approach for implementing change from opt-out to opt-in research permissions**. Marshall, E. A., et al. (2017). PLoS One
- **A randomised controlled trial evaluating the utility of a patient Decision Aid to improve clinical trial (RAVES 08.03) related decision-making.** Sundaresan, P., et al. (2017). Radiother Oncol
- **Predicting Recruitment Feasibility for Acute Spinal Cord Injury Clinical Trials in Canada Using National Registry Data.** Thibault-Halman, G., et al. (2017). J Neurotrauma
- **Understanding the Role of Message Frames on African-American Willingness to Participate in a Hypothetical Diabetes Prevention Study**. Langford, A. T., et al. (2017). J Health Commun

PROs, SBDH, and Patient Perspectives

Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment

Basch E, et al. JAMA (Letter) July 2017

- **Objective:** Assess overall survival associated with electronic patient-reported symptom monitoring vs usual care based on follow-up from a randomized clinical trial.

- **Methods**: Patients on routine chemotherapy for metastatic solid tumors at Memorial Sloan Kettering Cancer Center between September 2007 and January 2011 invited to a RCT
  - Participants were randomly assigned either to the usual care group or to the PRO group, in which patients provided self-report of 12 common symptoms from the National Cancer Institute's Common Terminology Criteria for Adverse Events
  - At/between visits via a Web-based PRO questionnaire platform.
  - Participation continued until cessation of cancer treatment, voluntary withdrawal, transition to hospice care, or death.
- PRO of severe or worsening symptom -> email alert to a clinical nurse
- Report for each participant's symptom burden generated at clinic visits for the treating oncologist.
- The usual care group received the standard procedure

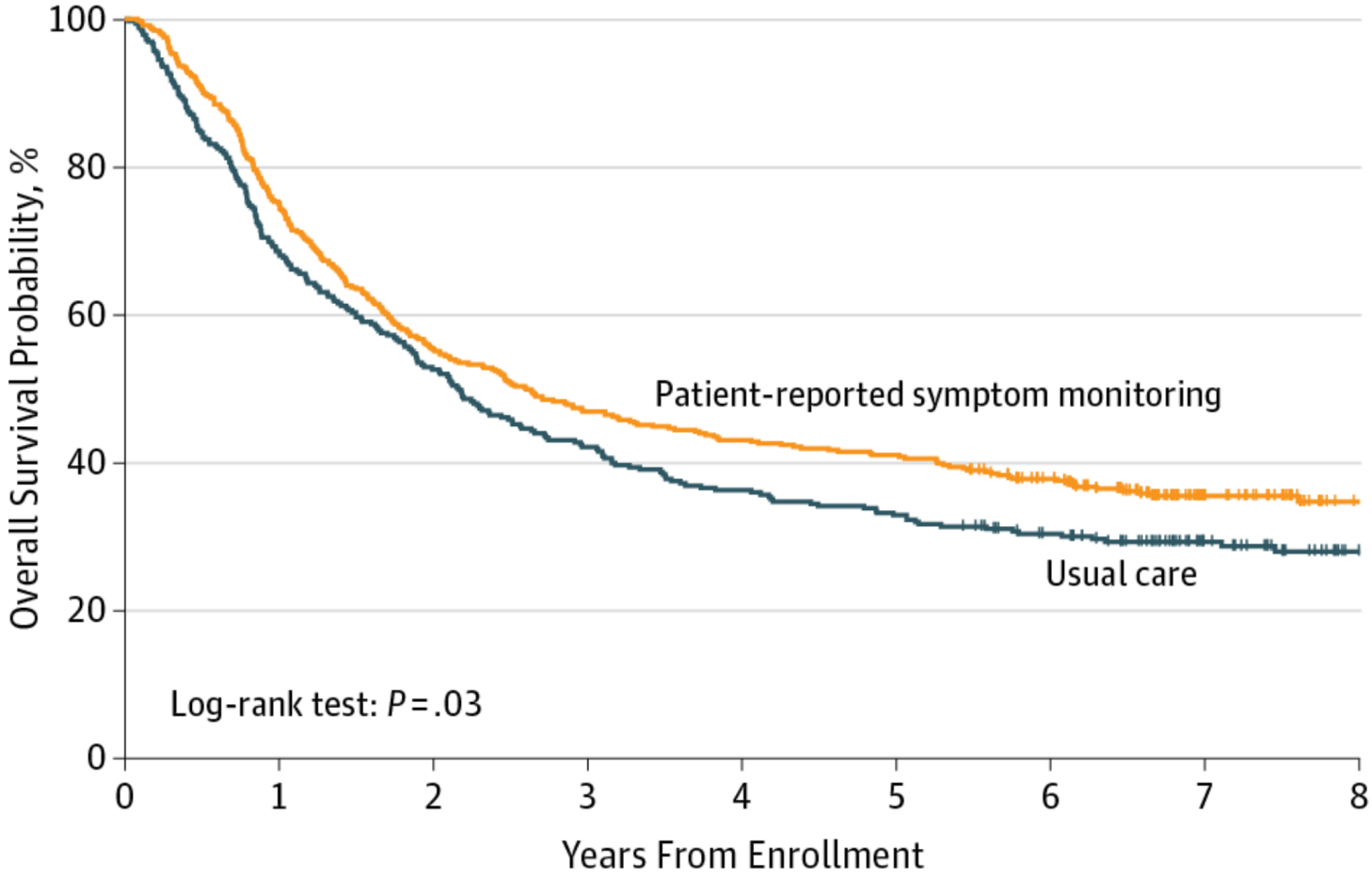
Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment

Basch E, et al. JAMA (Letter) July 2017

- **Results:** Of 766 patients randomized, the median age was 61 years (range, 26-91), 86% were white, 58% women, 22% had less than a high school education, and 30% were computer inexperienced, as reported.
  - Baseline variables were well balanced between study groups.
- Overall survival was assessed in June 2016 after 517 of 766 participants (67%) had died, at which time the median follow-up was 7 years (interquartile range, 6.5-7.8).
- Median overall survival was 31.2 months (95% CI, 24.5-39.6) in the PRO group and 26.0 months (95% CI, 22.1-30.9) in the usual care group (difference, **5 months**; *P* = .03).
  - In the multivariable model, results remained statistically significant with a hazard ratio of 0.83 (95% CI, 0.70-0.99; *P* = .04).

Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment

Basch E, et al. JAMA (Letter) July 2017



No. at risk									
Patient-reported symptom monitoring	441	331	244	207	190	181	148	65	33
Usual care	325	223	171	137	118	107	89	50	27

Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment

Basch E, et al. JAMA (Letter) July 2017

- **Discussion:** Integration of PROs into the routine care of patients with metastatic cancer was associated with **increased survival** compared with usual care. Why?
- One potential mechanism of action is early responsiveness to patient symptoms preventing adverse downstream consequences.
  - Nurses responded to symptom alerts 77% of the time with discrete clinical interventions including calls to provide symptom management counseling, supportive medications, chemotherapy dose modifications, and referrals.
- Another potential mechanism is that patients in the intervention group were able to tolerate continuation of chemotherapy longer than usual care (mean, 8.2 months in the PRO group vs 6.3 months in the usual care group; difference, 1.9 months [95% CI, 0.7-3.0]; *P* = .002).[4]
- **Conclusions:** Electronic patient-reported symptom monitoring may be considered for implementation as a part of high-quality cancer care.
- **My Conclusion:** Wow! If this was a drug, how much would we charge for it?

Detecting Atrial Fibrillation using a Smart Watch - the mRhythm study (Abstract)

Sanchez JM, et al. Heart Rhythm. May 2017

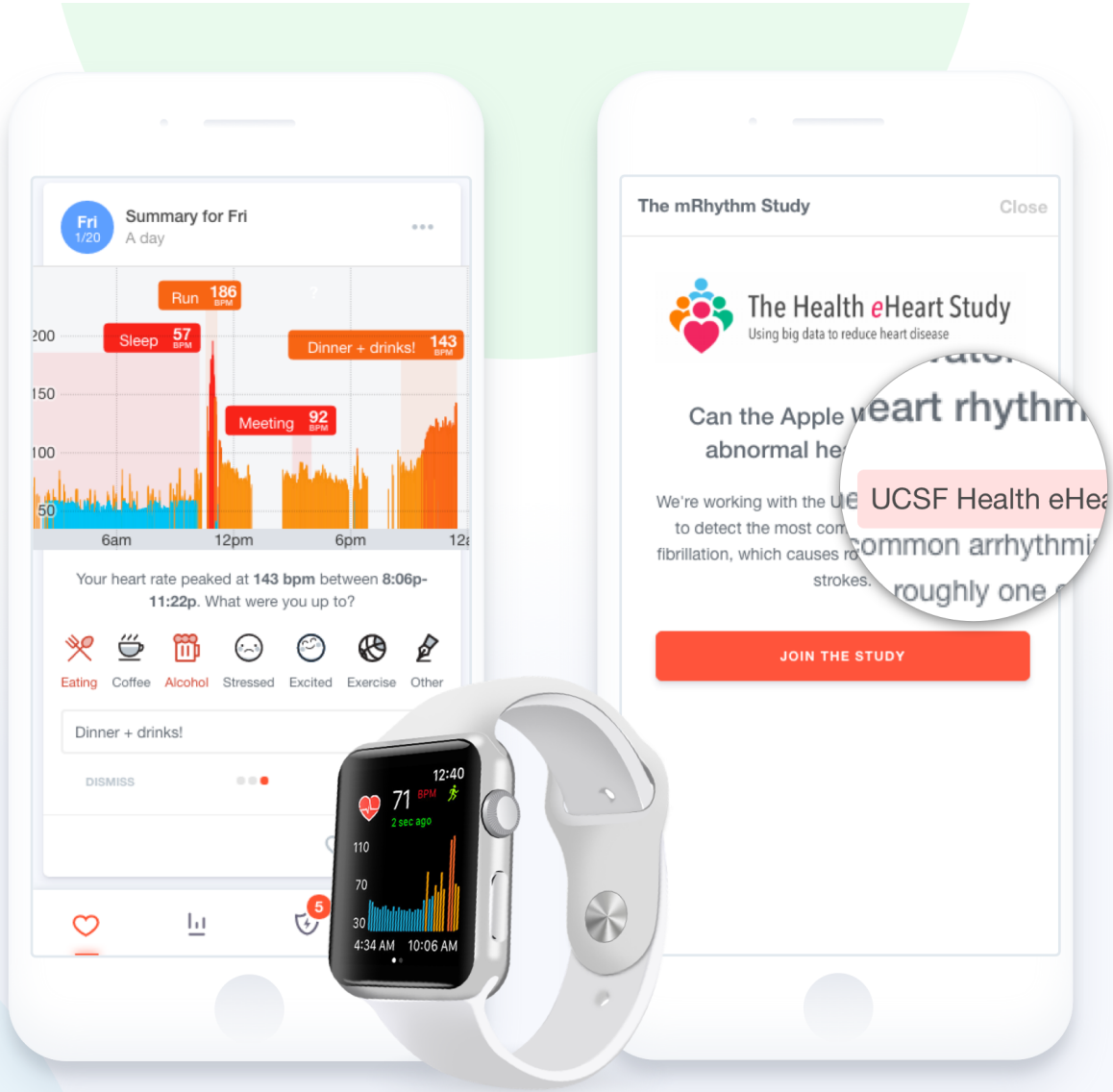
- **Background:** Atrial fibrillation (AF) is one of the most common causes of stroke, but it is often asymptomatic. Smartwatches use photoplethysmography (PPG) to detect heart rate, and could provide a way to detect “silent” AF.

- **Objective:** To determine if a deep learning algorithm could detect AF using heart rate data measured by PPG on an Apple Watch.

- **Methods:** AF patients without a ventricular paced rhythm undergoing cardioversion were enrolled. Participants were fitted with an Apple Watch for 20 minutes pre- and post-cardioversion, and continuous heart rate data in “workout mode” (enabling heart rate measurements every 5 seconds) was obtained. A standard 12-lead electrocardiogram was used as the reference standard.

Detecting Atrial Fibrillation using a Smart Watch - the mRhythm study

Sanchez JM, et al. Heart Rhythm. May 2017



Detecting Atrial Fibrillation using a Smart Watch - the mRhythm study

Sanchez JM, et al. Heart Rhythm. May 2017

Method	C-Statistic
RMS Diffs	0.87
Sh. Entropy	0.70
DNN	**0.94**

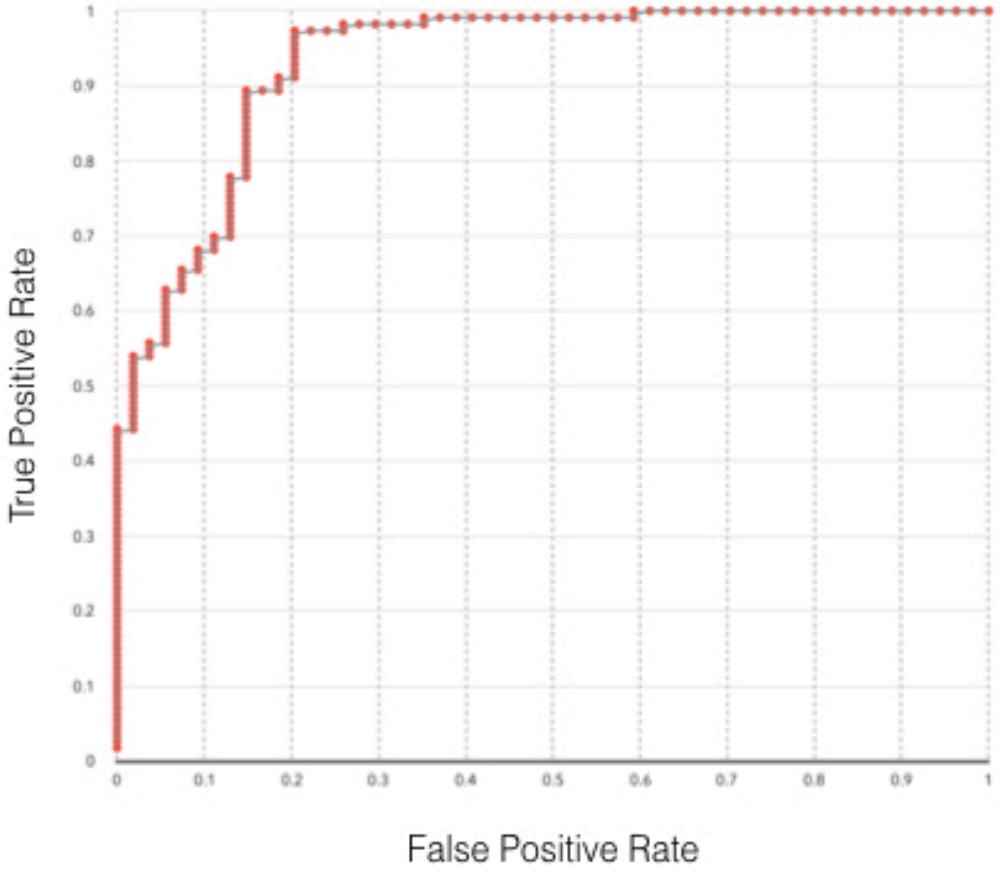


Figure: C-statistic for detecting AF using the root mean square of successive differences of RR intervals (RMS Diffs), Shannon Entropy (Sh Entropy), and the deep neural network (DNN). ROC curve for the DNN is shown (right).

Detecting Atrial Fibrillation using a Smart Watch - the mRhythm study

Sanchez JM, et al. Heart Rhythm. May 2017

- **Results:** Successful cardioversion was performed in 41 patients. They were 66 +/- 11 years old, 28 (68%) male, 25 (61%) white, and 22 (54%) had normal left ventricular function. The C-statistic for AF detection using the deep learning algorithm was 0.94, higher than previously validated algorithms for AF detection.

- **Conclusions:** An Apple Watch accurately distinguished pulse recordings during AF from those obtained during normal sinus rhythm. Detecting AF using commonly and continuously worn devices may represent a novel opportunity to passively and automatically detect asymptomatic AF.

- **My conclusions:** Preliminary findings. COIs. Early results. But, rings true… We need to learn how to utilize these devices. This is an advance!

What Do These Scores Mean? Presenting Patient-Reported Outcomes Data to Patients and Clinicians to Improve Interpretability

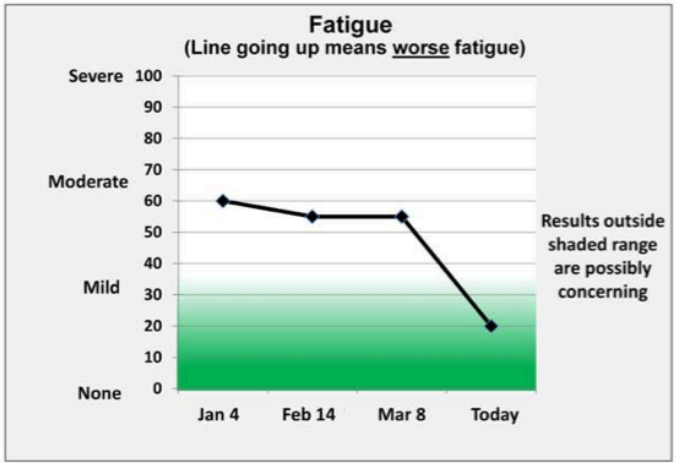
Snyder CF, et al. Cancer. May 2017

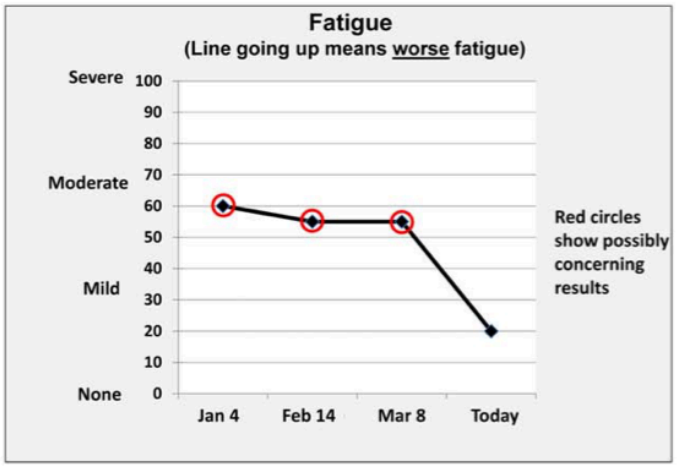
- **Objective:** Interpreting PRO meaning can be challenging. The authors tested approaches for presenting PRO data to improve interpretability.
- **Methods:**
  - Mixed-methods study including Internet survey of cancer patients/survivors, oncology clinicians, and PRO researchers circulated via snowball sampling, plus individual in-person interviews.
  - Clinical importance conveyed using 3 approaches (presented in random order):
    - normal score range shaded green,
    - concerning scores circled in red, and
    - red threshold lines indicating normal versus concerning scores.
  - Versions also tested 2 approaches to score directionality:
    - higher = more (better for function, worse for symptoms) and
    - higher = better for both function and symptoms.
  - Qualitative data from online comments and in-person interviews supplemented quantitative results on interpretation accuracy, clarity, and the “most useful” format.

What Do These Scores Mean? Presenting Patient-Reported Outcomes Data to Patients and Clinicians to Improve Interpretability

Snyder CF, et al. Cancer. May 2017

- Example presentations
  - Clinical importance conveyed using 3 approaches
    - normal score range shaded green,
    - concerning scores circled in red, and
    - red threshold lines indicating normal versus concerning scores.
  - Note directionality – line going up means worse fatigue in these





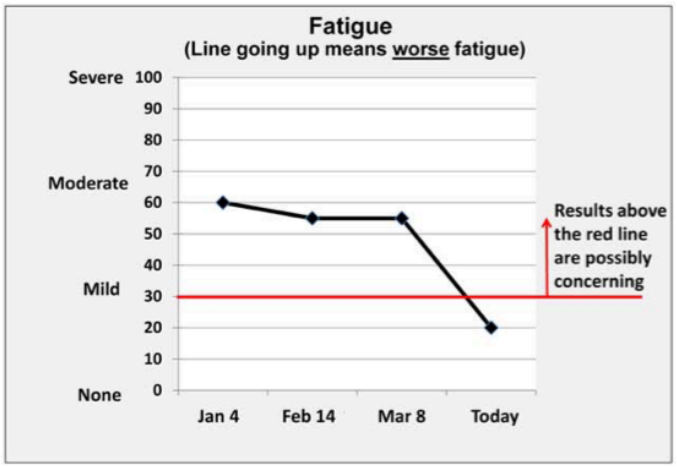


Figure 1. Examples of the 3 formats tested are illustrated: green shading, red circles, and threshold line.

What Do These Scores Mean? Presenting Patient-Reported Outcomes Data to Patients and Clinicians to Improve Interpretability

Snyder CF, et al. Cancer. May 2017

- **Results:** The survey included 1113 respondents: 627 survivors, 236 clinicians, and 250 researchers, plus 10 patients and 10 clinicians who were purposively sampled interviewees.

- **Higher = better** were interpreted more accurately than higher = more
  - (odds ratio [OR], 1.30; 95% confidence interval [CI], 1.07-1.58) and
  - Also more likely to be rated “very”/“somewhat” clear
- Red circle formats interpreted more accurately than green-shaded formats when the first format presented
  - (OR, 1.29; 95% CI, 1.00-1.65).
- Threshold-line formats were more likely to be rated “very” clear than green-shaded
  - (OR, 1.43; 95% CI, 1.19-1.71) and red-circled (OR, 1.22, 95% CI, 1.02- 1.46) formats.
- Threshold lines were most often selected as “most useful.”

- **Conclusions:** The current results support presenting PRO data with higher=better directionality and threshold lines indicating normal versus concerning scores.

- **My Conclusions:** We need more studies like these re: how to best present PRO data

Framework To Guide The Collection And Use Of Patient-Reported Outcome Measures In The Learning Healthcare System.

Franklin PD, et al. eGEMs. 2017

- **Background:** As the value of PROMs in patient care expands, a framework to guide the implementation planning, collection, and use of PROs to serve multiple goals and stakeholders is needed.

- **Methods:** Targeted diverse clinical, quality, and research settings where PROMs have been successfully integrated into care and routinely collected and analyzed drivers of successful implementation.
- Key informant interviews with 46 individuals representing 38 organizations, of whom 40 participated in a webinars series, and 25 attended an in-person workshop designed to enable broad stakeholder input, review and refinement of the proposed PROMs implementation model.

- Stakeholders identified differing uses of PROMs to support…

Framework To Guide The Collection And Use Of Patient-Reported Outcome Measures In The Learning Healthcare System.

Franklin PD, et al. eGEMs. 2017

Table 1. Shared Value of PROMs by User Groups

PROMS USERS	SHARED VALUE FOR PROMS
1. Patients and Clinicians	*Individual patient care decisions:* Individual patient-centered decisions to prioritize, treat, and monitor disease symptoms and health status
2. Hospital Leaders and Clinicians	*Quality improvement:* Monitor and improve aggregate patient outcomes as compared to national best practice and benchmarks
3. Insurers and Hospital Leaders	*Value-based payment:* Measure outcomes as compared to costs and utilization to optimize health care value
4. Researchers, Policy makers, and Funders	*Population health and research:* Generate new evidence for best clinical practices across patients to achieve optimal health status over time.

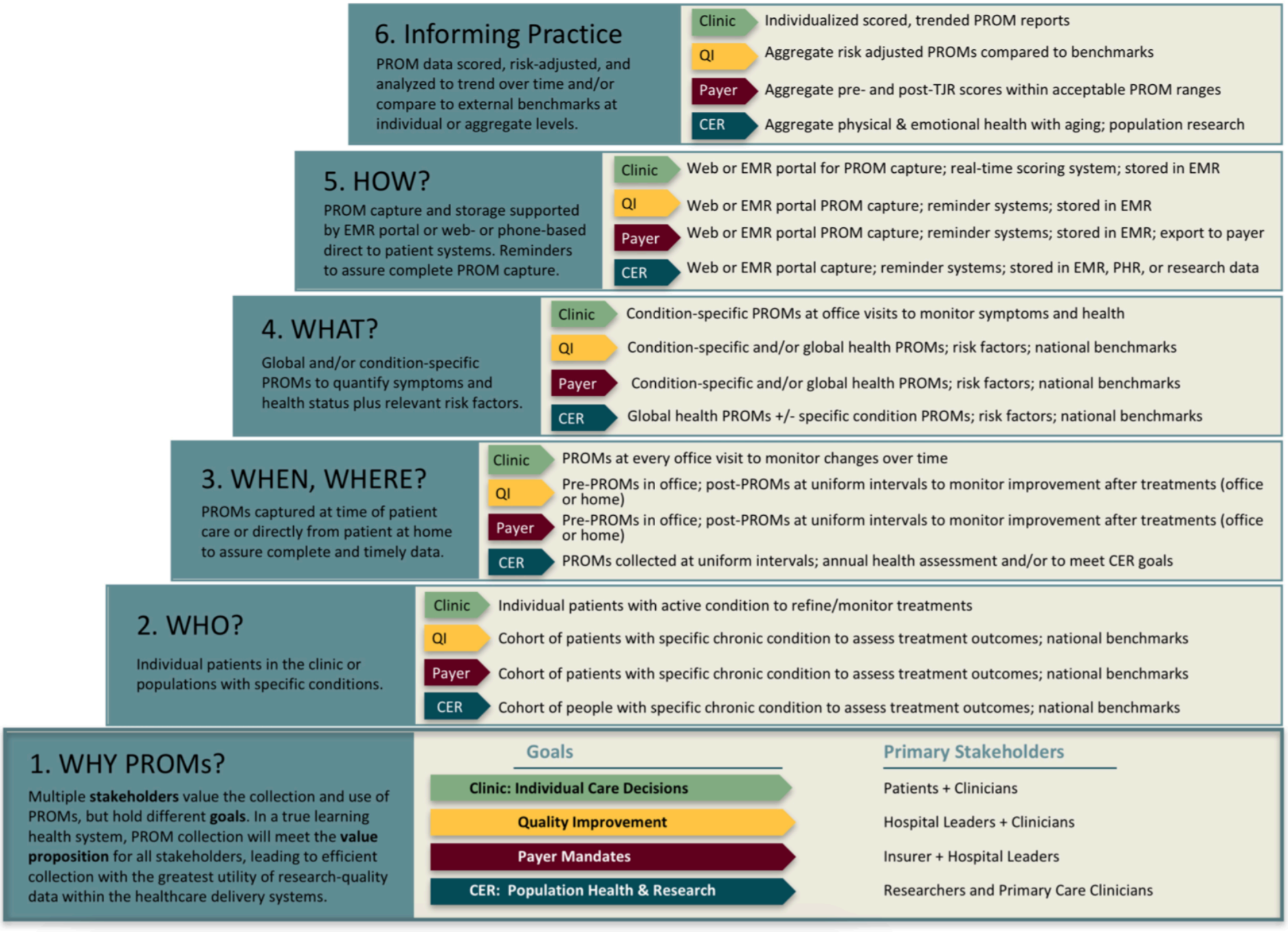
Framework To Guide The Collection And Use Of Patient-Reported Outcome Measures In The Learning Healthcare System.

Franklin PD, et al. eGEMs. 2017

- **Results:** Implementation framework and steps that are consistently identified by stakeholders as best practices to guide PROM capture and use are described.
- Of note, participants indicate that web-based informatics tools are necessary but not sufficient for PROM use, suggesting that successful PROM implementation **requires integration into clinic operations and careful planning for user's analytic needs**.
- Each of the four identified uses may require implementation modifications at each step to assure optimal use.

- **Conclusions:** Useful framework to guide future PROM implementation efforts across learning health care systems

Figure 1. Collection and use of PROMs in the Learning Health Care System



Other notable papers in this (PRO, SBDH and Perspectives) category:

- **Using social media to monitor mental health discussions – evidence from Twitter.** Chandler et al. JAMIA 2017
- **Users' Guide to Integrating Patient - Reported Outcomes in Electronic Health Records** Snyder/Wu editors. Johns Hopkins Univ. May 2017
- **Using structured and unstructured data to identify patients' need for services that address the social determinants of health.** Vest JR, et al. Int. Journ. Med. Informatics. 2017
- **Integrating Social Determinants of Health into Primary Care Clinical and Informational Workflow during Care Transitions.** Hewner S, et al. eGEMs. 2017
- **An Initial Evaluation of the Impact of Pokemon GO on Physical Activity**." Xian, Y, et al .J Am Heart Assoc 2017

Learning Health Systems and Delivery Science

Toward an Information Infrastructure for Global Health Improvement. Friedman, CP, et al. Yearbook Medical Informatics 2017

- LHSs can function at organizational, network, regional, and national levels of scale—and have the capability of continuous data-driven self-study that promotes change and improvement.
- The LHS concept, which originated in the U.S. in 2007, is rapidly gaining attention around the world.
- LHSs require, but also transcend, the secondary use of health data.
- Friedman and colleagues describe:
  - The key features of LHSs,
  - How effective and sustainable LHSs must be supported by infrastructures that allow them to function with economies of scale and scope
  - Describes the services that such infrastructures must provide.
- Great overview of LHS and informatics implications, in context of larger needs for operationalizing them

Toward an Information Infrastructure for Global Health Improvement. Friedman, CP, et al. Yearbook Medical Informatics 2017

Table 1 Learning Health System Consensus Core Values

1.)	Person-Focused	The LHS will protect and improve the health of individuals, families, groups, communities, and the general population by informing choices about health and care.
2.)	Privacy	The LHS will protect the privacy, confidentiality, and security of all data, as well as build trust among all stakeholders.
3.)	Inclusiveness	Every individual and organization committed to improving the health of individuals, communities, and diverse populations is invited and encouraged to participate.
4.)	Transparency	With a commitment to integrity, all aspects of LHS operations will be open and transparent to safeguard and deepen the trust of all stakeholders.
5.)	Accessibility	All should benefit from the public good derived from the LHS; therefore, the LHS should be available and should deliver value to all.
6.)	Adaptability	The LHS will be designed to enable iterative, rapid adaptation and incremental evolution to meet current and future needs of stakeholders.
7.)	Governance	The LHS will have that governance which is necessary to support its sustainable operation, to set required standards, and to build and maintain trust.
8.)	Cooperative and Participatory Leadership	The leadership of the LHS will be a multi-stakeholder collaboration across the public and private sectors.
9.)	Scientific Integrity	The LHS and its participants will share a commitment to the most rigorous application of science to ensure the validity and credibility of findings.
10.)	Value	The LHS will support learning activities that can serve to optimize both the quality and affordability of healthcare.

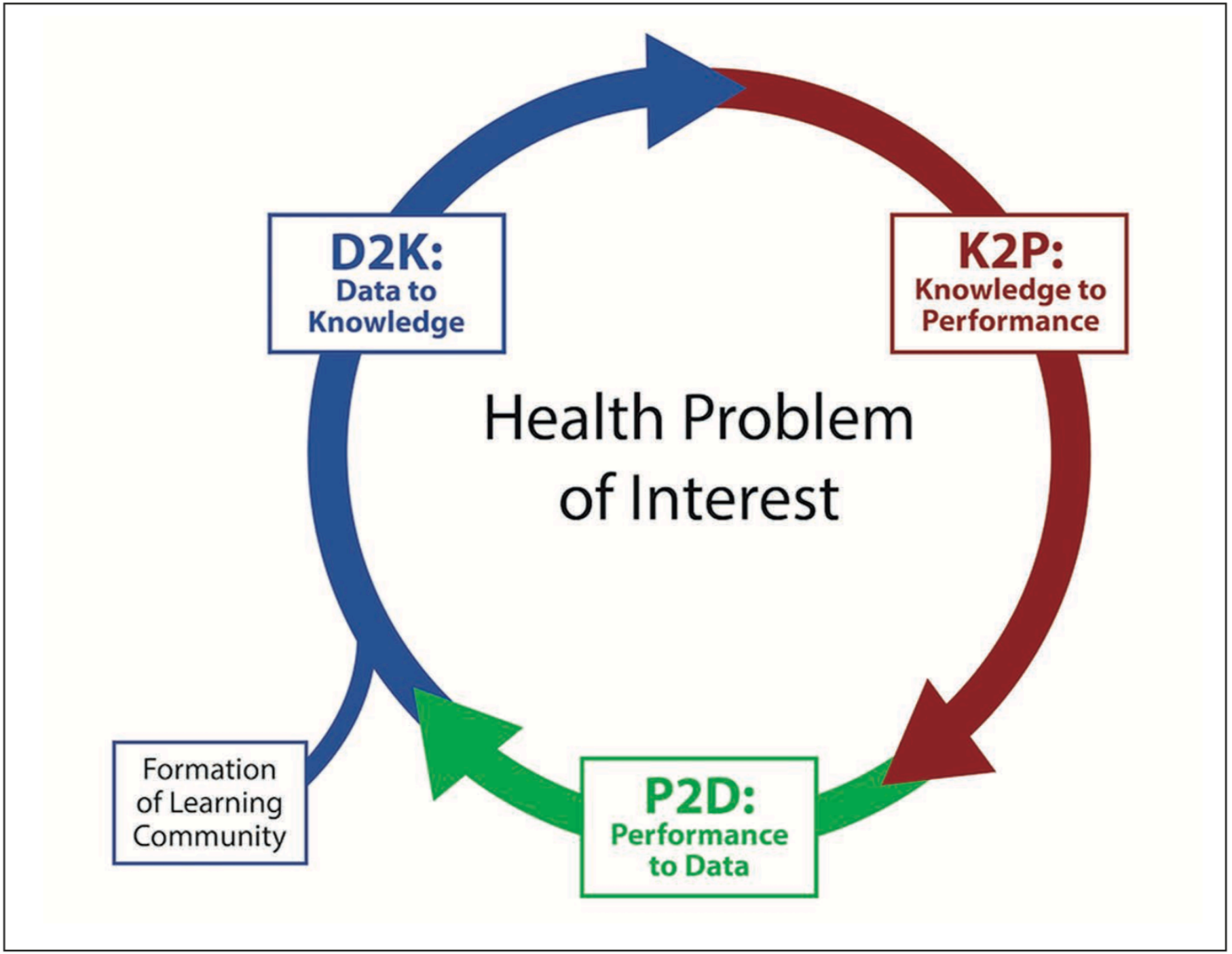


Fig. 1 The Learning Cycle

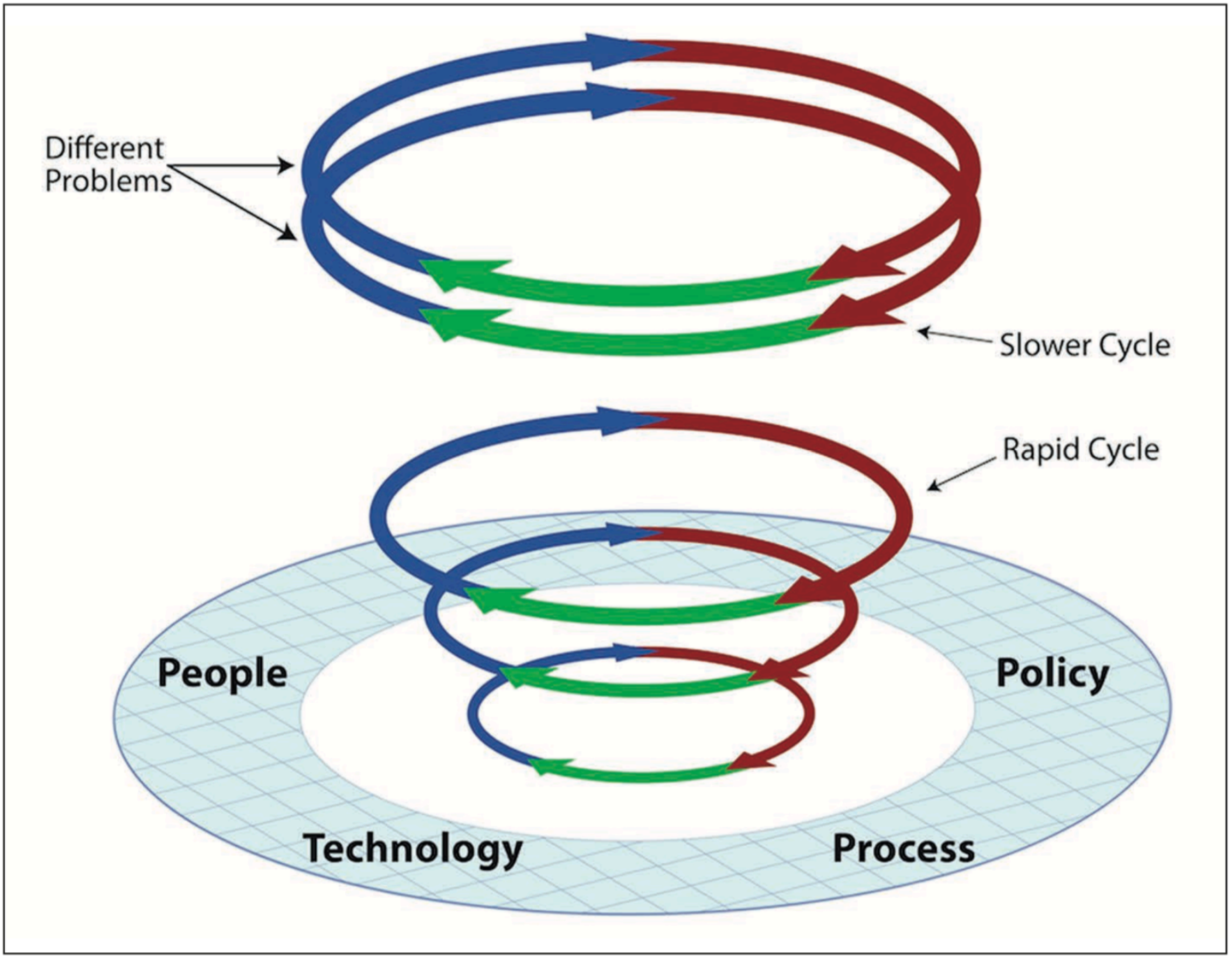


Fig. 2 Infrastructure Supporting Multiple Simultaneous Learning Cycles

Development of the Learning Health System Researcher Core Competencies.

Forrest CB et al. Health Serv Res. Aug 4 2017

- **OBJECTIVE:** To develop core competencies for learning health system (LHS) researchers to guide the development of training programs.
- **DATA SOURCES/STUDY SETTING:** Data obtained from literature review, expert interviews, a modified Delphi process, and consensus development meetings.
- **STUDY DESIGN:** The competencies were developed from August to December 2016 using qualitative methods.
- **DATA COLLECTION/EXTRACTION METHODS:** The literature review formed the basis for the initial draft of a competency domain framework. Key informant semi-structured interviews, a modified Delphi survey, and three expert panel (n = 19 members) consensus development meetings produced the final set of competencies.

Development of the Learning Health System Researcher Core Competencies.

Forrest CB et al. Health Serv Res. Aug 4 2017

- **PRINCIPAL FINDINGS:**
  - The iterative development process yielded seven competency domains:
  - (1) systems science;
  - (2) research questions and standards of scientific evidence; (3) research methods;
  - (4) **informatics**;
  - (5) ethics of research and implementation in health systems;
  - (6) improvement and implementation science; and
  - (7) engagement, leadership, and research management.
  - A total of 33 core competencies were prioritized across these seven domains. The real-world milieu of LHS research, the embeddedness of the researcher within the health system, and engagement of stakeholders are distinguishing characteristics of this emerging field.
- **CONCLUSIONS:** The LHS researcher core competencies can be used to guide the development of learning objectives, evaluation methods, and curricula for training programs.

Other notable papers in this (LHS/DS) category:

- **Analytical Methods for a Learning Health System: Delivery System Science.** Stoto M, Parry G, Savitz L. eGEMs 2017
- **Lessons Learned When Introducing Pharmacogenomic Panel Testing into Clinical Practice**. Rosenman, M. B., et al. Value Health 2017
- **Patient-Centered Network of Learning Health Systems: Developing a resource for clinical translational research** Rutten LF, et al. Journal of Clinical and Translational Science. 2017
- **The Delivery Science Rapid Analysis Program: a research and operational partnership at Kaiser Permanente Northern California.** Schittdiel JA, et al. Learning Health Systems. 2017
- **Bedside back to bench: building bridges between basic and clinical genomic research**. Manolio TA, et al. Cell. 2017 Mar 23;169(1):6-12.

CRI Ethics, Policy & Perspectives:

CRI Ethics, Policy & Perspectives:

- **Ethics, big data and computing in epidemiology and public health.** Salerno J, et al. Annals of Epidemiology 2017
- **Health information technology as a universal donor to bioethics education**. Goodman KW. Cambridge Quarterly of Healthcare Ethics 2017
- **Crossing the health IT chasm: considerations and policy recommendations to overcome current challenges and enable value-based care.** Adler-Milstein J, et al. JAMIA 2017
- **Pragmatic (trial) informatics: a perspective from the NIH Health Care Systems Research Collaboratory.** Richesson RL et al. JAMIA 2017
  - 4 broad categories of informatics-related challenges:
    - (1) using clinical data for research, (2) integrating data from heterogeneous systems, (3) using electronic health records to support intervention delivery or health system change, and (4) assessing and improving data capture to define study populations and outcomes.
    - These challenges impact the validity, reliability, and integrity of PCTs.
    - Informs work to enable PCTs and LHS.

CRI Ethics, Policy & Perspectives:

Emerging Role of the CRIO.

Sanchez-Pinto, et al. ACI 2017

The Emerging Role of the Chief Research Informatics Officer in Academic Health Centers

L. Nelson Sanchez-Pinto[1]; Abu S. M. Mosa[2]; Kate Fultz-Hollis[3]; Umberto Tachinardi[4]; William K. Barnett[5]; Peter J. Embi[3]*
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Keywords
Medical Informatics, Biomedical Research, Leadership, Academic Health Centers, Chief Research Informatics Officer

Summary
Background: The role of the Chief Research Informatics Officer (CRIO) is emerging in academic health centers to address the challenges clinical researchers face in the increasingly digitalized, data-intensive healthcare system. Most current CRIOs are the first officers in their institutions to hold that role. To date there is very little published information about this role and the individuals who serve it.
Objective: To increase our understanding of the CRIO role, the leaders who serve it, and the factors associated with their success in their organizations.
Methods: The Clinical Research Informatics Working Group of the American Medical Informatics Association (AMIA) conducted a national survey of CRIOs in the United States and convened an expert panel of CRIOs to discuss their experience during the 2016 AMIA Annual Symposium.
Results: CRIOs come from diverse academic backgrounds. Most have advance training and extensive experience in biomedical informatics but the majority have been CRIOs for less than three years. CRIOs identify funding, data governance, and advancing data analytics as their major challenges.
Conclusion: CRIOs play an important role in helping shape the future of clinical research, innovation, and data analytics in healthcare in their organizations. They share many of the same challenges and see the same opportunities for the future of the field. Better understanding the background and experience of current CRIOs can help define and develop the role in other organizations and enhance their influence in the field of research informatics.

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Citation: Sanchez-Pinto LN, Mosa ASM, Fultz-Hollis K, Tachinardi U, Barnett WK, Embi PJ. The Emerging Role of the Chief Research Informatics Officer in Academic Health Centers. Appl Clin Inform 2017; 8: 845–853
https://doi.org/10.4338/ACI-2017-04-RA-0062

* For the Clinical Research Informatics Working Group of the American Medical Informatics Association.

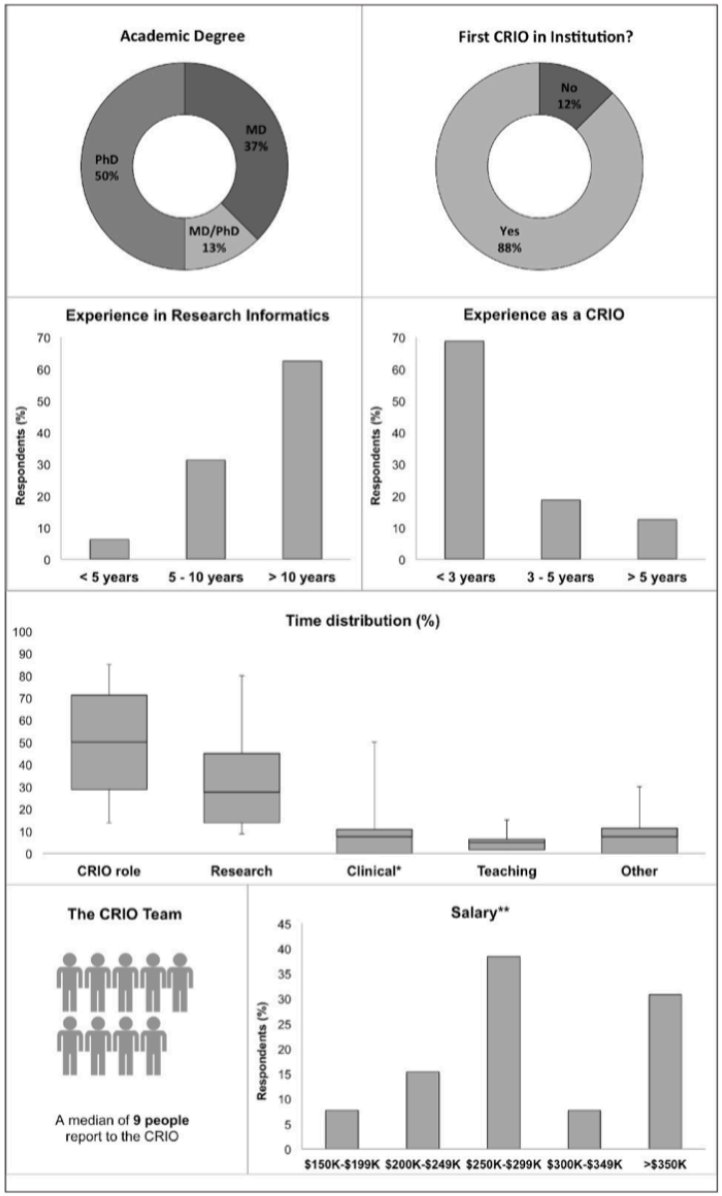
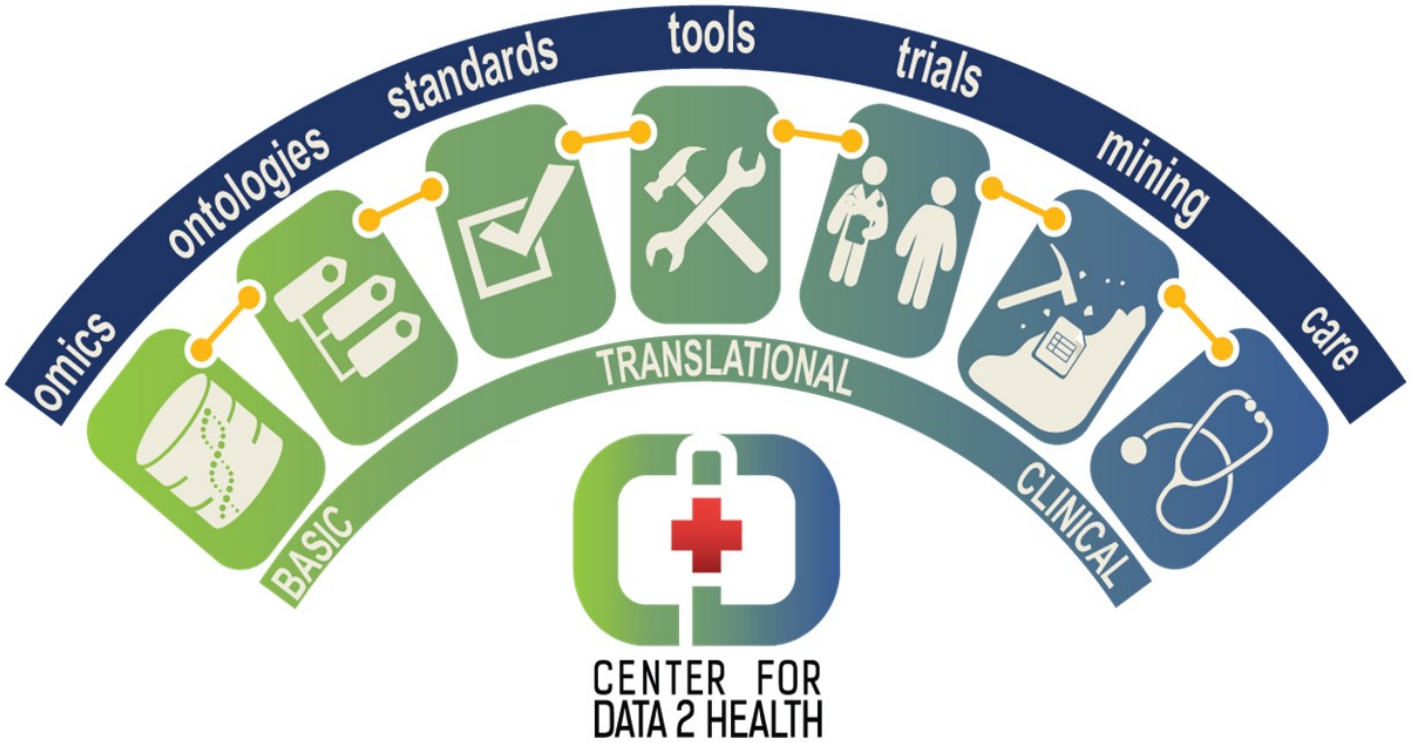


Fig. 1 Chief Research Informatics Officers (CRIOs) at al glance. *Clinical time calculated only for phys-

Notable CRI-Related Events

- NCATS CD2H Initiative



CD2H (NCATS) Haendel, Mooney, Wilbanks Holmes, Chute - PIs

Notable CRI-Related Events-2018

- NLM Strategic Plan
  - Released March 2018
  - "A Platform for Biomedical Discovery and Data-Powered Health," how NLM intends to achieve three core goals over the next ten years.
    - Accelerate discovery and advance health through data-driven research;
    - Reach more people in more ways through enhanced dissemination and engagement;
    - Build a workforce for data-driven research and health.

- NIH Releases draft Data Science Strategic Plan
  - Released concurrently with NLM strategic plan
  - Comments due first part of April

Notable CRI-Related Events

- **21st Century Cures Implementation**
  - Congressional support for research funding, especially at the NIH, has been essential given the severe cuts (20+ percent) proposed by White House
    - Bipartisan agreement in both the House and Senate around funding places many programs related to the 21st Century Cures Act on firm ground
  - Several activities and actions taken across FDA, NIH, ONC, and other HHS divisions have made progress on implementing the 21st Century Cures Act of 2016. Some examples to discuss:
    - FDA guidance on clinical decision support software
    - NIH All of Us and Cancer Moonshot
    - ONC Trusted Exchange Framework and Common Agreement

HIEs, Interoperability and TEFCA

- **ONC Trusted Exchange Framework and Common Agreement** (TEFCA) (https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement)
  - Ambitious set of policies meant enable more prevalent and ubiquitous sharing of clinical data
  - Research is among the permitted purposes for sharing clinical data (assuming additional requirements – e.g. common rule / HIPAA are met)
    - "Additionally, we seek a system where public health agencies and researchers can rapidly learn, develop, and deliver cutting edge treatments by having secure, appropriate access to Electronic Health Information."
  - Controversial; ONC has received a **high** volume of comments

- **Health Information Exchange Use (1990-2015): A Systematic Review.** Devine EB, et al. eGEMS 2017

Notable CRI-Related Events
Common Rule Enactment/Delays

- **Jan. 2017**: Obama administration finalizes 2018 Common Rule Revisions
  - Effective date and Compliance date: January 19, 2018
- **Jan. 2017**: Trump administration announces regulatory freeze, inc Common Rule
- Over next 12 months (the entirety of the Trump administration's first year): treated the 2018 Common Rule Revisions as though they were still under review
  - Difficult for federal officials to discuss policies and advance them
- **July 2017**: AMIA's Board of Directors sent a letter extolling the benefits of the 2018 Revisions and the need to move forward in a timely manner
- **January 2018**: Administration issues an Interim Final Rule (IFR), effectively gave stakeholders until July 2018 to comply with 2018 Revisions –additional six months of compliance
  - AMIA letter cited in the IFR to support six month delay to give regulated industry time to harmonize old and new provisions
- **March 2018**: AMIA submitted comments supporting the proposed effective date of **July 2018**, with a compliance date of January 2019.
  - This will allow institutions who are able to implement 2018 Revisions by July to do so, while giving others additional time to come into compliance

Notable CRI-Related Events: ***All of US* and *Cancer Moonshot***

- ***All of Us* Research goes beta, *Cancer Moonshot* takes flight** (https://allofus.nih.gov) (https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative)
  - NIH's All of Us Research Program has begun to enroll participants in its million-person cohort
    - Sync for Science – collaboration among researchers and EHR vendors to enable patients to donate their data for science (http://syncfor.science/)
      - pilots progressing; will have big implications for EHR-based research
    - Sync for Genes - step toward integrating clinical genomics into point-of-care encounters (http://www.sync4genes.org/)
      - pilot has concluded and advisors have suggested a 50,000-participant demonstration

Don Rucker, MD – ONC Director

Notable CRI-Related Events

In Summary…

- Informatics approaches in CRI continue to accelerate
  - **Much** more activity than in years past
  - I'm sure it will only continue!
- CRI continues to *mature* and is driving science
- Despite challenges, multiple federal and state initiatives continue to advance field
- CRI initiatives and investments beginning to realize the vision of the "*learning health system*"
- No question CRI is and will remain relevant
- A **very** exciting time to be in CRI!

Thanks!

Special thanks to those who suggested articles/events to highlight, particularly:

- Rachel Richesson
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- Erin Holve
- Jessie Tenenbaum
- Nick Anderson
- Jeff Smith

Thanks!

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