# Data Standards and PCOR: Thoughts, Priorities, and Recommendations

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MEDICAL SCHOOL
UNIVERSITY OF MICHIGAN

LEARNING HEALTH SCIENCES
*Revolutionizing Learning, Transforming Health*

**Evaluate**

Collect data and analyze results to show what does and does not work

**Real World Data**

**Real World Evidence**

**Adjust**

Use evidence to influence continual improvement

In a learning health care system, research influences practice and practice influences research

**Disseminate**

Share results to improve care for everyone

**Internal and External Scan**

Identify problems and potentially innovative solutions

**Implement**

Apply the plan in pilot and control settings

**Design**

Design care and evaluation based on evidence generated here and elsewhere

**Internal**

**External**

# Data Required for PCOR

- Patients / persons
  - Condition / phenotype
  - Status
  - Problem lists
  - Risk or protective factors
- Treatments and Interventions
  - Medical or Behavioral
    - (target – provider, pt., organization)
  - Nursing, PT, OT, Dietary, Education
  - Coordinated care
  - Person-controlled
  - Fidelity
- Goals and Preferences
- Outcomes & Endpoints
  - General and condition specific
  - Calculated or summary data
  - Clinical / Treatment response
  - Patient-reported
  - Patient-delivered

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# Standards to Consider

- SNOMED CT  ⟶  *Comprehensive Semantic based Concept-oriented Poly-hierarchical*
  - Problems
  - Medical
  - Nursing
  - Other clinical
  - Goals, preferences
  - Outcomes
- LOINC
  - questions / answers
  - document names
- Open mHealth – questions / answers
- HL7 – LHS care team; Gender Harmony
- HL7 FHIR – profiles, FHIR Accelerator projects
- BPM+ Health – clinical pathways, interventions, use cases
- AHRQ Outcome Measures Framework

What role can ASPE play in supporting effective standards to build data capacity that supports PCOR studies?

What characteristics of HHS' public mission, programs, or authorities could be leveraged?

Table 1.

## Patient characteristics:

**Table 1.** Patient Demographics and Baseline Characteristics

| Characteristic | No. (%) of Patients[a] | |
| --- | --- | --- |
| | Gentamicin-Collagen Sponge (n = 753) | Control (n = 749) |
| Patient demographics | | |
| Age, median (IQR), y | 64.2 (58.0-71.5) | 64.9 (57.2-72.1) |
| White race | 688 (91.4) | 683 (91.2) |
| Weight, median (IQR), kg | 98.0 (86.1-113.0) | 98.8 (85.0-111.1) |
| Body mass index, median (IQR) | 33.1 (30.2-37.2) | 32.8 (30.0-36.2) |
| Body mass index >30 | 574 (76.2) | 563 (75.2) |
| Male sex | 530 (70.4) | 530 (70.8) |
| Medical history | | |
| History of hypertension | 659 (87.5) | 659 (88.0) |
| History of diabetes | 493 (65.5) | 513 (68.5) |
| Current or history of smoking | 458 (60.8) | 450 (60.1) |
| Current smoking | 136 (29.7) | 123 (27.3) |
| History of chronic obstructive pulmonary disease | 117 (15.5) | 107 (14.3) |
| History of peripheral vascular disease | 105 (13.9) | 89 (11.9) |
| Previous median sternotomy | 52 (6.9) | 42 (5.6) |
| History of TIA or stroke | 77 (10.2) | 81 (10.8) |
| History of myocardial infarction | 233 (31.0) | 245 (32.7) |
| History of congestive heart failure | 89 (11.8) | 90 (12.0) |
| History of hyperlipidemia | 619 (82.2) | 607 (81.0) |
| Steroid use ≤1 mo prior to surgery | 28 (3.7) | 33 (4.4) |
| Receiving dialysis preoperatively | 4 (0.5) | 2 (0.3) |
| Preoperative diagnostic values | | |
| Left ventricular ejection fraction, median (IQR), % | 55 (45-60) | 55 (45-60) |
| Serum glucose, median (IQR), mg/dL | 125 (101-160) | 124 (103-167) |
| Serum hemoglobin A₁c, median (IQR), % | 6.5 (5.9-7.6) | 6.6 (5.9-7.7) |
| Hematocrit, median (IQR), % | 39 (36-42) | 39 (36-42) |
| Serum creatinine, median (IQR), mg/dL | 1.0 (0.9-1.3) | 1.0 (0.9-1.2) |
| Preoperative core temperature, median (IQR), °C | 97.6 (97.0-98.2) | 97.7 (97.0-98.2) |
| Preoperative hospital stay, median (IQR), d | 1.0 (0-3.0) | 1.0 (0-3.0) |
| Parsonnet risk score, median (IQR)[b] | 9.0 (6.0-14.5) | 9.0 (6.0-16.0) |

Abbreviations: IQR, interquartile range; TIA, transient ischemic attack.
SI conversion factors: To convert creatinine to μmol/L, multiply by 88.4; glucose to mmol/L, multiply by 0.0555.
[a]Unless otherwise indicated.
[b]Theoretical range is 0 to 148; 50% in Parsonnet et al[11] had a score between 0 and 9.

## Multiple possible phenotypes:

**SUPREME-DM Phenotype**

Definition:
Adult Durham Population patients who meet **ONE OR MORE** of the following criteria during a DukeMed encounter between 2007-2011:

- One or more instances of the specified ICD-9-CM diagnosis codes (**see table 7**) on an inpatient encounter
- OR 2 or more instances of the specified ICD-9-CM diagnosis codes (**see table 7**) on outpatient encounters on separate days
- OR 1 or more instances of active stand-alone medication (**see table 8**) reported during outpatient medication reconciliation[3]
- OR 1 or more Oral Glucose Tolerance Test (OGTT) 2-hour 75g result >= 200 mg/dl where there is NO DIAGNOSIS CODE on the same encounter indicating pregnancy (V22, V23)[4]
- OR 2 or more hemoglobin A1c results >= 6.5% on 2 different days within 730 day span
- OR 2 or more fasting glucose results >= 126 mg/dl on 2 different days within 730 day span
- OR 2 or more random glucose results >= 200 mg on 2 different days within 730 day span
- OR within a 730 day span on 2 different days:
  - Fasting glucose results >= 126 mg/dl
  - AND Random glucose results >= 200 mg
- OR within a 730 day span (can be same day):
  - Hemoglobin A1c results >= 6.5%
  - AND Fasting glucose results >= 126 mg/dl

**Abnormal Lab Results**

Source:
Laboratory results

Definition:
Adult Durham Population patients who meet **ONE OR MORE** of the following criteria during a DukeMed encounter between 2007-2011:

- One or more instances of hemoglobin A1c results >= 6.5%
- OR one or more fasting glucose results >= 126 mg/dl within 365 day span
- OR one or more random glucose results >= 200 mg/dl within 365 day span

**Abnormal HbA1c (NCY A1c Registry Definition)**

Source:
Glycated hemoglobin laboratory results

Definition:
Adult Durham Population patients who meet **ONE OR MORE** of the following criteria during a DukeMed encounter between 2007-2011:

- One or more instances of hemoglobin A1c results >= 6.5%
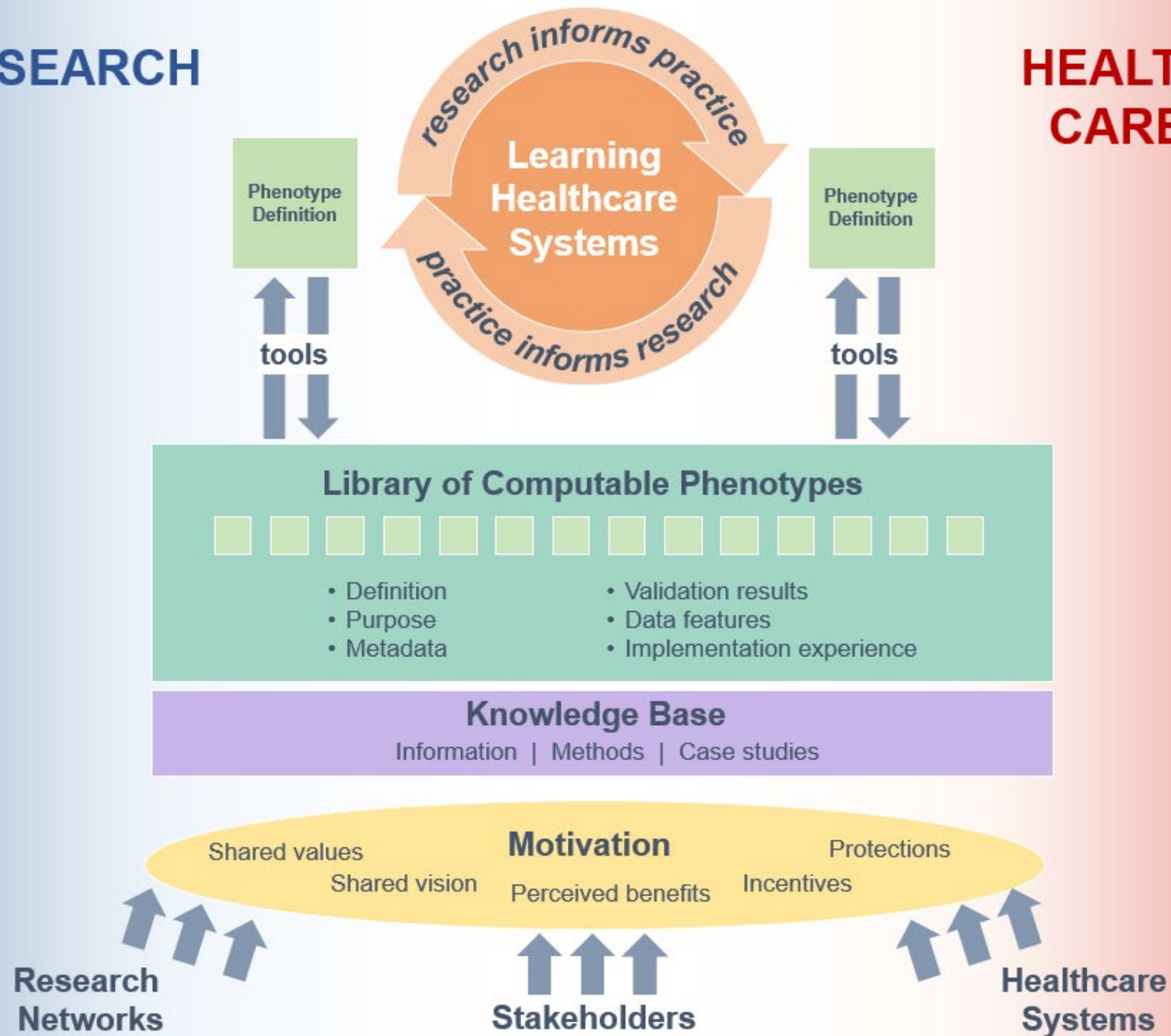
**Opportunity –**

**Intensional value sets**: Willett, Duwayne L et al. "SNOMED CT Concept Hierarchies for Sharing Definitions of Clinical Conditions Using Electronic Health Record Data." *Applied clinical informatics* vol. 9,3 (2018) 667-682. doi:10.1055/s-0038-1668090

From: Richesson et al. "A Framework to Support the Sharing and Reuse of Computable Phenotype ..." *EGEMS* 2016, doi:10.13063/2327-9214.1232

# Approaches

- Leverage processes of existing SDOs

- Encourage patient <u>engagement</u> in SDOs (e.g., HL7 PEW)

- Support <u>tooling</u> for use of standards in <u>real-world settings</u>

- Promote terminologies (semantic) & intrinsic value sets "groupers"

- Concept maps / Information Models – see nursing work
  - Westra BL et al. A refined methodology for validation of information models derived from flowsheet data and applied to a genitourinary case. J Am Med Inform Assoc. 2020 Nov 1;27(11):1732-1740. doi: 10.1093/jamia/ocaa166. PMID: 32940673

- Show <u>value</u> of standards for App development and dissemination

- Create tools to <u>make it easy</u> for App developers (of all types)

- Standards roadmaps

- Feedback loops on standards – are they useful? Granular enough?

- Rinse and repeat