The Office of the National Coordinator for Health Information Technology
Clinical Decision Support
Evidence to Action

Clinical Decision Support

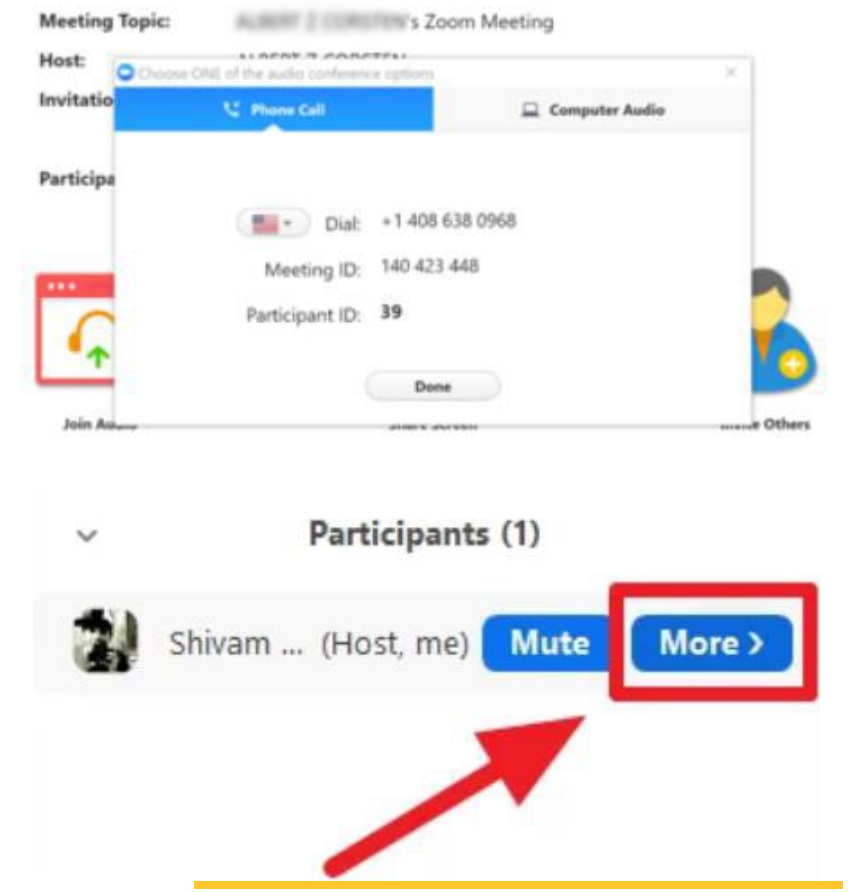
Tuesday, September 15, 2020

10:00am – 4:30pm

The Office of the National Coordinator for Health Information Technology

Housekeeping: Steps for Joining the Meeting

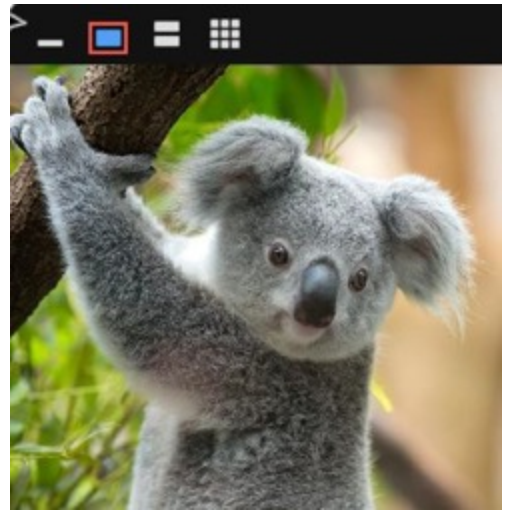
1. You can join via phone or computer to access audio. **Please keep yourself muted to avoid background noise and turn off your webcam.**
2. Please ensure that you list your full name by hovering over your name on the participant list, clicking “More” and clicking “**Rename**.” This is important so we know who you are.
3. If you have questions during the meeting, please send them via the **chat box** on your Zoom dashboard, which will be monitored by the meeting facilitators.

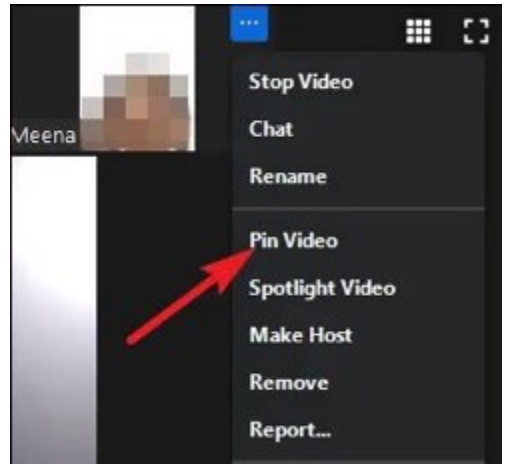


The Office of the National Coordinator for Health Information Technology

Housekeeping cont.

- How to use active speaker view
  - To view speaker's video as a large Active Speaker panel, click the Active Speaker Panel icon above the video panel.
- How to pin video
  - At the top of your screen, hover over the three dots on the video of the speaker you want to pin and click Pin Video





National Academies of Medicine Report: *Optimizing Strategies for Clinical Decision Support*

James E. Tcheng, MD – Duke University
james.tcheng@duke.edu

DukeHealth

Project Background

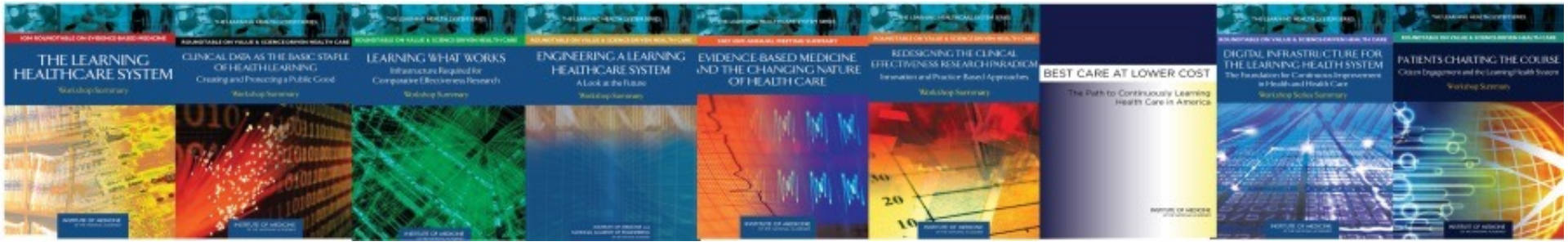
- **Partnership:** National Academy of Medicine (NAM) & Office of the National Coordinator for Health IT (ONC)
- **Aim:** To reflect on the current CDS environment, then identify potential approaches & recommend practical strategies for improving CDS practices and adoption
- **Leadership:** External Planning Committee
- **Deliverable:** Special NAM Publication (Nov 2017)

Planning Committee Members

- James Tcheng, Duke University (Chair)
- Suzanne Bakken, Columbia University
- David Bates, Brigham and Women's Hospital
- Hugh Bonner III, Saint Francis Hospital
- Tejal Gandhi, National Patient Safety Foundation
- Meredith Josephs, Privia Health
- Edwin A. Lomotan, AHRQ
- Erin Mackay, National Partnership for Women & Families
- Jonathan Teich, Harvard University
- Scott Weingarten, Cedars-Sinai Health System

Developing Priorities for Action

- Over the course of the project, a comprehensive key set of actions was identified. Participants prioritized the following actions for optimizing strategies for CDS adoption and use, offered actionable collaborative steps that could be initiated over the next 5 years.
- These actions will require commitment by multiple stakeholders and are intended to move forward the discussion in a way that complements and enhances clinical practice.



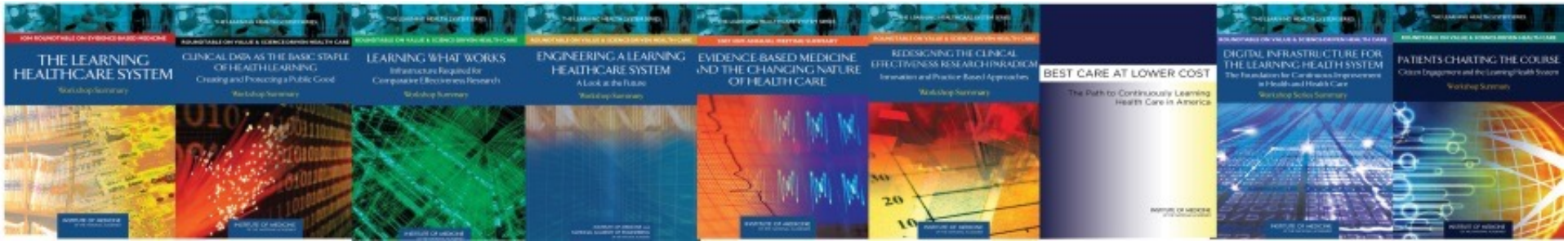
Workgroups

Presenter	Institution and Role	Topic
James Tcheng, MD	Professor, Duke University Chair, NAM Planning Committee	Overview of National Academy of Medicine (NAM) CDS initiative
Kensaku Kawamoto, MD, PhD, MHS	Associate CMIO, Univ. of Utah	Strategies for CDS content
Scott Weingarten, MD, MPH	SVP & Chief Clinical Trans-formation Officer, Cedars-Sinai	Strategies for CDS implementation
Blackford Middleton, MD, MPH, MS	Chief Informatics & Innovation Officer, Apervita, Inc.	Strategies for CDS dissemination
Jonathan Teich, MD, PhD	Dept. Med. & Emergency Med. Brigham & Women's / Harvard	Strategies for CDS operations
James Tcheng, MD	Professor, Duke University Chair, NAM Planning Committee	Cross-cutting recommendations

Priorities for Action

1. Establish Clinical Decision Support (CDS) technical standards.

- Develop coordinated activities to stand up standard intervention templates, methods, artifacts, and intervention repositories.
- Develop a standard set of each of the core CDS operational elements such as EHR trigger points, action items, and supporting data [leveraging existing work such as the 2012 NQF Expert Panel report and existing HL7 standards] to increase predictability of the EHR environment.
- Establish repeatable conventions [e.g., FHIR resources, APIs] to pass data and context/situational info from the EHR to the CDS and to accept recommendations from the CDS back to the EHR.
- Stand up an entity of appropriate stakeholders to resolve governance issues and drive EHR vendor acceptance for support of CDS standards.



Priorities for Action

- **Develop, test, establish, validate, and apply standards**
  - Establish CDS technical standards
  - Provide federal funding for CDS standards management
  - Create a CDS technical information resource
- **Encourage adoption, use & assessment at the delivery system level**
  - Disseminate best practices
  - Create a national CDS repository network
  - Measure CDS usage
  - Develop tools to assess CDS efficacy
  - Publish performance evaluations
  - Leverage meaningful financing and measurement incentives
  - Market CDS to stakeholders
- **Establish a national CDS infrastructure**
  - Create a CDS legal framework
  - Develop a multi-stakeholder CDS learning community to inform usability
  - Establish a federal investment program in CDS research

NATIONAL ACADEMY of MEDICINE

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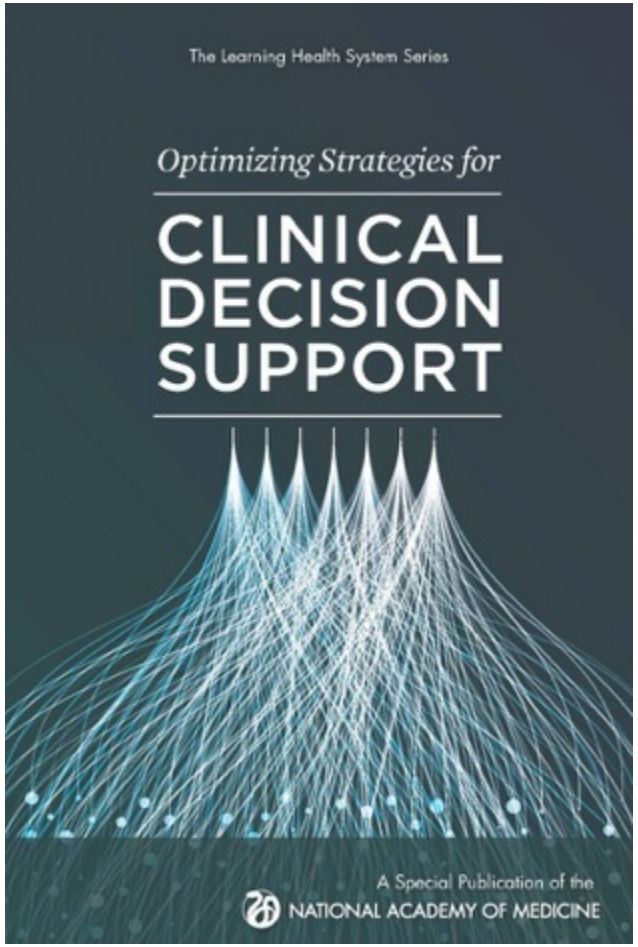
Optimizing Strategies for Clinical Decision Support

| Summary of a Meeting Series

https://nam.edu/optimizing-strategies-clinical-decision-support/





AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

AHRQ

Interoperable CDS to Support Dissemination and Implementation of New Clinical Knowledge: Evidence from Two Pain Management Projects

Roland Gamache, PhD, MBA, FAMIA, Staff Fellow, Division of Digital Healthcare Research, AHRQ

Kristen E. Miller, DrPH, CPPS, National Center for Human Factors in Healthcare, MedStar Health

Joshua E. Richardson PhD, MS, MLIS, RTI International

Agenda

- **Welcome and AHRQ Perspective** – Roland Gamache, PhD, MBA, FAMIA
- **Clinical Decision Support (CDS) for Chronic Pain Management** – Kristen Miller, DrPH, CPPS
- **Shareable Clinical Decision Support for Chronic Pain Management to Promote Shared Decision-Making (CDS4CPM)** – Joshua Richardson, PhD, MS, MLIS
- **Summary**
- **Question and Answer Session**

AHRQ's Introduction to the Shareable Clinical Decision Support Pain Management Projects

Roland Gamache, PhD, MBA, FAMIA

AHRQ Clinical Decision Support

Advancing evidence into practice through CDS and making CDS more shareable, standards-based and publicly- available

https://cds.ahrq.gov

Vision for the Future

Advanced analytic techniques:
Artificial intelligence
- Natural language processing
- Machine learning

My Data
- Clinical & Contextual
- Patient-generated

Biomedical Knowledge
- Guidelines
- Relevant research findings

Advanced Analytics

Needs to be computable and FAIR!

- **F**indable
- **A**ccessible
- **I**nteroperable
- **R**eusable

Pain Management Contract Aims

The purpose is to develop, implement, disseminate, and evaluate CDS for both patients and clinicians in the area of chronic pain management

AHRQ developed and generated interest in CDS that:

- Is interoperable and publicly-shareable
- Meets the needs of both patients and clinicians
  - Through both
    - patient-facing channels and formats
    - clinician-facing channels and formats
- Has demonstrable impact
  - Can be evaluated using appropriate measures and outcomes
  - Share lessons learned through presentations and publications

Brief Introduction to the Individual Projects

MedStar

- Focus on non-pain management specialists in primary care
- Optimizing pain therapy and support opioid-dose reductions

RTI

- Develop, implement, and disseminate two types of FHIR-based CDS for chronic pain management in primary care and pain clinics

Clinical Decision Support (CDS) for Chronic Pain Management

MedStar Health
National Center for Human Factors in Healthcare

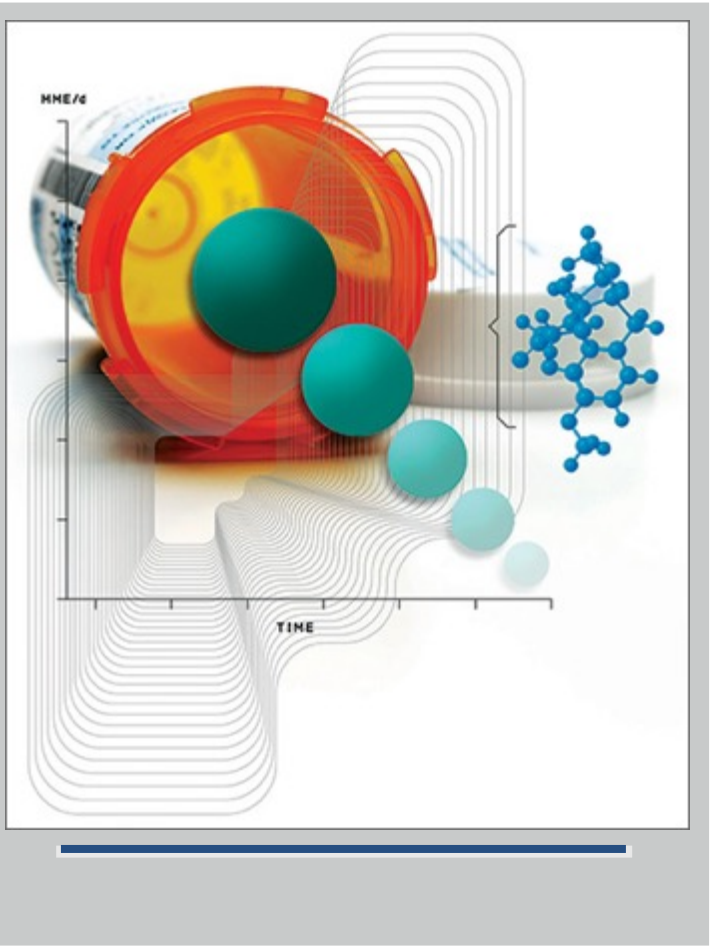
Principal Investigators: Kristen Miller, DrPH
& Aaron Zachary Hettinger, MD, MS
Project Managers: Robin Littlejohn, MS & Christopher Washington, MA

MedStar Team Members: Jim Houston, MD, Elias Shaya, MD, Peter Basch, MD, Bonnie Levin, PharmD, MBA, FASHP, Kathryn Walker, PharmD, Ella Franklin, MSN, RN, Long La, PharmD, Sidd Nambiar, PhD, Joseph Blumenthal, Shrey Mathur, MS, Shrenik Shah, MS, John Erkus, Peter Kuehl, MD, Deliya Wesley, MPH, PhD, Sadaf Kazi, PhD, Kelly Smith, PhD, Nawar Shara, PhD, Ronald Romero Barrientos, Christian Boxley, Deanna Busog

Development Team: Perk Health
Collaborators: Georgetown University Medical Center, George Washington University, IMPAQ Int.

Consultants: Alan Staples, II, CRCR, Ross Teague, PhD, Ranit Mishori, MD, MH

Opioid Tapering



- Liberal prescribing of opioids for chronic pain has acute and chronic problems for patients on long term opioid therapy
- Long-term opioid use: physical dependence, constipation and nausea, fatigue, depression…
- Patients may be reluctant to taper fearing increased pain and withdrawal symptoms: vomiting, hallucination, tremors…
- Clinicians must assess and weigh risks versus benefits to decide whether tapering is indicated
- Tapering plans should be individualized and should minimize symptoms of opioid withdrawal while maximizing pain treatment with nonpharmacologic therapies and nonopioid medications
- Barriers include challenging and exhausting communications, inadequate resources, and lack of training

Task Overview

- Goal: Optimize pain therapy and support opioid-dose reductions
- Clinician-facing CDS
  - » Provide personalized evidence-based guidelines to support opioid tapering
  - » Optimize presentation of patient generated and electronic health record data
- Patient-facing CDS
  - » Track and manage pain and daily function to support reduced opioid use
  - » Support continued patient engagement including education and resources
- Implementation and Evaluation

Application of Human Factors Engineering Methods

- **Multi-Disciplinary Research Workgroups**
  - » Experts in pain management, behavioral science, patient reported outcomes, health IT, clinical medicine including chronic pain management, human factors engineering
- **Stakeholder Interviews**
  - » Patients with chronic pain; family members of patients with chronic pain
  - » Primary care providers; pain management specialists
  - » Health IT developers focused on patient-facing and clinician-facing technologies
- **Design Workshops**
- **Usability Testing**

Application Flow

Initial Visit

1. Introduce a Taper
2. Set Taper Parameters
3. Confirm Medication Plan

Home Experience

1. Track and Manage Pain and Daily Function
2. Support Continued Patient Engagement

Follow-Up Visit

1. Review Patient-Reported Data
2. Update Medication Plan

MedStar Health
National Center for Human Factors in Healthcare

Taper App

Help & Guidelines

EHR Patient Data Screen

Create Taper

- Patient Context
- Taper Settings
- Opioid Taper Plan
- Non-Opioid Plan
- Patient App

Patient Context

Start

Current Opioid Medications

Oxycodone ER 40mg, 40mg PO Q12hrs	80 mg (120 MME)
Oxycodone IR 5mg, 5mg PO Q4 hours	30 mg (45 MME)
	Total 165 MME

PDMP

(5/2/20) oxycodone ER 40mg, Q12 hours PO, 60 tablets
(5/2/20) oxycodone IR 5mg, Q4 hours PO, 60 tablets, 180 tablets
(5/2/20) oxycodone ER 40mg, Q12 hours PO, 60 tablets
(5/2/20) oxycodone IR 5mg, Q4 hours PO, 60 tablets, 180 tablets
(5/2/20) oxycodone ER 40mg, Q12 hours PO, 60 tablets
(5/2/20) oxycodone IR 5mg, Q4 hours PO, 60 tablets, 180 tablets

Controlled Substance Agreement Last updated 10/27/19
Last Urine Toxicology: Positive for Marijuana: 2/15/20 Details

Other Current Medications

ibuprofen 800mg Q8hrs PO PRN Pain
metoclopramide 10mg Q6hrs PO PRN Nausea

Social History

Marijuana

Current Relevant Diagnosis

Chronic Pain, Diabetes

How to use Taper App - Placeholder

1. Use this tool to create a guidelines based opioid reduction, non-opioid pain plan, and withdrawal support plan for next taper interval.

2. Collect relevent Patient Reported Outcomes from the patient app.

Patient App - Placeholder

Placeholder for …PROMIS Measures

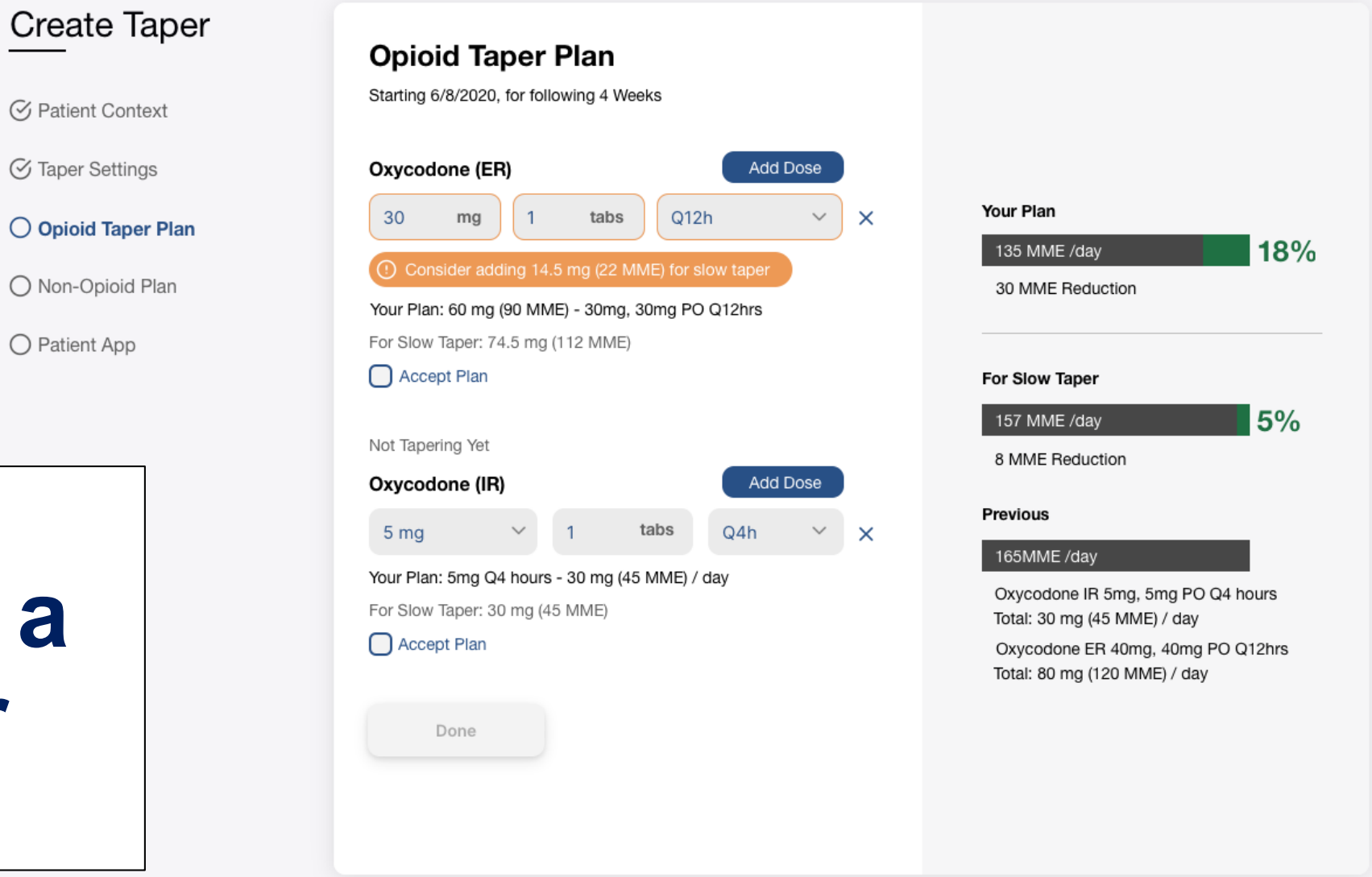
Pain Journal

Patient Education

Taper Guidelines - Placeholder

Placeholder for …links to VA/CDC

Create a Taper



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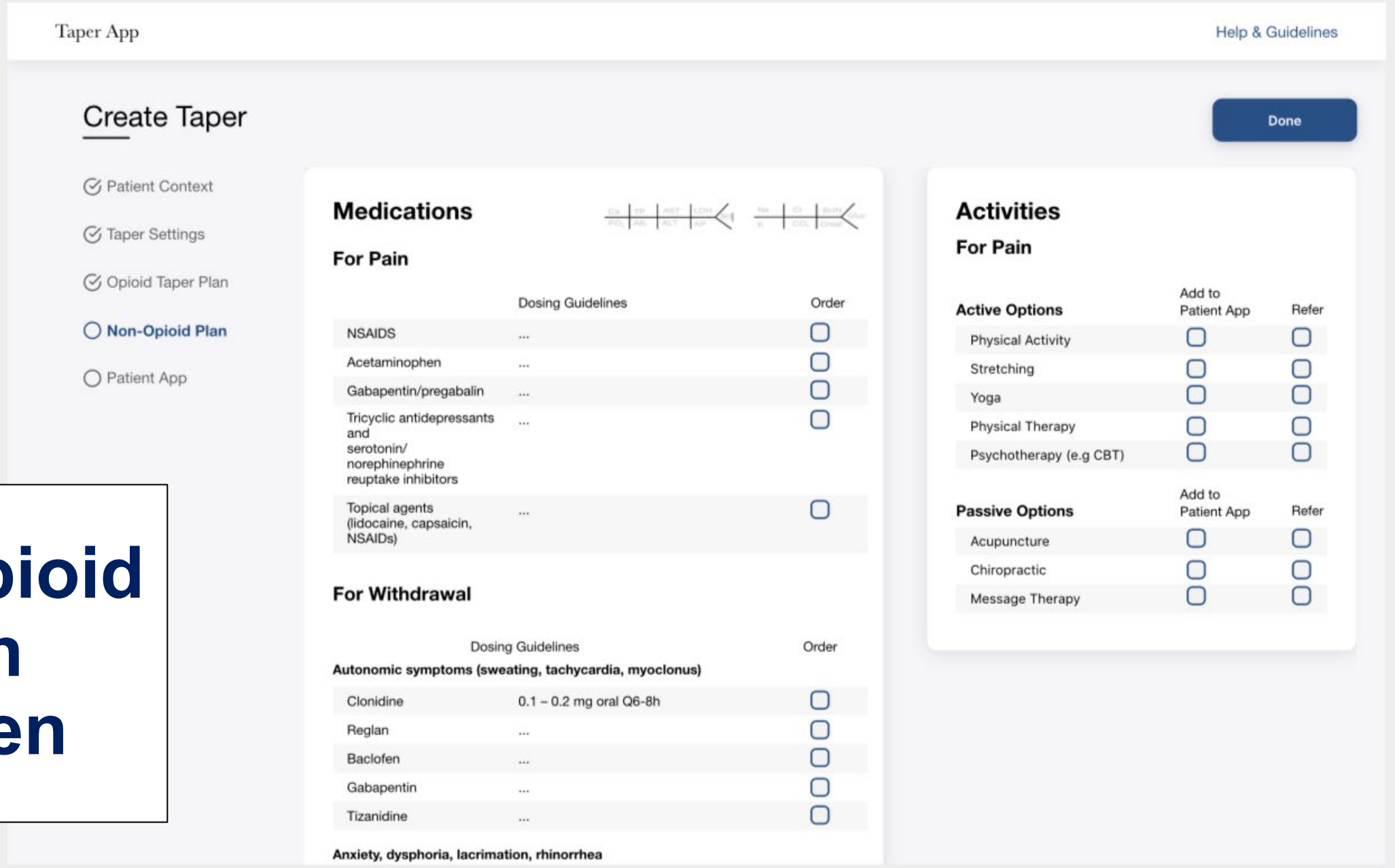
Non-Opioid Pain Screen



Application Flow

Initial Visit

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Home Experience

1. Track and Manage Pain and Daily Function
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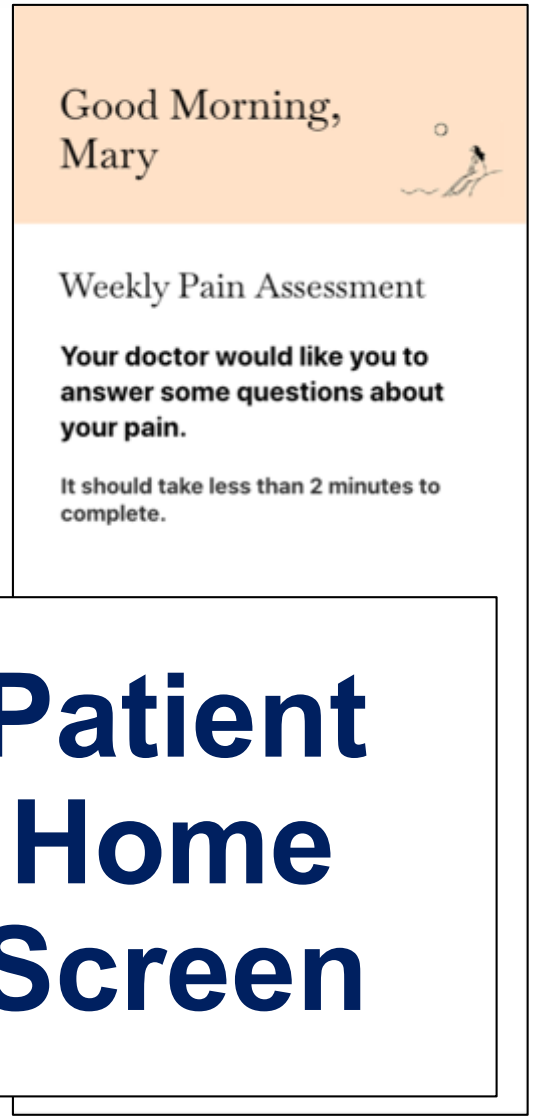
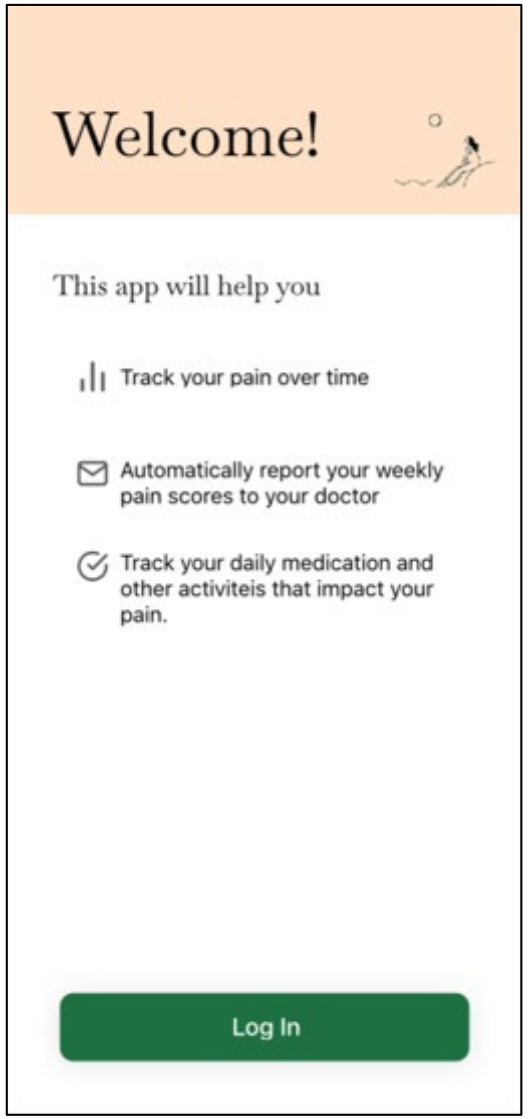
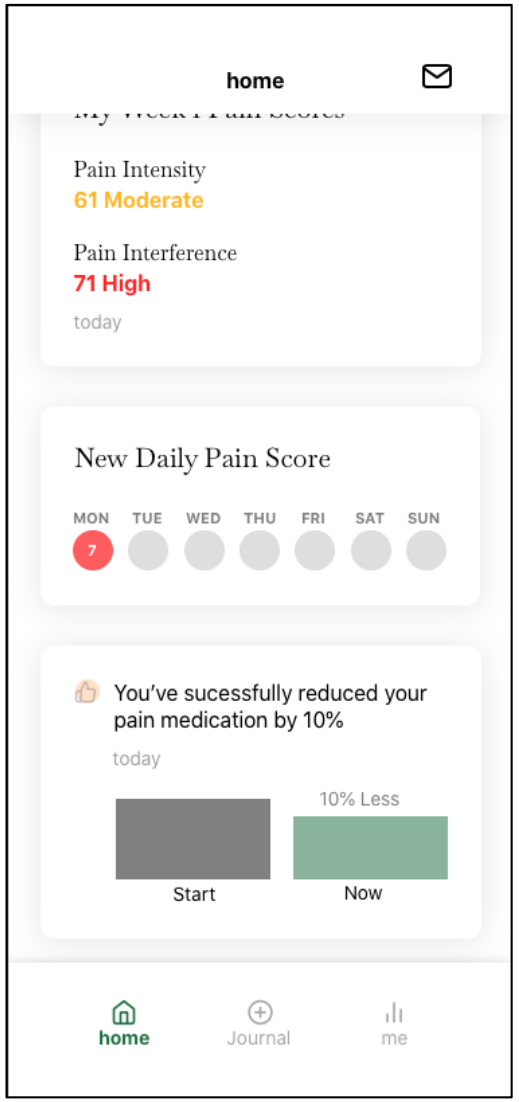
Follow-Up Visit

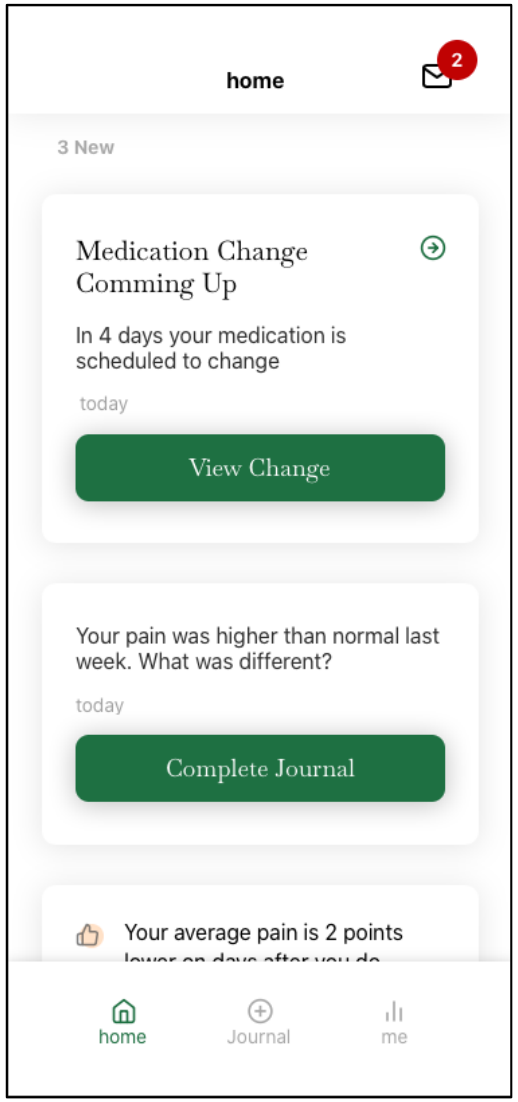
1. Review Patient-Reported Data
2. Update Medication Plan

Patient Home Screen









1

PROMIS

Adult Item Bank: e.g. from Pain Interference

In the past 7 days…

	Not at all	A little bit	Somewhat	Quite a bit	Very much
How difficult was it for you to take in new information because of pain?	1	2	3	4	5
How much did pain interfere with your enjoyment of life?	1	2	3	4	5
How much did pa… to participate in le…					
How much did pa… personal relations…					
How much did pa… to concentrate?…					
How much did pa… day activities?…					
How much did pa… enjoyment of recr…					

2

PROMIS

Adult Item Bank: e.g. from Pain Intensity

Please respond to each item by marking one box per row.

In the past 7 days…	Had no pain	Mild	Moderate	Severe	Very severe
How intense was your pain at its worst?…	1	2	3	4	5
How intense was your average pain?…	1	2	3	4	5

	No pain	Mild	Moderate	Severe	Very severe
What is your level of pain right now?…	1	2	3	4	5

In The Past 7 Days...

How much did pain interfere with your day to day activities?

- Not At All
- A little Bit
- Somewhat
- Quite A Bit
- Very Much

In The Past 7 Days...

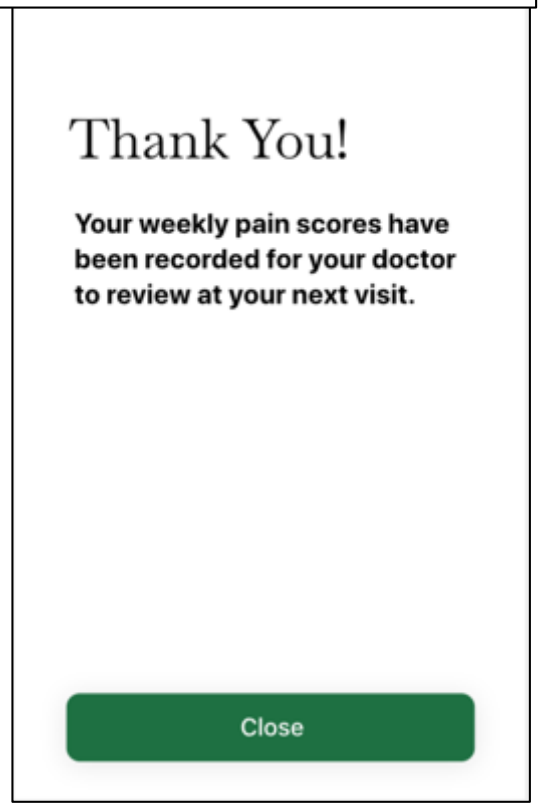
How much did pain interfere with your ability to participate in social activities?

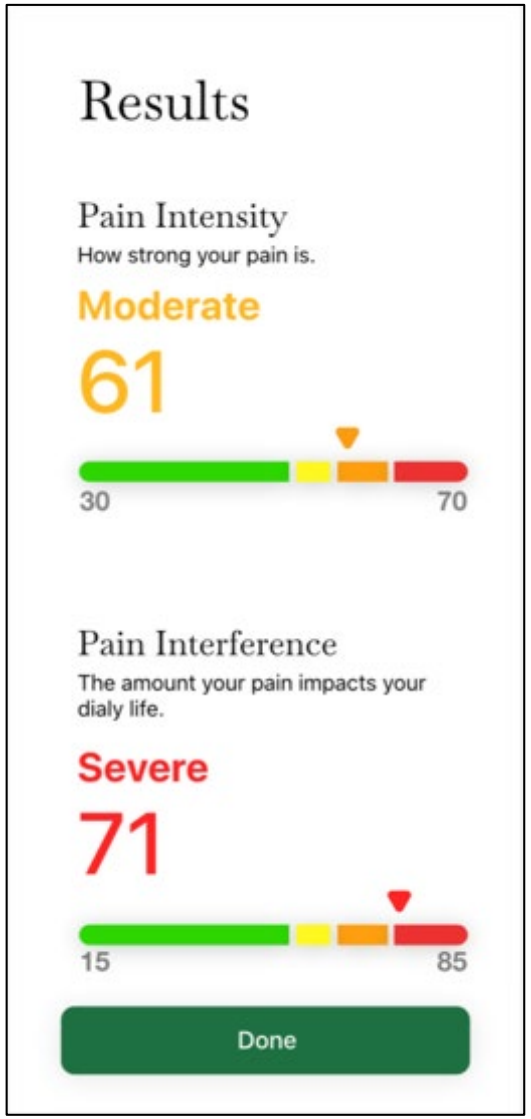
- Not At All
- A little Bit
- Somewhat
- Quite A Bit
- Very Much

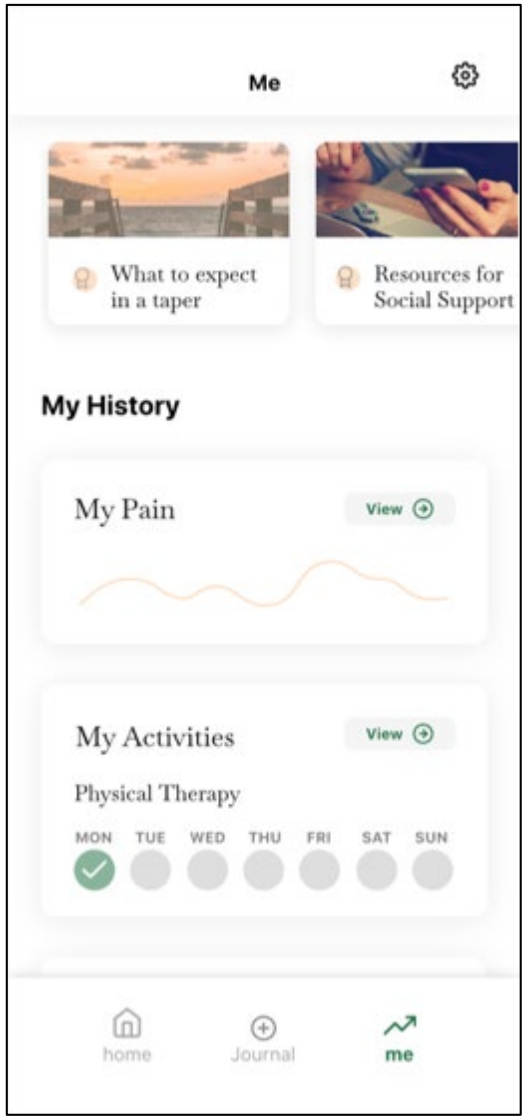
In The Past 7 Days...

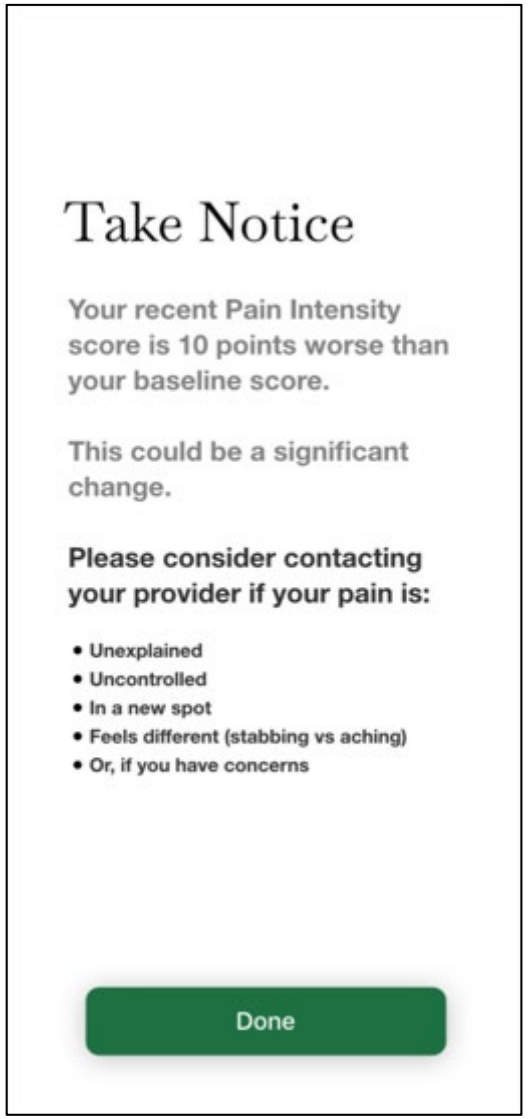
How intense was your pain at its worst?

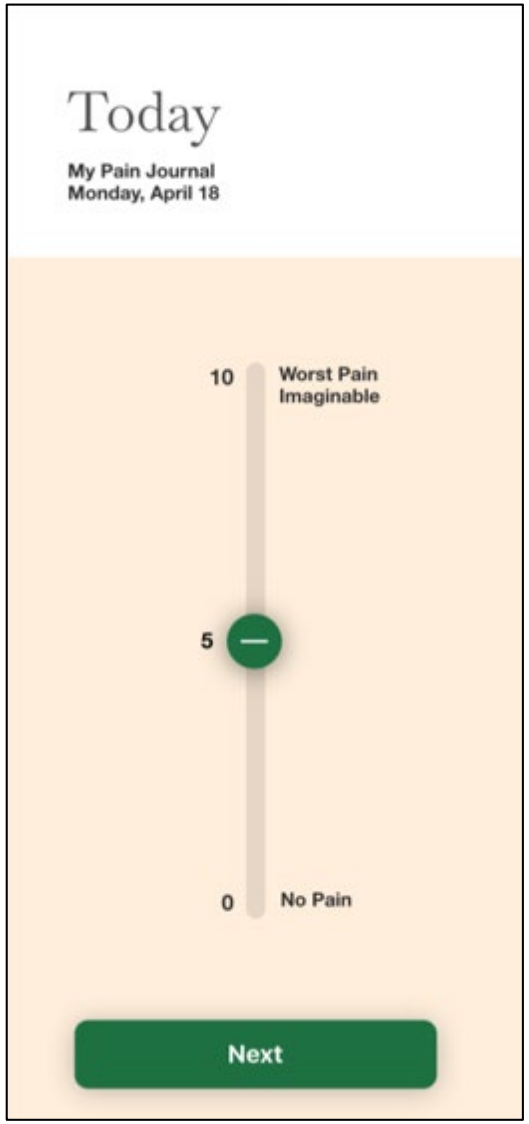
- Had No Pain
- Mild
- Moderate
- Severe
- Very Severe

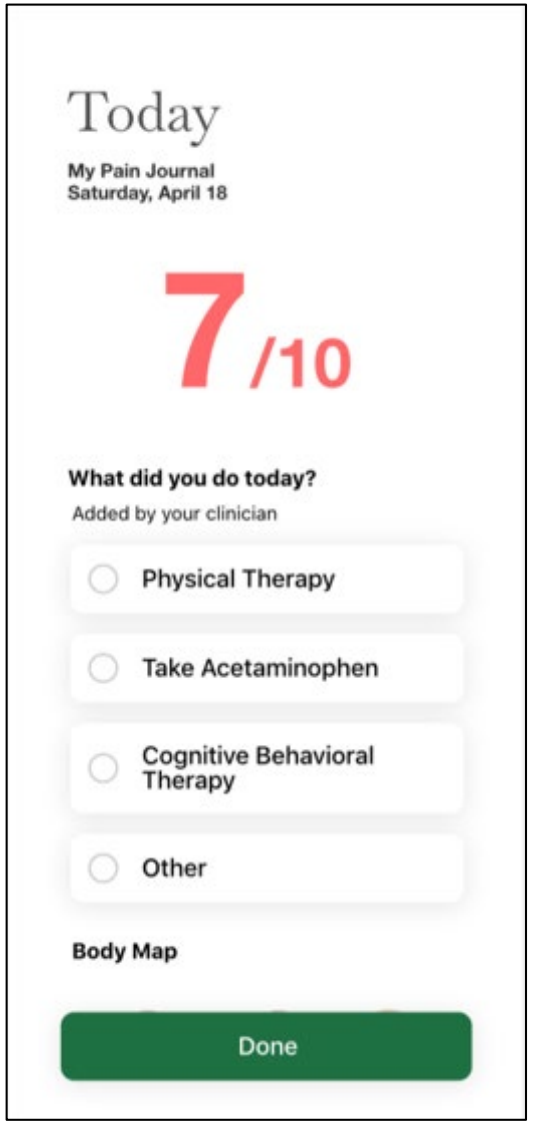

Thank You!
Your weekly pain scores have been recorded for your doctor to review at your next visit.
Close

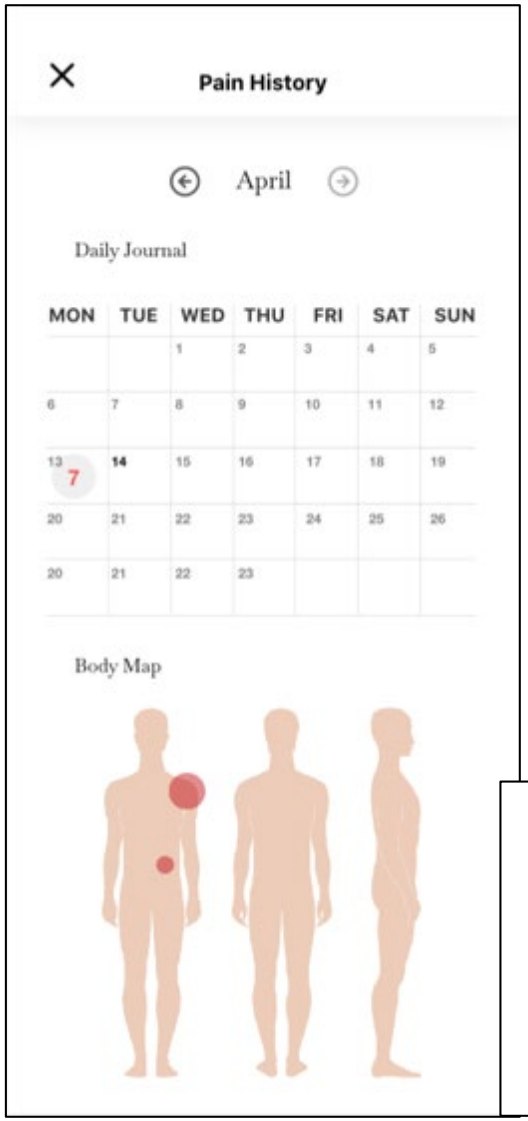

Results
Pain Intensity
How strong your pain is.
Moderate
61
30
70
Pain Interference
The amount your pain impacts your dialy life.
Severe
71
15
85
Done

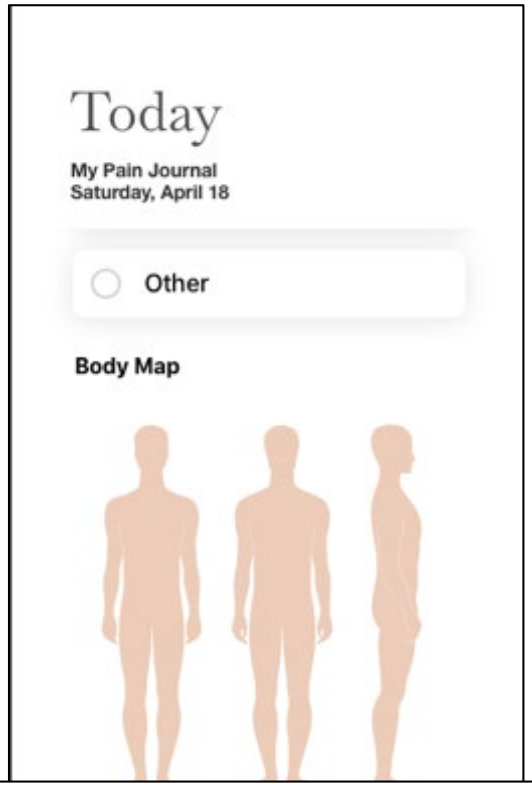

Me
What to expect in a taper
Resources for Social Support
My History
My Pain
View
My Activities
View
Physical Therapy
MON TUE WED THU FRI SAT SUN
home
Journal
me


Take Notice
Your recent Pain Intensity score is 10 points worse than your baseline score.
This could be a significant change.
Please consider contacting your provider if your pain is:
• Unexplained
• Uncontrolled
• In a new spot
• Feels different (stabbing vs aching)
• Or, if you have concerns
Done









Patient Engagement

Application Flow

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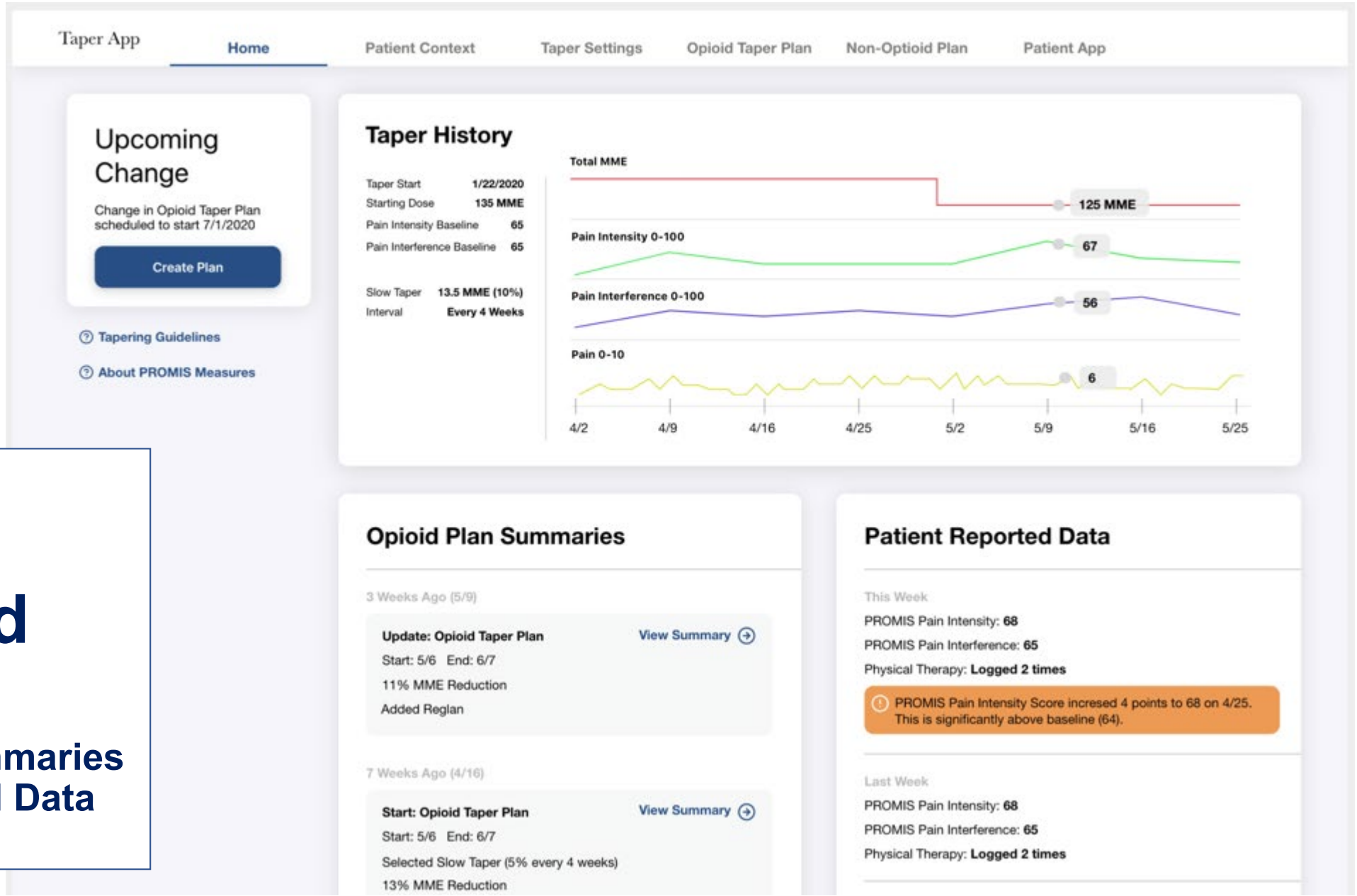
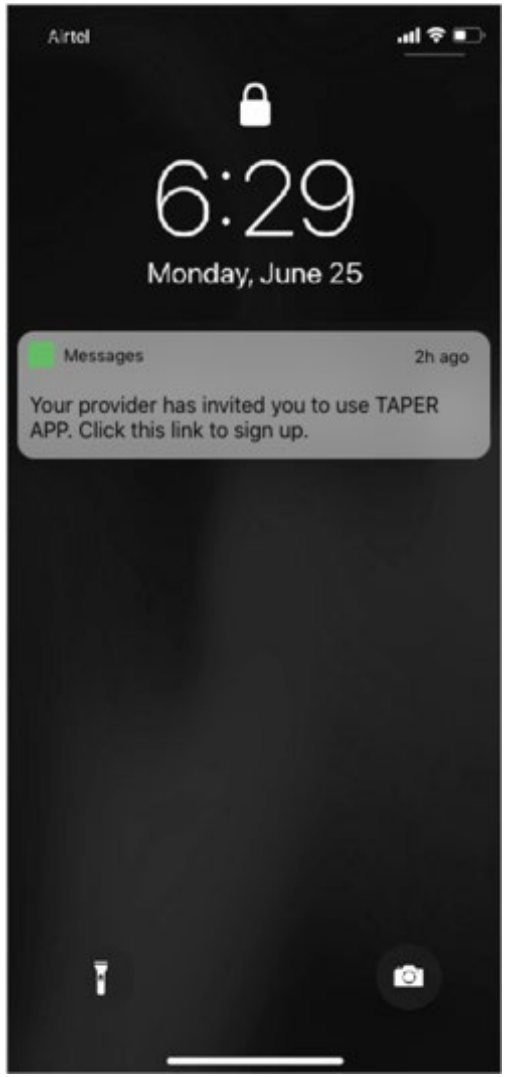
MedStar Health
National Center for
Human Factors in Healthcare



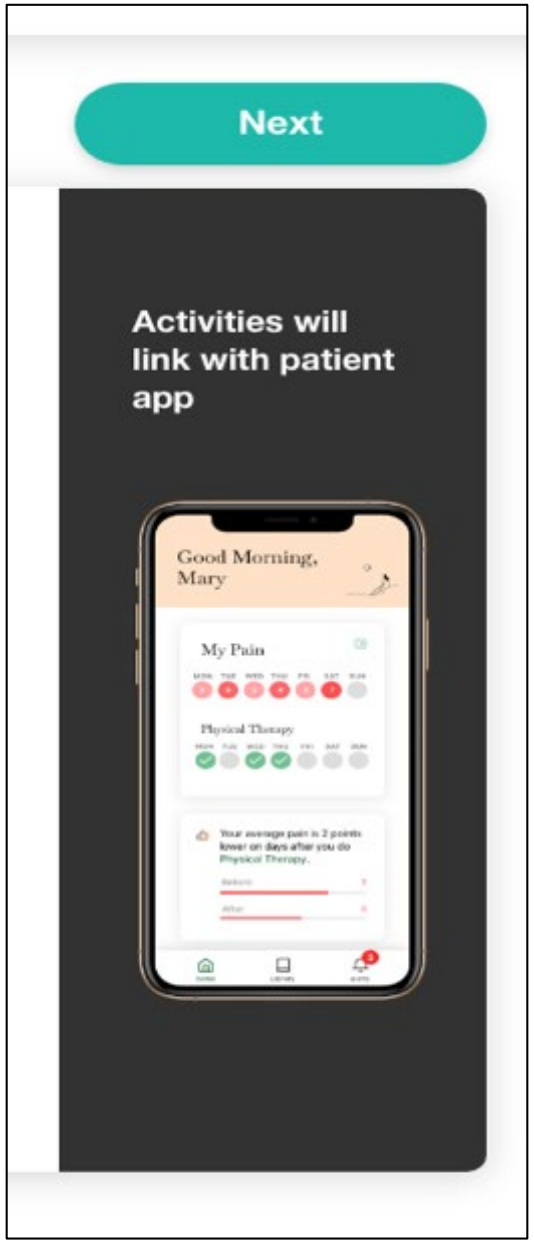
Provider Dashboard

- Taper History
- Opioid Plan Summaries
- Patient Reported Data



Implementation

- 3 Phase Roll-Out
  - February, March, April 2021
- 15 Individual Primary Care Sites
  - Small to large sites
  - MedStar Health
  - CAPRICORN network
  - George Washington University
- 3 Different Electronic Health Record Vendors
  - Cerner, Nextgen, Allscripts



Challenges to Date & Anticipated Challenges

Ethical, legal, policy challenges

- Escalation protocol
- Legal liability
- Security of patient-facing applications (HIPAA)

Technical challenges

- Local EHR customizations required for vendor sites that have not adopted current FHIR standards
- Not all the desired data can easily and consistently be found in the FHIR resources (or may be documented in multiple places)
- Varying EHR vendor whitelisting requirements for applications

Acknowledgment

MedStar Health
National Center for
Human Factors in Healthcare

Funding provided by the Agency for Healthcare Research and Quality

Contract Number: HHSP233201500022I

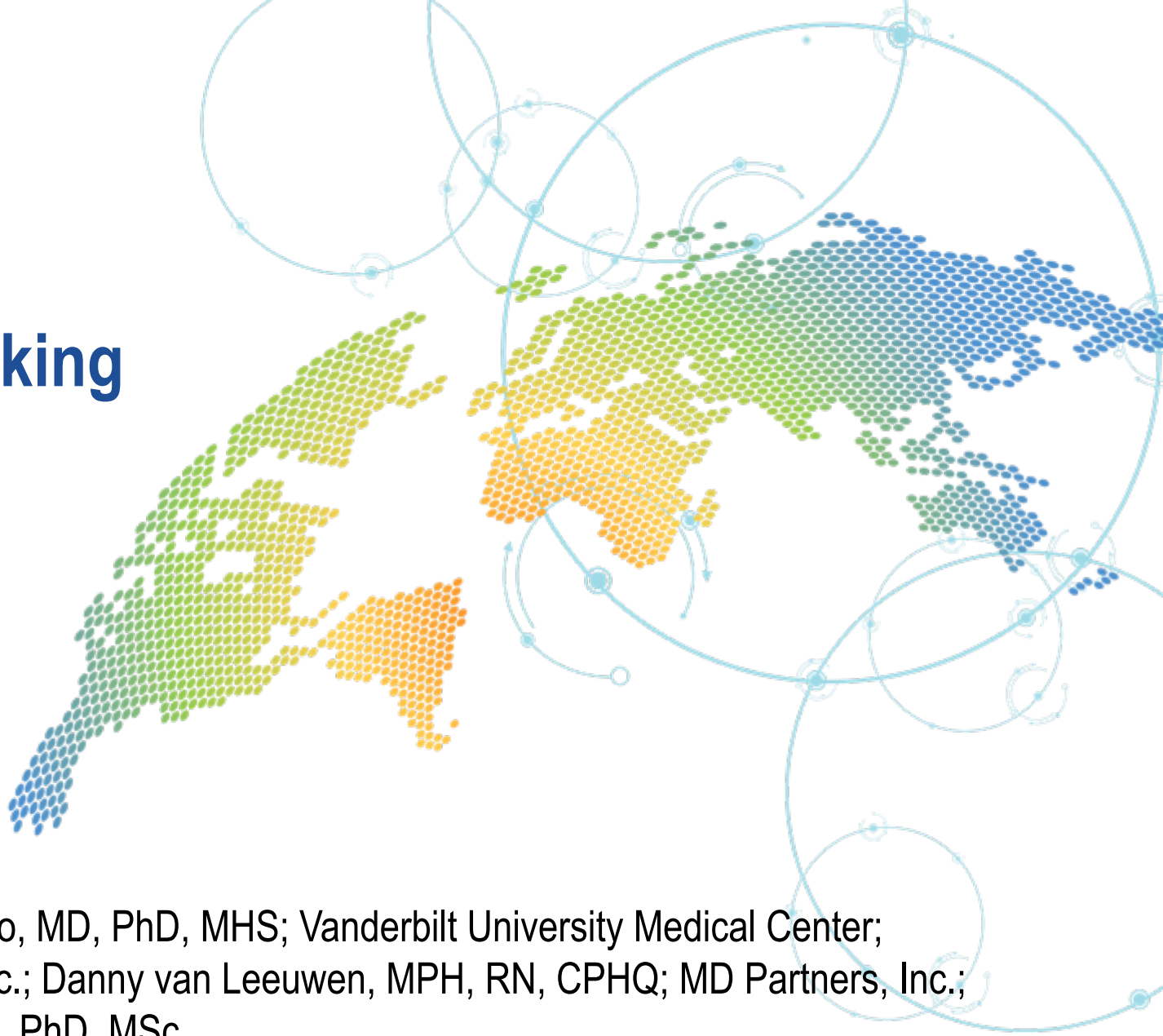
Kristen Miller, DrPH, CPPS

MedStar Health National Center for Human Factors in Healthcare

Washington, DC

Kristen.E.Miller@medstar.net

Shareable Clinical Decision Support for Chronic Pain Management (CDS4CPM) to Promote Shared Decision-Making



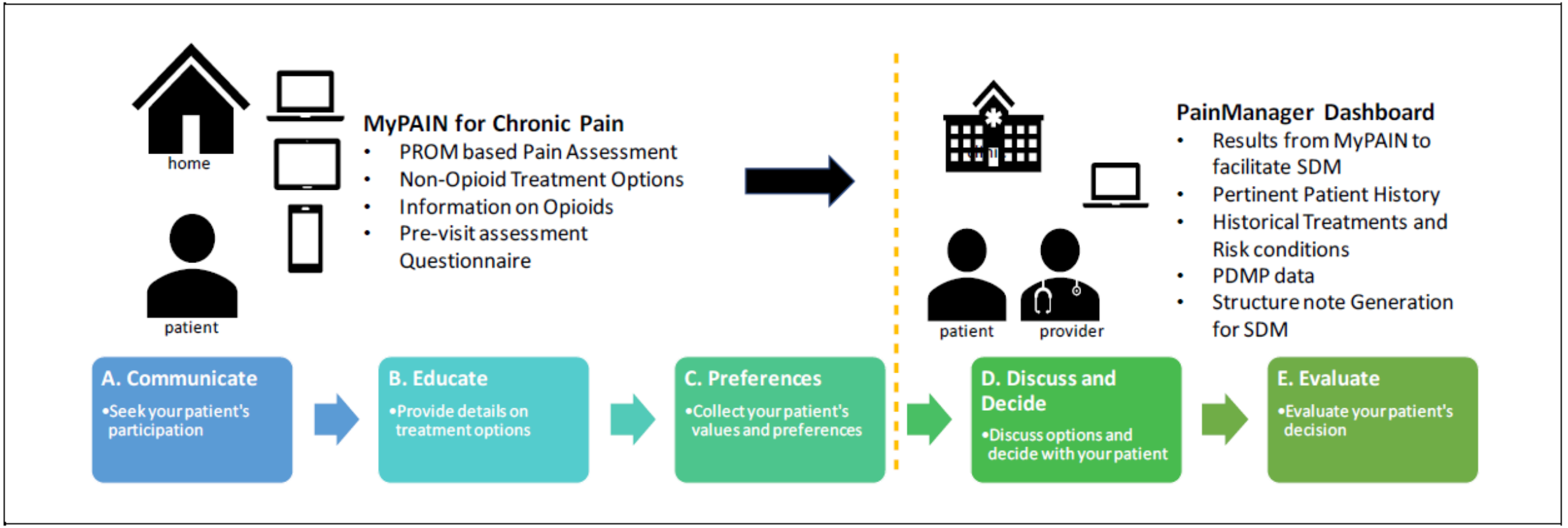
PD: Joshua E. Richardson, PhD, MS, MLIS

APD: Laura Haak Marcial, PhD

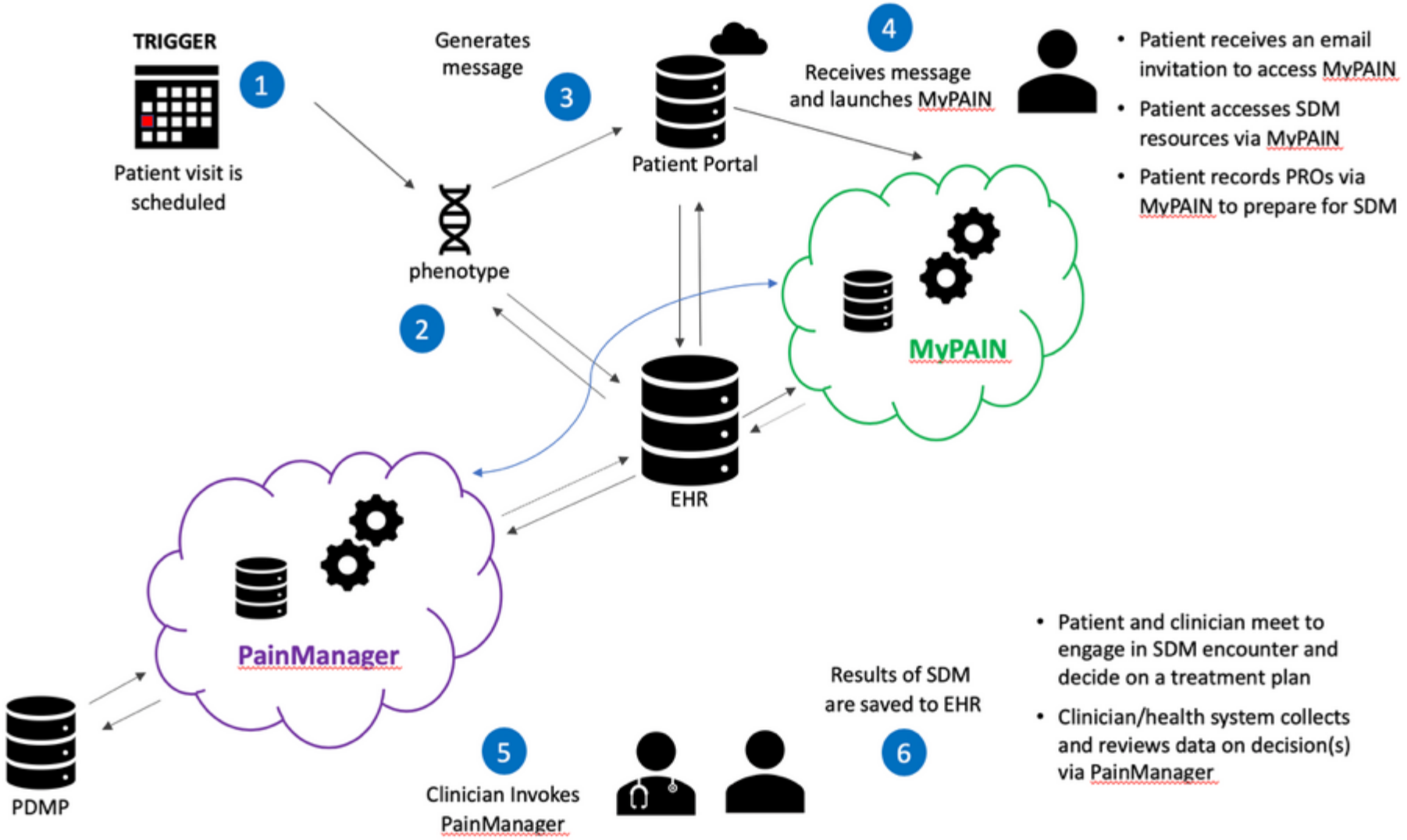
Team Members: Barry Blumenfeld, MD, MS; Stephen Brown, MS; Jessica DeFrank, PhD; Sonya Goode, MPH; Sara Jacobs, PhD; Stephanie Rizk, MS

Collaborators: Kensaku Kawamoto, MD, PhD, MHS; Vanderbilt University Medical Center; University of Chicago; Alphora, Inc.; Danny van Leeuwen, MPH, RN, CPHQ; MD Partners, Inc.; iParsimony, LLC. Glyn Elwyn, MD, PhD, MSc

Aim to Use CDS that Promotes Shared Decision-Making (SDM)

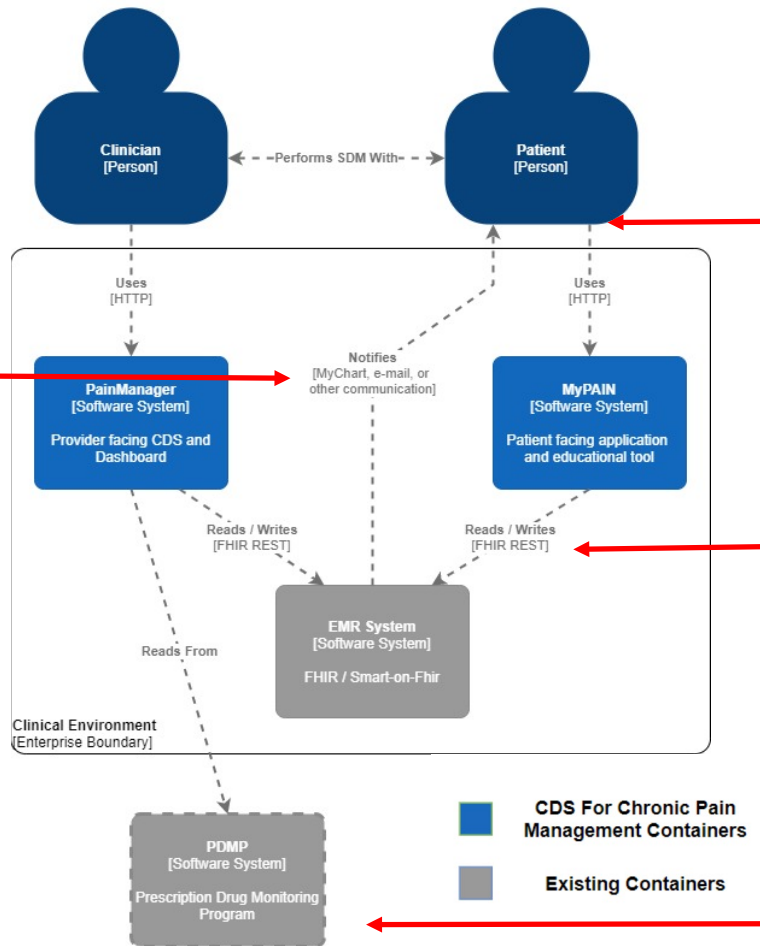


Overall System Architecture



EHR Interactivity Achieved via a “FHIR Façade”

1. EHR Portal Invitation



2. Web Browsers

3. FHIR Facade

4. PDMP

MyPAIN to Collect Patient-Reported Outcomes

We'd like to ask you a few questions about your pain and how it is affecting your life.

Please describe the location(s) of any pain you have had in the **past 7 days**.

Select one or more locations

Head

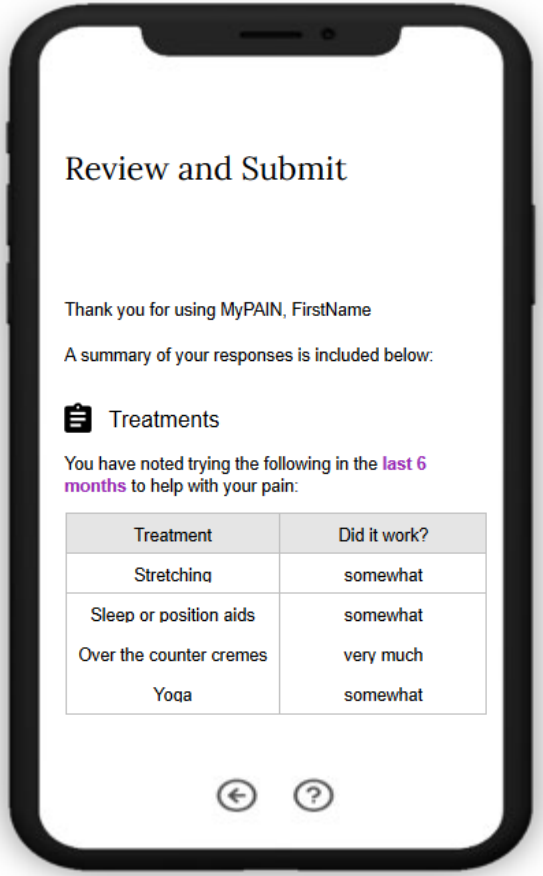
Shoulders

What type of **shoulder** pain?

Burning | Aching | Stabbing

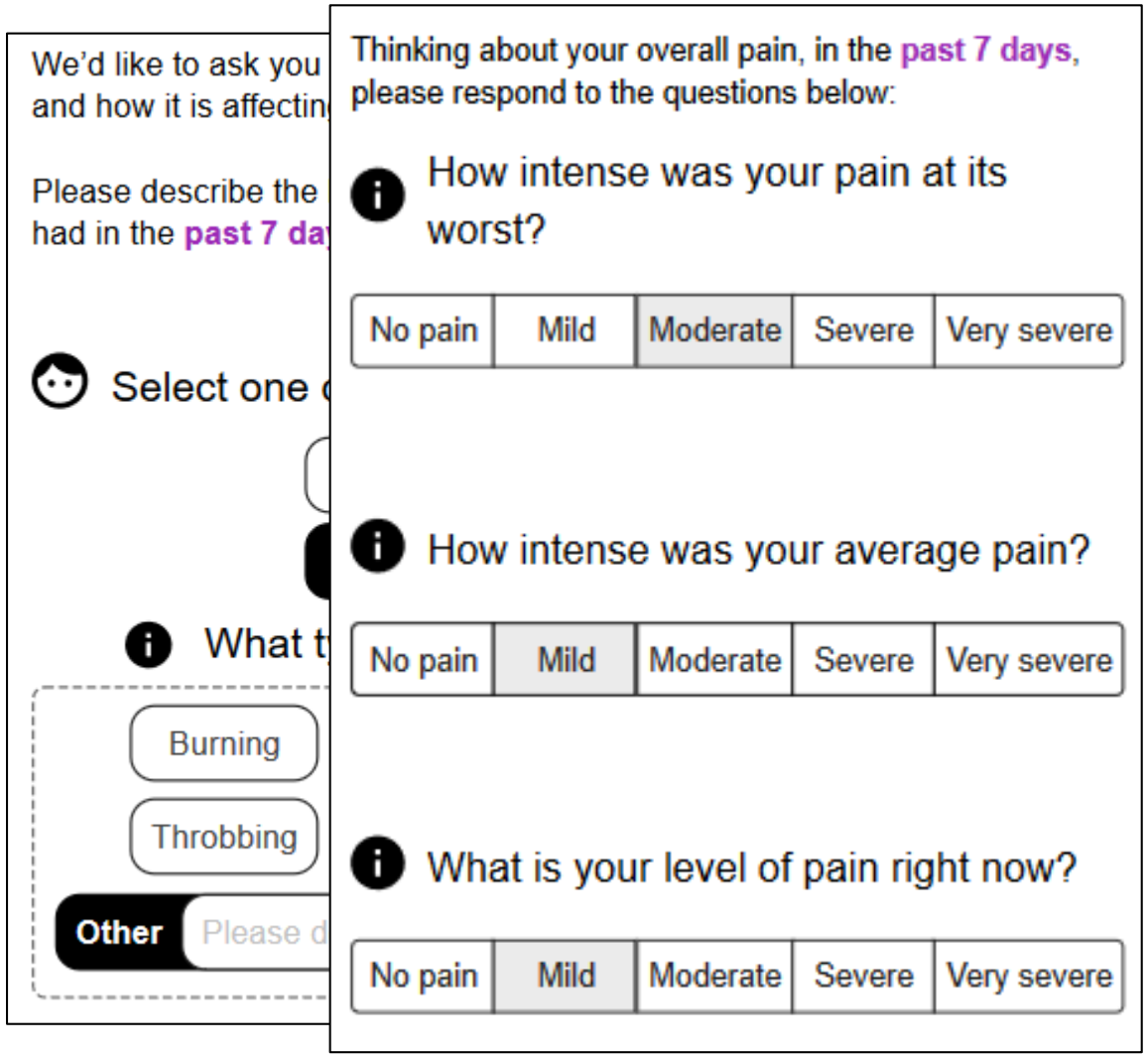
Throbbing | Tingling | Prickling

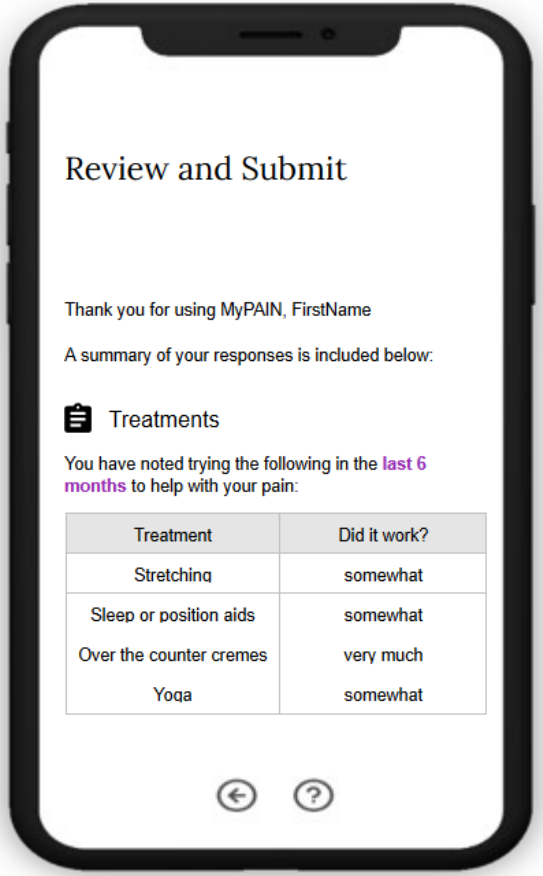
Other Please describe



MyPAIN

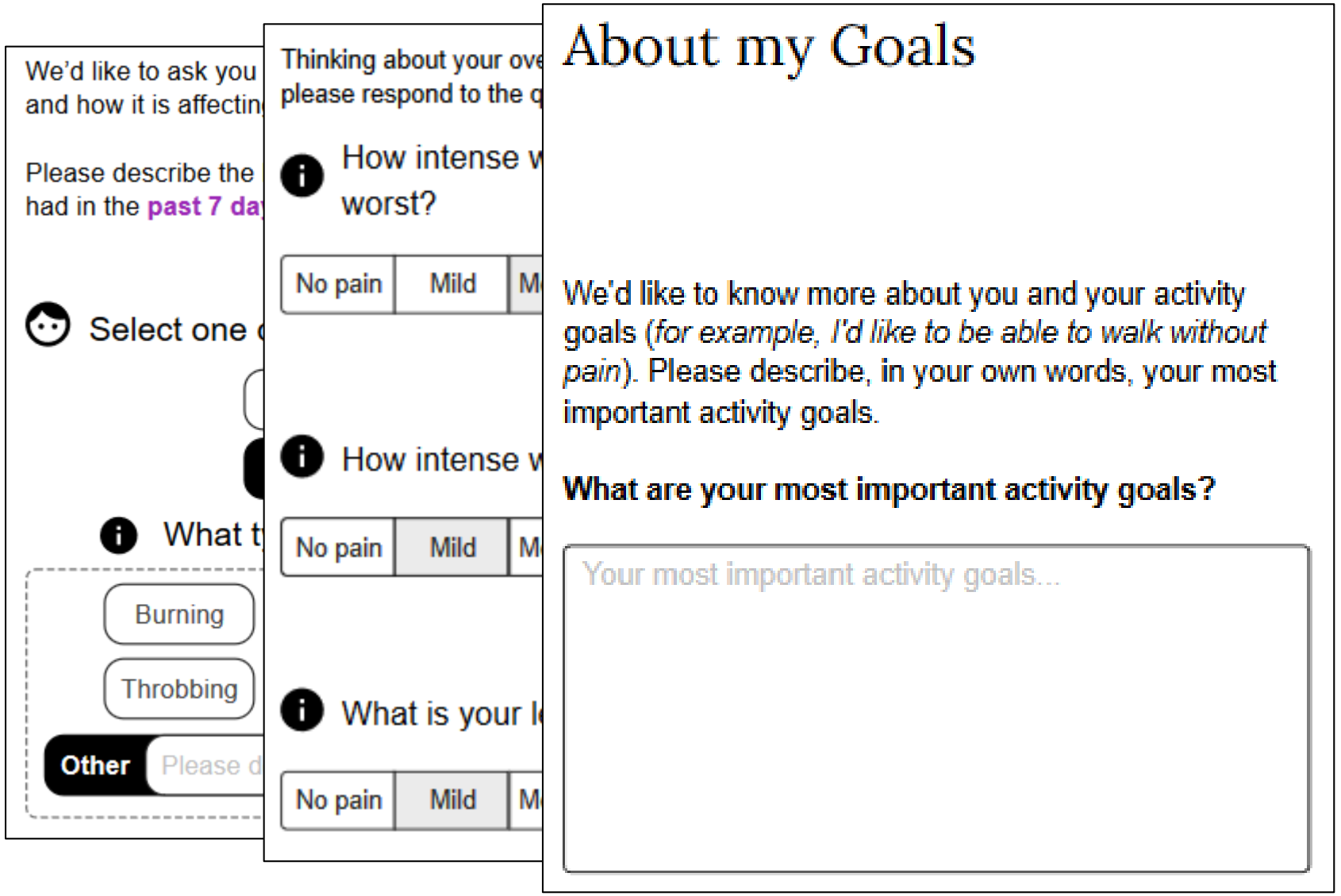
MyPAIN to Collect Patient-Reported Outcomes

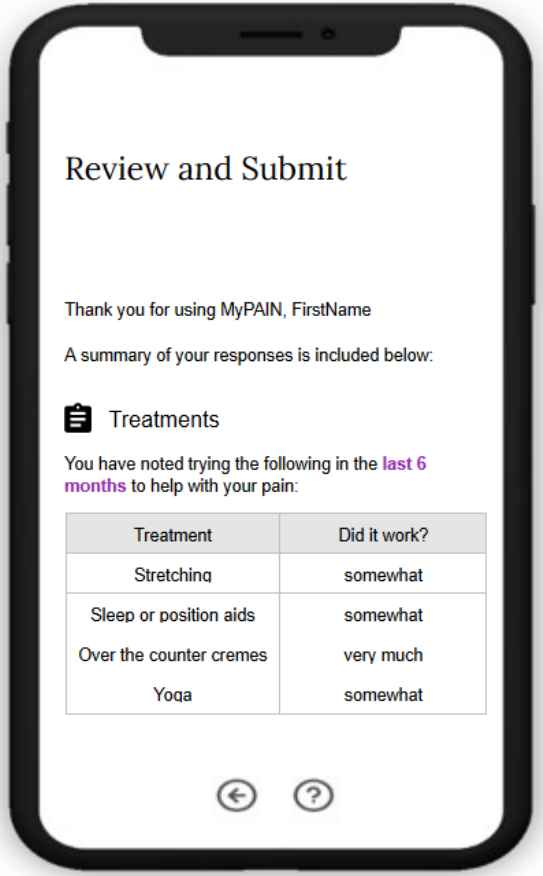




MyPAIN

MyPAIN to Collect Patient-Reported Outcomes





MyPAIN

PainManager for Displaying Patient-reported Data

PainManager

NOTE: This summary is not intended for patients who are undergoing end-of-life (hospice or palliative) or active cancer treatment.

Pertinent Conditions
Current Pain Treatments
Urine Drug Screening
Shared Decision Making

Factors to Consider in Managing Chronic Pain

- Pertinent Conditions ▶
- Current Treatments ▶
- Urine Drug Screening ▶
- Shared Decision Making ▼

The information below was provided by the patient on [MyPAIN submit date: XX/XX/XXXX] using the MyPAIN application:

ACTIVITY GOALS

I want to be able to walk to my mailbox free of pain. I'd like to get back to enjoying a walk in the neighborhood with my grandkids.

ACTIVITY BARRIERS

On a bad day, I have trouble putting on my clothes or getting a shower. I need to take care of my cat but have trouble just taking care of myself some days.

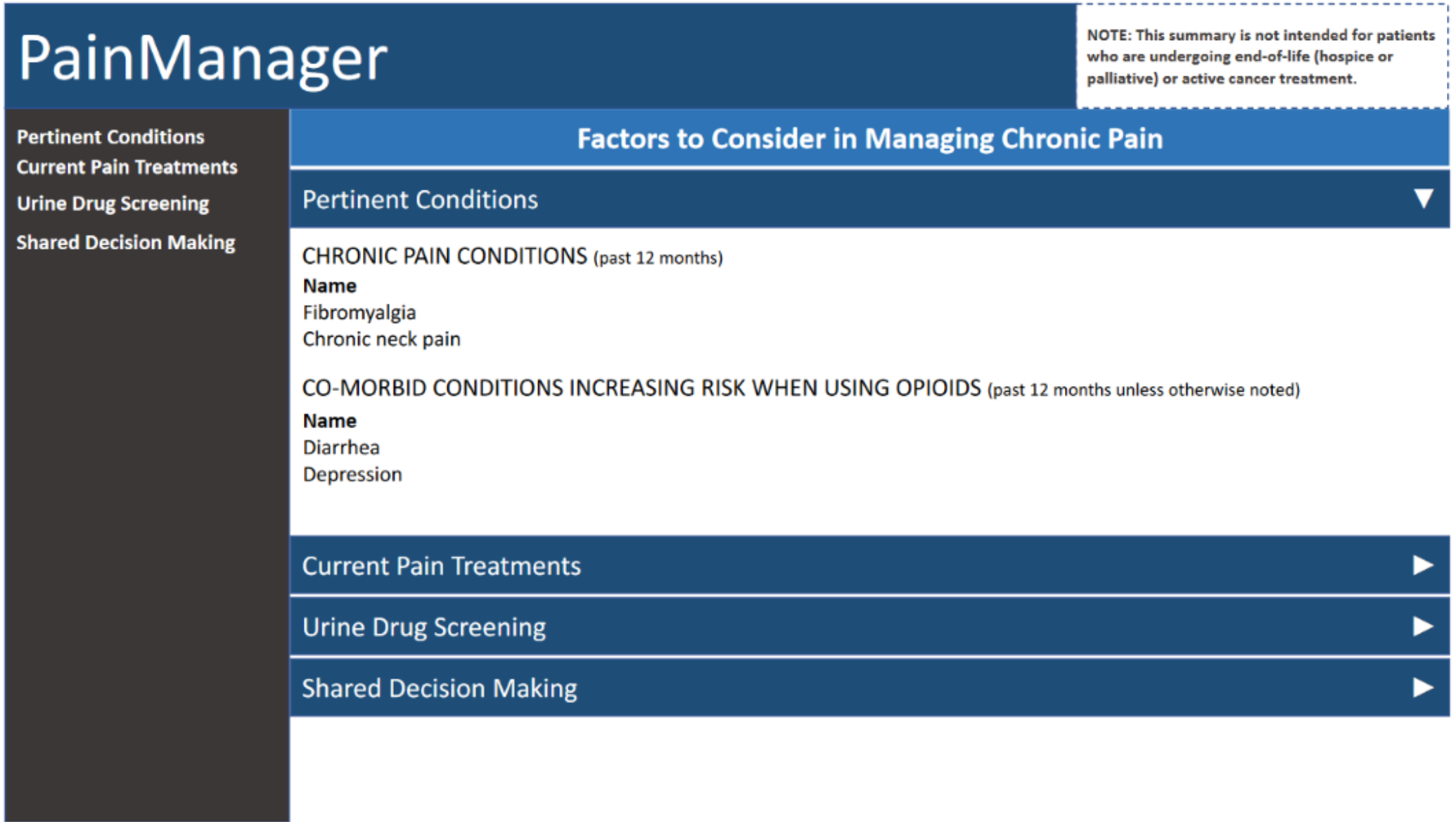
PAIN LOCATIONS (only yes responses shown)

Location	Pain Y/N	Type
Head	Y	burning
Neck	Y	burning
Shoulders	Y	aching
Arms	Y	aching

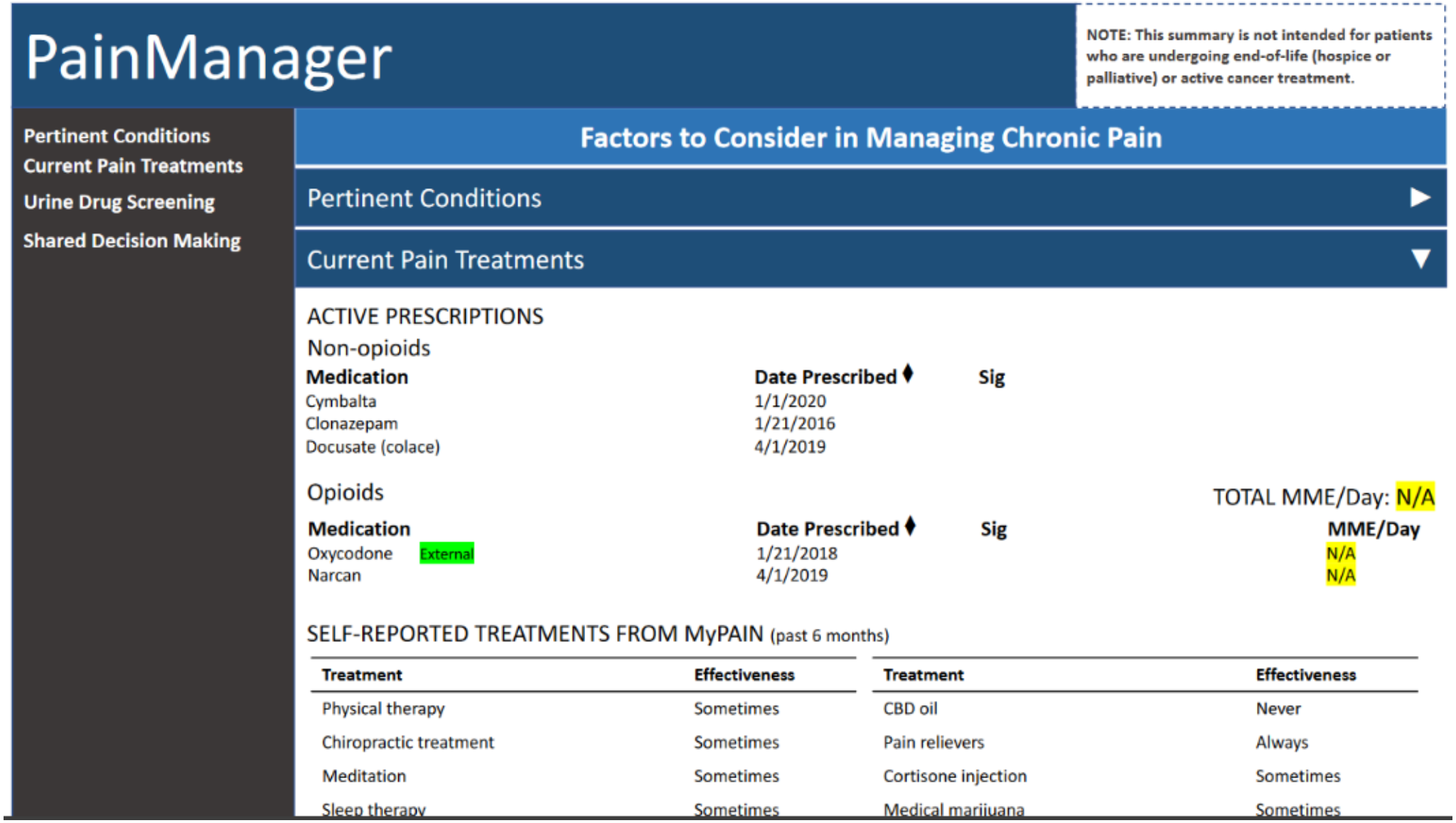
PAIN INTENSITY AND INTERFERENCE

Question	Response
How **intense** was your pain at its worst?	Somewhat
How intense was your average pain?	Somewhat
What is your level of pain right now?	Somewhat
How much did pain **interfere** with your day	Somewhat

PainManager for Displaying EHR-based Pertinent Conditions



PainManager for Displaying Current Treatments + MME



PainManager

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Pertinent Conditions
Current Pain Treatments
Urine Drug Screening
Shared Decision Making

Factors to Consider in Managing Chronic Pain

Pertinent Conditions ▶

Current Pain Treatments ▼

ACTIVE PRESCRIPTIONS

Non-opioids

Medication	Date Prescribed	Sig
Cymbalta	1/1/2020	
Clonazepam	1/21/2016	
Docusate (colace)	4/1/2019	

Opioids

TOTAL MME/Day: N/A

Medication	Date Prescribed	Sig	MME/Day
Oxycodone External	1/21/2018		N/A
Narcan	4/1/2019		N/A

SELF-REPORTED TREATMENTS FROM MyPAIN (past 6 months)

Treatment	Effectiveness	Treatment	Effectiveness
Physical therapy	Sometimes	CBD oil	Never
Chiropractic treatment	Sometimes	Pain relievers	Always
Meditation	Sometimes	Cortisone injection	Sometimes
Sleep therapy	Sometimes	Medical marijuana	Sometimes

Challenges CDS4CPM has Encountered

- Anticipating future developments for standards
  - Proprietary vs standard APIs
  - Evolving vendor challenges per information blocking regulations
  - What happens if/when the FHIR façade is no longer needed due to changes in vendor APIs?
- Managing data models (via FHIR façade) depending how US Core meets various needs
  - Extending US Core for QuestionnaireResponse (future versions?)
  - Dosage information requiring more specificity than what US Core currently provides, suggest for USCDI v2
- PDMP
  - Technical solution may not align with state capabilities and governance
  - Technical solution may not align with local governance
- Artifact Stewardship
  - Assigning long-term oversight of artifacts and value sets
  - Determining when oversight is best handed off to different parties
  - Covering costs of stewardship

Acknowledgment

Funding provided by The Agency for Healthcare Research and Quality: HSP233201500024I

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RTI International
Chicago, IL
jrichardson@rti.org

Summary Points

- Interoperable CDS Expectations
  - Improve the spread of adoption/dissemination of medical knowledge and practice guidelines
  - Reduce provider burden
  - Provide tools for “shared decision making”
- Areas for improvement
  - Data resources are not uniformly available at different sites
  - Workflows for local CDS deployment is still being validated
  - Validation of data streams outside of the EHR is a concern

AHRQ Announcements

- New FOA
  - Disseminating and Implementing Patient-Centered Outcomes Research (PCOR) Evidence into Practice through Interoperable Clinical Decision Support
    - https://grants.nih.gov/grants/guide/pa-files/PA-20-074.html
- Upcoming AHRQ Division of Digital Healthcare Research "2019 Year in Review" report
- Resources
  - AHRQ CDS main page https://cds.ahrq.gov
  - AHRQ resource mailbox ClinicalDecisionSupport@ahrq.hhs.gov

QUESTIONS?

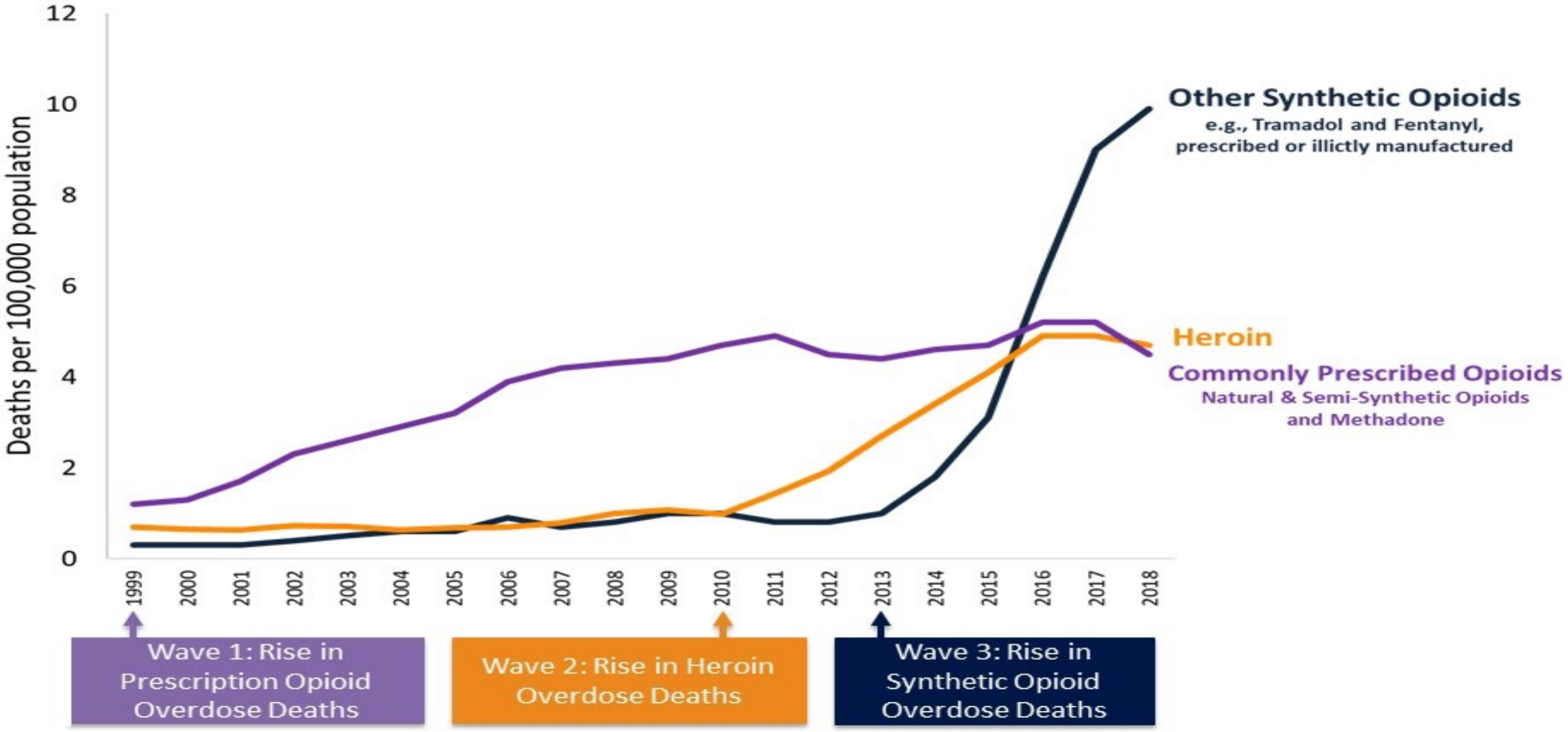
Supporting Providers and Health Systems Through Electronic Clinical Decision Support Tools

Wesley Sargent, EdD, MA
Health Scientist

Division of Overdose Prevention
National Center for Injury Prevention and Control

September 15, 2020

3 Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

RISE IN OPIOID OVERDOSE DEATHS IN AMERICA

A Multi-Layered Problem in Three Distinct Waves

450,000 people died from an opioid overdose (1999-2018)

1990s mark a rise in **prescription opioid** overdose deaths

2010 marks a rise in **heroin** overdose deaths

2013 marks a rise in **synthetic opioid** overdose deaths

Rx OPIOIDS
Include natural, semi-synthetic, and methadone and can be prescribed by doctors

HEROIN
An illegal opioid

SYNTHETIC OPIOIDS
By 2018, 2/3 of all opioid overdose deaths involved a synthetic opioid, such as illicitly manufactured fentanyl.

CDC

Learn more about the evolving opioid overdose crisis: **www.cdc.gov/drugoverdose**

CDC North Star

VISION

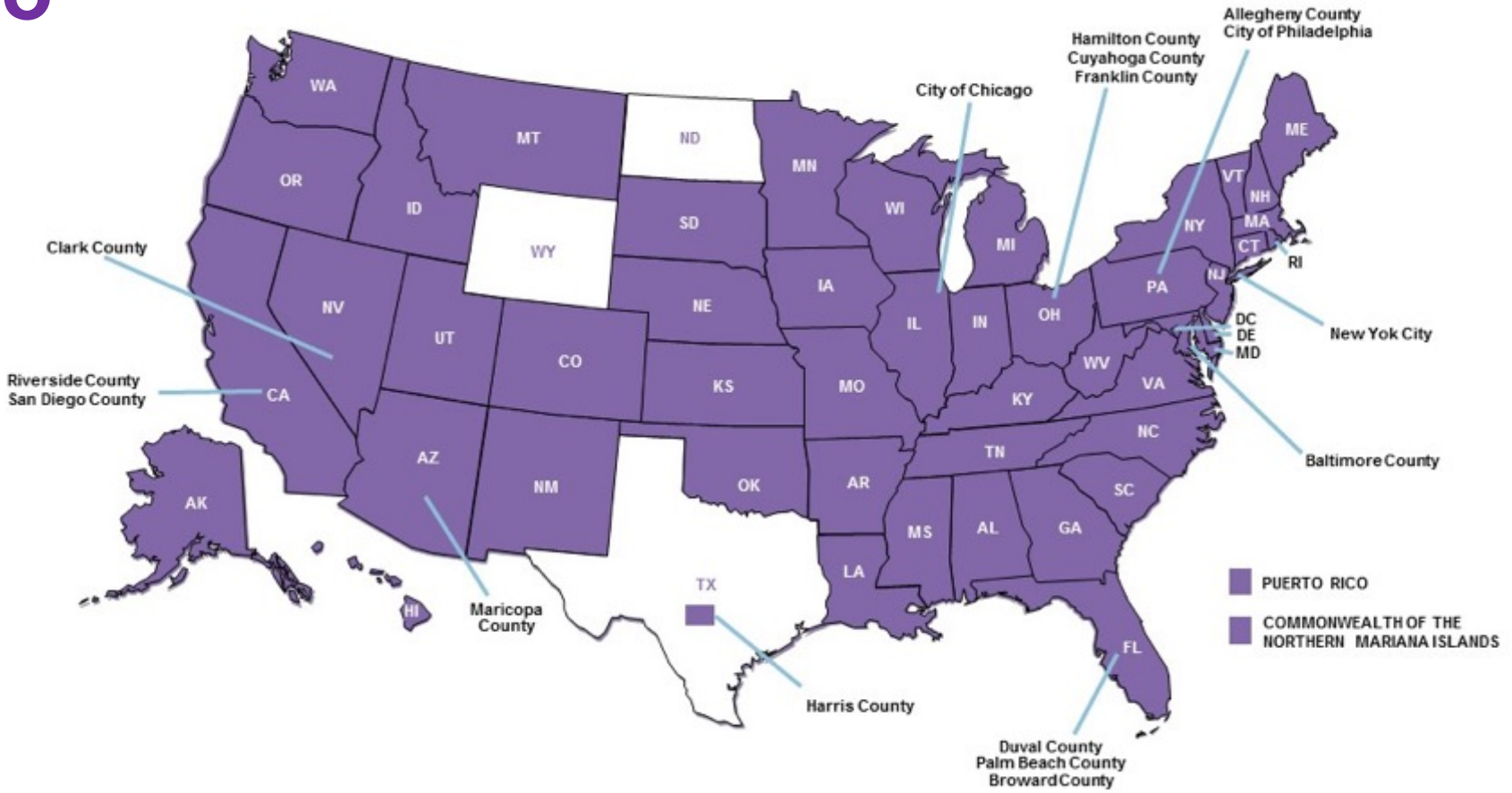
Prevent opioid-related harms & overdose death

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Preventing Opioid Overdoses and Opioid-Related Harms

Overdose Data to Action OD2A

- Integrates previous funding into one announcement
- $300M per year for 3 years
- Seamless integration of data and prevention programs
- 66 jurisdictions funded including 47 states, DC, 2 territories, and 16 hard hit cities and counties



Surveillance

PDMPs

Health System

Public Safety

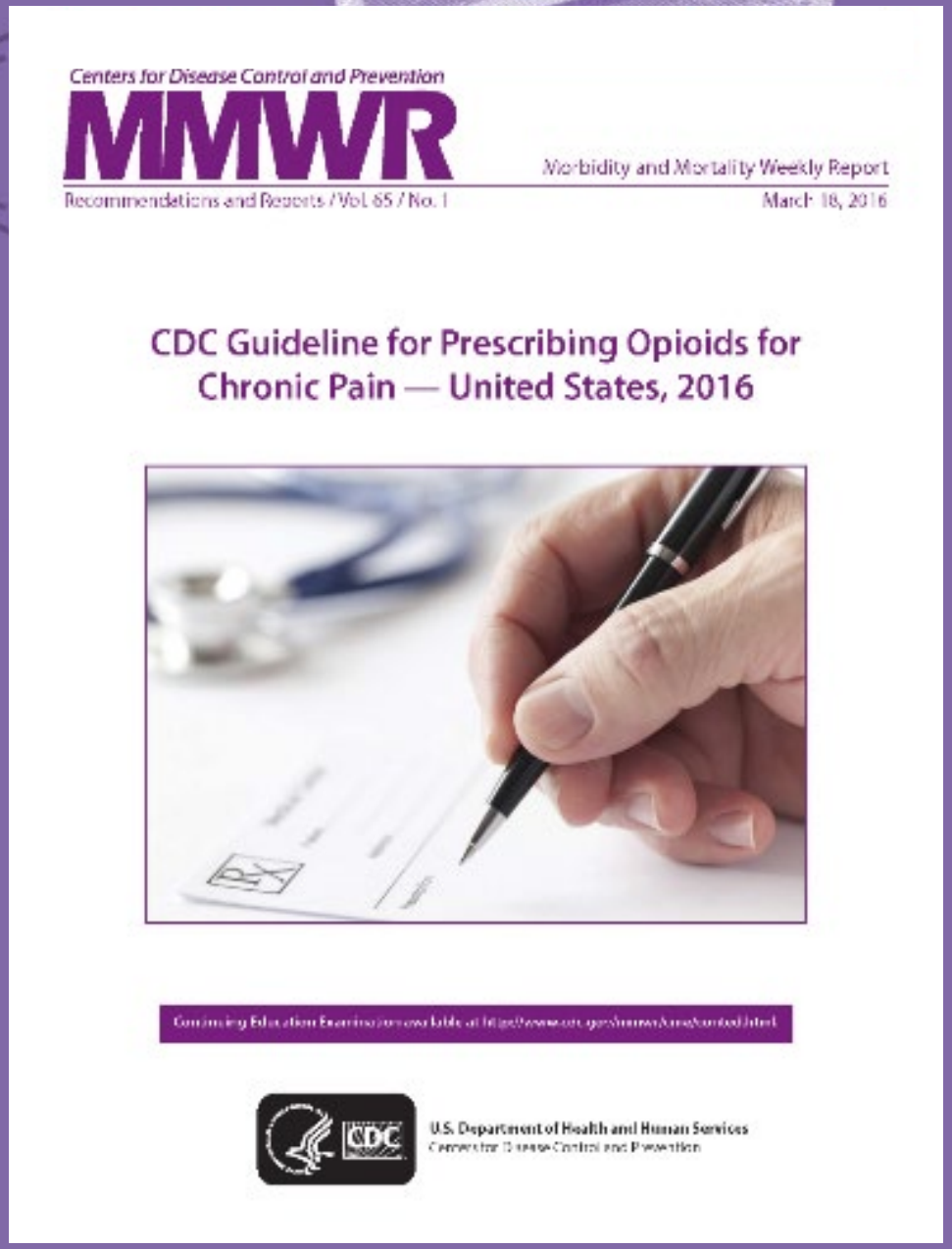
Linkage to Care

Empower Consumers

Local Response

Support Health Systems and Providers

- Promote use of the *CDC Guideline for Prescribing Opioids for Chronic Pain*
- Train healthcare providers on implementation of Guideline
- Provide tools to help integrate into clinical practice



- Primary care providers
- Patients 18 years or older with chronic pain
- Outpatient settings
- Outside of active cancer, palliative, and end of life care

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

www.cdc.gov

Organization of Guideline Recommendations

12 recommendations grouped into 3 conceptual areas:

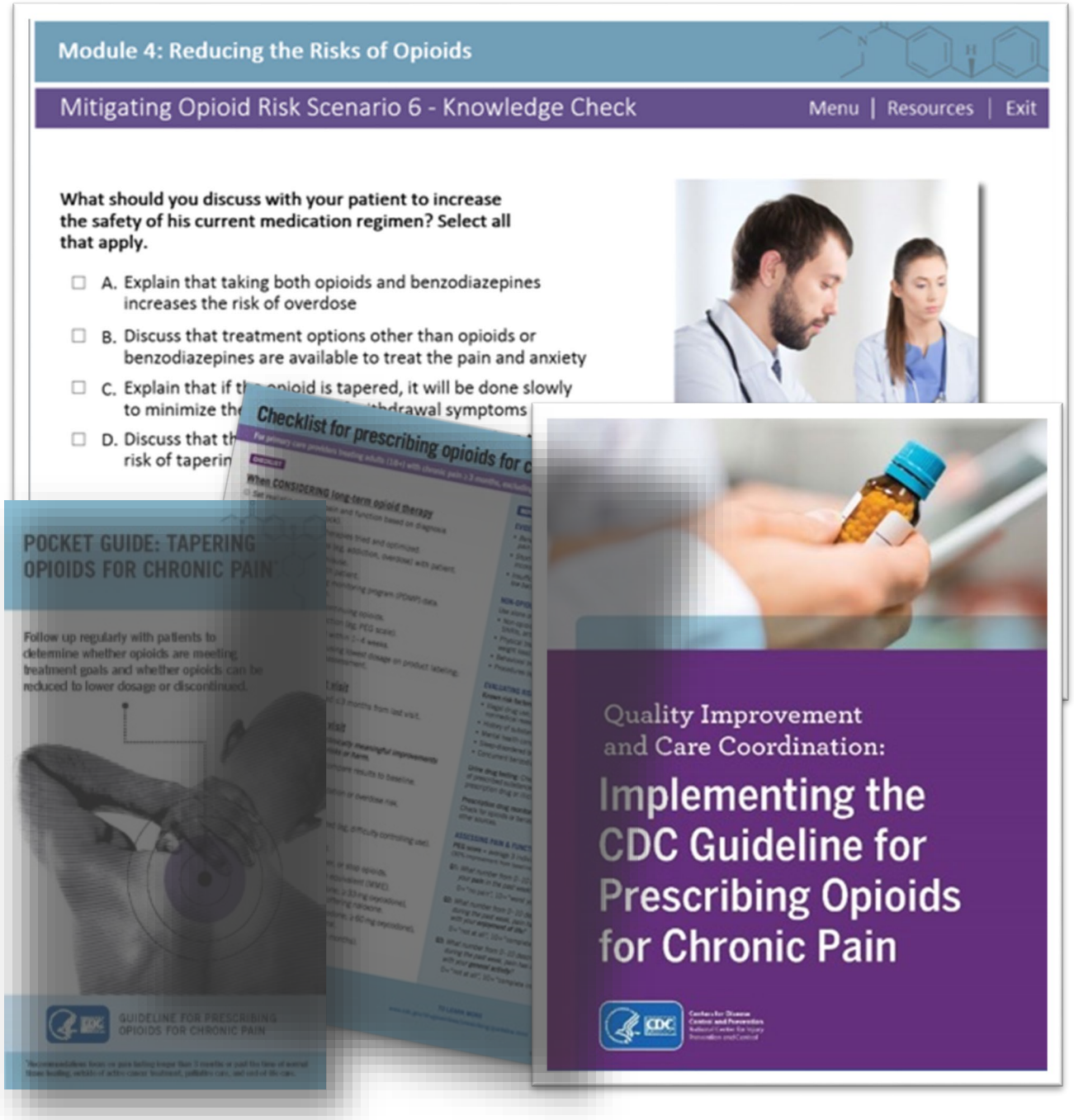
- Determining when to initiate or continue opioids for chronic pain
- Opioid selection, dosage, duration, follow-up, and discontinuation
- Assessing risk and addressing harms of opioid use

EMPOWERING PROVIDERS.

www.cdc.gov GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Provider Resources

- Clinical Tools
- Mobile App
- Trainings (CME)
- Digital & Print Resource



To learn more:
https://www.cdc.gov/drugoverdose/prescribing/resources.html

Health Systems Interventions

- Clinical Quality Improvement and Care Coordination
- EHR and PDMP (prescription drug monitoring program) Data Integration
- **Clinical decision support (CDS) tools embedded into electronic health records (EHRs)**

Electronic CDS Evaluation

- Implemented pilot CDS tools at four participating healthcare systems:
  - Regional primary care health system based in Kansas
  - Large metropolitan hospital with outpatient clinics in Texas
  - Large hospital and outpatient care system in New York City
  - Regional hospital and primary care health system in Pennsylvania
- Evaluated implementation process, use, and utility of CDS tools:
  - Pre-/post- of EHR-generated measures using existing data
  - Conducted semi-structured interviews (n=8) with project champions and IT leads at participating healthcare systems

Electronic CDS Evaluation

- Each participating health system developed EHR-embedded CDS tools that align directly with the CDC Guideline recommendations and integrated directly into system clinical workflow. CDS tools developed included:
  - Alerts
  - Access to prescription drug monitoring program (PDMP) data
  - Patient registries
  - Auto-population of prescription fields (e.g., quantity)
  - Order sets (e.g., SmartSet)
  - Morphine milligram equivalents (MMEs) calculators
  - Templates for clinical notes and referrals

Evaluation Results

- The number of patients with counseling on opioid risks and benefits increased from 5% to 7.5% (TX)
- Short-term follow-up increased slightly at (TX)
- Use of immediate release opioids when obtaining a new opioid prescription increased from 91% to 96% (TX)
- Urine drug testing increased by 50% (PA)
- Naloxone counseling increased by six-fold (PA)
- Use of PDMP information increased by 60% (KS)

Lessons Learned

- Development and implementation of CDS tools aligned with the CDC Guideline has the potential to promote safer opioid prescribing and improve patient care.
- Design, validation, and implementation process for CDS tools can be highly variable
- Healthcare systems' capabilities and resources are critical in determining which CDS modules to implement and how
- Flexibility in creating CDS tools and data definitions is KEY to successful integration into clinical workflow

Lessons Learned Continued

- Facilitators:
  - In-house IT staff expertise and availability
  - Access to and relationship with EHR service advisor
  - EHR system-specific administrative regulations and clinical policies
  - Shared learning with other systems
- Barriers/Challenges:
  - EHR system-specific limitations to how data are captured, or need to be built
  - Length of time to build, test, iterate, and implement
  - Limited resources available
  - Lacking internal expertise or IT experience with opioid-related data

Current Electronic CDS Projects

- Health systems can help encourage the uptake and use of the CDC Guideline for Prescribing Opioids for Chronic Pain
- CDC-funded effort to create electronic CDS tools that map to the 12 Guideline recommendations
  - Contributors: ONC, AHRQ, Yale, Indiana University, Duke, and Security Risk Solutions
- Current work includes further refinement and development of electronic CDS to be used in electronic health records (EHRs), at the point-of-care

Electronic CDS Implementation Guide

Home | Profiles | Artifacts | Terminology | Examples | Test Data | Documentation | Downloads

Opioid Prescribing Support Implementation Guide

1.0.0 Opioid Prescribing Support Implementation Guide

Contents

1.1.0 Introduction

This implementation guide provides resources and discussion in support of applying the Centers for Disease Control and Prevention (CDC) Opioid Prescribing Guidelines:

CDC guideline for prescribing opioids for chronic pain

This implementation guide was developed as part of the Clinical Quality Framework Initiative, a public-private partnership sponsored by the Centers for Medicare & Medicaid Services (CMS) and the U.S. Office of the National Coordinator for Health Information Technology (ONC) to identify, develop, and harmonize standards for clinical decision support and electronic clinical quality measurement.

This project is a joint effort by the Centers for Disease Control and Prevention (CDC) and the Office of the National Coordinator for Health IT (ONC) focused on improving processes for the development of standardized, shareable, computable decision support artifacts using the CDC Opioid Prescribing Guideline as a model case.

1.2.0 Scope

This implementation guide includes support for the following guideline recommendations:

- Recommendation #1 - Nonpharmacologic and Nonopioid Pharmacologic Therapy Consideration
- Recommendation #2 - Opioid Therapy Goals Discussion
- Recommendation #3 - Opioid Therapy Risk/Benefit Discussion
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- Recommendation #12 - Evidence-based Treatment for Patients with Opioid Use Disorder

1.3.0 Getting Started

For a quick start to get up and running and see how the artifacts work, refer to the Quick Start

CDC Resources

CDC Opioid Overdose Prevention Website
www.cdc.gov/drugoverdose

State Efforts
https://www.cdc.gov/drugoverdose/states/index.html

CDC Guideline for Prescribing Opioids for Chronic Pain
https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

Resources for Patients
https://www.cdc.gov/drugoverdose/patients/index.html

Resources for Providers
https://www.cdc.gov/drugoverdose/providers/index.html

Clinical Decision Support Resources

- **Implementation Guide Output:** http://build.fhir.org/ig/cqframework/opioid-cds-r4/
- **Source for the implementation guide:** https://github.com/cqframework/opioid-cds
- **Supporting Java packages for the CQL-to-ELM translator and CQL Engine:** https://github.com/cqframework/opioid-cds-logic
- **Agency for Healthcare Research Quality's CDS Connect:** https://cds.ahrq.gov/cdsconnect/artifact/factors-consider-managing-chronic-pain-pain-management-summary

Contact:

Wes Sargent
Wsargent@cdc.gov

Please note that the findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Project Overview - From Evidence to Executable CDS

Greg White

Security Risk Solutions, Inc.

The Office of the National Coordinator for Health Information Technology

CDC Prescribing Guideline Decision Support

- Goal: provide point-of-care support for CDC Guideline for Prescribing Opioids for Chronic Pain
- Process: Progress from narrative to executable CDS
- CDC-sponsored effort. Contributors: ONC, AHRQ, Yale, Indiana University, Duke, Security Risk Solutions Inc., Epic, Cerner, and many others.
- Approach:
  - Leverage health IT standards for representing clinical knowledge & integrating into EHRs
  - Pilot with multiple healthcare organizations and EHR products

Current Guideline Development and Implementation

Develop guidelines

Research Results

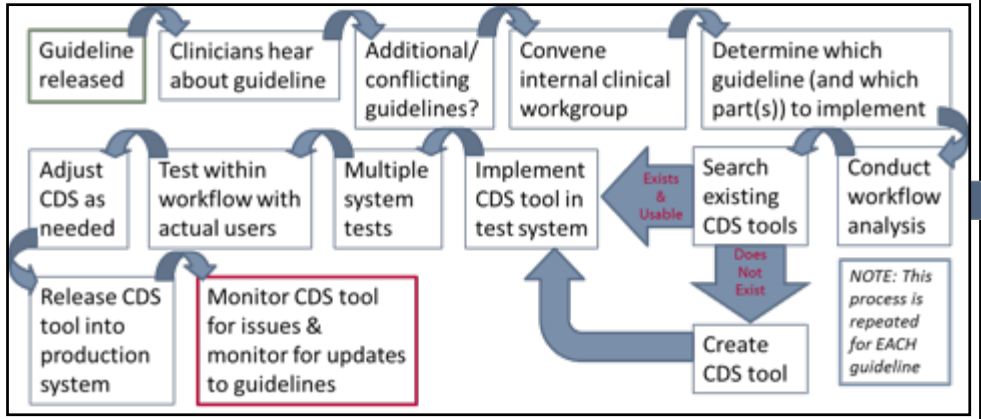
Literature Review

Meta-analysis

Guideline Narrative

PDF

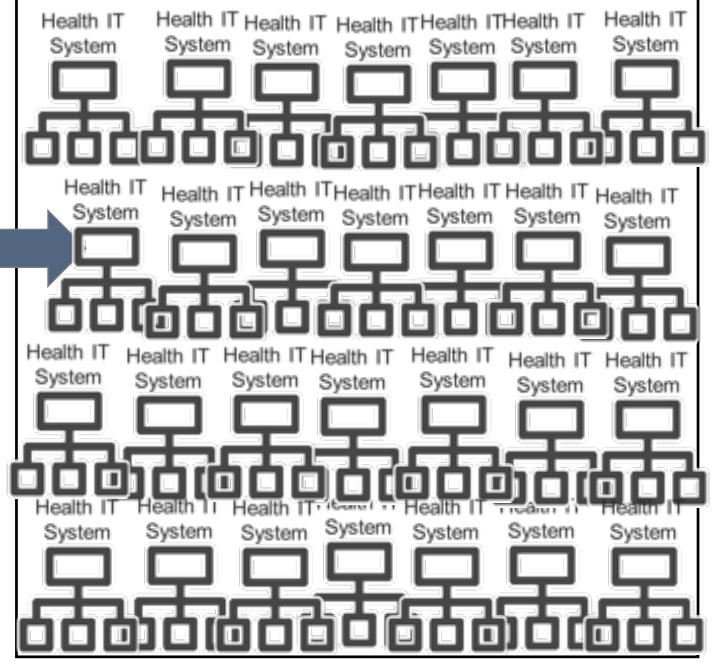
Interpret guidelines



96% of ~5500 hospitals utilize a certified EHR

80% of ~355,000 MDs utilize a certified EHR

Implement guidelines



https://dashboard.healthit.gov/quickstats/quickstats.php

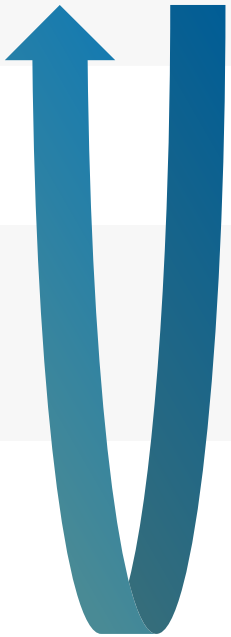
Slide courtesy of Maria Michaels, Centers for Disease Control and Prevention

Utilization of Standards-Based Dissemination

- **EHR data retrieval: HL7 FHIR**
  - FHIR = Fast Healthcare Interoperability Resources
- **Guideline knowledge representation: HL7 CQL**
  - CQL = Clinical Quality Language
  - CQL can be utilized within a CDS service or directly executed within a health information system
- **EHR workflow integration: HL7 CDS Hooks**
- **EHR app integration: HL7 SMART**
  - SMART = Substitutable Medical Apps, Reusable Technologies
- **Key enabler: EHR vendor support for these standards**

Translating Evidence to Executable CDS

Knowledge Level	Description	Example
L1	Narrative CDC Prescribing Guideline	Guideline for a specific disease that is written in the format of a peer-reviewed journal article
L2	Semi-structured Functional Descriptions Process Flow Diagrams	Flow diagram, decision tree, or other similar format that describes recommendations for implementation (HUMAN READABLE)
L3	Structured CQL, FHIR Resources, Terminology Libraries	Standards-compliant specification encoding logic with data model(s), terminology/code sets, value sets that is ready to be implemented (COMPUTER/MACHINE READABLE)
L4	Executable Pilot sites: University of Utah, Duke, Yale, Indiana University	CDS implemented and used in a local execution environment (e.g., CDS that is live in an electronic health record (EHR) production system) or available via web services



Adapted from: Boxwala, AA, et al.. A multi-layered framework for disseminating knowledge for computer-based decision support. *J Am Med Inform Assoc* 2011(18) i132-i139.

Thank You!

Greg White
gw@securityrs.com

CDS Knowledge Artifacts, Pilots, and Lessons Learned

Kensaku Kawamoto, MD, PhD, MHS

Vice Chair for Clinical Informatics, Department of Biomedical Informatics

Associate Chief Medical Information Officer

University of Utah

The Office of the National Coordinator for Health Information Technology

Artifact development is focused on the 12 CDC Guideline recommendation statements

Determining when to initiate or continue opioids for chronic pain

1. Opioids are not first-line therapy
2. Establish goals for pain and function
3. Discuss risks and benefits

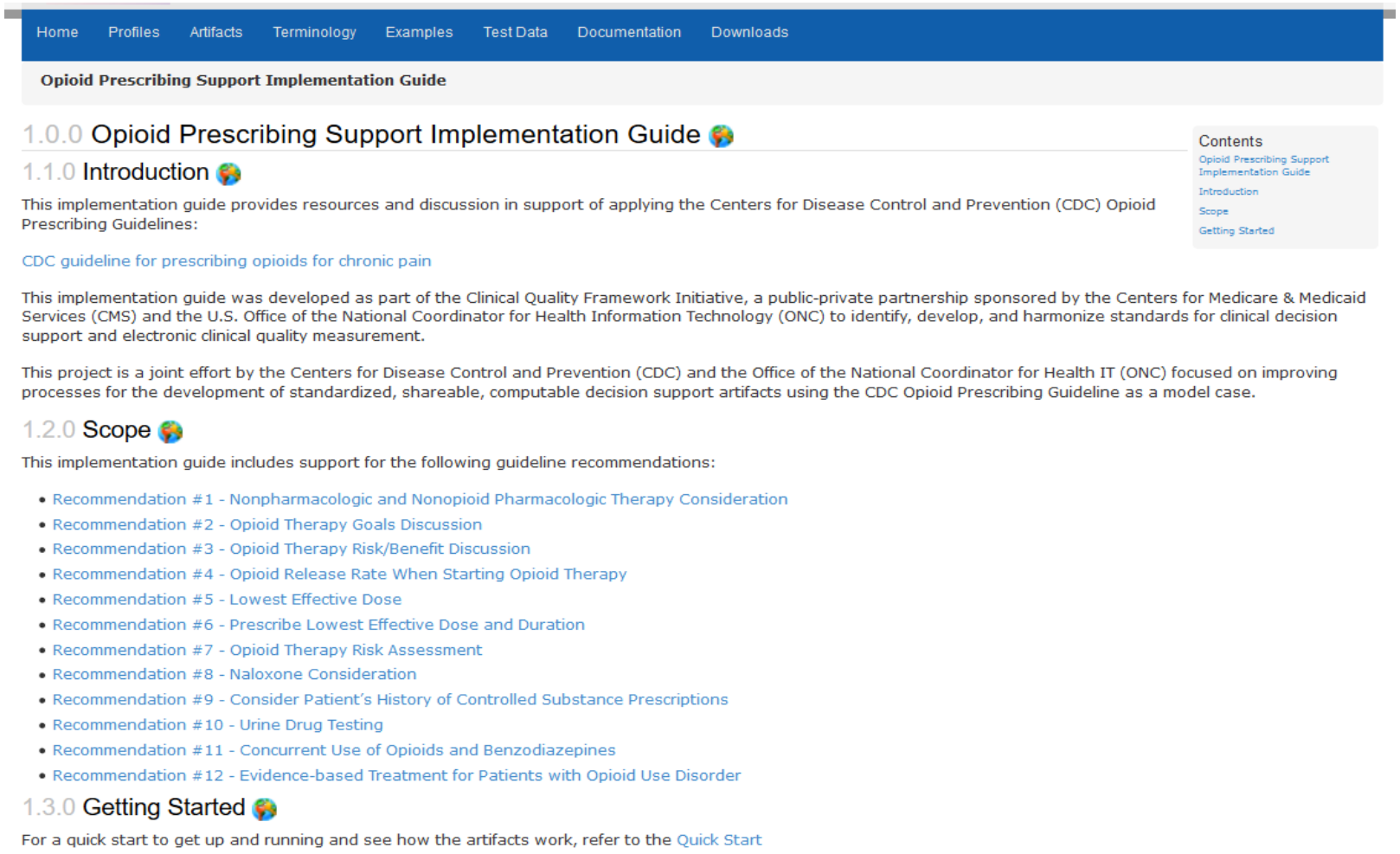
Opioid selection, dosage, duration, follow-up, and discontinuation

4. Use immediate-release opioids when starting
5. Use the lowest effective dose; appreciate daily morphine milligram equivalents
6. Prescribe immediate-release opioids only for short durations for acute pain
7. Evaluate benefits and harms frequently

Assessing risk and addressing harms

8. Use strategies to mitigate risk
9. Review PDMP data
10. Use urine drug testing
11. Avoid concurrent opioid and benzodiazepine prescribing
12. Offer treatment for opioid use disorder

Artifacts for all 12 recommendation statements are available in an Opioid Prescribing Support FHIR IG



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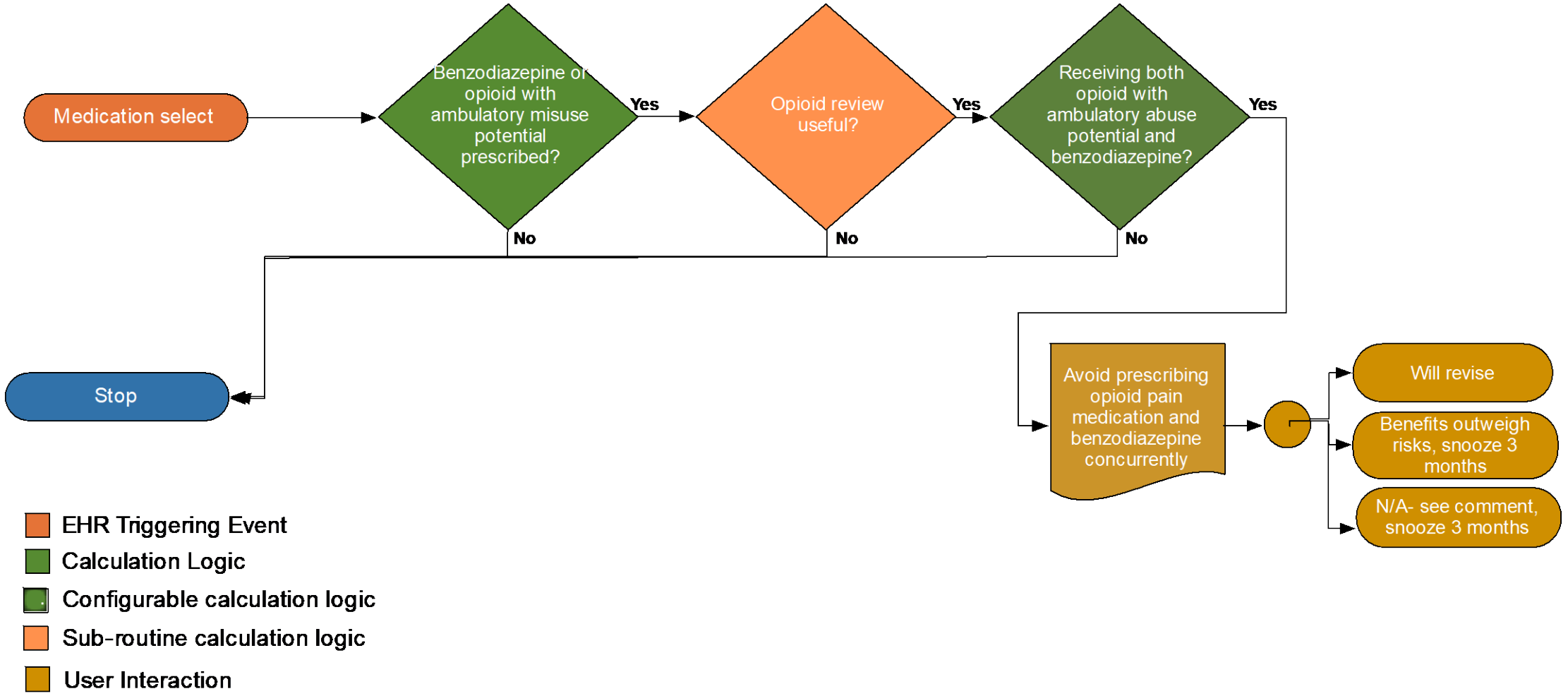
http://build.fhir.org/ig/cqframework/opioid-cds-r4/

Level 2 Process Flow Diagrams



Level 3 Artifact Example (CQL, Rec. #11)

```
36  define "Inclusion Criteria":
37    AgeInYears() >= 18
38      and (
39        exists (Common."Active Ambulatory Benzodiazepine Rx")
40          and exists (Common."Active Ambulatory Opioid Rx")
41      )
42
43  define "Get Indicator":
44    if "Inclusion Criteria"
45      then 'warning'
46    else null
47
48  define "Get Summary":
49    if "Inclusion Criteria"
50      then 'Patient has active prescriptions for opioid pain medication and benzodiazepines'
51    else null
52
53  define "Get Detail":
54    if "Inclusion Criteria"
55      then 'Avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible'
56    else null
```

Standardized CDS Approaches and Pilots

- **Direct CQL execution – Indiana University and Cerner**
  - Enables fast execution, even across large populations of patients
  - Requires native EHR vendor system to understand CQL
- **CDS Hooks – Yale, Duke**
  - Alert or reminder; could contribute to alert fatigue
  - Emerging EHR vendor support, including for required “hooks”
- **SMART on FHIR – University of Utah**
  - Accessible as a tab in the EHR
  - Broad EHR vendor support
- **Approaches are complementary and can be synergistic**
  - E.g., SMART on FHIR app uses CDS Hooks service, which in turn uses direct CQL execution

Direct CQL Execution

```
In [2]: query= """
library OpioidCDS_STU3_REC_10 version '0.1.0'

using FHIR version '3.0.0'

include FHIRHelpers version '3.0.0' called FHIRHelpers
include OpioidCDS_STU3_Common
```

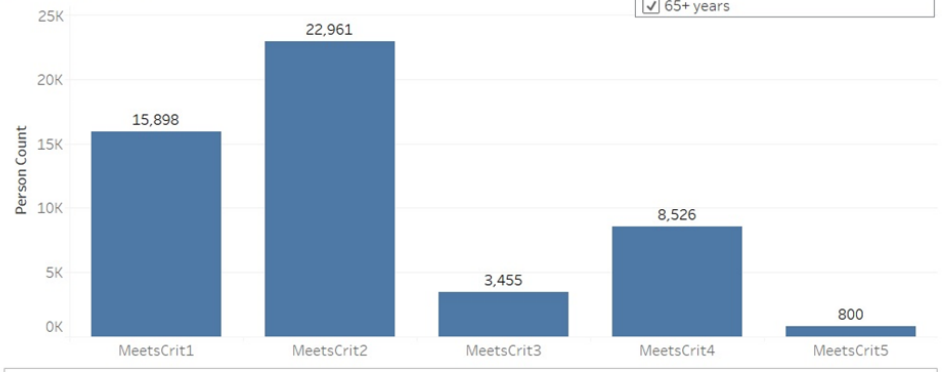
```
In [3]: from fore
fhir_data
version =
fhir_data
```

Recommendation Outcomes

Total Population	Total Met	Excluded
113,227	36,602	26,167

Has Dx CHF: True | Gender: (All) | Age Group: (All), 0-18 years, 19-64 years, 65+ years

Criteria Met

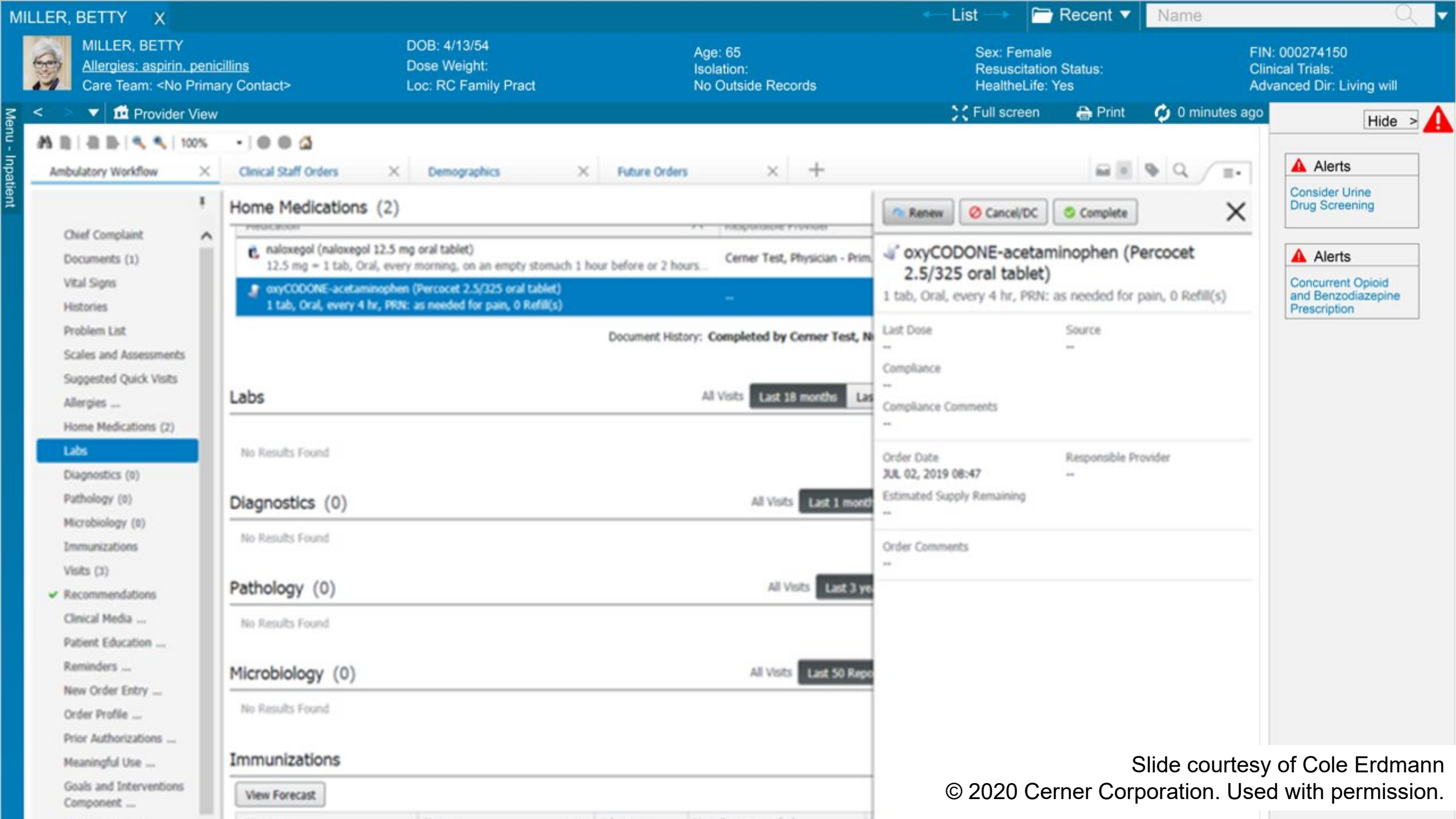



```
In [28]: read_results

Out[28]: 113227
```

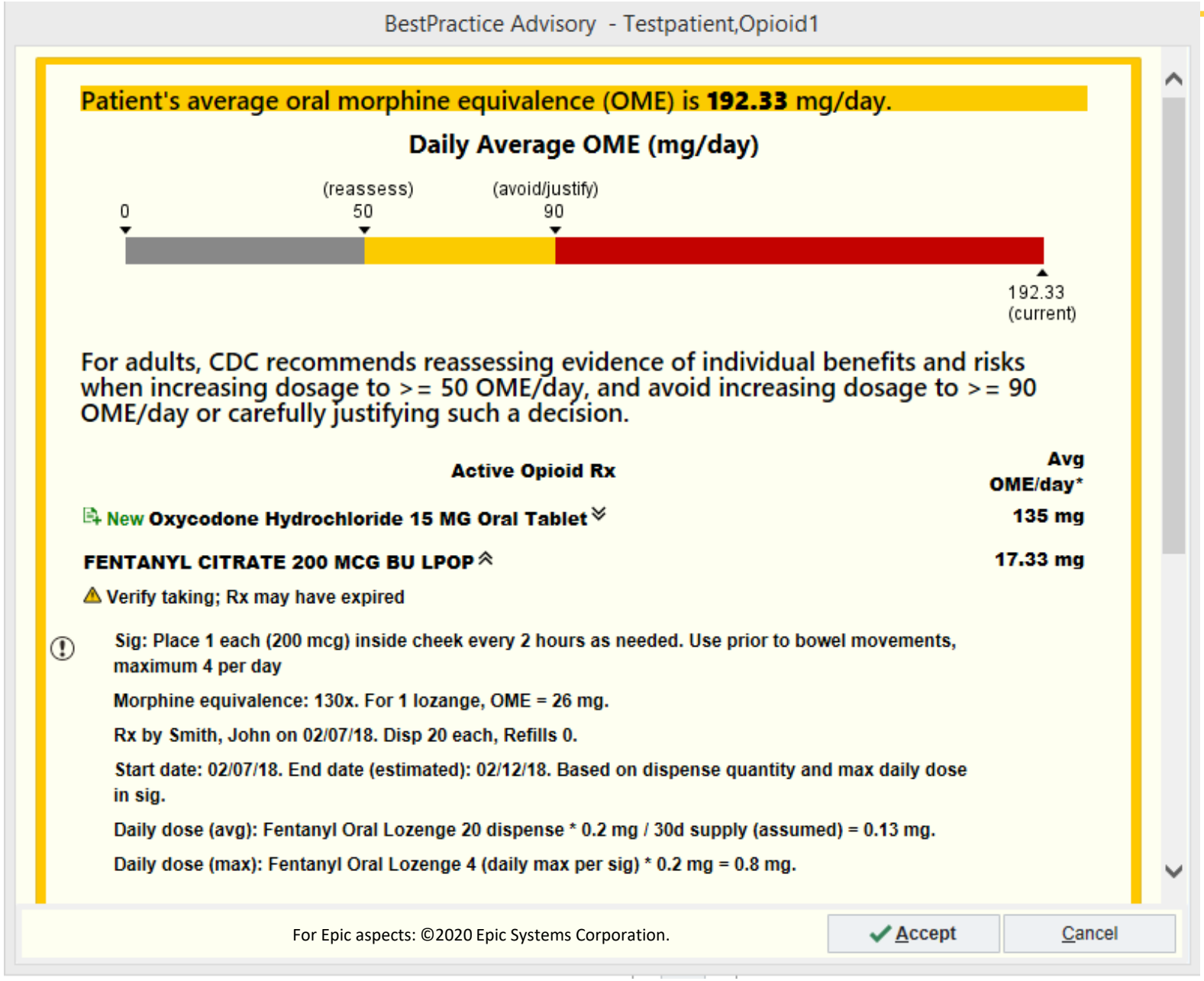
```
"Evidence of Opioids Detail",
"Evidence of Illicit Drugs Indicator",
"Evidence of Illicit Drugs Summary",
"Evidence of Illicit Drugs Detail"],
session_today="2018-12-31T14:40:00-00:00")
```

Slide courtesy of Cole Erdmann

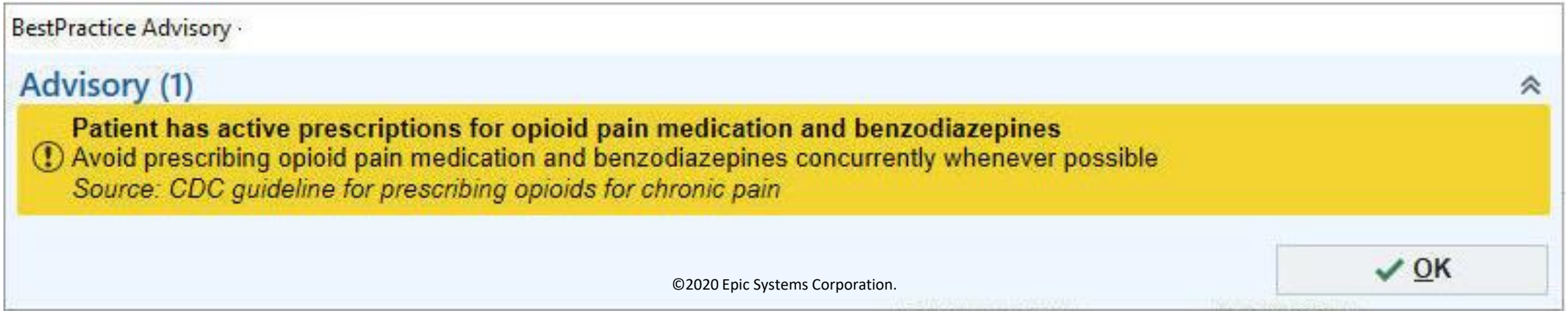


Slide courtesy of Cole Erdmann

CDS Hooks


BestPractice Advisory - Testpatient,Opioid1
Patient's average oral morphine equivalence (OME) is 192.33 mg/day.
Daily Average OME (mg/day)
(reassess)
(avoid/justify)
0
50
90
192.33
(current)
For adults, CDC recommends reassessing evidence of individual benefits and risks when increasing dosage to >= 50 OME/day, and avoid increasing dosage to >= 90 OME/day or carefully justifying such a decision.
Active Opioid Rx
Avg OME/day*
New Oxycodone Hydrochloride 15 MG Oral Tablet
135 mg
FENTANYL CITRATE 200 MCG BU LPOP
17.33 mg
Verify taking; Rx may have expired
Sig: Place 1 each (200 mcg) inside cheek every 2 hours as needed. Use prior to bowel movements, maximum 4 per day
Morphine equivalence: 130x. For 1 lozange, OME = 26 mg.
Rx by Smith, John on 02/07/18. Disp 20 each, Refills 0.
Start date: 02/07/18. End date (estimated): 02/12/18. Based on dispense quantity and max daily dose in sig.
Daily dose (avg): Fentanyl Oral Lozenge 20 dispense * 0.2 mg / 30d supply (assumed) = 0.13 mg.
Daily dose (max): Fentanyl Oral Lozenge 4 (daily max per sig) * 0.2 mg = 0.8 mg.
For Epic aspects: ©2020 Epic Systems Corporation.
Accept
Cancel

CDS Hooks

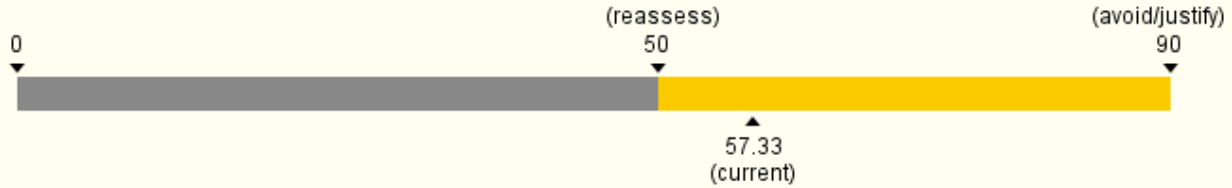


SMART on FHIR

Outpatient Opioid Oral Morphine Equivalence (OME) Calculator

Patient's average oral morphine equivalence (OME) is **57.33** mg/day.

Daily Average OME (mg/day)



For adults, CDC recommends reassessing evidence of individual benefits and risks when increasing dosage to >= 50 OME/day.

Active Opioid Rx	Avg OME/day*
FENTANYL CITRATE 200 MCG BU LPOP ⌄⌄	**17.33 mg**
⚠ Verify taking; Rx may have expired	
HYDROCODONE-ACETAMINOPHEN 10-325 MG PO TABLET ⌄⌄	**40 mg**
⚠ Verify taking; Rx may have expired	
⚠ Not adding OME for presumed redundant Rxs with start dates of 02/07/18 and 03/07/18.	
Total Average OME/Day	**57.33 mg**

*Avg OME = (qty dispensed)/(days supply). 30d supply assumed unless otherwised noted in Sig or note to pharmacy.
*Max OME (see details) = max amount patient may take on a given day according to Sig, even if patient runs out of med early.

OME conversion table
CPG opioid Rx guideline
Source: CDC opioid Rx guideline -- recommendation #5

Summary and Lessons Learned

- Standards-based CDS knowledge artifacts are now available for all 12 recommendations in CDC guideline
- Pilot implementations have spanned direct CQL execution, CDS Hooks, SMART on FHIR, and combinations thereof
- Performance optimization must be a key focus
- Shareable CDS could reduce the time taken to develop, test and deploy CDS, expediting guideline adoption
- Local skills are still required for deployment, testing, and maintenance; should be reduced as approach matures
- Additional EHR capabilities are desired for optimal user experience (e.g., triggering based off of ordering workflow, 1-click execution of recommended actions)

Thank you

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  - Amber Patel
  - Greg White
  - Johnathan Coleman
- Project Subject Matter Experts
  - Bryn Rhodes
  - Floyd Eisenberg
  - Ken Kawamoto
  - Rob McClure

Discussion

- Can you share anything your organization is engaged in that is similar?
- Do you see opportunities for this approach to be applied to your work and priorities?
- What concerns would you have surrounding implementing standardized CDS in your environment?

CDS for the CDC Prescribing Guideline Resources

- CDC Guideline for Prescribing Opioids for Chronic Pain https://www.cdc.gov/drugoverdose/prescribing/guideline.html
- Opioid Prescribing Support Implementation Guide FHIR R4 http://build.fhir.org/ig/cqframework/opioid-cds-r4/
- Opioid Prescribing Support Implementation Guide FHIR STU3 and DTSU2 http://build.fhir.org/ig/cqframework/opioid-cds
- Quick Start Guide http://build.fhir.org/ig/cqframework/opioid-cds-r4/quick-start.html

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The Office of the National Coordinator for Health Information Technology

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Health IT Feedback Form:
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Break

Please return by 11:40 am EDT

The Office of the National Coordinator for Health Information Technology

SHIELD: Harnessing National COVID-19 Test Data to Provide Customizable Decision Support for Patients with Underlying Medical Conditions

Michael Waters, Ph.D.

$SHIELD_x$ Team Lead/OIR RWE Representative

COVID-19 National Response Operations: HHS Data Strategy and Execution Workgroup (DSEW)

OHT 7: Office of In Vitro Diagnostics and Radiological Health (OIR)
Center for Devices and Radiologic Health (CDRH)
Food and Drug Administration (FDA)

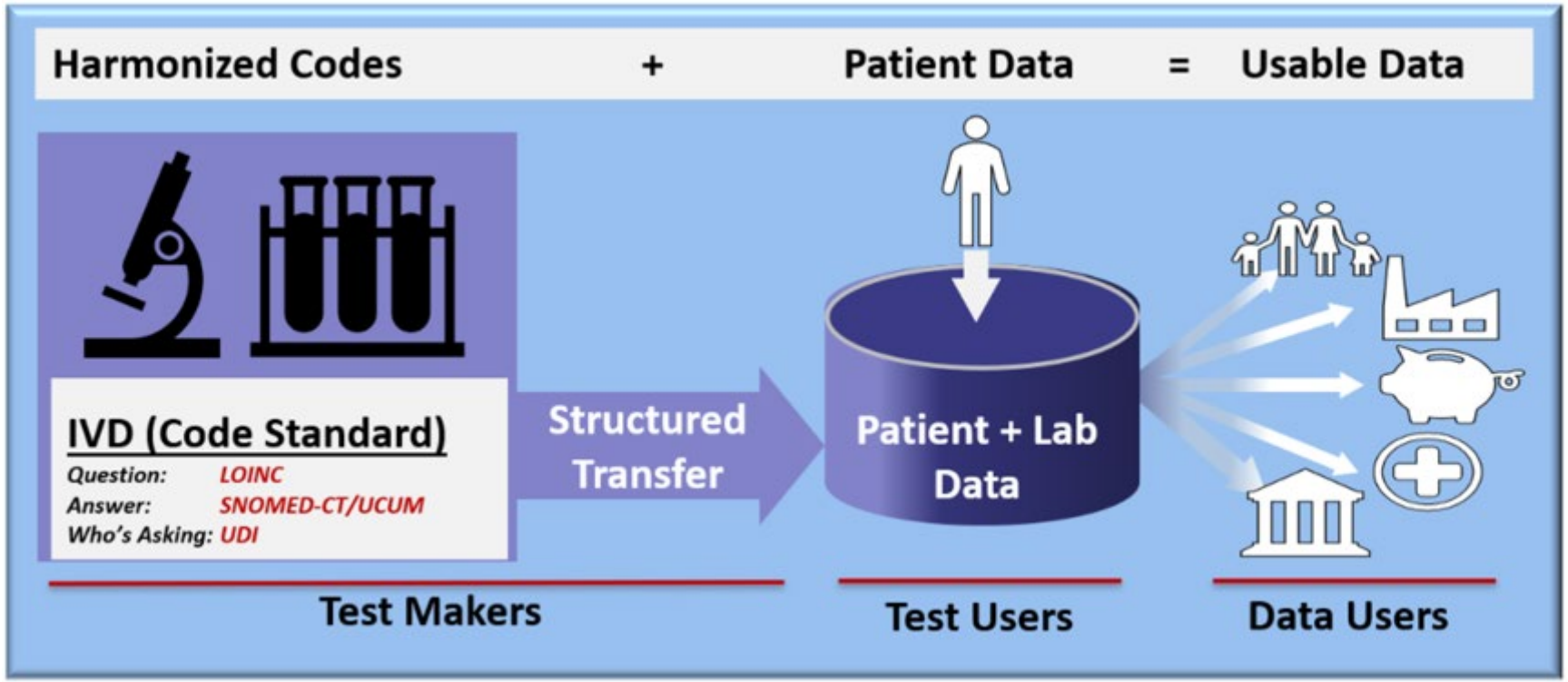
$SHIELD_x$ *Systemic Harmonization and Interoperability Enhancement for Lab Data*

SHIELD$_x$

Systemic Harmonization and Interoperability Enhancement for Lab Data

Mission:

SHIELD$_x$ is a public-private partnership focused on the adoption/development, harmonized application and implementation of diagnostic data standards to advance innovation.



70+ Stakeholders:

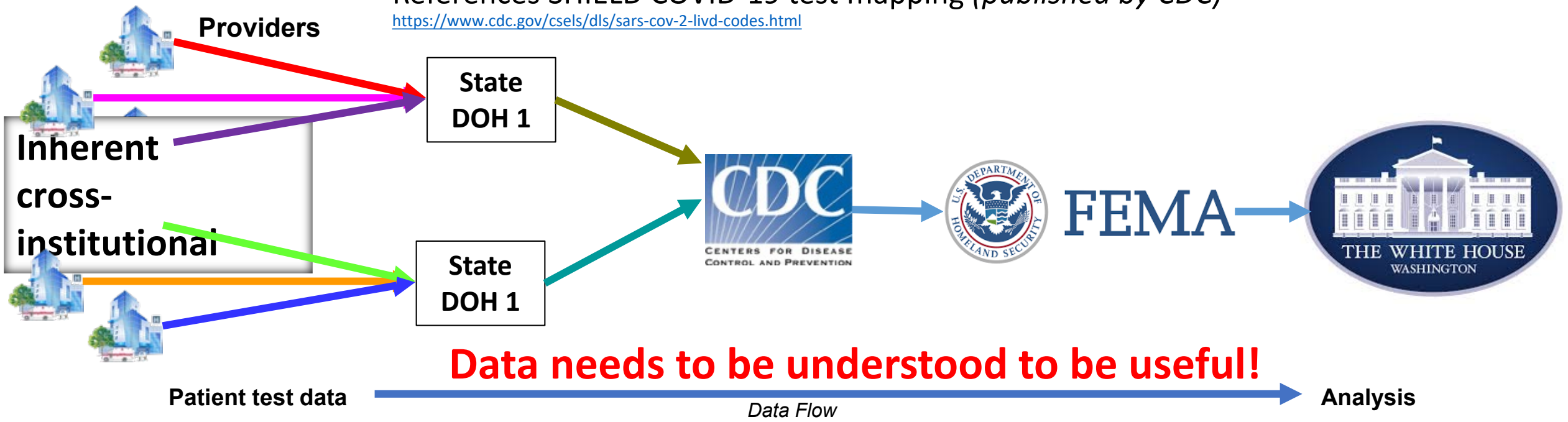
FDA (CDRH, CDER, CBER), CDC, NIH, ONC, CMS, VA, CAP, IVD Manufacturers, EHR Vendors, Laboratories, Standards Developers, PEW Charitable Trusts, NEST/MDIC, Academia

https://mdic.org/program/systemic-harmonization-and-interoperability-enhancement-for-lab-data-shield/

COVID-19 Laboratory Data Reporting Requirements

Daily COVID-19 Laboratory Data Reporting Required – *March 29, 2020*
HHS COVID-19 Laboratory Data Reporting Guidance – *June 4, 2020*
https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf

- Under CARES Act 116-136, § 18115(a)
- Applies to all testing performed in CLIA labs and home use settings
- Outlines the data elements for COVID-19 test data submission to HHS
- Implementation deadline: August 1, 2020
- References SHIELD COVID-19 test mapping *(published by CDC)*
  https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html



How do COVID-19 tests get to market?

Notes:

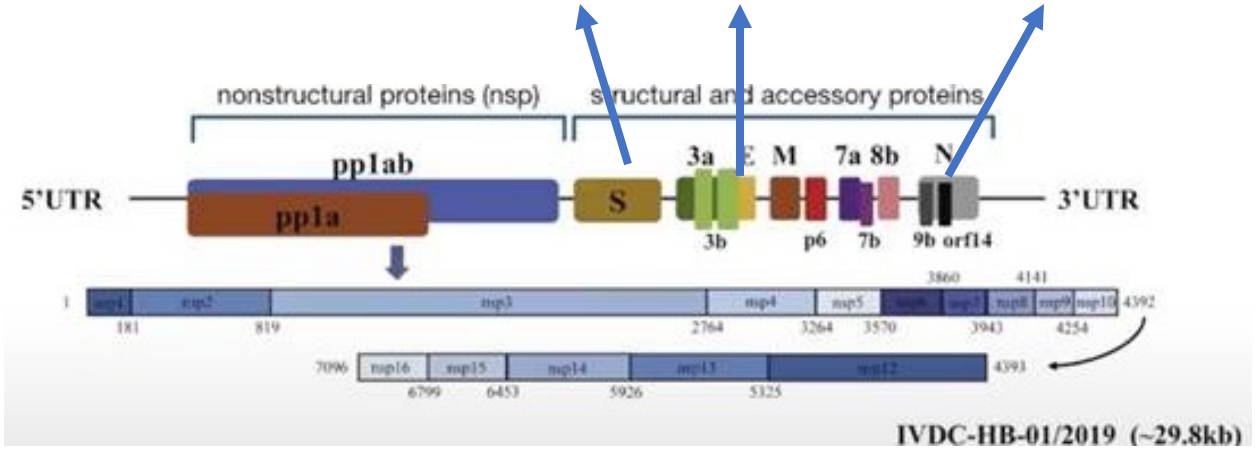
- Emergency Use Authorization (EUA)…… *Data reviewed by FDA*
- Notification (with intent to attain an EUA)…… *Self-validation*

Types of COVID-19 tests:

Do you have SARS-CoV-2 Virus?

Notes:

- RNA Amplification Tests (e.g. RT-PCR)…… *Indicates viral presence*
- Antigenic Tests (e.g., proteins – spike, envelope, nucleocapsid…… *Indicates viral presence*

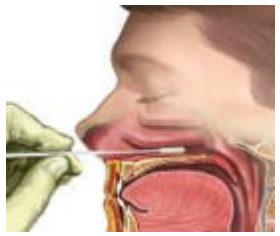


Do you have antibodies to SARS-CoV-2?

- Serology Tests (e.g., IgM, IgG, IgA)…… *Indicates exposure*

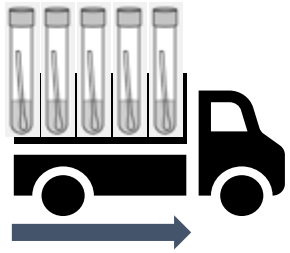
Harmonizing COVID-19 Test Data

Each test asks a ‘question’ of a specimen to get an ‘answer’.



nasopharyngeal

1) Collect



transport

prepare

2) **Ask Question:**

e.g., Does the nasopharyngeal swab contain SARS-CoV-2 RNA by PCR?

Type Test Performed
(LOINC code: 94500-6)

Specimen Type
(SNOMED-CT code: 258500001)

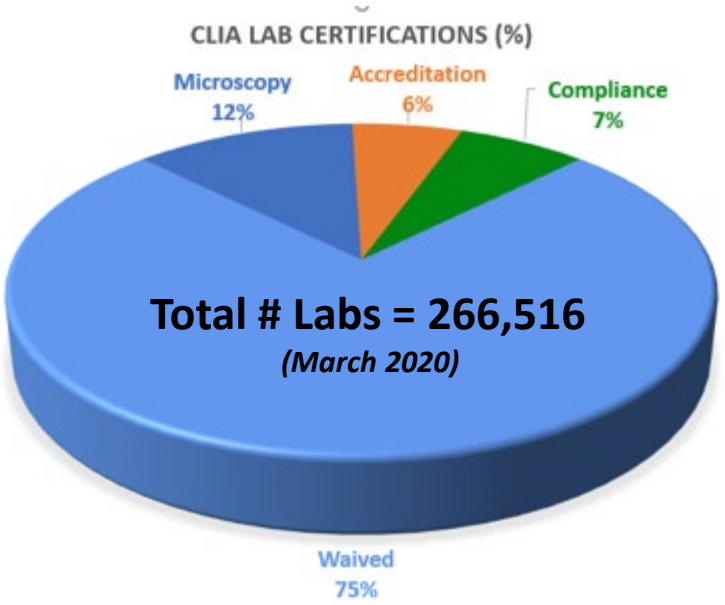
3) **Provide Answer:**

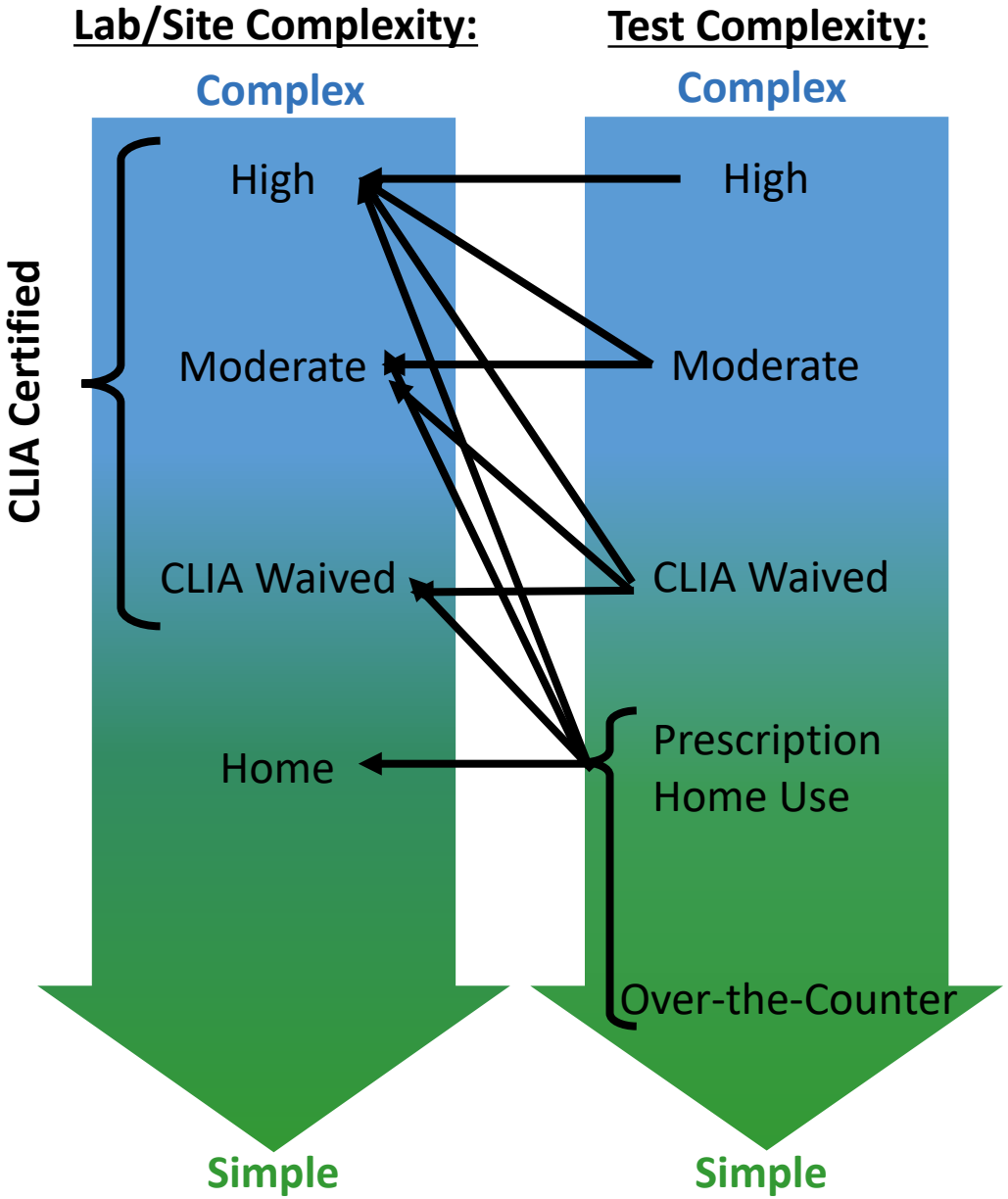
e.g., SARS-CoV-2 RNA is:

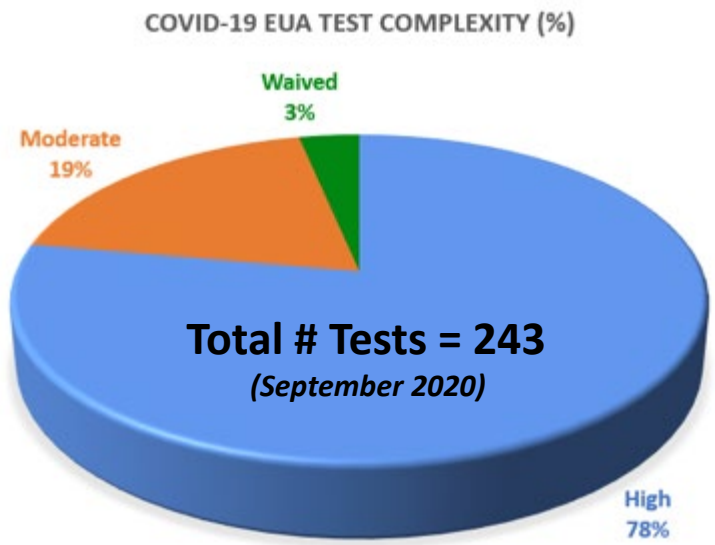
Detected
(SNOMED-CT code: 260373001)

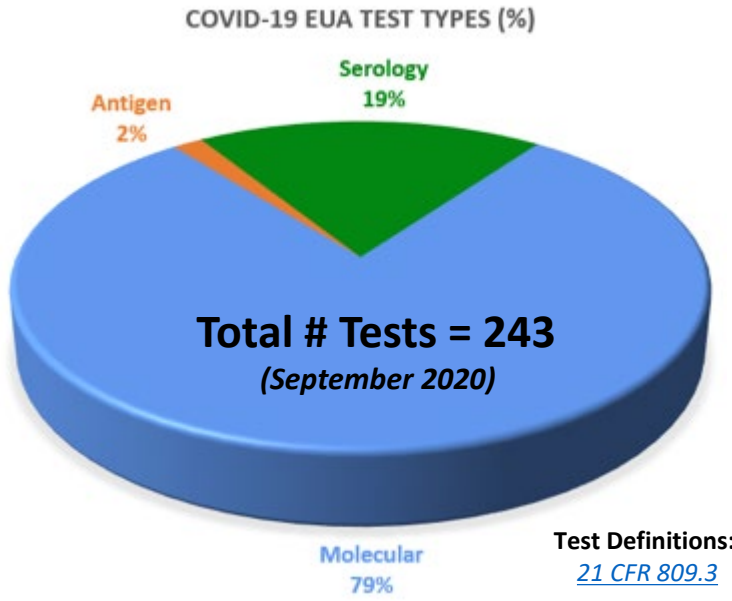
Not Detected
(SNOMED-CT code: 260415000)

COVID-19 Tests: Types, #s and Authorized Settings









Lab Definitions:
42 USC 263a
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/statcer.pdf

Test Definitions:
21 CFR 809.3

Daily Reportable Data Elements for All COVID-19 Tests

(summary; reportable to federal/state/local authorities, as appropriate)

Test orders:

- Test ordered
- Ordering provider name & NPI
- Ordering provider location/contact

Test results:

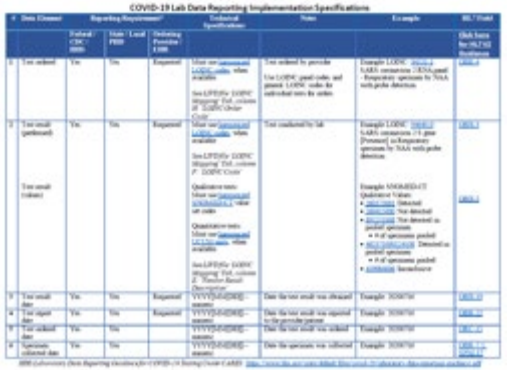
- Test result
- Device Identifier
- Specimen source
- Date specimen collected
- Test Result date
- Accession #/Specimen ID
- Performing facility name/CLIA#
- Performing facility location

Patient Demographics:

- Unique patient identifier
- Patient name
- Patient date of birth/age
- Patient race
- Patient ethnicity
- Patient sex
- Patient location/contact
- Patient occupation
- Patient congregate care/living setting
- Patient symptoms
- Patient test & hospitalization history
- Patient pregnancy status

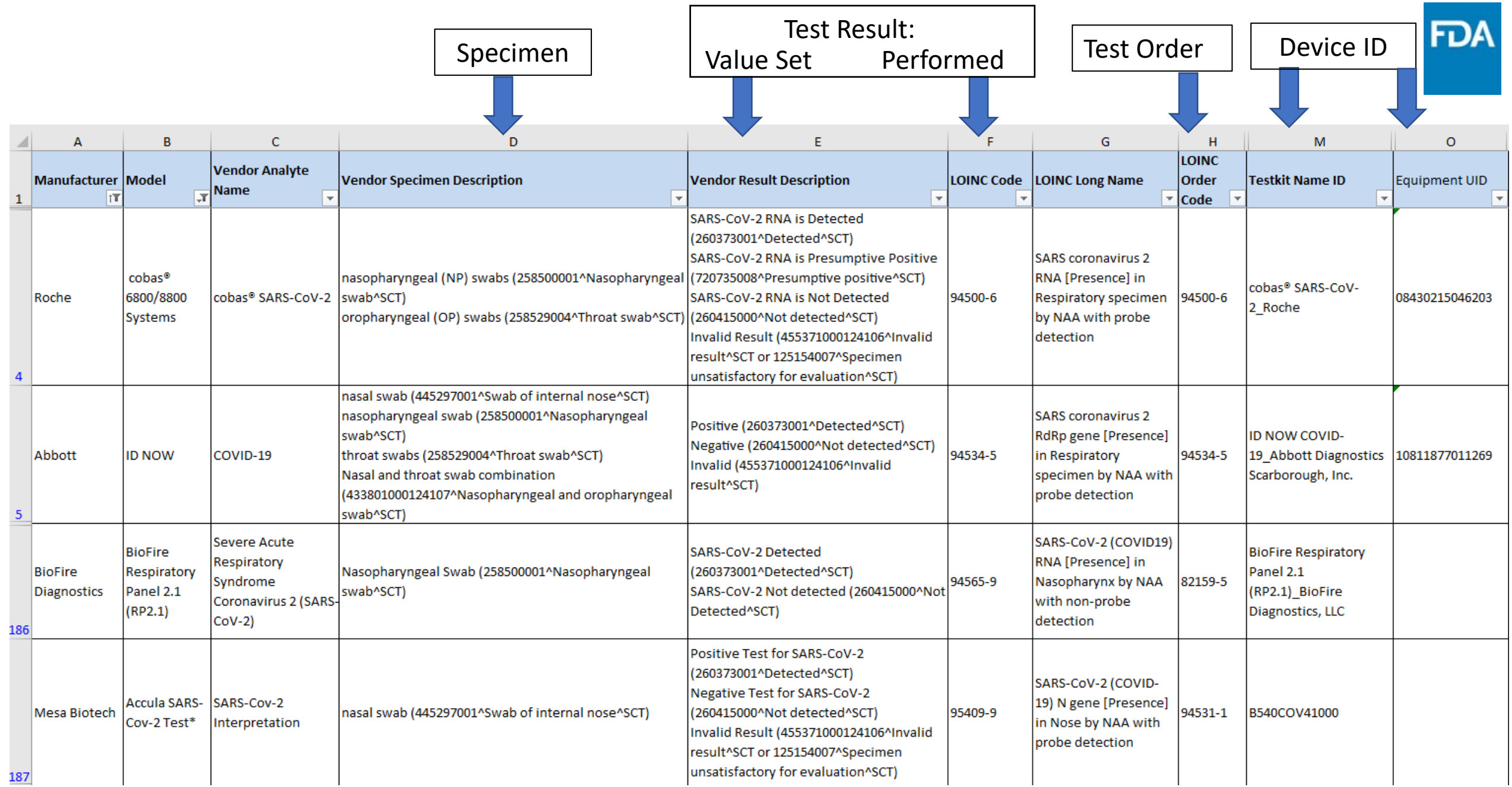
Harmonization Tools

HHS COVID-19 Guide:



COVID-19 Test Code Mapping:

https://www.hhs.gov/answers/is-additional-information-including-technical-specifications-available-to-support-laboratories-with-implementation/index.html



	A	B	C	D	E	F	G	H	M	O
1	Manufacturer	Model	Vendor Analyte Name	Vendor Specimen Description	Vendor Result Description	LOINC Code	LOINC Long Name	LOINC Order Code	Testkit Name ID	Equipment UID
4	Roche	cobas® 6800/8800 Systems	cobas® SARS-CoV-2	nasopharyngeal (NP) swabs (258500001^Nasopharyngeal swab^SCT) oropharyngeal (OP) swabs (258529004^Throat swab^SCT)	SARS-CoV-2 RNA is Detected (260373001^Detected^SCT) SARS-CoV-2 RNA is Presumptive Positive (720735008^Presumptive positive^SCT) SARS-CoV-2 RNA is Not Detected (260415000^Not detected^SCT) Invalid Result (455371000124106^Invalid result^SCT or 125154007^Specimen unsatisfactory for evaluation^SCT)	94500-6	SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection	94500-6	cobas® SARS-CoV-2_Roche	08430215046203
5	Abbott	ID NOW	COVID-19	nasal swab (445297001^Swab of internal nose^SCT) nasopharyngeal swab (258500001^Nasopharyngeal swab^SCT) throat swabs (258529004^Throat swab^SCT) Nasal and throat swab combination (433801000124107^Nasopharyngeal and oropharyngeal swab^SCT)	Positive (260373001^Detected^SCT) Negative (260415000^Not detected^SCT) Invalid (455371000124106^Invalid result^SCT)	94534-5	SARS coronavirus 2 RdRp gene [Presence] in Respiratory specimen by NAA with probe detection	94534-5	ID NOW COVID-19_Abbott Diagnostics Scarborough, Inc.	10811877011269
186	BioFire Diagnostics	BioFire Respiratory Panel 2.1 (RP2.1)	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)	Nasopharyngeal Swab (258500001^Nasopharyngeal swab^SCT)	SARS-CoV-2 Detected (260373001^Detected^SCT) SARS-CoV-2 Not detected (260415000^Not Detected^SCT)	94565-9	SARS-CoV-2 (COVID19) RNA [Presence] in Nasopharynx by NAA with non-probe detection	82159-5	BioFire Respiratory Panel 2.1 (RP2.1)_BioFire Diagnostics, LLC	
187	Mesa Biotech	Accula SARS-Cov-2 Test*	SARS-Cov-2 Interpretation	nasal swab (445297001^Swab of internal nose^SCT)	Positive Test for SARS-CoV-2 (260373001^Detected^SCT) Negative Test for SARS-CoV-2 (260415000^Not detected^SCT) Invalid Result (455371000124106^Invalid result^SCT or 125154007^Specimen unsatisfactory for evaluation^SCT)	95409-9	SARS-CoV-2 (COVID-19) N gene [Presence] in Nose by NAA with probe detection	94531-1	B540COV41000	

https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html

COVID-19 Lab Data Reporting Implementation Specifications

#	Data Element	Reporting Requirement*			Technical Specifications	Notes	Example	HL7 Field
		Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR				Click here for HL7 V2 Guidance

2	Test result (performed)
	
	Test result (values)
		Yes	Yes	Requested	Must use harmonized LOINC codes, when available
					See LIVD file 'LOINC Mapping' Tab, column F: 'LOINC Code'
					
					Qualitative tests: Must use harmonized SNOMED-CT value set codes
					
					Quantitative tests: Must use harmonized UCUM units, when available.
					
					See LIVD file 'LOINC Mapping' Tab, column E: 'Vendor Result
						Test conducted by lab	Example LOINC: 94640-0: SARS coronavirus 2 S gene [Presence] in Respiratory specimen by NAA with probe detection
							
							Example SNOMED-CT Qualitative Values:
							• 260373001 Detected
							• 260415000 Not detected
							• 895231008 Not detected in pooled specimen
							  • # of specimens pooled
							• 462371000124108 Detected in pooled specimen
							  • # of specimens pooled
							• 419984006 Inconclusive
								OBX-3
								
								OBX-5

7	Device Identifier	Yes	Yes	Requested	Must use harmonized Device Identifiers (DI), when available. The DI is contained within the unique device identifier (UDI), created by manufacturer *See LIVD file 'LOINC Mapping' Tab, column M: 'TestkitName ID' for assay and column O: 'Equipment UID' for instrument*	Manufacturer requests UDI issuance, then provides DI, or pull from GUDID database If DI unavailable: Use 'Trade Name_Manufacturer Name' (a unique element controlled under 21 CFR 209.10(b)(1))	Example DI: 01234567891011 Example Trade Name: SARS-CoV-2 Test_Company	OBX-17, OBX-18 (barcode)

Location of data element in LIVD SARS-CoV-2 mapping file

Reporting using codes for pooled specimens

2 nce

COVID-19 Lab Data Reporting Implementation Specifications

#	Data Element	Reporting Requirement*			Technical Specifications	Notes	Example	HL7 Field
		Federal / CDC / HHS	State / Local PHD	Ordering Provider / EHR				Click here for HL7 V2 Guidance
33	AOE: Pregnant	Requested	Requested		Pregnant Not Pregnant UNK - Unknown		LOINC: 82810-3 SNOMED-CT Pregnancy Status: • 77386006 Pregnant • 60001007 Not Pregnant • 261665006 Unknown • 276727009 Null	OBX-5

Reporting requirement clarifications

* Reporting Requirements:

This table represents a visual, side-by-side comparison of which entities ultimately receive each of the reported data elements. For example, not all data elements reported to the State / Local PHD are reported to the Federal authorities.

- This table is not meant to indicate how data elements are reported in terms of their flow between entities. Current information on reporting requirements for laboratories and associated FAQs are available on CDCs website: "How to Report COVID-19 Laboratory Data"

Requirement/Request Level:

- Yes = Required to be reported by August 1st, 2020
- Requested = Every reasonable effort should be made to achieve reporting by August 1st, 2020
- Optional = Strongly encouraged to begin reporting by August 1st, 2020, if possible
- No = Not required to be reported

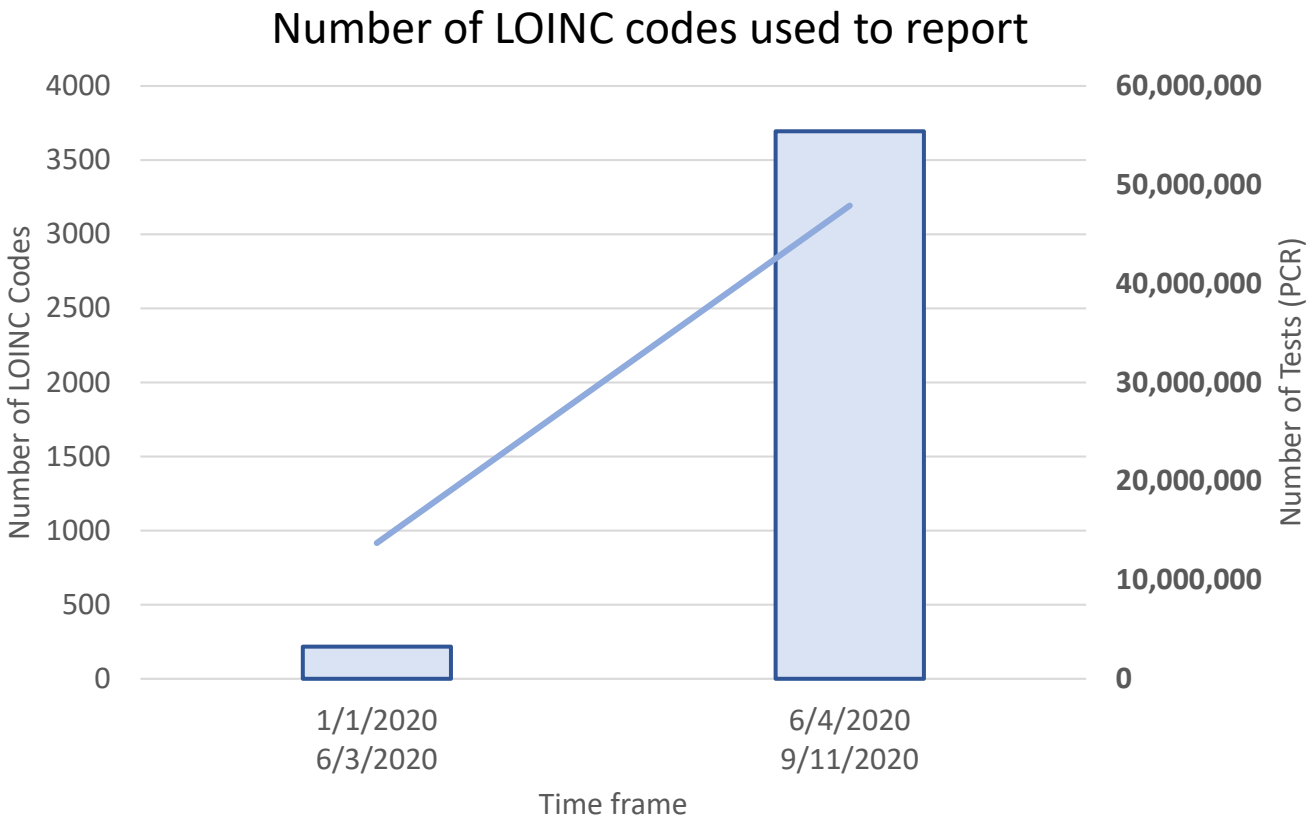
New - National ELR Flat File and HL7 Generator Tool Package

https://preparedness.cste.org/?page_id=136

Completeness and Harmonization of One Data Element

~ 77 million reported PCR test results *as of 9/11

>99% of transmitted results report data element “Test Result”



12.4% of test results don’t use harmonized LOINC codes

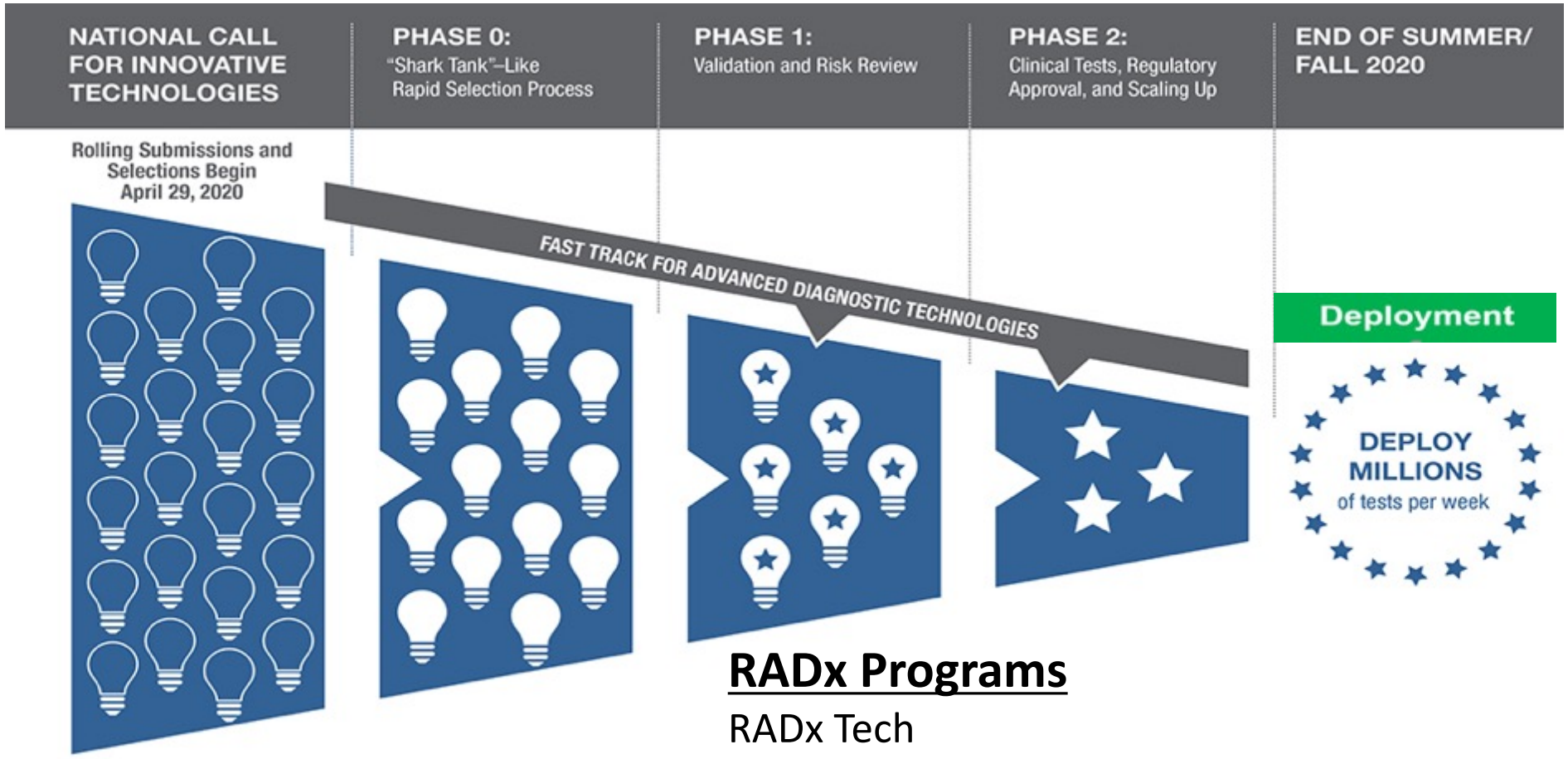
↓

Top three codes

1. NOVELCORONAPCR
2. COVID19
3. Null (empty field)

Data harmonization is improving!

Rapid Acceleration of Diagnostics (RADx) for COVID-19



Goal:

Deployment of COVID-19 tests anywhere.

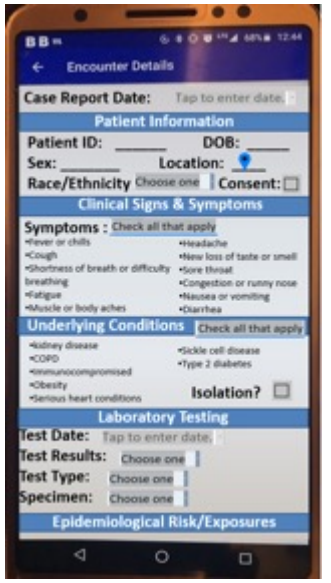
RADx Programs

RADx Tech

RADx Underserved Populations (RADx-UP)

RADx Radical (RADx-rad)

RADx Advanced Technology Platforms (RADx-ATP)



Reporting Enabled App

https://www.nih.gov/research-training/medical-research-initiatives/radx/radx-programs

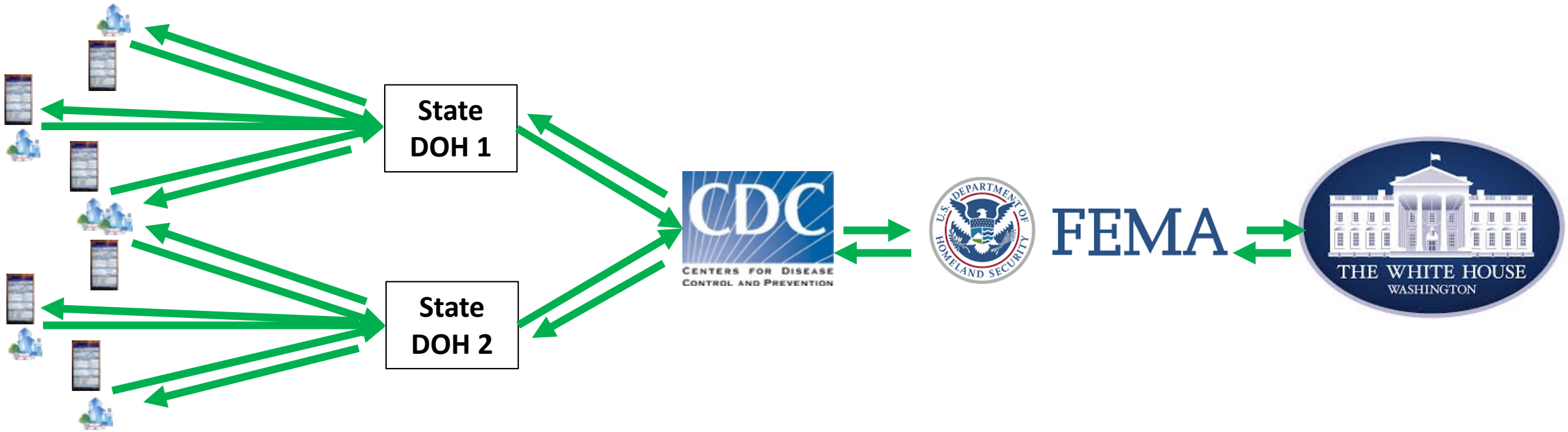
Mapping Underlying Medical Conditions

- 1 Home
- 2 Logica Comparison to E ICR
- 3 Patient Demographics and Vital Signs
- 4 Case Reporting Info
- 5 Exposure Info
- 6 Signs Symptoms Diagnoses Comorbidities
- 7 Lab Profiles
- 8 Smoking Status Pregnancy Status
- 9 Exposure Questionnaire
- 10 History
- 11 Artifacts Summary
  - 11.7 COVID-19 gastrointestinal and hepatic underlying condition
  - 11.8 COVID-19 hemoglobinopathy underlying condition
  - 11.9 COVID-19 ICD 10 Diagnosis
  - 11.10 COVID-19 immune underlying condition
  - 11.11 COVID-19 renal underlying condition
  - 11.12 COVID-19 respiratory underlying condition
  - 11.13 COVID-19 SNOMED Diagnosis
  - 11.14 COVID 19 Symptoms Absent
  - 11.15 COVID 19 Symptoms Present
  - 11.16 COVID-19 uncategorized underlying condition
  - 11.17 COVID-19 cardiovascular underlying condition
  - 11.18 COVID-19 immunocompromised underlying condition
  - 11.19 COVID-19 General Comorbidities Absent
  - 11.20 COVID-19 General Comorbidities Present
  - 11.21 COVID-19 metabolic underlying condition
  - 11.22 COVID-19 neurologic underlying condition

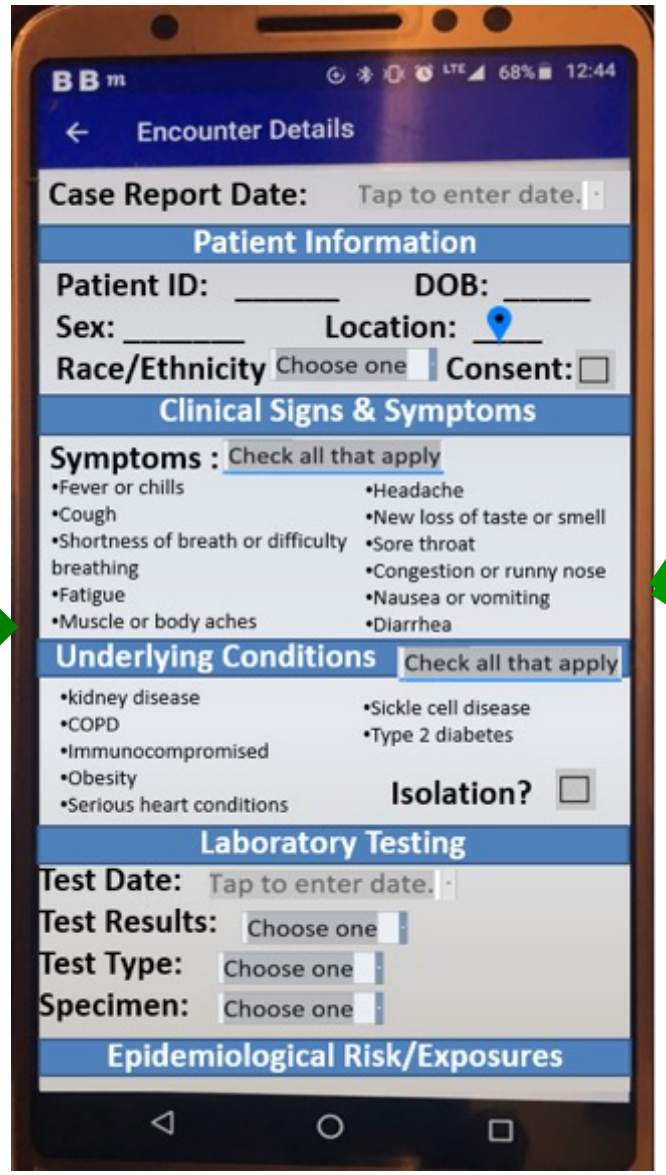
Code	Display
427099000	Active tuberculosis (disorder)
22607003	Asbestosis (disorder)
195967001	Asthma (disorder)
12295008	Bronchiectasis (disorder)
63480004	Chronic bronchitis (disorder)
13645005	Chronic obstructive lung disease (disorder)
39871006	Chronic respiratory failure (disorder)
719218000	Cryptogenic organizing pneumonia (disorder)
190905008	Cystic fibrosis (disorder)
931000119107	Dependence on supplemental oxygen (finding)
37471005	Extrinsic allergic alveolitis (disorder)
51615001	Fibrosis of lung (disorder)
700250006	Idiopathic pulmonary fibrosis (disorder)
64667001	Interstitial pneumonia (disorder)
233703007	Interstitial lung disease (disorder)
40100001	Obliterative bronchiolitis (disorder)
78275009	Obstructive sleep apnea syndrome (disorder)
87433001	Pulmonary emphysema (disorder)
991000119106	Reactive airway disease (disorder)
36485005	Restrictive lung disease (disorder)
31541009	Sarcoidosis (disorder)
56717001	Tuberculosis (disorder)

https://covid-19-ig.logicahealth.org/toc.html

Ensuring Maximal Data Utility



Goal: Provider & Patient Utility from At-Anywhere Tests



Just took a home test… now what?

Should I go back to work/school?

I have underlying medical conditions, is are there special considerations for me?

Can we get supplies?

Should I get tested? When? Where?

Office of the CHIEF TECHNOLOGY OFFICER

The Office of the National Coordinator for Health Information Technology

Clinical Response through Emerging Technology (CRET)

An Integrated Health IT Tool for Providers to Respond to Public Health Hazards

Daniel Chaput; ONC; daniel.chaput@hhs.gov

September 15, 2020

What is CRET?

The Clinical Response through Emerging Technology (CRET) program is an HHS initiative to improve clinical response to emerging public health hazards using EHRs and IT tools and infrastructure.

Purpose:

CRET's goal is to provide clinicians with near-real-time updates to information and best practices to improve their medical response to a broad range of natural and manmade hazards

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The Need for CRET

When health hazards occurs, each response is slightly different. CRET addresses the critical in-the-moment information needs of the medical community:

- Immediate access to the latest science about response without the need for extensive research when time is of the essence
- Translation of public health agency guidance into computer-readable information that can be shared with computer systems (including EHRs and clinical decision support) to deliver needed information to doctors at the point of care.

CRET provides clinicians with the latest science and response protocols from federal, state, tribal, local, and territorial public health communities by delivering critical knowledge to clinical decision support tools within existing clinical workflows.

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Common Hazards Requiring CRET Response

- Infectious diseases

- Environmental, chemical, and biological hazards

- Events based on (intentional or unintentional) human behavior

- Natural events such as extreme weather

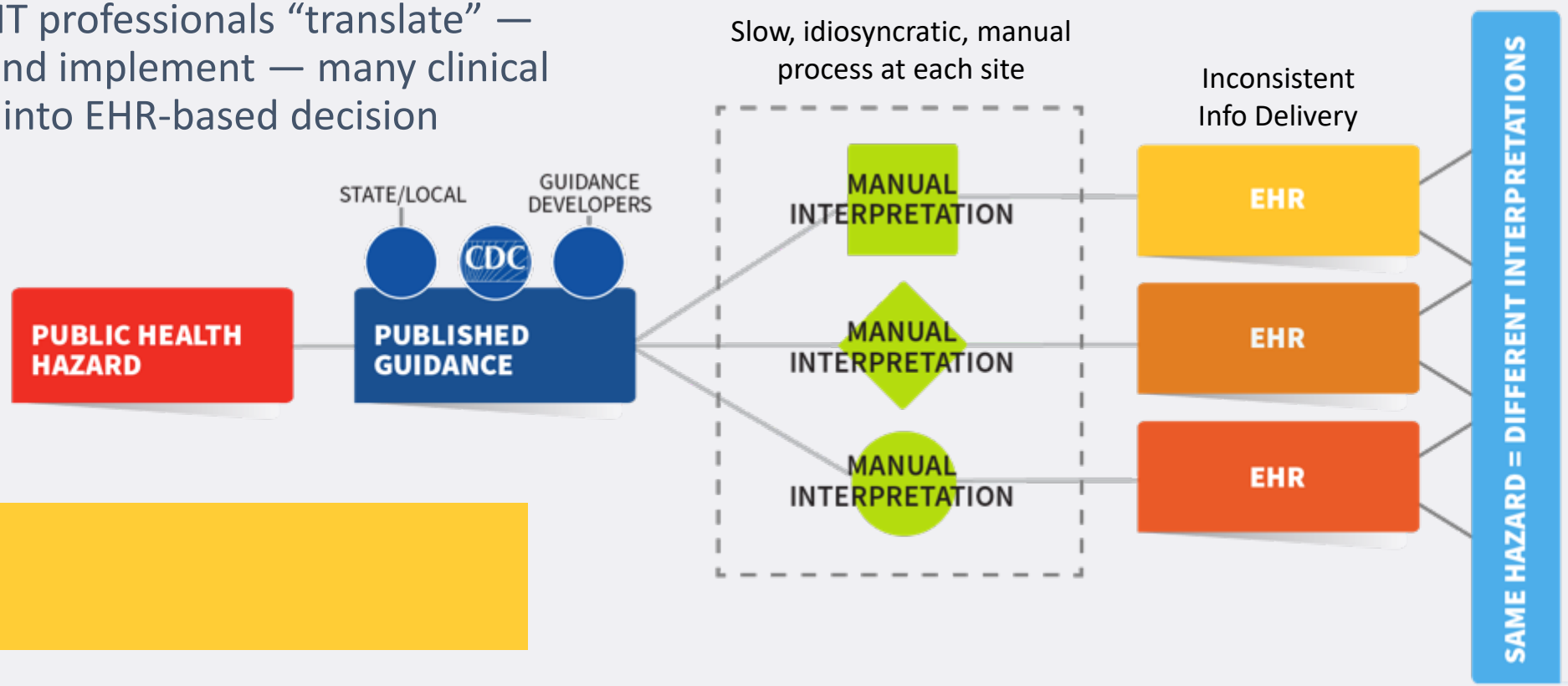
Risk Identification & Response at Point of Care

CRET is adaptable for different audiences (e.g., clinicians, clinical software vendors, average citizens). It addresses:

- **Risk Identification:** Exposures (e.g., travel, residence, occupation, recreational activities), symptoms, physical findings, and diagnostic tests (e.g., laboratory, imaging and pathology)
- **Risk Reduction and Mitigation:** Isolation, personal protective equipment, exposure avoidance, treatment and supportive care
- **Education:** Recommendations for individuals at risk (patients, caregivers, employment sites)

Current Manual Process for Information Distribution

Currently, IT professionals “translate” — interpret and implement — many clinical guidelines into EHR-based decision support



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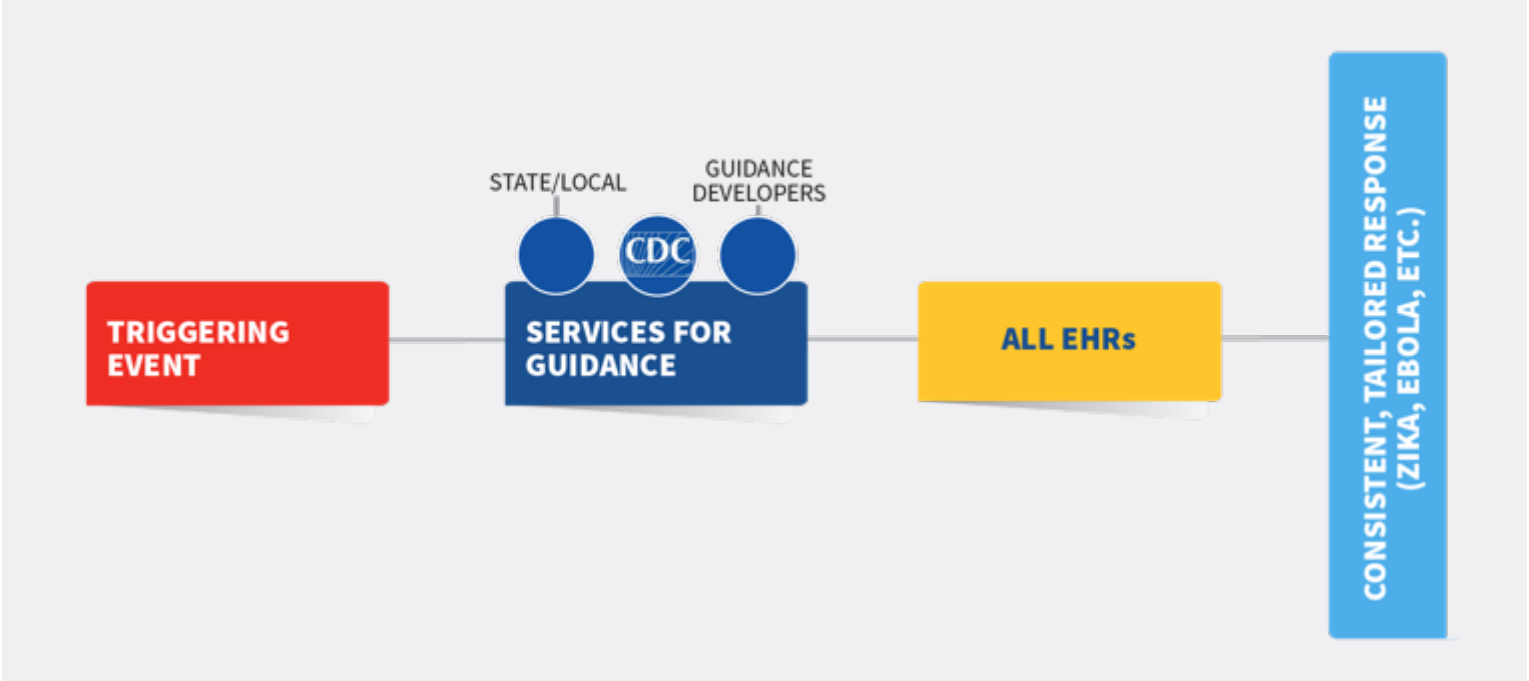
CRET: Changing The Picture

CRET framework and tools = an approach to share information on evolving threats

- Rapid dissemination of the most updated, accurate science
- Information delivery using clear data standards and definitions
- Flexibility and re-use of logic to rapidly address new threats



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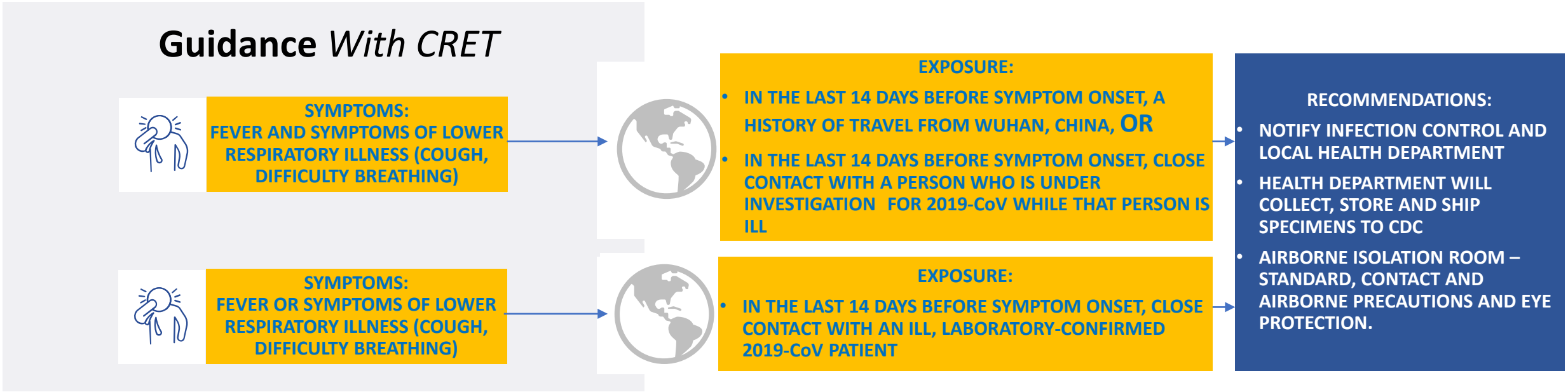
Emerging Infectious Diseases: 2019nCoV Coronavirus



Source: Centers for Disease Control and Prevention. 2019 Novel Coronavirus, Wuhan, China: Interim Guidance for Healthcare Professionals. Available at: https://www.cdc.gov/coronavirus/2019-nCoV/clinical-criteria.html

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Improving Public Health Response With Modern Systems

Clinicians must understand complex and rapidly evolving guidelines

- Currently, IT professionals “translate” — interpret and implement — many clinical guidelines into EHR-based decision support
- This process can lead to inconsistent and inaccurate implementation

Let’s consider an example and its implications:
ACUTE LYME

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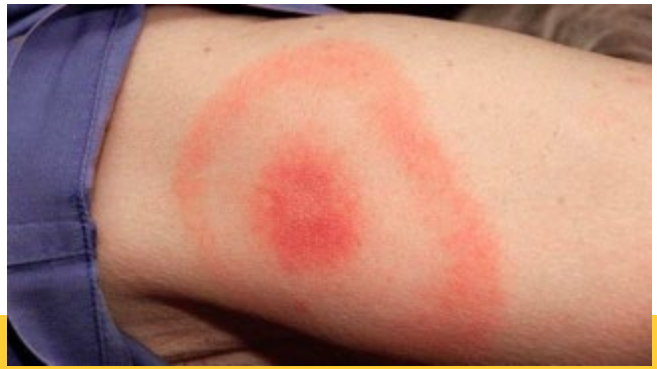
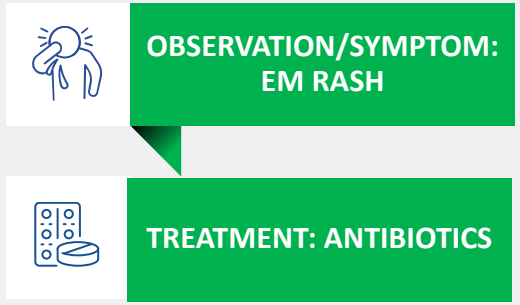
ONC/CTO Office of the Chief Technology Officer

Acute Lyme: The Bulls-Eye Rash, an Easy Diagnosis



- After tick bite, some patients present with erythema migrans (EM) rash.
  - The rash is diagnostic for Lyme disease, unlike non-specific symptoms, which are inconclusive
- Do all clinicians know this?

Accurate Clinical Guidance for Patient with EM Rash



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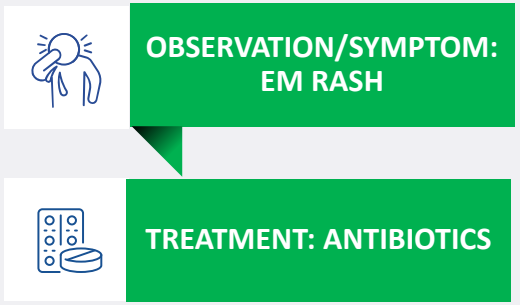
Acute Lyme: A Dangerous Reality

Wasted Steps *Without CRET*

vs.

Each step = time lost

Accurate Guidance *With CRET*



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CRET For Acute Lyme: Take-aways

Before

- Legacy IT without shared standards or interpretation
- Complex guidelines “translated” by IT professionals
- One-way communication
- EHR updates fail to keep pace with evolving state of science

After

- Flexible, scalable platform (extendable to many hazards) with shared standards
- Complex guidelines “translated” by SMEs
- Bidirectional communication
- EHR updates are rapid with near-real time information

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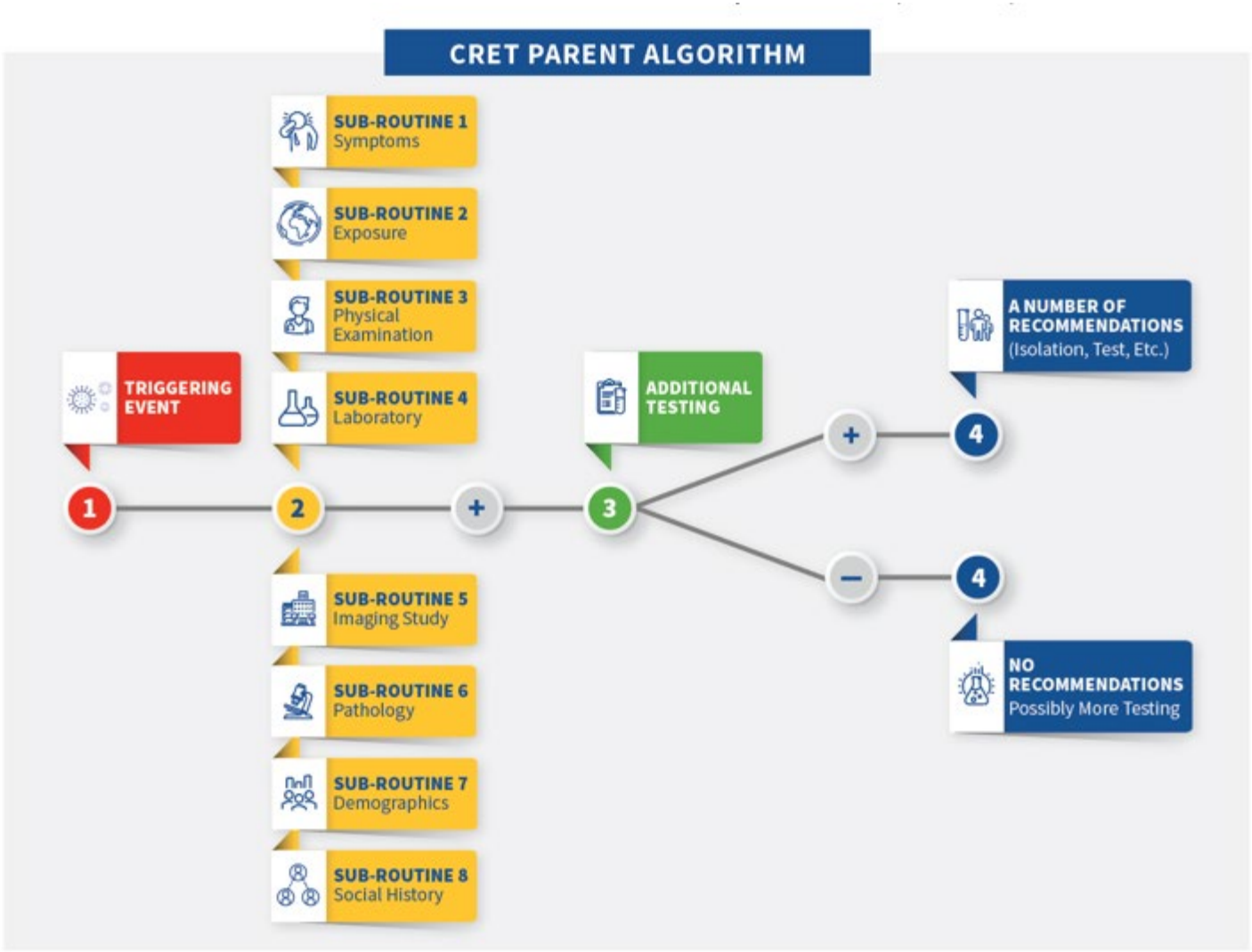
CRET Parent Algorithm

CRET emphasizes traits critical to rapid response to health threats:

- Flexibility
- Diversity of experiences
- Ability to handle uncertainty



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CTO

Thanks to

- Rachel Abbey, ONC
- Floyd Eisenberg, iParsimony
- James Daniel, Amazon Web Services (formerly with CTO)
- Michael Wittie, ONC
- Kristen Honey, CTO
- Alexander Wilson, CTO
- Rachel Melo, CTO

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Q&A Discussion

Lunch Break
Please return by 1:30 pm EDT

The Office of the National Coordinator for Health Information Technology

CPG-on-FHIR: Computable Guidelines for CDS and Beyond

Maria Michaels
Centers for Disease Control and Prevention

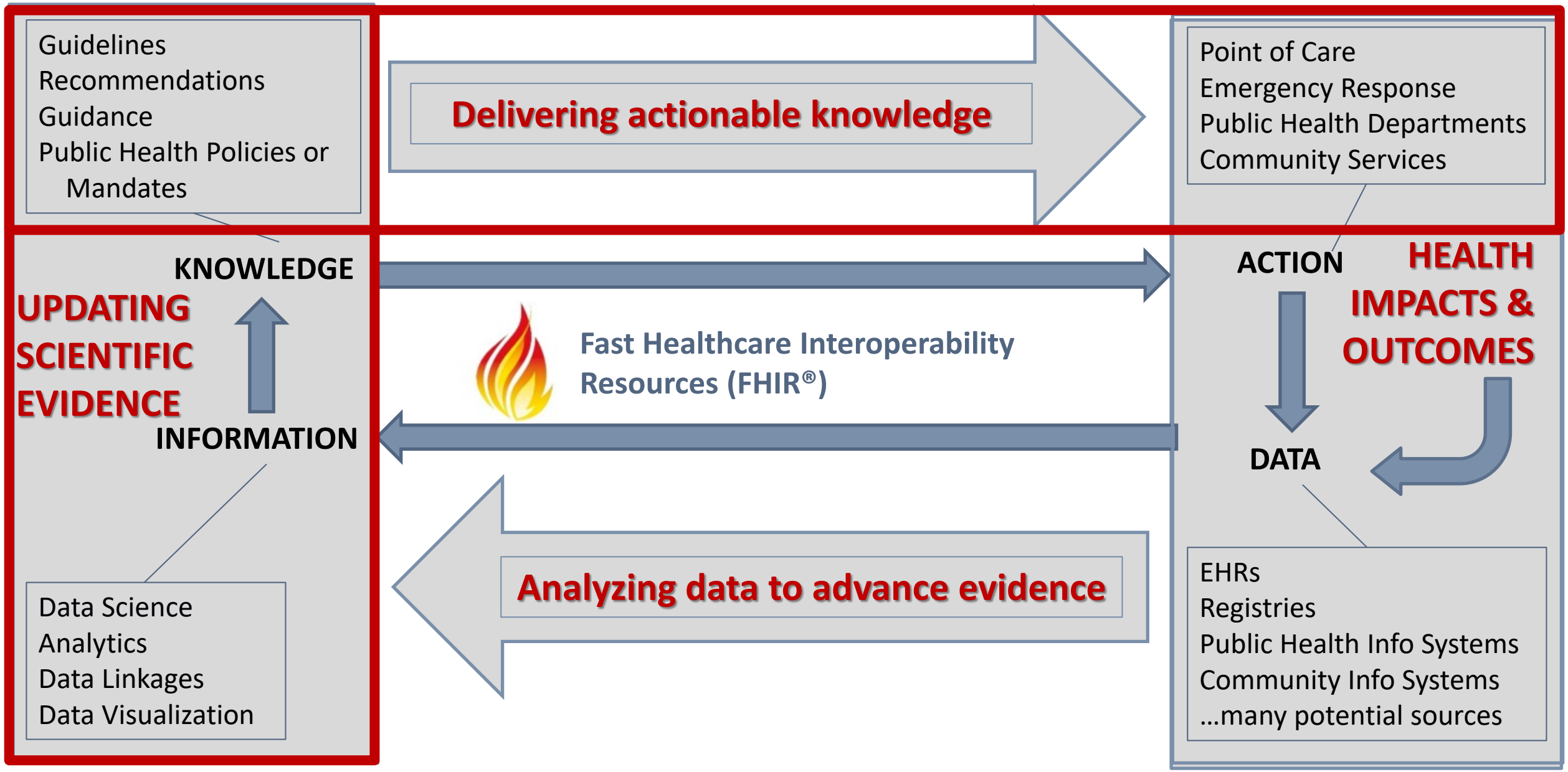
Matthew Burton
Apervita, Inc.

Bryn Rhodes
Database Consulting Group

September 15, 2020

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

The Data Lifecycle & Impacts to the Public's Health



Redesigning Guideline Development and Implementation

SEQUENTIAL & SILOED

CURRENT STATE

Guidelines

10s-100s of translations

CDS

Informatics

Implementation

Evaluation (maybe)

100s-1000s of translations

Patient Care

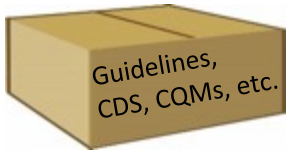
Communication

CQMs

Inconsistent (or nonexistent) feedback loop

PARALLEL & ITERATIVE

PROPOSED FUTURE STATE



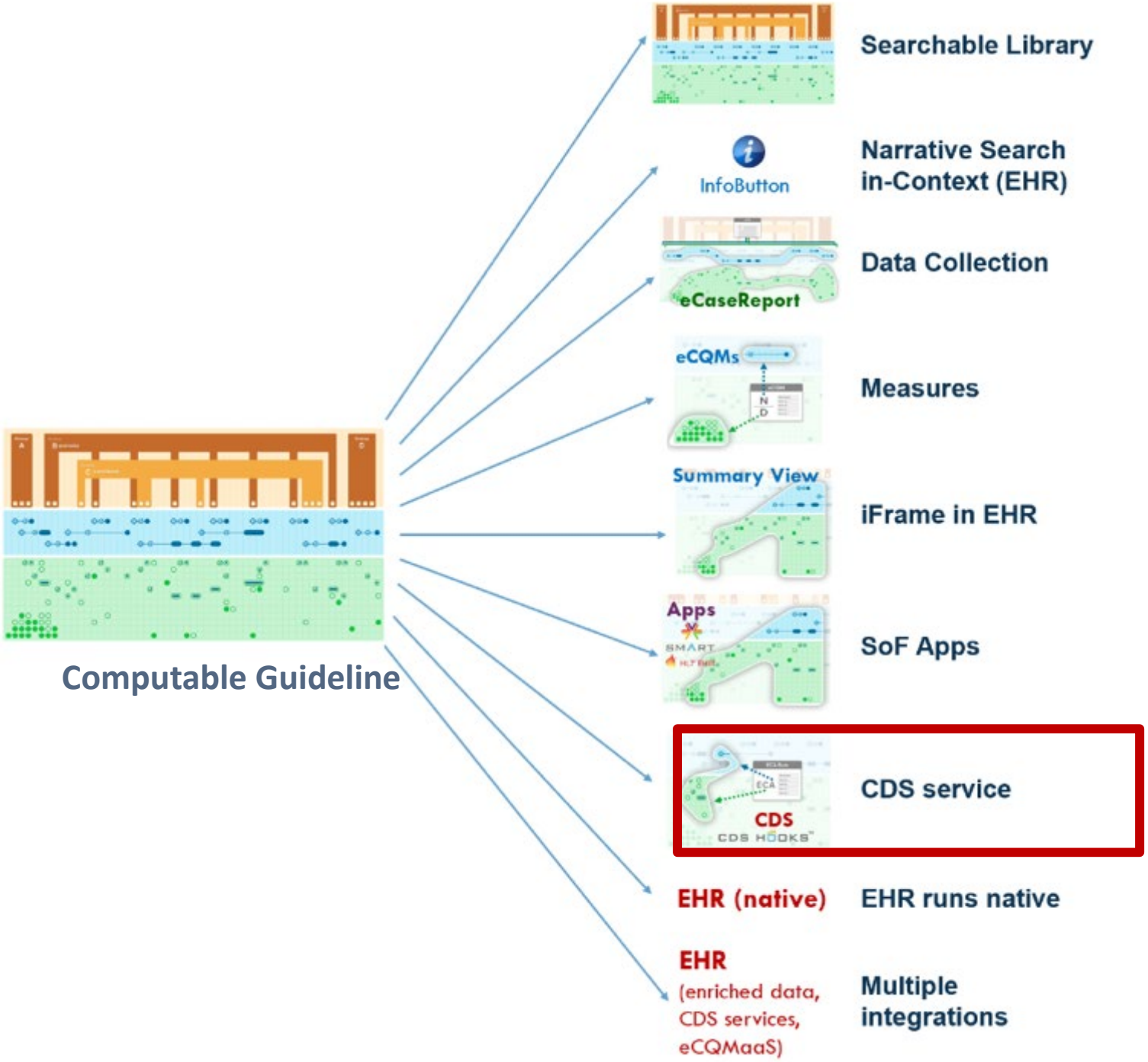
Guidelines
Informatics
Communication
Implementation
Local Implementation & Evaluation

Concurrent guideline development, translation, & implementation with early engagement and iteration

Patient Care

Consistent feedback loop

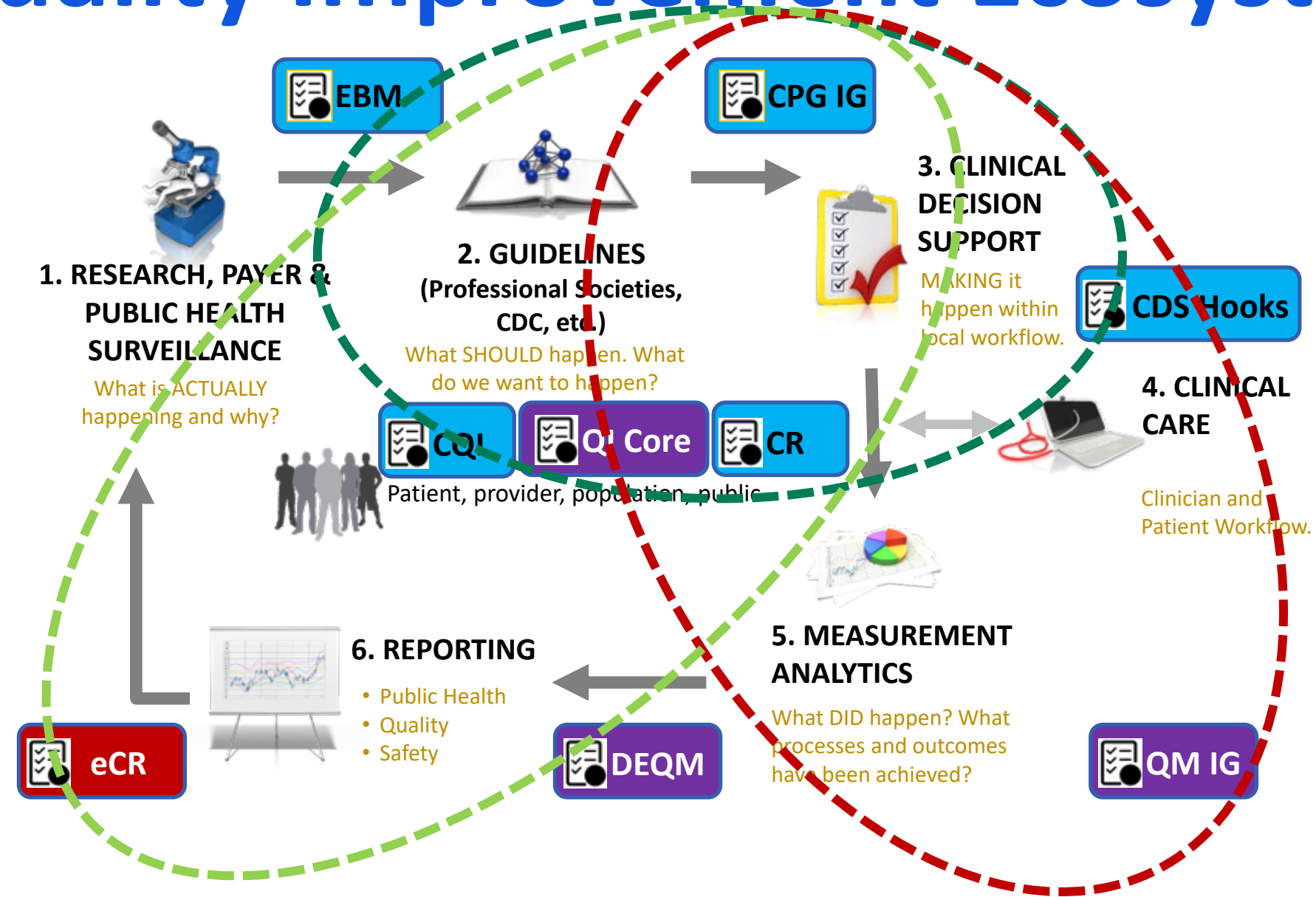
One Translation Many Ways to Implement It



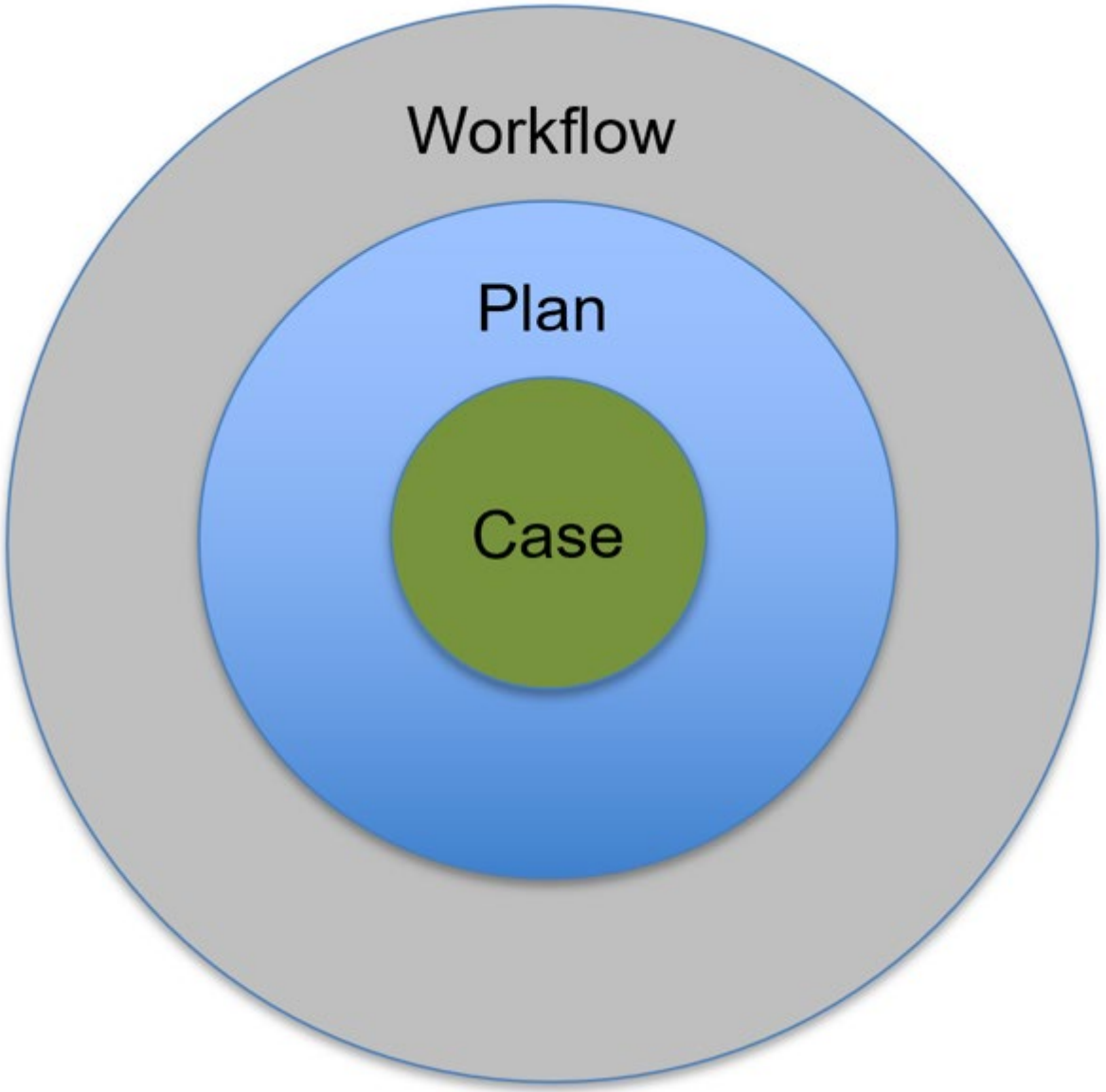
CPG-on-FHIR

Setting the standard for a new approach for evidence to practice

Quality Improvement Ecosystem



Separation of Concerns



Case – patient “clinical pathophysiological processes”, their manifestations and qualifications thereof

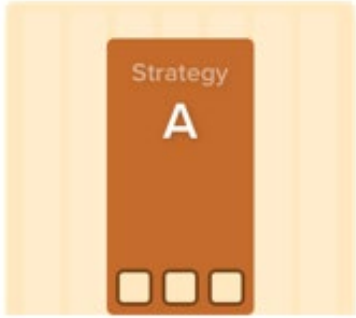
Plan – the approach to the patient’s current, historical, and potential future state of disease and well-being including medical decision-making

Workflow – how the Plan is implemented through interactions with clinical information systems and/or through real-world human tasks and activities

CPG Basic Components

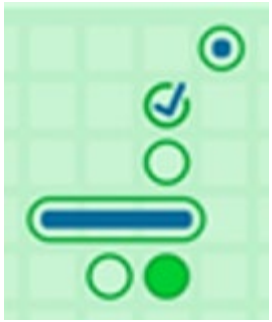
Plan

- Pathway
- Strategy
- Recommendation



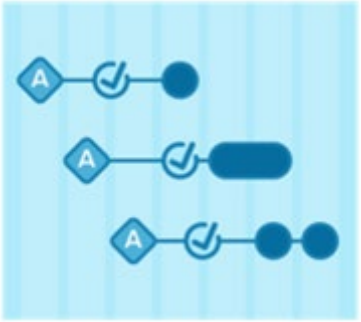
Case

- Case Feature
- Derived Case Feature
- Case Feature (Request)
- Case Feature (Events)



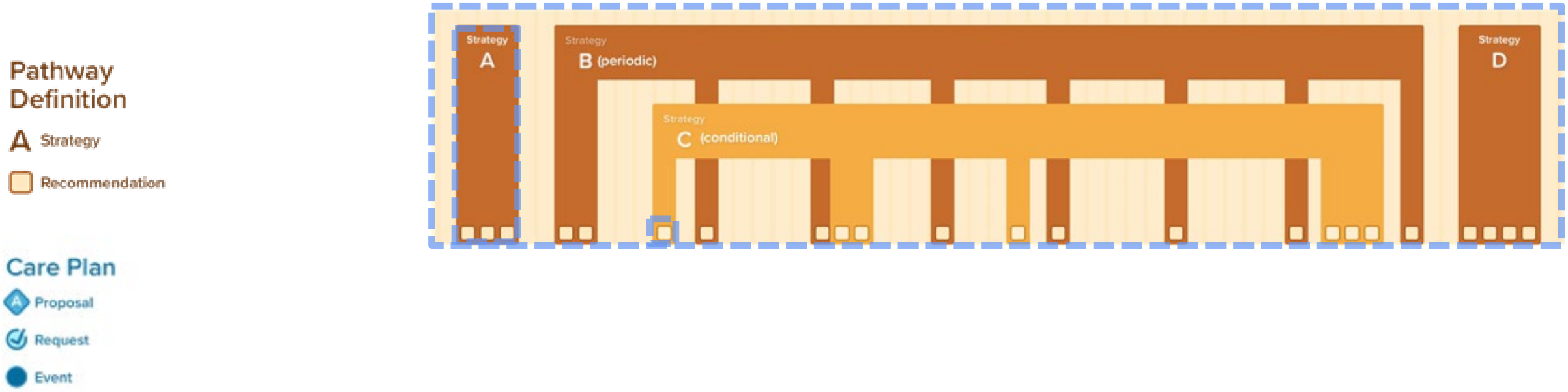
Care Plan

- Proposal
- Request
- Event



Conceptual CPG Knowledge

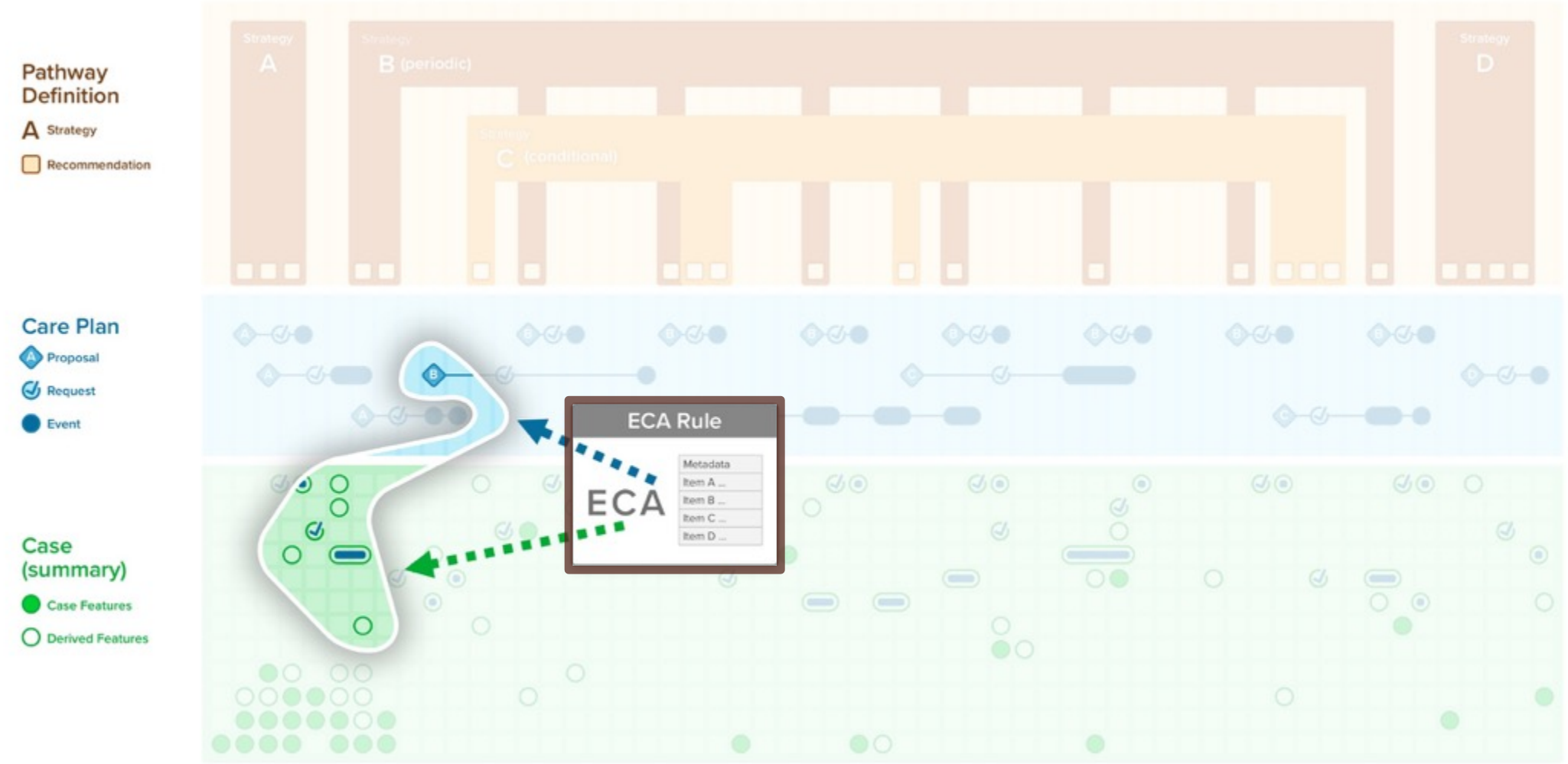
Expressed as (Profiled) FHIR Plan Definitions + CQL



http://build.fhir.org/ig/HL7/cqf-recommendations/index.html

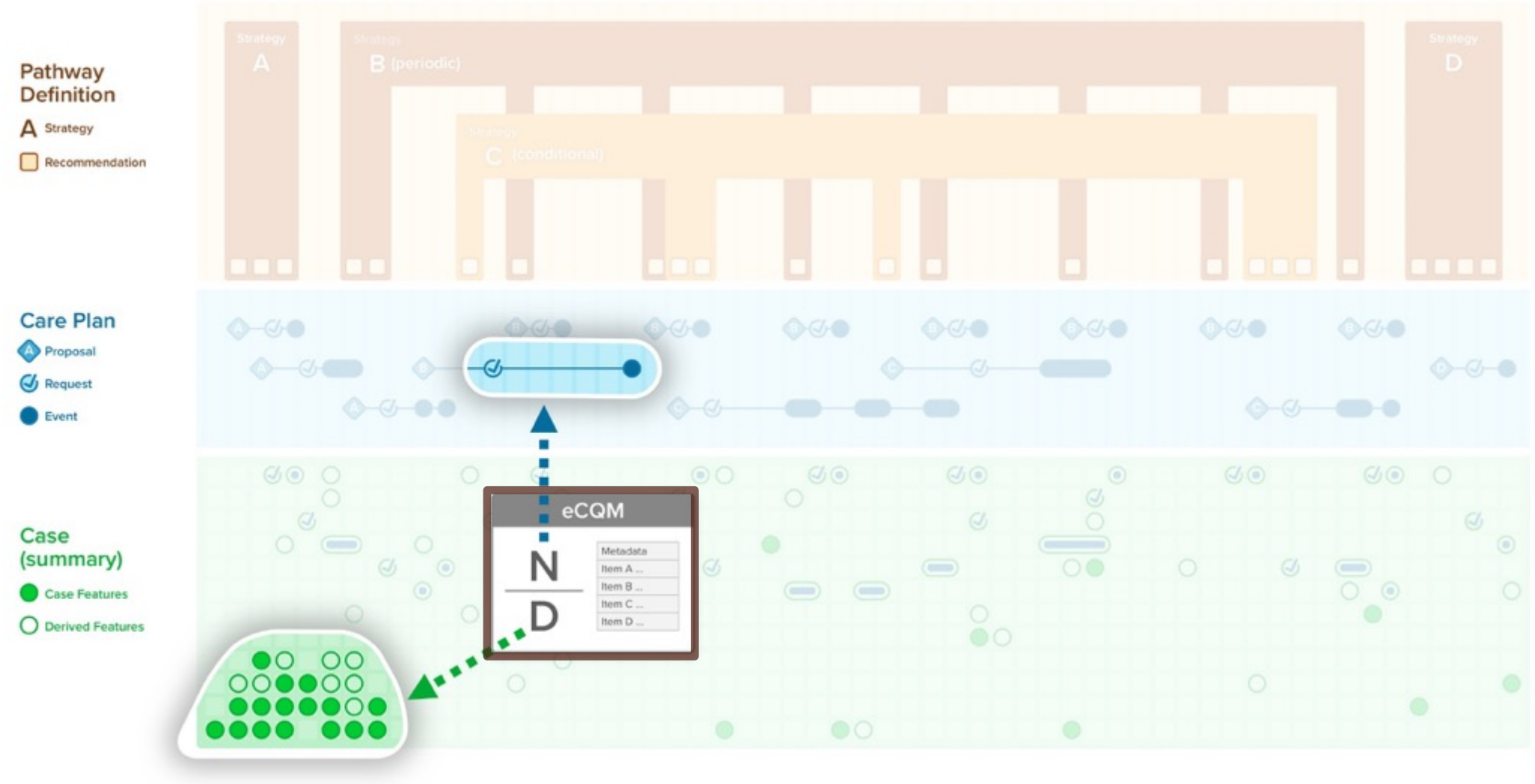
CDS Reminder (Event-Condition-Action Rule)

(Profiled) FHIR Plan Definition + CQL



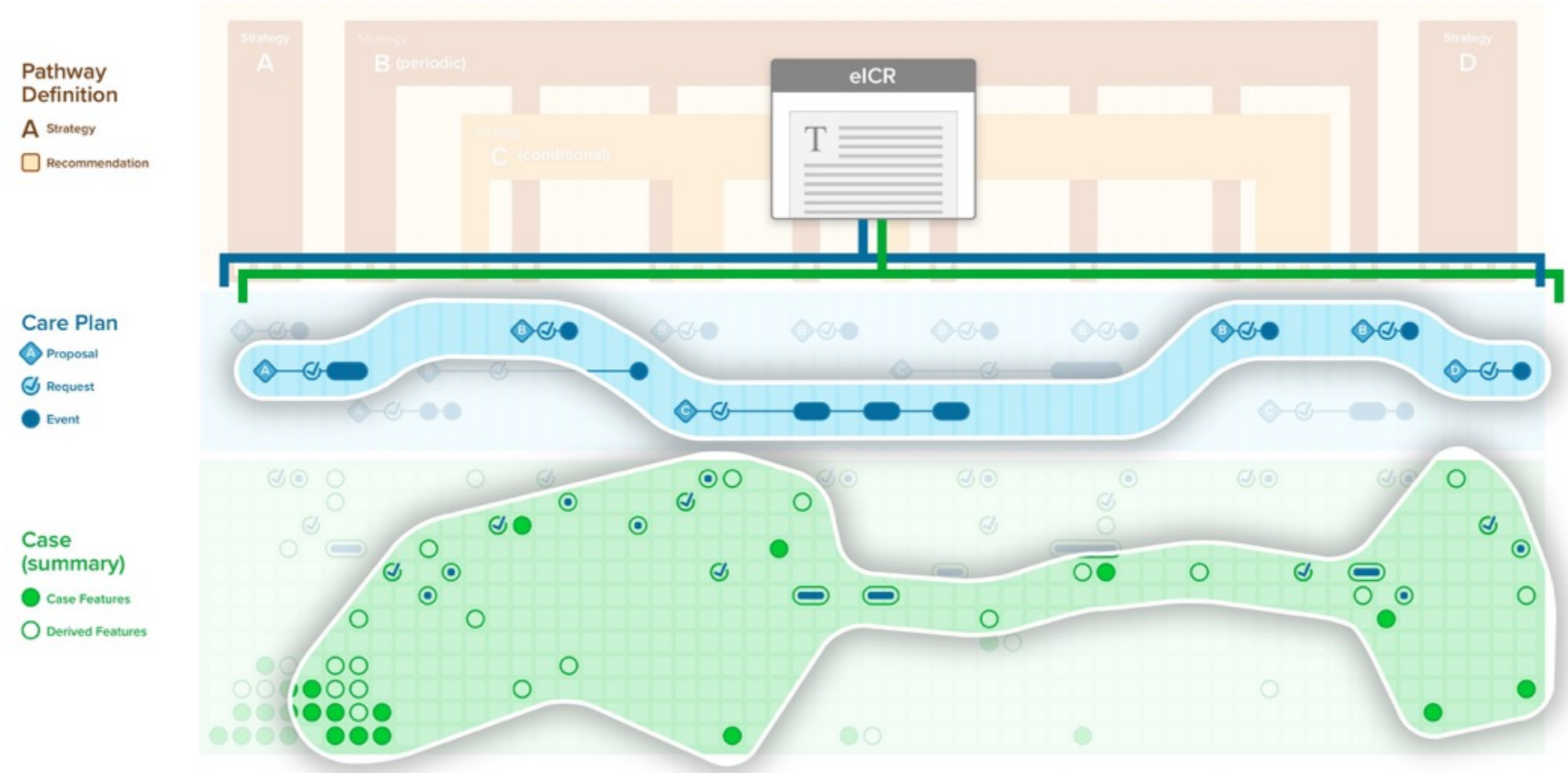
Clinical Quality Measure (eCQM)

FHIR Measure + CQL

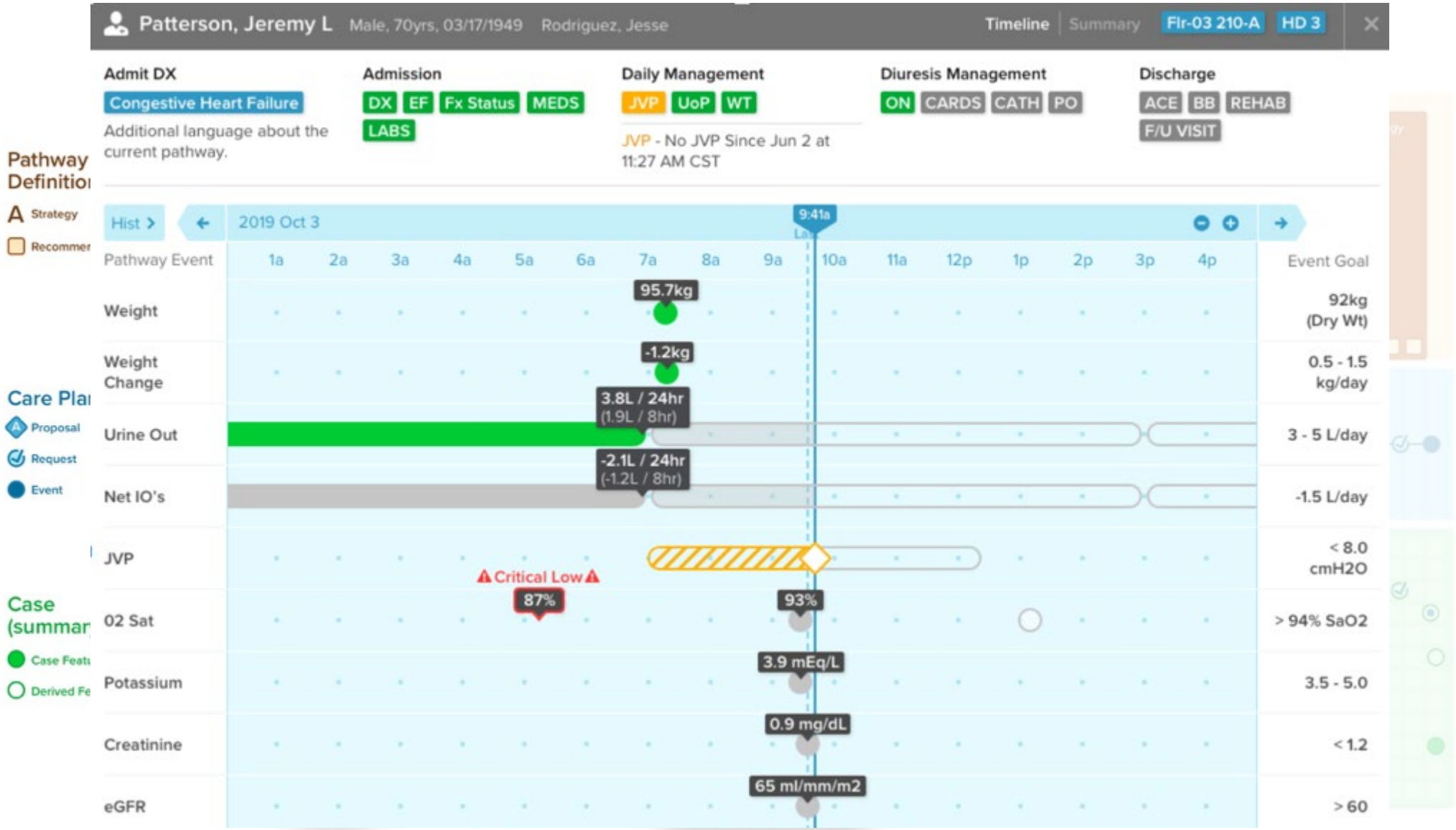


eCase Report (Registries)

(Profiled) FHIR Composition + CQL

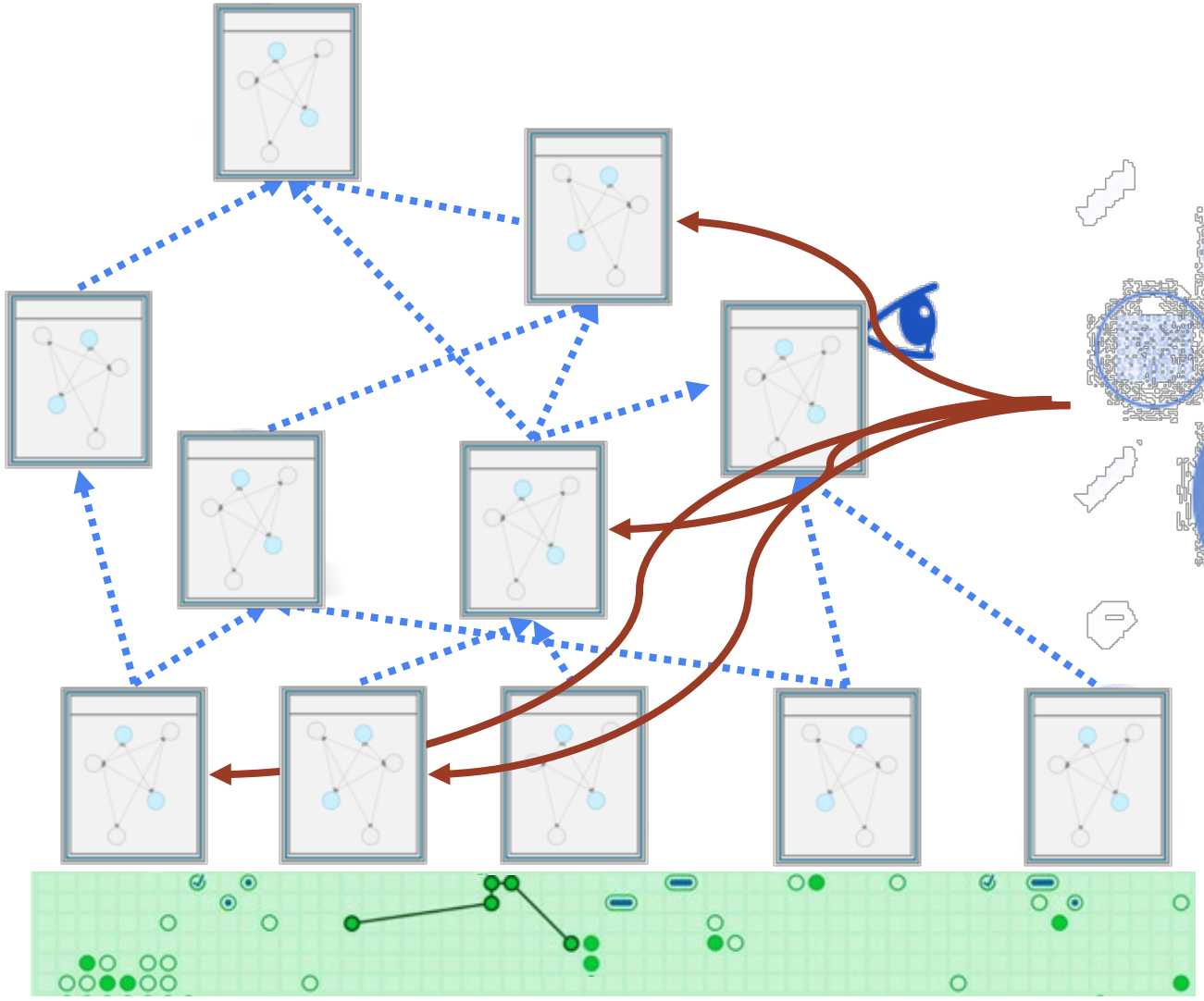


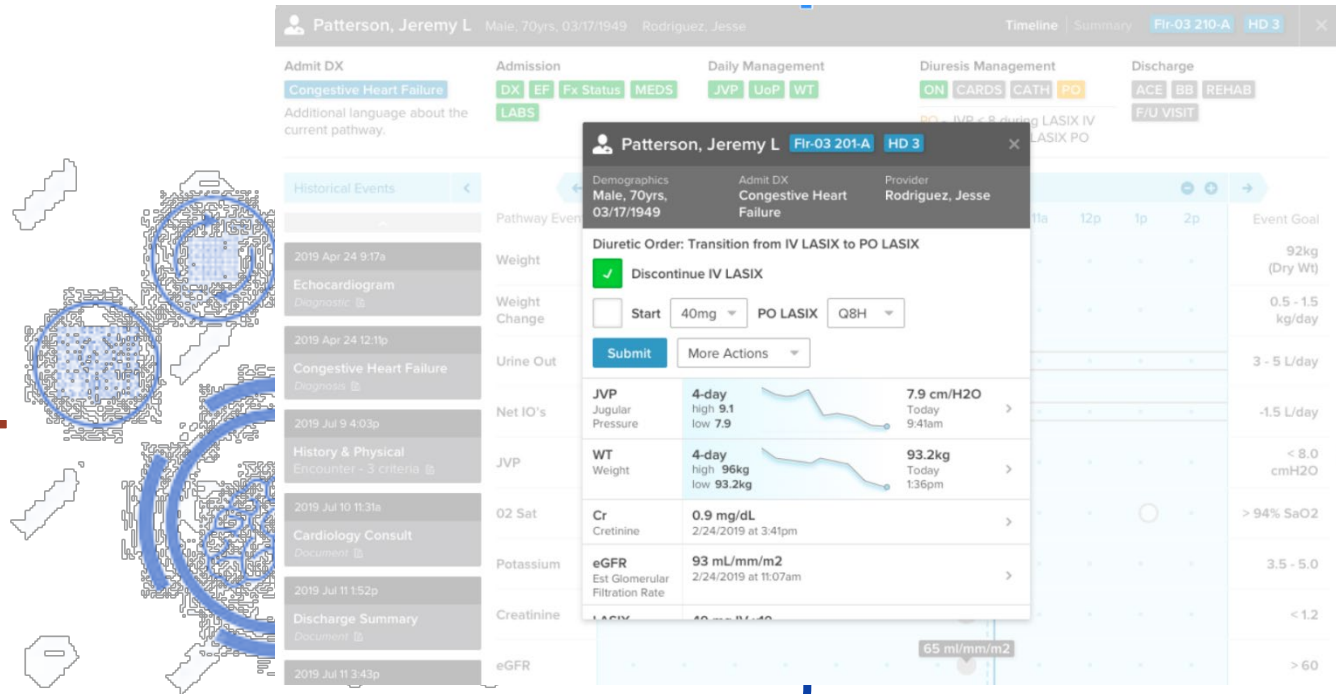
http://hl7.org/fhir/us/ecr/2018Sep/


Patterson, Jeremy L
Male, 70yrs, 03/17/1949
Rodriguez, Jesse
Timeline
Summary
Flr-03 210-A
HD 3
Admit DX
Congestive Heart Failure
Additional language about the current pathway.
Admission
DX
EF
Fx Status
MEDS
LABS
Daily Management
JVP
UoP
WT
JVP - No JVP Since Jun 2 at 11:27 AM CST
Diuresis Management
ON
CARDS
CATH
PO
Discharge
ACE
BB
REHAB
F/U VISIT
Pathway Definitio
Strategy
Recommer
Care Pla
Proposal
Request
Event
Case (summar
Case Featu
Derived Fe
Hist
2019 Oct 3
9:41a
Pathway Event
1a
2a
3a
4a
5a
6a
7a
8a
9a
10a
11a
12p
1p
2p
3p
4p
Event Goal
Weight
95.7kg
92kg (Dry Wt)
Weight Change
-1.2kg
0.5 - 1.5 kg/day
Urine Out
3.8L / 24hr
(1.9L / 8hr)
3 - 5 L/day
Net IO's
-2.1L / 24hr
(-1.2L / 8hr)
-1.5 L/day
JVP
< 8.0 cmH2O
Critical Low
87%
02 Sat
93%
> 94% SaO2
Potassium
3.9 mEq/L
3.5 - 5.0
Creatinine
0.9 mg/dL
< 1.2
eGFR
65 ml/mm/m2
> 60

Deep Learning & Cognitive Computing on Case Features

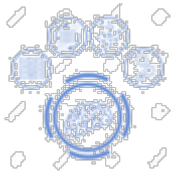
With Hybrid 'Knowledge' and a mix of Humans and Machines as Intelligent Agents





Symbolic AI

Data-driven AI



Hybrid AI

Guideline Development Process

Feedback, Iteration

Practice Governance

Knowledge Engineering Lifecycle

Feedback, Iteration

Local Informatics & EHR Build

InfoButton

EBM-on-FHIR

CPG-on-FHIR

KNOWLEDGE

ACTION

EBM on FHIR

EHR

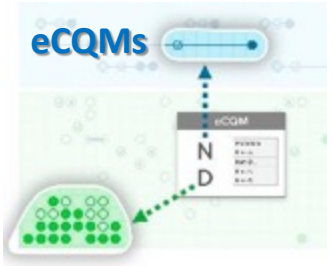
INFORMATION

DATA

RESEARCH

OMOP ←→ FHIR

eCR-on-FHIR

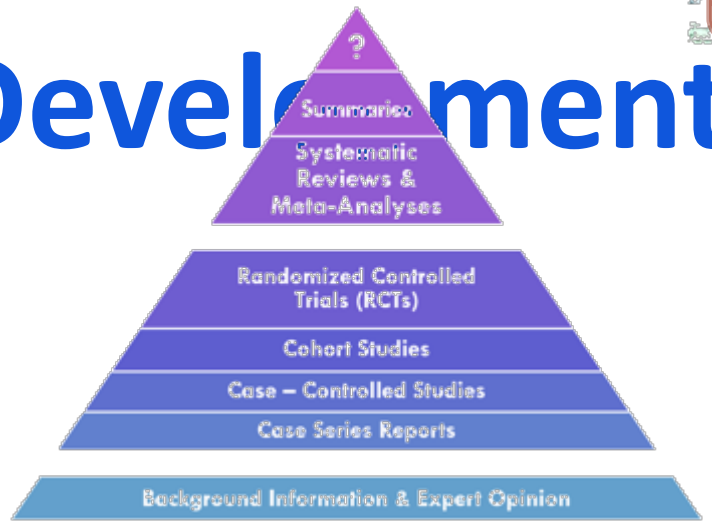


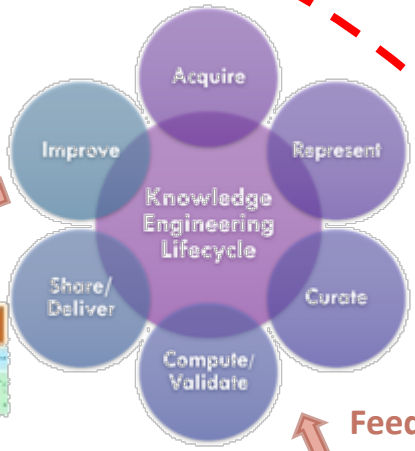
DEQM | QM-IG

Agile Approach to CPG Development

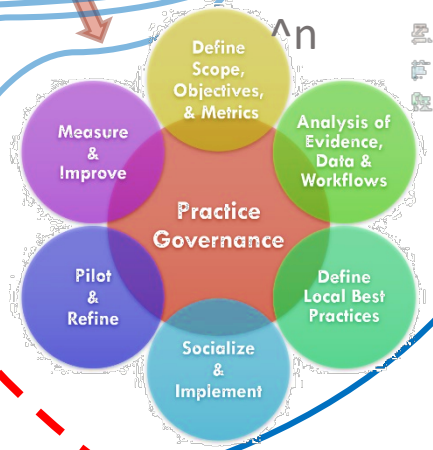
EBMonFHIR

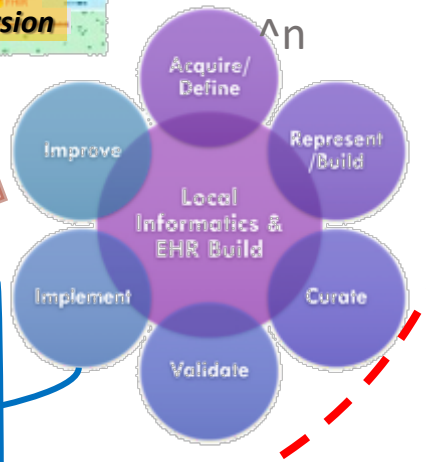
Feedback Loop & Iteration





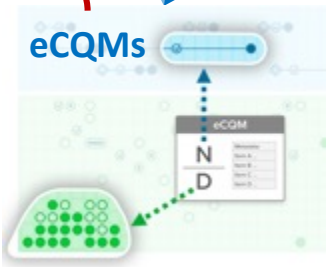
Feedback & Iteration during Development



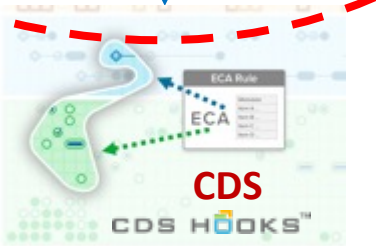


Potential for Feedforward or Fast Track

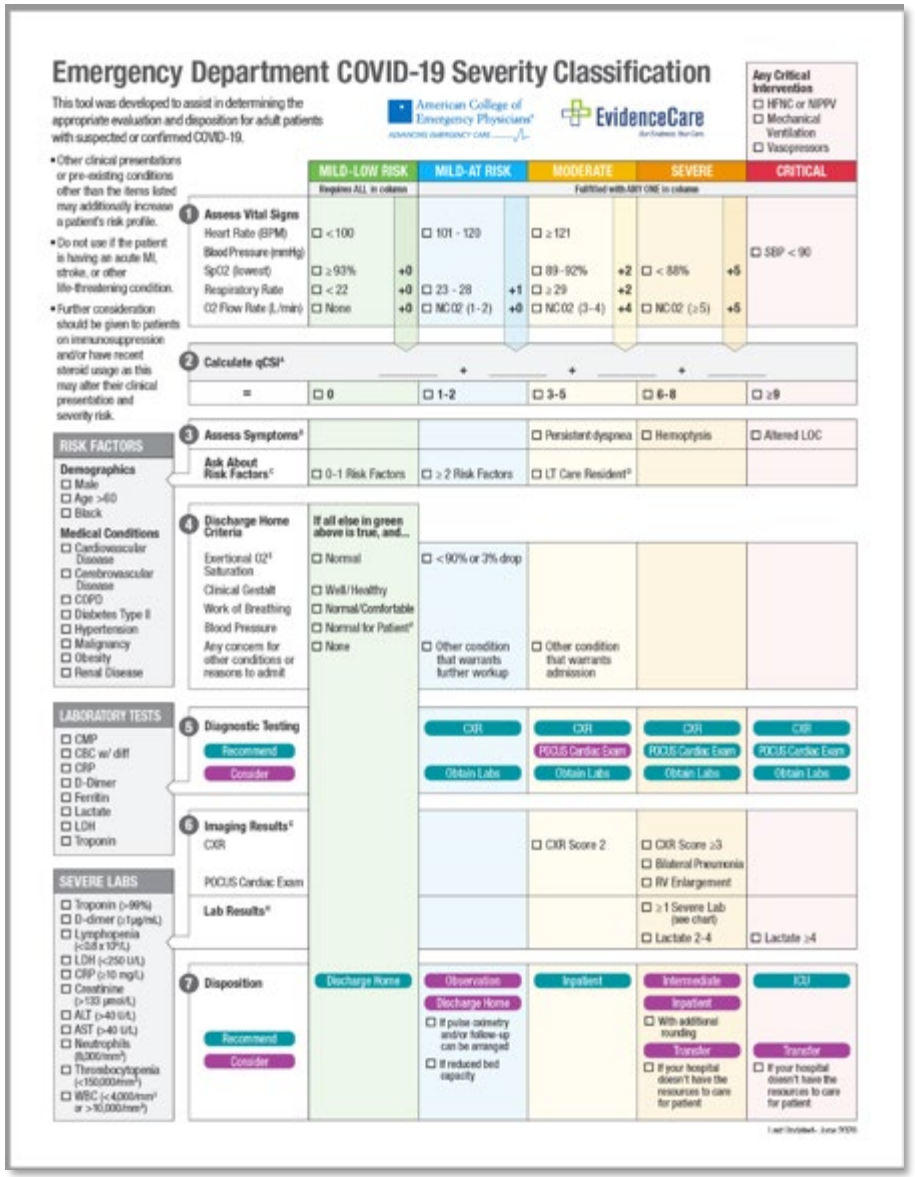
InfoButton



EHR



C19 Digital Guideline Working Group



Emergency Department COVID-19 Severity Classification

This tool was developed to assist in determining the appropriate evaluation and disposition for adult patients with suspected or confirmed COVID-19.

American College of Emergency Physicians — EvidenceCare

- Other clinical presentations or pre-existing conditions other than the items listed may additionally increase a patient's risk profile.
- Do not use if the patient is having an acute MI, stroke, or other life-threatening condition.
- Further consideration should be given to patients on immunosuppression and/or have recent steroid usage as this may alter their clinical presentation and severity risk.

	MILD-LOW RISK (Requires ALL in column)	MILD-AT RISK	MODERATE	SEVERE	CRITICAL (Fulfilled with ANY ONE in column)
Any Critical Intervention					☐ HFNC or NIPPV ☐ Mechanical Ventilation ☐ Vasopressors
1 Assess Vital Signs					
Heart Rate (BPM)	☐ < 100	☐ 101 - 120	☐ ≥ 121		
Blood Pressure (mmHg)					☐ SBP < 90
SpO2 (lowest)	☐ ≥ 93% +0	☐ 89 - 92% +2	☐ < 88% +5		
Respiratory Rate	☐ < 22 +0	☐ 23 - 28 +1	☐ ≥ 29 +2		
O2 Flow Rate (L/min)	☐ None +0	☐ NC O2 (1-2) +0	☐ NC O2 (3-4) +4	☐ NC O2 (≥5) +5	
2 Calculate qCSI[1]					
=	☐ 0	☐ 1-2	☐ 3-5	☐ 6-8	☐ ≥9
3 Assess Symptoms[2]			☐ Persistent dyspnea	☐ Hemoptysis	☐ Altered LOC
Ask About Risk Factors[3]	☐ 0-1 Risk Factors	☐ ≥ 2 Risk Factors	☐ LT Care Resident[4]		
4 Discharge Home Criteria	If all else in green above is true, and...				
Exertional O2[1] Saturation	☐ Normal	☐ < 90% or 3% drop			
Clinical Gestalt	☐ Well/Healthy				
Work of Breathing	☐ Normal/Comfortable				
Blood Pressure	☐ Normal for Patient[5]				
Any concern for other conditions or reasons to admit	☐ None	☐ Other condition that warrants further workup	☐ Other condition that warrants admission		
5 Diagnostic Testing		CXR / POCUS Cardiac Exam / Obtain Labs	CXR / POCUS Cardiac Exam / Obtain Labs	CXR / POCUS Cardiac Exam / Obtain Labs	CXR / POCUS Cardiac Exam / Obtain Labs
Recommend / Consider					
6 Imaging Results[1]					
CXR			☐ CXR Score 2	☐ CXR Score ≥3 ☐ Bilateral Pneumonia ☐ RV Enlargement	
POCUS Cardiac Exam					
Lab Results[6]				☐ ≥1 Severe Lab (see chart) ☐ Lactate 2-4	☐ Lactate ≥4
7 Disposition	Discharge Home	Observation / Discharge Home ☐ If pulse oximetry and/or follow-up can be arranged ☐ If reduced bed capacity	Inpatient	Intermediate / Inpatient ☐ With additional rounding / Transfer ☐ If your hospital doesn't have the resources to care for patient	ICU / Transfer ☐ If your hospital doesn't have the resources to care for patient
Recommend / Consider					

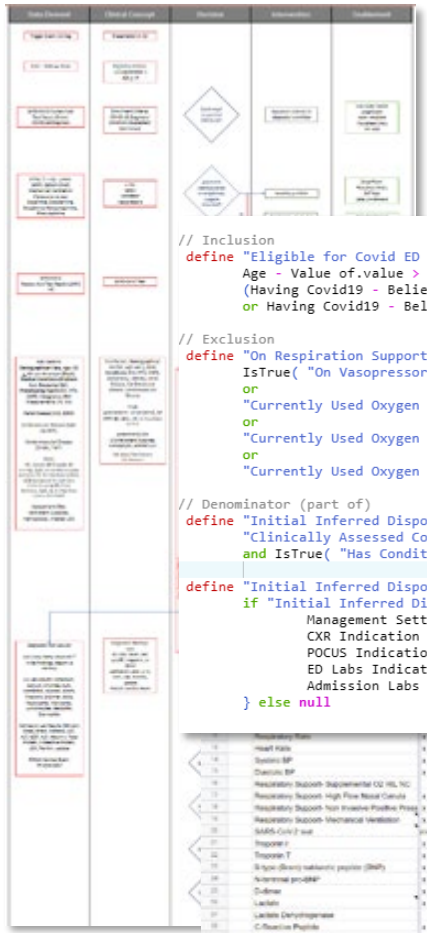
RISK FACTORS

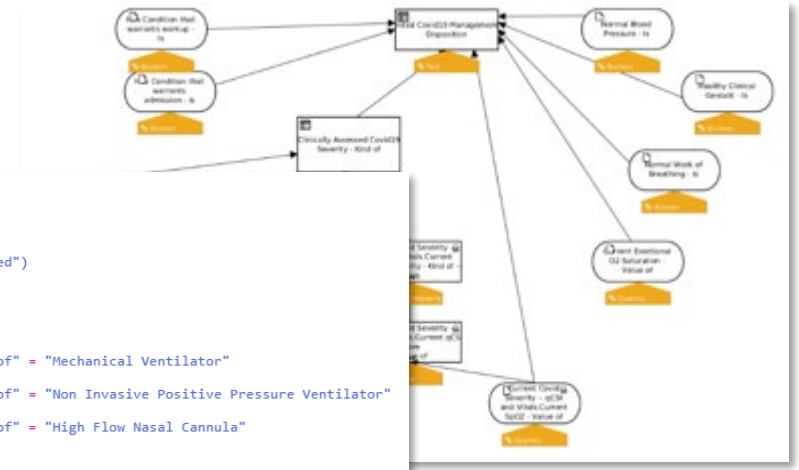
Demographics
- ☐ Male
- ☐ Age >60
- ☐ Black

Medical Conditions
- ☐ Cardiovascular Disease
- ☐ Cerebrovascular Disease
- ☐ COPD
- ☐ Diabetes Type II
- ☐ Hypertension
- ☐ Malignancy
- ☐ Obesity
- ☐ Renal Disease

LABORATORY TESTS
- ☐ CMP
- ☐ CBC w/ diff
- ☐ CRP
- ☐ D-Dimer
- ☐ Ferritin
- ☐ Lactate
- ☐ LDH
- ☐ Troponin

SEVERE LABS
- ☐ Troponin (>99%)
- ☐ D-dimer (>1µg/mL)
- ☐ Lymphopenia (<0.8 x 10⁹/L)
- ☐ LDH (>250 U/L)
- ☐ CRP (≥10 mg/L)
- ☐ Creatinine (>133 µmol/L)
- ☐ ALT (>40 U/L)
- ☐ AST (>40 U/L)
- ☐ Neutrophils (8,000/mm³)
- ☐ Thrombocytopenia (<150,000/mm³)
- ☐ WBC (<4,000/mm³ or >10,000/mm³)



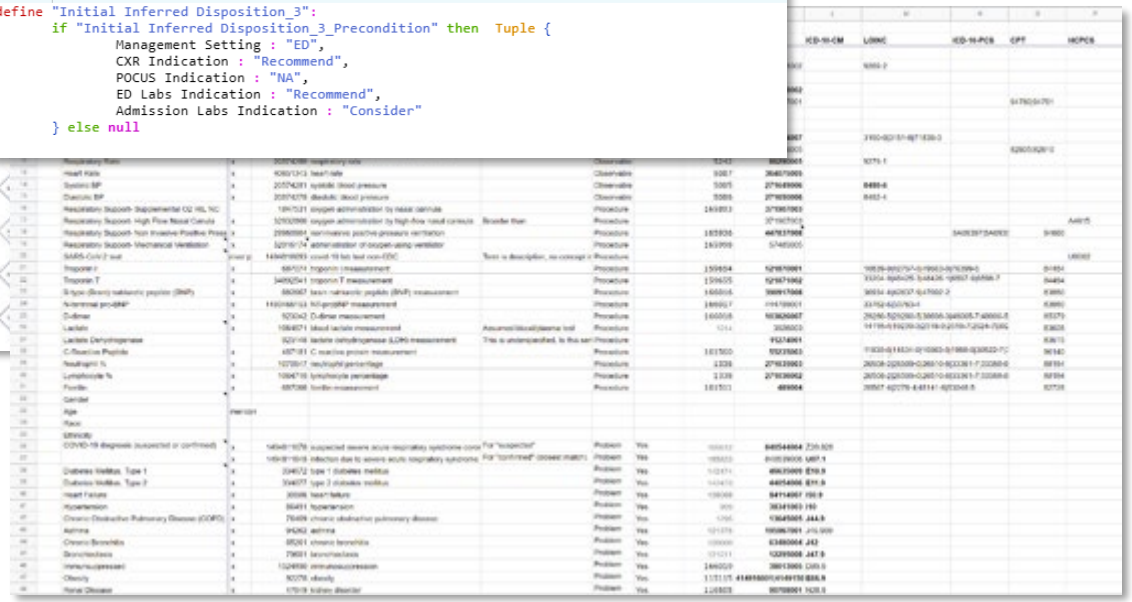


```
// Inclusion
define "Eligible for Covid ED Management - Is":
        Age - Value of.value > 18 and
        (Having Covid19 - Belief in = "Known"
        or Having Covid19 - Belief in = "Suspected")

// Exclusion
define "On Respiration Support":
        IsTrue( "On Vasopressors - Is" )
        or
        "Currently Used Oxygen Equipment - Kind of" = "Mechanical Ventilator"
        or
        "Currently Used Oxygen Equipment - Kind of" = "Non Invasive Positive Pressure Ventilator"
        or
        "Currently Used Oxygen Equipment - Kind of" = "High Flow Nasal Cannula"

// Denominator (part of)
define "Initial Inferred Disposition_2_Precondition":
        "Clinically Assessed Covid19 Severity - Kind of" in {"Moderate","Mild","Benign"}
        and IsTrue( "Has Condition that warrants admission - Is" )

define "Initial Inferred Disposition_3":
        if "Initial Inferred Disposition_3_Precondition" then  Tuple {
                Management Setting : "ED",
                CXR Indication : "Recommend",
                POCUS Indication : "NA",
                ED Labs Indication : "Recommend",
                Admission Labs Indication : "Consider"
        } else null
```



CPG-on-FHIR Example Use Case

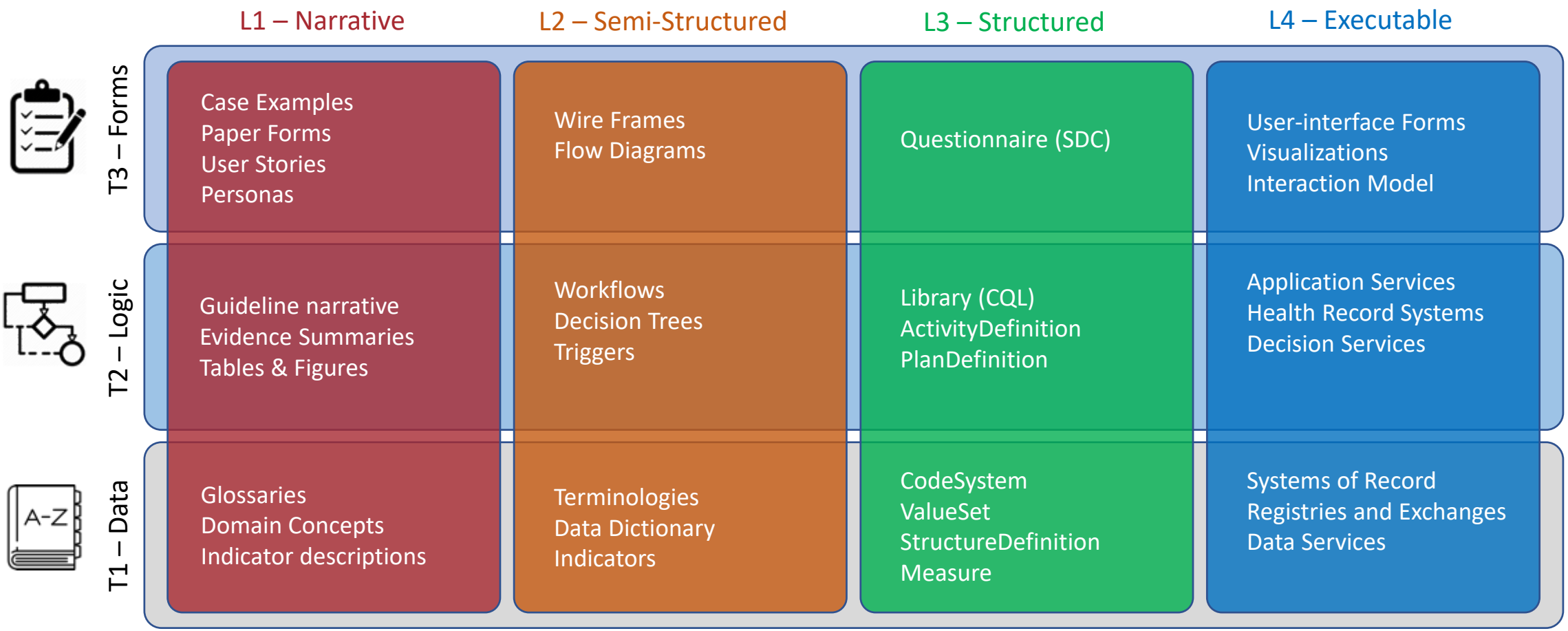
Enabling Opioid-related Quality Improvement

Translating Knowledge to Execution

Knowledge Level	Description	Example
L1	Narrative	Guideline for a specific disease that is written in the format of a peer-reviewed journal article
L2	Semi-structured	Flow diagram, decision tree, or other similar format that describes recommendations for implementation **(HUMAN READABLE)**
L3	Structured	Standards-compliant specification encoding logic with data model(s), terminology/code sets, value sets that is ready to be implemented **(COMPUTER/MACHINE READABLE)**
L4	Executable	CDS implemented and used in a local execution environment (e.g., CDS that is live in an electronic health record (EHR) production system) or available via web services

Adapted from: Boxwala, AA, et al.. A multi-layered framework for disseminating knowledge for computer-based decision support. *J Am Med Inform Assoc* 2011(18) i132-i139.

Requirements to Running Code



Levels of Representation Reconceptualized

Framework for Describing *Nature* of Representation (NOT Process)

Tradition Knowledge Engineering Approach:

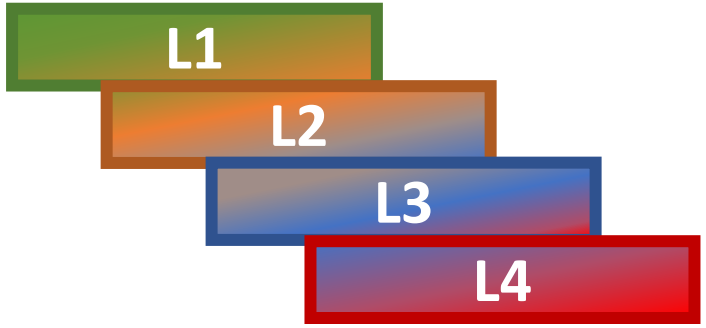
- Process Steps that mimicked Progression of Levels-
- L2 only on Final L1
- L3 only on completion of L2

Agile KE:

- Concurrent, iterative, integrated, and cross-functional
- Different Expertise work on Different Levels concurrently
- Knowledge Increments across Levels

Waterfall
GDP, KE, CDS, & Implementation

Agile
Integrated
Cross-functional
CPG-IG Approach



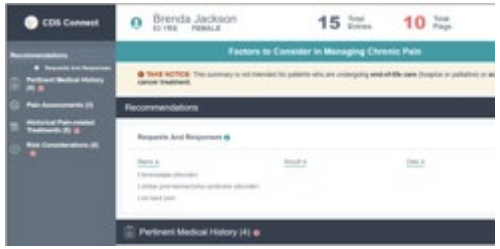
- Shared Tooling
- Shared Information
- Incremental
- Concurrent Development
- Iterative, Rapid Feedback
- Test-Driven
- Reuse Content

Opioid-related Projects

CDC Opioid Prescribing Guideline

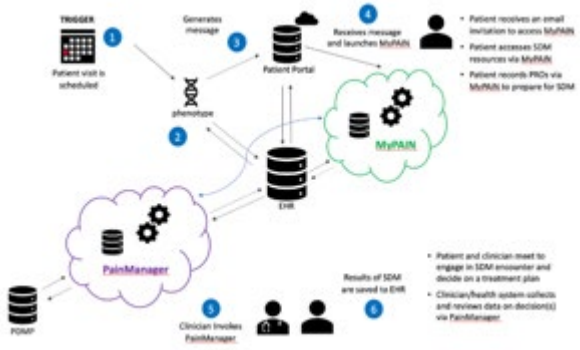
CDC Opioid Prescribing IG

AHRQ Pain Management Summary

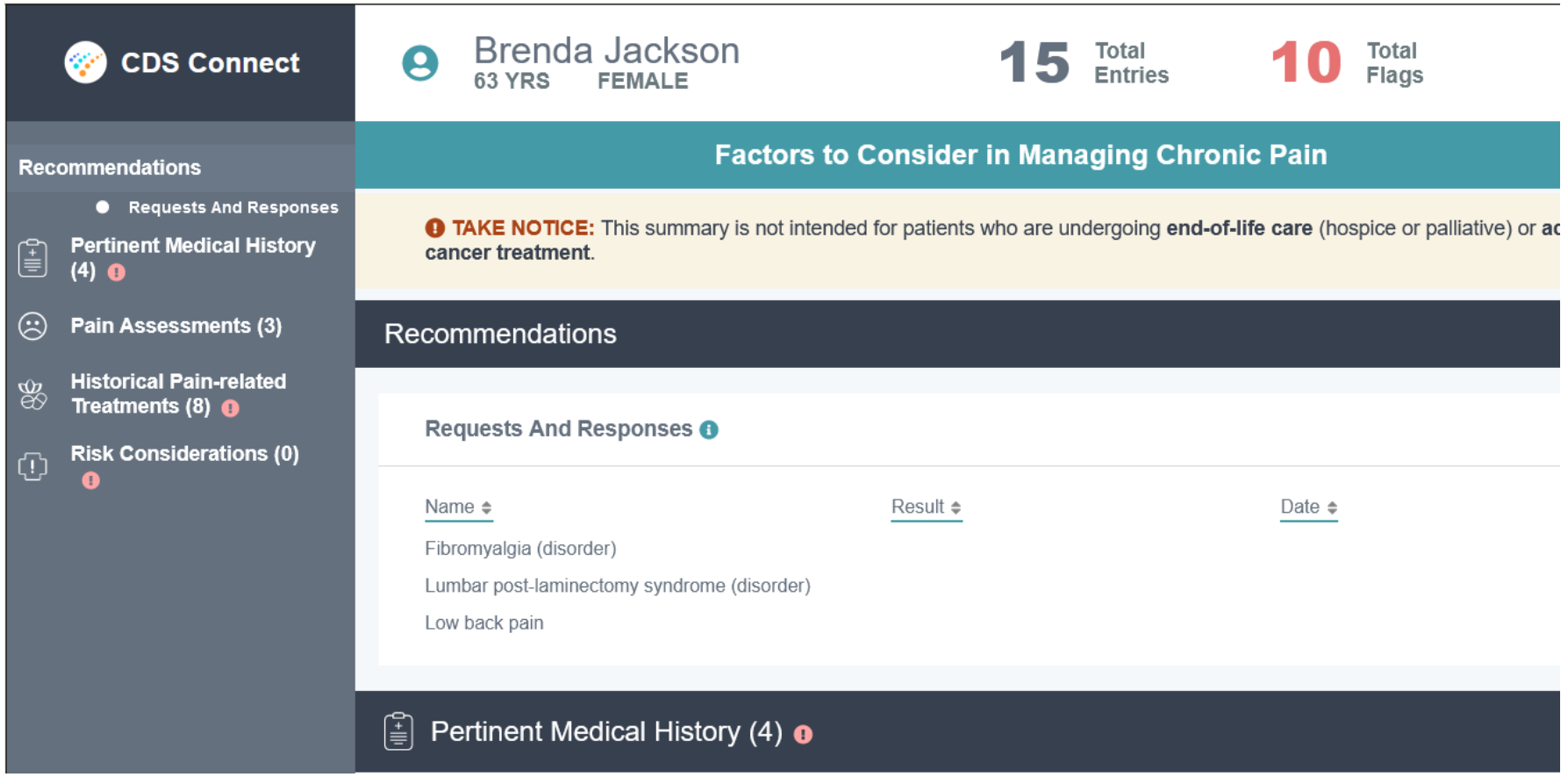


Opioid eCQMs

AHRQ Chronic Pain Management



AHRQ Pain Management Summary



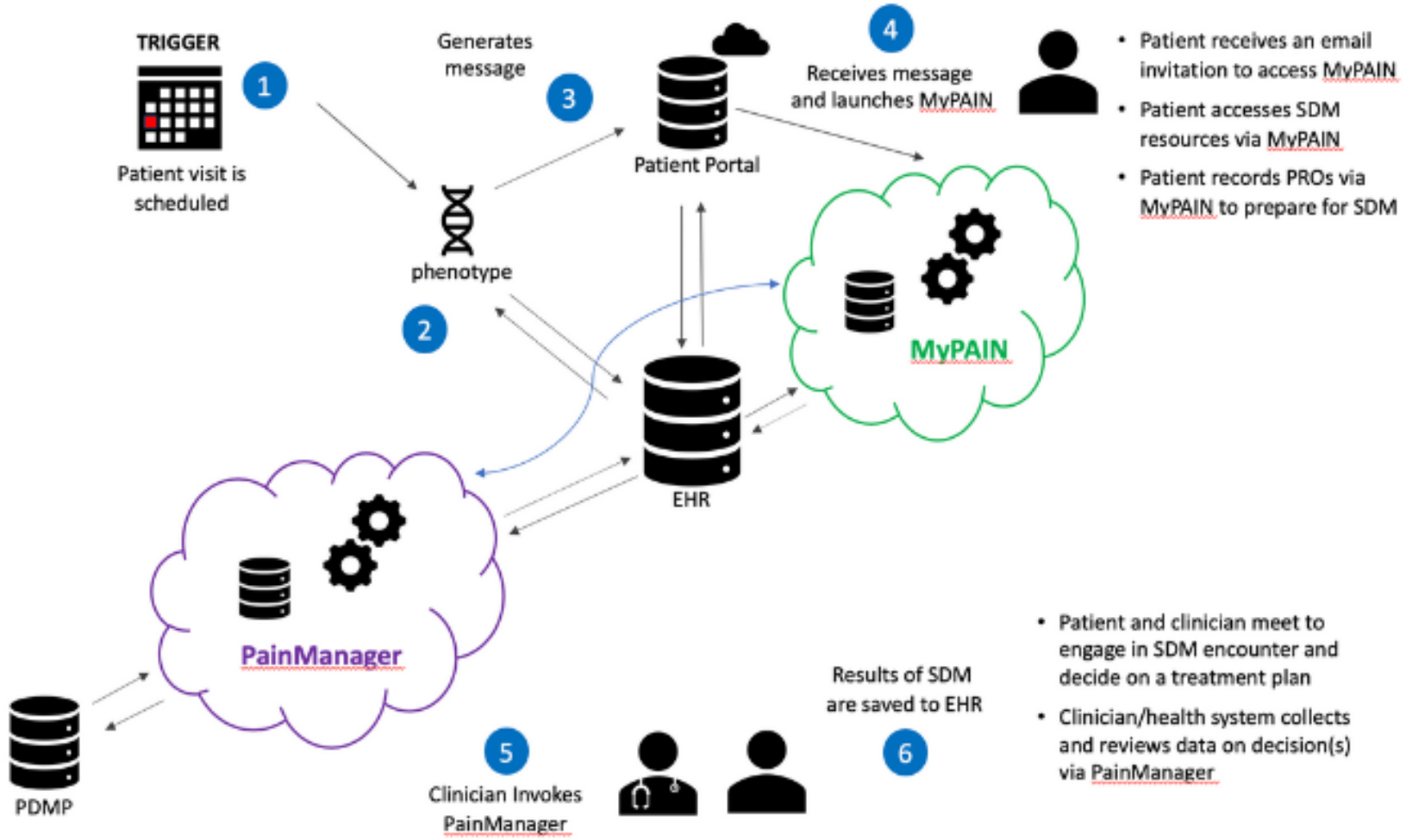
https://github.com/AHRQ-CDS/AHRQ-CDS-Connect-PAIN-MANAGEMENT-SUMMARY

Opioid eCQMs

eCQM Title	**Potential Opioid Overuse**		
eCQM Identifier (Measure Authoring Tool)	460	**eCQM Version Number**	2.2.000
NQF Number	Not Applicable	**GUID**	442edef2-7347-4080-988f-16c9d1998803
Measurement Period	January 1, 20XX through December 31, 20XX		
Measure Steward	Centers for Medicare & Medicaid Services (CMS)		
Measure Developer	Mathematica		
Endorsed By	None		
Description	Percentage of patients aged 18 years and older who receive opioid therapy for 90 days or longer with no more than a 7-day gap between prescriptions with a daily dosage of 90 morphine milligram equivalents (MME) or more		
Copyright	Limited proprietary coding is contained in the Measure specifications for user convenience. Users of proprietary code sets should obtain all necessary licenses from the owners of the code sets. Mathematica disclaims all liability for use or accuracy of any third party codes contained in the specifications. CPT(R) contained in the measure specifications is copyright 2004-2019 American Medical Association. LOINC(R) copyright 2004-2019 Regenstrief Institute, Inc. This material contains SNOMED Clinical Terms(R) (SNOMED CT[R]) copyright 2004-2019 International Health Terminology Standards Development Organisation. ICD-10 copyright 2019 World Health Organization. All Rights Reserved.		
Disclaimer	These performance measures are not clinical guidelines, do not establish a standard of medical care, and have not been tested for all potential applications. THE MEASURES AND SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND. Due to technical limitations, registered trademarks are indicated by (R) or [R] and unregistered trademarks are indicated by (TM) or [TM].		
Measure Scoring	Proportion		
Measure Type	Process		
Stratification	None		
Risk Adjustment	None		
Rate Aggregation	None		
Rationale	More than 100 million people in the United States suffer from chronic pain (Institute of Medicine, 2011). An estimated 259 million opioid prescriptions to manage pain were written in the United States in 2012, approximately half of which were written by primary care providers (Cox et al., 2018). From 2000 to 2015, mortality from opioid-specific drug poisoning in the United States tripled, resulting in a reduction in life expectancy for non-Hispanic, white individuals (Dowell, Haegerich, & Chou, 2016). Although all opioids can be dangerous, chronic use of opioids at high doses are more likely to result in fatalities and other adverse drug events (Edlund et al., 2014; Morasco et al., 2010; Atluri, Akbik, & Sudarshan, 2012; Paulozzi et al., 2014). Recent guidelines recommend that providers use the lowest dose possible when initiating opioid therapy and that they carefully justify prescribing doses above 90 morphine milligram equivalents (MME) per day, considering the benefits and harms of the dose they select (Dowell et al., 2016). In a large cohort study of almost 18 million commercially insured patients in the United States, about 15 percent of opioid recipients received a daily dose of 100 MME or higher, and 12 percent received more than a 90-day supply (Liu et al., 2013).		

https://ecqi.healthit.gov/sites/default/files/ecqm/measures/CMS460v2.html

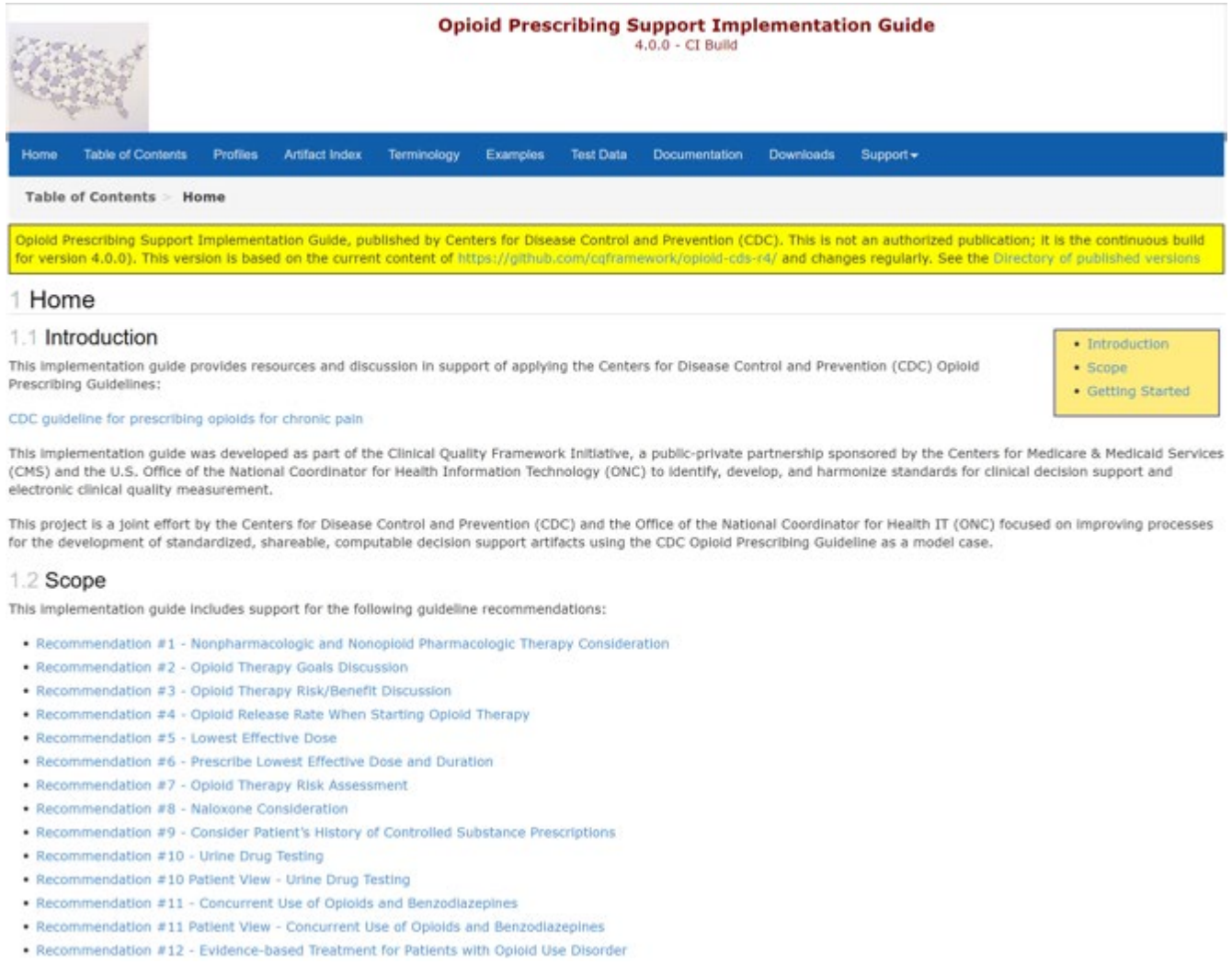
AHRQ Chronic Pain Management



SDC

SMART

CDC Opioid Prescribing IG



Opioid Prescribing Support Implementation Guide
4.0.0 - CI Build

Home | Table of Contents | Profiles | Artifact Index | Terminology | Examples | Test Data | Documentation | Downloads | Support

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Opioid Prescribing Support Implementation Guide, published by Centers for Disease Control and Prevention (CDC). This is not an authorized publication; it is the continuous build for version 4.0.0). This version is based on the current content of https://github.com/cqframework/opioid-cds-r4/ and changes regularly. See the Directory of published versions

1 Home

1.1 Introduction

- Introduction
- Scope
- Getting Started

This implementation guide provides resources and discussion in support of applying the Centers for Disease Control and Prevention (CDC) Opioid Prescribing Guidelines:

CDC guideline for prescribing opioids for chronic pain

This implementation guide was developed as part of the Clinical Quality Framework Initiative, a public-private partnership sponsored by the Centers for Medicare & Medicaid Services (CMS) and the U.S. Office of the National Coordinator for Health Information Technology (ONC) to identify, develop, and harmonize standards for clinical decision support and electronic clinical quality measurement.

This project is a joint effort by the Centers for Disease Control and Prevention (CDC) and the Office of the National Coordinator for Health IT (ONC) focused on improving processes for the development of standardized, shareable, computable decision support artifacts using the CDC Opioid Prescribing Guideline as a model case.

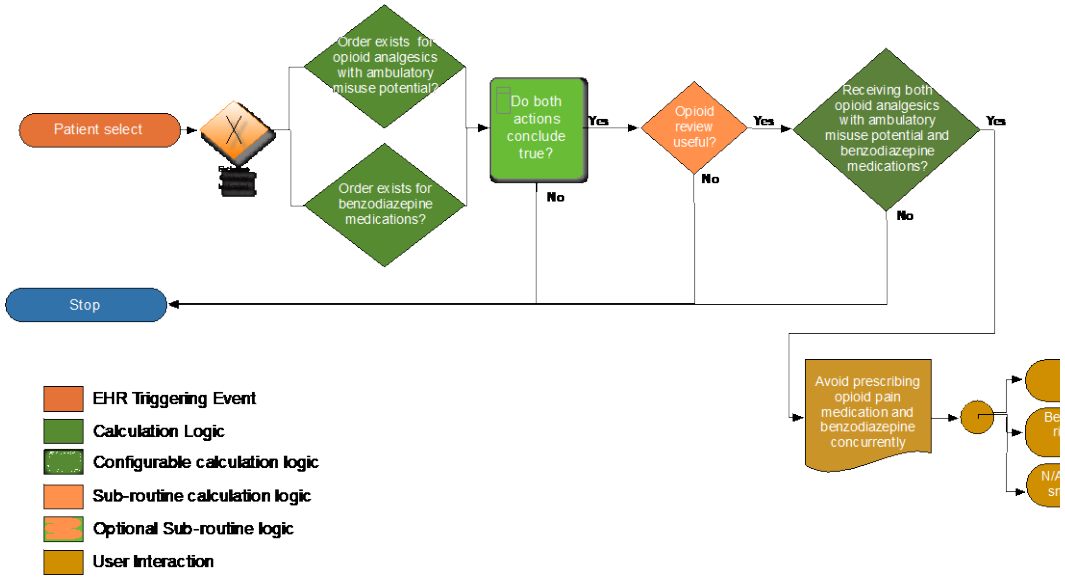
1.2 Scope

This implementation guide includes support for the following guideline recommendations:

- Recommendation #1 - Nonpharmacologic and Nonopioid Pharmacologic Therapy Consideration
- Recommendation #2 - Opioid Therapy Goals Discussion
- Recommendation #3 - Opioid Therapy Risk/Benefit Discussion
- Recommendation #4 - Opioid Release Rate When Starting Opioid Therapy
- Recommendation #5 - Lowest Effective Dose
- Recommendation #6 - Prescribe Lowest Effective Dose and Duration
- Recommendation #7 - Opioid Therapy Risk Assessment
- Recommendation #8 - Naloxone Consideration
- Recommendation #9 - Consider Patient's History of Controlled Substance Prescriptions
- Recommendation #10 - Urine Drug Testing
- Recommendation #10 Patient View - Urine Drug Testing
- Recommendation #11 - Concurrent Use of Opioids and Benzodiazepines
- Recommendation #11 Patient View - Concurrent Use of Opioids and Benzodiazepines
- Recommendation #12 - Evidence-based Treatment for Patients with Opioid Use Disorder

http://build.fhir.org/ig/cqframework/opioid-cds-r4/

Recommendation #11 – L2



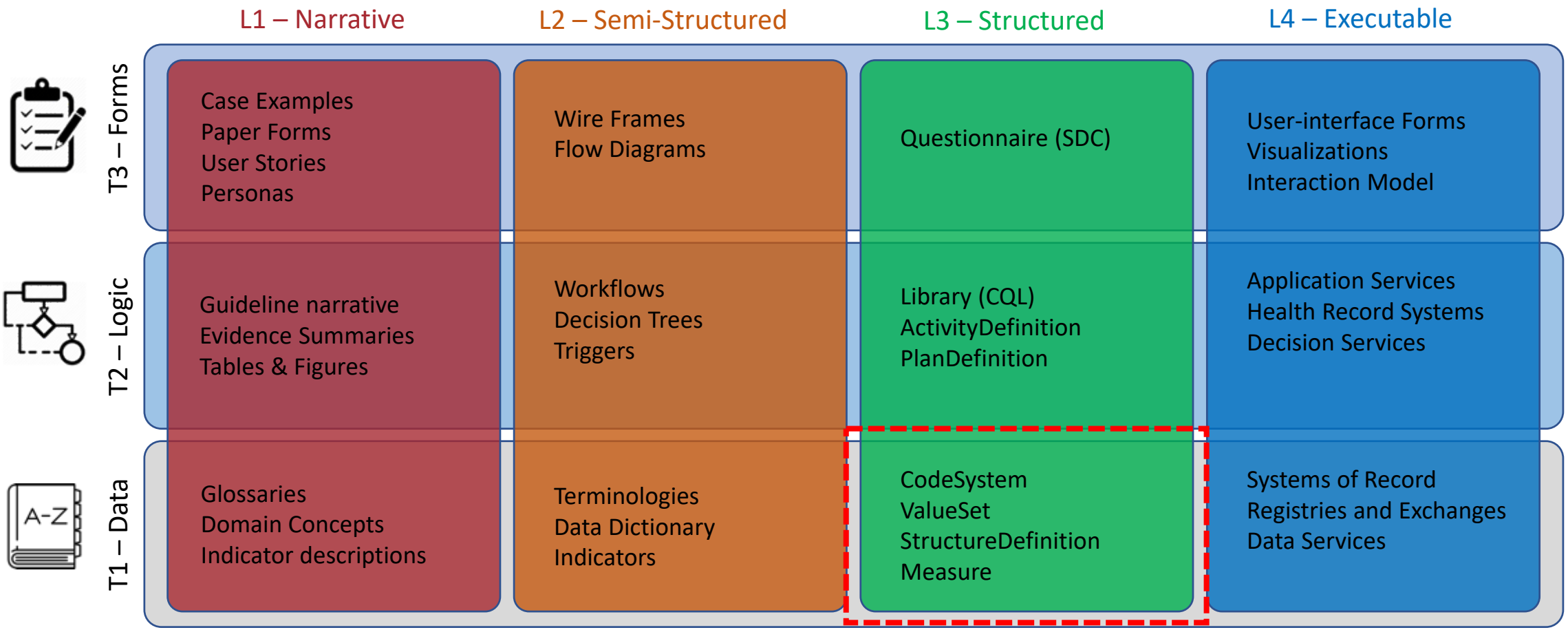
Recommendation 11			
Definition	**Answer to Proceed**	**Details**	**Data (Terminology) Requirement**
Order for opioid analgesics with ambulatory misuse potential?	Yes	Trigger based on a new prescription (order) for opioid analgesics with ambulatory misuse potential – ideally the prescription should be selected prior to being committed to the system. Provide indication either: • The opioid prescription request is concurrent with an active benzodiazepine prescription. Avoid prescribing opioid pain medication and benzodiazepine concurrently whenever possible.	Opioid analgesics with ambulatory misuse potential
Order for benzodiazepine medications?	Yes	Trigger based on a new prescription (order) for opioids or benzodiazepines in the relevant value sets – ideally the prescription should be selected prior to being committed to the system. Provide indication either: • The benzodiazepine prescription request is concurrent with an active opioid analgesic prescription. Avoid prescribing opioid pain medication and benzodiazepine concurrently whenever possible.	Benzodiazepine medications
Opioid review useful?	Yes	See sub-routine 1	
Receiving both opioid with ambulatory use potential and benzodiazepine?	Yes	New prescription is for an opioid and existing use of benzodiazepine evident, OR New prescription is for benzodiazepine and existing use of opioids evident.	Opioid analgesics with ambulatory misuse potential Benzodiazepine medications

Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible *(recommendation category: A, evidence type: 3)*.

26.0.1 Functional Description

- When
  - Provider is prescribing an opioid analgesic with ambulatory misuse potential in the outpatient setting:
  - Provider is prescribing a benzodiazepine medication
  - Opioid review is useful for this patient:
    - Patient is 18 or over
    - Patient does not have findings indicating limited life expectancy
    - Patient does not have orders for therapies indicating end of life care
    - Patient is not undergoing active cancer treatment:
      - Patient has had at least 2 encounters within the past year with any diagnosis of cancer
  - Patient prescribed opioid analgesic with ambulatory misuse potential and benzodiazepine medication concurrently
- Then
  - Recommend to avoid prescribing opioid pain medication and benzodiazepine concurrently:
    - Will revise
    - Benefits outweigh risks, snooze 3 months
    - N/A - see comment; snooze 3 months

Requirements to Running Code



L3 – Terminology

30.25.1 Opioid Analgesics With Ambulatory Misuse Potential

Summary

Defining URL:	http://fhir.org/guides/cdc/opioid-cds/ValueSet/opioid-analgesics-with-ambulatory-misuse-potential
Version:	4.0.0
Name:	Opioid_Analgesics_With_Ambulatory_Misuse_Potential
Status:	Experimental
Title:	Opioid Analgesics With Ambulatory Misuse Potential
Definition:	All opioid clinical drugs except cough medications, antisapasmodics, or those restricted to surgical use only a injectable form.
Publisher:	Centers for Disease Control and Prevention (CDC)
Copyright:	© CDC 2016+.
Source Resource:	XML / JSON / Turtle

References

This value set is not used

30.25.1.1 Content Logical Definition

30.25.1.2 Definition

This value set contains 1177 concepts

All codes from system `http://www.nlm.nih.gov/research/umls/rxnorm`

Code	Display
564334	Alfentanil 0.5 MG/ML [Alfenta]
576376	Buprenorphine 8 MG [Subutex]
566435	Buprenorphine 0.3 MG/ML [Buprenex]
1010601	Buprenorphine 2 MG / Naloxone 0.5 MG [Suboxone]

Recommendation 11			
Definition	**Answer to Proceed**	**Details**	**Data (Terminology) Requirement**
Order for opioid analgesics with ambulatory misuse potential?	Yes	Trigger based on a new prescription (order) for opioid analgesics with ambulatory misuse potential – ideally the prescription should be selected prior to being committed to the system. Provide indication either: • The opioid prescription request is concurrent with an active benzodiazepine prescription. Avoid prescribing opioid pain medication and benzodiazepine concurrently whenever possible.	Opioid analgesics with ambulatory misuse potential
Order for benzodiazepine medications?	Yes	Trigger based on a new prescription (order) for opioids or benzodiazepines in the relevant value sets – ideally the prescription should be selected prior to being committed to the system. Provide indication either: • The benzodiazepine prescription request is concurrent with an active opioid analgesic prescription. Avoid prescribing opioid pain medication and benzodiazepine concurrently whenever possible.	Benzodiazepine medications
Opioid review useful?	Yes	See sub-routine 1	
Receiving both opioid with ambulatory use potential and benzodiazepine?	Yes	New prescription is for an opioid and existing use of benzodiazepine evident, OR New prescription is for benzodiazepine and existing use of opioids evident.	Opioid analgesics with ambulatory misuse potential Benzodiazepine medications

L3 – Profiles (Data Elements)

30.2.1 StructureDefinition: CDC_MedicationRequest

Profile of MedicationRequest for use with CDC Opioid Prescribing Guidelines

The official URL for this profile is:

```
http://fhir.org/guides/cdc/opioid-cds/StructureDefinition/cdc-medicationrequest
```

30.2.1.1 Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work.

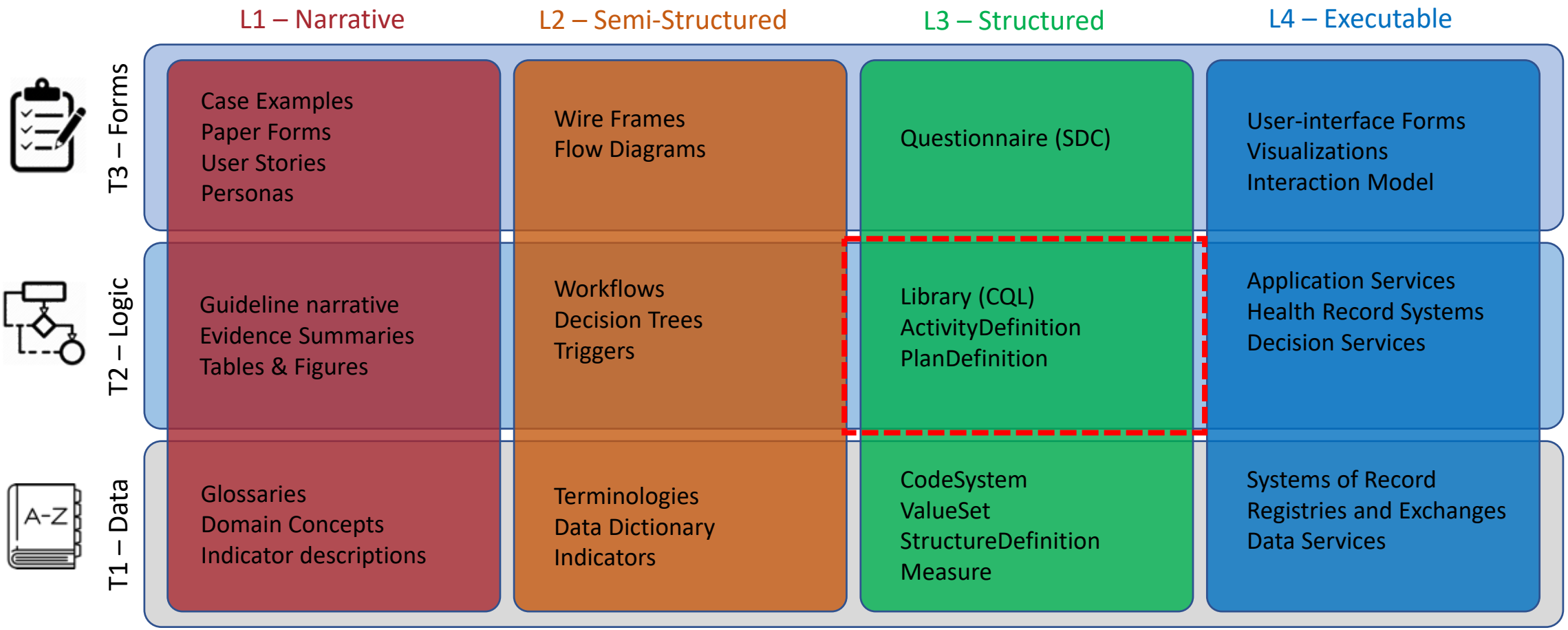
Text Summary | **Differential Table** | Snapshot Table | All

This structure is derived from CPGMedicationRequest

Name	Flags	Card.	Type	Description & Constraints
MedicationRequest		0..*	CPGMedicationRequest	Ordering of medication for patient or
medication[x]	S	1..1	CodeableConcept	Medication to be taken
dosageInstruction	S	1..1	Dosage	How the medication should be taken
timing	S	1..1	Timing	When medication should be administered
repeat	S	1..1	Element	When the event is to occur
frequency	S	1..1	positiveInt	Event occurs frequency times per period
period	S	1..1	decimal	Event occurs frequency times per period
periodUnit	S	1..1	code	s | min | h | d | wk | mo | a - unit of time (UCUM)
asNeeded[x]	S	0..1	boolean	Take "as needed" (for x)

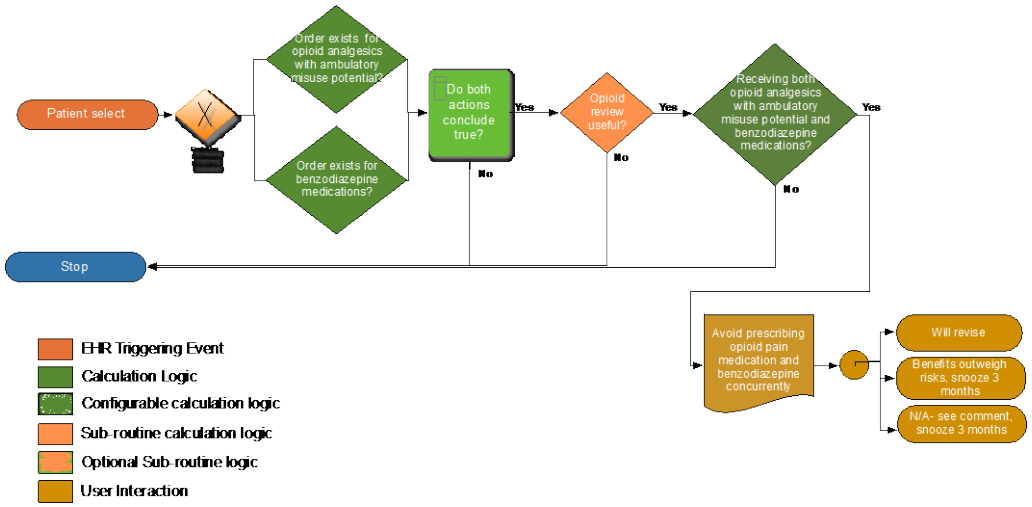
Recommendation 11			
Definition	**Answer to Proceed**	**Details**	**Data (Terminology) Requirement**
Order for opioid analgesics with ambulatory misuse potential?	Yes	Trigger based on a new prescription (order) for opioid analgesics with ambulatory misuse potential – ideally the prescription should be selected prior to being committed to the system. Provide indication either: • The opioid prescription request is concurrent with an active benzodiazepine prescription. Avoid prescribing opioid pain medication and benzodiazepine concurrently whenever possible.	Opioid analgesics with ambulatory misuse potential
Order for benzodiazepine medications?	Yes	Trigger based on a new prescription (order) for opioids or benzodiazepines in the relevant value sets – ideally the prescription should be selected prior to being committed to the system. Provide indication either: • The benzodiazepine prescription request is concurrent with an active opioid analgesic prescription. Avoid prescribing opioid pain medication and benzodiazepine concurrently whenever possible.	Benzodiazepine medications
Opioid review useful?	Yes	See sub-routine 1	
Receiving both opioid with ambulatory use potential and benzodiazepine?	Yes	New prescription is for an opioid and existing use of benzodiazepine evident, OR New prescription is for benzodiazepine and existing use of opioids evident.	Opioid analgesics with ambulatory misuse potential Benzodiazepine medications

Requirements to Running Code



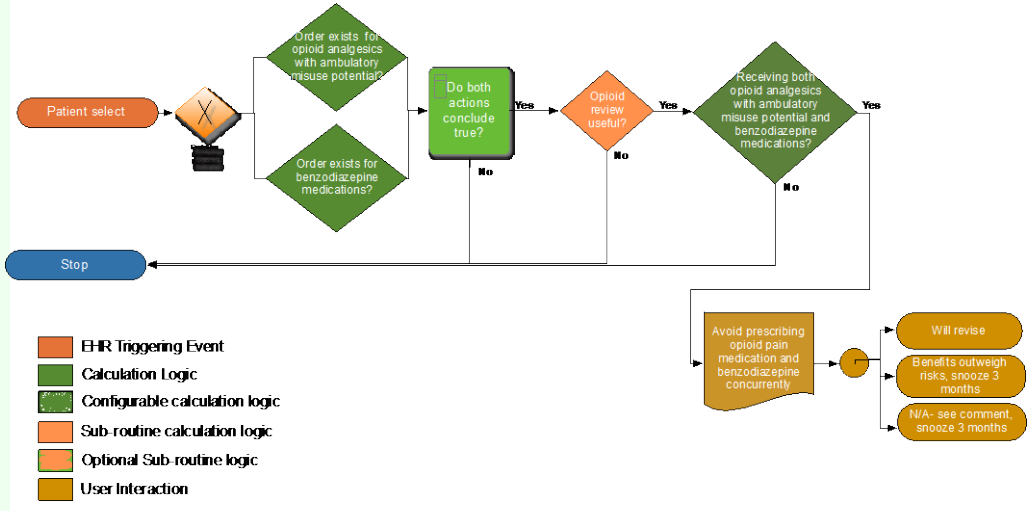
L3 – Logic (CQL Libraries)

```
context Patient

define "Opioid Analgesic with Ambulatory Misuse Potential Prescriptions":
  Common."Is Opioid Analgesic with Ambulatory Misuse Potential?"( ContextPrescriptions )

define "Benzodiazepine Prescriptions":
  Common."Is Benzodiazepine?"( ContextPrescriptions )

define "Patient Is Being Prescribed Opioid Analgesic with Ambulatory Misuse Potential":
  exists( "Opioid Analgesic with Ambulatory Misuse Potential Prescriptions" )

define "Patient Is Being Prescribed Benzodiazepine":
  exists( "Benzodiazepine Prescriptions" )

define "Is Recommendation Applicable?":
  "Inclusion Criteria"
    and not "Exclusion Criteria"

define "Inclusion Criteria":
  (
    (
      "Patient Is Being Prescribed Opioid Analgesic with Ambulatory Misuse Potential"
        and exists Common."Active Ambulatory Benzodiazepine Rx"
    )
      or (
        "Patient Is Being Prescribed Benzodiazepine"
          and exists Common."Active Ambulatory Opioid Rx"
      )
  )
    and Routines."Is Opioid Review Useful?"

define "Exclusion Criteria":
  Common."End of Life Assessment"
```



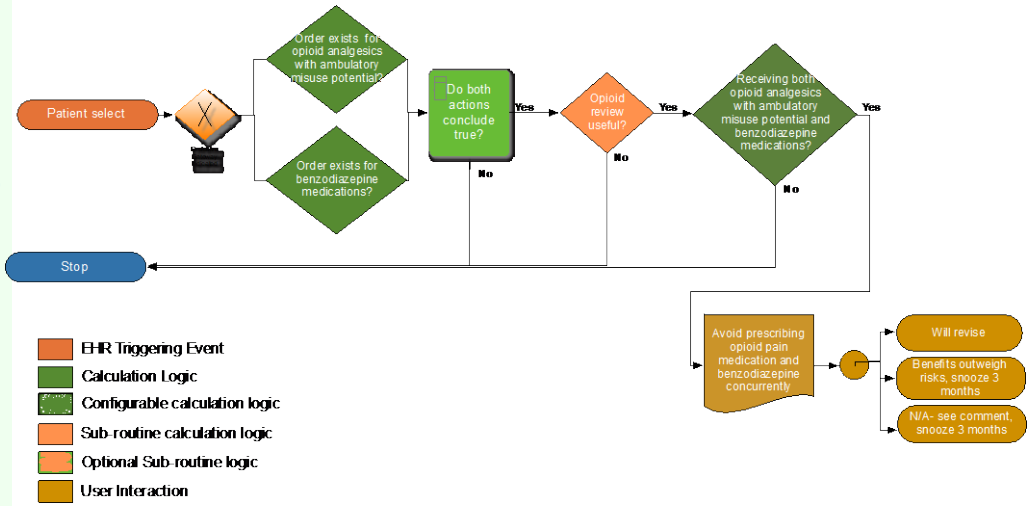
L3 – Recommendation


```
  "library" : [
    "http://fhir.org/guides/cdc/opioid-cds/Library/opioidcds-rec-11"
  ],
  "action" : [
    {
      "title" : "Existing patient has concurrent opioid and benzodiazepine prescriptions.",
      "description" : "Checking if the trigger prescription meets the inclusion criteria for recommendatio
n #11 workflow.",
      "documentation" : [
        {
          "type" : "documentation",
          "display" : "CDC guideline for prescribing opioids for chronic pain",
          "url" : "https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cd
c.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm"
        },
        {
          "type" : "documentation",
          "document" : {
            "extension" : [
              {
                "url" : "http://hl7.org/fhir/StructureDefinition/cqf-strengthOfRecommendation",
                "valueCodeableConcept" : {
                  "coding" : [
                    {
                      "system" : "http://terminology.hl7.org/CodeSystem/recommendation-strength",
                      "code" : "strong",
                      "display" : "Strong"
                    }
                  ]
                }
              },
              {
                "url" : "http://hl7.org/fhir/StructureDefinition/cqf-qualityOfEvidence",
                "valueCodeableConcept" : {
                  "coding" : [
```

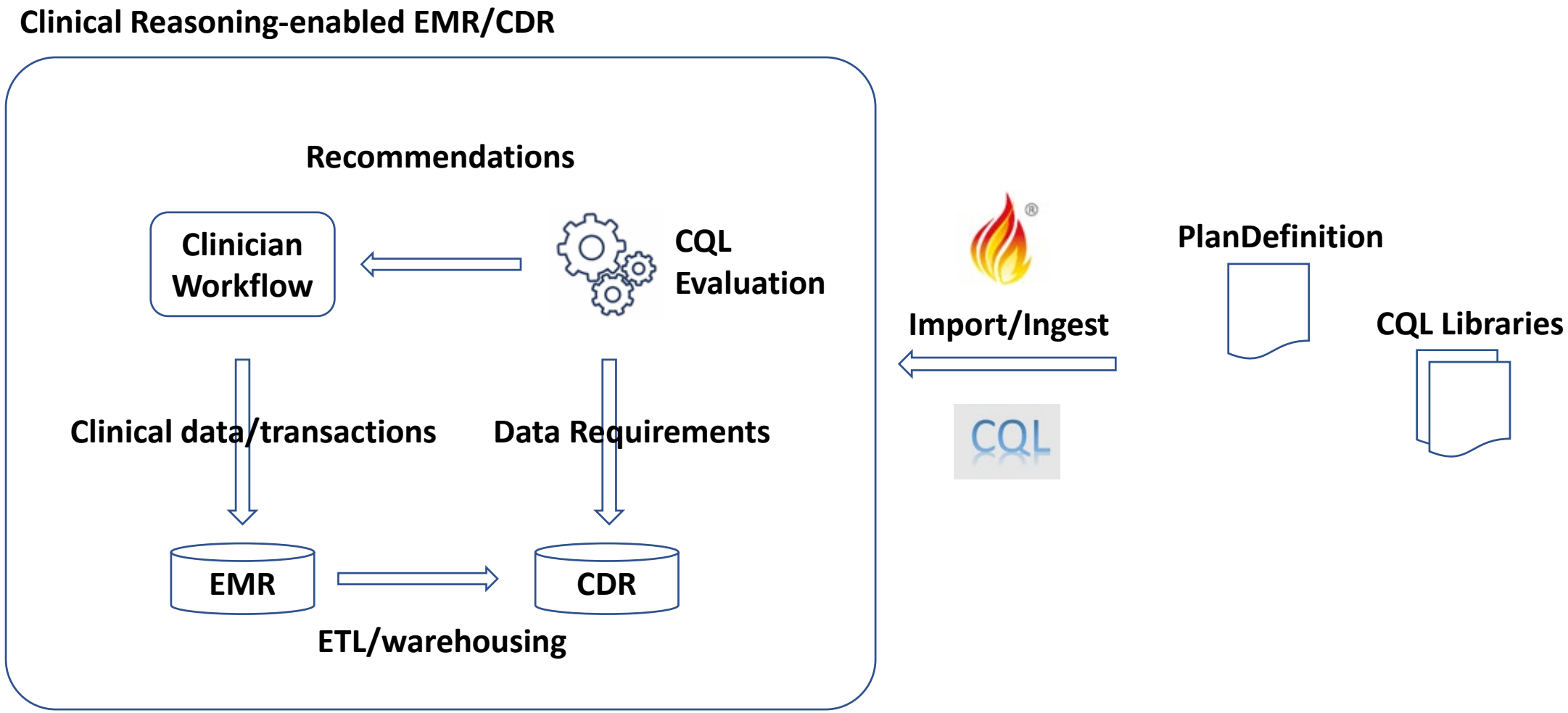



L3 – Recommendation (cont)

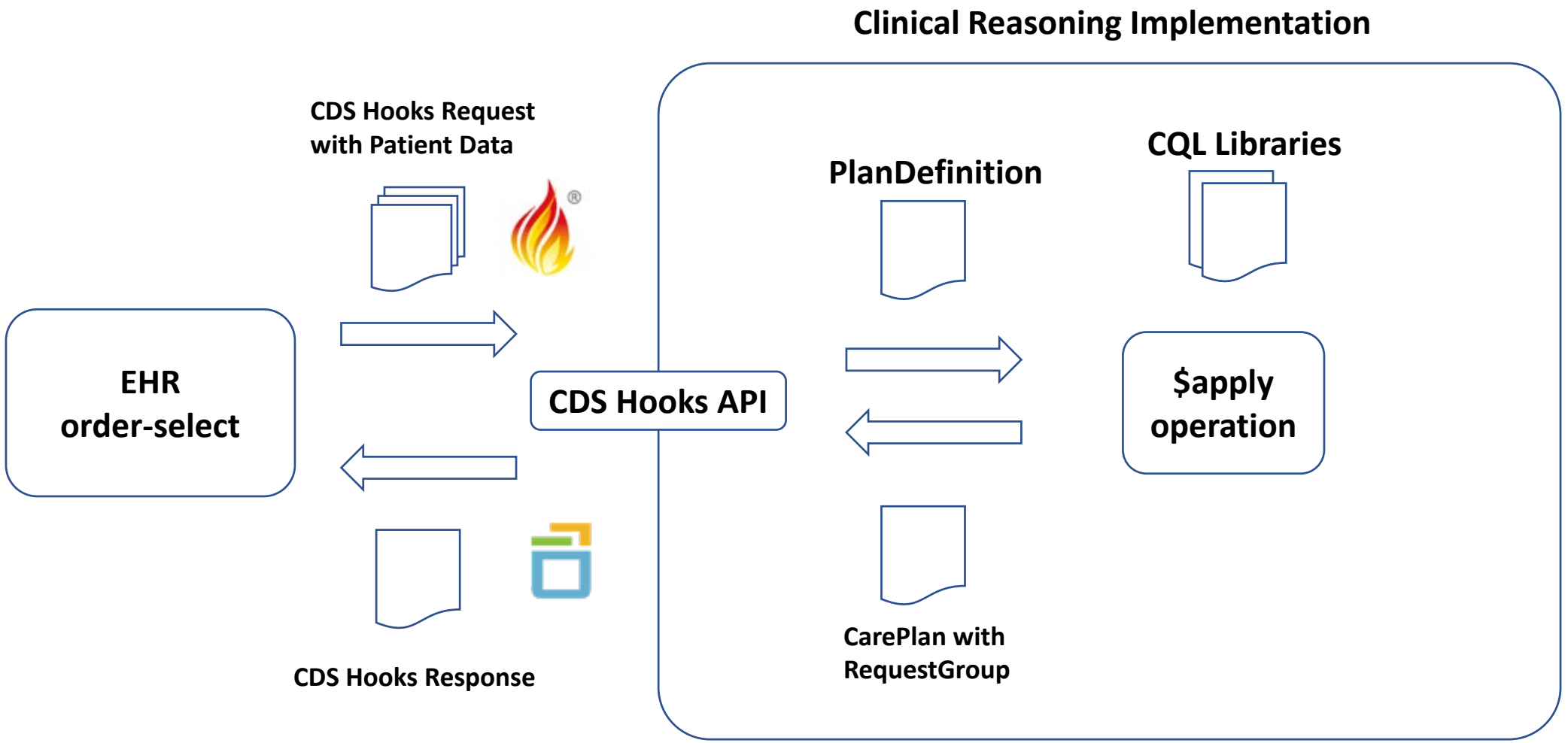
```
    "trigger" : [
      {
        "type" : "named-event",
        "name" : "order-select"
      }
    ],
    "condition" : [
      {
        "kind" : "applicability",
        "expression" : {
          "description" : "Check whether the existing patient is using opioids concurrently with benzodi
azepines.",
          "language" : "text/cql.identifier",
          "expression" : "Is Recommendation Applicable?"
        }
      }
    ],
    "groupingBehavior" : "visual-group",
    "selectionBehavior" : "exactly-one",
    "dynamicValue" : [
      {
        "path" : "action.description",
        "expression" : {
          "language" : "text/cql.identifier",
          "expression" : "Get Detail"
        }
      },
      {
        "path" : "action.title",
        "expression" : {
          "language" : "text/cql.identifier",
          "expression" : "Get Summary"
        }
      },
```



CQL Ingestion Integration



CDS Hooks Integration



For questions or more information please contact:
Maria Michaels – maria.michaels@cdc.gov
Matthew Burton – matthew.burton@apervita.com
Bryn Rhodes – bryn@databaseconsulting.com

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

Integration of Expert Systems in Clinical Radiology: NIH Perspective

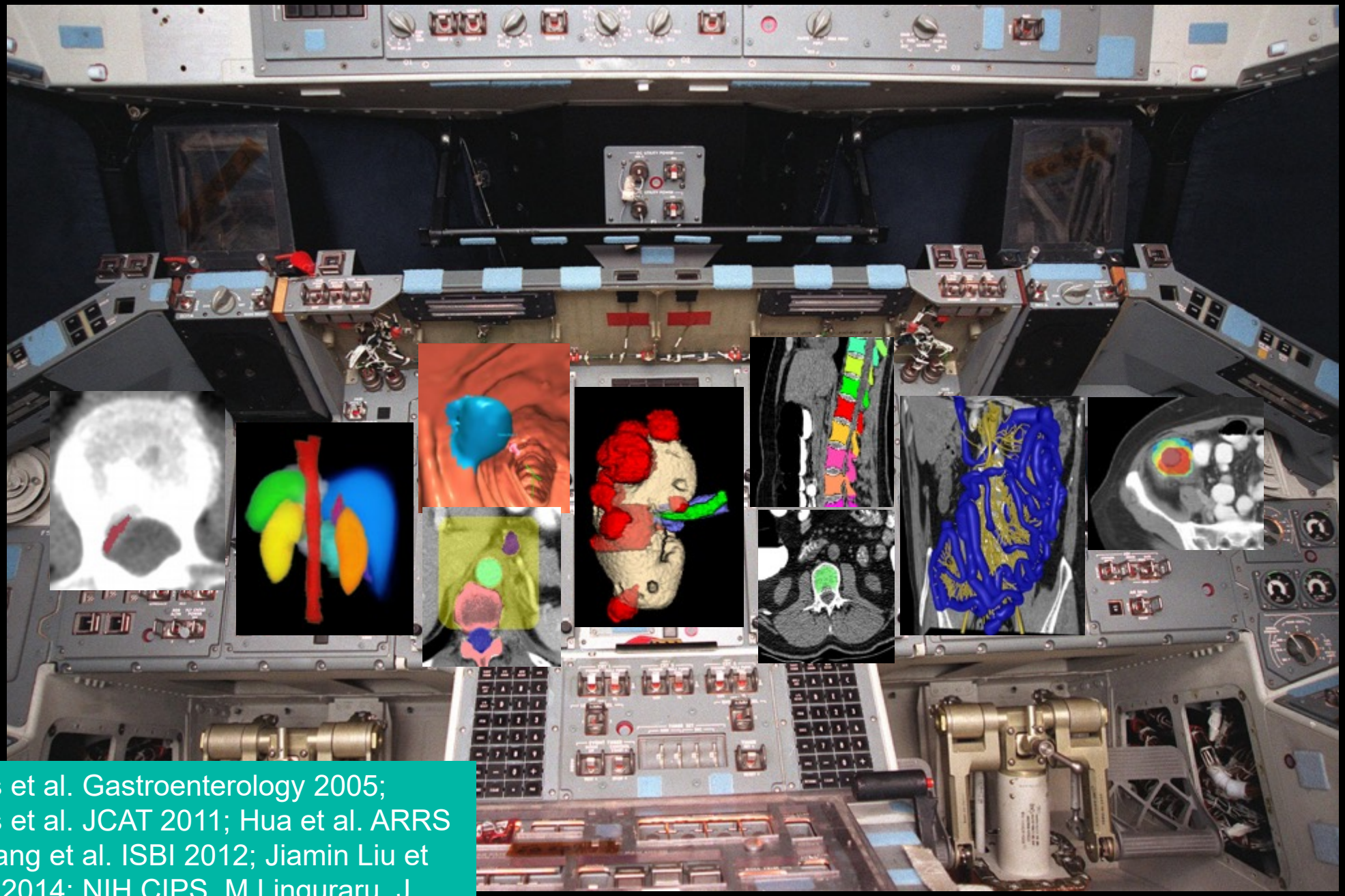
Ronald M. Summers, M.D., Ph.D.

Senior Investigator

Imaging Biomarkers and CAD Laboratory
Radiology and Imaging Sciences
NIH Clinical Center, Bethesda, MD

github.com/rsummers11
www.cc.nih.gov/drd/summers.html

Image Credit: Space shuttle Atlantis, nasa.gov



Summers et al. Gastroenterology 2005; Summers et al. JCAT 2011; Hua et al. ARRS 2012; Zhang et al. ISBI 2012; Jiamin Liu et al. CMIG 2014; NIH CIPS, M Linguraru, J Yao; J Liu et al. Medical Physics 2017

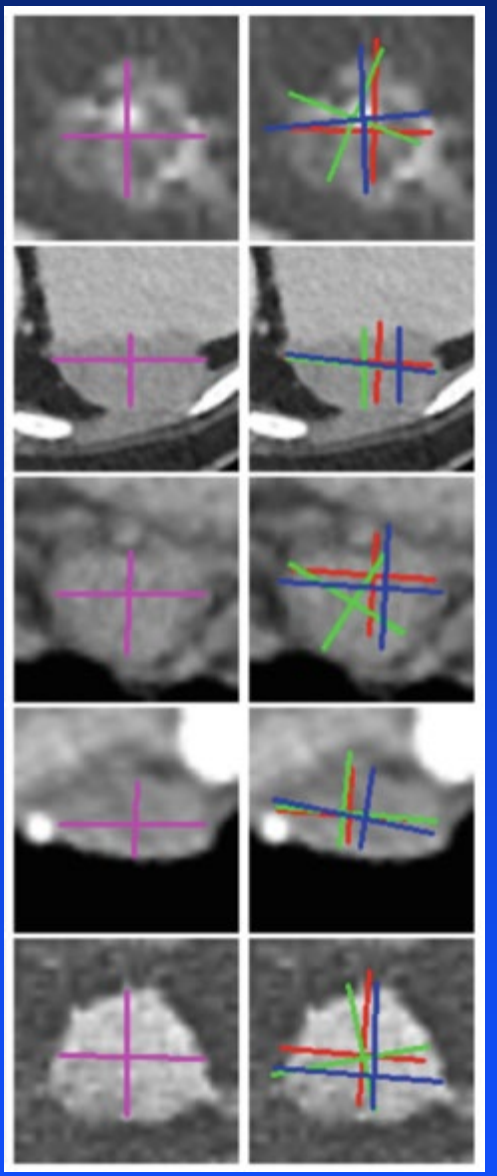
Image Credit: Space shuttle Atlantis, nasa.gov

Opportunities

- Integration of lab results, omics, medical record
- Routine automated quantitation
- Triage and critical result monitoring
- Prognosis prediction
- Global health
- Opportunistic screening

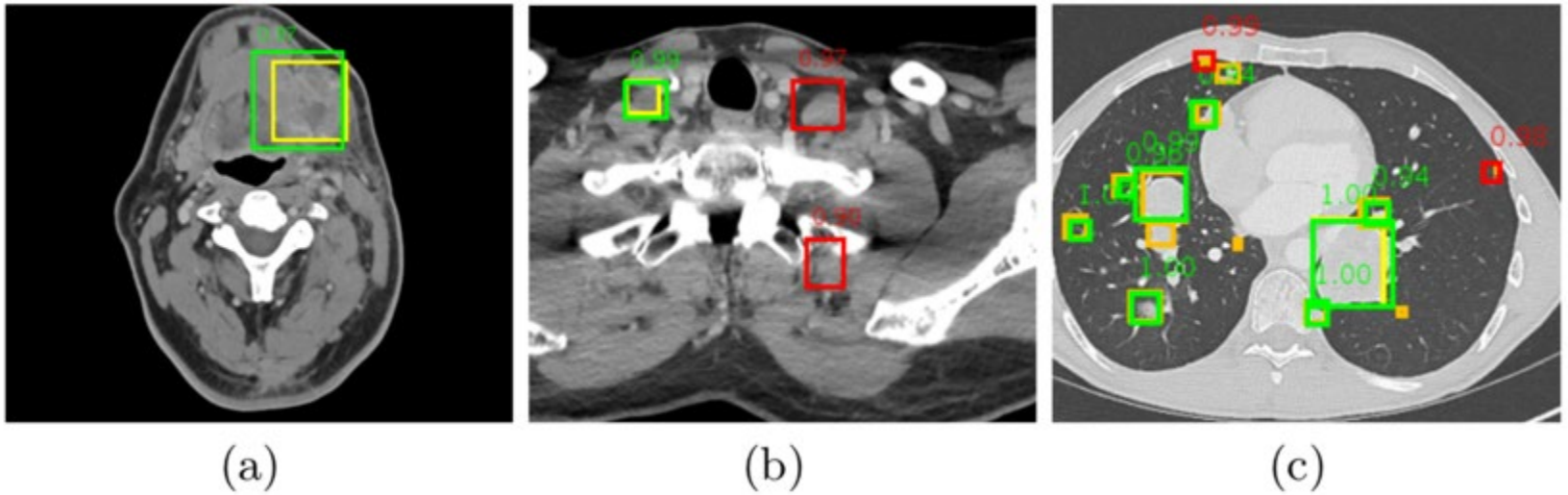
Broad Scope of Applications

- Detection (Lung nodules, TB, Breast masses)
- Segmentation (organ & lesion volumetrics)
- Quantification and measurement (RECIST)
- Workflow optimization (CXR & ICH triage)
- Image reconstruction (Accelerated MRI)
- NLP of reports



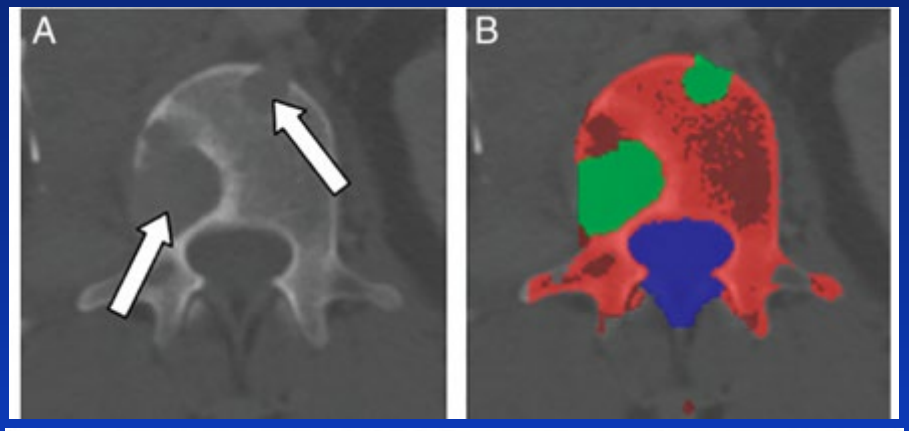
Youbao Tang et al. MICCAI 2018

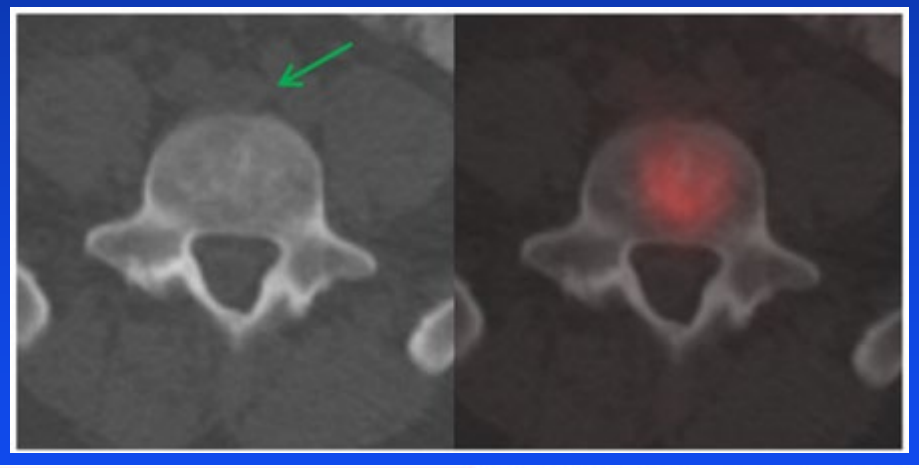
Universal Lesion Detector

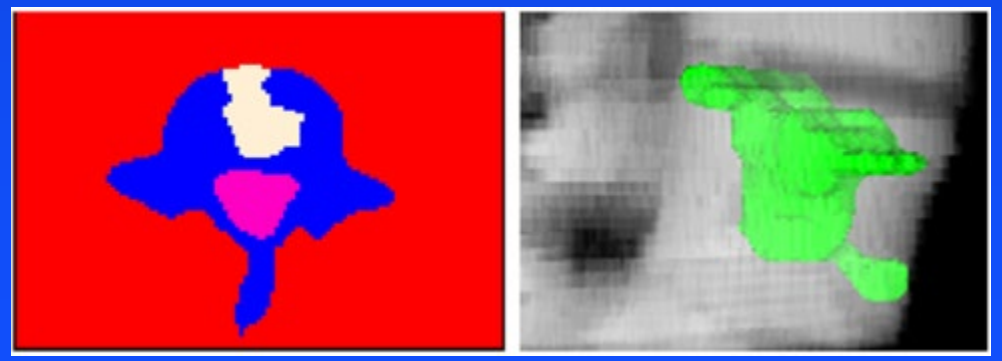


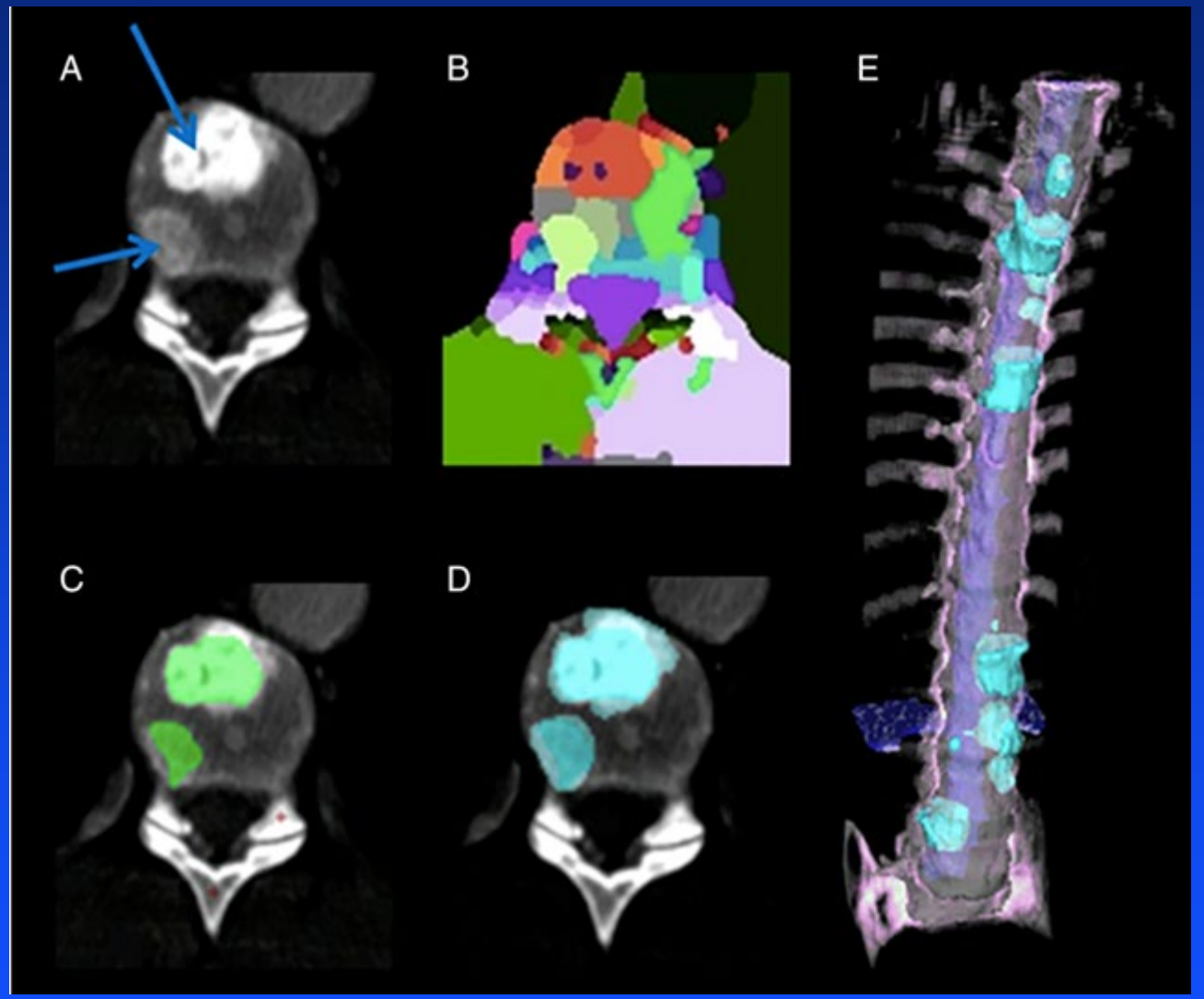
Yan et al. MICCAI 2018

Comprehensive Spine Oncology Analysis



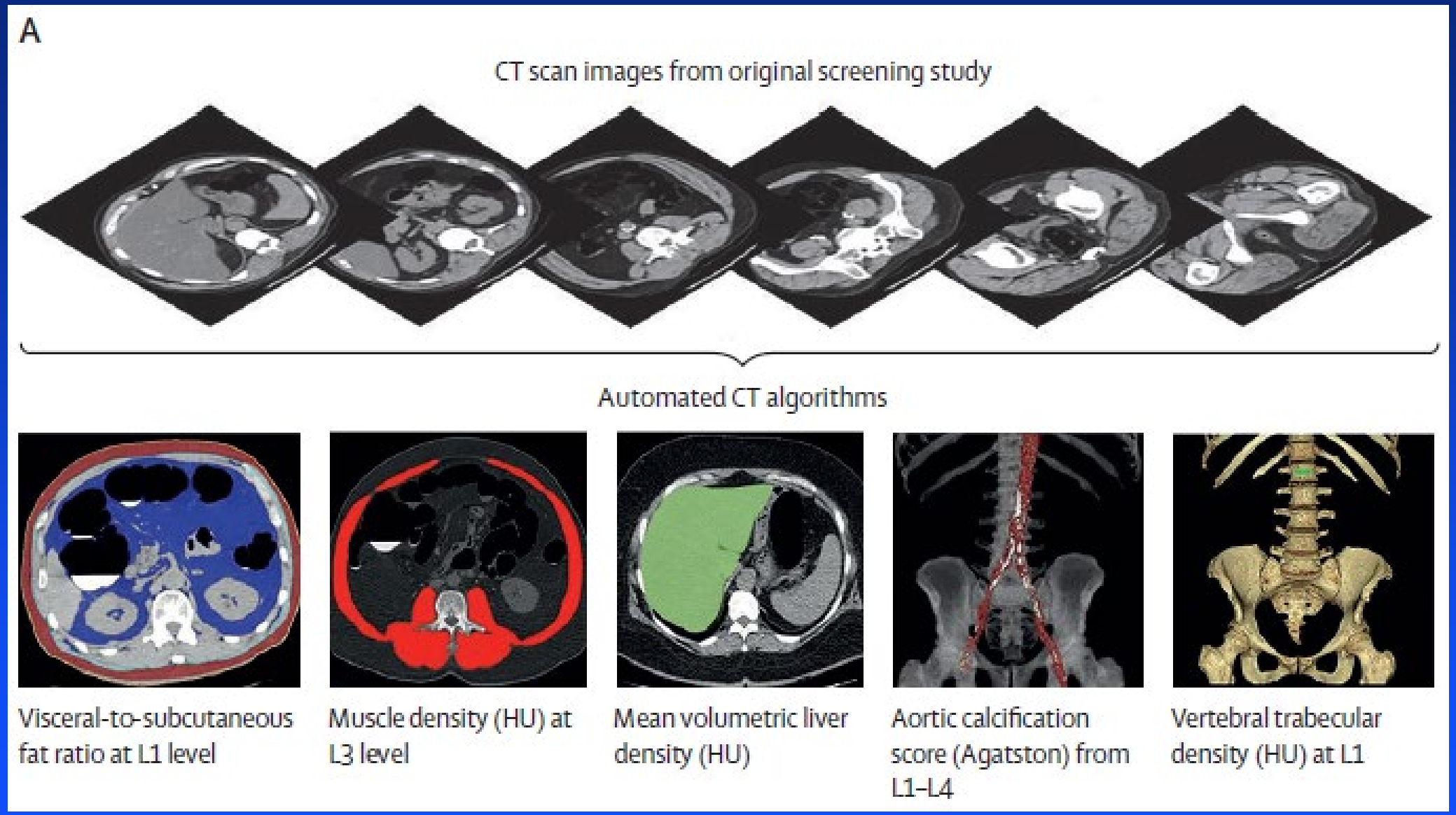






O'Connor et al. Radiology 2007; Yao et al. JMI 2017; Burns et al. JBMR 2020

Large-scale Body Composition Analysis



Pickhardt et al. Lancet Digital Health 2020

National Institutes of Health
Turning Discovery Into Health

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NEWS RELEASES

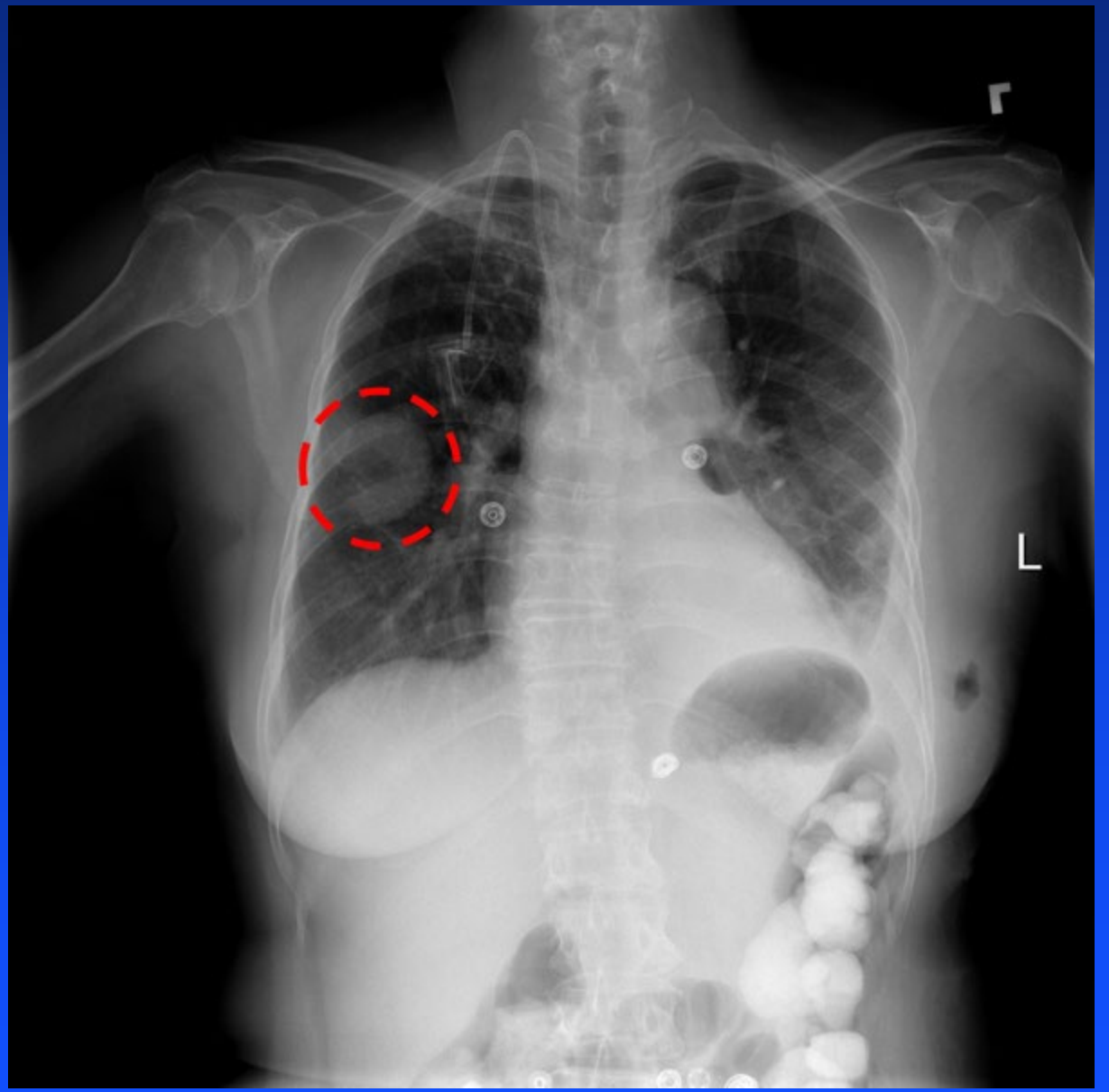
Media Advisory Wednesday, September 27, 2017

NIH Clinical Center provides one of the largest publicly available chest x-ray datasets to scientific community

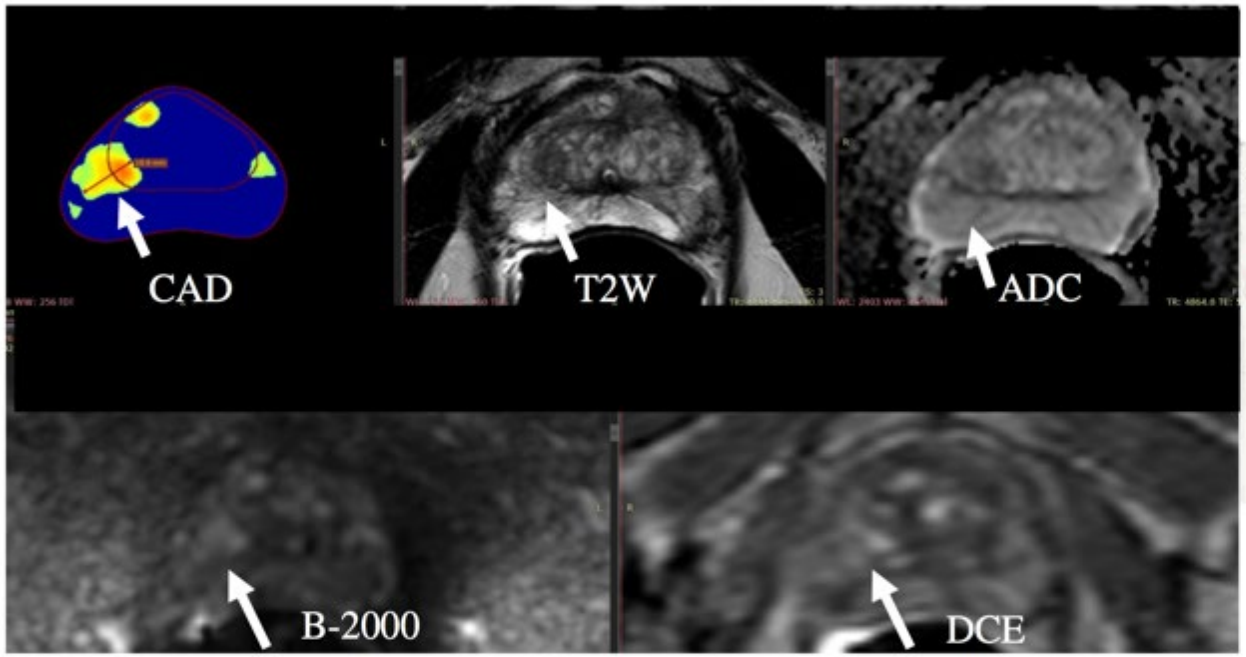
The dataset of scans is from more than 30,000 patients, including many with advanced lung disease.

ChestX-ray8 Dataset

- https://nihcc.app.box.com/v/ChestXray-NIHCC
- “ChestX-ray8 Dataset”
- 112,120 frontal-view chest radiographs, 30,805 unique patients
- 42 GB
- Metadata for all images
- Bounding boxes for 1000 images



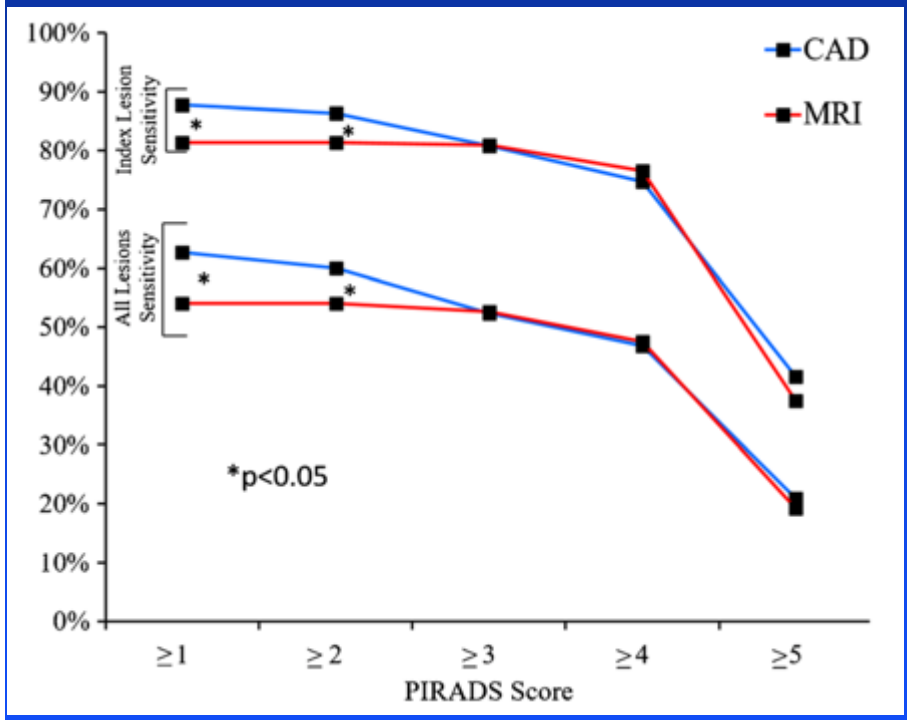
Case Study:
Prostate Cancer Detection



PI-RADS Score For Each Reader

Reader	1	2	3	4	5	6	7	8	9
CAD	1	1	2	4	ND	2	4	ND	2
MRI	ND	ND	ND	3	3	ND	ND	ND	3

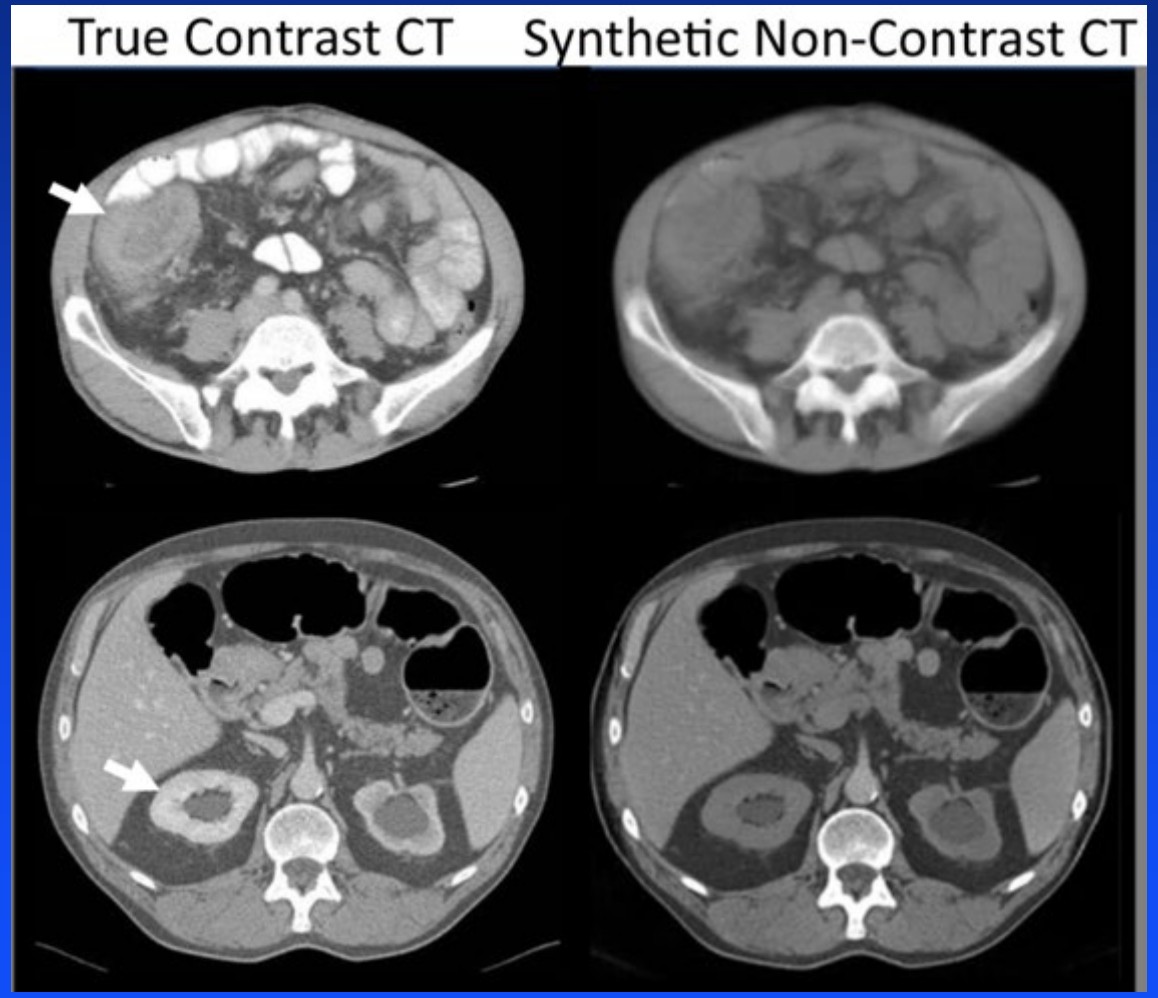
*ND= Not Detected



Greer et al. Eur Radiol 2018

Challenges & Questions

- Interpretability / explainability
- Brittleness
- Domain shift
- Ethics / Trustworthy AI

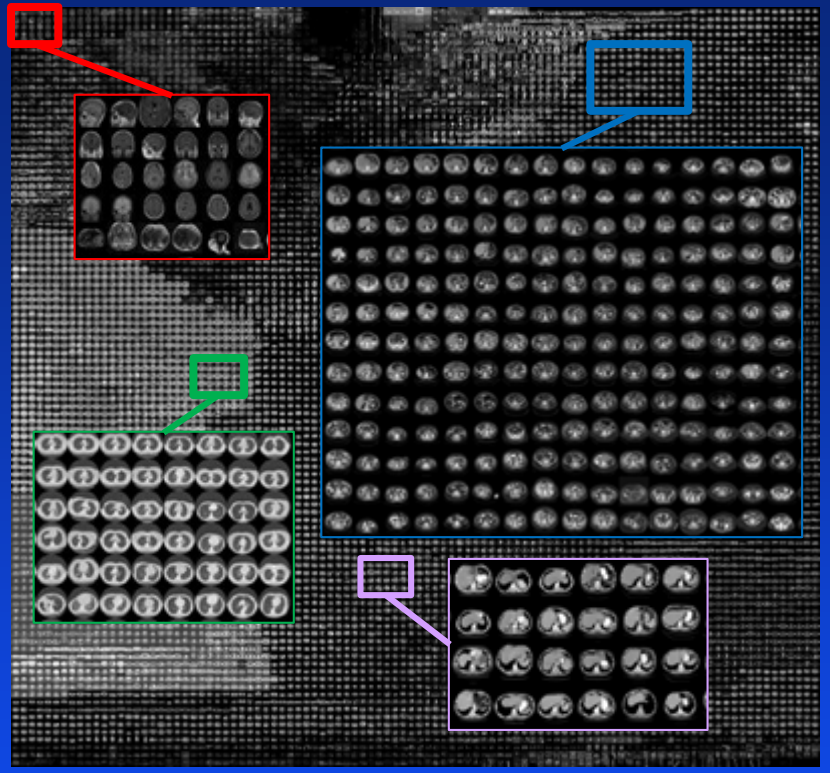


Sandfort et al. Sci Reports 2019

Challenges & Questions

- Dataset annotation is expensive; how to do it much more cost-effectively?
- Multi-institutional data; how to get it?
- Radiologists can diagnose 1000's of diseases; how to do this with ML?
- Radiologists can do "one-shot" learning, e.g., for rare diseases; how to do this with ML?

To Learn More …



E-mail: rms@nih.gov

www.cc.nih.gov/drd/summers.html

github.com/rsummers1

X Wang et al. RSNA 2016

Deep Medicine

Generating insights into complex disease patterns, risks and treatment effects

Dr. Dexter Canoy
University of Oxford
dexter.canoy@wrh.ox.ac.uk
http://deepmedicine.medsci.ox.ac.uk/

Deep Medicine Research Programme

An overview

Approach

- Data: large-scale, complex data
- Methods: Established analytics and machine intelligence
- People: Interdisciplinary team (clinical medicine, epidemiology, data science, computer science/engineering)

Research aimed at generating insights to

- Predict the risk of developing chronic disease
- Assess consequences of chronic diseases and their clustering (multimorbidity)
- Identify best practices and interventions

UK electronic health records (EHR)

- 97% of UK population are registered with a general practice as part of the National Health Service
- Primary care EHR linked to national databases for mortality, hospitalisations, and various disease registries
  - Clinical Practice Research Datalink (www.cprd.com)
- Data preparation/pre-processing – transforming raw data into meaningful markers ('phenotyping') using advanced algorithms
  - Data are highly imbalanced
  - Handling multi-modal data: irregular patient visits, numerous medical concepts, and non-numerical information

❑ 'Minimal processing'

Machine intelligence as applied in EHR data analysis

1. EHR, longitudinal data, and single risk factor
   - Long-term SBP in incident CVD risk prediction
2. Machine learning models and multiple predictors
   - Emergency admission prediction
3. Deep learning – which model?
   - Comparing performance of different models as applied to a single dataset
4. BEHRT model
   - Incorporating richness and complexity of EHR
5. BEHRT and some applications (ongoing work)
   - Risk prediction
   - Measuring uncertainty
   - Improving interpretability
6. Non-negative matrix factorization techniques
   - Multimorbidity – disease cluster and progression

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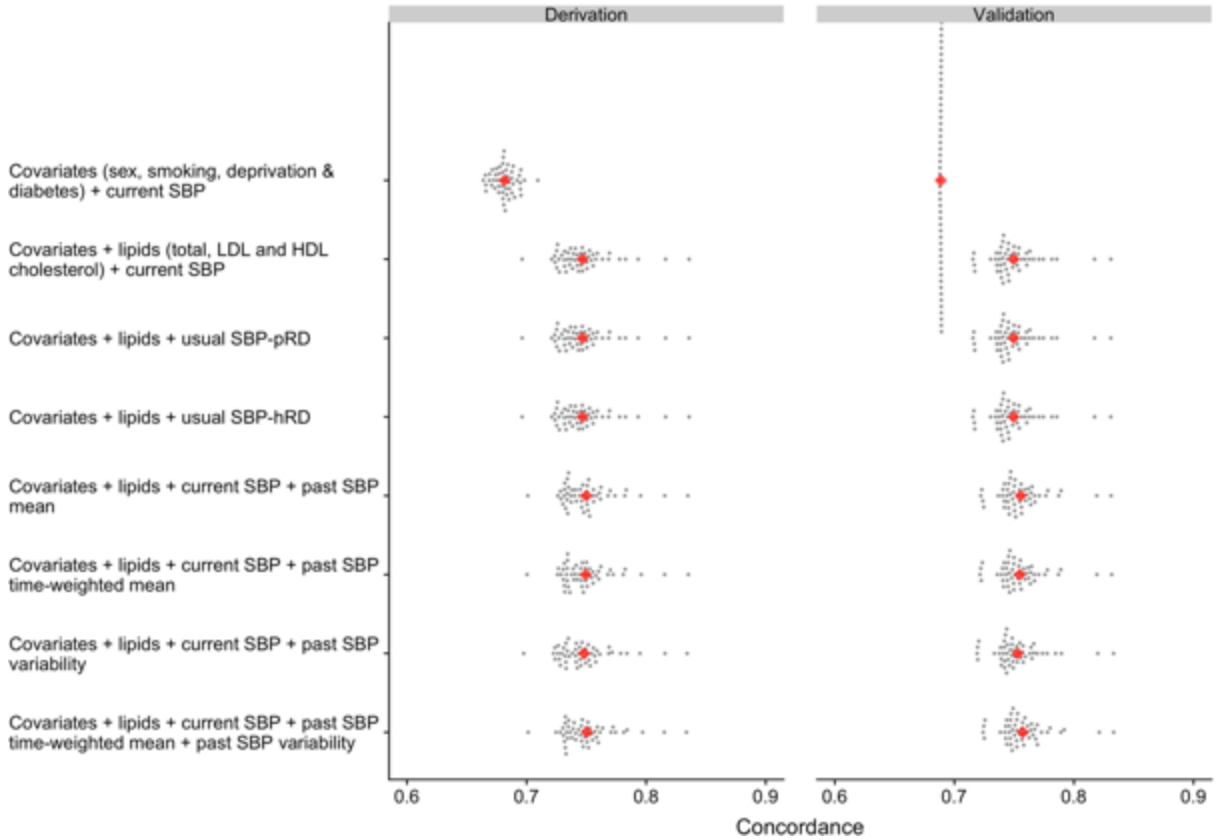
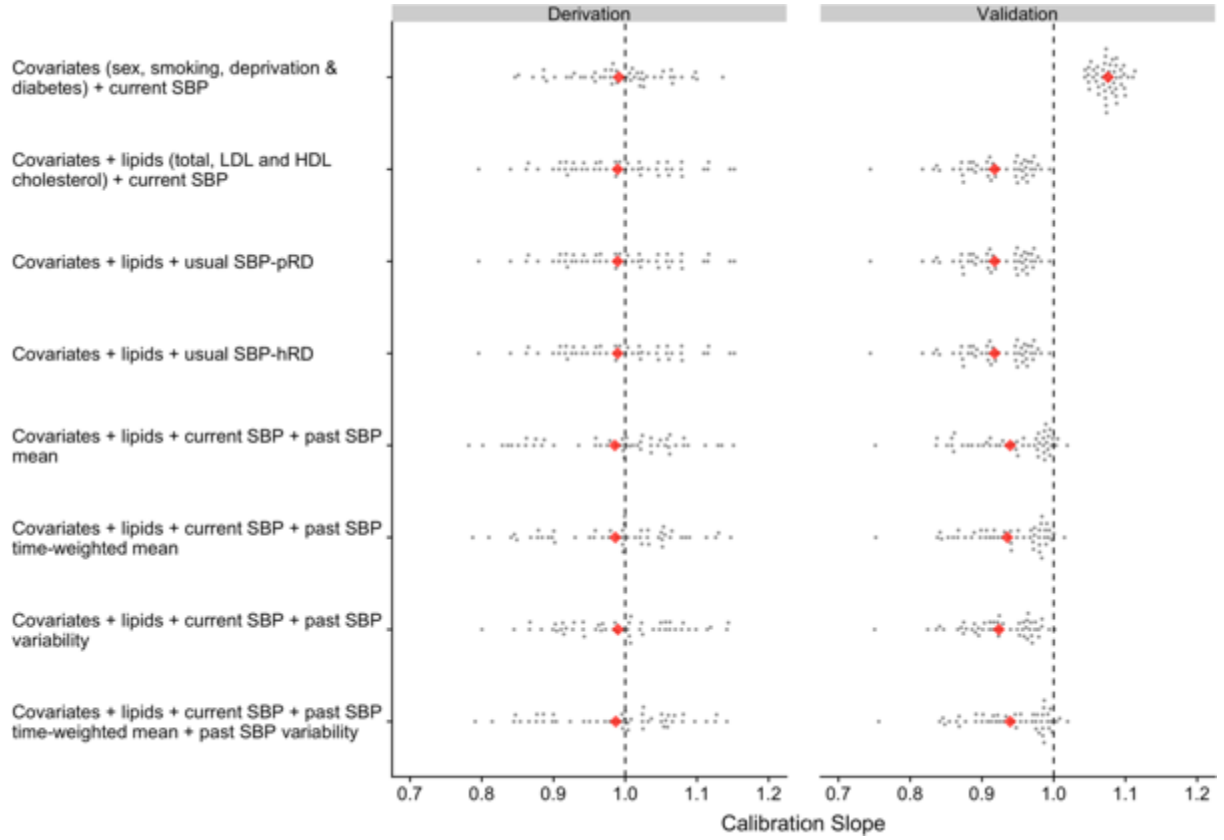
Long-Term Exposure to Elevated Systolic Blood Pressure in Predicting Incident Cardiovascular Disease: Evidence From Large-Scale Routine Electronic Health Records

Jose Roberto Ayala Solares, PhD; Dexter Canoy, MD, PhD; Francesca Elisa Diletta Raimondi, PhD; Yajie Zhu, PhD; Abdelaali Hassaine, PhD; Gholamreza Salimi-Khorshidi, DPhil; Jenny Tran, MD; Emma Copland, MSc; Mariagrazia Zottoli, MSc; Ana-Catarina Pinho-Gomes, MD; Milad Nazarzadeh, MSc; Kazem Rahimi, FRCP

Concordance



Calibration



(*J Am Heart Assoc.* 2019;8:e012129. DOI: 10.1161/JAHA.119.012129.)

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Predicting the risk of emergency admission with machine learning using linked EHR

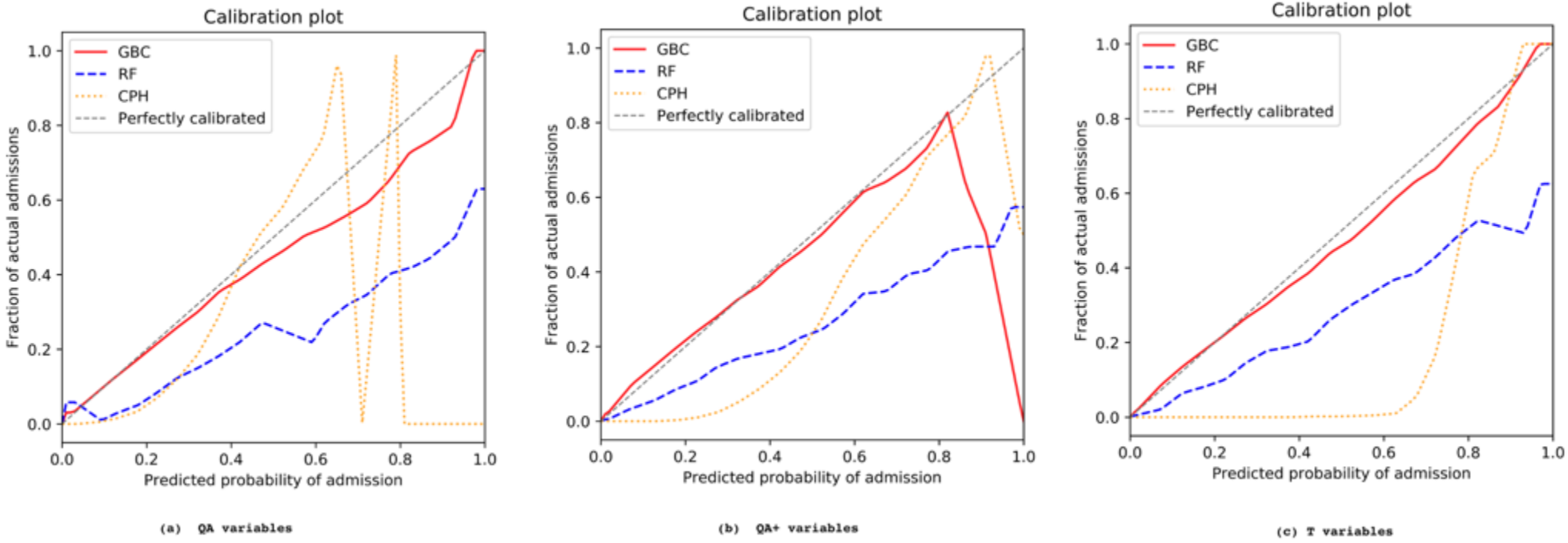
Model discrimination for different predictor sets and modelling techniques: Validation cohort.

Predictor set	Model		
	CPH	RF	GBC
QA	0.736	0.736	0.796
QA+	0.743	0.799	0.810
T	0.788	0.810	0.826

Predictor set T and GBC modelling constantly perform better than their counterparts. The results conform to the pattern observed in internal cross-validation.
CPH, Cox proportional hazards; GBC, gradient boosting classifier; RF, random forest.

https://doi.org/10.1371/journal.pmed.1002695.t004

Model calibration for different predictor sets and modelling techniques.



Rahimian F, et al. PloS Med 2018;15:e1002695

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Table 7
Comparison for the Demographics + Diagnoses + Medications scenario (Emergency Admission).

Model	AUROC	AUPRC	F1-Score
eNRBM	0.831 (0.831–0.832)	0.071 (0.071–0.071)	0.063 (0.062–0.063)
Deep Patient	0.813 (0.813–0.813)	0.060 (0.060–0.061)	0.059 (0.059–0.059)
Deepr	0.829 (0.828–0.831)	0.069 (0.067–0.071)	0.131 (0.118–0.144)
RETAIN	**0.847 (0.845–0.849)**	**0.083 (0.082–0.083)**	**0.153 (0.151–0.154)**
BOW + LR	0.646 (0.576–0.717)	0.019 (0.015–0.023)	0.054 (0.046–0.063)
RBM	0.840 (0.840–0.840)	0.072 (0.072–0.073)	0.066 (0.066–0.066)

*Data represented as: Mean (95% Confidence Interval).

Table 8
Comparison for the Demographics + Diagnoses + Medications scenario (Heart Failure).

Model	AUROC	AUPRC	F1-Score
eNRBM	0.920 (0.920–0.921)	0.020 (0.019–0.021)	0.014 (0.014–0.014)
Deep Patient	0.947 (0.947–0.948)	0.040 (0.039–0.041)	0.023 (0.022–0.023)
Deepr	0.949 (0.947–0.952)	0.039 (0.032–0.046)	0.085 (0.049–0.120)
RETAIN	**0.950 (0.946–0.954)**	**0.054 (0.053–0.056)**	**0.117 (0.098–0.136)**
BOW + LR	0.682 (0.613–0.752)	0.006 (0.002–0.009)	0.019 (0.011–0.027)
RBM	0.917 (0.917–0.917)	0.023 (0.022–0.023)	0.014 (0.014–0.014)

* Data represented as: Mean (95% Confidence Interval).

Ayala Solares, et al. J Biomed Informatics, 2020; 101: 1033

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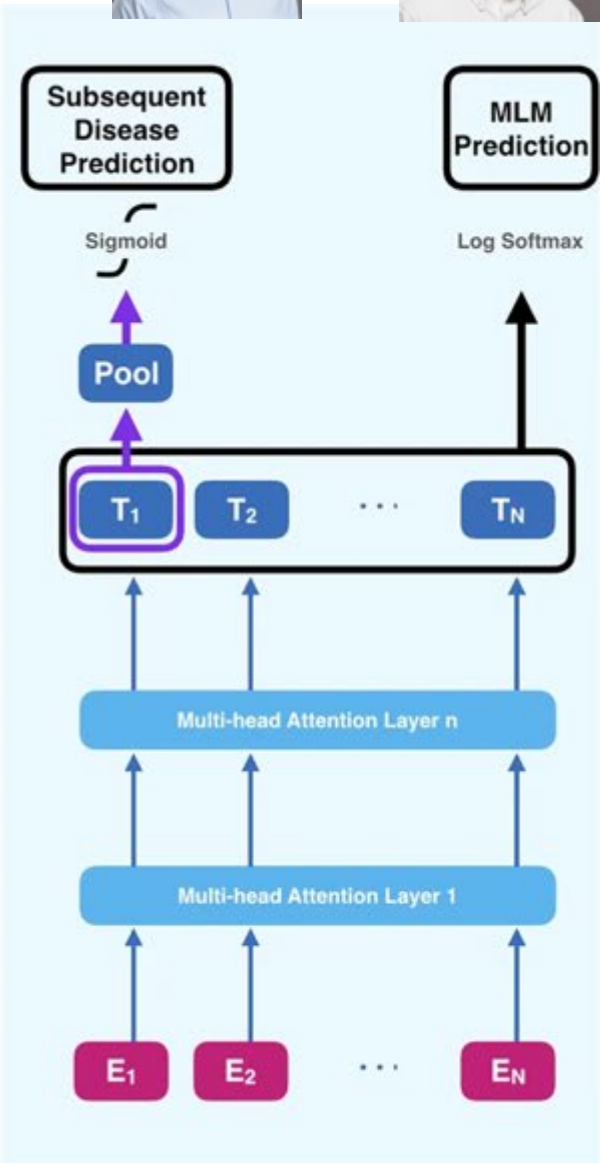
BEHRT: Transformer for Electronic Health Records

Bidirectional electronic health records transformer

Embedding Diagram and BEHRT Architecture



Data based on 1.6 million patients with ≥5 clinic visits

Li Y, Rao S, et al. Sci Rep 2020;10:715

BEHRT: TRANSFORMER FOR ELECTRONIC HEALTH RECORDS

Bidirectional electronic health records transformer Li Y, Rao S, et al. Sci Rep 2020;§0:7155

A deep neural sequence transduction model for EHR, capable of simultaneously predicting the likelihood of 301 conditions in one's future visits.

Model Name	Next Visit (APS|AUROC)	Next 6 M (APS|AUROC)	Next 12 M (APS|AUROC)
BEHRT	**0.462|0.954**	**0.525|0.958**	**0.506|0.955**
Deepr	0.360|0.942	0.393|0.943	0.393|0.943
RETAIN	0.382|0.921	0.417|0.927	0.413|0.928

Table 1. Model performances in the prediction tasks.

Model Name	Next Visit (APS|AUROC)	Next 6 M (APS|AUROC)	Next 12 M (APS|AUROC)
BEHRT	**0.216|0.904**	**0.228|0.907**	**0.226|0.905**
Deepr	0.095|0.800	0.104|0.814	0.098|0.805
RETAIN	0.108|0.836	0.115|0.845	0.109|0.836

Table 2. Model performances in the prediction tasks - First Incidence of Diseases.

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Ongoing work

- Incorporating more ‘features’ in the EHR
- Using BEHRT model in disease predictions
- Uncertainty estimation (Li Y, et at. arXiv:2003.10170v1)
- Interpretability
- Multimorbidity trajectories and outcomes

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Learning multimorbidity patterns from EHR using non-negative matrix factorisation

Hassaine A, et al. arXiv:1907.08577v2

Identification of disease clusters

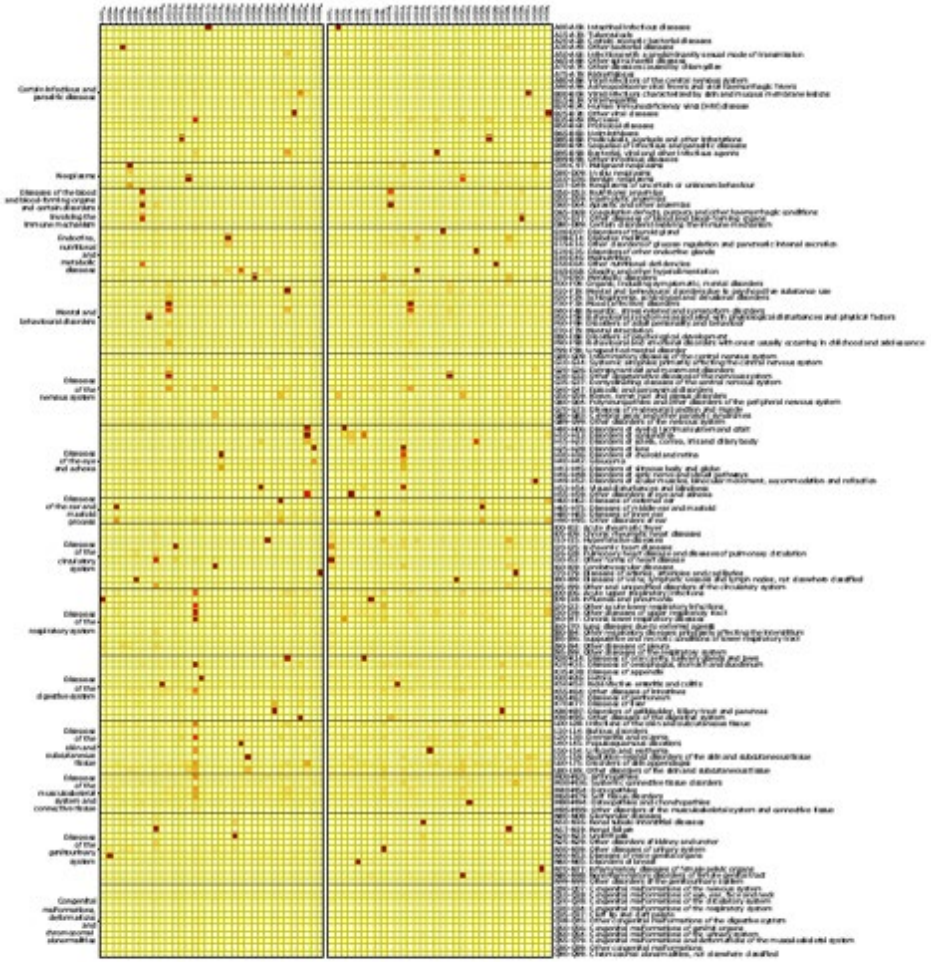

Figure 5: Disease clusters for male and female patients (on the left and right sides, respectively). The figure shows the transposed version ($\mathbf{B}^T$) of B matrices, after gamma correction (so that small values are visible).

Progression of disease clusters to another cluster

Untangling the complexity of multimorbidity with machine learning

Abdelaali Hassaine[a,b,c,1], Gholamreza Salimi-Khorshidi[a,c,1], Dexter Canoy[a,b,c], Kazem Rahimi[a,b,c,*]

Mechanisms of Ageing and Development 190 (2020) 111325

Deep Medicine

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Kazem Rahimi (PI)

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Jeannette Majert | Thomas Fisher | Naseem Akhtar

Funders

Oxford Martin School | NIHR Oxford Biomedical Research Centre | British Heart Foundation

DUKE University School of Medicine | DUKE Institute for Health Innovation

Integrating Deep Learning into Routine Care Delivery

Mark Sendak, MD, MPP
Population Health & Data Science Lead
Duke Institute for Health Innovation

September 15, 2020

Duke Institute for Health Innovation

Duke Institute for Health Innovation

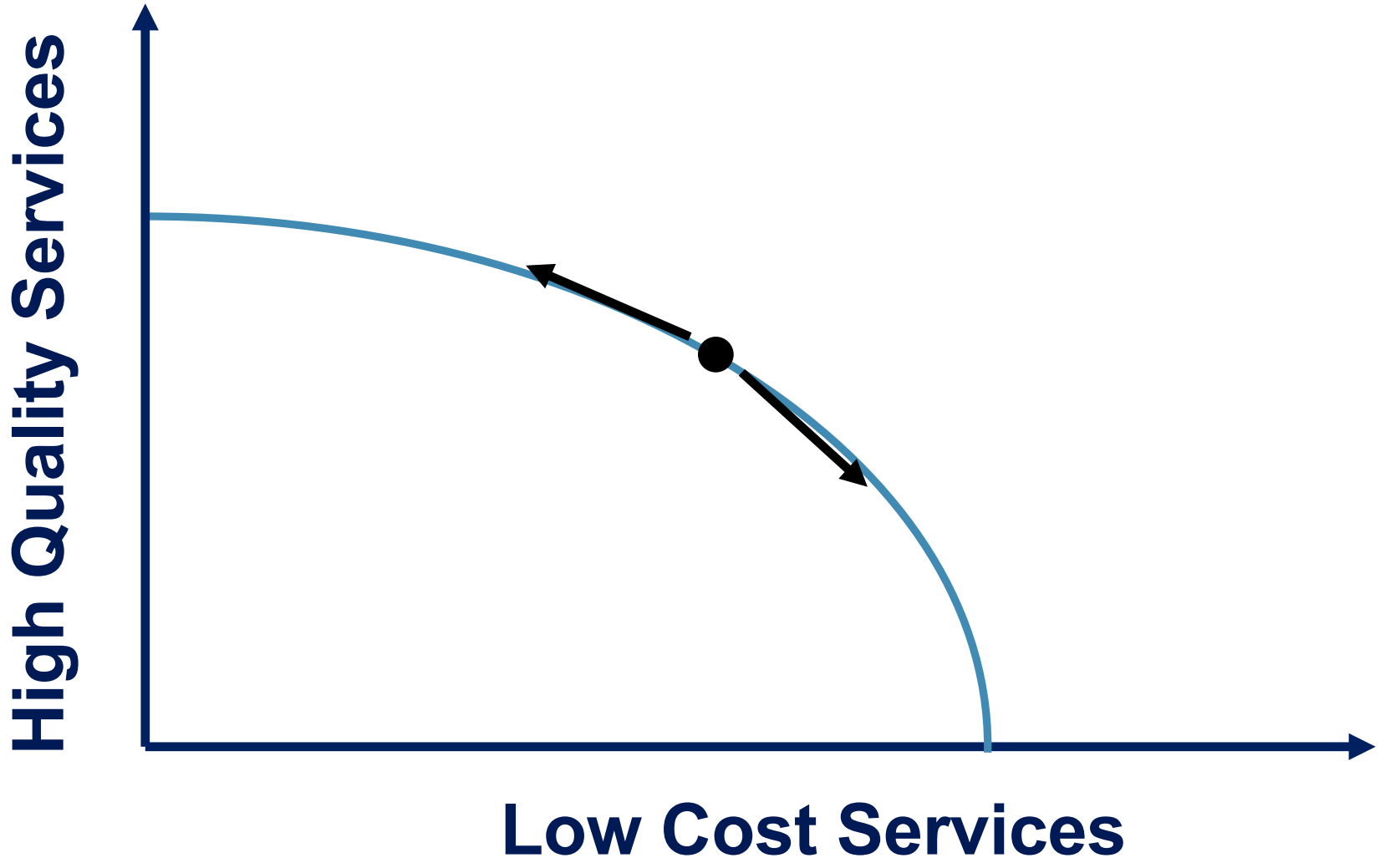
Our Mission: **Catalyze health innovation**

Catalyze transformative innovation in health and healthcare through high-impact research, leadership development and workforce training and the cultivation of a community of entrepreneurship

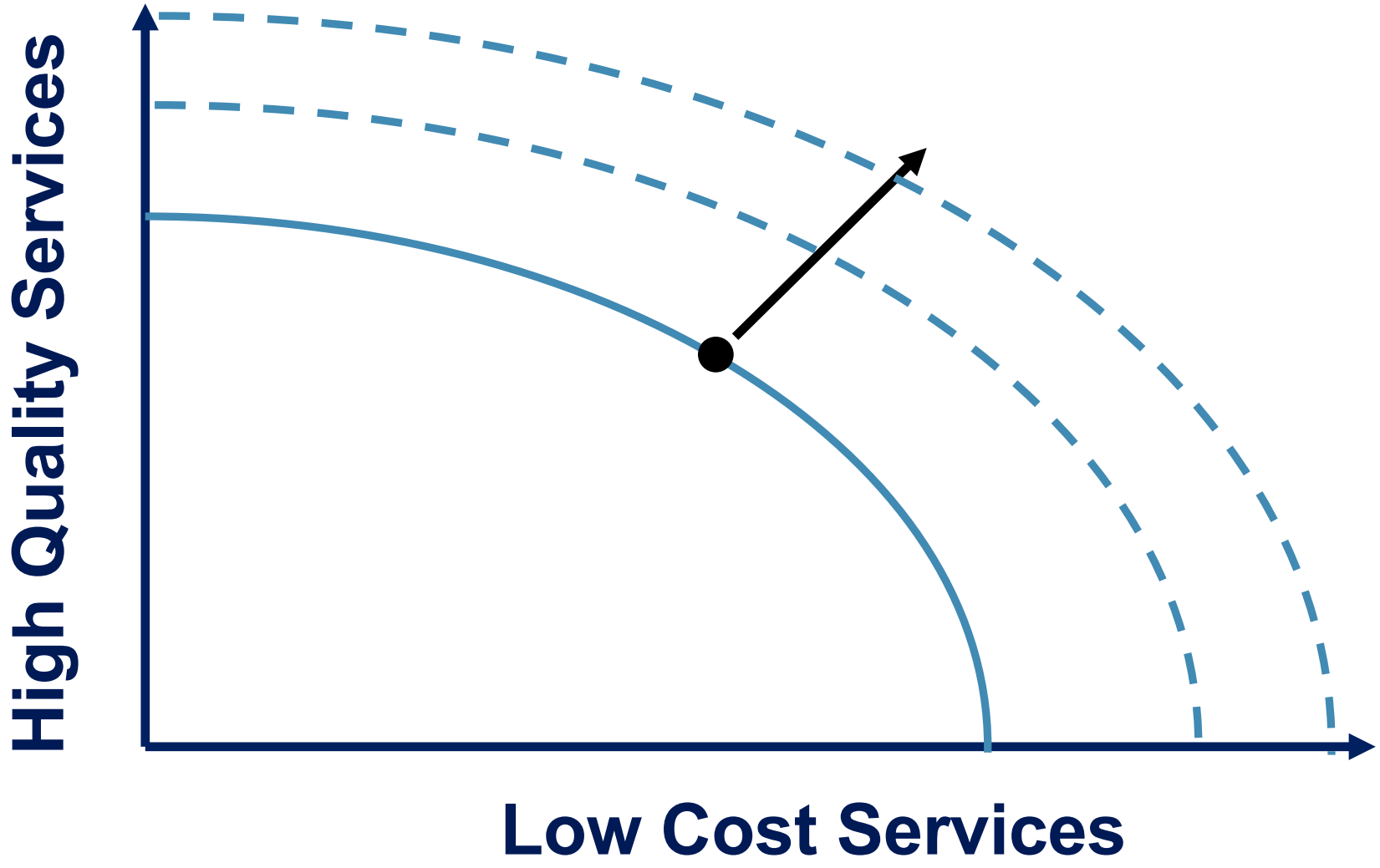
Our Approach: **Innovation by design**

Understand user workflow, desired outcomes and problems (needs) and then collaboratively develop concepts and prototypes, and iterate through to finalize solution

Health Care Possibility Frontier



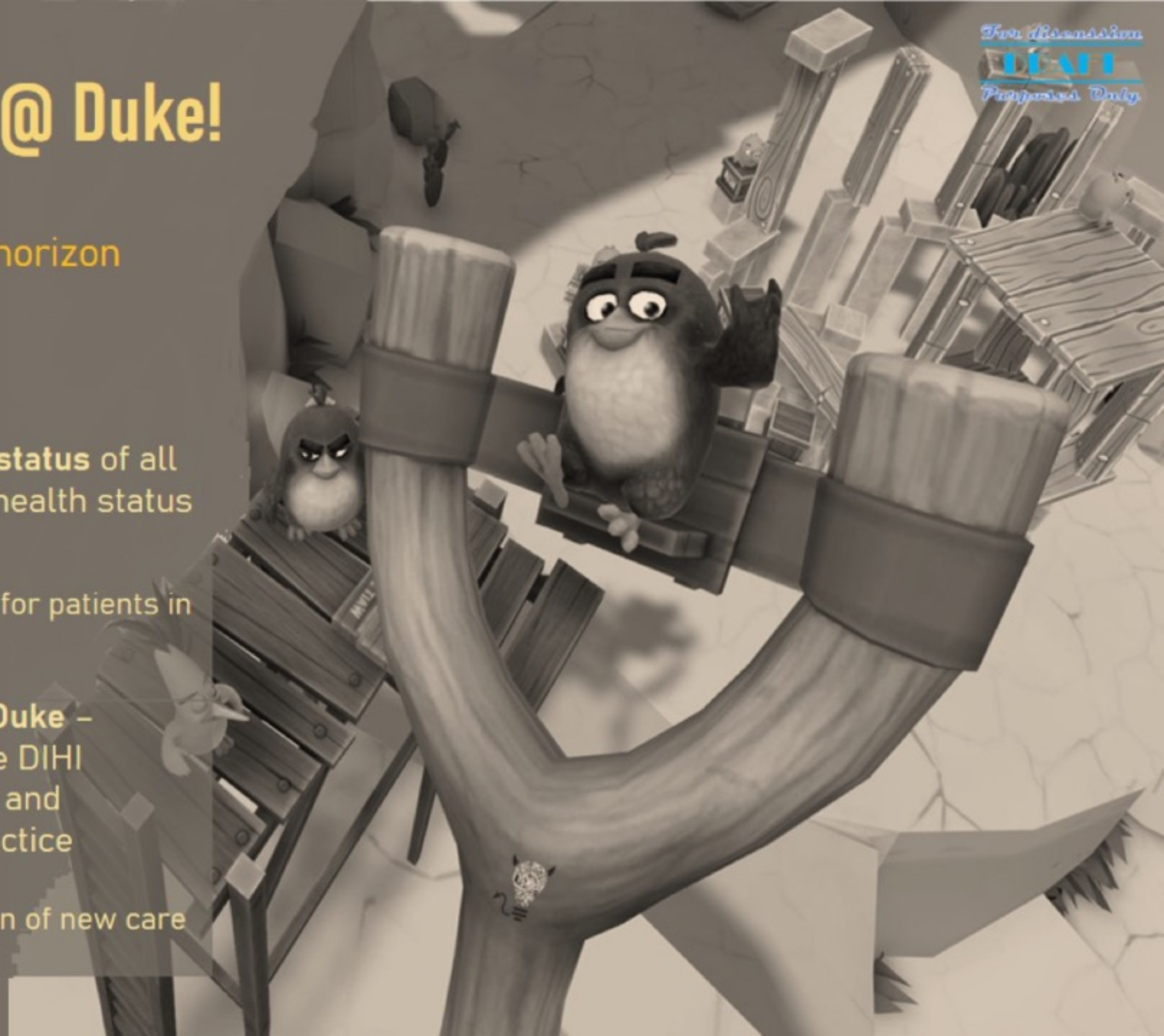
Health Care Possibility Frontier



DIHI : We dare to do it @ Duke!

- Explore the horizon
- Enable others to operate at the horizon
- Expand the horizon
- Help define the next horizon

- **Up-to-date representation of health status** of all patients and prediction of change in health status at all moments
  - Complete continuum of care coverage for patients in any DUHS or DUHS partner setting
- **Innovation as self-service model at Duke** – anyone at Duke should be able to use DIHI products and services to implement and evaluate changes in their clinical practice
  - Seamless A/B testing for rapid iteration of new care models using integrated technology



Sourcing Innovations: Structured and Opportunistic

RFA Innovation Pilots

Structured

DIHI RFA approach

"Top-down + Bottom-Up" approach to sourcing innovations

- Duke Health leadership carefully develops mission-aligned **strategic themes** for innovation pilots
- Front-line faculty and staff propose "**problems**" aligned themes **and novel solutions**
- **Systematic review** and **due diligence**: Assessments on team, feasibility, resource needs, impact and value to patients
- **8-12 innovation pilots** chosen and funded each year; Duration: **12-15 months**
- DIHI members embedded within project innovation teams to rapidly catalyze the innovations
- **Pivots as needed** to support rapid evolution to create value
- **Metrics**: clinical utility, economic utility, cultural impact, IP and academic outputs

7 Years Catalyzing Innovations

55+ Innovation Pilots

250+ Proposals

Innovation Jam

Unstructured

DIHI Innovation Jam

A Health focused Shark Tank at Duke

- Solicits and identifies high-potential healthcare and health **innovations ready for commercialization**
- **Duke Leadership as Sharks:**
  - DUHS leaders, Department Chairs, Deans of School of Medicine, Nursing, Engineering, OLV, I&E, MedBlue, Center and Institute Directors
- Innovation proposals from students, faculty, trainees and staff across campus
- **Funding** to support entrepreneurship / **formation of company** and also **develop the product/service** etc.
- Inventors offer portion of their share of Duke internal returns for investment from the sharks
- Internal syndicated investment agreements documented through MOUs.

5 Years of Jamming

30+ Pitches

10 Companies Incubated

Duke Institute
for Health Innovation

RFA 2021

All faculty, staff, students and trainees are invited to submit novel ideas to:

- Improve value of care through novel strategies
- Create digital solutions for care and monitoring (home monitoring, wearables etc.)
- Advance health equity
- Enhance provider and staff experience and well-being
- Accelerate population health solutions and strategies
- Enhance patient engagement and experience

Visit dihi.org/events/dihi-rfa or email DIHIrfa@duke.edu

Applications Due : Midnight, Friday, October 9, 2020.

@dukeinnovate

DIHI Spectrum of Value Creation

Inpatient Innovations	Transition Setting	Outpatient/ Gaps in Care	Patient & Community
		Pre-Operative Optimization	PrEP for HIV
Mortality Models (inpatient / 30-day)	High-utilizer dashboard	Home BMT	ePRO for Cancer Patients
Operational Enhancement	Complex Care Plans	Pallialytics	Sickle Cell – Selfie App
Procedure Safety	Index Admissions with MSSP	High Value Analytes	Cancer Distress Coach
Medication Safety	Readmissions (Social Drivers for HF)	PSA Screening Tool	Autism and Beyond
Early Detection of Deterioration	SNF transition	CKD population health rounding	Voices of Duke

Immersion in innovation and data science

- **Medical Students Scholarship**
- **Data Science in Health** masters course in BME
- **Summer Fellowship** in Data Science
- **Case Studies** and Data Camp
- **Journal Club**

Technology Infrastructure | Research | Education and Training

Duke Institute for Health Innovation [DIHI] – Spectrum of value creation across the ecosystem

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Technology Infrastructure | Research | Education and Training

Duke Institute for Health Innovation [DIHI] – Spectrum of value creation across the ecosystem

Sepsis Watch

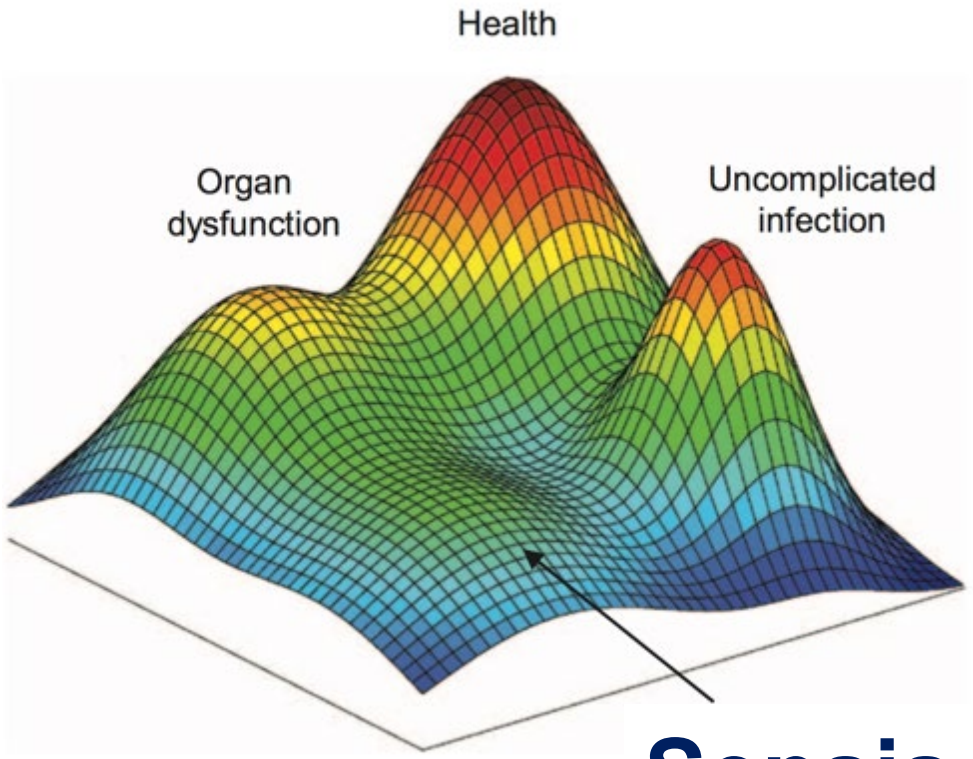
Sepsis

- Most common cause of in-hospital deaths in the United States
- 20% of all global deaths (49 million incident cases per year, 11 million deaths per year)
- At Duke, 68% of sepsis cases occur within 24 hours of presenting to hospital

    ~20 cases per day, ~2 deaths per day

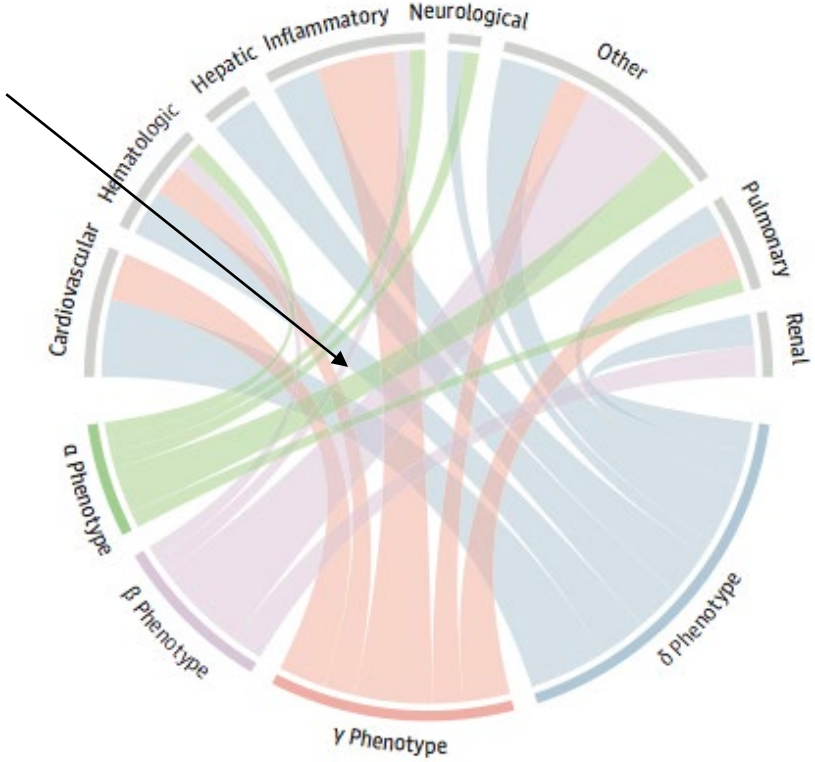
"The Human Body is a Black Box"

2016 Visual Aid



Sepsis

2019 Visual Aid



Sepsis

"it is an elusive task to generate a single all-encompassing definition"

The Challenge

- Sepsis as a label is not explainable or interpretable to clinicians (even experts)
- Urgency to improve the detection and management of a deadly condition
  - Once diagnosed, implement guideline-recommended care
- Needed broad adoption by front-line clinical staff, health system leadership, and medical community
  - 3 hospitals, nearly 2,000 hospital beds

The Challenge

- Sepsis as a label is not explainable or interpretable to clinicians (even experts)
- Urge
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Given the circumstances, what are the best strategies to build trustworthiness and accountability with various stakeholder groups?

Strategies To Promote Trustworthiness, Transparency, & Accountability	Idea generation & resource gathering	Model development & validation	Tool design, development & evaluation	Workflow development, integration & education	Handoff, maintenance & improvement
Problem formulation	Problem-based project selection; Clinician initiated and led	Local and context-specific training data used; Local monitoring & validation by clinicians & dev team	Iterative tool refinement with stakeholders; Recognition of socio-technical dimensions	Boundaries of appropriate use defined; Infrastructure and testing to meet enterprise user requirements	Tool usage limited to original boundaries of intervention; Ongoing monitoring of relevant clinical research
Stakeholder relationship building	Stakeholder mapping; Multiple modes of stakeholder engagement leveraged; Close clinical collaboration	Sustained engagement with ML researchers; Close clinical collaboration	Full time role created to support integration; Sustained engagement with tech vendors; Close clinical collaboration	Stakeholder capacity-building around tech literacy; Close clinical collaboration	Collaborating with existing institutional performance monitoring; Close clinical collaboration
Stakeholder feedback loops	IRB approved research protocol; Data-safety monitoring board created; Multi-disciplinary team assembled;	Local monitoring & validation by clinicians & dev team	Regular meetings to create space for feedback; Trial “silent phase” integration	Multi-stakeholder governance committee established; Full time role manages and supports project integration	Ongoing technical monitoring by dev team; Multi-stakeholder governance committee oversight
Upholding professional discretion	Explicit goal: to augment, not replace clinicians	Local monitoring & validation by clinicians & dev team	Designed as an “algorithm in the loop”; Register clinical trial and report outcomes	Elevate the work and expertise of integrating the tool into clinical care	Multi-stakeholder governance committee draws on multiple forms of expertise; New projects initiated!

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	SIRS ≥2	qSOFA ≥2	SIRS ≥2 + any culture ordered	SIRS ≥2 + any culture ordered + element of organ damage	SIRS ≥2 + blood culture ordered + element of organ damage	qSOFA ≥2 + any culture ordered	ICD diagnosis code associated with sepsis	SIRS ≥2 + bacteremia	Total
# of encounters	32928	17423	14327	13358	**9184**	7110	2884	1419	43046
Median length of stay in days (lower-upper quartiles)	4.6 (2.8-8.1)	5.9 (3.2-10.7)	6.4 (3.7-12.1)	6.9 (3.9-12.8)	**7.3 (4.1-14.6)**	8.3 (4.5-16.3)	7.5 (4.1-15.4)	11.0 (5.9-23.7)	4.0 (2.4-7.0)
Inpatient mortality rate (%)	3.7%	6.7%	6.9%	7.4%	**9.7%**	12.6%	16.3%	15.0%	2.9%
ICU requirement rate (%)	21.3%	32.0%	28.7%	30.0%	**34.5%**	45.0%	46.4%	38.9%	18.9%
Antibiotic administration rate (%)	62.4%	69.0%	82.8%	83.2%	**90.0%**	85.5%	98.5%	97.8%	63.2%
IV fluid administration rate (%)	38.0%	37.8%	47.4%	48.5%	**56.7%**	49.6%	86.7%	67.1%	42.4%
Vasopressor administration rate (%)	10.2%	17.1%	15.0%	16.0%	**19.4%**	27.3%	32.8%	28.8%	9.6%

Strategies To Promote Trust & Accountability	Idea generation & resource gathering	Model development & validation	Tool design, development &	Workflow development, integration	Handoff, maintenance & improvement
Problem formulation	Problem-based project selection; Clinician initiated and led	**Local and context-specific training data used**			
Stakeholder relationship building	Stakeholder mapping; Multiple modes of stakeholder engagement leveraged; Close clinical collaboration	Sustained engagement with ML researchers; Close clinical collaboration			
Stakeholder feedback loops	IRB approved research protocol; Data-safety monitoring board created; Multi-disciplinary team assembled;	Local monitoring & validation by clinicians & dev team			
Upholding professional discretion	Explicit goal: to augment, not replace clinicians	Local monitoring & validation by clinicians & dev team		the tool into clinical care	draws on multiple forms of expertise; New projects initiated!

Dataset

- **42,000+** inpatient encounters at Duke Hospital over 14 months, **21.3%** with a sepsis event; no specific inclusion/exclusion criteria.
- **34** physiological variables (5 vitals, 29 labs).
  - At least one value for each vital in 99% of encounters.
  - Some labs rarely measured (2-4%), most measured 20-80% of the time.
- **35** baseline covariates (e.g. age, transfer status, comorbidities).
- **10** medication classes (antibiotics, opioids, heparins).
- **32+ million data points**: 25 million vital sign measurements, 2 million med admins and 5.2 million labs.

Strategies To Promote Trust & Accountability	Idea generation & resource gathering	Model development & validation	Tool design, development & evaluation	Workflow development, integration & education	Handoff, maintenance & improvement
Problem formulation	Problem-based project selection; Clinician initiated and led	Loca spec used & va clini			usage limited to nal boundaries of vention; Ongoing itoring of relevant cal research
Stakeholder relationship building	**Stakeholder mapping; Multiple modes of stakeholder engagement**	Sust with Clos colla			aborating with existing tutional performance itoring; Close clinical aboration
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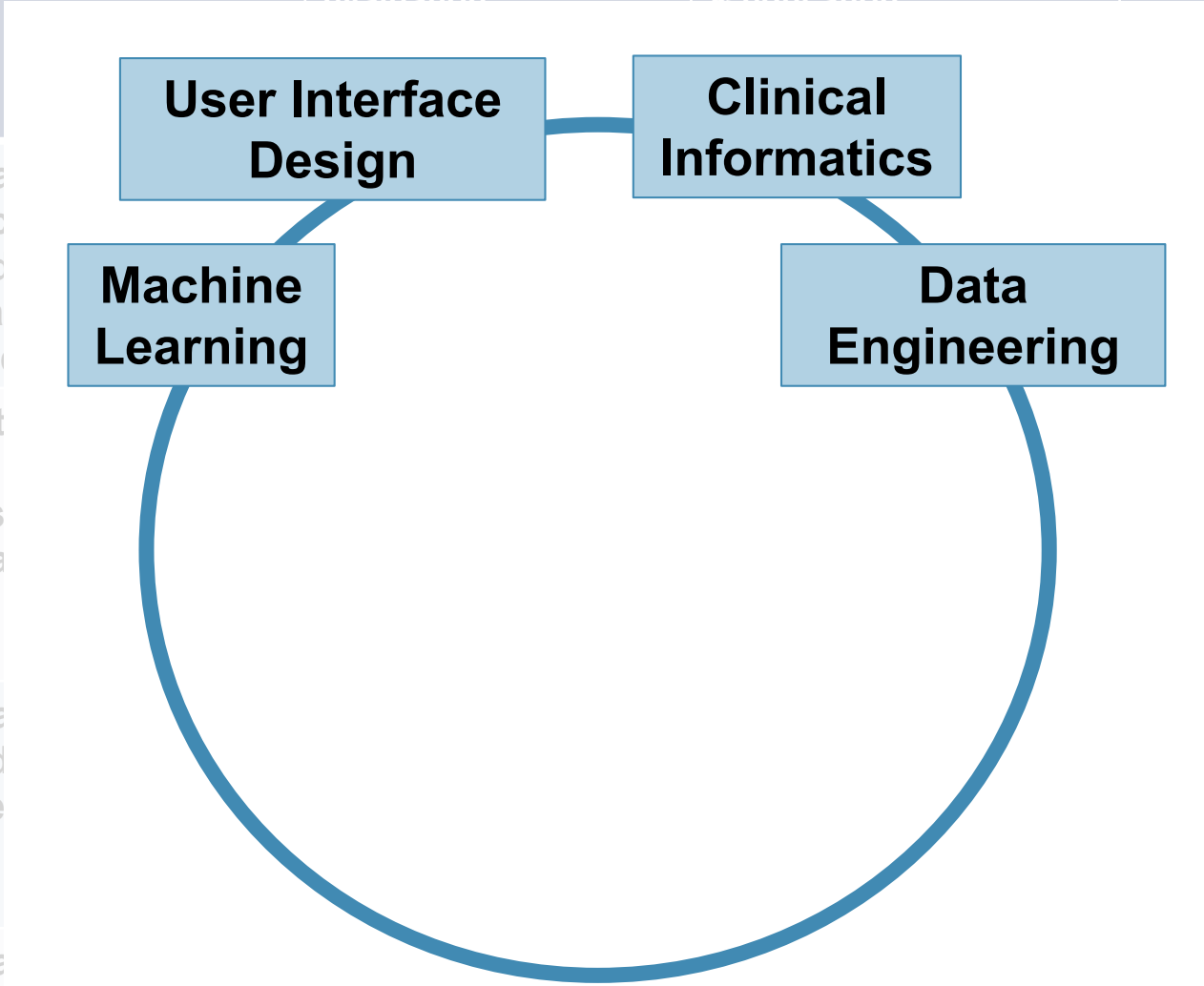

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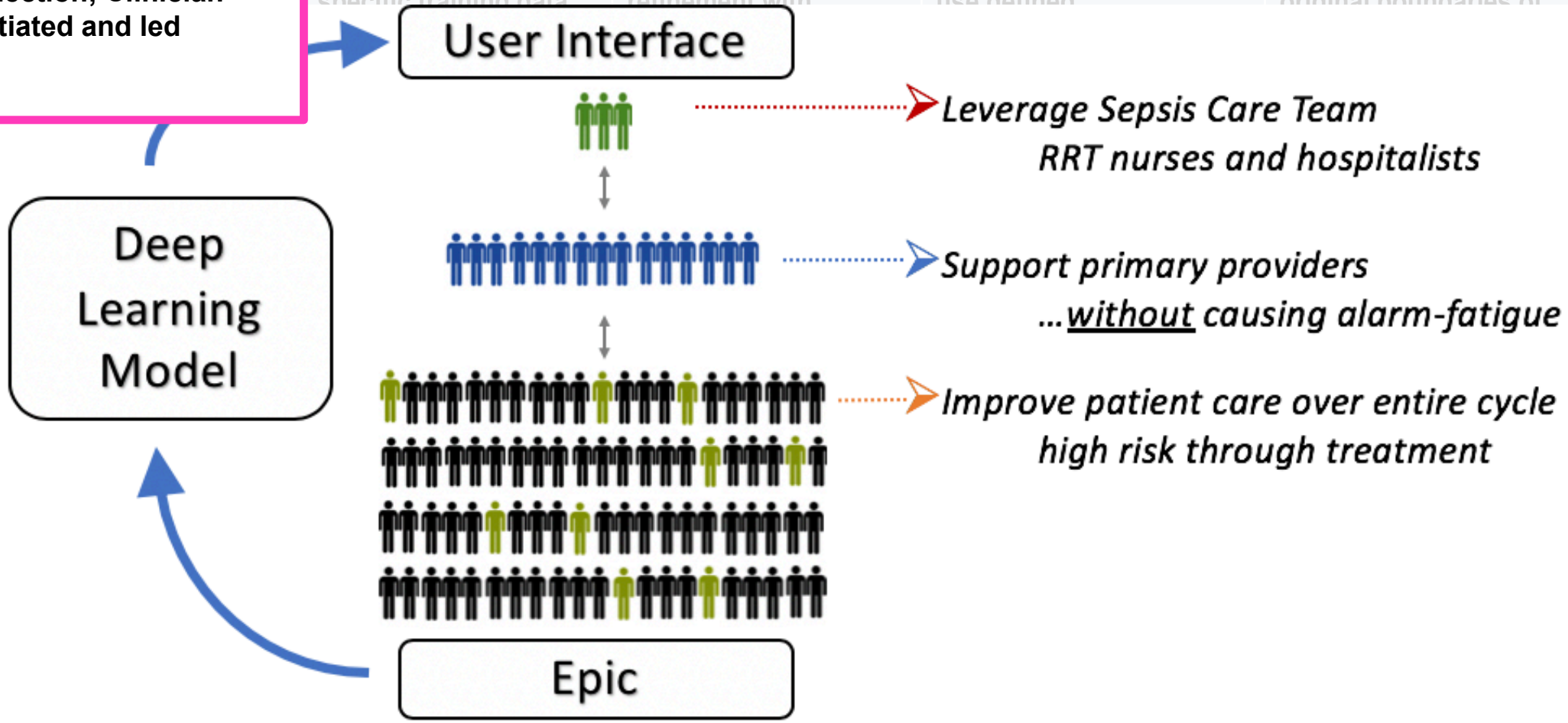
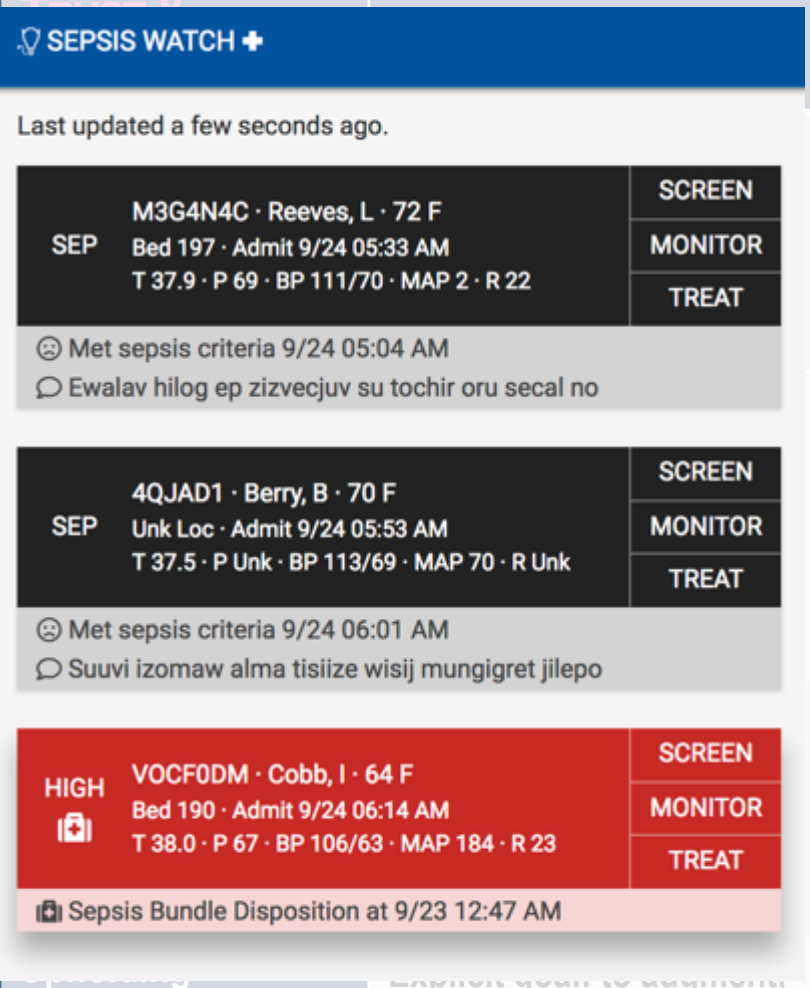
Problem formulation	Problem-based project selection; Clinician initiated and led	Local and context-specific training data	Iterative tool refinement with	Boundaries of appropriate use defined;	Tool usage limited to original boundaries of
Stakeholder relationship building	Sta Mu sta lev co				
Stakeholder feedback loops	IRI pro mo Mu as				
Upholding professional discretion	Ex no				

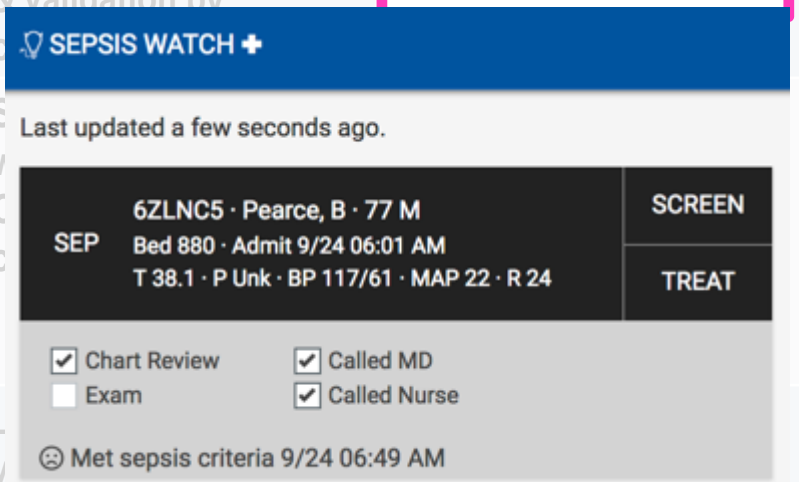


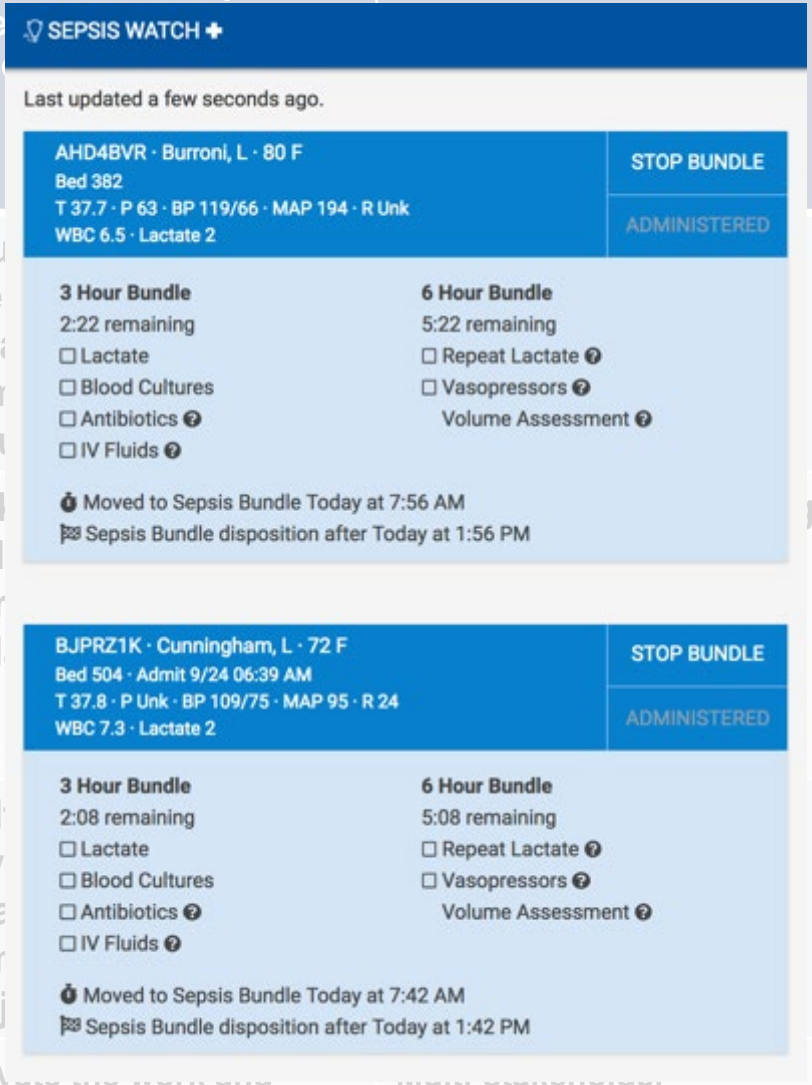
Duke Institute for Health Innovation

Strategies To Promote	Idea generation & resource gathering	Model development & validation	Tool design, development & evaluation	Workflow development, inte & e	Handoff, maintenance
professional discretion	Explicit goal to augment, not replace clinicians	Local monitoring & validation by clinici & dev	Designed as an "algorithm in the loop"	Elevate the work and expertise of integrating the tool into care	governance committee draws on multiple forms of expertise; New projects initiated!
		Local and context-specific training data used; Local monitoring & validation by	"silent phase" integration		

Iterative tool refinement with stakeholders







Triage → **Monitor** → **Treat**

Strategies To Promote Trust & Accountability	Idea generation & resource gathering	Model development & validation	Tool design, development & evaluation	Workflow development, integration & education	Handoff, maintenance & improvement
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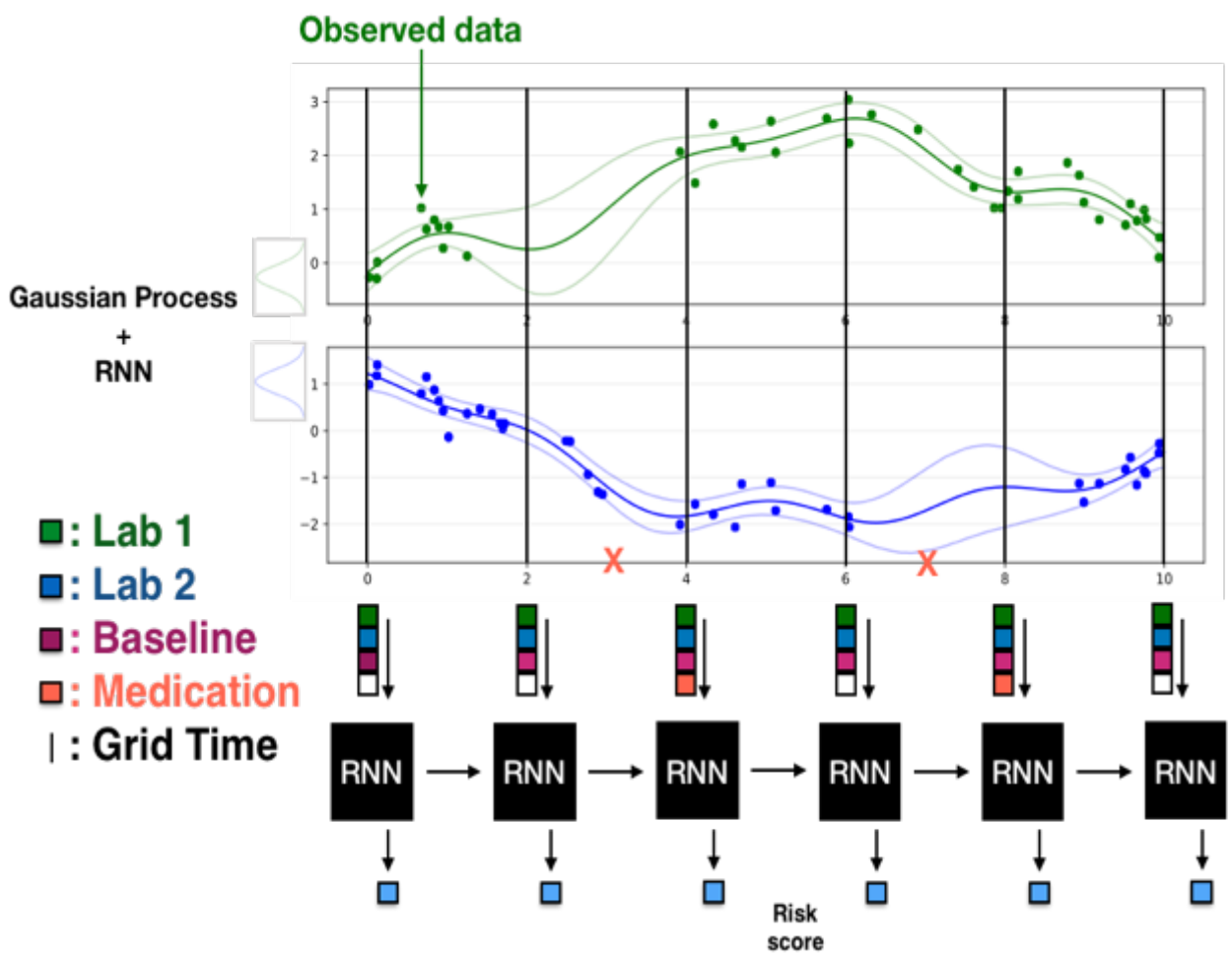
Stakeholder relationship building	Stakeholder mapping; Multiple modes of stakeholder engagement leveraged; Close clinical collaboration	**Sustained engagement with ML researchers**			
Stakeholder feedback loops	IRB approved research protocol; Data-safety	Local monitoring & validation by clinicians & dev team			
Upholding professional discretion			algorithm in the loop	expertise of integrating the tool into clinical care	governance committee draws on multiple forms of expertise; New projects initiated!

Futoma, Hariharan, Heller ICML 2017

Futoma, Hariharan, Sendak et al MLHC 2017

Bedoya, Futoma, et al JAMIA Open 2020



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Stakeholder feedback loops					
Upholding professional discretion					

Model Facts

Model name: Deep Sepsis **Locale:** Duke University Hospital

Approval Date: 09/22/2019 **Last Update:** 09/24/2019. **Version:** 1.0

Summary

This model uses EHR input data collected from a patient's current inpatient encounter to estimate the probability that the patient will meet sepsis criteria within the next 4 hours. It was developed in 2016-2019 by the Duke Institute for Health Innovation. The model was licensed to Cohere Med in July 2019.

Mechanism

- **Outcome** .....sepsis within the next 4 hours, see (1) for sepsis criteria
- **Output** .....0% - 100% probability of sepsis occurring in the next 4 hours
- **Patient population** .....all adult patients >18 y.o. presenting to DUH ED and admitted
- **Time of prediction** .....every hour of a patient's encounter
- **Input data source**.....electronic health record (EHR)
- **Input data type** .....demographics, analytes, vitals, medication administrations
- **Training data location and time-period** .....DUH, 10/2014 – 12/2015
- **Model type**..... Recurrent Neural Network

Validation and performance

	Prevalence	AUC	PPV @ Sensitivity of 60%	Sensitivity @ PPV of 20%
Local Retrospective	18.9%	0.88	0.14	0.50
Local Temporal	6.4%	0.94	0.20	0.66
Local Prospective	TBD	TBD	TBD	TBD
External	TBD	TBD	TBD	TBD

Uses and directions

- **Operational use case(s):** Every hour, data is pulled from the EHR to calculate risk of sepsis for every patient at the DUH ED. A rapid response team nurse reviews every high-risk patient with a physician in the ED to confirm whether or not to initiate treatment for sepsis.
- **General use:** This model is intended to be used to by clinicians to identify patients for further assessment for sepsis. The model is not a diagnostic for sepsis and is not meant to guide or drive clinical care. This model is intended to complement other pieces of patient information related to sepsis as well as a physical evaluation to determine the need for sepsis treatment.
- **Examples of appropriate decisions to support:** Patient X has a high risk of sepsis according to the model. A rapid response team nurse discusses the patient with the ED physician caring for the patient and they agree the patient does not require treatment for sepsis.
- **Before using this model:** Test the model retrospectively and prospectively on local data to confirm generalizability of the model to the local setting.
- **Safety and efficacy evaluation:** Analysis of data from clinical trial (NCT03655626) underway. Preliminary data shows rapid response team, nurse-driven workflow was effective at improving sepsis treatment bundle compliance.

Boundaries of appropriate use defined

Warnings

- **General warnings:** This model was not trained or evaluated on patients receiving care in the ICU. Do not use this model in the ICU setting without further evaluation. This model was trained to identify the first episode of sepsis during an inpatient encounter. During long inpatient stays with multiple sepsis episodes, model accuracy needs to be further evaluated. The model is not interpretable and does not provide rationale for high risk scores. Clinical end users are expected to place model output in context with other clinical information to make final determination of diagnosis.
- **Examples of inappropriate decisions to support:** This model may not be accurate outside of the target population, primarily adults in the non-ICU setting. This model is not a diagnostic and is not designed to guide clinical diagnosis and treatment for sepsis.
- **Discontinue use if:** Clinical staff raise concerns about utility of the model for the indicated use case or large, systematic changes occur at the data level that necessitates re-training of the model.

Other information:

- **Outcome Definition:** https://doi.org/10.1101/648907
- **Related model:** http://doi.org/10.1001/jama.2016.0288
- **Model development & validation:** arxiv.org/abs/1708.05894
- **Model implementation**: jmir.org/preprint/15182
- **Clinical trial:** clinicaltrials.gov/ct2/show/NCT03655626
- **Clinical impact evaluation:** TBD
- **For inquiries and additional information:** please email mark.sendak@duke.edu

Strategies To Promote Trust & Accountability	Idea generation & resource gathering	Model development & validation	Tool design, development & evaluation	Workflow development, integration & education	Handoff, maintenance & improvement
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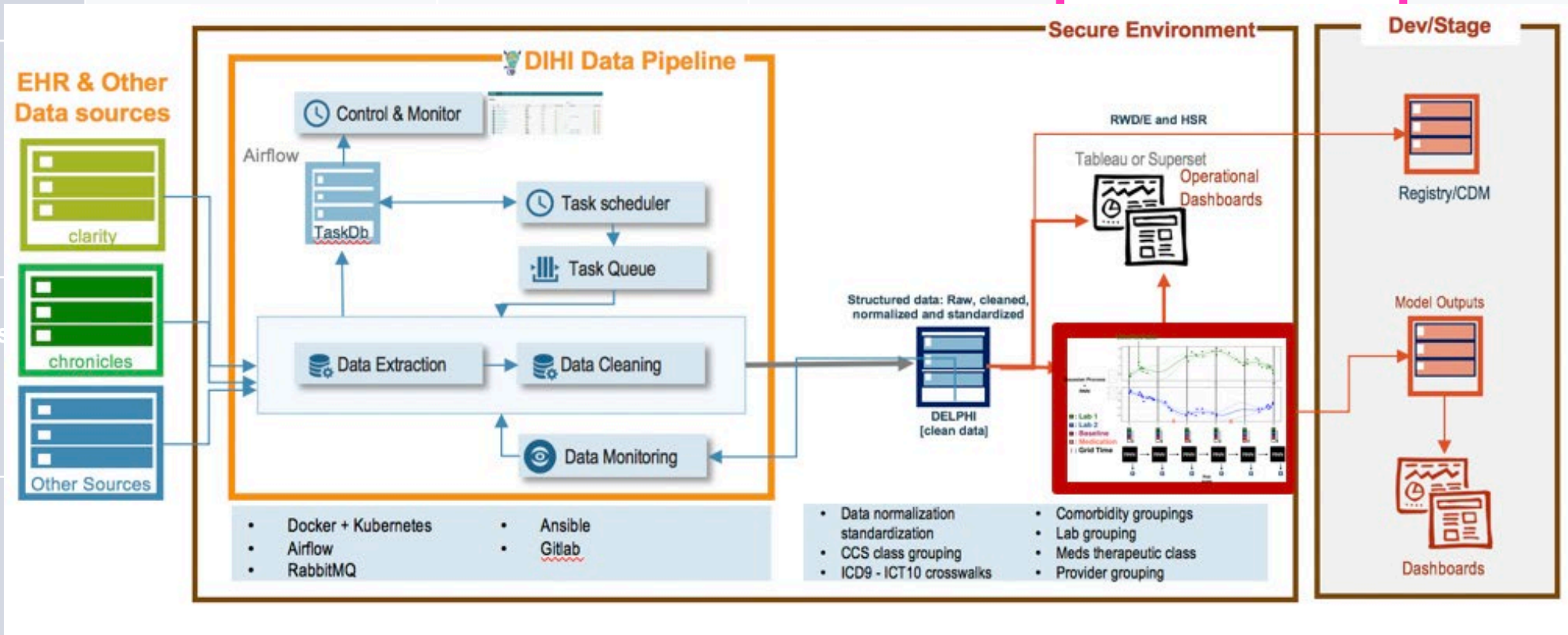
Stakeholder relationship building					g with existing performance Close clinical
Stakeholder feedback loops					hnical y dev team; older committee
Upholding professional discretion					older committee ltiple forms of ew projects initiated!



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Problem formulation	Problem-based project selection; Clinician initiated and led	Local and context-specific training data used; Local monitoring	Iterative tool refinement with stakeholders;	Boundaries of appropriate use defined; Infrastructure and testing to meet enterprise user requirements	Tool usage limited to original boundaries of intervention; Ongoing monitoring of relevant clinical research
Stakeholder relationship building				Stakeholder capacity-building around tech literacy; Close clinical collaboration	Collaborating with existing institutional performance monitoring; Close clinical collaboration
Stakeholder feedback loops				**Multi-stakeholder governance committee established;** project integration	Ongoing technical monitoring by dev team; Multi-stakeholder governance committee oversight
Upholding professional discretion				Elevate the work and expertise of integrating the tool into clinical care	Multi-stakeholder governance committee draws on multiple forms of expertise; New projects initiated!

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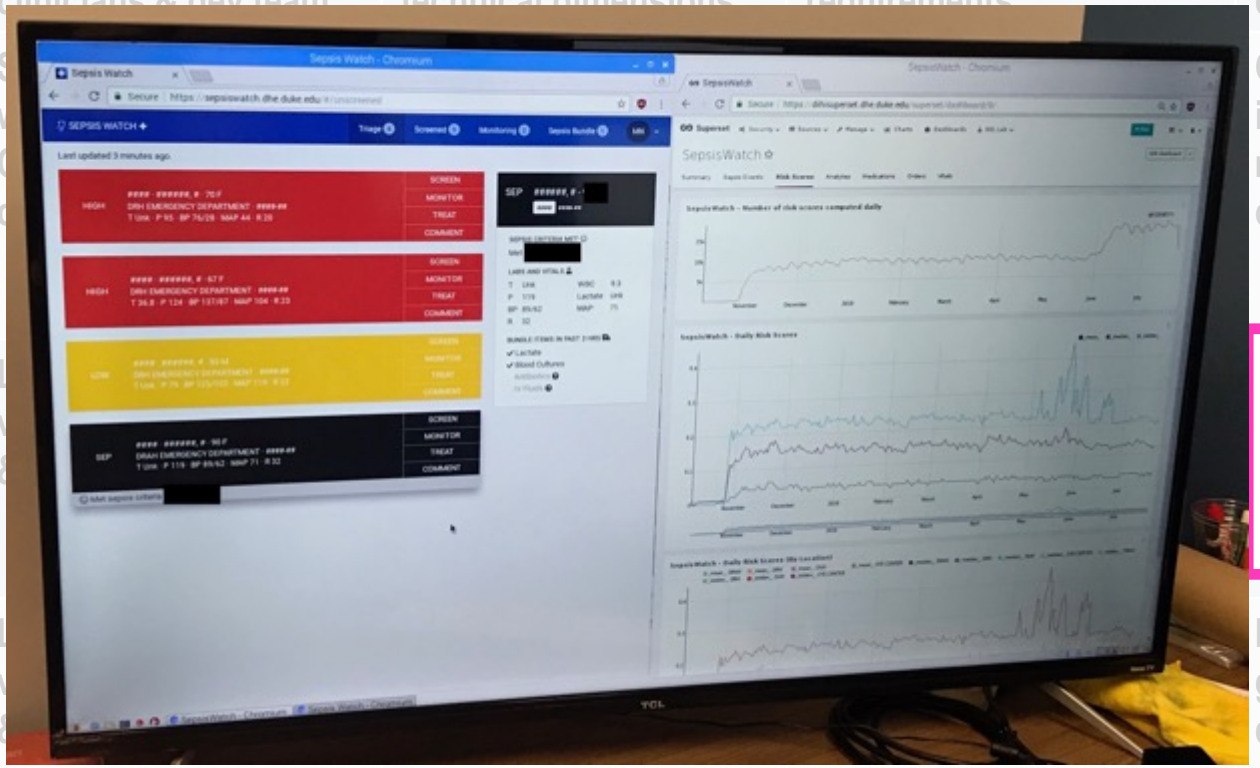

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Stakeh relatio buildin				Stakeholder capacity-building around tech literacy; Close clinical collaboration	Collaborating with existing institutional performance monitoring; Close clinical collaboration
Stakeh feedba				Multi-stakeholder governance committee established; Full time role manages and supports project integration	Ongoing technical monitoring by dev team; Multi-stakeholder governance committee oversight
Uphold profes discret		& dev team		**Elevate the work and expertise of integrating the tool into clinical care**	Multi-stakeholder governance committee draws on multiple forms of expertise; New projects initiated!

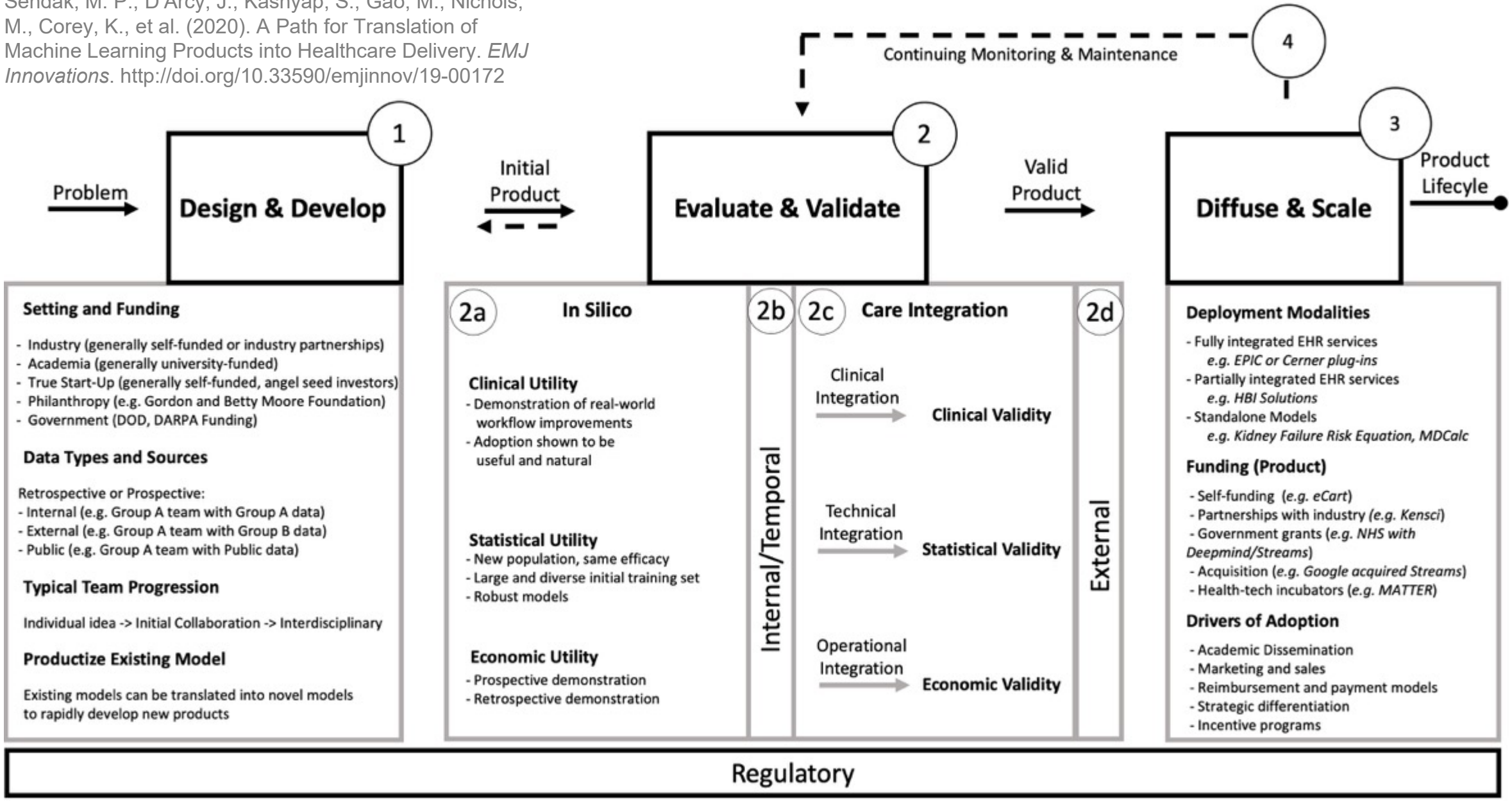
"And it's cool you know, it's a totally new job title under the RRT role. And a new responsibility and one I welcome."

- *RRT interviewee*

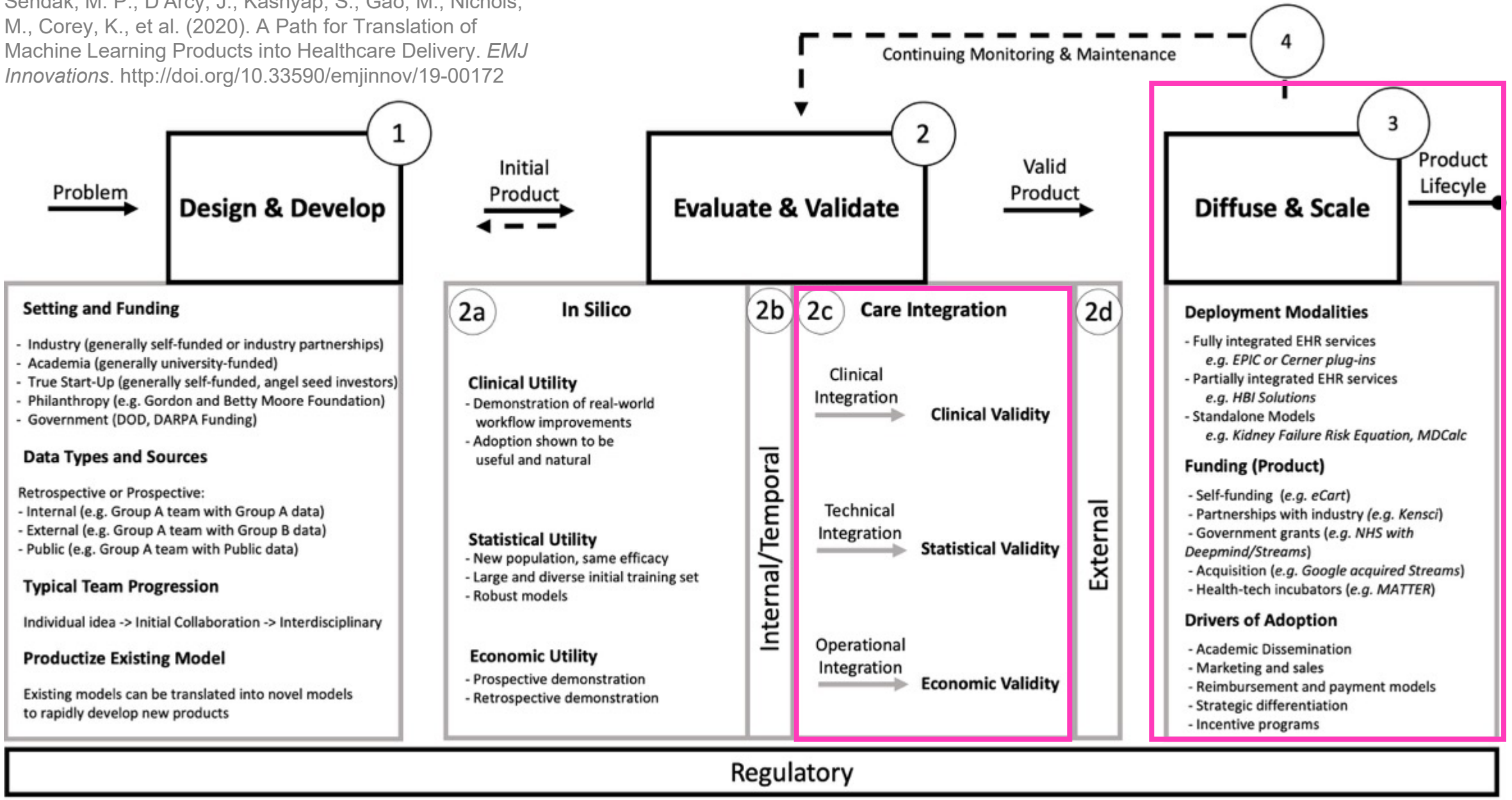
Strategies To Promote Trustworthiness, Transparency, & Accountability	Idea generation & resource gathering	Model development & validation	Tool design, development & evaluation	Workflow development, integration & education	Handoff, maintenance & improvement
Problem formulation	Problem-based project selection; Clinician initiated and led	Local and context-specific training data used; Local monitoring & validation by clinicians & dev team	Iterative tool refinement with stakeholders; Recognition of socio-technical dimensions	Boundaries of appropriate use defined; Infrastructure and testing to meet enterprise user requirements	Tool usage limited to original boundaries of intervention; Ongoing monitoring of relevant clinical research
Stakeholder relationship building	Stakeholder mapping; Multiple modes of stakeholder engagement leveraged; Close clinical collaboration	Sustained engagement with ML researchers; Close clinical collaboration	Full time role created to support integration; Sustained engagement with tech vendors; Close clinical collaboration	Stakeholder capacity-building around tech literacy; Close clinical collaboration	Collaborating with existing institutional performance monitoring; Close clinical collaboration
Stakeholder feedback loops	IRB approved research protocol; Data-safety monitoring board created; Multi-disciplinary team assembled;	Local monitoring & validation by clinicians & dev team	Regular meetings to create space for feedback; Trial “silent phase” integration	Multi-stakeholder governance committee established; Full time role manages and supports project integration	Ongoing technical monitoring by dev team; Multi-stakeholder governance committee oversight
Upholding professional discretion	Explicit goal: to augment, not replace clinicians	Local monitoring & validation by clinicians & dev team	Designed as an “algorithm in the loop”, Register clinical trial and report outcomes	Elevate the work and expertise of integrating the tool into clinical care	Multi-stakeholder governance committee draws on multiple forms of expertise; New projects initiated!

On the Horizon

Sendak, M. P., D'Arcy, J., Kashyap, S., Gao, M., Nichols, M., Corey, K., et al. (2020). A Path for Translation of Machine Learning Products into Healthcare Delivery. *EMJ Innovations*. http://doi.org/10.33590/emjinnov/19-00172



Sendak, M. P., D'Arcy, J., Kashyap, S., Gao, M., Nichols, M., Corey, K., et al. (2020). A Path for Translation of Machine Learning Products into Healthcare Delivery. *EMJ Innovations*. http://doi.org/10.33590/emjinnov/19-00172



Building a Data Science & Innovation Network

Health System Learning Network

- Rapid and continuous integration and evaluation of data science and machine learning technologies and innovations across sites
- Unified, EHR agnostic infrastructure to integrate into operational IT systems
- Close collaboration between IT, clinical, and operational leaders
- Funding opportunities through federal agencies and sponsored research studies

Jefferson Health
HOME OF SIDNEY KIMMEL MEDICAL COLLEGE

NYU Langone Health

Penn Medicine

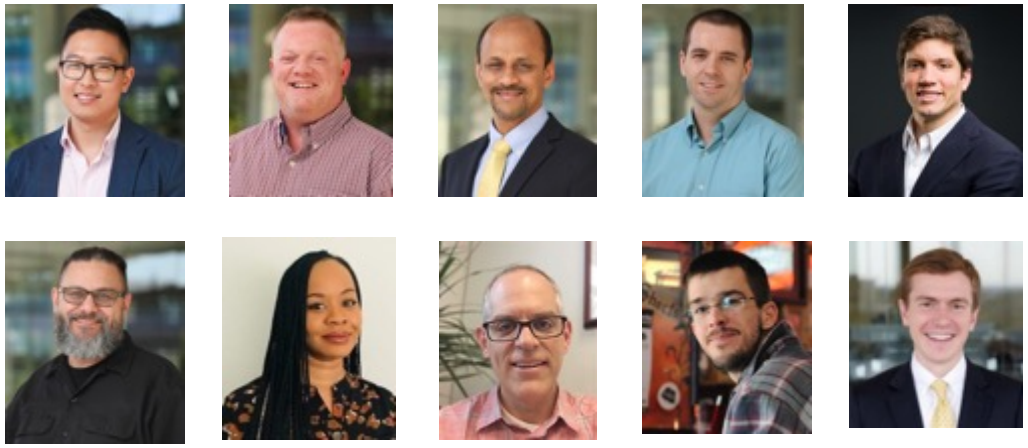
KAISER PERMANENTE®

SickKids®

Thank You

mark.sendak@duke.edu

@DukeInnovate, https://dihi.org



Sepsis Watch Team

Clinicians

Physicians
Cara O'Brien
Armando Bedoya
Meredith Clement
Jason Theiling
Rebecca Donahoe

Nurses
Elizabeth Alderton
Dina Sorro
Dustin Tart
Cory Miller
Kelly Kester

Students

Masters, Statistics
Brian Cozzi

Medical Students
Nathan Brajer
Anthony Lin

PhD, Statistics
Joseph Futoma

IT Leadership

Chris Fowler
Tres Brown
Armando Bedoya
Eric Poon
Jeffrey Ferranti

Health System Leadership

Bill Fulkerson
Tom Owens
Mary Ann Fuchs
Tracey Gosselin
Mary Lindsay
Jill Engel
Allan Kirk
Charles Gerardo

Appendix

Academic Output

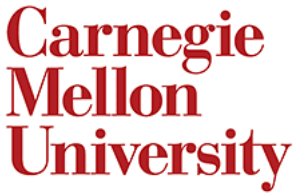
- Sepsis Watch model manuscripts
  - https://arxiv.org/abs/1706.04152
  - https://arxiv.org/abs/1708.05894
  - https://academic.oup.com/jamiaopen/article/3/2/252/5819230
- Sepsis Watch implementation manuscripts
  - https://medinform.jmir.org/2020/7/e15182/
  - https://dl.acm.org/doi/abs/10.1145/3351095.3372827
- Machine learning best practices manuscripts
  - https://www.nature.com/articles/s41591-019-0548-6
  - https://www.nature.com/articles/s41746-020-0253-3

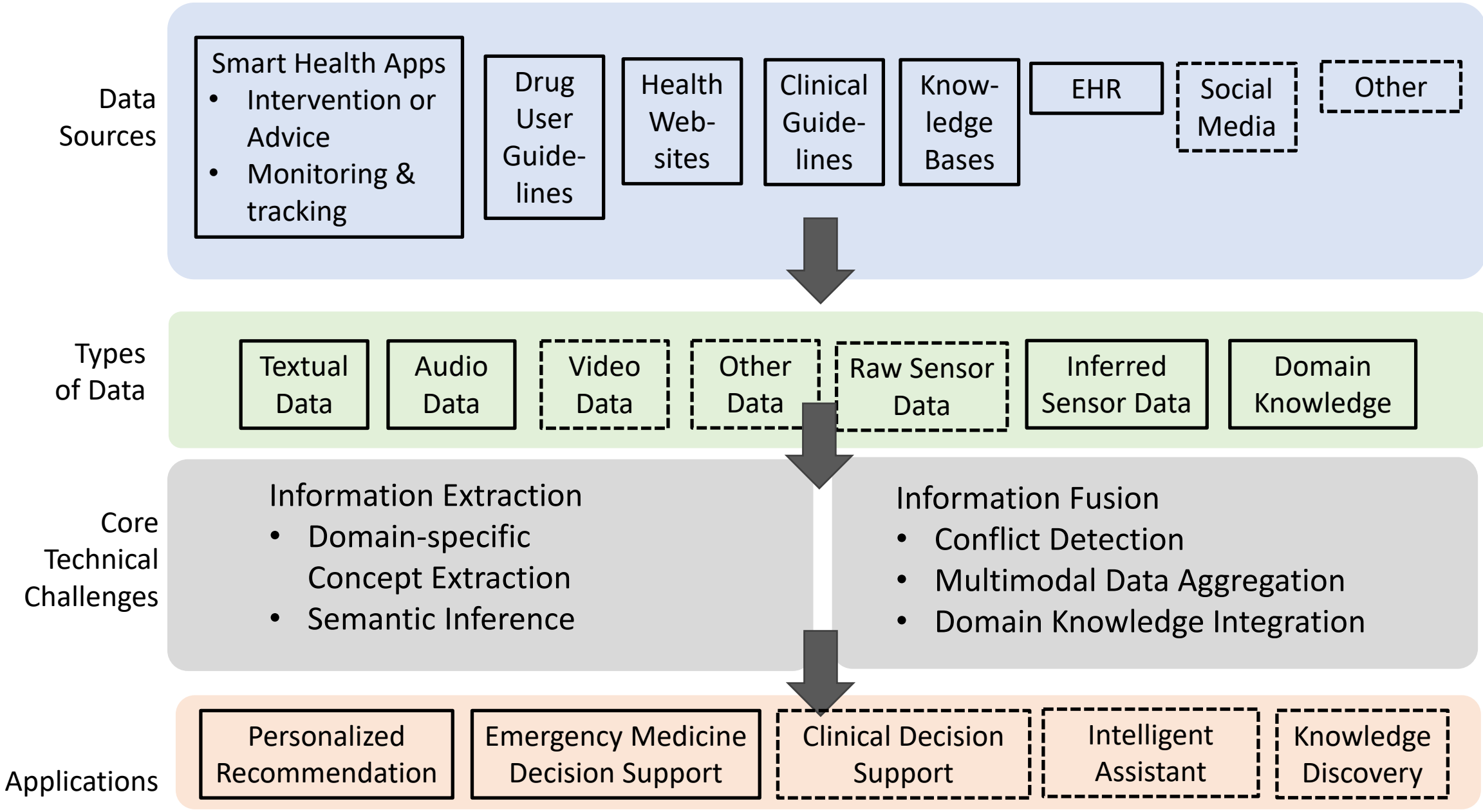
Future Directions for Clinical Decision Support

Sarah M. Preum

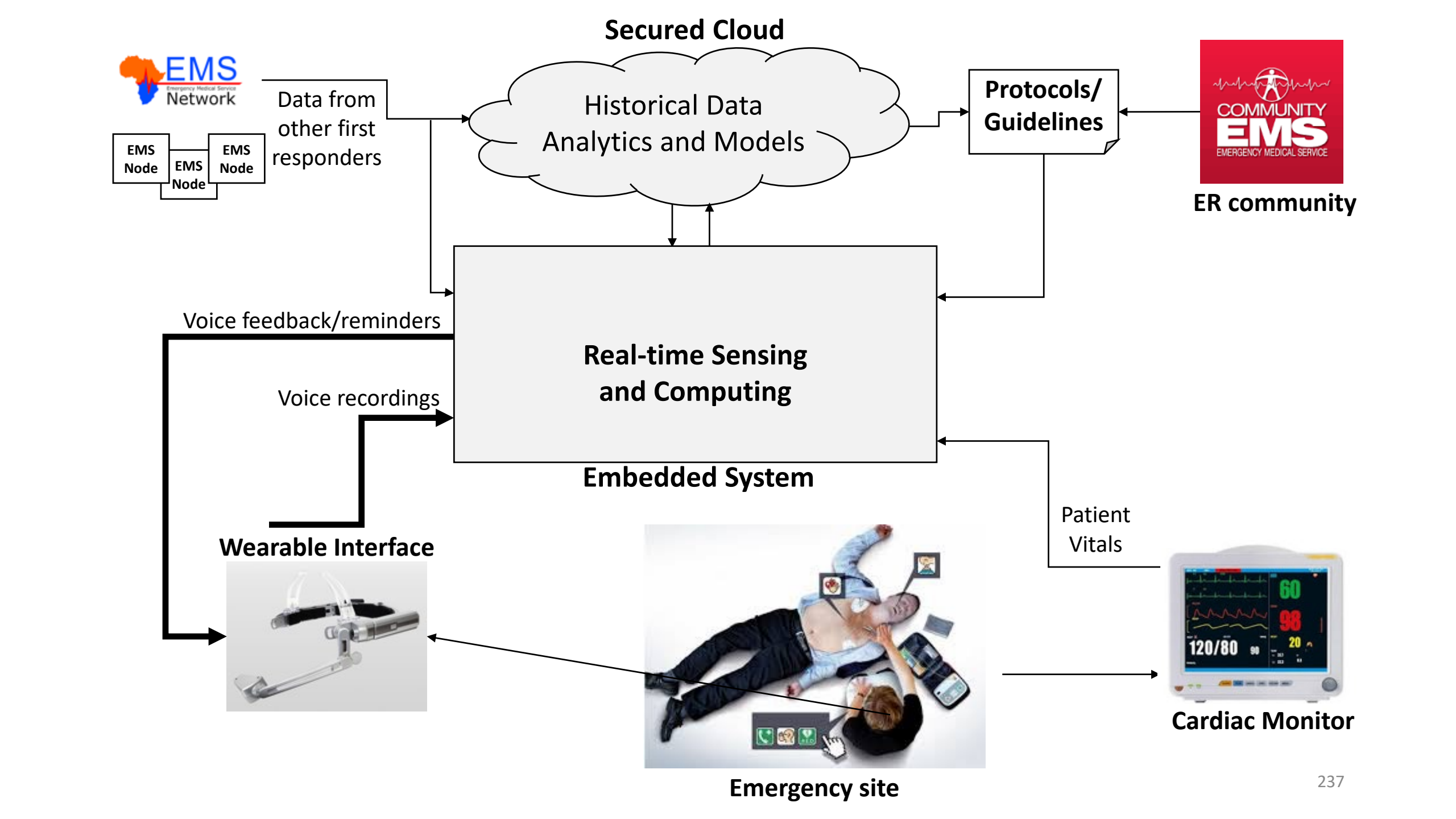
Postdoctoral Fellow

HCII, School of Computer Science, CMU





spreum@andrew.cmu.edu


Secured Cloud
EMS Emergency Medical Service Network
EMS Node
EMS Node
EMS Node
Data from other first responders
Historical Data Analytics and Models
Protocols/ Guidelines
COMMUNITY EMS EMERGENCY MEDICAL SERVICE
ER community
Voice feedback/reminders
Voice recordings
Real-time Sensing and Computing
Embedded System
Wearable Interface
Patient Vitals
60
98
120/80
20
Cardiac Monitor
Emergency site

Future Directions for CDS

- Big data or better quality of data?
  - Data quality and data validation process
  - Heterogeneous data aggregation
  - Robustness and generalization
  - Medical errors and health disparity
- Decision support to improve health outcome
  - Under stress and time constraints
    - Emergency medicine, ICU, ER
  - Personalized intelligent assistant / cognitive assistant

Healthcare **C**ognitive **A**ssistants (HCA)

A Review of Cognitive Assistants for Healthcare: Trends, Prospects, and Future Directions, ACM CSUR, 2020

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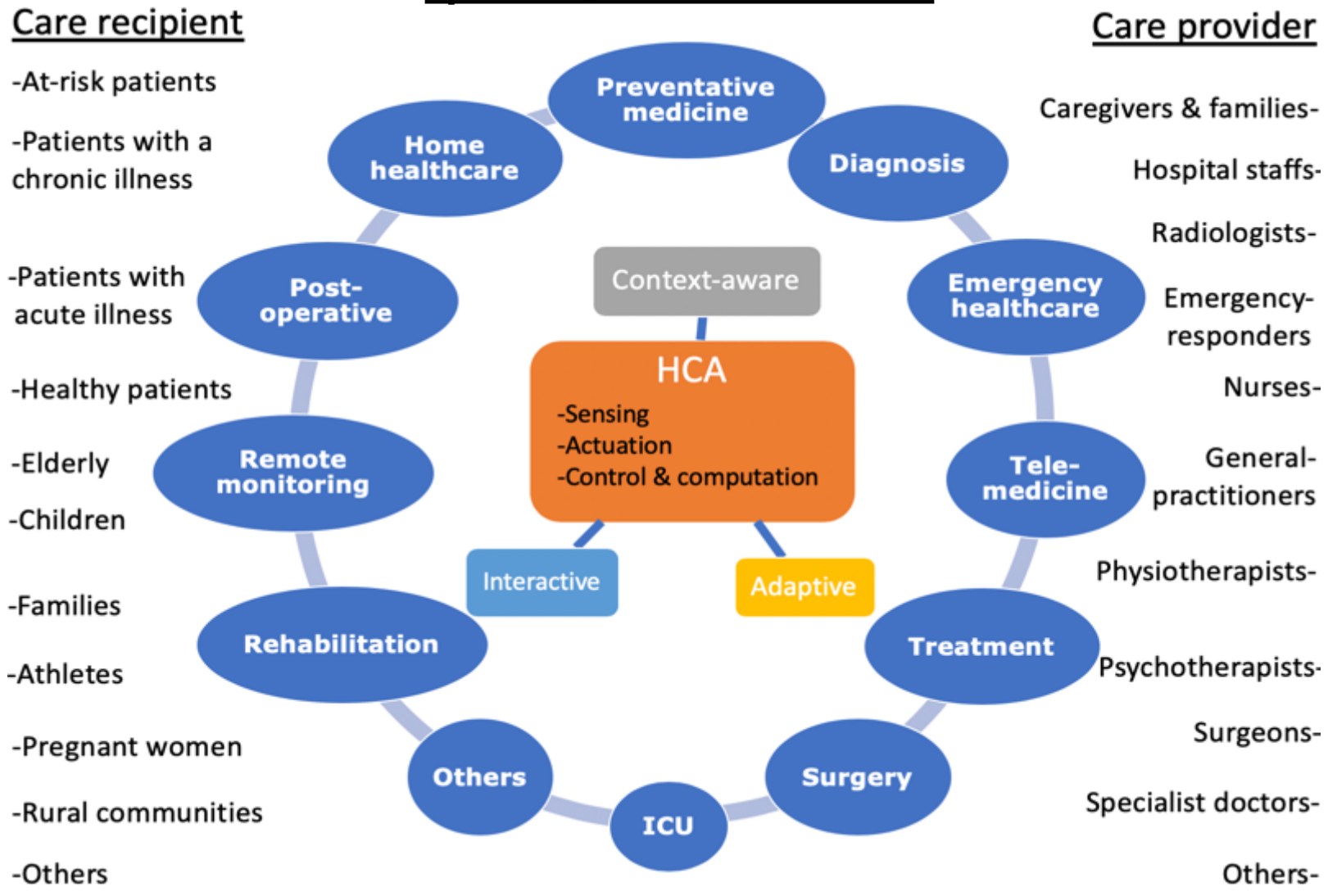
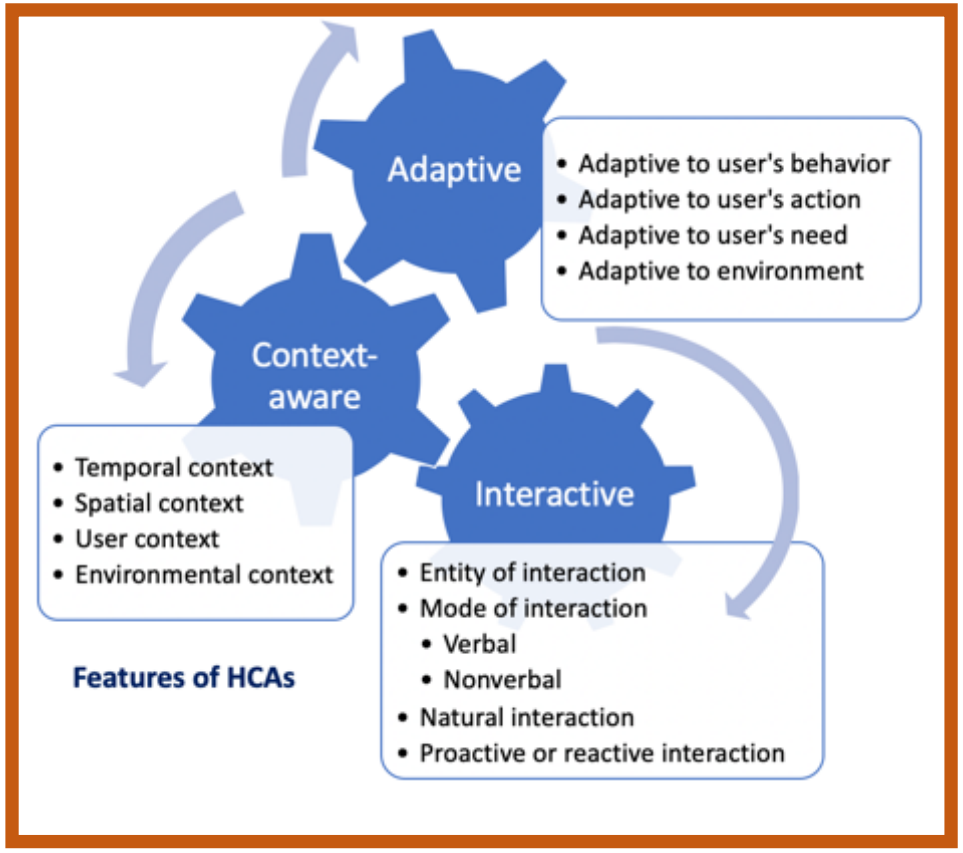


Healthcare **C**ognitive **A**ssistants (HCA)



Neuro-symbolic AI
- Modeling technique
- Data-driven Knowledge Extraction and representation

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Moving Beyond Decision Support

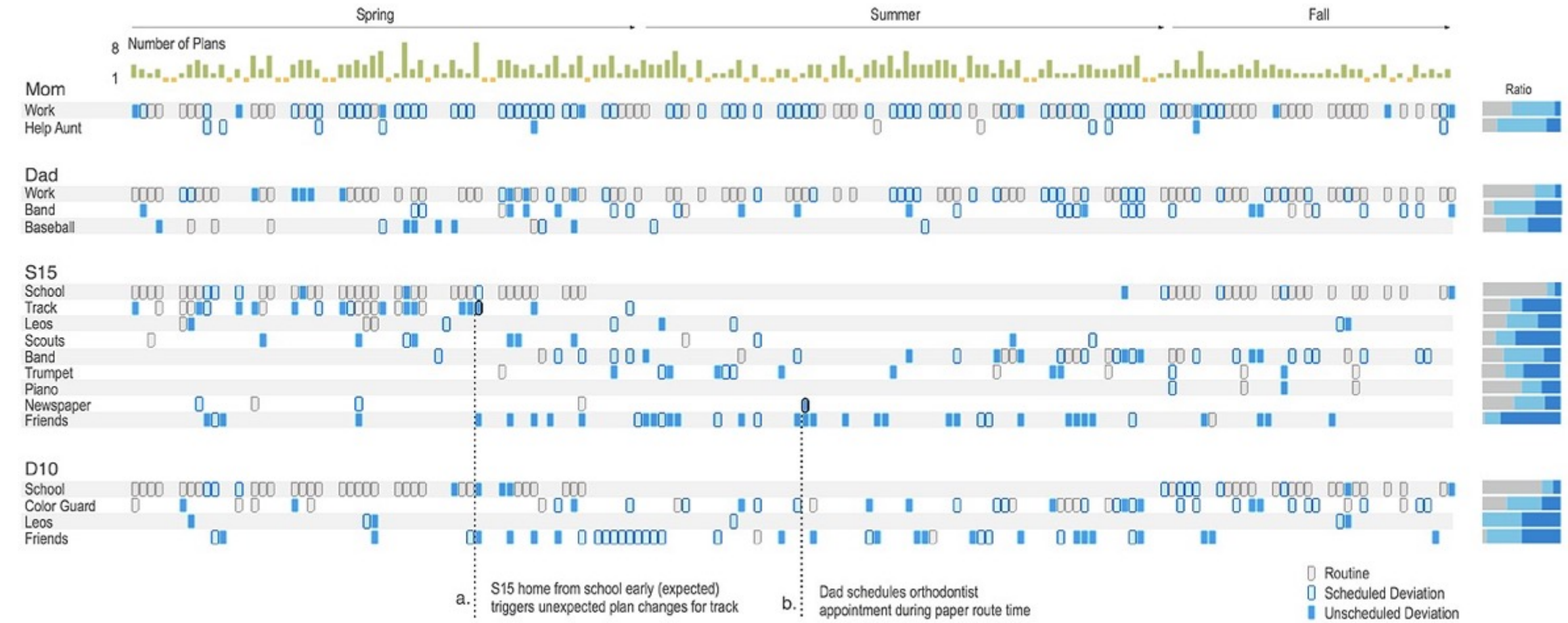
John Zimmerman
Tang Family Prof of AI and HCI
Carnegie Mellon University

CDS frame problem as clinician medical error; they love alerts! Clinicians NOT motivated to use CDS.

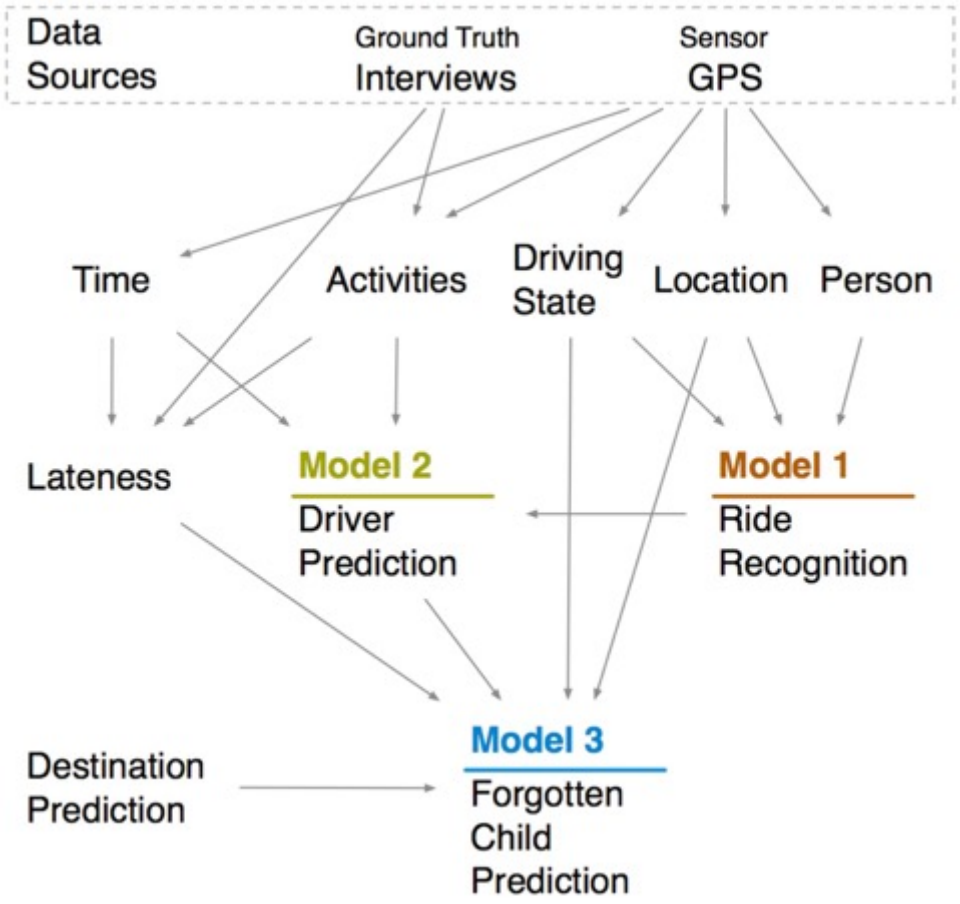
People love things that help them becoming the person they desire to be.

Data from one family's activities for 6-months: routines and deviations

More than 90% of days are not routine



Person-place-time-view
Prevents forgetting children



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Quality of EHR data is often poor. Data is sparse,more oriented towards billing than health.

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Quality of EHR data is often poor. Data is sparse,more oriented towards billing than health.
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Data-driven innovation has transformed innovation in the tech community.

AI great for automating repetitive, procedural tasks.

CDS frame problem as clinician medical error; they love alerts! Clinicians not motivated to use CDS.

Quality of EHR data is often poor. Data is sparse,more oriented towards billing than health.

CDS support textbook cases. Machine intelligence helps with cases where clinicians need the least help.

Interactions with EHR reduce rapport with patients.

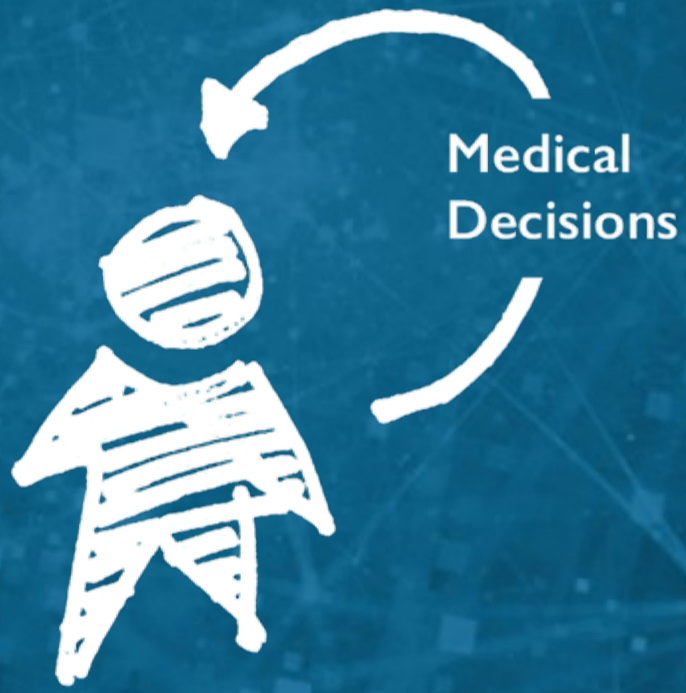
People love things that help them becoming the person they desire to be.

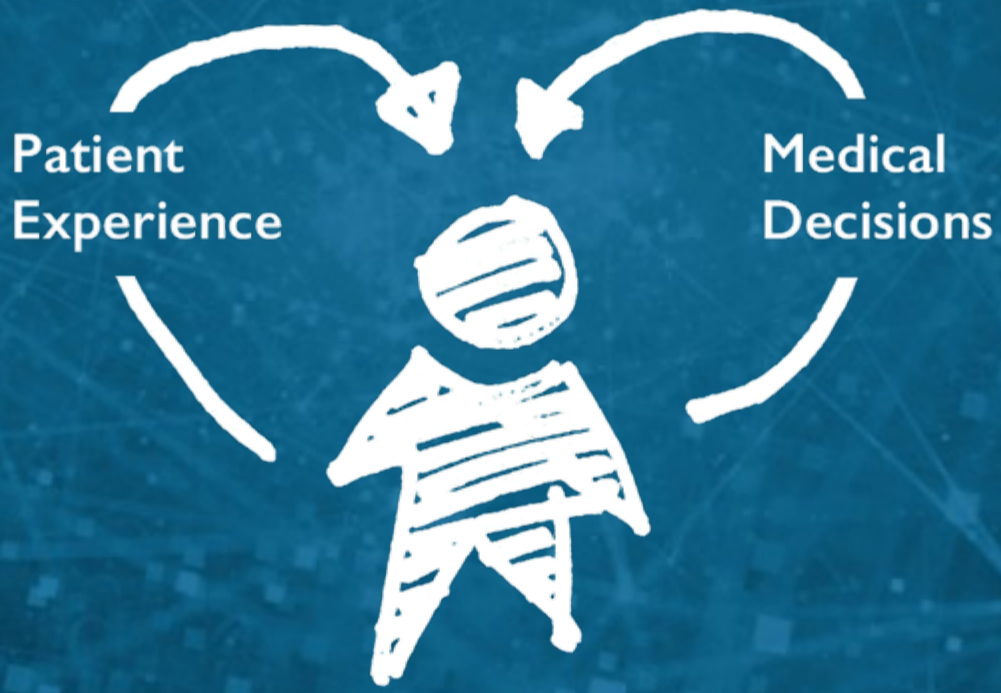
Data-driven innovation has transformed innovation in the tech community.

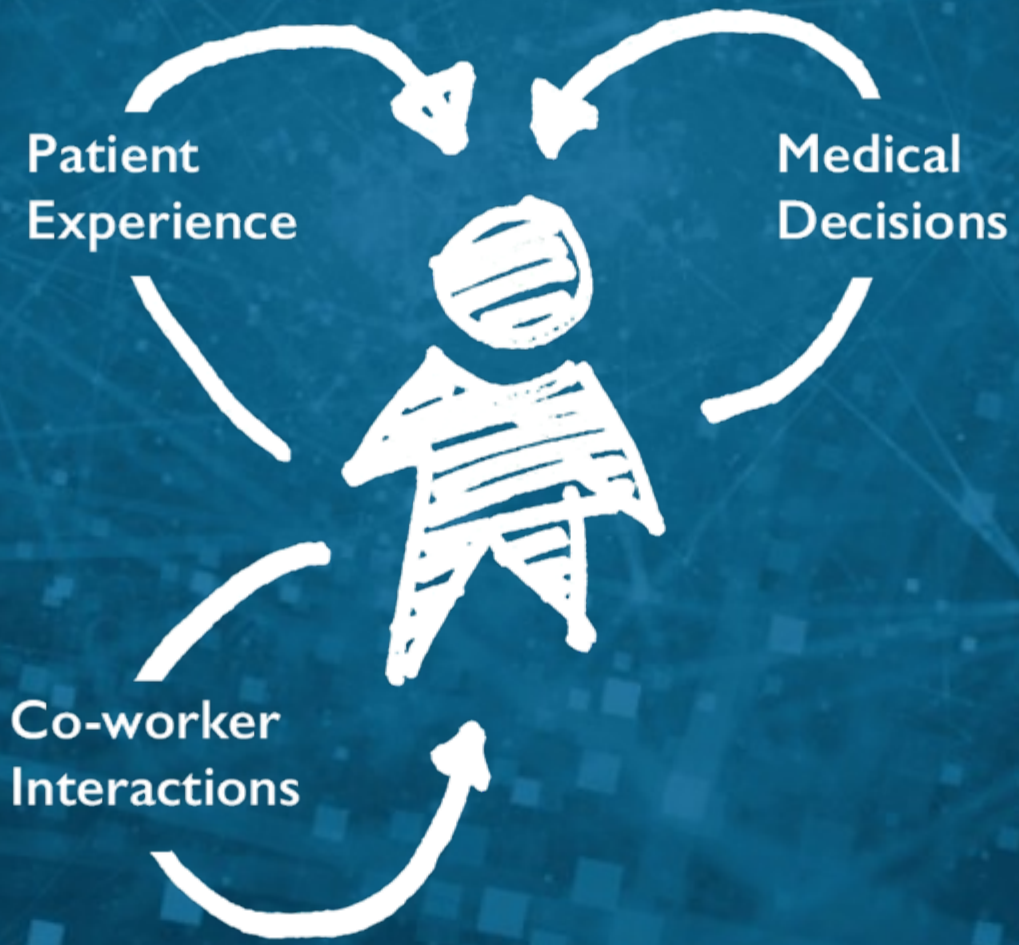
AI great for automating repetitive, procedural tasks.

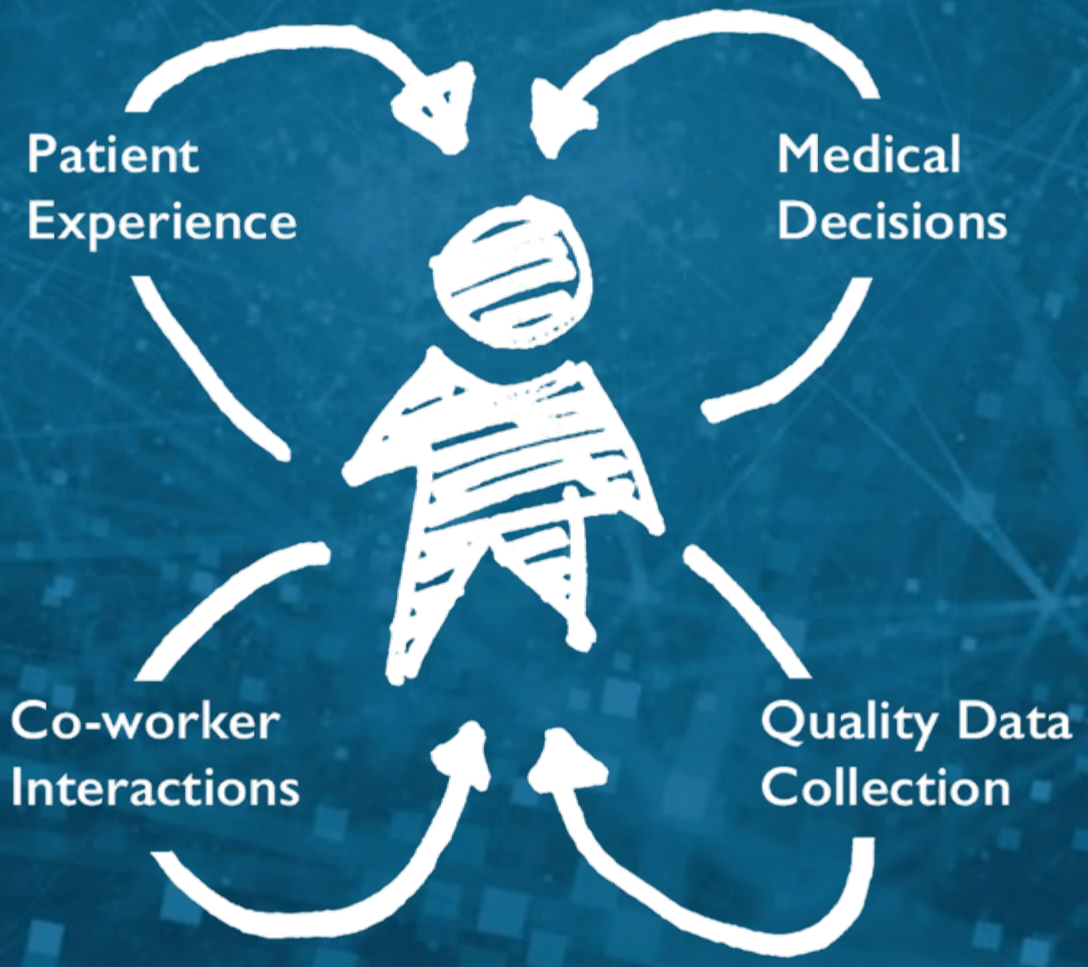
Great healthcare involves clinicians, patients, and informal caregivers.

Vision of the Future

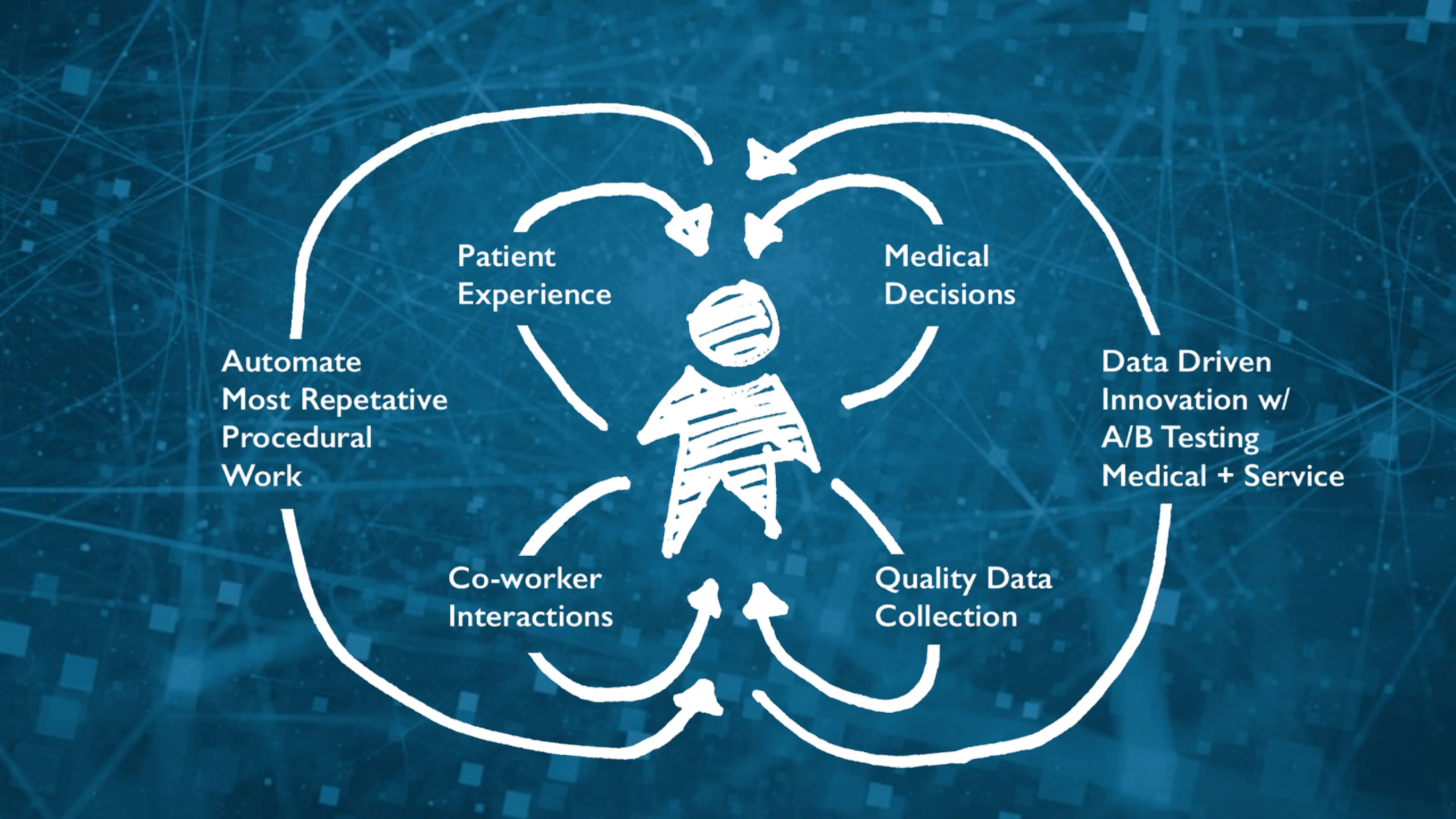

Medical
Decisions


Patient
Experience
Medical
Decisions


Patient
Experience
Medical
Decisions
Co-worker
Interactions


Patient
Experience
Medical
Decisions
Co-worker
Interactions
Quality Data
Collection


Patient Experience
Medical Decisions
Automate Most Repetative Procedural Work
Co-worker Interactions
Quality Data Collection


Patient Experience
Medical Decisions
Automate Most Repetative Procedural Work
Data Driven Innovation w/ A/B Testing Medical + Service
Co-worker Interactions
Quality Data Collection

Moving Beyond Decision Support

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