



IDeA States Pediatric Network



# CDW Involvement in OPCTN Studies

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NIH National Institute of General Medical Sciences



Award Numbers: UG10D024950 U54GM104938

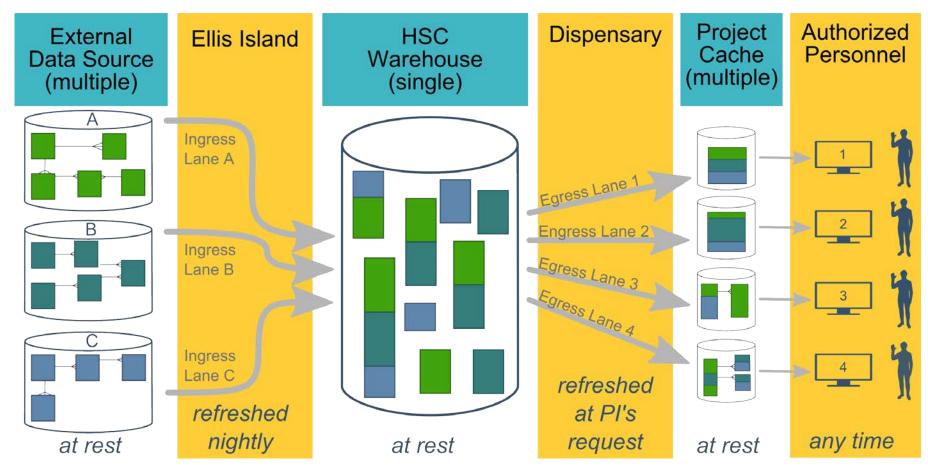




## Prairie Outpost — CDW (Clinical Data Warehouse)

https://github.com/OuhscBbmc/prairie-outpost-public

Ecosystem Architecture



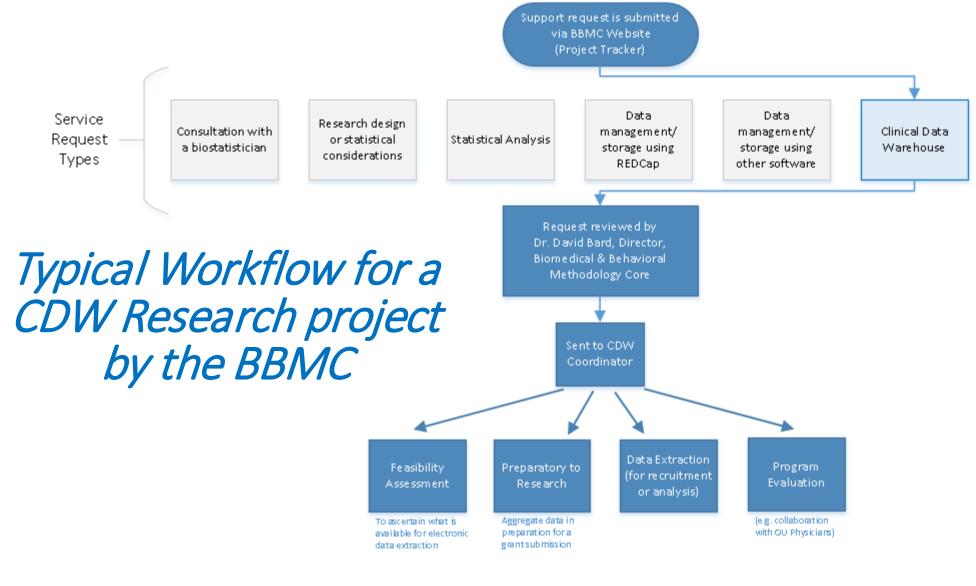
- Data Source (column 1): contains unique info
- Warehouse (column 3): contains copy after manipulation
- Project Cache (column 5): contains copy of copy after a lot of manipulation

#### HSC Data Sources

#### Patient

- Outpatient (Centricity)
- Scheduling & Registration (GECB)
- Inpatient (Meditech)
- Billing and Claims Data (GECB)
- Dozens of departmental sources
- Biomedical Research Data
- Provider
- External Agencies
  - Service Provided (by the Health Dept of Oklahoma)
  - Child Protective Services (Oklahoma Dept of Human Services)
  - Immunization (Health Dept of Oklahoma)
  - Vital Records (Health Dept of Oklahoma)
  - ...
- Administrative Cost
- Employee & Student





Output: REDCap Project CSV via Secure Email Editing

manuscript,

abstract, or

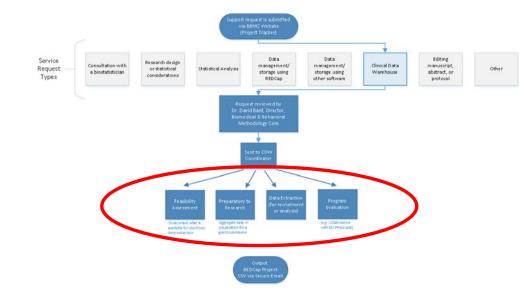
protocol

Other



#### Commonly Requested CDW Support Services

- Feasibility assessment in preparation for research (20% of projects; 10% of CDW staff time)
- Static eligibility (70% of projects; 20% of CDW staff time)
  - Virtually all projects require identification of a patient pool
- Rolling eligibility –Especially relevant to the OPCTN studies (30% of projects; 30% of CDW staff time)
  - Remember study team's assessment of eligibility as well as the participant's response
  - Daily automation requires stability & good logging;
     e.g., a 3 hour delay might mean zero subjects are enrolled
- Clinical outcomes for retrospective investigations (50% of projects; 30% of CDW staff time)
- Administrative outcomes for quality improvement (10% of projects; 2% of CDW staff time)
- Program evaluation (20% of projects; 8% of CDW staff time)





# POPS Study

Pharmacokinetics of Understudied Drugs Administered to Children per Standard of Care



#### POPS Overview

Primary Aim: Evaluate PK of understudied drugs administered to children

 Part of Oklahoma Pediatric Clinical Trial Network (OPCTN), a site for the NIH-funded ECHO IDeA States Pediatric Clinical Trials Network (ISPCTN)

- Enrollment Criteria:
  - Child receiving understudied drug of interest (DOIs) per standard of care
  - meet age range or condition (pre-term, obese, ECMO) open for enrollment.

	c	D	E	F	G	Н		J	K	L	M	N	0
2	Drug of Interest (DOI)		Target Ages 1 mo-2 Yrs					2-12 Yrs				≤ 20 y	ears*
3	Drug of Interest (DOI)	Pre-term	<1 mo	1-5 mos	6-11 mos	1 Yr	2-4 Yrs	5-8 Yrs	9-12 Yrs	13-16 Yrs	17-20 Yrs	Obese	ECMO
	alfentanil (IV) <sup>16</sup>		х	Х	X	х	Х	Closed	Closed			х	х
5	amikacin <sup>5</sup>	X	х	x	x	х	x	x	x	x	х	x	
6	atropine (IV) <sup>14</sup>		х	x	х	х	х	х	х	х	х	x	х
7	cefepime <sup>5</sup>	X	Х	x	х	х	Х	х	х	x	Х	х	
8	ceftazidime											х	Х
9	cidofovir											х	
10	ciprofloxacin											х	
-	clozapine <sup>4</sup>		х	x	x	х	х	x	х	x	x	х	x
12	dexmedetomidine <sup>13</sup>		Closed	Closed	Closed	Closed	Closed	Closed	Closed	Closed	х	х	Х
13	diazepam											х	
14	etomidate <sup>7, 16</sup>		х	X	x	х	x	x				х	x
15	fosphenytoin											х	
16	haloperidol <sup>4</sup>		х	X	x	х	х	х	х	х	х	х	х
17	heparin (low molecular weight) <sup>8</sup>		х	Closed	Closed	Closed	Closed	Closed	Closed	Closed	Closed	х	x
18	hydromorphone <sup>15, 16</sup>		Closed	Closed	Closed	Closed	Closed	Closed	Closed	Closed		x	x
19	lidocaine (IV)		х	x	x	х	х	х	х	x	х	х	х
20	lurasidone <sup>4</sup>		х	x	x	х	X	х	х	х	х	х	X
21	meropenem (IV) <sup>2, 5</sup>	Х	х	x	x	х	X						
I	methylprednisolone <sup>11</sup> (See special	1. Age ≤30 days on the day of surgery											

#### Resource Efficiency: fewer patients, quicker review, less redundancy

#### Old System

#### 2019-01-12 Inpatient Extract

- Finds patients who received a drug of interest
- 109 unique patients
- Record review: ~15 min/pt
- ~1,635 minutes

#### 2019-01-13 Inpatient Extract

• 112 unique patients @15 min/pt (forgets yesterday)

#### New System

#### **2019-01-12 Inpatient Screening Report**

- Finds patients who received a drug of interest and meet an age range or condition currently open for enrollment
- 31 unique patients
- Record review: ~5 min/pt
- ~155 minutes

#### 2019-01-13 Inpatient Screening Report

• 6 <u>new</u> patients @5 min/pt (remembers yesterday)

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# Enrollment Rate by Institution

		Total # enrolled	Months	
ISPCTN Sites	Activation Date	since	since	Average enrollment per month
Alaska Native Medical Center	6/19/2018		13	0.15
Children's Mercy Hospitals and Clinics	8/7/2018		11	1.73
Dartmouth-Hitchcock Medical Center	1/7/2019		6	1.33
Kapiolani Women's and Children's Medical Center	11/14/2018		8	1.13
Oklahoma University Medical Center	12/5/2018		7	8.43
Rhode Island Hospital	8/3/2018		11	4.18
Tulane University Health Science Center	5/8/2018	4	14	0.29
University of Kansas Medical Center	5/14/2019		2	1.00
University of Mississippi Medical Center	10/18/2018	16	9	1.78
University of Montana	9/17/2018	12	10	1.20
University of Nebraska Medical Center	7/3/2018	14	12	1.17
University of New Mexico, Health Sciences Center	4/11/2018	15	15	1.00
University of South Carolina - Palmetto Health	5/30/2018	19	14	1.36
University of Vermont Medical Center	10/15/2018	2	9	0.22
West Virginia University Hospital	6/6/2018	9	13	0.69
Alfred I. duPont Hospital for Children	11/8/2013	150	68	2.21
Arkansas Children's Hospital Research Institute	12/20/2011	69	91	0.76
Medical University of South Carolina Children's Hospital	9/4/2012	90	82	1.10
University of Louisville Norton Children's Hopsital	2/1/2012	138	89	1.55

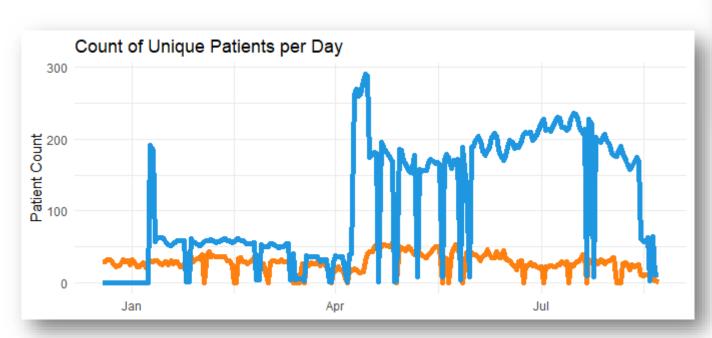


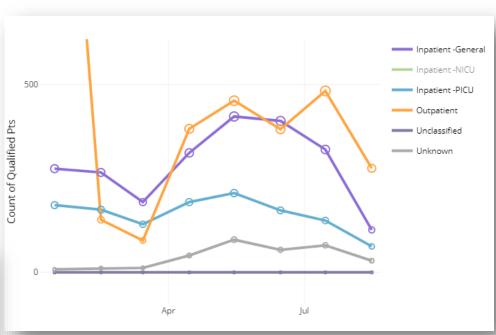
## New Participant Enrollment (by Site and Month)

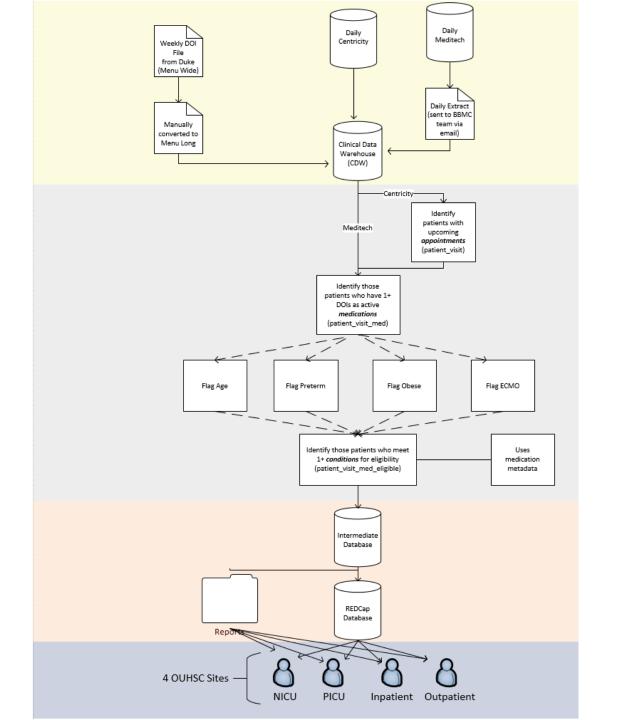
	Outpatient	NICU	PICU	Inpatient	Grand Total
Dec 2018			1		1
Jan 2019	7	1			8
Feb 2019	1				1
Mar 2019	1				1
Apr 2019	7		2		9
May 2019	13		1		14
Jun 2019	13	1	2	2	18
Jul 2019	6	1	1	3	11
Aug 2019	5	1	3		9
<b>Grand Total</b>	53	4	10	5	72

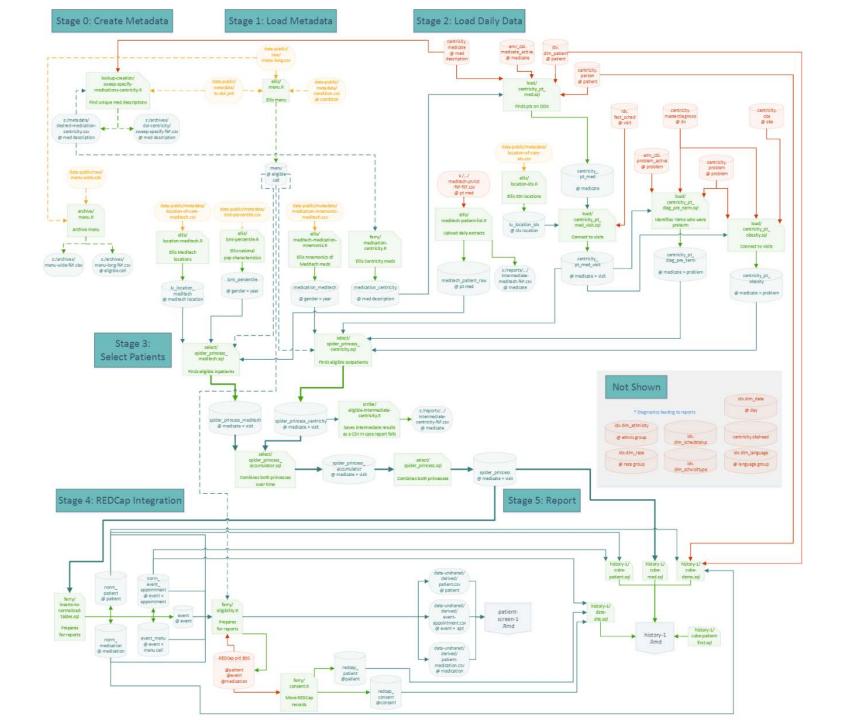


# New Participant Enrollment (by Site and Month)



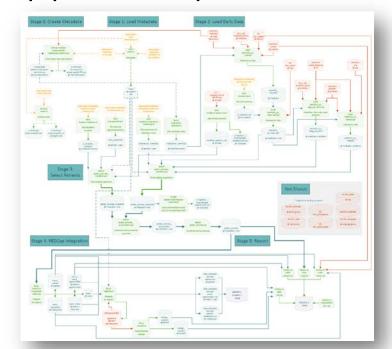


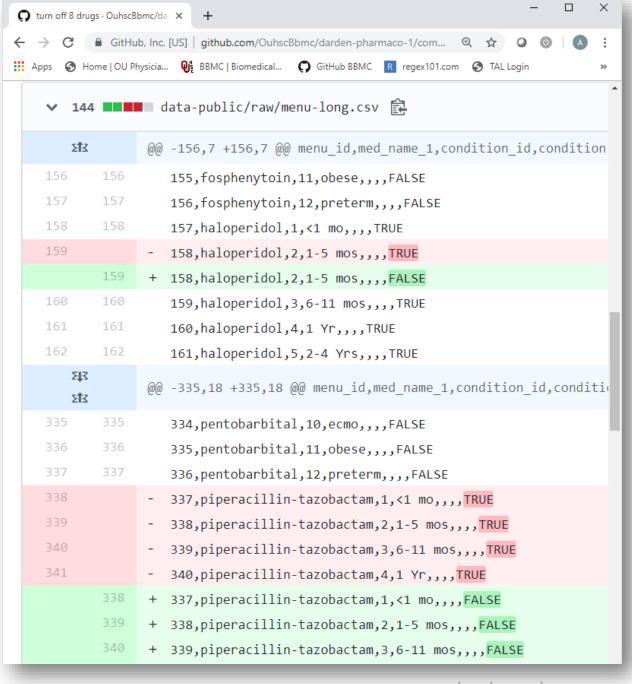




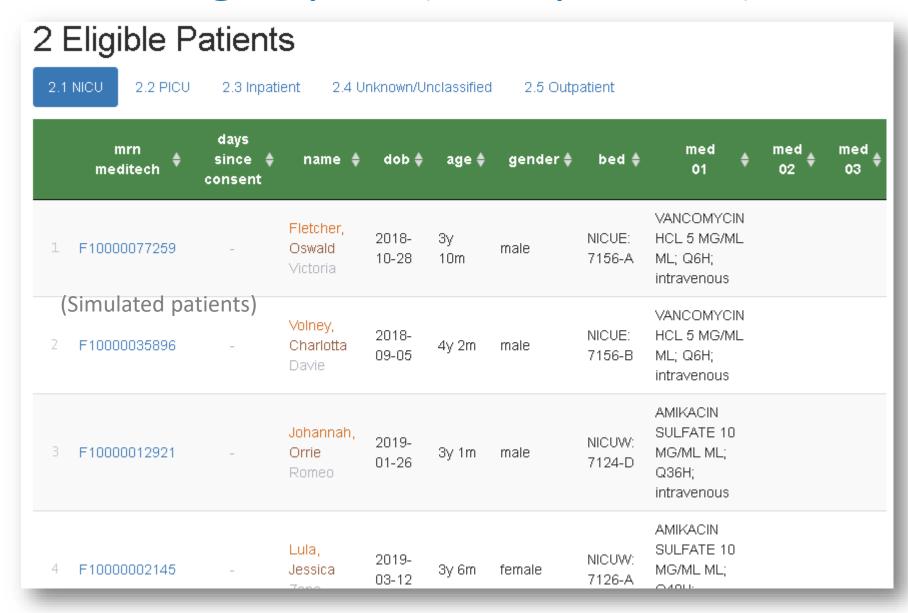
## Agile Responses to Changes in the DOI List

- When the new DOI list is released:
  - New drugs take ~20 min to add.
  - Old drugs take ~0.1 min to remove.
  - Only the CSV changes;
     the pipeline & report code is constant





# Screening Report (for inpatients)



Hyperlinks to REDCap

Consent stop watch

Filter, search, & sort



# REDCap Project

Days since consent		View equation				
Days since the previous consent		View equation				
This repeated consent is not necessary. A consent is valid for	a period of 90 days.	4				
Has the patient been approached to participate in this	○ Yes					
study?	○ No		t			
	Time Constraint		reset			
	Incorrect Location					
Why has the patient not been approached?	Unable to Collect R	equired Specimen				
wity has the patient not been approached.	Ineligible per Manu					
	Other					
			reset			
If 'other', please explain.						
	Accepted					
Consent result	Opeclined					
Consent result	O Deferred (patient is willing to discuss participation in the					
	future, but has not accepted yet)					
Warning: Documenting 'declination' of consent will permane	ntly remove this pati	ent from the daily eligibility reports	s.			
Reason for Declination of Consent						
Date of Consent	<u>31</u> To	day Y-M-D				
Age at date of consent		View equation				
	Accepted	,				
Assent Result	O Declined	A				
Assert Result	Unable to Assent					
			reset			
Warning: Documenting 'declination' of assent will permanen	tly remove this patie	nt from the daily eligibility reports.				
Reason Assent Not Given						
Date of Assent	31 To	day Y-M-D				

## Approached?

Consented?

Assented?

## Progress Reports



See the forest.

3-way breakdowns of:

- time
- site
- drug
- age
- gender
- stage
  - 1. qualified
  - 2. approached
  - 3. consented
  - 4. assented



# Progress Reports

#### 3 Activity By Site

Summary of screening and recruitment acitivities by site.

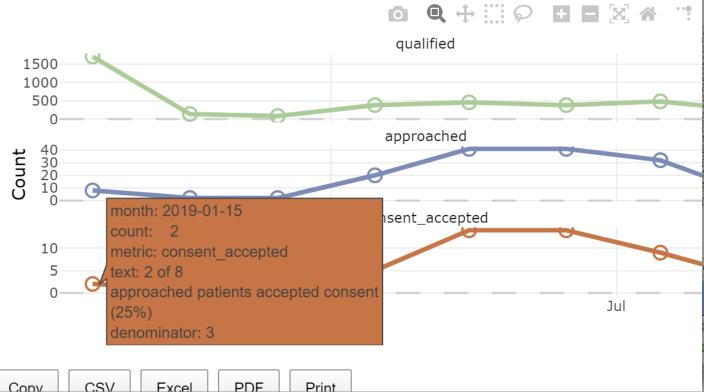
3.1 General

**3.2 NICU** 

3.3 PICU

3.4 Outpatient

Daily count of patients qualified by the POPS team by their site.



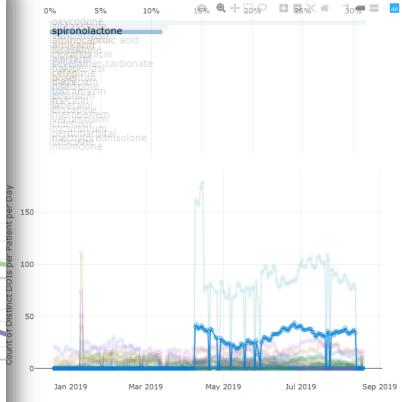


#### 6.1 Overall

The DOI per day is calculated by (a) counting the orders of a DOI and then (b) dividing by the daily count of unique patients. Since a patient may receive more than one DOI order on a single day, the DOI percentages will exceed 100%.

The histogram represents 'Sum of Daily Medication Counts': (out of 34,867 total medication-days across 237 days)'. Sum of Daily Medication Counts'. The uniqueness of the DOI is considered; a patient eligible for three variations of the same DOI will lengthen the bar by only 1.

e spaghetti represents the count of each DOI during a given day.



Сору	CSV Excel	PDF	Print		Search:		
	date +	patient count	amikacin 👇	aminocaproic acid +	bosentan +	cefepime +	cidofovir (
) 1	2019-08-19	77	0	16	7	0	0
) 2	2019-08-18	14	0	1	0	0	0
3	2019-08-17	7/	0	16	7	0	

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## CDW Strategy: don't overbuild

- Some studies don't require a full reporting solution
  - Scenario 1: big study already has an established tracking pipeline
  - Scenario 2: small study has a tight focus;
     2 part-time nurses can review the ~3 patients each morning

- If only a CSV of daily patients is required, we can deliver within 10 man-hours.
- This includes:
  - Pulling fresh info from inpatient & outpatient EMRs
  - Saving a CSV each morning to a file server
  - Logging of pipeline steps to a protected text files to facilitate quick diagnoses & fixes



# **VDORA Study**

Vitamin D Supplementation in Children With Obesity-Related Asthma

#### appt.csv

mrn	name	dob	age_years	city	zip	distance_in_miles	date_last_office_visit	date_last_bmi	bmi_percentile	appt_duration	provider_name	visit_type	appt_date_time
1234567	a, Amelia	1/1/2010	7	OKLAHOMA CITY	73104	52.91793823	11/11/2011	11/11/2011	98	30	KATZ MD, ROBERT W	RETURN VISIT	Jun 10 2019 2:30PM
2345678	B, Milo	1/2/2010	8	TULSA	74105	112.3245316	6/6/2018	12/12/2018	87	30	DORRIS PA, JANISLYNN	RETURN VISIT	Jun 28 2019 9:15AM
3456789	C, Isla	1/3/2010	9	OKLAHOMA CITY	73104	8.626083374	1/1/2019	1/22/2019	87	30	DORRIS PA, JANISLYNN	RETURN VISIT	Jun 6 2019 12:45PM
4567890	D, Jasper	1/4/2010	10	TULSA	74105	20.26898193	11/11/2018	11/11/2018	99	30	MEHDI MD, NIGHAT	RETURN VISIT	Jun 17 2019 1:45PM
5678901	E, Cora	1/5/2010	11	OKLAHOMA CITY	73104	NA	4/24/2019	4/24/2019	86	30	DORRIS PA, JANISLYNN	RETURN VISIT	Jun 22 2019 10:15AM
6789012	F, Asher	1/6/2010	12	TULSA	74105	19.1277132	4/19/2019	4/19/2019	91	30	MCCRABB APRN CNP, TIFFANY J	RETURN VISIT	Jun 24 2019 2:45PM
7890123	G, Charlotte	1/7/2010	13	OKLAHOMA CITY	73104	3.259526253	2/7/2019	2/7/2019	94	30	DORRIS PA, JANISLYNN	RETURN VISIT	Jun 8 2019 10:15AM
8901234	H, Henry	1/8/2010	14	TULSA	74105	8.123344421	12/12/2018	6/26/2016	87	30	DORRIS PA, JANISLYNN	RETURN VISIT	Jun 27 2019 12:45PM
9012345	I, Iris	1/9/2010	15	OKLAHOMA CITY	73104	89.85191917	5/7/2019	4/27/2019	100	30	BUTLER RD, DANIELLE J	NEW VISIT	Jun 14 2019 3:00PM

(Simulated patients)

#### Resource Efficiency: fewer patients, quicker review, less redundancy

#### **Manual Screening Process**

- Obtain a list of appointments scheduled the following week
- Review <u>each</u> medical record using the inclusion/exclusion checklist:
  - Other criteria
  - Age
  - Diagnosis of asthma
  - Documentation of obesity
- Email providers for review/input
- Volume: 130 charts
- Time: 240 minutes

#### **Automated Screening Process**

- Review <u>select</u> medical records for:
  - Other criteria

- Email providers for review/input
- Volume: 24 charts (screened out 106)
- Time: 45 minutes

# Brief Summary of CDW Value

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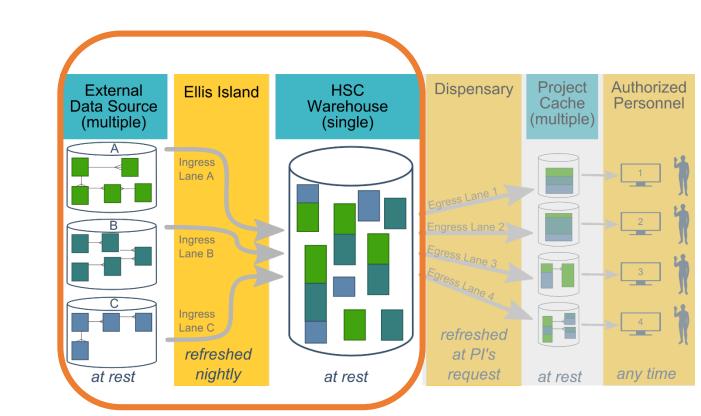
- POPS: dynamic recruitment
- OxyContin: electronic sorting and merging/patient matching
- ADHD studies: Apply standard clinical vocabulary to support interoperability to help information exchange; isolated retrieval of text documents for mining
- Diabetes Management/Transition of Care: Sharing of data across various sources improves quality of care and efficiency; maximizes utility of data
- Immunization: Harmonization of records for quality reporting and improved accuracy of record history



# Current Developments: Common Campus-wide Warehouse

A tighter collaboration with

- IT
- BBMC
- OU Physicians
- Hospital







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# Thank you

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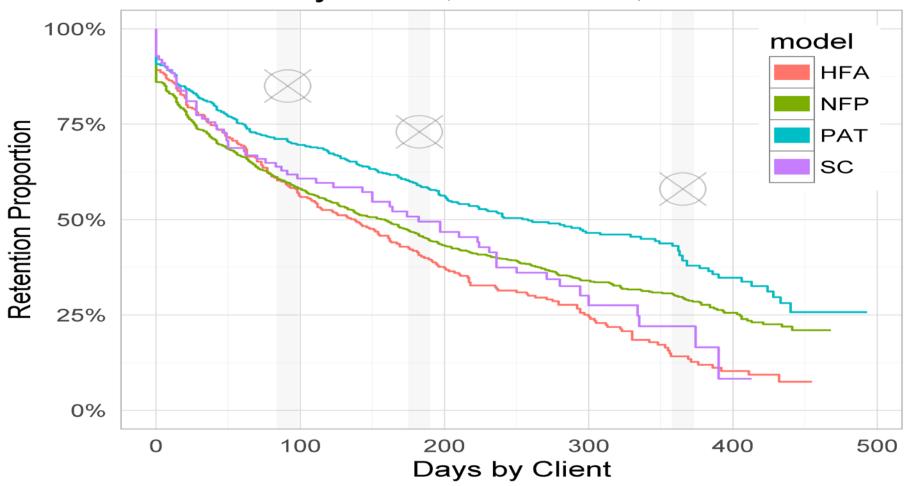


# Extras

# OK HV-CollN

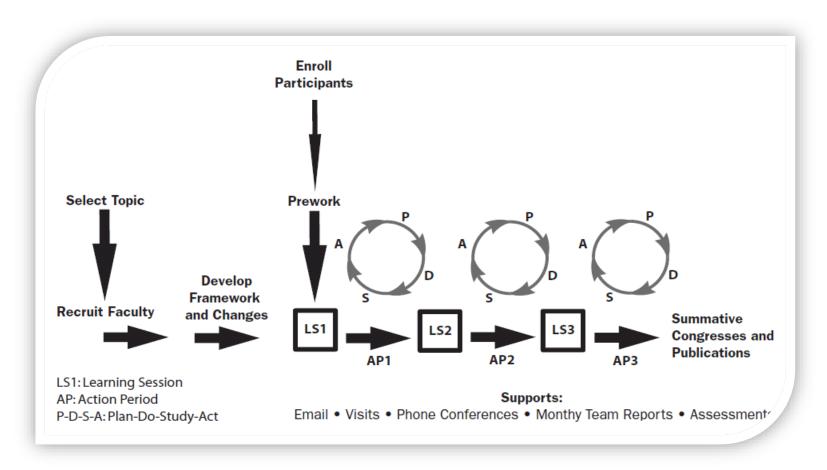
Oklahoma Home Visiting Collaborative Improvement and Innovation Network

#### Retention by Model, Oklahoma, 2015 Referrals





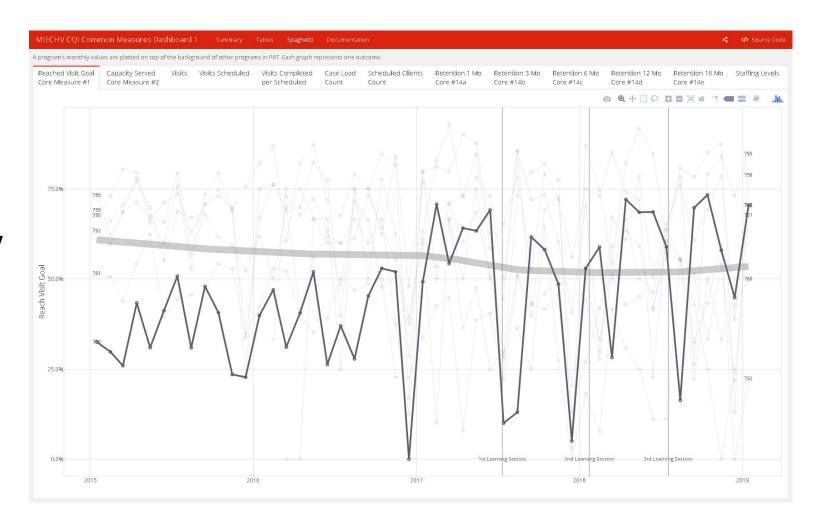
# The IHI Breakthrough Series as the HV CollN Framework



#### Dashboards

 Two versions of a user-friendly dashboard were developed and administered weekly by team of analysts

- Common measures
- Individual



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 Two versions of a user-friendly dashboard were developed and administered weekly by team of analysts

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