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# A Closer Look at Blood Draw Volume Practices in Research Patients Across a Hospital System

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**National Cancer Institute**  
**December 9, 2020**



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# Objectives

1. Identify current NIH policies, tracking methods & documentation of blood collection volumes
2. Review literature and evidence based practices related to safe blood collection
3. Analyze present blood collection volume practices & documentation using Institute for Healthcare Improvement (IHI) Toolkit
4. Introduce recommendations for reducing blood collection volumes



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# Background

- Care of research patients is complex
- Blood collection practices play a significant role in safe patient care
  - Volume, size of tubes, collection methods, ordering sequences
- NIH blood collection can be categorized as either clinical or research
- Variation in blood collection volumes and collection methods is common
- Potential impacts of excessive blood volume loss include:
  - Hemodynamic instability
  - Allo-immunization
  - Hospital Acquired Anemia (HAA)

**Primary focus = Do No Harm**



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# Objective 1

**Identify current NIH policies, tracking methods & documentation of  
blood collection volumes**



Medical Administrative Series	
M95-9 (rev.)	3 July 2018 (I)
MANUAL TRANSMITTAL SHEET	
POLICY: Guidelines for Limits of Blood Drawn for Research Purposes in the Clinical Center	

# NIH MAS Policy M95-9: Guidelines for Limits of Blood Drawn for Research Purposes

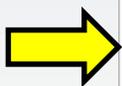
- **Adult patients**
  - >18 years of age
  - **\*Research** purposes only:
    - Shall not **exceed 10.5 mL/kg or 550 mL**, whichever is smaller, over any **eight week** period.
- **Pediatric Patients:**
  - ≤ 18 years of age
  - **\*Research** purposes only:
    - No more than **5 mL/kg** may be drawn for research purposes in a **single day**
    - No more than **9.5 mL/kg** may be drawn over any **eight week** period.

***\*Research blood is not defined***

***The body cannot distinguish between “research” and “clinical” blood volume loss***



# EMR Blood Volume Tracker Tool: Pediatric Patient



DISCLAIMER: These blood draw volumes represent estimates and should not be interpreted as exact or absolute totals. These totals are calculated using actual tube size blood volume and do not take into account factors such as underfill, overfill, or waste. The volume for Research, Blood orders are from the CRIS Order. All other volumes are from those blood specimens scanned into SoftID.

Draw Limits (in mL)	
Draw Limit Volume [Past 8-weeks + Today]	158.65
Pediatric Daily Limit	N/A

**OVER DRAW LIMIT [over by 1671.35 mL]**  
**IS A PEDIATRIC PATIENT**

Most Recent Vitals/Results			
* Collection Date	Weight (in kg)	HCT	HGB
07/11/2018 00:00:00	16.7 kg [07/11/2018 09:01]	24.2 [07/11/2018 04:23]	8.8 [07/11/2018 04:23]

\* Collection Date is the most recently identified blood draw collection. If 'Collection Date' is N/A, then no blood draws have been identified in the past 8-weeks.  
\* Collection Date is used as the maximum date for identifying the most recent Vitals/Results. If 'Collection Date' is N/A, today's date is used as the maximum date.

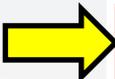
	Past [8-weeks]		Today [07/11/2018]		Future [8-weeks]	
	# of Tubes Collected	Volume (in mL)	# of Tubes Collected	Volume (in mL)	# of Tubes Collected	Volume (in mL)
Non-research (from LIS)*	403	1819.00	3	11.00	N/A	N/A
Research (from SCM)†	0	0.00	0	0.00	0	0.00
Cumulative	403	1819.00	3	11.00	0	0.00
Cumulative [Past 8-weeks + Today]	-	-	406	1830.00	-	-

**8 week limit = 158.65 mLs**  
**\*Amount drawn in 8 weeks = 1830 mLs**  
**\*Amount over = 1671.4 mLs**

\*This volume is based on TOTAL fill amount of the tube, but is it the actual amount drawn?



# EMR Blood Volume Tracker Tool: Adult Patient



**DISCLAIMER:** These blood draw volumes represent estimates and should not be interpreted as exact or absolute totals. These totals are calculated using actual tube size blood volume and do not take into account factors such as underfill, overfill, or waste. The volume for Research, Blood orders are from the CRIS Order. All other volumes are from those blood specimens scanned into SoftID.

### Draw Limits (in mL)

Draw Limit Volume [Past 8-weeks + Today]	550.00	<b>OVER DRAW LIMIT [over by 142.000 mL]</b>
Pediatric Daily Limit	N/A	not a pediatric patient

### Most Recent Vitals/Results

* Collection Date	Weight (in kg)	HCT	HGB
01/23/2020	103.5 kg [01/22/2020 06:00]	24.6 [01/23/2020 04:35]	8.1 [01/23/2020 04:35]

\* 'Collection Date' is the most recently identified blood draw collection. If 'Collection Date' is N/A, then no blood draws have been identified in the past 8-weeks.

\*\* 'Collection Date' is used as the maximum date for identifying the most recent Vitals/Results. If 'Collection Date' is N/A, today's date is used as the maximum date.

### Blood Draw

	Past [8-weeks]		Today [01/23/2020]		Future [8-weeks]	
	# of Tubes Collected	Volume (in mL)	# of Tubes Collected	Volume (in mL)	# of Tubes Collected	Volume (in mL)
Non-research (from LIS)*	229	671.00	6	21.00	N/A	N/A
Research (from SCM)†	0	0.00	0	0.00	0	0.00
<b>Cumulative</b>	229	671.00	6	21.00	0	0.00
<b>Cumulative [Past 8-weeks + Today]</b>	-	-	235	<b>692.00</b>		

**8 week limit = 550 mLs**  
**\*Amount drawn in 8 weeks = 692 mLs**  
**\*Amount over = 142 mLs**

\*This volume is based on TOTAL fill amount of the tube, but is it the actual amount drawn?

# NIH Clinical Center Nursing Blood Collection Procedure

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CLINICAL CENTER  
CLINICAL CENTER NURSING DEPARTMENT

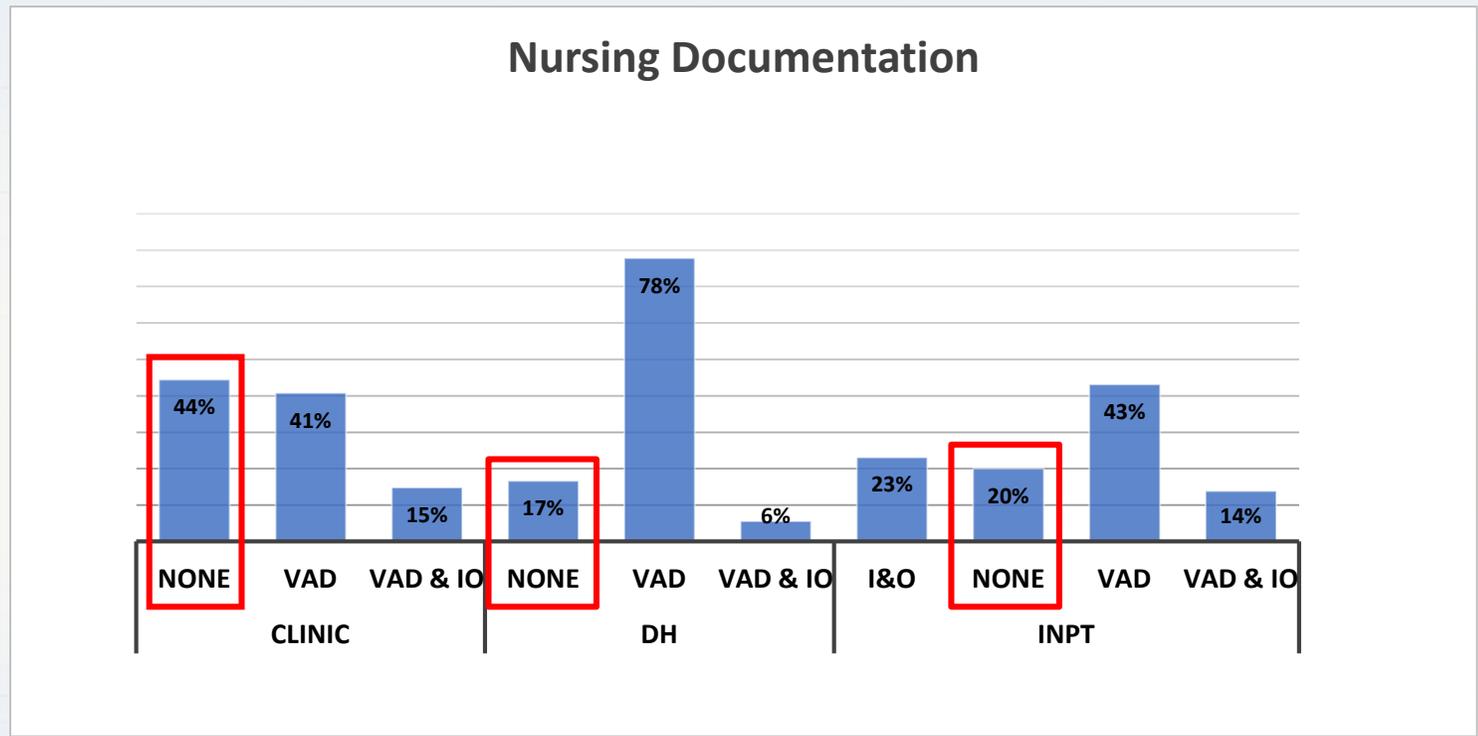
**Procedure: Central Venous Access Device: Obtaining a Blood Specimen**

- **Documentation:**
  - Only addresses pediatric volumes of collection
  - Does not specify where within the EMR (VAD or I&O flowsheet) to document
- **Discard volumes:**
  - Pediatrics: returned
  - Adults:
    - 5mLs
    - 20mLs for coagulation studies with heparinized lines



# Variation in Nursing Documentation

- **Survey** at morning huddle over 4 days in clinics, DHs, and inpatient units
- **3 questions:**
  1. Present documentation
  2. Preferred documentation
  3. Areas of practice
- **113 Responses**



**Phlebotomy = No documentation**



# In Summary

## Policy

- Research only
  - No definition
- Clinical labs?

## EMR: Tracker

- Pulls full volume
- Do we completely fill the collection tubes?
- How accurate is the Tracker Tool?

## Documentation

- Phlebotomy: no documentation of collection volumes
- Nursing: inconsistent documentation of volumes
  - No guidelines for documentation in EMR



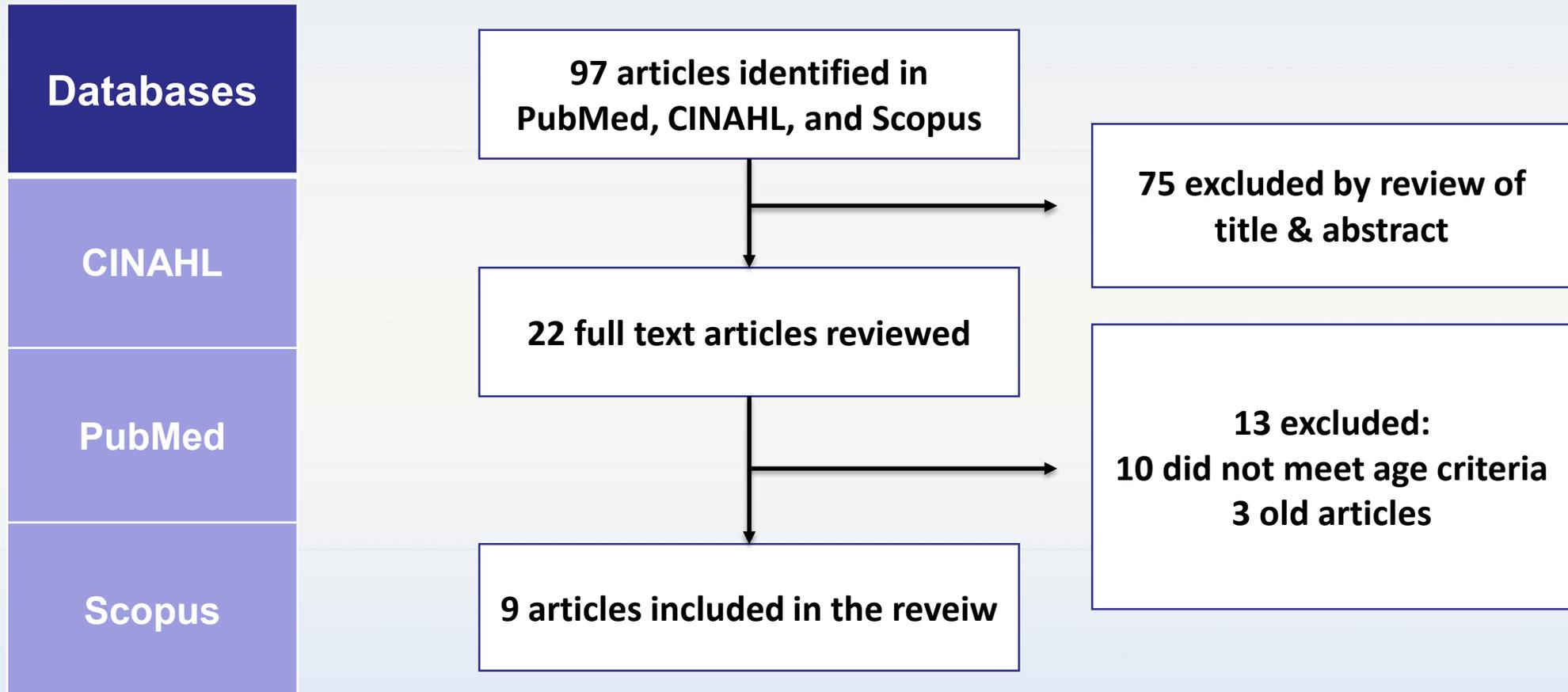
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## Objective 2

**Review of literature and evidence based practices as it relates to  
safe blood collection**



# Literature & Evidence Based Practices



# Synthesis Table: Levels of Evidence

	1	2	3	4	5	6	7	8	9
Level I: Systematic Review or meta-analysis									
Level II: Randomized Control trial									
Level III: Controlled without randomization									
Level IV: Case-control or cohort study									
Level V: Systematic Review of qualitative or descriptive studies									
Level VI: Qualitative or descriptive study(includes evidence implementation projects)	<b>X</b>	<b>X</b>		<b>X</b>			<b>X</b>	<b>X</b>	<b>X</b>
Level VII: Expert opinion or consensus			<b>X</b>		<b>X</b>	<b>X</b>			

1. Dolman, H., Evans, K., Zimmerman, L., Lavery, T., Baylor, A., Wilson, R. & Tyburski, J. (2015)
2. Eaton, K. P., Levy, K., Soong, C., Pahwa, A., Petrilli, C., Ziembra, J., Cho, H., Alban, R., Blank, J., & Parsons, A. (2017)
3. Howie, S. R. (2011)
4. Jones, S., Spangler, P., Keiser, M., Turkelson, C. (2019)
5. Kim, J., & Na, S. (2015)
6. Secher, E., Stensballe, J., & Afshari, A. (2013)
7. Steffen, K., Doctor, A., Hoerr, J., Gill, J., Markham, C., Brown, S. M., et al. (2017)
8. Sztéfko, K., Beba, J., Mamica, K., & Tomasik, P. (2013)
9. Thakkar, R. N., Kim, D., Knight, A. M., Riedel, S., Vaidya, D., & Wright, S. M. (2015)

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# Review of Pediatric Safe Limits

- **Recommendations regarding blood sampling in pediatric research patients include:**
  - Maximum of **3mL/kg** in a **healthy child** per day
  - Effective coordination of research and clinical phlebotomy to reduce burden to the patient
  - Blood volumes needed for both clinical and research care should be carefully assessed with justification to the Institutional Review Board (IRB) and ethics committees
- **HHS Guidance on blood volume (Expedited Review Categories)**
  - The amount drawn may not exceed the lesser of **550mLs or 3mLs/kg in an 8-week period**
  - Collection may not occur more frequently than **2 times per week**

Bulletin of the World Health Organization

World Health Organization

Language: English | Arabic | French | Spanish | Russian |

Blood sample volumes in child health research: review of safe limits

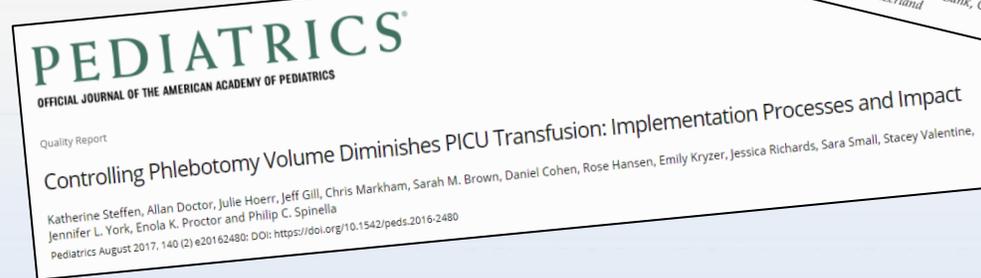
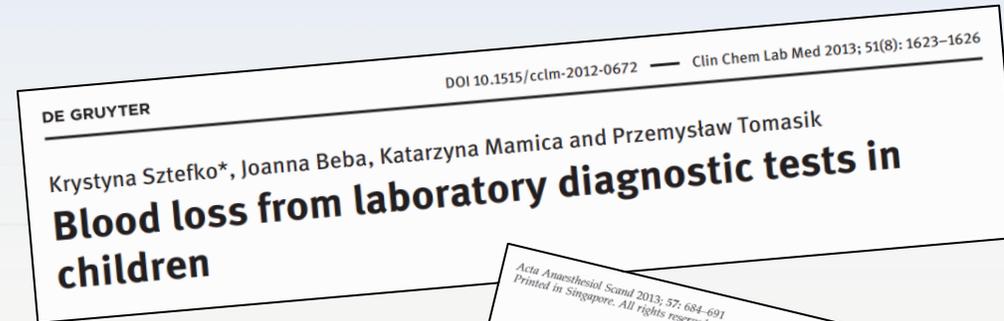
Stephen RC Howie



# Effects of Excessive Blood Collection Volumes

- **Excessive, repetitive and unnecessary phlebotomy causes:**
  - Blood volume depletion
  - Hospital acquired anemia (HAA)
  - Increased need for transfusions

(Secher et al, 2013; Steffen, Doctor, Hoerr, Gill, Markham, Brown, et al., 2017; Sztéfko, Beba, Mamica, & Tomasik, 2013).





# Effects of Excessive Blood Collection Volumes Cont.

- **Compromised immune systems increases risk of:**
  - Infection
  - Allo-immunization
  - Hemolytic reactions
- **Transfusion-Related Acute Lung Injury (TRALI)**
  - Serious life threatening injury
  - Mortality rates
    - 20% in general population
    - 47% in critically ill population

(Secher et al., 2013) (Kim & Na, 2015).



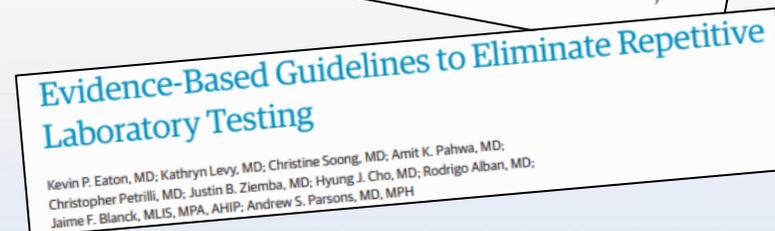
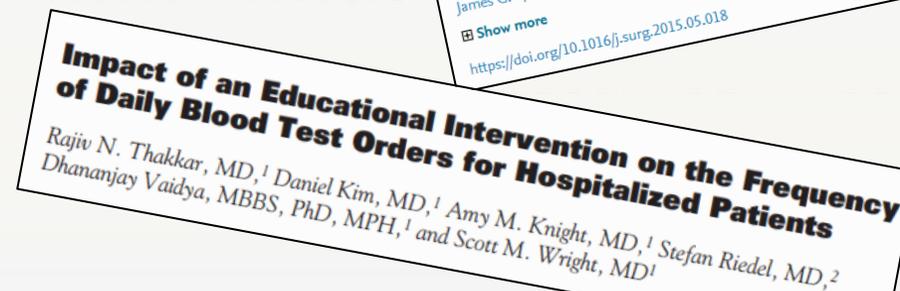
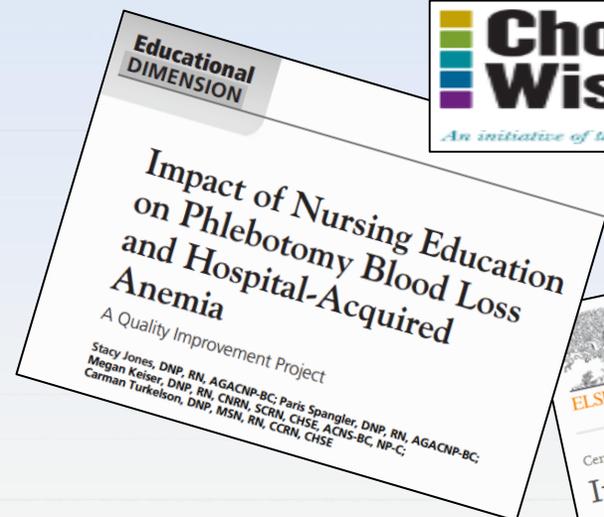


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# Reduction Strategies

- **Managing phlebotomy volumes by:**
  - Monitoring duplicate and excessive ordering
  - Bundling scheduled tests
  - Advocating for blood volume reduction practices including use of:
    - Closed system collection devices
    - Small volume collection tubes
- **Successful EBP QI projects:**
  - Avoid duplicate testing
  - Frequent clinical evaluation of routine or repetitive testing
  - Adoption of excessive phlebotomy reduction strategies

(Eaton et al, 2017, Dolman et al, 2015, Jones et al, 2019 & Thakkar et al, 2015).





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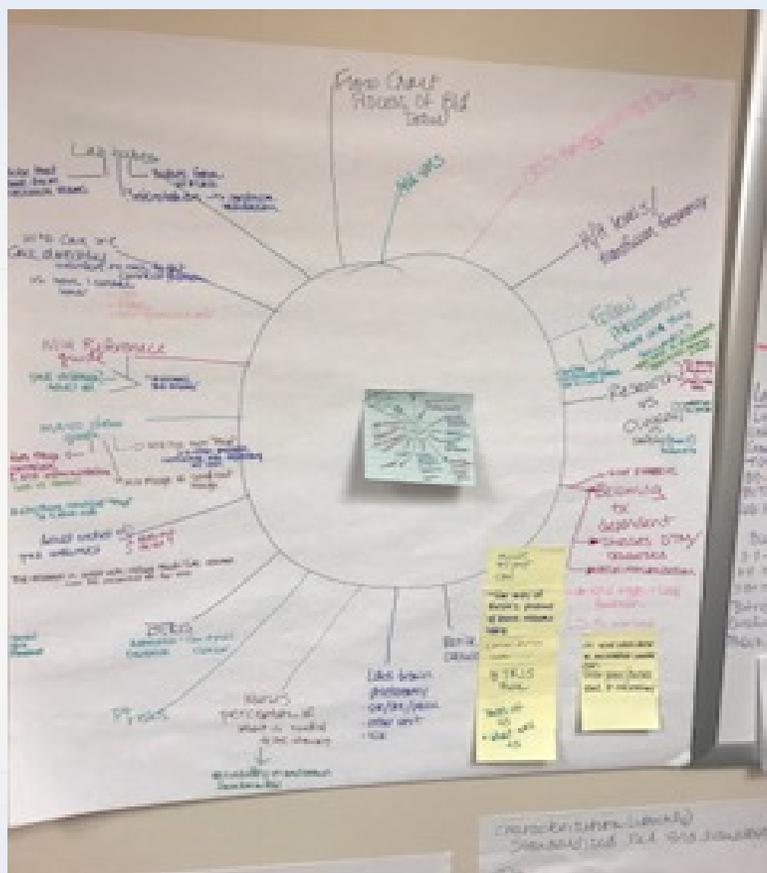
## Objective 3

**Analysis of present blood collection volume practice & documentation  
using Institute for Healthcare Improvement (IHI) Toolkit**

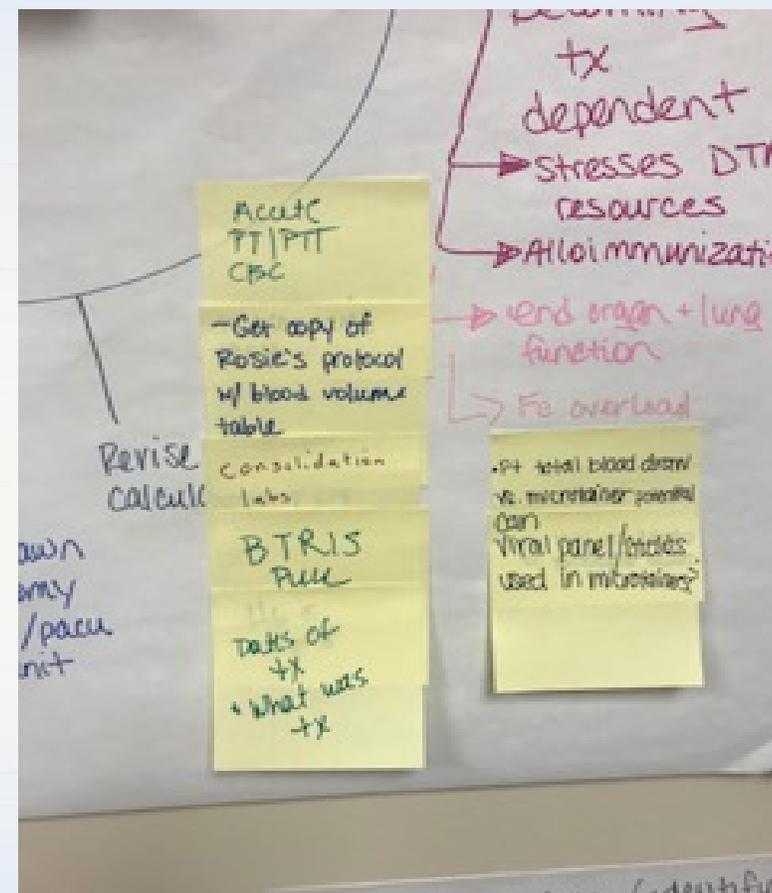


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# Brainstorming

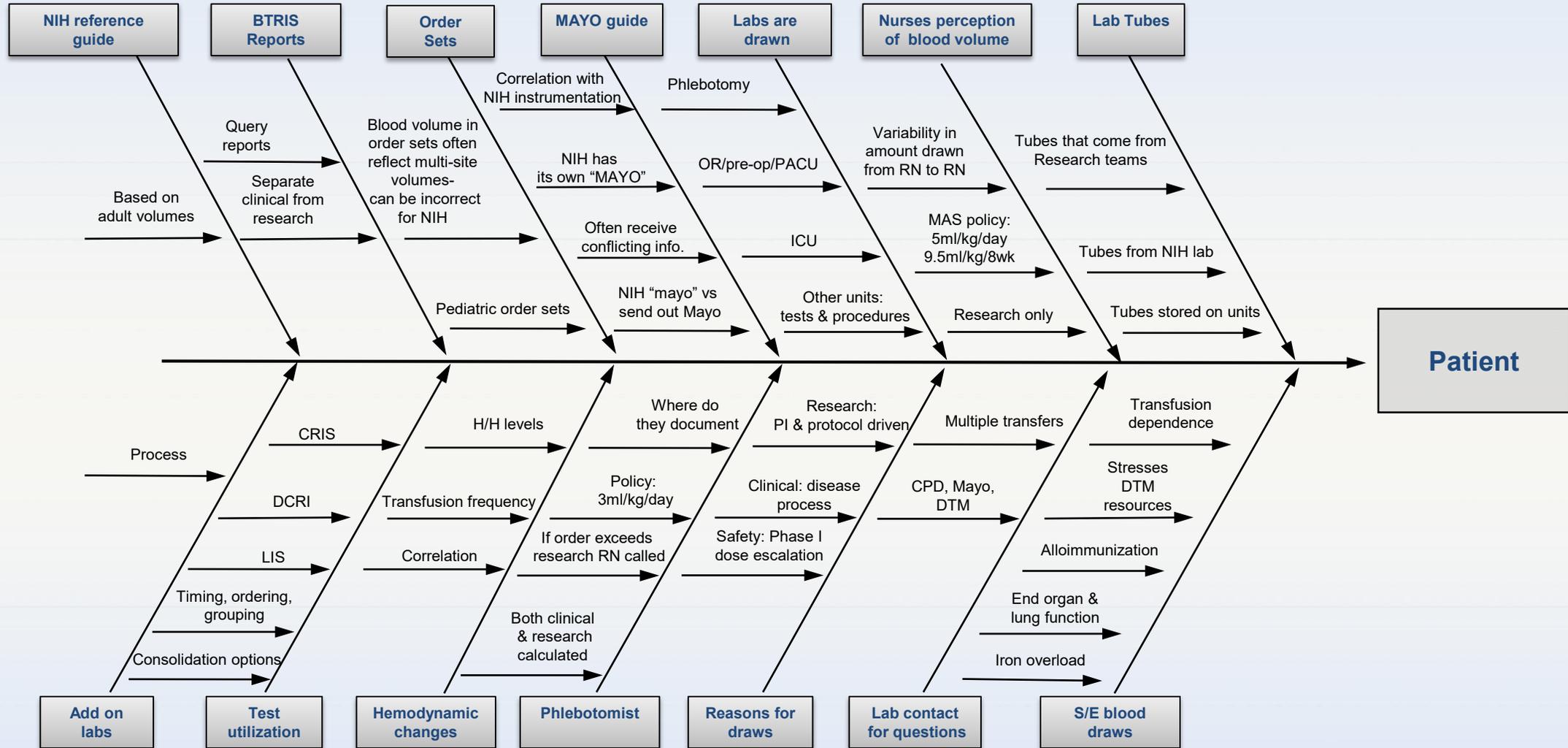


Our Team





# Cause and Effect Diagram

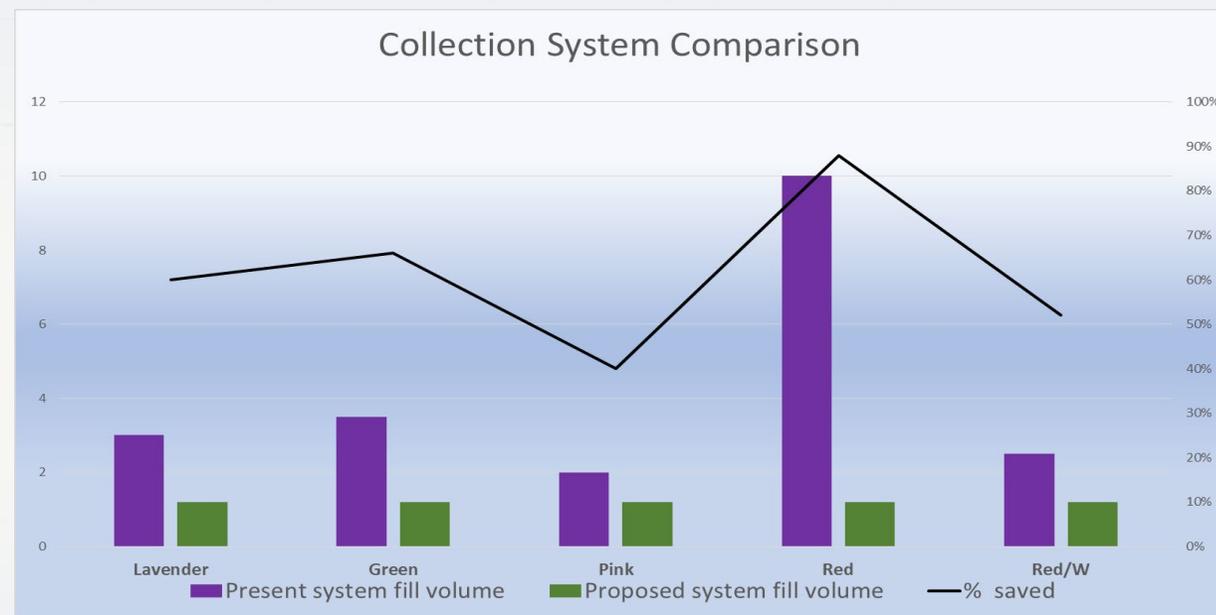




# Gap Analysis

## External

- **HHS Guidance on blood volume for testing:**  
**“Minimal harm”**
  - The amount drawn may not exceed the lesser of **550mLs or 3mLs/kg in an 8-week period** and collection may not occur more frequently than **2 times per week**
- **Pediatric hospital benchmarking comparison:**
  - Limit ranges **1.7mLs/kg to 3mLs/kg**
- **Collection Systems available**



- Product is a low volume enclosed multiple blood collection system.
- Potential savings: 40-94% volume, cost of Kobe, vacutainer, syringes & cost of biohazardous waste



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# Gap Analysis

## Internal

	Present Practice	Evidence Based Practice
<b><u>Policy:</u> Blood Volumes</b>	5mL/kg/day for research only	3mL/kg for both research and clinical
<b><u>Collection Tubes</u></b>	Large volume collection tubes	Small volume collection tubes
<b><u>Nursing Practice:</u> Volume of Collection</b>	Observed to vary from RN to RN	Standardized nursing practice for blood collection volumes
<b><u>Nursing Documentation:</u> Total Volumes</b>	Inaccurate and inconsistent documentation	Accurate and consistent documentation recommended



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# Stakeholder Collaboration



Our Team: nursing, licensed providers, lab, phlebotomy, central supply, quality management



# Stakeholder Collaboration

## Lab, Providers, & Quality

- **Hemolysis** of specimens
- Number & frequency of “**add-on**” tests
- **Utilization** of specimen:
  - How many tests are run in each tube?
  - How often are same tests ordered per day by each team?
- **Lab processing equipment** scheduled for updates
- MEC, IRB and Assembly of Scientists

## Nursing Practice

- **Accuracy:**
  - How much volume is actually drawn compared to the Blood Volume Tracker tool?
  - How much waste is drawn? Is this documented?
- **Current RN practice:**
  - What methods (kobe, vacutainer, syringe) do we use and where (clinic, DH, inpatient)?
  - Actual volumes drawn
- **Documentation**
  - Cumulative volumes
  - Location in EMR
  - Waste amounts



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# Project Overview: Phase 1

## Phase 1

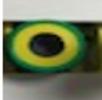
Determine current  
phlebotomy practices in  
pediatric nurses in the clinic,  
DH, & inpatient

## Phase 2

## Phase 3

# Tool & Method

DATE	TIME	AGE	WEIGHT

TUBE TYPE					
	Lavender	Green: yellow top	Pink	Red	Red: white top
Length of blood-filled portion of the tube in cm:					

Type of catheter	PIV	PICC	Central Line	Comments
Method of Draw	Syringe	Kobe	Vacutainer	Comments
Area of the draw:	<i>Circle one</i> Clinic                      Day Hospital                      Inpatient			

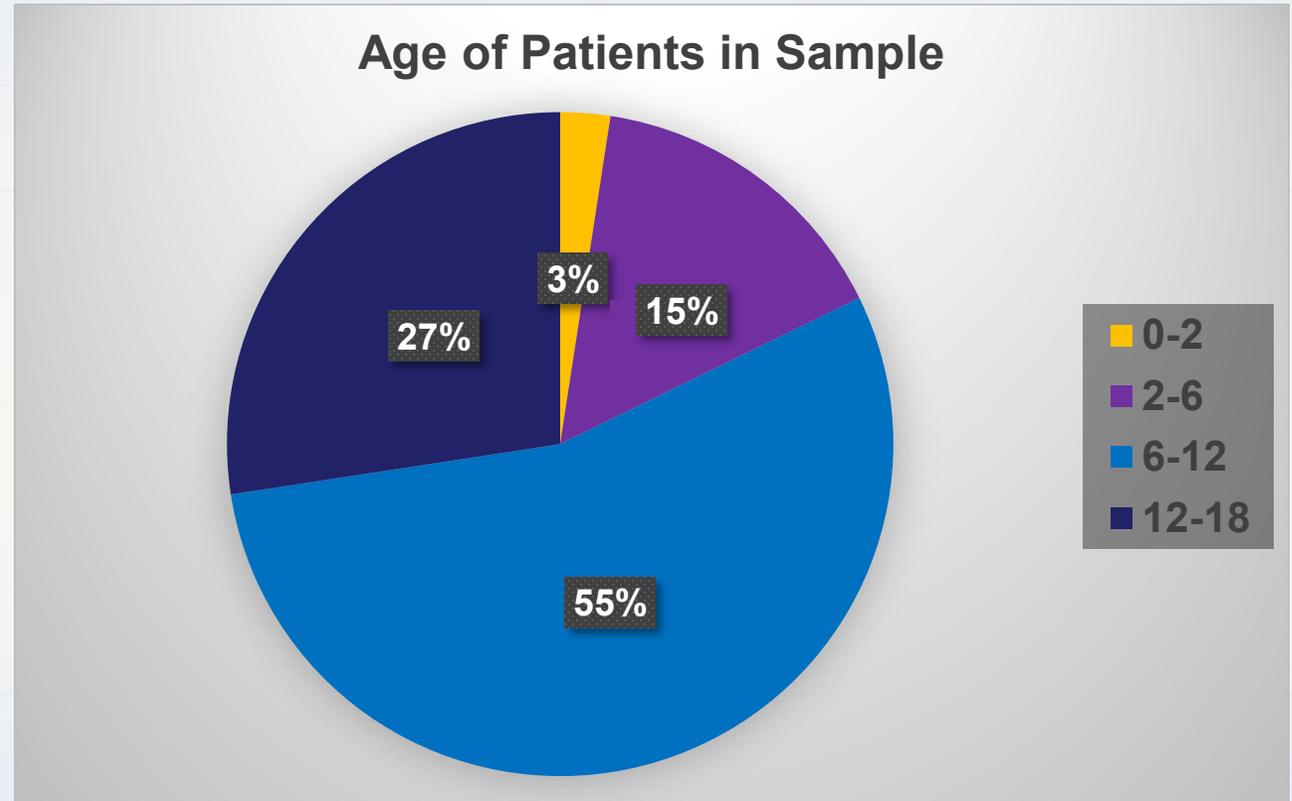


$$\frac{\text{Actual blood draw volume: mL (blood filled tube)}}{\text{Length of blood-filled portion of the tube: cm}} \times \frac{\text{Known maximum volume: mL}}{\text{Known length of max volume: cm}}$$

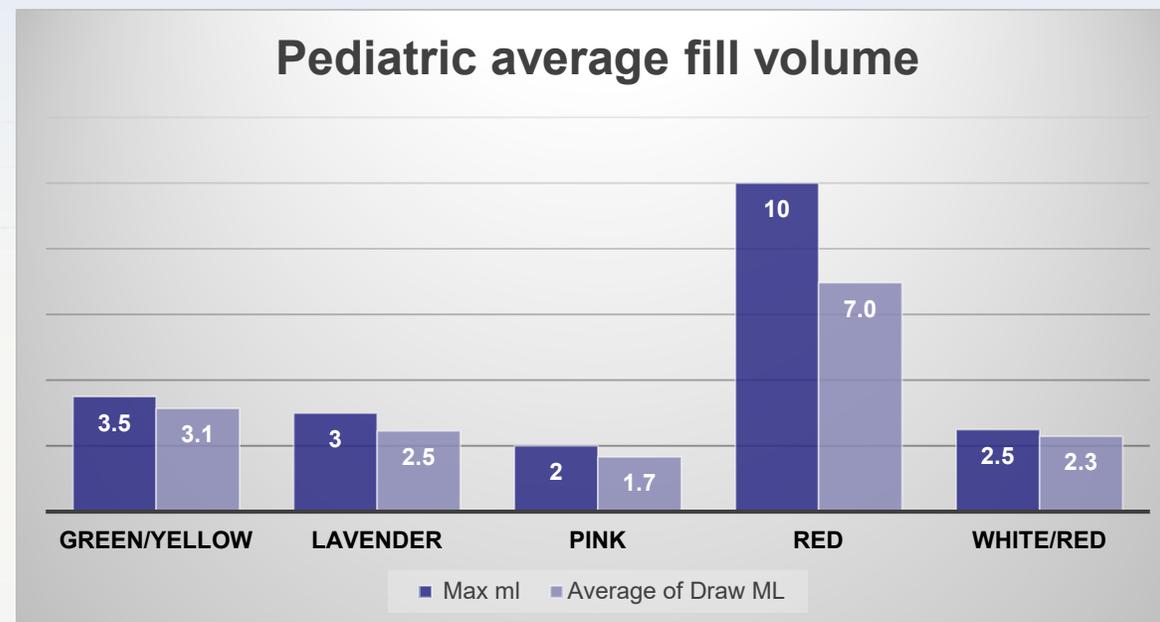
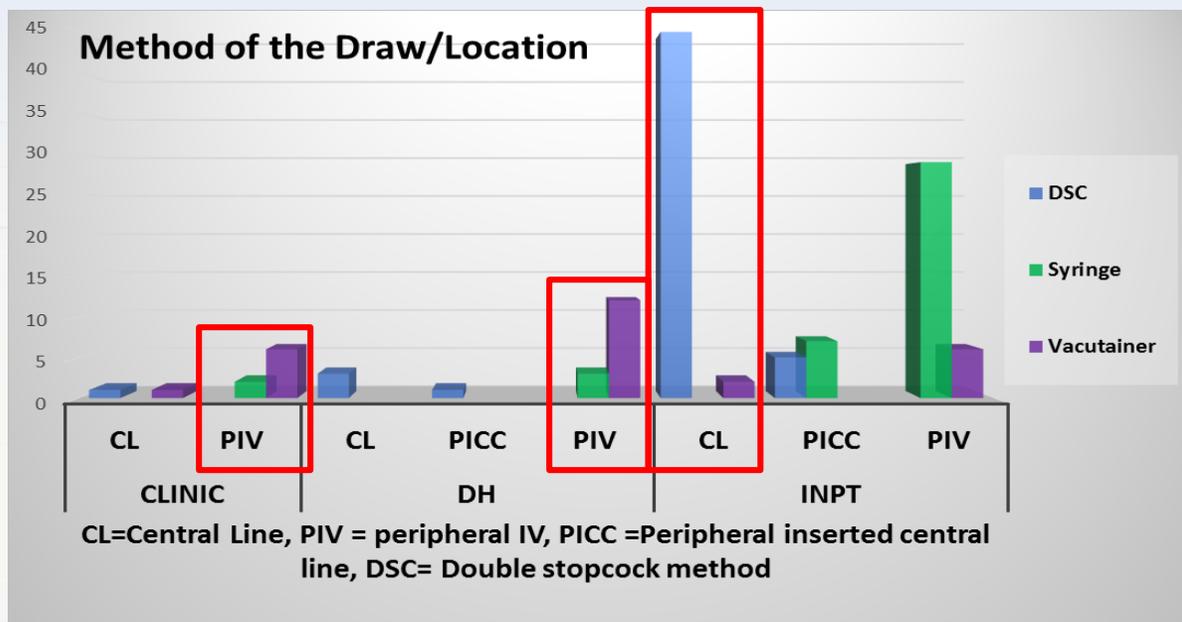


# Pediatric Findings: Sampling

- 123 patients for a total of 355 blood collection samples
- Ages: 3 months – 18 years



# Pediatric Findings: Method & Fill Volumes



- **Most common method of collection:**
  - Peripheral IV with a syringe or vacutainer
  - Central Line with Double Stopcock

- **Pediatric Average Fill Volume:**
  - Less than maximum tube volume

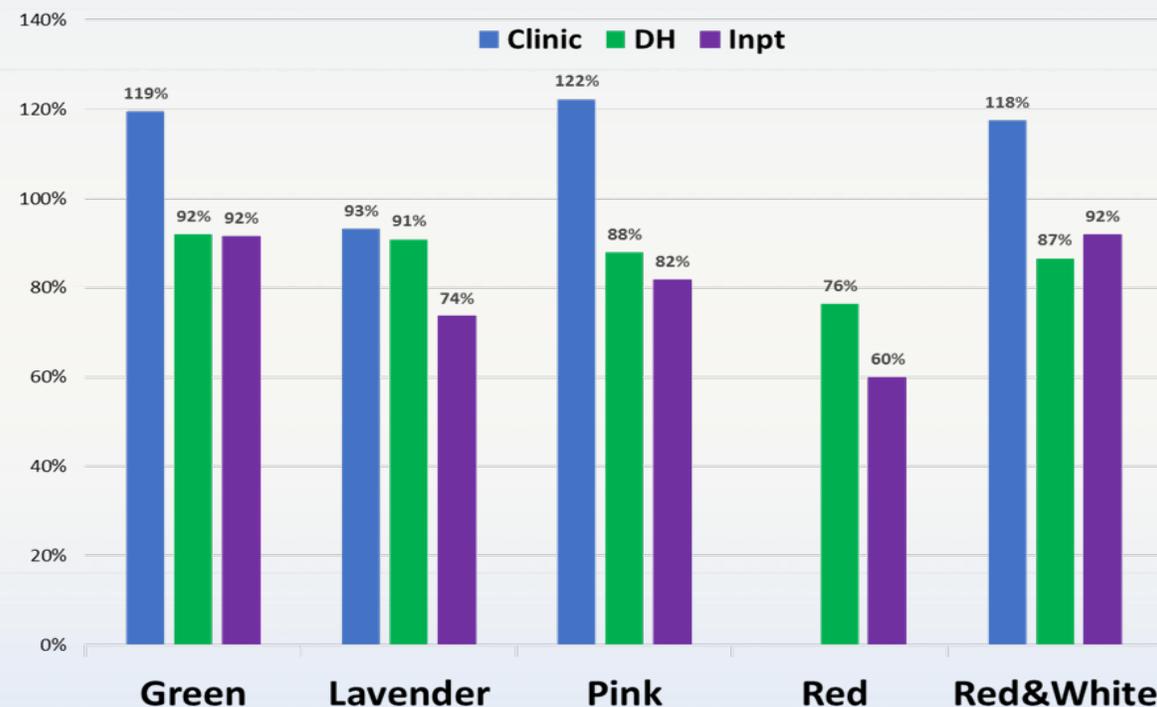


# Pediatric Findings: Over-fills & Under-fills

- **Over-filling** occurred in 14% of the samples
  - Clinic: 60%, DH: 12%, Inpatient: 10%
  - Method: PIV by way of vacutainer & CL with the use of a double stop cock (kobe)
- **Under-filling** occurred in 50.6% of the samples
  - Reasons: serial testing, difficult sticks & individual nurse decision to minimize volumes

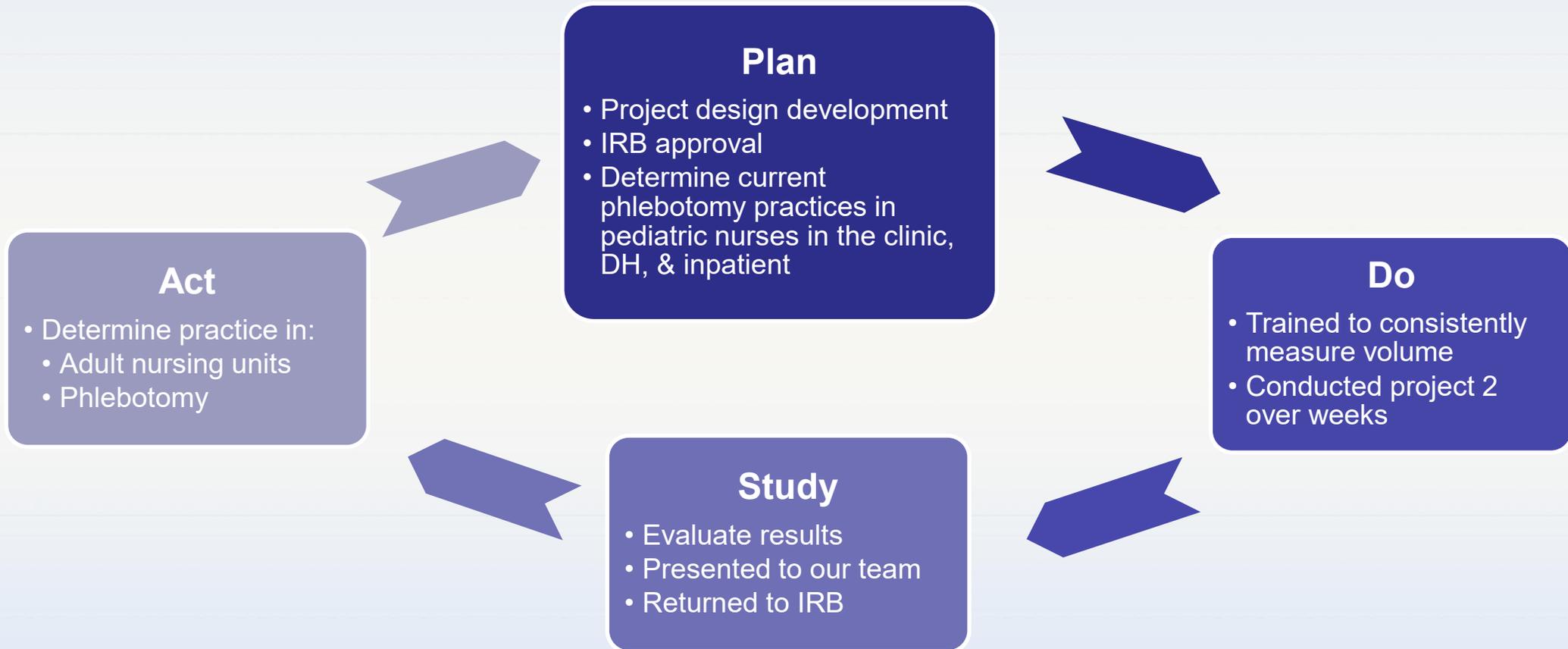
**Combined Overfills & Underfills =  
64.6% of the samples**

Overfill & Underfill Average Tube Fill /Location of the Draw





# Plan- Do- Study- Act Cycle





# Project Overview: Phase 2

## Phase 1

Determine current phlebotomy practices in pediatric nurses in the clinic, DH, & inpatient

## Phase 2

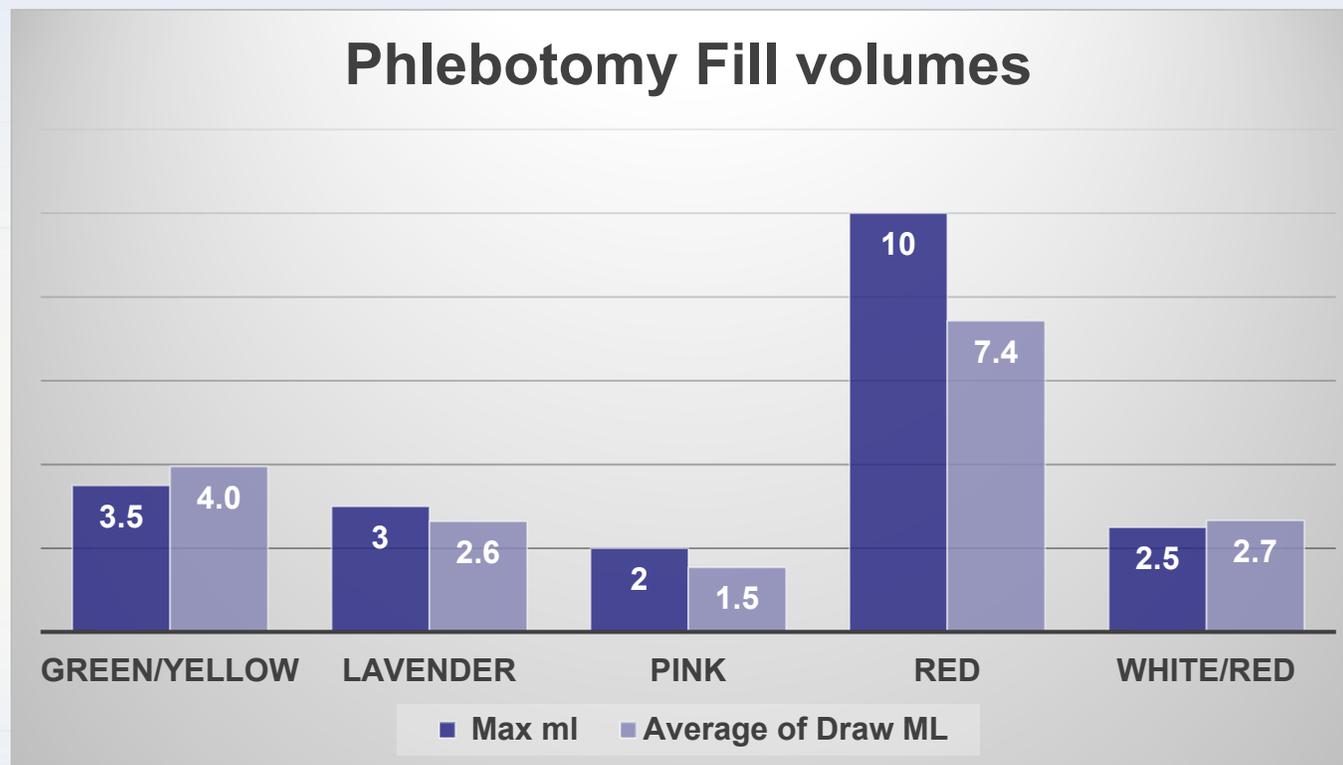
**Replicate project to determine practices with:**

- **Adult nurses in clinics, DHs, and inpatient units**
- **Phlebotomy technicians**

## Phase 3



# Phlebotomy Findings: Method & Fill Volumes



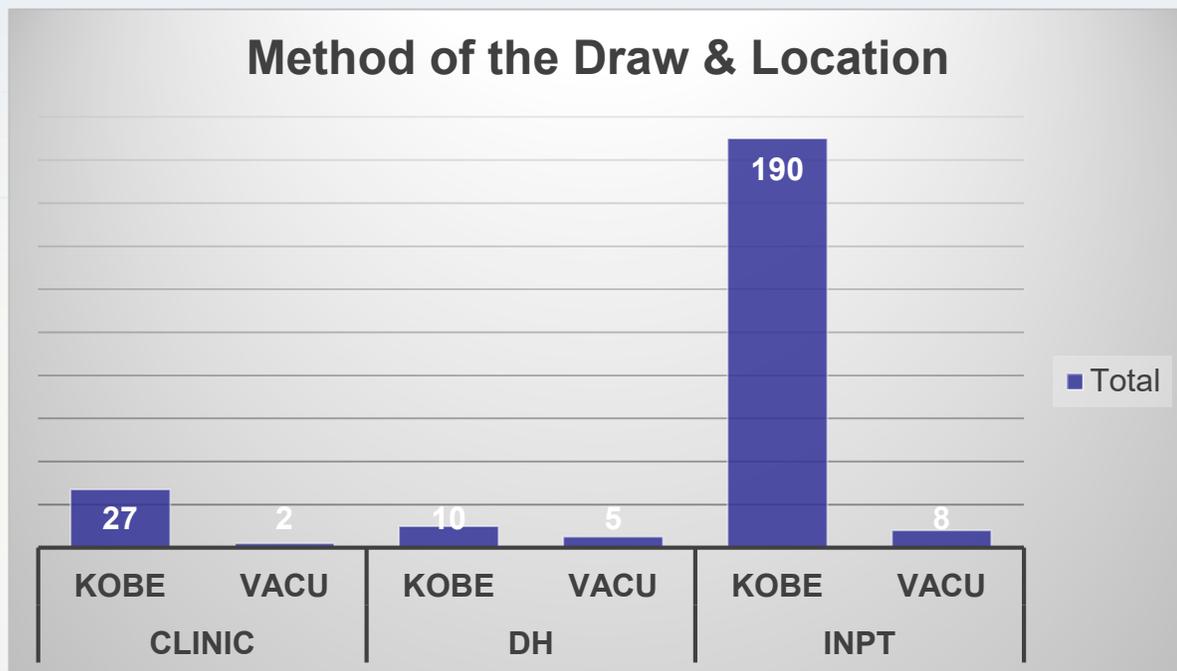
Sample size: 344

Method: venipuncture only



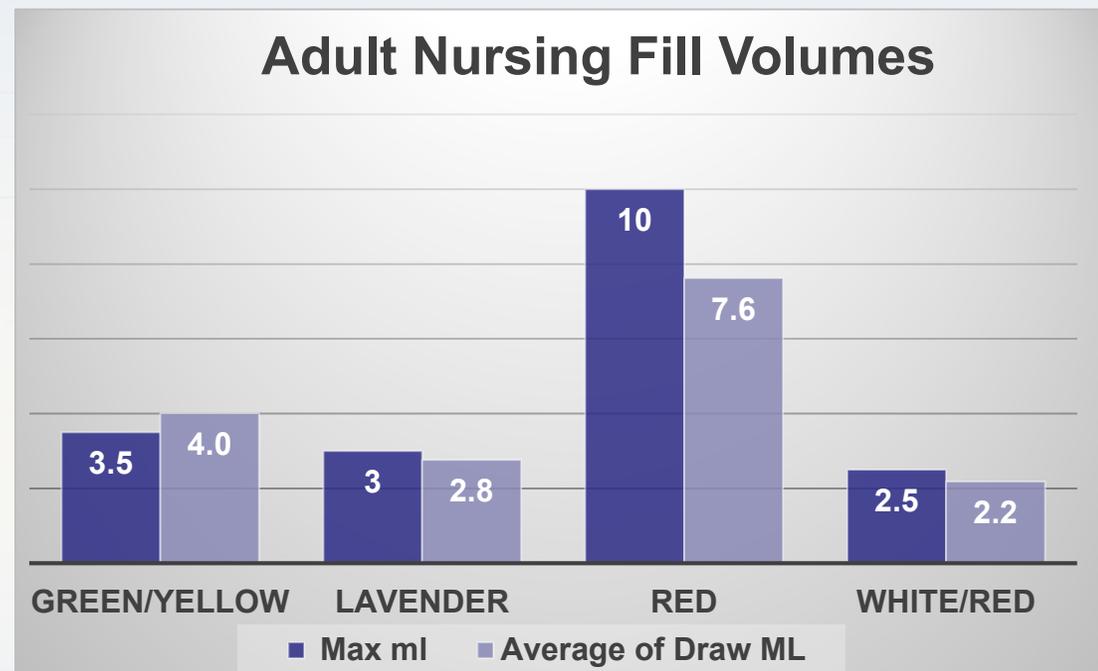
# Adult Findings: Method & Fill volumes

### Method of the Draw & Location



\*Sample size: 242  
Kobe method (double stopcock) method

### Adult Nursing Fill Volumes



\*Does not include an 8-20 mL waste amount with each collection.



# Tracker Accuracy vs Actual Volume Fill

Row Labels	Max (mLs)	Average volume (mLs) in all areas	Percent Fill
Green/Yellow	3.5	3.7	105%
Lavender	3.0	2.6	87%
Pink	2.0	1.7	85%
Red	10.0	7.2	72%
White/Red	2.5	2.4	96%
<b>Percent fill volume of all tubes</b>			<b>91%</b>

DISCLAIMER: These blood draw volumes represent estimates and should not be interpreted as exact or absolute totals. These totals are calculated using actual tube size blood volume and do not take into account factors such as underfill, overfill, or waste. The volume for Research, Blood orders are from the CRIS Order. All other volumes are from those blood specimens scanned into SoftID.

Draw Limits (in mL)	
Draw Limit Volume [Past 8-weeks + Today]	158.65
Pediatric Daily Limit	N/A

**OVER DRAW LIMIT [over by 1671.35 mL]  
IS A PEDIATRIC PATIENT**

Most Recent Vitals/Results			
Collection Date	Weight (in kg)	HCT	HGB
07/11/2018 00:00:00	16.7 kg [07/11/2018 09:01]	24.2 [07/11/2018 04:23]	8.8 [07/11/2018 04:23]

\*Collection Date is the most recently identified blood draw collection. If Collection Date is N/A, then no blood draws have been identified in the past 8-weeks.  
\*Collection Date is used as the maximum date for identifying the most recent Vitals/Results. If Collection Date is N/A, today's date is used as the maximum date.

	Past [8-weeks]		Today [07/11/2018]		Future [8-weeks]	
	# of Tubes Collected	Volume (in mL)	# of Tubes Collected	Volume (in mL)	# of Tubes Collected	Volume (in mL)
Non-research (from LIS) <sup>†</sup>	403	1819.00	3	11.00	N/A	N/A
Research (from SCM) <sup>‡</sup>	0	0.00	0	0.00	0	0.00
Cumulative	403	1819.00	3	11.00	0	0.00
Cumulative [Past 8-weeks + Today]	-	-	406	1830.00	-	-

**Tracker tool = 91% accurate for these 5 tubes  
(Does not include waste volume for each collection)**



# Project Overview: Phase 3

## Phase 1

Determine current phlebotomy practices in pediatric nurses in the clinic, DH, & inpatient

## Phase 2

Replicate project to determine practices with:

- Adult nurses in clinics, DHs, and inpatient units
- Phlebotomy technicians

## Phase 3

- Policy
- Volume Reduction Strategies
- RN Practice



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# Objective 4: Recommendations

## **Policy:**

- Include ALL blood; research & clinical
- Define research blood
- Pediatric: maximum 3mL/kg
- Adult: maximum 550mL in 8 week period

## **Volume Reduction Strategies:**

- Low volume tubes
- Monitor test utilization

## **RN Practice:**

- Evidence based waste amount
- Accurate consistent documentation
- Patient advocacy

# CRIS Screens: How to view Blood Tracker Tool while placing an order

Allocate Order to Protocol:

Conditional Order  Max # of activations:

Priority:  Reason for STAT or Priority Request:

Collect Specimen On:

Cumulative Blood Draw Information:  Cumulative Blood Draw Volume:

Draw Limits (in mL)	
Draw Limit Volume [Past 8-weeks + Today]	169.10 <b>OVER DRAW LIMIT (over by 851.400 mL)</b>
Pediatric Daily Limit	N/A <b>IS A PEDIATRIC PATIENT</b>

Most Recent Vitals/Results			
Collection Date	Weight (in kg)	HCT	HGB
12/02/2020	17.8 kg [12/02/2020 08:00]	20.3 [12/02/2020 06:18]	7.5 [12/02/2020 06:18]

\* 'Collection Date' is the most recently identified blood draw collection. If 'Collection Date' is N/A, then no blood draws have been identified in the past 8-weeks.  
 † 'Collection Date' is used as the maximum date for identifying the most recent Vitals/Results. If 'Collection Date' is N/A, today's date is used as the maximum date.

	Blood Draw					
	Past [8-weeks]		Today [12/02/2020]		Future [8-weeks]	
	# of Tubes Collected	Volume (in mL)	# of Tubes Collected	Volume (in mL)	# of Tubes Collected	Volume (in mL)
Non-research (from LIS)	273	964.00	4	15.50	N/A	N/A
Research (from SCM)†	5	41.00	0	0.00	0	0.0
<b>Cumulative</b>	<b>278</b>	<b>1005.00</b>	<b>4</b>	<b>15.50</b>	<b>0</b>	<b>0.0</b>
<b>Cumulative [Past 8-weeks + Today]</b>	<b>-</b>	<b>-</b>	<b>282</b>	<b>1020.50</b>	<b>-</b>	<b>-</b>

\* For non-research, 'Volume (in mL)' indicates 'Max Tube Volume'; this information may be delayed by up to 1 hour.  
 † For research, 'Volume (in mL)' indicates 'Collected Volume'; this information is provided in real-time.

For more information: [Patient Blood Volume Collection Summary](#)

# CRIS Screens: How to view report



DOB	06/08/2015	Patient Location	CRC-1NW-11624-AM
Age	5y5m	Visit Type	Inpatient
Pediatrics	<b>YES</b>	Admit Protocol	20-C-0070

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### Draw Limits (in mL)

Draw Limit Volume [Past 8-weeks + Today]	169.10	<b>OVER DRAW LIMIT [over by 851.400 mL]</b>
Pediatric Daily Limit	N/A	<b>IS A PEDIATRIC PATIENT</b>

### Most Recent Vitals/Results

* Collection Date	Weight (in kg)	HCT	HGB
12/02/2020	17.8 kg [12/02/2020 08:00]	20.3 [12/02/2020 06:18]	7.5 [12/02/2020 06:18]

\* 'Collection Date' is the most recently identified blood draw collection. If 'Collection Date' is N/A, then no blood draws have been identified in the past 8-weeks.

\* 'Collection Date' is used as the maximum date for identifying the most recent Vitals/Results. If 'Collection Date' is N/A, today's date is used as the maximum date.

### Blood Draw

	Past [8-weeks]		Today [12/02/2020]		Future [8-weeks]	
	# of Tubes Collected	Volume (in mL)	# of Tubes Collected	Volume (in mL)	# of Tubes Collected	Volume (in mL)
Non-research (from LIS)*	273	964.00	4	15.50	N/A	N/A
Research (from SCM)†	5	41.00	0	0.00	0	0.0
Cumulative	278	1005.00	4	15.50	0	0.0
Cumulative [Past 8-weeks + Today]	-	-	282	<b>1020.50</b>		

\* For non-research, 'Volume (in mL)' indicates 'Max Tube Volume'; this information may be delayed by up to 1 hour.

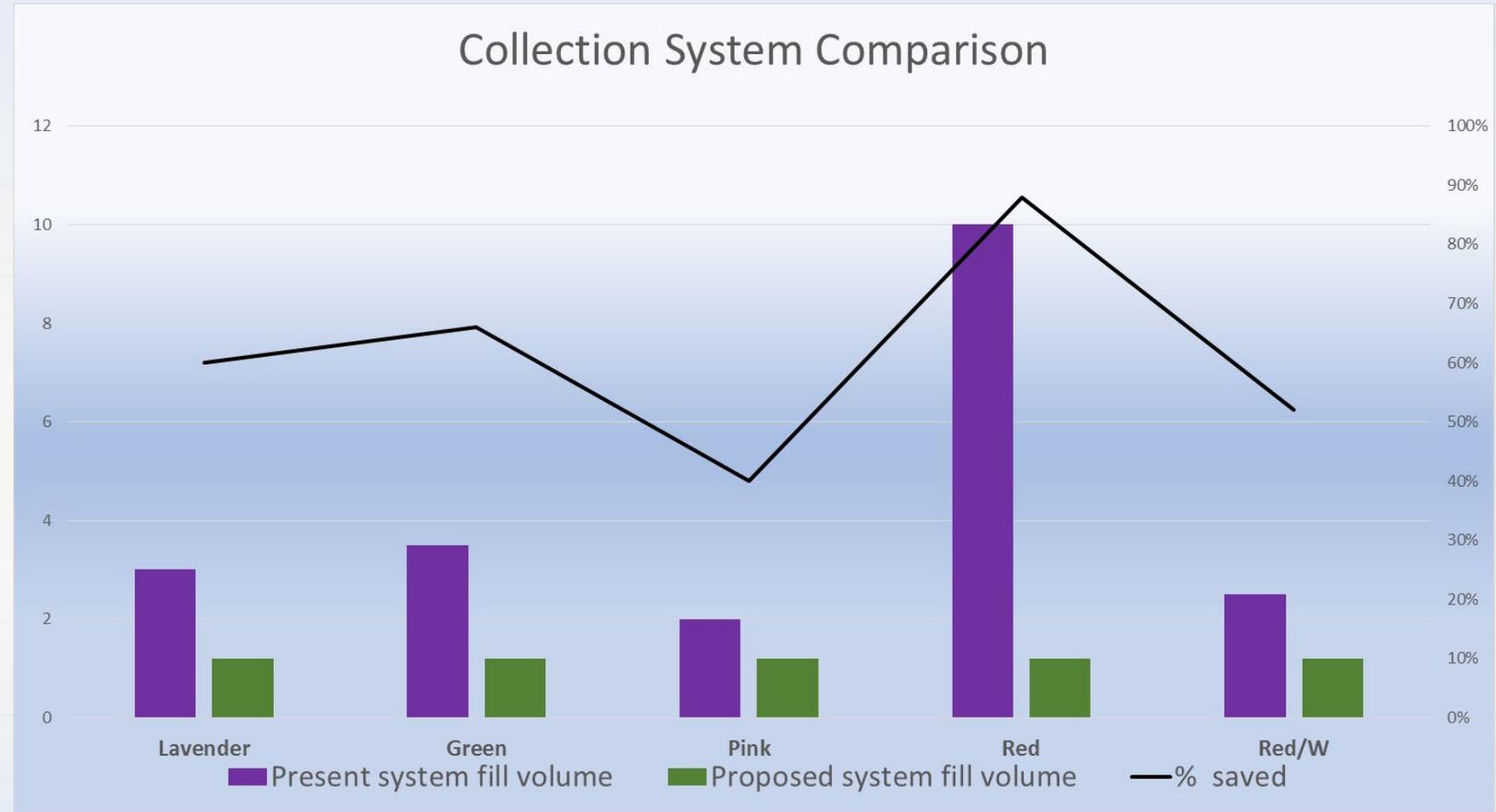
† For research, 'Volume (in mL)' indicates 'Collected Volume'; this information is provided in real-time.

For more information: [Patient Blood Volume Collection Summary](#)

# Market Analysis: Available collection systems

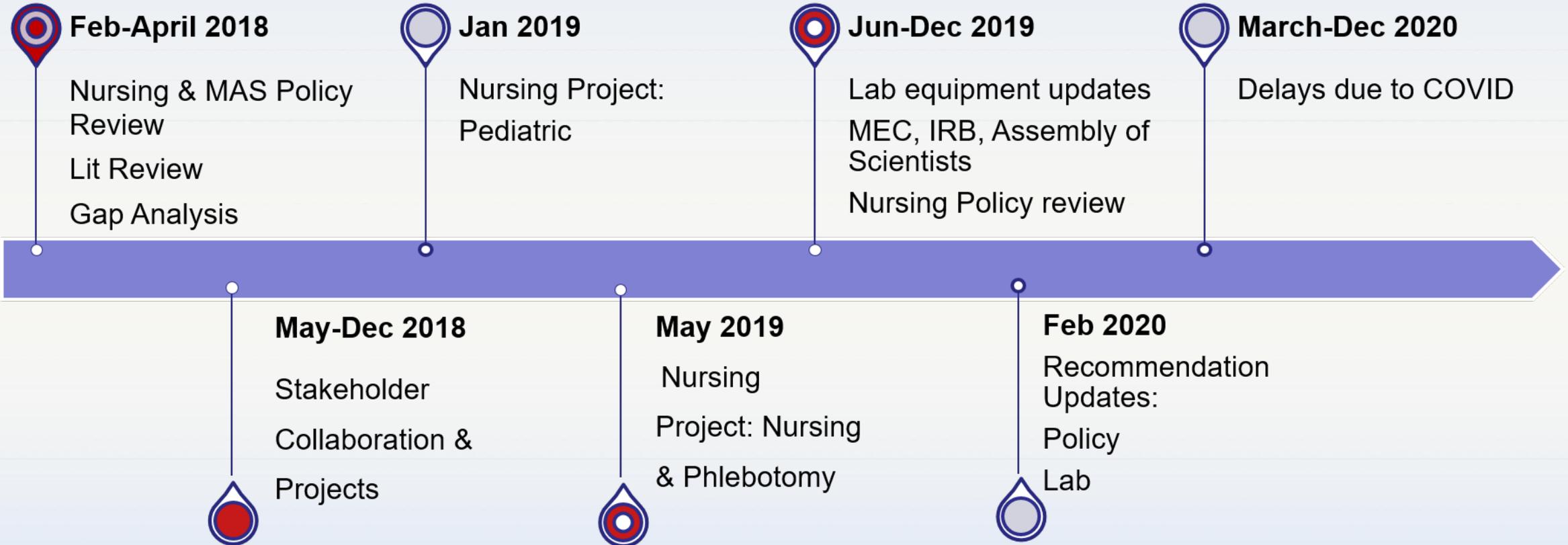
- Low volume tubes need <1.2 mLs
- If our current tubes were **converted to low volume tubes, only 1.2mL** is needed for each.

**Potential blood volume saving between 40 - 94%**





# Project Review



# Questions



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