



**PHARMACY  
VISION  
20/20**

CSHP SEMINAR 20 • OCTOBER 21-25  
**Disneyland**  
RESORT

# SETTING UP A CONTROLLED SUBSTANCE DIVERSION PREVENTION OVERSIGHT PROGRAM

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**LUCILE PACKARD CHILDREN'S HOSPITAL**



# DISCLOSURE

I have no potential conflict of interest (COI).

# LEARNING OBJECTIVES

At the end of this session, the attendee will be able to :

- Identify three key members of the Controlled Substance Diversion Prevention Oversight Committee (CSDPOC)
- Determine metrics to measure improvement in compliance in identified gaps
- Apply the strategies discussed in this presentation to your specific institution
- Understand potential challenges associated with implementing the committee

# TEST QUESTION #1

Which of the following key stakeholders should be included as core members of the CSDPOC? Select all that apply.

- a. Nurse Leadership
- b. Security
- c. Pharmacy
- d. Anesthesia

# TEST QUESTION #2

Which of the following are **not** metrics that can improve compliance in identified gaps?

- a. Percent compliance
- b. # of discrepancies
- c. # of documentation errors
- d. Reported number of employee sick days

# TEST QUESTION #3

What are potential challenges faced with implementing a CSDPOC?

- a. Staff turnover
- b. Pandemic
- c. Leadership support
- d. Budget restrictions
- e. All of the above

# LUCILE PACKARD CHILDREN'S HOSPITAL (LPCH)

- Private, non-profit women and children's hospital
  - Located in Palo Alto, California
- Acute, quaternary care academic medical center
- Affiliated with Stanford Medicine
- 397 licensed beds





# DIVERSION PREVENTION

# DIVERSION PREVENTION

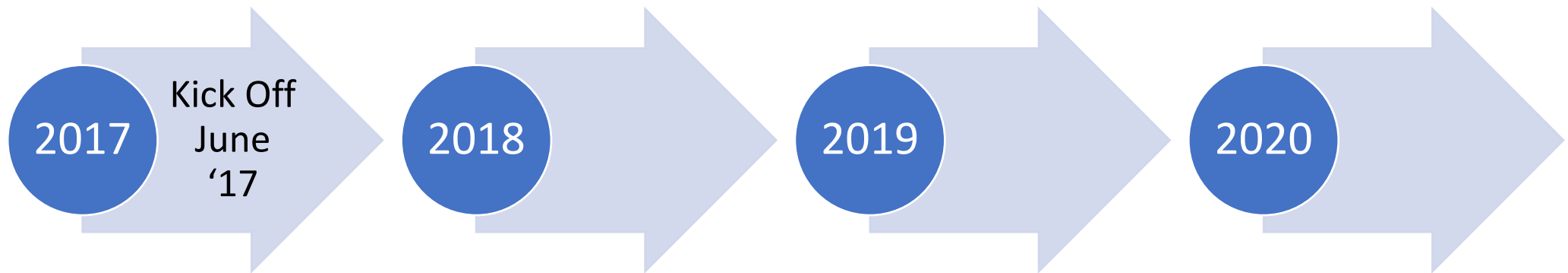
- Adverse impact on patients, health care workers (HCW), hospitals and public care
- Employee Risk
- Regulatory
- Hospital fines

1. *J. Hosp. Med.* 2019 July;14(7):419-428. Published online first June 12, 2019. | DOI 10.12788/jhm.3228

# MULTIDISCIPLINARY COMMITTEE

- Key stakeholders from nursing, pharmacy and anesthesia leadership invited to join

# TIMELINE OF CONTROLLED SUBSTANCES DIVERSION PREVENTION OVERSIGHT COMMITTEE (CSDPOC) AT LPCH



# BACKGROUND – DEA FINDINGS AND WARNINGS



2018 DEA Warnings – University of Michigan Hospital Drug Diversion Civil Penalty Case – record breaking 4.3M

- “Anything short of full compliance [Controlled Substance Act, 21 U.S.C. §§801-904] can have grave public health consequences. This case should alert all health systems – large or small – that complying with the Controlled Substance Act is not only their legal responsibility but also a matter of public trust.”

2. Drug Enforcement Agency (DEA) Press Releases 2018/08/30

# GOALS

- Guide assessment of drug processes against known vulnerabilities
- Identify safeguards that may improve capacity to prevent or detect diversion

1. *J. Hosp. Med.* 2019 July;14(7):419-428. Published online first June 12, 2019. | DOI 10.12788/jhm.3228

# CHARTER STATEMENT

- Oversight of diversion prevention, detection and response activities at LPCH
- Review and track methods of surveillance/auditing
- Review policies and procedures pertaining to controlled substances (CS)
- Review analysis of each diversion event and approve corrective action plans
- Report to Pharmacy and Therapeutics Committee and other hospital committees as needed

3. Presenter data on file.

# CORE COMMITTEE MEMBERS

- Chief Nursing Officer (CNO)/ Assistant Chief Nursing Officer (ACNO)
- Anesthesiologists
  - Pediatrics (Peds)
  - Obstetrics (OB)
- Pharmacy
  - Director of Pharmacy
  - Assistant Director of Pharmacy
  - Committee Lead (Controlled Substance Pharmacist)
- Regulatory/Compliance

# AD HOC COMMITTEE MEMBERS

- Employee Labor Relations
- Security
- Risk Management
- Administration
- Legal
- Media/Communications
- Employee Health
- Information Systems
- Infectious Disease
- Housekeeping

## EXAMPLES OF COMMON RISK POINTS FOR DIVERSION

Procurement

Preparation  
and  
Dispensing

Prescribing

Administration

Waste and  
Removal

4. Am J Health-Syst Pharm. 2017; 74:325-348

## Administration

- CS are withdrawn from an automated dispensing cabinet (ADC) on discharged or transferred patient
- Medication documented as given but not administered to patient
- Waste is not witnessed and subsequently diverted
- Substitute drug is removed and administered while CS is diverted

# Waste and Removal

- CS waste is removed from unsecure waste container
- CS waste in syringe is replaced with saline
- Expired CS are diverted from holding area

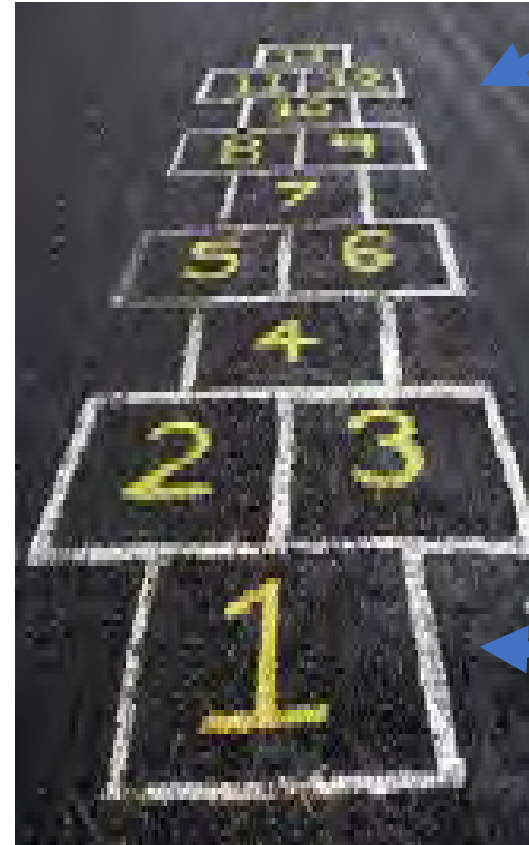


# COMMITTEE FOCUS

# OVERSIGHT OF DIVERSION PREVENTION, DETECTION AND RESPONSE ACTIVITIES

## Administration of Medications:

- Access to controlled substances
- Granting and Removing Access



Administration is one of the final steps to controlled substance management

Access is Step 1

# UNDERSTANDING THE WORKFLOW

## **Dose reconciliation:**

Amount Issued = Amount Administered + Waste or returned

## **Waste requirement:**

All controlled substances require a witness to waste

## **Understanding technology and workflow:**

In-service to Employee Labor Relations (ELR) about ADC and waste documentation

# WASTE DOCUMENTATION

Wasting Medication for Unit, Training  
Allergies: Unknown - Check MAR

Morphine (Training) 10mg/1ml 1ml Vial

Outstanding Issued Amount: 10 mg

Administration Amount: **6 mg**

Waste Amount: **4 mg**

Waste Reason:

Administration Amount = 6 mg

Waste Amount = 4 mg

Enter the amount of waste and the administration amount. Also, enter the reason for waste, or select from list.

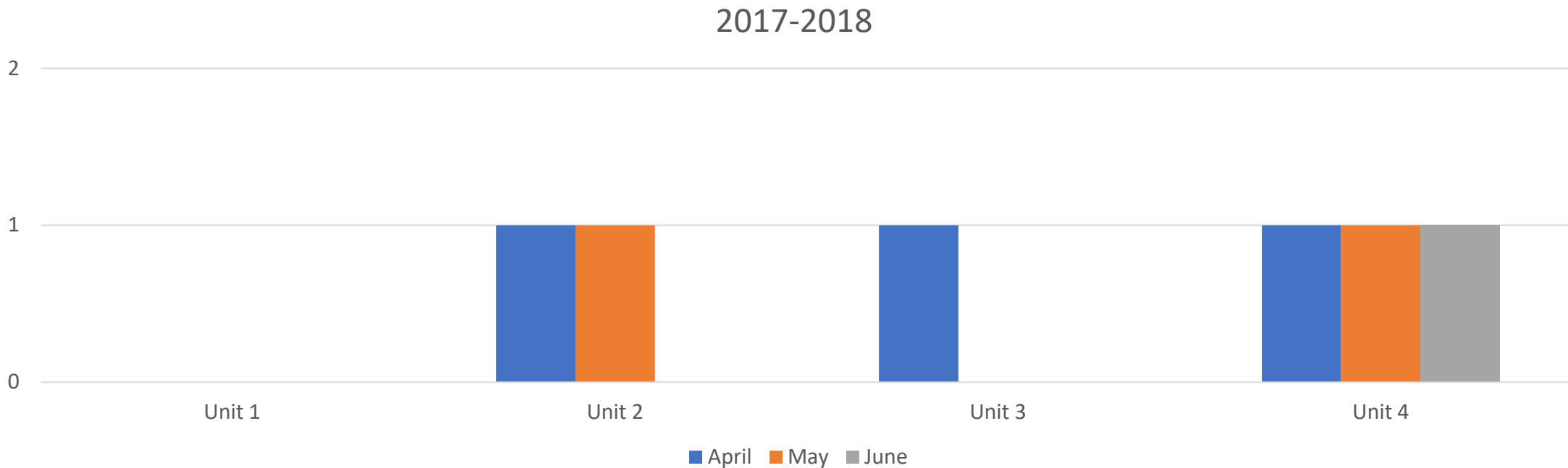
# GAPS IN STRATEGIES

# CONTROLLED SUBSTANCES: CONTROLLED DRUG AUDITS POLICY

“Controlled drug access and usage will be audited on a regular basis to monitor accountability and documentation of controlled drugs as well as to identify potential misuse or diversion.”



# PATIENT CARE UNIT NON-COMPLIANCE IDENTIFIED



# CONTROLLED DRUG AUDITS POLICY

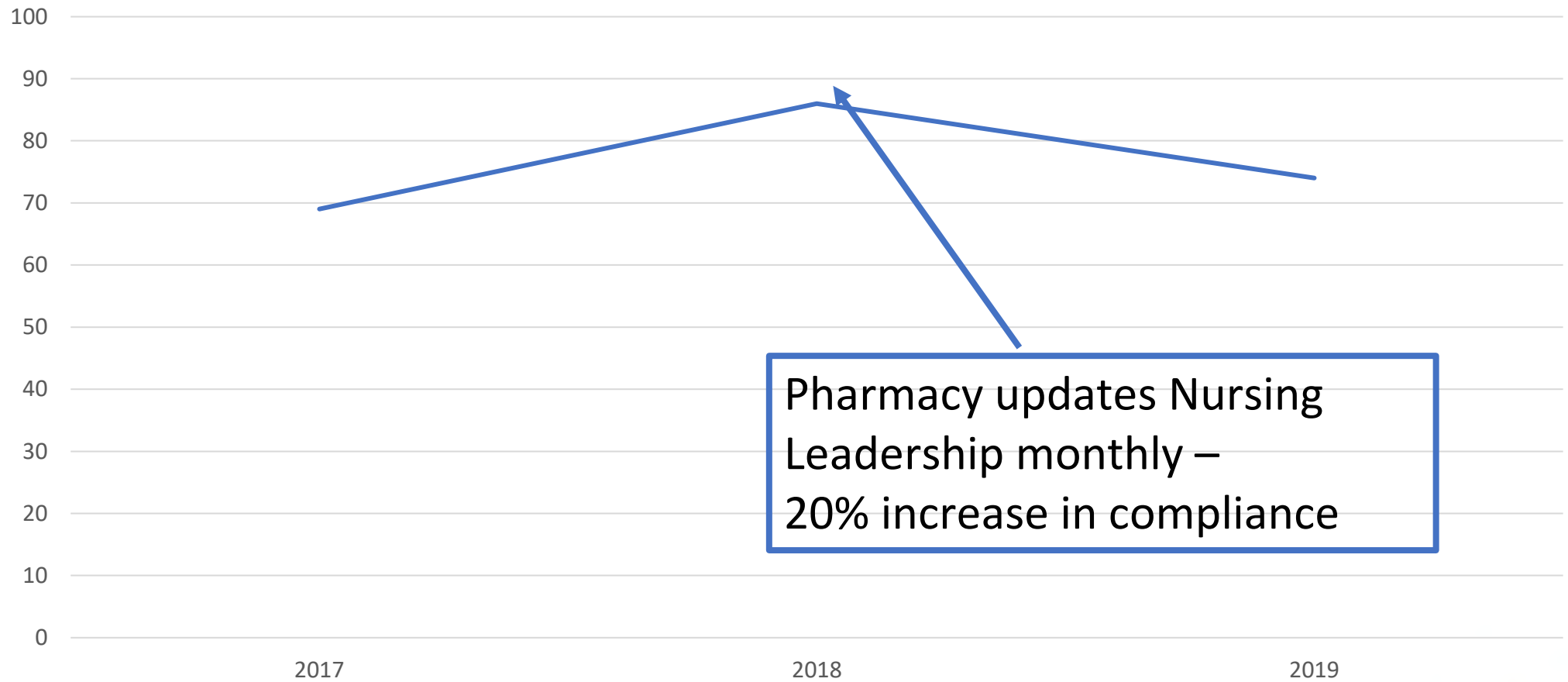


# MONTHLY UPDATE TO NURSING LEADERSHIP

Provided updates on non-compliance

- Patient Care Units
- Identified month(s) of audits

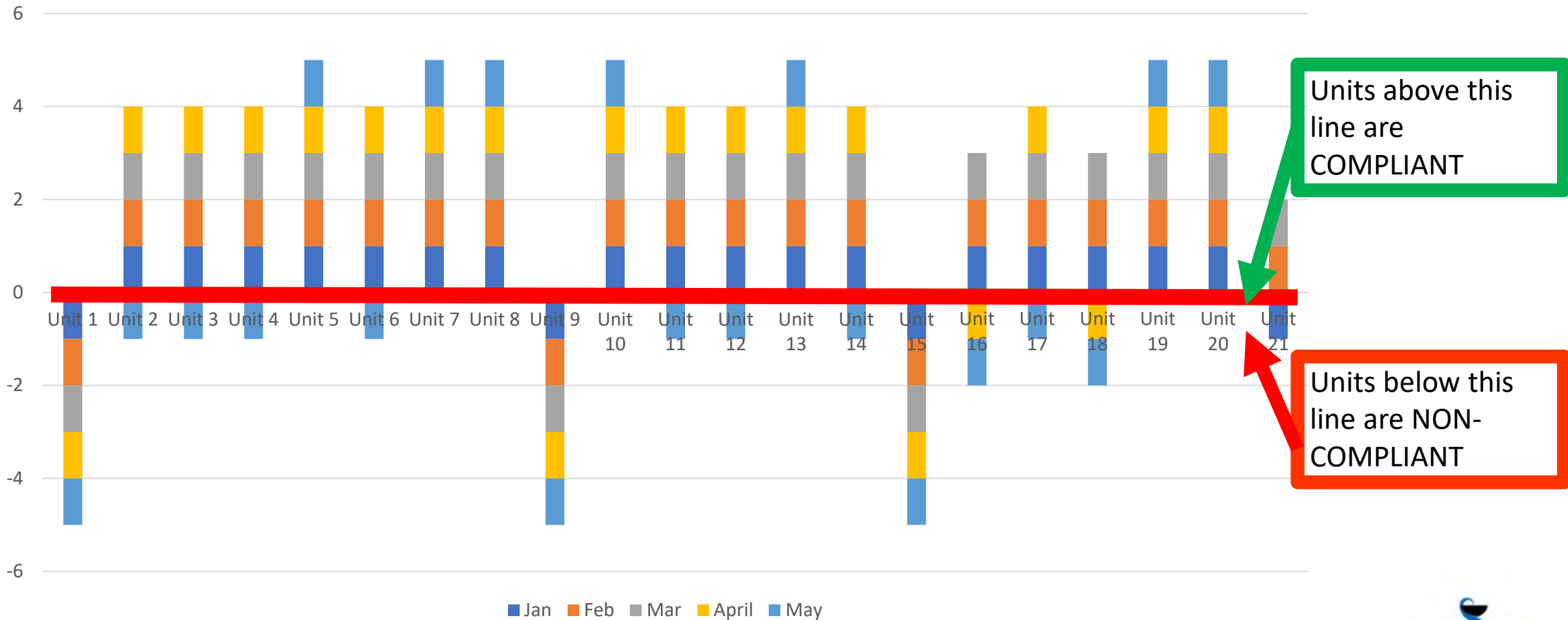
### % Compliance\*





# HOW DO WE PROVIDE THE DATA IN A MORE MEANINGFUL WAY?

## Summary of Audits as of 7/7/2020



Units above this line are COMPLIANT

Units below this line are NON-COMPLIANT

# CONTROLLED SUBSTANCES: CONTROLLED DRUG POLICY

Weekly cycle counts of CII-CV medications will be performed



# WEEKLY CYCLE COUNT NON-COMPLIANCE

1/30/19

16 cabinets non-compliant

- Unit 1
- Unit 5
- Unit 7
- Unit 8
- Unit 10...



# WEEKLY CYCLE COUNT NON-COMPLIANCE

7 cabinets non-compliant

| As of 5/7/19 | Last Cycle Count |
|--------------|------------------|
| Unit 1       | 1/7/19           |
| Unit 3       | 2/12/19          |
| Unit 6       | 4/29/19          |
| Unit 8       | 4/29/19          |
| Unit 11      | 3/24/19          |
| Unit 20      | 4/29/19          |
| Unit 22      | 4/27/19          |

Overflow units – not always open

# SET UP AUTOMATED CYCLE COUNT NON-COMPLIANCE REPORTS IN ADC

| Cabinets Reported with Non-compliance | As of 8/14/19 |
|---------------------------------------|---------------|
| Unit 2                                | 7/15/19       |
| Unit 4                                | 8/5/19        |
| Unit 6                                | 8/5/19        |
| Unit 8                                | 7/29/19       |
| Unit 10                               | 8/5/19        |

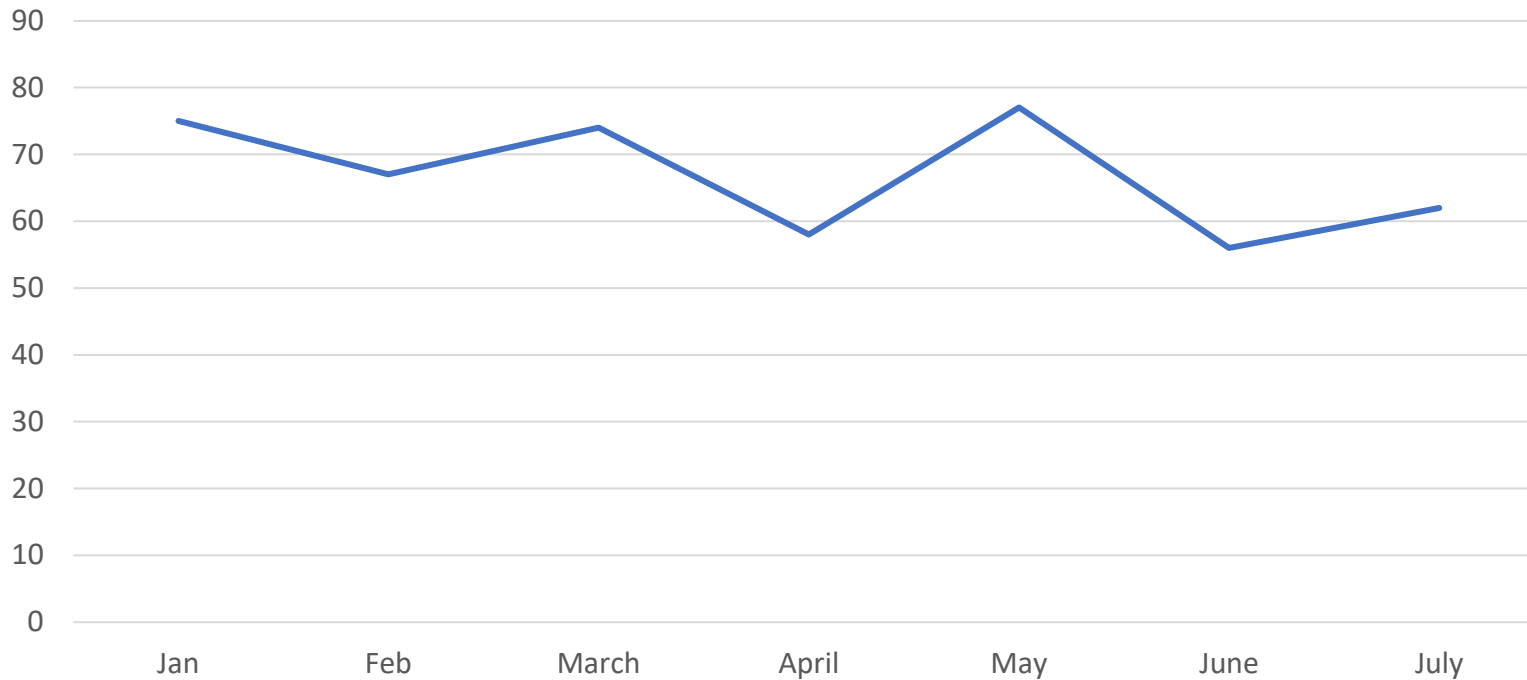
# ANESTHESIA IN PEDS AND OB

# PERI OP (PEDIATRIC ANESTHESIA)

- # of Controlled Substances issued from pediatric anesthesia machines
- Post Case Reconciliation (PCR) audits conducted M-F by Operating Room (OR) Pharmacist
- Dose Documentation Errors: Issued  $\neq$  Administered + waste
- Time consuming

# PERI OP PEDS ANESTHESIA JAN – JULY 2019

Narcotic Documentation Errors Jan-July 2019\*



Reported to

- Anesthesia Oversight Committee
- CSDPOC

# DIVERSION DETECTION SOFTWARE: THE FOUR W'S (WHO? WHY? WHERE? WHEN?)

## Who?

- Key stakeholders presented with Diversion Detection Software
- Approved via Committee with Pharmacy Support

## Why?

- Improve reconciliation to goal of 100%

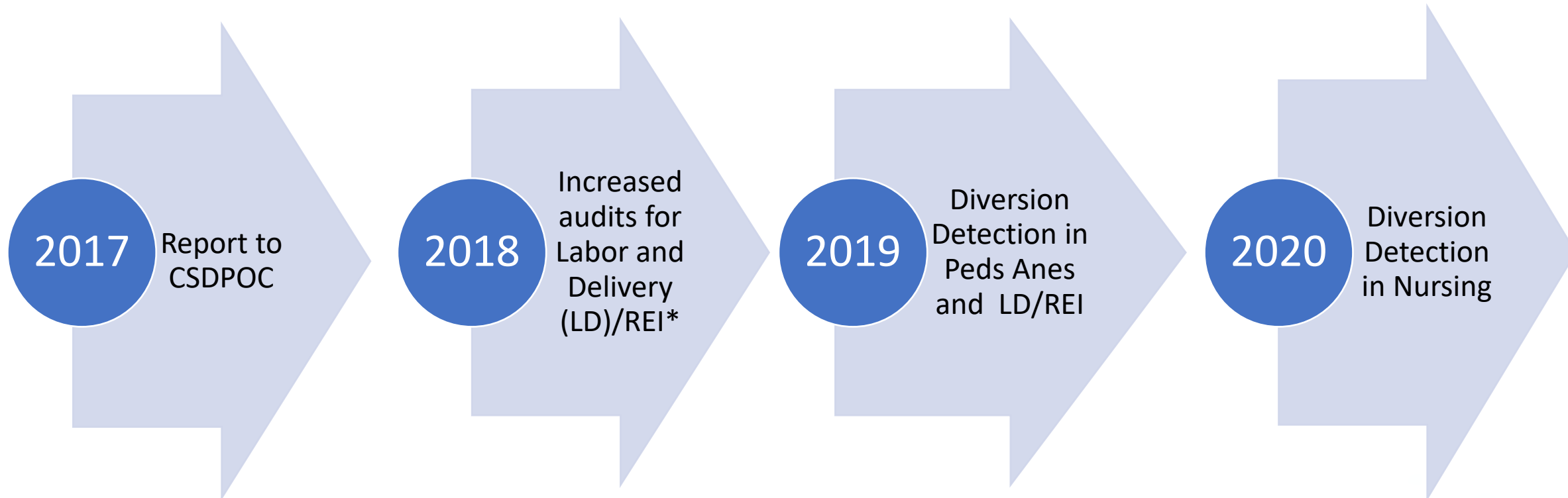
## Where?

- Anesthesia and Nursing

## When? Implementation Strategy

- Anesthesia → Nursing

# DOSE RECONCILIATION



# DIVERSION DETECTION SOFTWARE

- DEA, CMS<sup>1</sup>, JC<sup>2</sup> compliant
- Integration of electronic health record and automated dispensing cabinet data
- Complete audit coverage of OR, nursing and hospital procedural areas
- Ability to view discrepancies easily
- Option to email managers directly from site
- Dashboard
- Artificial Intelligence

# NUMBER OF CLOSED AND RECONCILED CASES Nov 2019- APRIL 2020

## Diversion Detection Software Terminology

- **Open** = Administered  $\neq$  Issued/ waste
- **Closed – Diversion Software** = Auto closed, no issues
- **Closed – Reconciled** = Pharmacy resolved the issue and closed case

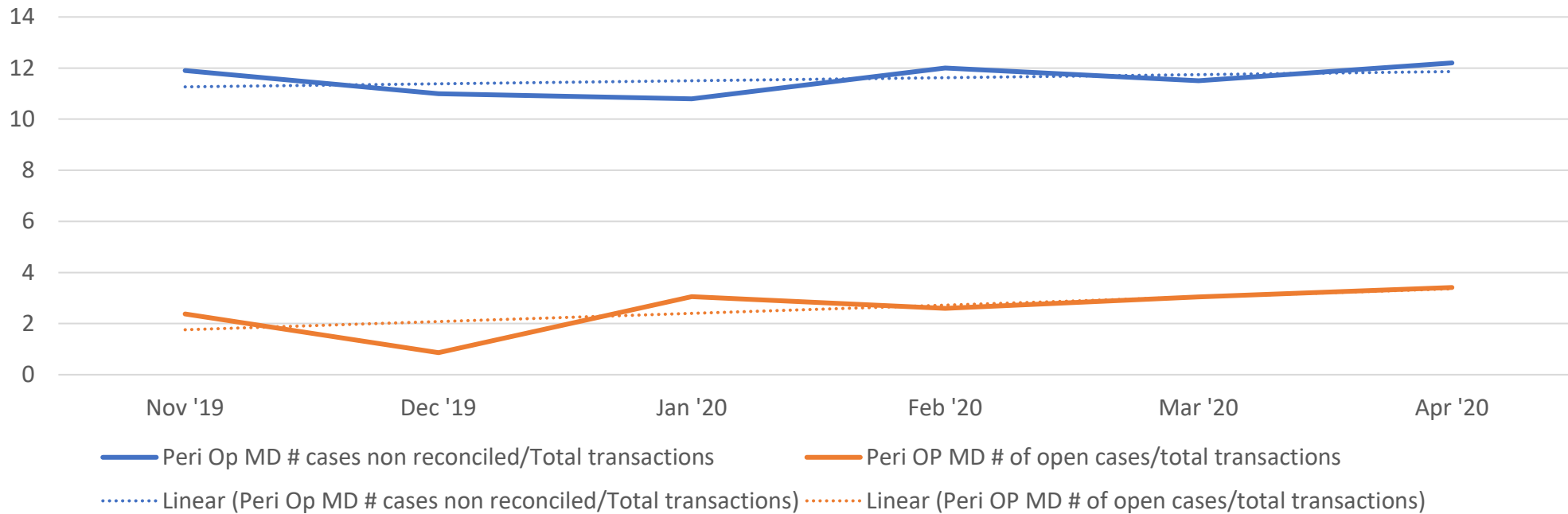
# NUMBER OF CLOSED AND RECONCILED CASES

## Nov 2019- APRIL 2020

- Majority of cases are auto reconciled by Diversion Detection Software
- Remaining cases are reviewed and reconciled by Pharmacist

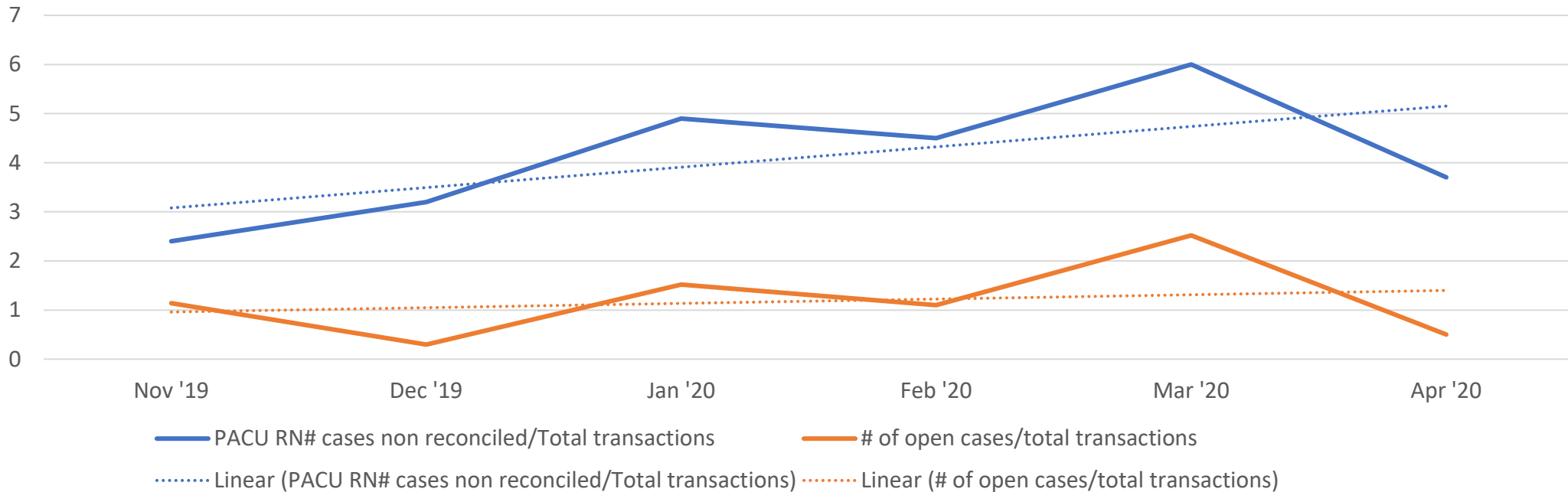
# PERI OP PEDS ANESTHESIA: NOV 2019- APRIL 2020

## Peri OP MD\*



# PERI OP PEDS ANESTHESIA: NOV 2019- APRIL 2020

## Peri Op RN\*



# DIVERSION DETECTION ANALYTICS

# DIVERSION DETECTION ANALYTICS

Artificial intelligence assigns individual ranking based on:

- Behavior patterns
- Documentation trends
- Other anomalous usage information

# COMMITTEE'S ROLE REGARDING DATA

## Access

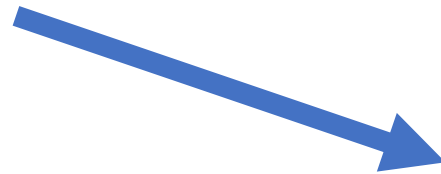
- Who will have access to data?

## Application

- How to use data?

# LEVEL OF RISK IS MULTIFACTORIAL

Diversion Detection  
Software can be a *useful tool*  
to accessing individual's  
level of risk





# EMPLOYEE LABOR RELATIONS – ACTIVE AND PAST CASES

# ANNUAL REPORTS OF ELR CASES - 2018

Monthly narcotic audits (1-2 nurses/month per patient care area)

## Examples

- Unit 1 (#4 nurses)
  - Dose not charted or wasted
- Unit 2 (#1 nurse)
  - Dose not charted or wasted



# EXAMPLE – MONITORING DASHBOARD

| Nursing Unit | Employee Name | Audit Month/Yr (xx/xx) | If Discrepancy found: Date Communicati on Tool Sent | If Discrepancy found: Date additional Audit sent | Tally    | Case Closed | Case Open | If Discrepancy found: Date Investigation completed |
|--------------|---------------|------------------------|-----------------------------------------------------|--------------------------------------------------|----------|-------------|-----------|----------------------------------------------------|
| Unit 1       |               |                        |                                                     |                                                  |          |             | 0         |                                                    |
| Unit 2       |               |                        |                                                     |                                                  |          |             | 0         |                                                    |
| Unit 3       | AC            | May -20                | 6/24/2020                                           | 6/24/2020                                        | 1        |             | 1         |                                                    |
| Unit 4       | DT            | May-20                 | 6/1/2020                                            | 6/1/2020                                         | 1        |             | 1         |                                                    |
| Unit 5       | EA            | Jan-20                 | 4/10/2020                                           | 4/22/2020                                        | 1        |             | 1         |                                                    |
| Unit 6       | DE            | Apr-20                 | 5/13/2020                                           | 5/13/2020                                        | 1        | 1           | 0         |                                                    |
| Unit 7       |               |                        |                                                     |                                                  |          |             | 0         |                                                    |
| Unit 8       |               |                        |                                                     |                                                  |          |             | 0         |                                                    |
| Unit 9       | TT            | Feb-20                 |                                                     |                                                  | 1        |             | 1         |                                                    |
| <b>Total</b> |               |                        |                                                     |                                                  | <b>5</b> | <b>1</b>    | <b>4</b>  |                                                    |

# DATA ISSUES

- What data is presented?
  - Frequency of updates
  - Is data useful?
    - # of discrepancies per unit (did not tell the complete story)

# COMMITTEE ANNUAL REVIEW

- Losses reported to DEA or Board of Pharmacy
- Summary of ELR investigations

# POTENTIAL CHALLENGES

- Staff Turnover
- Competing projects (hospital expansion)
- Pandemic
- Lack of hospital leadership
- Budget

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1. Nursing Leadership
2. Security
3. Pharmacy
4. Anesthesia

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What are potential challenges faced with implementing a CSDPOC?

- a. Staff turnover
- b. Pandemic
- c. Leadership support
- d. Budget restrictions
- e. All of the above

# TEST QUESTION #3

What are potential challenges faced with implementing a CSDPOC?

- a. Staff turnover
- b. Pandemic
- c. Lack of hospital leadership support
- d. Budget restrictions
- e. **All of the above**

# REFERENCE LIST

1. Fan M, Tscheng D, Hamilton M, Hyland B, Reding R, Trbovich P. Diversion of Controlled Drugs in Hospitals: A Scoping Review of Contributors and Safeguards. *J. Hosp. Med* 2019;7;419-428. Published online first June 12, 2019. doi:10.12788/jhm.3228.
2. Drug Enforcement Agency (DEA) Press Releases 2018/08/30.
3. Presenter data on file.
4. Brummond P, Chen D, Churchill W, Clark J, Dillon K, Dumitru D, Eschenbacher L, Fera T, Fortier C, Gullickson K, Jurakovich K, Kent S, Keonavong J, Marchese C, Meyer T, Murdaugh L, Ogden Jr R, O'Neal B, Rough S, Saenz R. *American Journal of Health-System Pharmacy*. 3/1/2017, Vol. 74 Issue 5, p325-348. 24p. 3 Diagrams. DOI: 10.2146/ajhp160919.

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