# Pharmacy Residency Project Pearls in Chicago

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# Provider experience and satisfaction with access to specialty medications

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No financial disclosures or conflicts of interest

## Objectives

- Describe the common characteristics of specialty medications
- Identify access barriers for specialty medications

## Background

- In 2015, nearly 50% of medications approved by the FDA were specialty medications
- Common characteristics of specialty medications include:
  - High cost
  - Targeted disease states
  - Complex monitoring and management
  - Limited access or distribution
  - Special claims processing - prior authorization (PA)

U.S. Food and Drug Administration. "Novel Drug Approvals for 2015". March 2016

## Background

**EMD Serono Specialty Digest Report (11th ed.)**

- Utilization management strategies
  - Prior authorization
  - Preferred products
  - Partial fill
  - Outcome based contracts
- ≥ 76% of healthcare plans utilize prior authorization for provider-administered drugs

EMD Serono. Managed care strategies for specialty pharmaceuticals. March 2015

## Residency Research Project

- Objectives
- Methods
- Results
- Discussion
- Future direction

## Study objectives

**Primary**

- Assess overall healthcare provider experience and satisfaction with access to specialty medications

**Secondary**

- Assess overall healthcare provider experience and satisfaction with specialty pharmacy services

***Access to specialty medications was defined as the ability of providers to obtain specialty medications and includes the following factors: **medication cost, prior authorization requirements, monitoring requirements, preferred pharmacies and limited distribution.**

## Methods

- Cross-sectional survey
- Surveyed physicians, nurses and pharmacists
- Two phases:
  - Phase 1 - Conducted at UIH
  - Phase 2 - Conducted at other institutions
- Exempt by UI Health IRB
- Descriptive statistics utilized to assess study endpoints. A significance level of 0.05 was assumed.

## Survey details

- Consisted of three parts
  - Part 1: Provider demographics
  - Part 2: Assessment of access barriers and specialty pharmacy services
  - Part 3: Suggestions to improve access barriers and specialty pharmacy services
- Average completion time of 10 minutes

## Results

**Phase 1**

- Conducted at UIH (inpatient and outpatient)
- 36% survey response rate
- 65% survey completion rate
- Sample size of 47 providers

## Table 1: Provider demographics

| | No. (%) |
|---|---|
| **Provider type (n = 46)** | |
| Physician | 13 (28.3) |
| **Pharmacist** | **26 (56.5)** |
| Clinical | 24 (92.3) |
| Dispensing | 2 (7.70) |
| Nurse | 7 (15.2) |
| **Practice setting (n = 47)** | |
| Inpatient | 8 (17.0) |
| **Outpatient** | **39 (83.0)** |
| **Length of practice experience with specialty medications (n = 46)** | |
| **< 5 years** | **24 (52.2)** |
| 5 – 10 years | 10 (21.7) |
| > 10 years | 12 (26.1) |
| **Presence of an onsite specialty pharmacy (n = 47)** | |
| **Yes** | **40 (85.1)** |
| No | 4 (8.50) |
| I don't know | 3 (6.40) |

## Summary of phase 1 results

- 34% of providers were satisfied or completely satisfied with access to specialty medications
- > 60% of providers indicated that **medication cost, prior authorization requests and preferred pharmacies** had a negative impact on their ability to provide patient care
- 55% of providers were satisfied or completely satisfied with specialty pharmacy services

## Results

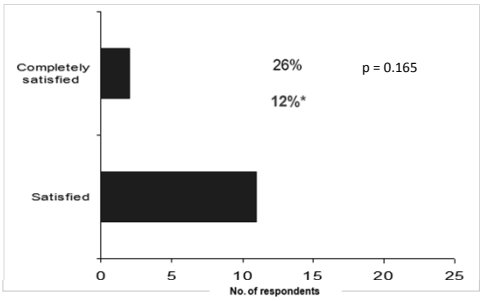
**Phase 2**

- Survey distributed via UHC consortium and ACCP ambulatory care PRN network
- ~6% survey response rate
- 45% survey completion rate
- Sample size of 50 providers

## Table 2. Provider demographics

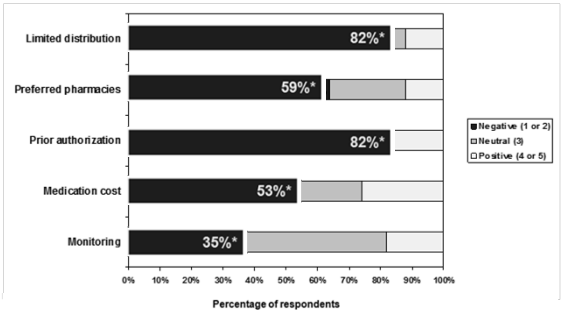
| | No. (%) |
|---|---|
| **Location by state (n = 45)** | |
| Western | 6 (13.3) |
| Mid-Western | **15 (33.3)** |
| Southern | 12 (26.7) |
| North-Eastern | 12 (26.7) |
| **Provider type (n = 49)** | |
| Physician | 2 (4.01) |
| Pharmacist | **45 (91.8)** |
| Nurse | 2 (4.01) |
| **Practice setting (n = 50)** | |
| Inpatient | 2 (4.00) |
| Outpatient | **41 (82.0)** |
| Inpatient and outpatient | 7 (14.0) |
| **Length of practice experience with specialty medications (n = 50)** | |
| < 5 years | **32 (64.0)** |
| 5 – 10 years | 7 (14.0) |
| > 10 years | 11 (22.0) |
| **Presence of an onsite specialty pharmacy (n = 50)** | |
| Yes | **32 (64.0)** |
| No | 17 (34.0) |
| I don't know | 1 (2.00) |

## Figure 1. Overall satisfaction with access to specialty medications (n = 50)



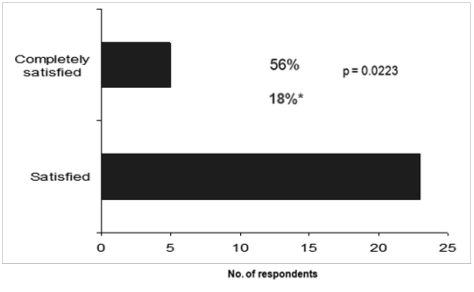

* Satisfaction rate (satisfied or completely satisfied) of providers without onsite specialty pharmacies

## Figure 2. Impact of access barriers on provider's ability to provide patient care (n = 50)



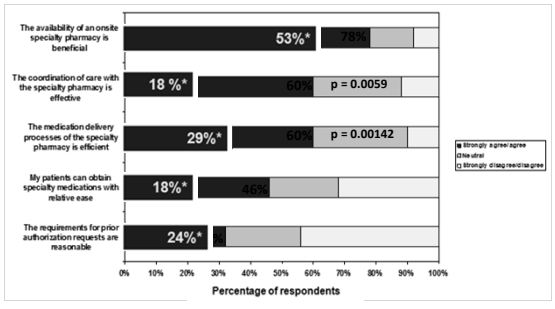

*Agreement rate (strongly agree or agree) of respondents without onsite specialty pharmacies

## Figure 3. Overall satisfaction with specialty pharmacy services (n = 50)



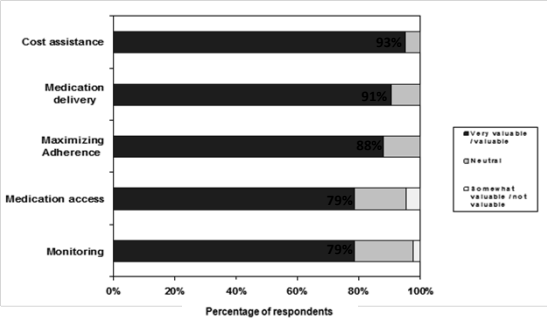

* Satisfaction rate (satisfied or completely satisfied) of providers without onsite specialty pharmacies

## Figure 4. Statements regarding access to specialty medications and specialty pharmacy services (n = 50)




*Agreement rate (strongly agree or agree) of providers without onsite specialty pharmacies

## Figure 5. Value of specialty pharmacy services (n = 42)




## Table 3. Prior authorization evaluation

| Phase 1 | All respondents (n = 32) | Non pharmacist respondents (n = 8) | P-value |
|---|---|---|---|
| Average time spent completing one PA submission (minutes) | 41.7 ± 37.3 | 66.9 ± 55.9 | 0.259 |
| Average time spent per day on PA claims (minutes) | 74.2 ± 83.6 | 101 ± 101 | 0.503 |
| **Phase 2** | **All respondents (n = 43)** | **Respondents without onsite pharmacy (n = 14)** | **P-value** |
| Average time spent completing one PA submission (minutes) | 34.8 ± 28.6 | 37.0 ± 32.9 | 0.147 |
| Average time spent per day on PA claims (minutes) | 157 ± 177 | 95.0 ± 115 | 0.783 |

## Table 4. Provider suggestions to reduce access barriers for specialty medications**

| Suggestion | Physicians (n = 6) | Pharmacists (n = 31) | Nurses (n = 3) | Total |
|---|---|---|---|---|
| **Eliminating preferred pharmacies and limited distribution** | - | 17 | 1 | 18 |
| Improve PA process/clearer rules for implementation | 1 | 4 | - | 5 |
| Having a pharmacist in clinic/personnel dedicated to PA duties | 2 | 3 | - | 5 |
| Improve coordination of care | 2 | - | 1 | 3 |
| Financial support for specialty pharmacies (grants)/reduce cost for patient | - | 2 | 1 | 3 |
| Presence of an onsite specialty pharmacy | - | 1 | - | 1 |
| Overall healthcare reform | 1 | - | - | 1 |
| Allow insurance companies have access to EHR data | - | 1 | - | 1 |
| Healthcare background requirement for insurance representatives | - | 1 | - | 1 |

**Combined results from phase 1 and phase 2

## Table 5. Provider suggestions to improve coordination of care between specialty pharmacies and specialty clinics**

| Suggestion | Physicians (n = 5) | Pharmacists (n = 21) | Nurses (n = 4) | Total |
|---|---|---|---|---|
| **Having a pharmacist in clinic** | **2** | **5** | **2** | **9** |
| Improve communication | 2 | 3 | 2 | 7 |
| Improve coordination of care between provider, specialty pharmacy and patient | 1 | 3 | - | 4 |
| Improve staffing of specialty pharmacy | - | 3 | 1 | 4 |
| Access to EHR | - | 3 | - | 3 |
| Onsite specialty pharmacy | - | 3 | - | 3 |
| Improve turnaround time for services (PA, delivery) | - | 3 | - | 3 |

**Combined results from phase 1 and phase 2

## Conclusion

- Preferred pharmacies, limited distribution, medication cost and PA process were perceived as access barriers that negatively impacted provider's ability to provide patient care
- Specialty pharmacy services were perceived as valuable or very valuable
- Absence of an onsite specialty pharmacy was associated with lower provider satisfaction with specialty pharmacy services
- Provider's suggestions:
  - Elimination of preferred pharmacies and limited distribution
  - Presence of pharmacists in specialty clinics

## Limitations

- Recall bias
- Survey response rate
- Sampling
- Reliability of survey questions- questions may not evoke reproducible answers

## Future direction

- ❖ Resend survey to increase physician and nurse participation
- ❖ Utilize results from phase 1 to improve services provided by UIH specialty pharmacy

## Post assessment question

Which of the following is a common characteristic of specialty medications?

A. High cost

B. Management of common disease states

C. Simple monitoring requirements

D. Open access or distribution

## Post assessment question

Which of the following is **NOT** a potential access barrier for specialty medications?

A. Prior authorization process

B. Medication cost

C. Preferred pharmacies

D. Bioavailability of the medications

## Acknowledgment

**Co-investigators**

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## Trends in Opioid and Non-steroidal Anti-inflammatory Drug Prescriptions Before and After an Opioid Safety Initiative

VA MedSAFE
VA Center for Medication Safety

## DISCLOSURES

I have no actual or potential conflict of interest in relation to this activity.

## RESEARCH TEAM

- Veronica Fassio, PharmD
- Fran Cunningham, PharmD
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- Donald Miller, ScD
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## BACKGROUND

- Opioid safety has received widespread attention
- Safety initiatives addressing opioid use may encourage utilization of non-opioid alternatives (e.g. NSAIDs)
- Risk for adverse events has also been noted for NSAIDs

## BACKGROUND

- Important to assess the use and safety of opioids and NSAIDs in a Veteran population

## OBJECTIVES

**#1** Discuss the PREVALENCE and INCIDENCE rates of NSAID and OPIOID USE in relation to the implementation of an opioid safety initiative

**#2** Estimate the risk of ADVERSE EVENTS typically associated with NSAIDs among incident NSAID and OPIOID users

## METHODS

**Design:**

Obj 1- Descriptive time series analysis

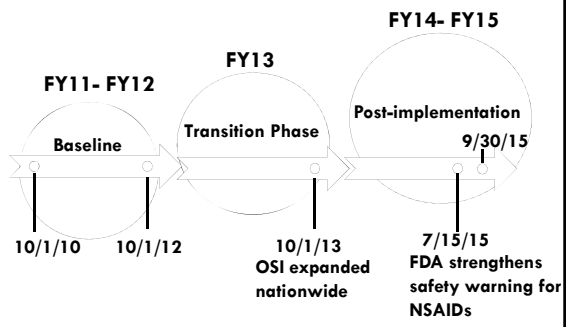
Obj 2- Retrospective cohort study

**Population:** Veterans, 18 years of age or older, who were regular users of VHA health care

**Study Period:** FY11-FY15

**Index Date:** Date of first opioid or NSAID prescription

## TIMELINE OF STUDY PERIOD




## METHODS (cont.)

**Outcomes:**

- Prevalence vs. Incidence Rates
  - Prevalent user = receiving drug during time period of interest
  - Incident user = sub-group of prevalent users; no opioids/NSAIDs during prior year
- Adverse Event Rates

**Table 1: Characteristics of Patients on an Opioid Only, NSAID Only, and NSAID plus Opioid at Index Date**

| | Total N=3,315,986 (col %) | Opioid Only N=1,669,853 (col %) | NSAID Only N=1,401,854 (col %) | NSAID and Opioid N=244,279 (col%) |
|---|---|---|---|---|
| % Users | | 50.4 | 42.3 | 7.4 |
| **Age** (years), mean (SD) | 55.8 (16.5) | 58.1 (14.0) | 53.5 (15.3) | 51.7 (15.2) |
| **Male** (%) | 91.9 | 93.5 | 90.2 | 90.4 |
| **Race** (%) | | | | |
| White | 63.9 | 67.1 | 60.2 | 63.1 |
| Black | 17.8 | 15.3 | 20.7 | 18.6 |
| Other | 3.1 | 2.9 | 3.3 | 3.0 |
| Unknown | 15.2 | 14.7 | 15.8 | 15.4 |
| **Hispanic** (%) | 6.1 | 5.1 | 7.3 | 5.9 |

**Table 1: Characteristics of Patients on an Opioid Only, NSAID Only, and NSAID plus Opioid at Index Date (cont.)**

| | Total N=3,315,986 (col %) | Opioid Only N=1,669,853 (col %) | NSAID Only N=1,401,854 (col %) | NSAID and Opioid N=244,279 (col%) |
|---|---|---|---|---|
| **Region** (%) | | | | |
| East | 16.8 | 16.1 | 18.0 | 14.4 |
| Central | 21.9 | 22.7 | 21.2 | 20.8 |
| South | 40.2 | 38.8 | 41.6 | 42.0 |
| West | 21.0 | 22.3 | 19.2 | 22.8 |
| **VHA Care Utilization** | | | | |
| Outpatient visits; mean, (SD) | 16.8(18.1) | 18.6 (18.4) | 14.5 (17.4) | 17.3 (18.6) |
| Hospitalization (%) | 12.6 | 15.6 | 7.1 | 9.8 |
| **Charleson Comorbidity Index**; mean, (SD) | 1.1 (1.6) | 1.5 (1.9) | 0.7 ( 1.1) | 0.8 (1.3) |

## KEY MESSAGES

- NSAID only users were predominantly younger, female, from a minority, utilized VHA care less often, and had less comorbidities vs. opioid users.
- Concomitant opioid and NSAID users were similar to the NSAID only users.

## PREVALENCE AND INCIDENCE

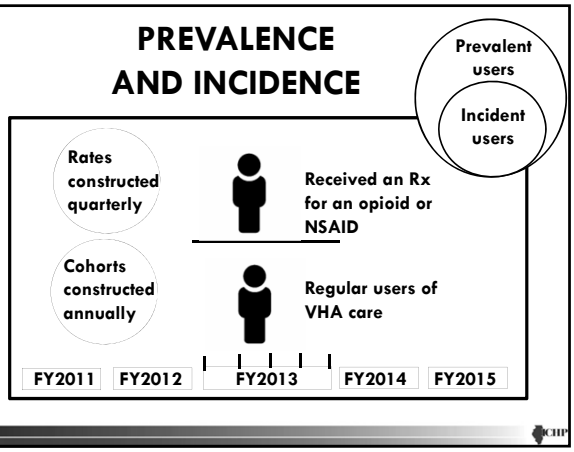


**Figure 1: Quarterly Prevalence Rates of Opioids and NSAIDs**

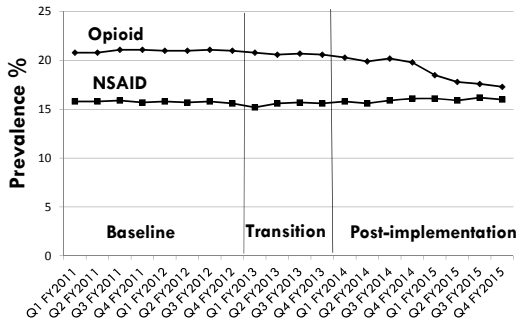
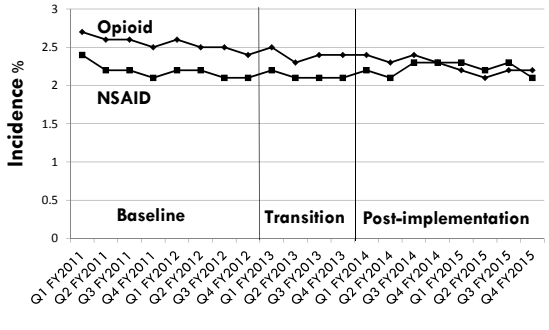



**Figure 2: Quarterly Incidence Rates of Opioids and NSAIDs**




## KEY MESSAGES

- Opioid use (prevalence and incidence rates) decreased after the start of the opioid safety initiative.
- NSAID use remained constant during the study period.

## ADVERSE EVENTS

**Cohort:** Incident users
- NSAID only = 979,303 patients
- Opioid only =1,155,527 patients

**Data Collection**: Cardiovascular events , GI bleed, Acute kidney injury

**Follow Up:** 1 year from index date

**Censoring:**
- Switches to NSAID/Opioid
- Multiple adverse events

**Table 2. Adverse Event Rates in Incident NSAID and Opioid Users within One Year**

| Adverse Event | Person-years | | No. of events | | Incidence rate (per 1000 person-years) | |
|---|---|---|---|---|---|---|
| | Opioid | NSAID | Opioid | NSAID | Opioid | NSAID |
| **Total** | 227969 | 239120 | 12497 | 3380 | 55 | 16 |
| **Cardiovascular** | 228876 | 239254 | 8032 | 2266 | 35 | 11 |
| MI | 230321 | 239539 | 1003 | 316 | 4 | 2 |
| Stroke | 230230 | 239504 | 1453 | 521 | 6 | 3 |
| Heart Failure | 229647 | 239482 | 3953 | 629 | 17 | 3 |
| ACS | 230385 | 239530 | 551 | 271 | 2 | 1 |
| Coronary Revascularization | 230245 | 239497 | 1072 | 529 | 5 | 3 |
| **Acute Kidney Injury** | 230025 | 239549 | 2230 | 314 | 10 | 2 |
| **GI Bleed** | 230068 | 239494 | 2033 | 691 | 9 | 3 |

## DISCUSSION/CONCLUSIONS

- Characteristics
  - NSAID users younger & healthier vs. opioid users
- Trends
  - Decrease in opioid initiation & increase in opioid discontinuation post OSI
  - No change in NSAID use
- Adverse events
  - Higher rates of adverse events among opioid users
  - Unanticipated adverse events for opioid users

## LIMITATIONS

- Incomplete capture of medication use and adverse events outside VA
- Descriptive statistics – no analysis done to adjust for confounding

## QUESTIONS?

Veronica Fassio – veronica.fassio1@va.gov

## REFERENCES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2. Jones CM, Mack KA, Paulozzi LJ. Pharmaceutical overdose deaths, United States, 2010. *JAMA*. 2013;309:657-9.
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## The Impact of Statin Use on Severity of Community-Associated *Clostridium difficile* Infection

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The speaker has no conflicts of interest to disclose

## Learning Objectives for Pharmacists and Technicians

- Recognize the evidence of statin use in hospital-associated *Clostridium difficile* infection (CDI).
- Define the Infectious Diseases Society of America (IDSA) guideline criteria and Zar criteria used to classify *Clostridium difficile* infection severity.

## Background

- *Clostridium difficile*: Gram positive, anaerobic, spore-forming
- *Clostridium difficile* Infection (CDI):
  - Diarrhea: ≥ 3 unformed stools in ≤ 24 hours
  - Stool test: toxigenic *Clostridium difficile*, toxin A & B
- Epidemiology (2011):
  - Estimated 453,000 cases annually
  - 29,300 deaths within 30 days of diagnosis

Lessa F. *NEJM* 2015.
Cohen S. *Infect Control Hosp Epidemiol* 2010.

## Classification of Severe CDI

**Infectious Diseases Society of America (ICHE 2010)**

Must meet ≥ 1 of the following:

- White blood cell count ≥ 15,000 cells/mcL
- Serum creatinine ≥ 1.5 times baseline level

**Fred A. Zar Criteria (CID 200**

Must obtain ≥ 2 points:

**1 point:**

- Age > 60 years old
- Temperature > 38.3°C
- Albumin < 2.5mg/dL
- White blood cell count > 15,000 cells/mcL

**2 points:**

- CDI treatment in ICU
- Pseudomembranous

## Pleiotropic HMG-CoA Reductase Inhibitor (Statin) Effects

- Cardiovascular benefit beyond reduction in cholesterol
- Immunomodulatory effects:
  - Reduce T cell proliferation and differentiation
  - Prevent cytokine transcription
- Clinical application:
  - Graft rejection reduced in heart transplant

Palinski W. *JASN. 2002*
Arnaud C. *Current Drug Targets*. 2005

## Statins and Infection-Related Mortality

Statins are associated with reduced mortality:

- Bacteremia: 13% vs 24% p=0.001
- ICU patients: aOR =0.60 (95% CI: 0.36, 0.99)
- Pneumonia: aOR 0.86 (95% CI: 0.79, 0.93)

Nseir W. *Infection*. 2012
Rothberg MB. *J Gen Intern Med*. 2012
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## Statins and CDI

| Study | Population | Results | Conclusion |
|---|---|---|---|
| Motzkus-Feagans 2012 | 31,472 CDI 78,096 control | • 1/5 patients on statins<br>• CDI Risk w/ statins: aOR 0.78 (0.76-0.84)<br>• CDI risk w/ niacin, ezetimibe, fibrates: NS | Reduced risk of healthcare facility-onset CDI |
| Park 2013 | 949 statin user 750 controls | • Successful response: statin exposure OR 1.449 (1.02, 2.07)<br>• 60d CDI recurrence: RR 0.39 (0.167, 0.926) | Greater symptom resolution within 6 days, lower risk of recurrence |
| Nseir 2013 | 197 CDI 169 controls | • CDI: 32.5% statin user vs 51.5% control (p=0.02)<br>• CDI RF: Statin naïve OR: 2.2 (1.82, 2.73) | Lower risk of hospital-onset CDI |
| Saliba 2014 | 669 statin user 1219 naïve | • Overall 30d mortality: 18%<br>• Statin users 13.3% vs controls 20.6% (p <0.001)<br>• aOR 0.77 for each additional Rx filled | Reduced 30d all-cause mortality; greater benefits for long-term statin users. |
| Naggie 2011 | 66 CDI 114 controls | • Statins: 42% controls vs 27% cases (p=0.05)<br>• aOR=0.31 (0.11-0.84)<br>• 38% hospitalized, mean LOS 4.4 days | Risk Factors: statin nonusers, bowel surgery, antibiotics, household contacts |

Naggie S. *Am J Med*. 2011
Motzkus-feagans CA. *Gut*. 2012
Park SW. *Pharmacol Ther*. 2013
Nseir W. *Infection*. 2012
Saliba W. *Clin Microbiol Infect*. 2014

## Primary Study Question

**Is there a difference in community-associated CDI severity between outpatient statin users and nonusers who present to the hospital**

## Secondary Study Questions

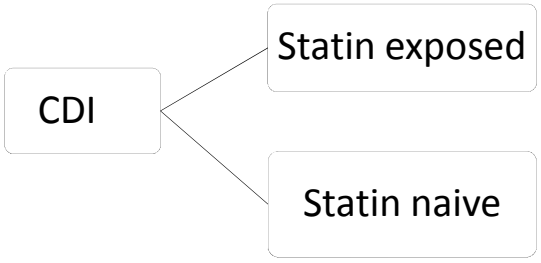
**Is there a difference between outpatient statin users and nonusers with community-associated CDI and clinical outcomes?**

- CDI therapy and duration
- Inpatient antibiotic use and duration
- Intensive care unit (ICU) admission
- ICU length of stay (LOS)
- Hospital LOS
- Use of vasopressors
- Disposition location
- Inpatient all-cause mortality

## Northwestern Memorial Hospital Chicago, Illinois

- 894-bed Academic Medical Center Hospital
- Primary teaching affiliate of Northwestern University Feinberg School of Medicine
- Fiscal Year 2015
  - Inpatient Admissions: 44,472
  - Emergency Room Visits: 86,022

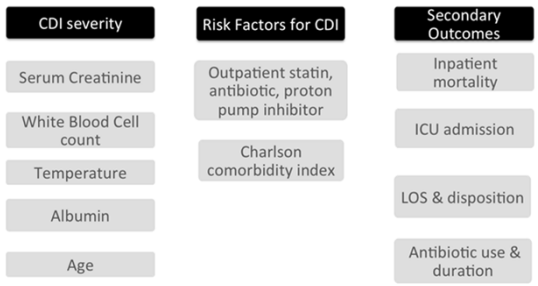
## Methods: Retrospective, single-center study




## Study Criteria

- Inclusion criteria:
  - Positive *C. difficile* PCR within 72 hours of admission
  - ≥ 18 y/o
- Exclusion criteria:
  - Transfer from outside hospital/long term care facility
  - Hospitalization ≤ 4 weeks prior to current admission
  - History of CDI
  - History of chronic diarrhea, irritable bowel syndrome (IBS), ulcerative colitis (UC), Crohn's disease (CD)
  - History of HIV infection

## Data Collection




## Statistics

Continuous variables:

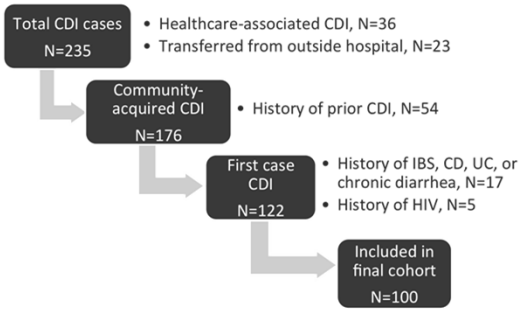
•Student's t-test

•Mann-Whitney U test

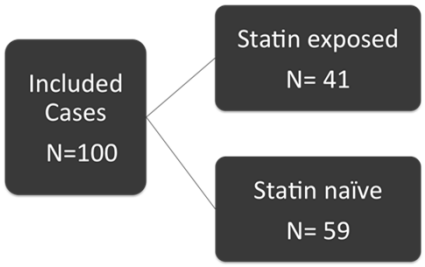
Categorical variables:

•Chi-squared test

## Results




## Results




## Patient characteristics of community-associated CDI

| Patient Characteristic | Statin users N=41 (%) | Statin naïve N=59 (%) | P-value |
|---|---|---|---|
| Male | 24 (58.5) | 25 (42.4) | 0.112 |
| Age [Mean ± IQR] | 63.8 ± 17.1 | 57.7 ± 17.9 | 0.092 |
| Race | | | |
| White | 13 (31.7) | 27 (46.6) | 0.138 |
| African American | 7 (17.1) | 6 (10.2) | 0.313 |
| Hispanic | 0 (0) | 2 (3.4) | 0.234 |
| Asian | 1 (2.4) | 0 (0) | 0.228 |
| Other | 20 (48.8) | 23 (38.9) | 0.330 |

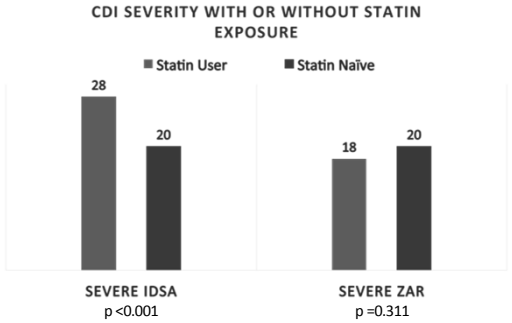
## Patient characteristics of community-associated CDI

| Patient Characteristics | Statin users N=41 (%) | Statin naïve N=59 (%) | P-value |
|---|---|---|---|
| Coronary artery disease | 17 (41.5) | 6 (10.2) | <0.001 |
| Diabetes Mellitus | 20 (48.8) | 15 (25.4) | 0.016 |
| Hypertension | 36 (87.8) | 27 (45.8) | <0.001 |
| Heart failure | 8 (19.5) | 6 (10.2) | 0.185 |
| Stroke | 7 (17.1) | 6 (10.2) | 0.313 |
| CKD stage 3 or greater | 13 (31.7) | 7 (11.9) | 0.015 |
| Dialysis | 4 (9.8) | 4 (6.8) | 0.589 |
| Liver disease | 2 (4.9) | 10 (16.9) | 0.068 |
| Charlson Comorbidity Index [Median (IQR)] | 5 (3-6) | 4 (2-6) | 0.072 |

## Patient characteristics of community-associated CDI

| Patient Characteristic | Statin users N=41 (%) | Statin naïve N=59 (%) | P-value |
|---|---|---|---|
| Outpatient antibiotics | 3 (7.5) | 9 (15.3) | 0.246 |
| Outpatient PPI | 15 (36.6) | 18 (30.5) | 0.525 |

## Primary outcome



## Clinical Outcomes

| | Statin users N=41 | Statin naïve N=59 | P-value |
|---|---|---|---|
| Type of CDI treatment [N (%)] | | | |
| PO Metronidazole | 25 (60.9) | 32 (54.2) | 0.503 |
| PO Vancomycin | 19 (46.3) | 23 (38.9) | 0.463 |
| IV Metronidazole | 15 (36.6) | 13 (22.0) | 0.111 |
| PR Vancomycin | 1 (2.4) | 1 (1.7) | 0.794 |
| Days of CDI therapy [Median (IQR)] | 4 (2-6) | 4 (1-6.5) | 0.608 |
| Days of inpatient antibiotics [Median (IQR)] | 3 (1-5) | 3 (1-5) | 0.162 |
| ICU admission [N (%)] | 9 (22.5) | 13 (22.0) | 0.956 |
| ICU LOS [Median (IQR)] | 4 (1-4) | 4 (2-7) | 0.664 |
| Hospital LOS [Median (IQR)] | 4 (3-7) | 4 (2-7) | 0.252 |
| Vasopressor use [N (%)] | 1 (2.4) | 5 (8.5) | 0.211 |
| Discharge Home [N (%)] | 31 (75.6) | 48 (84.2) | 0.288 |
| In-Hospital Death[N (%)] | 2 (4.9) | 1 (1.7) | 0.359 |

## Conclusions

- Statin users were more likely to have severe CDI per IDSA criteria
  - Statin users displayed greater increases in baseline serum creatinine
- No difference CDI severity with Zar criteria
- No differences in clinical outcomes based on statin use
- Healthy user effect not observed

## Limitations

- Definition of baseline serum creatinine
- Capturing recent hospitalizations at outside hospitals
- Retrospective
- Limited sample size

## Next Steps

- Expanded sample size: matched cohorts or stratification by comorbidities and demographics
- Evaluate outpatient healthcare exposure

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## The Impact of Statin Use on Severity of Community-Associated *Clostridium difficile* Infection


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Northwestern Memorial Hospital

## Self-Assessment Question #1

Which of the following has been reported in the literature as a significant outcome of statin users and hospital-associated CDI?

A. Faster symptom resolution
B. Higher risk of hospital-onset CDI
C. Increased risk of recurrence of hospital-associated CDI
D. Reduced 30 day all-cause mortality

## Self-Assessment Question #2

Which of the following laboratory or physical finding is involved in assessing CDI severity through the Zar criteria?

A. Serum creatinine
B. Heart rate
C. Body temperature
D. Neutrophil count

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## Creation of a multidisciplinary controlled substances diversion prevention and detection taskforce


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## Disclosure

- The author of this presentation has no actual or potential conflicts of interest

## Objectives

- Explain the importance for the creation of the diversion prevention and detection taskforce
- List the tasks assigned to the diversion prevention and detection taskforce

## NorthShore University HealthSystem

- Four community hospitals with pharmacy services in
  - Inpatient
  - Outpatient
  - Oncology infusion
  - Oncology outpatient
- NorthShore Medical Group
- NorthShore Research Institute
- NorthShore Foundation

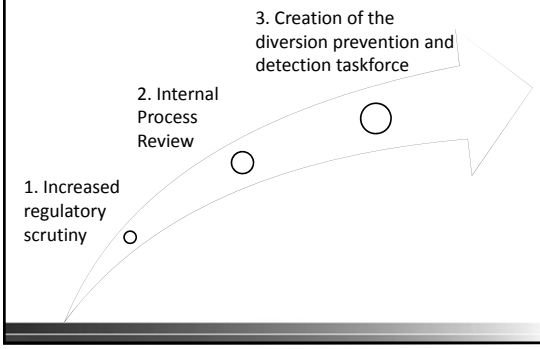

## How many people believe drug diversion is a problem in the healthcare settings?

## Is there a drug diversion problem?

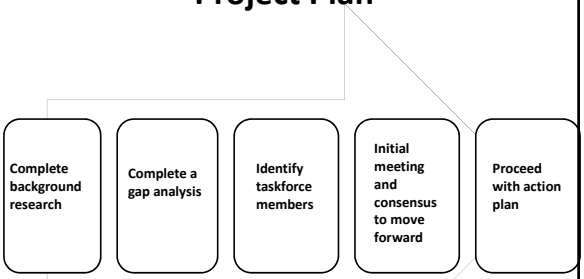
- The Drug Enforcement Agency estimates that prescription drug diversion is a "$25 billion-a-year industry"[1]
- About 1 in 10 health professionals struggle with addiction or drug abuse by using medications that are not prescribed for them[2]

1.*Pain Med* 2007 Mar; 8(2): 171–183.
2. US Department of Health and Human Services. Substance Abuse and Mental Health Services Administration. Office of Applied Studies. National survey on drug use and health, 2007.

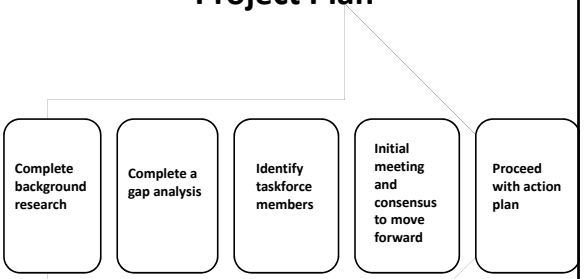
## NorthShore's Call to Action




## Project Plan




## Project Plan



## Why should hospitals care?

Patient harm
Financial burden
Negative publicity
Legal liability

Patient trust
Employee productivity
Accurate documentation
Regulatory compliance

Mayo Clin Proc. 2012 Jul;87(7):674-82

## Regulatory requirements

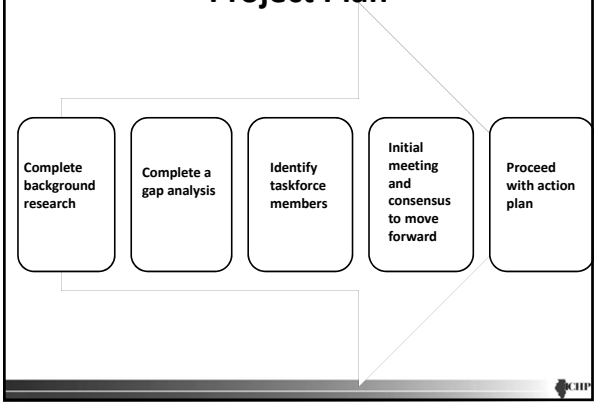
- Employee recruitment—background checks and drug screening
- Surveillance
- Limited access to the pharmacy
- Physical storage and security of controlled substances
- Recordkeeping
- Inventory control
- Reporting theft or loss of controlled substances

Title 21 U.S.C- Controlled Substances Act
225 ILCS 85 Pharmacy Practice Act
720 ILCS 570 Illinois Controlled Substances Act
The Joint Commission

## Creation of a diversion prevention and detection taskforce is important because it can assist to

A. Maximize patient safety
B. Ensure compliance with regulatory requirements
C. Minimize loss of resources
D. All of the above

## Project Plan




## Gap Analysis

Minnesota Hospital Association

Road Map to Controlled Substance Diversion Prevention 2.0

Patient Safety | Controlled Substance Diversion Prevention

## Review Current Practices

- Purchasing
- Receiving
- Distribution
- Administration
- Waste
- Other

## Purchasing Considerations

- How are medications are purchased?
- Who has the legal authority to order?
- Does each person with authority to order need it?
- Are the purchase orders reviewed for feasibility on a regular basis?
- Is the purchase history compared to utilization?

## Receiving Considerations

- Is there a separation of duty?
- Are the physical quantities delivered to the pharmacy compared to the invoice?
  - Who reviews it?
  - Is there documentation that the review occurred?
  - Is there a dual signature?
- Is there reconciliation of the physical quantity placed into stock against the invoice?

## Distribution Considerations

- How often are the controlled substances inventoried?
- Is there a perpetual inventory of all controlled substances?
- Is technology utilized to help with distribution?
- What areas/units are controlled substances distributed to?
- Is there documentation of the controlled substances dispensed for use in procedural areas?

## Administration Considerations

- Where is the administration of the medication documented?
- Is the documentation consistent across the various patient care areas?
- Is there reconciliation of medication removals from automated dispensing machines to administration?
- Is there reconciliation of the medication dispensed from the central pharmacy to the administration?

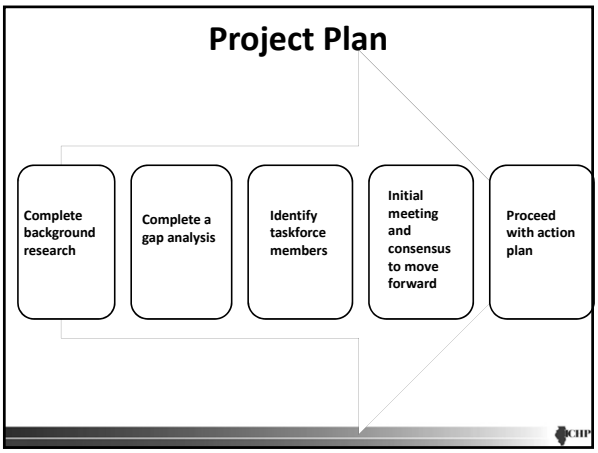
## Waste Considerations

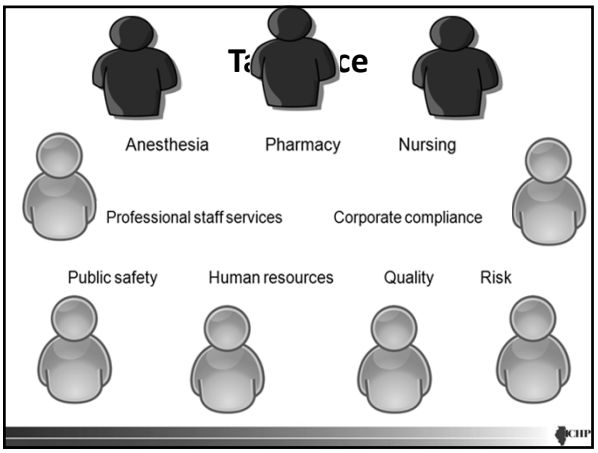
- Where is waste documented?
- Is a witness required to waste?
- Is the wasted tested for integrity?
- How is the wasted destroyed?
- Is the wasted reconciled with the documented quantity distributed and the amount administered?
- Is there reconciliation of the medications picked up by the reverse distributors?

## Other Considerations

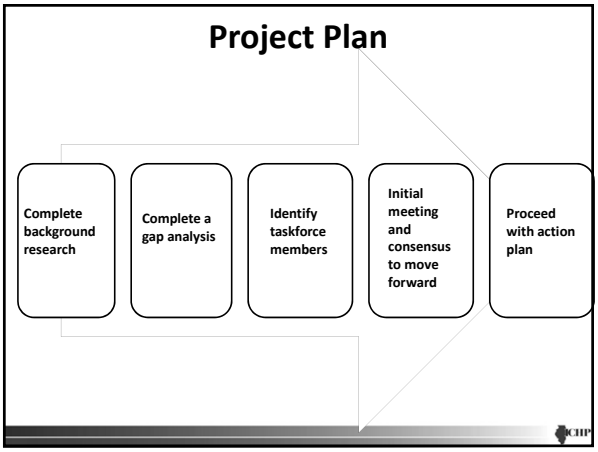
- Does the organization have a dedicated person for diversion prevention and detection activities?
- What audits are completed to detect diversion?
- Does the staff know the process to report suspected or identified diversion?
- Is the investigation process clearly outlined for the management team?
- Are there any policies and procedures in place related to controlled substances?
- Do the policies and procedures align with the regulations at a minimum?

## Project Plan



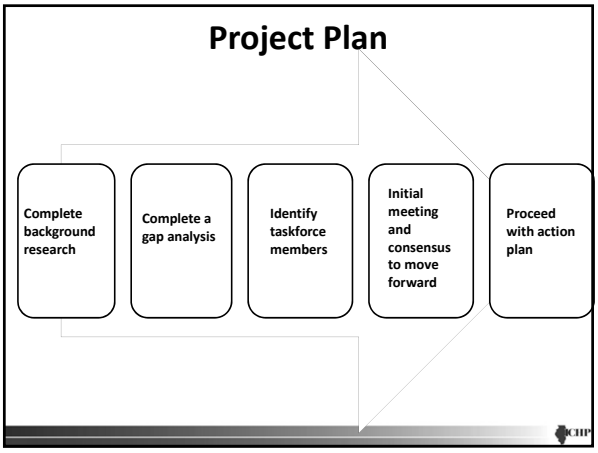

## Project Plan




## Taskforce Goals

| | |
|---|---|
| 1 | • Ensure mechanisms are in place to prevent diversion |
| 2 | • Develop a sustainable auditing plan to detect diversion |
| 3 | • Review policies and procedures related to controlled substances |
| 4 | • Update the investigation and response process |
| 5 | • Educate staff and promote awareness |

## Project Plan




## NorthShore's Action Plan

| Policies | Education | Audits |
|---|---|---|
| • Revise to better align with procedures<br>• Outline the investigation process<br>• Ongoing regular review | • Reinforce "Just Culture"<br>• Multidisciplinary grand rounds<br>• Annual education material | • Standardize across sites<br>• Define and delegate audit responsibilities<br>• Validate dashboard |

## Audit Results Dashboard

| | % of Audit Completed | Follow-up Items | Actions Taken |
|---|---|---|---|
| Purchasing<br>•Inventory Intake<br>•Buy/Sell Review | | | |
| Storage<br>• Weekly Pyxis inventory<br>• Stock Replenishment | | | |
| Distribution<br>• Pyxis Refill Reconciliation<br>• Anesthesia Kit Removal | | | |
| Administration<br>• Unreconciled Pyxis Dispense<br>• Patient Specific Dose-Admin | | | |
| Waste<br>• Anesthesia Waste Reconciliation<br>• Refractometer Testing | | | |

## Measurement of Success

- May change over time as the goals are revised and the program develops
- Currently: Increase in identification of diversion through the comprehensive auditing plan when compared to historical trends

## Identify which task will be completed by the diversion prevention and detection taskforce

A. Provide education about drug diversion
B. Complete weekly unit inspections
C. Assist in the annual pharmacy inventory
D. Review the medication purchase history

## Recommendations

- Engage the administrators by beginning the conversation in a proactive manner
- Utilize the resources available to determine the best practices for your organization
- Consider dedicated personnel to assist the with maintenance of the program

## Conclusion

- A multidisciplinary approach is preferred for proper management of controlled substances
- Leadership at NorthShore University HealthSystem recognize the importance of preventing and detecting diversion
- The creation of the multidisciplinary taskforce allowed the organization to identify key areas of focus to optimize the processes to prevent and detect controlled substance diversion

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- Christine Bloomfield, Director Accreditation and Licensure
- Elisa Juhasz, Manager Internal Audit
- Anthony Ringgold, Corporate Director Public Safety
- Peggy King, Assistant Vice President Risk Management
- Carrie Bradford, Senior Director Professional Staff & Service of Credentialing

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Minnesota Hospital Association

# Road Map to Controlled Substance Diversion Prevention 2.0

Patient Safety | *Controlled Substance Diversion Prevention*

# Road Map to Controlled Substance Diversion Prevention

Patient Safety | *Controlled Substance Diversion Prevention*

## Applies to health care professionals, patients, families, visitors, others.

| SAFE Component | Assessment Questions | Yes | No |
|---|---|---|---|
| **Safety Teams/ Organizational Structure** | 1a. The organization has an interdisciplinary team involved in developing and overseeing the CS DiversionPrevention Program. | ☐ | ☐ |
| | 1b. The CS Diversion Prevention Program includes prevention, detection, and investigation. | ☐ | ☐ |
| | 1c. The CS Prevention Program is reviewed by the team and updated at least annually. | ☐ | ☐ |
| | 1d. CS Diversion Prevention Program champions have been identified and have designated clear roles with expectations from the following areas:<br>• Medical staff<br>• Pharmacy<br>• Nursing<br>• Security<br>• Human Resources<br>• Patient safety/Risk Management/Compliance<br>• Administration<br>• Legal Ad hoc<br>• Communications Ad hoc | ☐ | ☐ |
| | 2a. The organization has a designated coordinator(s) for the CS Diversion Prevention Program. | ☐ | ☐ |
| | 2b. The coordinator(s) has dedicated time to serve in this coordination function. | ☐ | ☐ |
| | 2c. The organization has a team prepared to respond to suspected CS diversion situations. | ☐ | ☐ |
| | 2d. The organization has policies and procedures that address all aspects of the CS use processes and are regularly reviewed. | ☐ | ☐ |
| | 2e. Policies and procedures are regularly reviewed to assure compliance with state and federal laws. | ☐ | ☐ |
| | 3a. The organization (e.g. security) has engaged local law enforcement (e.g. county sheriff, chief of police) to discuss CS diversion prevention program and establish a communication strategy (including public) prior to CS diversion situations. | ☐ | ☐ |
| | 4a. The organization is aware of the reporting requirements found in the statutes and rules administered by Minnesota's Health-Related Licensing Boards, including the provisions of Minnesota Statutes Section 214.33. | ☐ | ☐ |
| | 4b. DEA registrant or their designee reports all controlled substance thefts or significant loss to the DEA and as required by federal and state rules. | ☐ | ☐ |
| **Access to information/ Accurate Reporting/ Monitoring/ Surveillance/ Detection System** | 1a. The organization has a process to generate controlled substance data on a minimum monthly basis such as controlled substance surveillance reports, high user report, CS use through reports/log-sheets, CS "Disposition and Inventory" sheets. | ☐ | ☐ |
| | 2a. The organization has a process in place to review and analyze CS data on a regular basis. | ☐ | ☐ |
| | 2b. The organization shares findings from the data analysis on a regular basis. | ☐ | ☐ |
| | 2c. If diversion is suspected there is a process in place to activate response team to include patient care manager, pharmacy, HR, security. | ☐ | ☐ |
| | 2d. If diversion is suspected, the organization has a process in place to contact local, state, federal law enforcement. | ☐ | ☐ |
| **Facility Expectations** | 1a. Senior leadership has clearly communicated that all staff are expected to speak up and will be supported in speaking up when they become aware of possible diversion. | ☐ | ☐ |
| | 1b. The organization has a clearly defined process for speaking up and "stopping the line" if a potential safety issue has been identified by staff. The process clearly outlines:<br>• when to stop the line;<br>• how to stop the line (e.g. "I need clarity");<br>• the chain of command to follow if not supported in stopping the line;<br>• clear communication to staff from managers and leadership that staff will be supported if they speak up. | ☐ | ☐ |
| | 2a. The organization has a clearly defined full disclosure policy and process to communicate to patients/ families that are impacted by CS prevention diversion. | ☐ | ☐ |

| SAFE Component | Assessment Questions | Yes | No |
|---|---|---|---|
| | 3a. Organization has established and communicated ways for staff to anonymously speak up (e.g. hot line, paper or electronic submission). | ☐ | ☐ |
| | 3b. Organization has a process in place to remove impaired caregiver from patient care. | ☐ | ☐ |
| | 3c. The organization conducts pre-employment background check and drug testing for Licensed Independent Practitioner (LIP) and employees. | ☐ | ☐ |
| | 3d. A log of staff photographs and signatures are maintained as appropriate. | ☐ | ☐ |
| | 3e. The organization has a process to manage employee access to CS when terminated or transferred in a timely fashion. | ☐ | ☐ |
| | 3f. Organization has developed a "for cause policy" for drug testing. | ☐ | ☐ |
| | 4a. Organization establishes and enforces a policy of not sharing pass codes [e.g. EMR, Automated Distribution Machine (ADM), pharmacy door code]. | ☐ | ☐ |
| **Educate Staff (and Patients)** | 1a. The CS Diversion and Prevention team attend training on CS diversion prevention and statutory requirements. [e.g. National Association of Drug Diversion Investigators) (NADDI), professional associations, licensing boards, state, local, and federal law enforcement] | ☐ | ☐ |
| | 1b. Expectations and supporting education have been incorporated into training for all new staff and Licensed Independent Practitioner (LIP). | ☐ | ☐ |
| | **Expectations and training includes, at a minimum:** | | |
| | 1c. Providing awareness training to know the signs of diversion. | ☐ | ☐ |
| | 1d. Resources are available to support employees and LIP, e.g. Employee Assistance Programs (EAP) and Health Professional Services Programs (HPSP). | ☐ | ☐ |
| | 1e. The facility requires training on CS policies and procedures prior to authorizing staff to have CS access. | ☐ | ☐ |
| | 1f. The facility provides ongoing staff education at least annually to promote the safe handling of CS andawareness of CS diversion. | ☐ | ☐ |
| | 1g. The organization provides patient education on safe medication handling, including potential for diversion. | ☐ | ☐ |

# STORAGE AND SECURITY

| Audit Questions | Yes | No | If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete. |
|---|---|---|---|
| **The organization has a process in place for securing CS which includes:** | | | |
| 1a. CS are not to be left unattended at any time. | ☐ | ☐ | |
| 1b. CS are stored in a locked location [Automated Distribution Machine (ADM), CII vault, locked cabinet/drawer/box] at all times. (ADM is a robotic or computerized device in which the device components are designed to distribute drugs in a licensed healthcare facility. A pharmacist is responsible for the drug entry into the patient's profile, final review and distribution of the patient medications.) | ☐ | ☐ | |
| 1c. ADM managed CS are stored in a location with single pocket access. n/a: ☐ | ☐ | ☐ | |
| 1d. Access to CS storage areas is limited to authorized staff. | ☐ | ☐ | |
| 1e. Non-ADM CS cabinets are secured with an electronic lock, cipher lock or key. | ☐ | ☐ | |
| 1f. Removing ADM and non-ADM access for terminated employees. | ☐ | ☐ | |
| 1g. Patient specific CS infusions (PCAs, epidurals, and continuous infusions) are enclosed in a locked box utilizing no-port tubing. | ☐ | ☐ | |
| 1h. Controlling and accounting for keys. | ☐ | ☐ | |
| 1i. Prescription pads/paper are stored in ADM, locked location, or under control of LIP. | ☐ | ☐ | |
| 1j. Facility designates authorized individuals to order prescription pads/paper direct from the vendor for the operating unit or patient care area. | ☐ | ☐ | |
| 1k. Electronic and non-electronic prescriptions comply with state and federal requirements | ☐ | ☐ | |
| 1l. CS brought in by a patient that cannot be returned home are inventoried by two authorized healthcare staff and stored in a locked, limited access area. | ☐ | ☐ | |
| 2a. Camera surveillance is used in primary CS Pharmacy storage area (e.g narc vault). | ☐ | ☐ | |
| 2b. Camera surveillance is use in areas deemed high risk as determined by the organization (e.g. procedural areas) CS medication preparation areas in pharmacy OR, ER or medication areas with high use of CS. | ☐ | ☐ | |

## PROCUREMENT

| Audit Questions | Yes | No | If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete. |
|---|---|---|---|
| **The organization has a process in place for procuring CS which includes:** | | | |
| 1a. All CS are obtained from the hospital pharmacy | ☐ | ☐ | |
| 1b. DEA 's Controlled Substance Ordering System (CSOS) is the preferred method for CII CS procurement. *(DEA's CSOS is an encrypted electronic controlled substance ordering system between a wholesaler and the DEA licensee's authorized user.)* | ☐ | ☐ | |
| 1c. Individuals authorized to order CII-V is limited to the DEA registrant and authorized individuals. | ☐ | ☐ | |
| 1d. DEA 222 forms are kept under perpetual inventory, secured, and only accessible by authorized individuals. *(Perpetual inventory is a Minnesota Board of Pharmacy requirement to monthly maintain and reconcile Schedule II controlled drugs.)* | ☐ | ☐ | |
| 1e. The person(s) authorized to order CS is not the same person who receives the CS. | ☐ | ☐ | |
| 1f. All invoices received will have the date when the medications are received and two signatures on the invoice. | ☐ | ☐ | |

## PRESCRIBING

| Audit Questions | Yes | No | If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete. |
|---|---|---|---|
| **The organization has a process in place for ordering/ prescribing CS which includes:** | | | |
| 1a. CS are prescribed only by licensed authorized prescribers with DEA registration or institutionally assigned DEA suffix. | ☐ | ☐ | |
| 1b. A valid order from an authorized prescriber exists for all CS administered. | ☐ | ☐ | |
| 1c. Patient specific CS orders are generated by electronic systems with controlled access except in emergency situations in accordance with applicable federal and state laws and rules. | ☐ | ☐ | |
| 1d. CS are not prescribed by an authorized prescriber for him/herself or an immediate family member. | ☐ | ☐ | |
| 1e. Range orders for CS are minimized. | ☐ | ☐ | |

## PREPARATION & DISPENSING

| Audit Questions | Yes | No | If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete. |
|---|---|---|---|
| **The organization has a process in place for dispensing CS which includes:** | | | |
| 1a. CS are dispensed in single-unit-dose packaging. *(Single-unit-dose packaging means a single-unit container for articles intended for administration as a single dose, direct from the container.)* | ☐ | ☐ | |
| 1b. Tamper-evident packaging is utilized for CS prepared by pharmacy. *(Tamper-evident packaging means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.)* | ☐ | ☐ | |
| 1c. Secure, locked, non-transparent medication delivery carts/ containers are used to deliver CS and accessible only by authorized individuals. | ☐ | ☐ | |
| 1d. CS transported via pneumatic tube are sent via secured transaction. n/a: ☐ | ☐ | ☐ | |
| 1e. AD Ms are utilized in patient care areas for the distribution of controlled substances and are interfaced with the electronic patient profile to limit access only to medications ordered for a specific patient. n/a: ☐ | ☐ | ☐ | |
| 1f. Bar code scanning is utilized when replenishing ADMs. n/a: ☐ | ☐ | ☐ | |
| 1g. A blind count process is used for narcotic vault and ADM distributed CS. (*Blind count is a process utilized with ADM when refilling a controlled substance into the drug's individual pocket. The ADM requests the person replenishing the controlled substance to the ADM to count the quantity in the machine before adding the refill. The count in the pocket is not presented to the person replenishing the CS. If the count entered by the person replenishing the ADM is correct, the ADM will allow the refill of the controlled substance.)* | ☐ | ☐ | |

| | | | |
|---|---|---|---|
| 1h. The number of CS on override status in profile ADMs is minimized (e.g. one time injectables for emergency situations only). n/a: ☐<br>1i. Biometric-ID technology is used instead of passwords. If password is used, there must be a process to force password resetting on a regular interval. n/a: ☐<br>1j. There must be a co-signature for delivery of CS to non-ADM areas<br>1k. ADM down time procedures must be defined to maintain the control, documentation and accountability of CS. n/a: ☐ | ☐<br>☐<br>☐<br>☐ | ☐<br>☐<br>☐<br>☐ | |

## ADMINISTRATION OF CS

| Audit Questions | Yes | No | If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete. |
|---|---|---|---|
| **The organization has a process in place for administering CS which includes:**<br>1a. Only health care providers operating within the scope of their practice may administer CS.<br>1b. Defined time between CS retrieval from storage areas and time of administration and documentation (e.g. within 30 minutes of ADM removal or within 30 min of the end of the procedure).<br>1c. The CS retrieved for a patient is the package size equivalent to, or the closest available to, the dose to be administered.<br>1d. CS are removed for one patient at a time from ADMs and/or locked storage areas.<br>1e. The individual retrieving the CS from ADM / locked storage area/box is also the person that administers the medication. The organization defines exceptions (e.g, emergencies) and has policy/process in place to assure chain of custody.<br>1f. All CS drawn up into syringes, if not immediately administered, are labeled per institutional policy. | ☐<br>☐<br>☐<br>☐<br>☐<br>☐ | ☐<br>☐<br>☐<br>☐<br>☐<br>☐ | |

## HANDLING CS WASTE

| Audit Questions | Yes | No | If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete. |
|---|---|---|---|
| **Pharmacy:**<br>1a. CS waste from Compounded Sterile Product (CSP) preparation in the Pharmacy is collected and randomly assayed.<br><br>**Areas outside Pharmacy:**<br>1b. All Potentially Reusable Product (PRP) drugs are returned to the pharmacy for evaluation of re-use/re-issue. *(PRP: Medications that have been issued to a patient, which have not been used, the integrity of such packaging remains intact and expiration/beyond use date allow for the medication to be re-issued to another patient.)*<br>1c. Unusable product (UP) CS are to be immediately wasted and witnessed by healthcare professionals per specific hospital procedures. *(UP: Any medication that may not be used for a patient due to either the integrity no longer being intact or the medication has exceed its expiration/beyond use date.)*<br>1d. The organization has identified the high risk areas (e.g. surgical, anesthesia, procedural) where CS diversion occurs.<br>1e. Organization has identified specific high risk CS medications (e.g., fentanyl) that are randomly assayed.<br>1f. The organization has a process to randomly obtain and assay UP CS. For random assays the UP CS would not be subject to immediate witnessed waste. | ☐<br><br>☐<br><br>☐<br>☐<br>☐ | ☐<br><br>☐<br><br>☐<br>☐<br>☐ | |
| **Wasting of UP CS:**<br>2a. Approved methods for wasting a CS are defined per federal, state and county laws and regulations.<br>2b. The wasting of all CS requires an independent licensed witness and must be documented in the ADM or via proof of use form, except in situations where UP CS are being returned to pharmacy for assay.<br>2c. An individual witnessing CS wasting verifies the volume/amount being wasted matches the documentation and physically watches the medication being wasted per policy.<br>2d. Empty containers of CS (e.g., vials) are discarded in limited access waste containers.<br>2e. The hospital takes measures to secure waste containers with trace UP CS to prevent tampering. | ☐<br>☐<br>☐<br>☐<br>☐ | ☐<br>☐<br>☐<br>☐<br>☐ | |

| | | | |
|---|---|---|---|
| **PRP Returns:**<br>2f. PRP ADM managed CS are returned to a secure return bin/pocket and not to the original ADM pocket. n/a: ☐<br>2g. All PRP CS returns to pharmacy require co-signature in the patient care area and in pharmacy | ☐<br>☐ | ☐<br>☐ | |
| **Waste or Reverse Distribution:**<br>2h. DEA registrant or their designee assists with all phases of transfer of CS to a reverse distributor and/or hazardous waste disposal company. | ☐ | ☐ | |

## Monitoring of CS and process if diversion is suspected

| Audit Questions | Yes | No | If answered question "No" – identify the Specific Action plan(s) including persons responsible and timeline to complete. |
|---|---|---|---|
| 1a. All personnel actions (e.g. suspension, terminations and resignations) are communicated to pharmacy immediately so access to CS can be removed in a timeframe as defined by the organization. | ☐ | ☐ | |
| **The organization has a defined process in place to monitor** CS on a regular basis which includes:<br>2a. Auditing CS purchase invoices against CS order with receipt into the pharmacy's perpetual inventory. Tracking any CS purchases outside of the pharmacy department.<br>2b. Tracking movement of CS throughout the hospital, e.g. reports match narcotic vault transactions with receipt into ADM and/or paper inventory record with RN signature of receipt.<br>2c. Inventorying, at least monthly, all medications within an ADM or narcotic vault.<br>2d. Inventorying non automated CS storage areas at each shift change.<br>2e. Review of ADM reports, at least monthly, by pharmacy or patient care managers as defined by the organization. Reports compare ADM activity with medication administration record. n/a: ☐<br>2f. Comparison of ADM CS activity to peers with similar staffing responsibilities and FTE appointments. n/a: ☐<br>2g. Comparison of transaction activity (e.g. inventory abnormalities, removal of quantities greater than prescribed dose, cancellations, returns and waste) to peers.<br>2h. Comparison of patient MAR–amount & quantity administered to what other caregivers administer on subsequent shifts (without patient change in condition).<br>2i. Comparison of non-ADM CS storage area record of use with MAR (e.g. anesthesia record, sedation record, eMAR) to assure appropriate documentation of waste. | ☐<br>☐<br>☐<br>☐<br>☐<br>☐<br>☐<br>☐<br>☐ | ☐<br>☐<br>☐<br>☐<br>☐<br>☐<br>☐<br>☐<br>☐ | |
| 3a. CS discrepancies are resolved upon discovery, no later than end of shift. Discrepancies which cannot be resolved are jointly reviewed by pharmacy and patient care leadership with resolution within 24 hrs (e.g. metric: unresolved nursing unit CS discrepancies > 24 hrs/total nursing unit CS discrepancies should be ≤8%). | ☐ | ☐ | |
| 4a. There is a standard process in place to investigate potential diversion cases. (Refer to models in Tool Kit) | ☐ | ☐ | |

## SELF-ASSESSMENT/POST-TEST QUESTIONS

1. **Which of the following is a common characteristic of specialty medications?**
   A. High cost
   B. Management of common disease states
   C. Simple monitoring requirements
   D. Open access or distribution

2. **Which of the following is NOT a potential access barrier for specialty medications?**
   A. Prior authorization process
   B. Medication cost
   C. Preferred pharmacies
   D. Bioavailability of the medications

3. **In relation to the project presented, which of the following statements is FALSE?**
   A. Prevalent users are a sub-group of incident users.
   B. Incident users are a sub-group of prevalent users.
   C. Incidence is the rate for the proportion of patients starting a medication during a specified time of interest.
   D. Prevalence is the rate for the proportion of patients on a medication during a specified time of interest.

4. **In which group is it more appropriate to assess whether a suspect medication contributes to an adverse event?**
   A. Incident medication user
   B. Prevalent medication user

5. **Which of the following has been reported in the literature as a significant outcome of statin users and hospital-associated CDI?**
   A. Faster symptom resolution
   B. Higher risk of hospital-onset CDI
   C. Increased risk of recurrence of hospital-associated CDI
   D. Reduced 30 day all-cause mortality

6. **Which of the following laboratory or physical finding is involved in assessing CDI severity through the Zar criteria?**
   A. Serum creatinine
   B. Heart rate
   C. Body temperature
   D. Neutrophil count

7. **Creation of a diversion prevention and detection taskforce is important because it can assist to:**
   A. Maximize patient safety
   B. Ensure compliance with regulatory requirements
   C. Minimize loss of resources
   D. All of the above

8. **Identify which task will be completed by the diversion prevention and detection taskforce:**
   A. Provide education about drug diversion
   B. Complete weekly unit inspections
   C. Assist in the annual pharmacy inventory
   D. Review the medication purchase history

Answers: 1) A 2) D 3) A 4) A 5) D 6) C 7) D 8) A

## Save – Important Information

### Continuing Pharmacy Education (CPE) Program Instructions to Process Credit

**CPE Program:** **Pharmacy Residency Project Pearls in Chicago**

**Program Date:** **May 24, 2016**

**Access Code: _____**
***Announced at the session. You will need this to process your credit.***

**CPE Processing Deadlines:**
**May 24 – You MUST complete your evaluation submission by end of day July 7, 2016.**

**Please honor the deadlines! Do NOT Delay in completing your CPE processing. If you encounter problems, we will need time to assist you before the deadline. Once the CPE Monitor deadline passes we are unable to upload your CPE credit into the CPE Monitor system due to the system restrictions put in place by ACPE and NABP. If you miss the deadline you will NOT receive credit for this program!**

Sign In Sheets: Please be sure and fill in the Attendance Sheet to confirm your presence for our records. Attendance sheets will be emailed or faxed to the ICHP office for the ACPE file. ACPE requires we confirm that live attendance matches those processing online CPE credit.

**Detailed instructions to complete evaluations online:**
Participants in this CPE program - You will need your own account on **CESally.com** as an ICHP association member in order to access the CPE program, do the evaluation, and submit for credit. This NISHP CPE is free to ICHP members. Non-members please contact ICHP to request CE.

***Only ICHP members who have accepted the association invitation from ICHP via CESally and created an account will be able to SEE and access ICHP member programs. For information on how to REQUEST and / or ACCEPT the members' invitation please go to the new link:***
http://www.ichpnet.org/pharmacy_practice/cesally/.

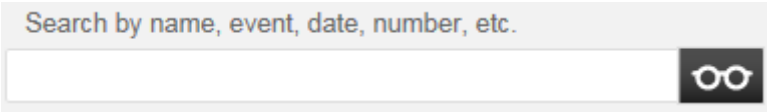
**To set up your account:**
1. Go to www.CESally.com and click on "Sign Up!" Or log in with your existing account. Go to your Account page and accept the association invitation in the right side column, if you have not already done so.
Or REQUEST an invitation to join ICHP on this Account page.
***Note: You must use the same email that received the invitation to log in!***
**Important: You will need to maintain a valid email address.**

2. Select a username and password and complete the Sign Up process. For HELP at any point, click on the HELP tab or go to: https://www.cesally.com/help/.

- Enter your NABP eProfile ID and birth day as MMDD when prompted. CESally.com now checks with NABP/CPE Monitor in real time, to confirm the NABP eProfile and birth day are a valid account.

3. Once you have created your account, or logged in, use the Search Box in the upper right corner to find your activity by typing in the title. You have several options for completing or saving for later.

*NOTE: If the title does not appear to you that may mean you are not logged in as an ICHP association member and / or have not requested / accepted the ICHP invitation.*



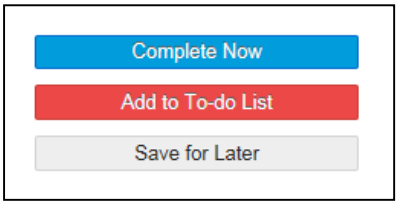

**Please pay CLOSE attention to the Title, Date, and if it says Pharmacist or Technician after the title.**

## Save – Important Information

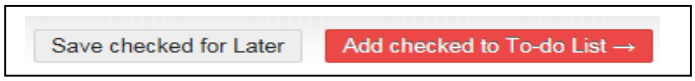
- **Pharmacists must do P-specific programs only.**
- **Technicians must do T-specific programs ONLY for PTCB recertification.**

4. Identify the program attended and choose between a) or b) below:

a) Click on that Activity title to open the information page, and you will see your options in the right hand column on the information page.




b) OR Click on the checkbox inside the small information box, then go to the bottom of the page and see your options there.




5. To finish the process after choosing to **Complete Now**, **Save for Later**, OR **ADD to To-do List.**

a) If you choose **Complete Now**, follow the actions as directed on the webpage. You will verify your attendance, provide the session ACCESS code given to you during the program, and complete an evaluation of the activity and the speaker(s). The status box indicates where you are in the process.

b) If you **Save for Later** or **Add to To-do List**, when you are ready to complete, please go to the appropriate webpage and click on **Start To-do List.** Follow the actions as directed on the webpage. You will verify your attendance, provide the session ACCESS code given to you during the program, and complete an evaluation of the activity and the speaker(s). The status box indicates where you are in the process.

6. Click **Go To Next Step** at the bottom of the page, as you finalize each step in the process.

7. Click on **Report CE**. Your CPE credit will be uploaded to CPE Monitor automatically upon **successful** completion and **submission** of your evaluation.

8. If an error occurs, the system will tell you on the screen so please wait for any error messages. CPE Monitor will not accept your submission if there are any errors, and your credit will NOT be reported to CPE Monitor. ***Please confirm your submissions.***

9. Go to www.NABP.net and CLICK on the CPE Monitor link to log into your personal CPE Monitor account to download an official statement of credit or full transcript.

If you have any questions, please contact ICHP at members@ichpnet.org.

**Please remember the ICHP processing deadline is by end of day July 7, 2016.**

***Thank you!***