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Divine Interventions: Promoting Best Practices in the ICU with Safe Medication Use Guidelines

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Disclosure

Joseph Dasta

- AcelRx: Consultant; bayer AG: Consultant; Medtronic: Consultant; Merck, Pfizer, Abbvie, Abbott, ESI, BMS, Lilly : Stockholder/Ownership Interest (excluding diversified mutual funds); Otsuka America Pharmaceuticals: Consultant; Pacira Pharmaceuticals: Consultant; The Medicines Company: Consultant
- **[Spouse/partner]** Merck, Pfizer, Abbvie, Abbott, ESI, BMS, Lilly : Stockholder/Ownership Interest (excluding diversified mutual funds)

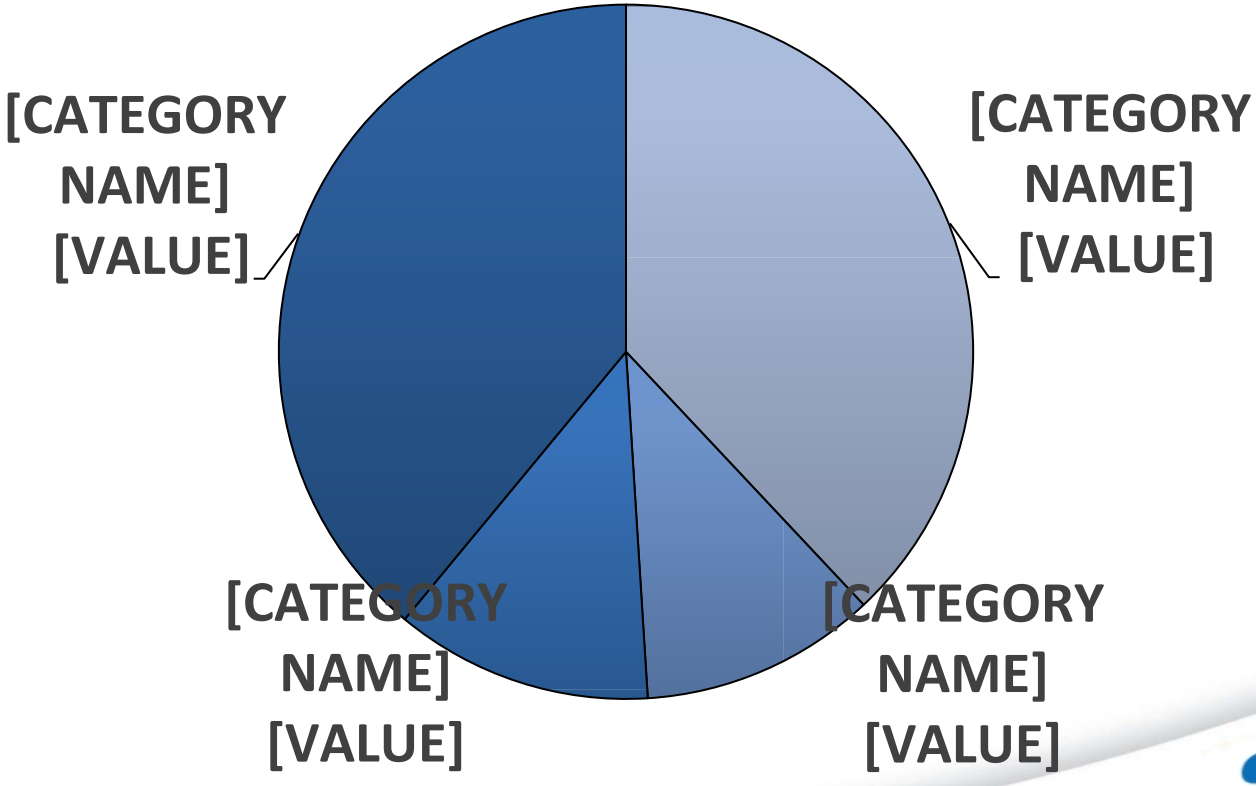
All other planners, presenters, and reviewers of this session report no financial relationships relevant to this activity.

Objectives

- Evaluate the impact of medication ordering technology (computerized physician order entry, drug dosing software, and clinical decision support systems) on clinical outcomes.
- Analyze the use of bar code medication administration, double-check systems, and validated subjective assessment tools.
- Recommend optimal patient safety surveillance strategies.

Overall Medication Error Rate:

Distribution in Medication Use Process



Leape LL. N Engl J Med 1991;324:377-384

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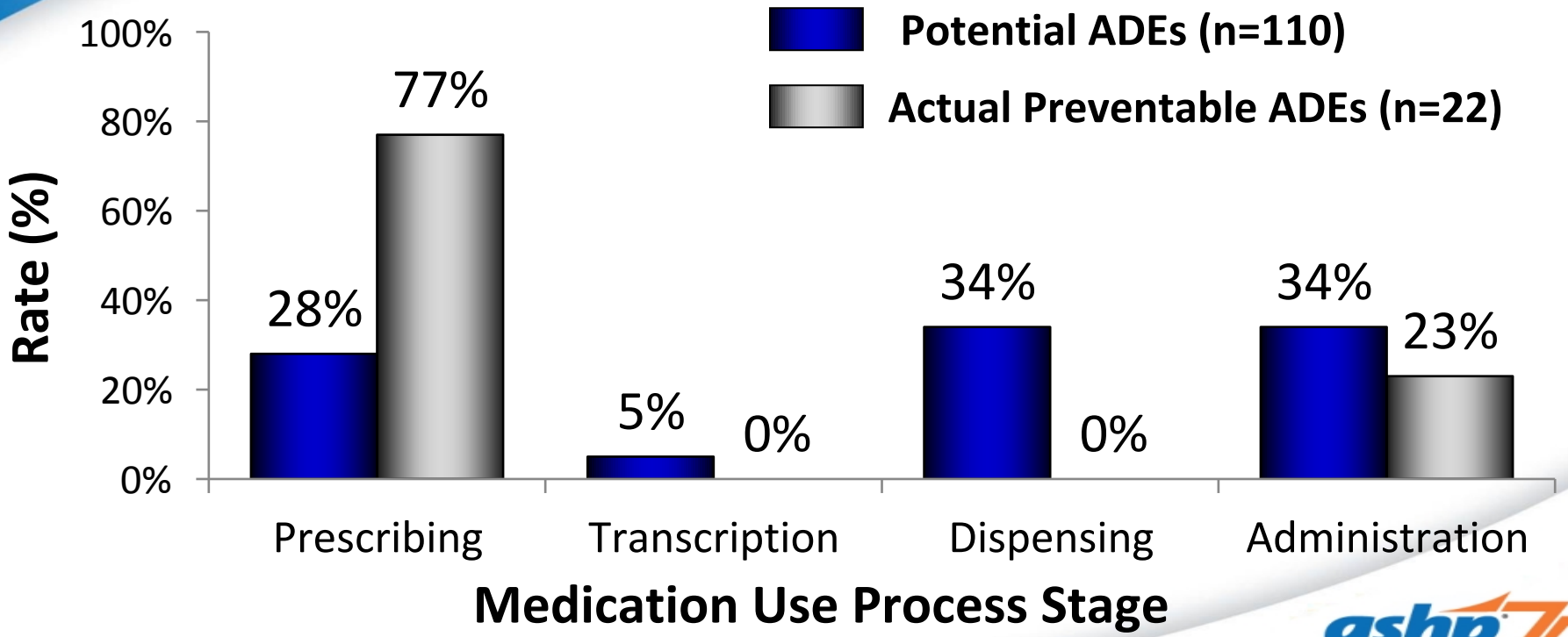
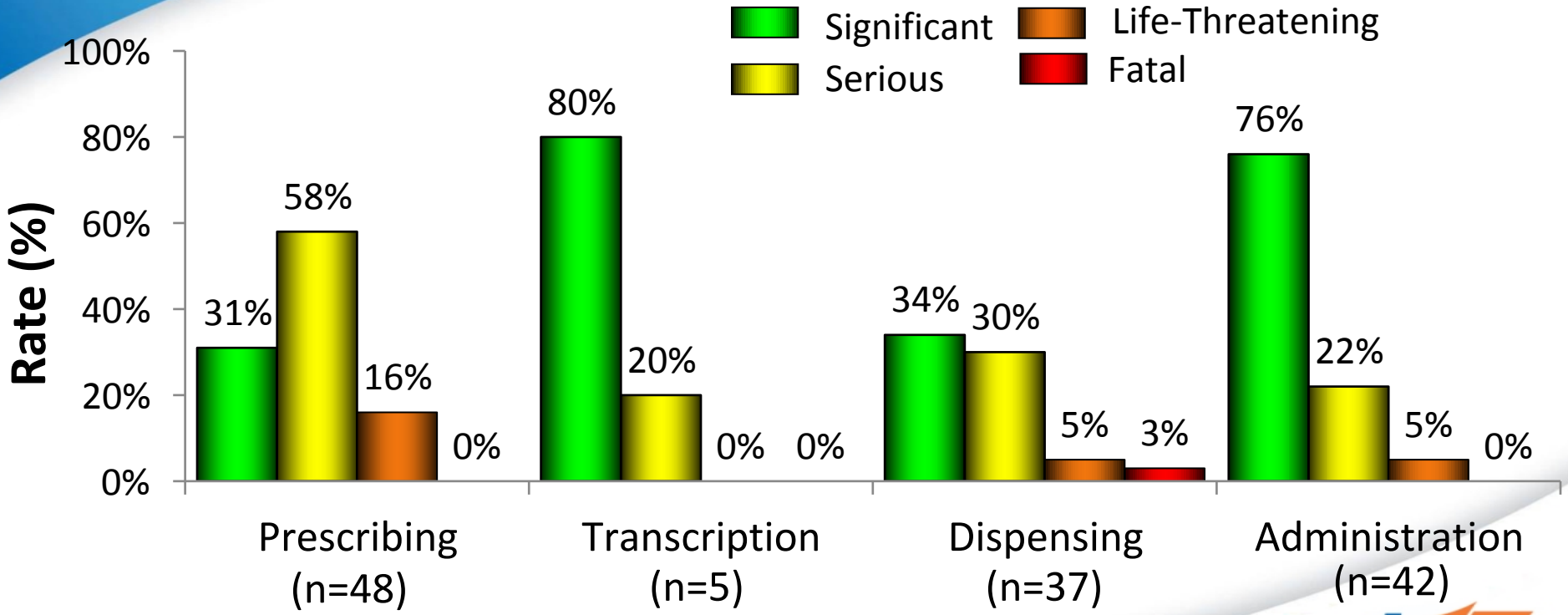
Incidence of ICU Medication Errors



Kopp BJ. Crit Care Med 2006;34:415-425

Severity of ICU Medication Errors



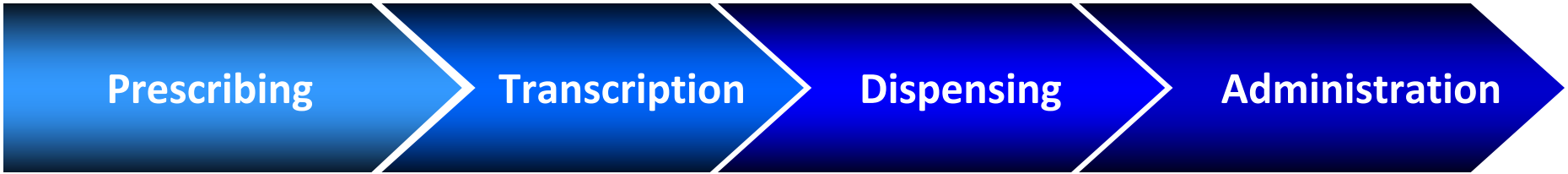
Kopp BJ. Crit Care Med 2006;34:415-425

Medication Safety Strategies

Computer Provider Order Entry

Automated Medication Dispensing Machine

Bar-coded Medication Administration



Clinical Decision Support Software

IV Infusion Safety Pumps

Oren E. Am J Health Syst Pharm 2003;60:1447-1458

Clinical Practice Guidelines: Safe Medication Use in the ICU

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Guideline Structure & Definitions

American College of Critical Care Medicine appointed 15-member interdisciplinary task force

3 Key Components

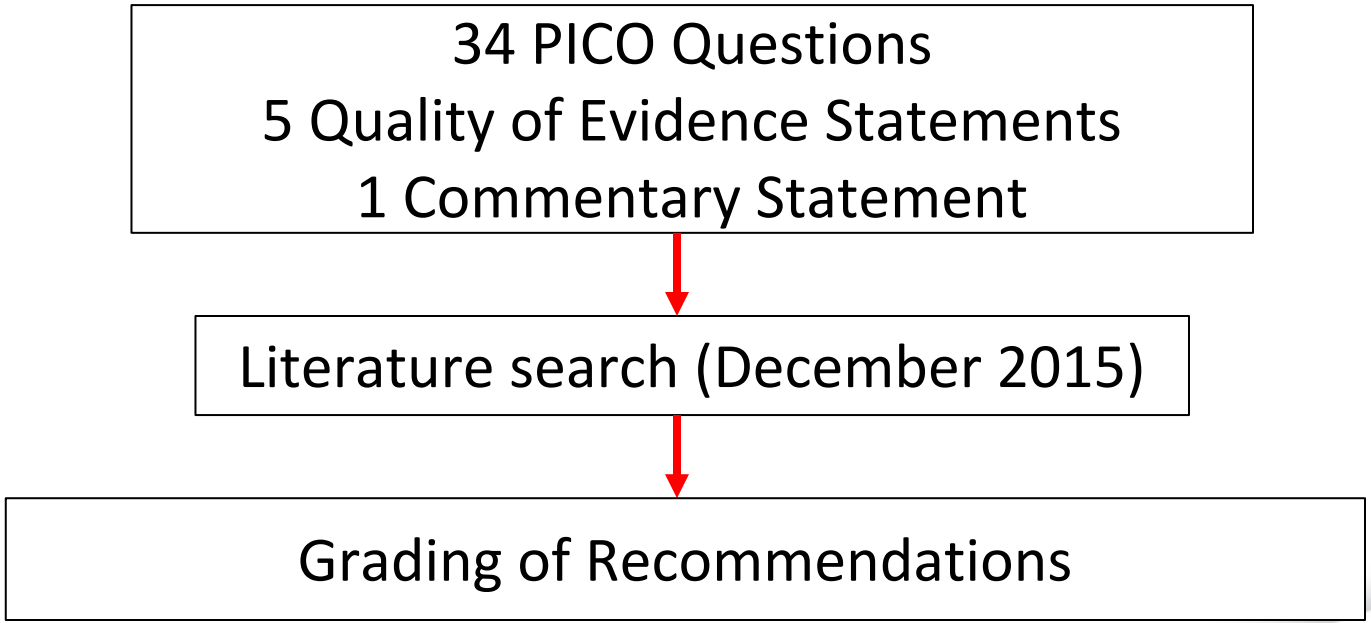
1) Environment and patient
2) Patient safety surveillance systems
3) Medication use process

Medication Use Process

- Prescription
- Dispensing
- Administration
- Monitoring

Kane-Gill SL. Crit Care Med 2017;45:e877-e915

Guideline Development Process



Kane-Gill SL. Crit Care Med 2017;45:e877-e915

GRADE System

Category Grade	Quality of Evidence
A	High
B	Moderate
C	Low
D	Very low

Category Grade	Quality of Evidence
1	Strong
2	Weak
0	No Recommendation

GRADE = Grading of Recommendations Assessment, Development, and Evaluation system

Kane-Gill SL. Crit Care Med 2017;45:e877-e915

Prescribing Node Recommendations

Medication Safety Strategies: Prescribing Node

- Computer provider order entry (CPOE)
- Clinical decision support software (CDSS)
- Protocols
- Medication reconciliation
- Broselow tape

Kane-Gill SL. Crit Care Med 2017;45:e877-e915

Drug Dosing Software & Protocols

- "We **suggest** using computerized drug dosing software to decrease the number of MEs and ADEs for insulin prescribing" (2C)

- "We **suggest** the use of protocols/bundles in the ICU to ensure ME and ADE reduction" (2B)

Kane-Gill SL. Crit Care Med 2017;45:e877-e915

Which of the following best represented the GRADE recommendation for impact of medication reconciliation on reducing MEs and/or ADEs in the ICU?

A. 1A (Strong recommendation / high quality of evidence)
B. 2A (Weak recommendation / high quality of evidence)
C. 2B (Weak recommendation / moderate quality of evidence)
D. 0 (No recommendation)

Medication Reconciliation

- "We make **no recommendation** regarding the use of medication reconciliation to decrease MEs and ADEs in ICU patients"

Kane-Gill SL. Crit Care Med 2017;45:e877-e915

Which of the following best represented the GRADE recommendation for impact of CPOE on reducing MEs and/or ADEs in the ICU?

A. 1A (Strong recommendation / high quality of evidence)
B. 2A (Weak recommendation / high quality of evidence)
C. 2B (Weak recommendation / moderate quality of evidence)
D. 0 (No recommendation)

Computer Provider Order Entry

Question

- In adult and pediatric ICU patients, does CPOE reduce medication errors (MEs) and preventable adverse drug events (ADEs) when compared without CPOE?

Answer

- "We **suggest** implementing CPOE to decrease MEs and preventable ADEs" (2B)

Kane-Gill SL. Crit Care Med 2017;45:e877-e915

CPOE ICU Data

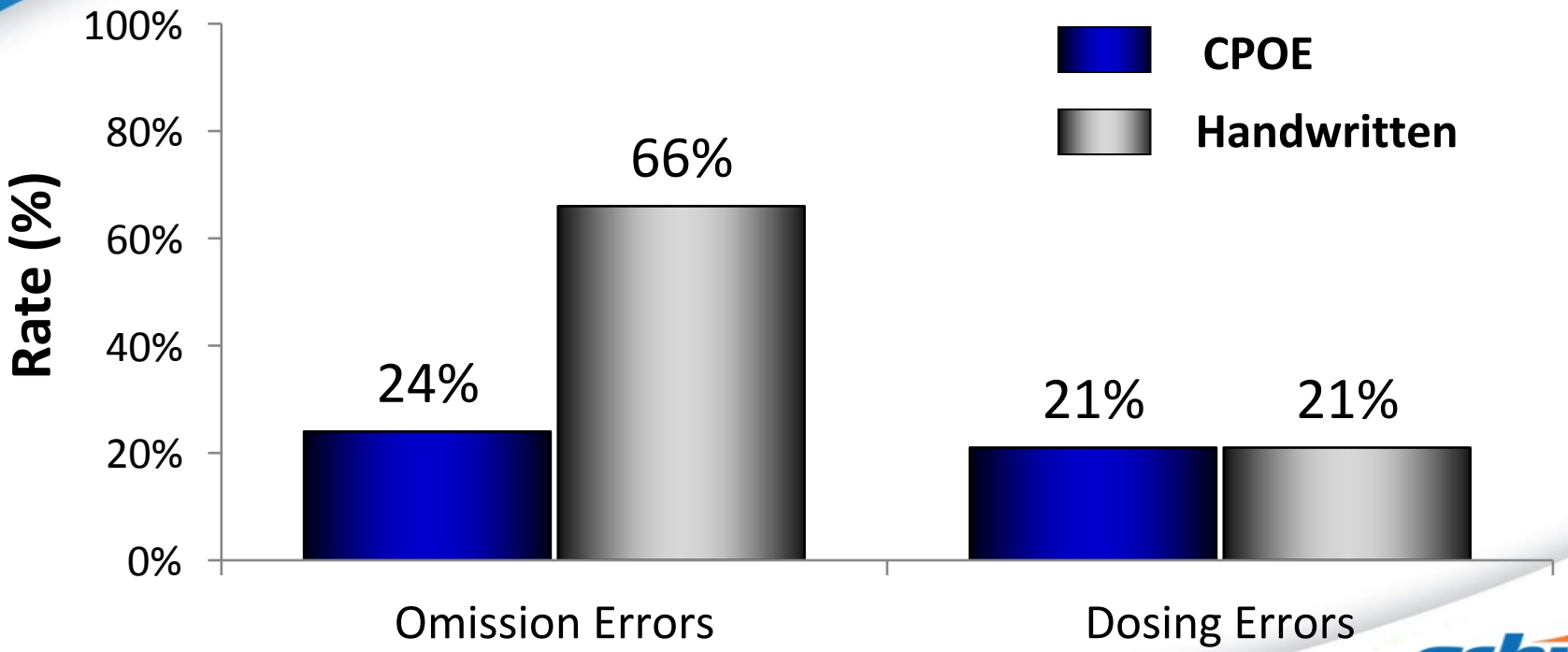
N=14 studies
(Pre- vs. post-implementation with ME and/or ADE outcomes)

12 studies = observational
2 studies = prospective, randomized

1 study = both ME and ADE outcomes reported
1 study = evaluated ADEs only

Kane-Gill SL. Crit Care Med 2017;45:e877-e915

Dosing Errors in Pediatric ICU



Maat B. Intensive Care Med 2014;40:458-9

Duplicate Order Errors in Adult ICU

Duplicate Errors	Pre-CPOE	Post-CPOE	P Value
Total	48	167	**<0.0001**
Errors per 1000 med orders	1.05	5.09	**<0.0001**
Errors per 100 patient-days	1.16	4.16	**<0.0001**

Wetterneck TB. J Am Med Inform Assoc 2011;18:774-782

Clinical Decision Support Software

Question

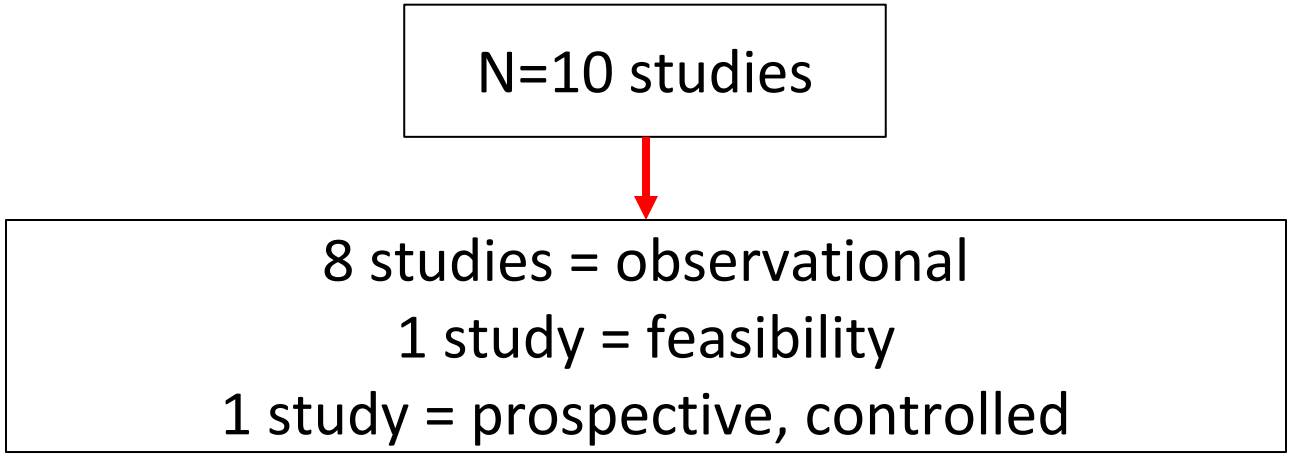
- In adult and pediatric ICU patients, does CDSS (electronic or paper) reduce MEs and ADEs when compared without CDSS?

Answer

- "We **suggest** the use of CDSS (electronic or paper) to decrease the number of MEs and ADEs " (2C)

Kane-Gill SL. Crit Care Med 2017;45:e877-e915

CDSS ICU Data



Kane-Gill SL. Crit Care Med 2017;45:e877-e915

Clinical Decision Support Software

- Decreased ADEs resulting from CDSS alerts (n=3 observational)
  - Drug allergies
  - Renal dosing
  - Inappropriate indications of use (i.e. contraindications)
- Impact of CPOE + CDSS on neonatal antibiotic order errors
  - Overall ME rate (error per order) decreased from pre- vs. post-implement (1.7 vs. 0.8 errors / order, $p<0.001$)
  - Prescribing ME rate (error per order) INCREASED from 0.4 to 0.7 ($p=0.03$)

Kane-Gill SL. Crit Care Med 2017;45:e877-e915

Key Takeaways

- Key Takeaway #1
  - Prescribing node of the medication use process remains a “high-risk” area for MEs with resulting preventable ADEs
- Key Takeaway #2
  - Technology may improve medication safety during prescribing phase
- Key Takeaway #3
  - Quality assurance MUST be conducted following any system changes targeting the prescribing phase

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Safe Drug Administration Practices Shouldn't Be a Bitter Pill to Swallow

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Administration node

Medication use process

- Drug administration is complex-requiring detailed communication among nurses, pharmacists and physicians
- Complexity creates competing demands and distractions
- 35-45% of ME's in the ICU happen in administration phase
- This is the last chance to detect and prevent a ME
- Many causes of ME
  - New processes and technology developed to minimize/eliminate errors

Kane-Gill et al. *Crit Care Med.* 2017;45:1546-1551

Polling Question

Bar code administration and smart infusion technologies have shown which of the following outcomes

1. Consistent reduction in all forms of medication errors/ADE's
2. Reduced the mortality and morbidity of ICU patients
3. Reduced cost of care in ICU patients
4. None of the above (but we wish they did)

Economics of ME's on inpatients receiving injectable drugs

- Preventable ADE's (ME) are important quality of care issues
- Impacts 7 million patients leading to 7000 deaths, costing $21 billion in US
- 10% of ICU infusion drugs run risk of ME
  - 1 in 10 errors cause harm requiring life-saving treatment
- Economics of ME's including medical liability costs with inpatient injectable drugs not previously studied

- Lahue BJ, et al. *Am Health Drug Benefits*; 2012;5:1-10

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National burden of ME's of injectable drugs

Healthcare and liability costs

- Numerous databases, i.e., MedMarx, Premier, Market Scan- Medicare 5% sample to generate ME data, incremental cost of ADE in hospital and following 4 months, and medical liability costs
- ME's impact 1.2 million hospitalizations annually
- Probability of an ME per injectable administration 0.25% overall
  - Insulin 1.16%, cv drugs 0.5%, narcotics/analgesics 0.33%, anti-infective 0.15%
- Annual cost of ME $3.8 billion, $3100/hospitalization, ($600,000/hospital, liability costs $72,000/patient, $450 million annually
- Lahue BJ, et al. *Am Health Drug Benefits*; 2012;5:1-10

Bar code medication administration (BCMA)

GRADE PICO question and response/recommendation

- **Question**
- In adult and pediatric ICUs, does the use of BCMA impact outcomes like ME's/ADEs?
- **Answer**
- We suggest using BCMA to reduce ME's/ADEs in the ICU (2C)

Kane-Gill, et al. *Crit Care Med* 2017;45:1546-51

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Effect of BCMA on ME's

- BCMA used in 93% of UA hospitals in 2016
- Before-after study 1465 drug administrations in MICU
  - ME Rate Before 19.7% - After 8.7% (*P*<0.001)
  - Significance lost when excluding wrong time errors
- Before-after study –
  - In ICU charting improved but no change in total drug and wrong time errors
  - Med-Surg ME rate decreased 58% when wrong time errors excluded but no change with wrong time errors included

DeYoung JL et al. *Am J Health-Syst Pharm* 2009;66:110-15, Pederson C et al. *Am J Health-Syst Pharm* 2017;74:1336-52; Helmons PJ et al. *Am J Health-Syst Pharm* 2009;^^:1202-10

Effect of BCMA on ME's

- BCMA and electronic drug administration record on ME's
- Before-after study in two community hospitals (unit and ICU)
- Overall accuracy rate improved from before to after
- However in Medical-Surgical ICUs decreased accuracy rate
  - 94% to 84%
  - 96 to 88 when wrong time errors excluded

Siebert HH et al. *Am J Health-Syst Pharm 2014;71:209-18*

Effect of BCMA on ME's

- Chart review of ME's in a NICU before and after BCMA
  - 92,400 doses to 958 patients
- Total ME's increased from 69 to 79 errors/1000 doses
  - Increased detection of wrong-time errors
- BCMA decreased relative risk of targeted preventable ADEs by 47% to 50% controlling for number of doses/patient/day

Morriss FH et al. J Pediatrics 2009; 154:363-68

Overall assessment of BCMA

- Generally effective in reducing ME's and ADE's in the ICU
- Benefit is limited by nursing work-around techniques
  - "Creative charting"
- Not applicable for all types of orders
  - Stat orders
  - Can generate alarm fatigue unless programming for ICU-specific issues
- Need better studies that consider work-arounds in ICU patients

Kane-Gill et al. *Crit Care Med.* 2017;45:1546-1551

Smart IV infusion technology

GRADE PICO question and response/recommendation

- **Question**
- In adult and pediatric ICUs, does the use of smart IV infusion pump technology reduce ME's/ADEs in ICU patients?
- **Answer**
- We suggest smart IV infusion pumps be used to reduce the rate of ME's/ADEs in the ICU (2C)

Kane-Gill, et al. *Crit Care Med* 2017;45:1546-51

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Survey: Smart IV Infusion Technology

YEAR	2012	2013	2014
% HOSPITALS USING	77	81	81

Note 2005 32% usage

Pederson CA et al. *Am J Health-Syst Pharm* 2015:72:1119-37

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Smart IV Infusion Technology

- Use of ‘drug libraries’ to reduce dose errors
  - Can be tailored to institution guidelines
  - “Smart” is a relative term depending on who uses it
- Technology is continuingly changing and improving
- Many studies evaluated older technology

Effect of smart pumps on ME's

- Retrospective chart review of preventable ADE's in 4600 patients before and after ICUs of two hospitals implemented smart pump technology
- Rate of ADE's did not change (4.78% vs 4.95%)
  - Only 4% of errors were capable of being prevented by smart pump
  - Evaluated older systems (study published in 2008)

Nucols TK et al, *J Gen Intern Med* 2008;23:41-45

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Effect of smart pumps on ME's

- Prospective RCT smart pump with decision support on ME
  - Cardiac surgery ICU and step down
- 10,600 medication administrations and 8100 smart pump days
- No effect on ADE's or serious ME's
- Primary reason is 'bypass' of drug library (work around)
- When adjusted for bypass there was a reduction (2.1 vs 0.36)

Rothchild JM et al. *Crit Care Med* 2005;33:533-40

Effect of smart pumps on ME's

- Observational study in a teaching hospital of smart pumps
  - ME rate reduced by 47%
  - If dosage limits were absent, no difference seen
- An evaluation of 863 alerts from anticoagulants by infusion
  - 372 reprogramming events and 401 cancellations
  - Prevention of 90 overdoses and 59 under-dose errors

Pang, RKY et al. J Pharm Pract Res 2011;341:192-95; Fanikos J, Am J Cardio 2007;99:1002-05

Effect of smart pumps on ME's

More recent studies published after guideline deliberations

- 2-year review of upper limit alerts of ICU smart pump usage in Mexico
  - 69% were programmed with dosage limits
  - One-third of total infusions programmed were outside established limits
  - Hence need periodic revisions are needed.

Ibarra-Perez R, et al. *J Patient Saf* 2017; (April 1 ahead of print)

Effect of smart pumps on ME's

More recent studies published after guideline deliberations

- 10 hospitals with dual evaluators assessed errors and their potential to cause harm
- 478 patients and 114 medication administrations
- 60% had at least one type of error
  - Most were violations of hospital policy
  - Only 5 errors were potentially harmful (0.4%)

Schnock KO et al. BMJ Qual Saf 2017;26:131-140

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Accompanying editorial

- Although widely advocated, the evidence for smart pumps benefit is Not clear-cut
- Procedure violations may require review of procedures
- Difficult to interpret the literature
  - Different views of what counts as an error
  - Hard to compare studies
- “It seems the role of smart pumps remains unclear”
- Smart pumps should not be regarded as “plug and play” systems
  - They should be used as an opportunity for wider transformation of the whole system”

Franklin BD. *BMJ Qual Saf* 2017;26:93-94

Key Takeaways

- Key Takeaway #1
  - Errors of injectable drugs are costly accounting for $3100/hospitalization and $600,000 per hospital, including medical liability costs
- Key Takeaway #2
  - Process variation is responsible for much of the findings of increased errors with this technology
- Key Takeaway #3
  - Smart infusion pump technology is Not a “plug and play” model

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Promoting Best Practices in the ICU with Safe Medication Use (SMU) Guidelines: Surveillance Strategies

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Associate Professor
University of Pittsburgh
Pittsburgh, PA

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Objective

- Recommend optimal patient safety surveillance strategies.

Background

- ERICE declaration (1997)
- Federal regulations require reporting
- Types of surveillance:
  - Retrospective: gain knowledge, improve systems & prevent future events
  - Prospective: prevent harm in real-time
- Institutions depend on voluntary reporting
  - Do not know what to report, do not know how to report, fearful of punitive action
- Other surveillance methods with evidence that support use

Which method of surveillance do you think identifies the most events?

A. Non-targeted chart review
B. Targeted chart review
C. Direct observation
D. Patient and family reporting

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Non-Targeted Chart Review

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SMU Guideline Recommendation

Recommendation

- Perform non-targeted chart reviews for detecting adverse drug events (ADEs) as part of a surveillance system. (2B)

Description

- A comprehensive review of the patient's entire medical record. It can be conducted concurrently, while the patient is in the intensive care unit (ICU), or retrospectively, after the patient is discharged.

Data

- Jha AK et al. J Am Med Inform Assoc 1998; 5:305–314.
- Olsen S, Neale G, Schwab K, et al. Qual Saf Health Care 2007;644-40:.

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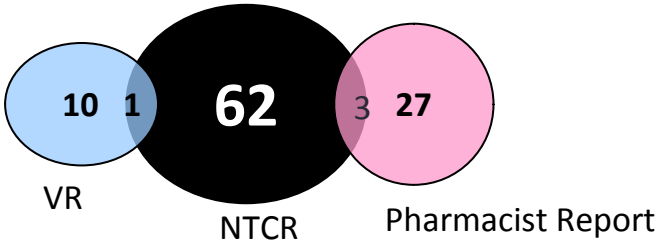
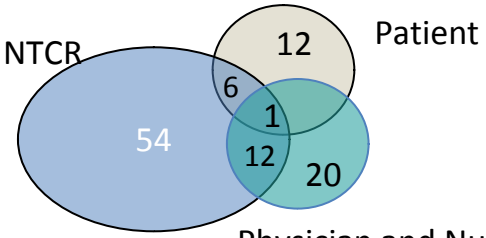
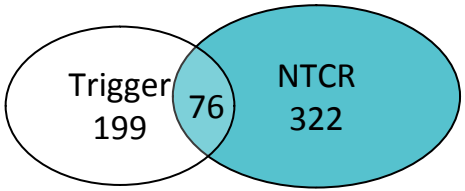
Supporting Data: Non-targeted Medical Record Review

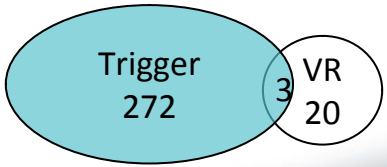


Olsen S et al. QSHC 2007;16:40-44.



Kaboli PJ et al. Pharmacotherapy 2010;30:529-53.





NTCR= non-targeted chart review
VR- voluntary reporting

Jha AK et al. JAMIA 1998;5:305-314

Process

- Establish multidisciplinary team.
- Determine the goal for performing a non-targeted chart review at your institution.
- Select a group of patients that non-targeted chart review is needed.
- Consider the following:
  - Time constraints
  - Logistical barriers
  - Personnel and resources
- Establish a process including information to be documented and responsible for the review.
- Document the results in a central location so that the information may be used for quality improvement and systematic changes within the institution.

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Targeted-Chart Review

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SMU Guideline Recommendation

Recommendation

- Use of trigger-initiated target chart review in addition to voluntary reports to increase the quantity of ADEs reported. (2B)

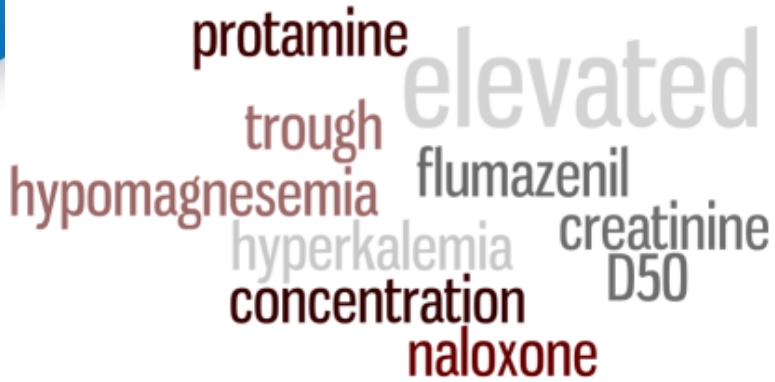
Description

- A targeted chart review includes only evaluating a specific section of the patient's medical record (i.e. ICU discharge notes, progress notes on a specific day, medication administration times surrounding an abnormal lab value, etc.) or reviewing a medical record for a specific patient based on a trigger alert.

Data

- Jha AK et al. J Am Med Inform Assoc 1998; 5:305–314.
- Takata GS, Mason W, Taketomo C, et al. Pediatrics 2008; 121:e927–e935.
- Anthes AM, Harinstein LM, Smithburger PL, et al. Pharmacoepidemiol Drug Saf 2013; 22:510–516.

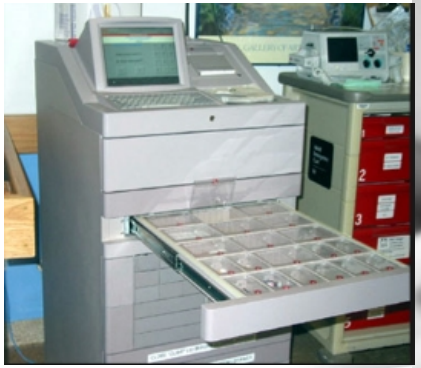
Targeted Chart Review



Triggers

Specific section of chart

Reports



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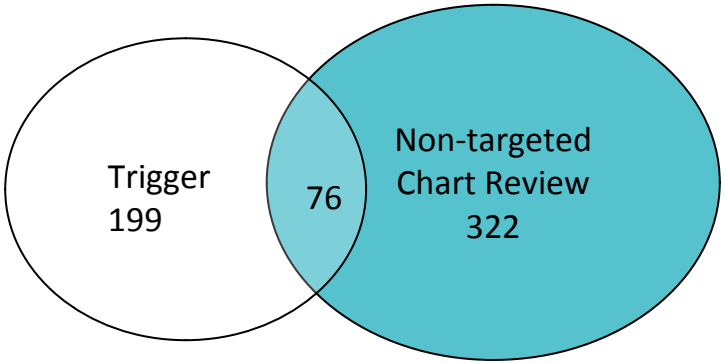
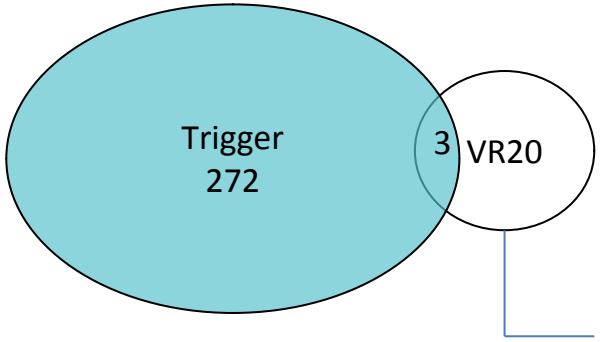
Supporting Data: Targeted Chart Review using Discharge Summaries

- Focus: ICU transfer summaries
- 124/254 (49%) of patients had at least 1 adverse drug reaction (ADR) with a total of 173 ADRs
- 34 vs. 14 per 1000 hospital days in ICU compared to hospital summary, respectively
- Associated medications: warfarin, antibiotics, furosemide and heparin
- ADRs: *C. difficile* associated diarrhea, hypotension, bleeding, acute kidney injury

Anthes AM et al. Pharmacoepidemiol Drug Saf 2013;22:510-16

Supporting Data: Targeted Chart Review using Triggers





Jha AK et al. JAMIA 1998;5:305-314

Process

- Same as non-targeted chart review, plus…
  - Determine if the targeted chart review will involve a section of the patient's medical record, a medical record review stimulated by a trigger or both.
    - Focusing on a section of a medical record such as the ICU discharge notes will provide more general information about ADEs in the ICU
    - Use of a trigger is identifying a specific type of ADE

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Direct Observation

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SMU Guideline Recommendation

Recommendation

- Include direct observation as a component of an active medication surveillance system to identify the medication errors. (1A)

Description

- Direct observation includes having a trained observer watch a subject's performance in their usual clinical environment and document the subject's activities so that it may be later evaluated for medication errors. This is usually done in the context of nurses administering drugs and pharmacists dispensing medications. Direct observation is sometimes referred to as the Barker method after Dr. Ken Barker who created the method of surveillance.

Data

- Barker KN, Flynn EA, Pepper GA, Bates DW, Mikeal RL. Arch Intern Med 2002;162:1897-903.
- Barker KN, Flynn EA, Pepper GA. Am J Health Syst Pharm 2002;59:2314-6.

Direct Observation Method

- Training required
- Non-obtrusive
- Video tape possible
- Process nodes ** Supporting data
  - Distribution
  - Administration
- Hawthorne effect
- Schedule observations

Barker KN et al. Arch Intern Med 2002;162:1897-1903

Process

- Establish multidisciplinary team to aid in executing the process.
- Determine the goal for performing direct observation at your institution.
- Consider the following:
  - Medication process node for focus (prescribing, dispensing, administration phase)
  - Time constraints
  - Logistical barriers
  - Personnel and resources
  - Acceptance and understanding of administrators and healthcare staff members being observed for the purpose of strategy
- Develop standardized data collection tool for consistency and reliability among observers
  - Data points for evaluation and recording
- Train observers on observation technique (non-interruptive) and data collection.
  - Often the observer is not intended to perform the evaluation of medication errors
- Document the results in a central location.

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Patient and Family Involvement

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SMU Guideline Recommendation

Recommendation

- Use of a patient/family reported outcome interviews at or after ICU discharge about possible medication errors or adverse drug events that occurred. (2C)

Description

- Formalize a process for interviewing patients or family members about possible medication errors or adverse drug events that occurred while the patient was in the ICU.

Data

- Kaboli PJ, Glasgow JM, Jaipaul CK, et al. *Pharmacotherapy* 2010;30:529-538
- van den Bemt PM, Egberts AC, Lenderink AW, et al. *Eur J Clin Pharmacol* 1999;55:155-158

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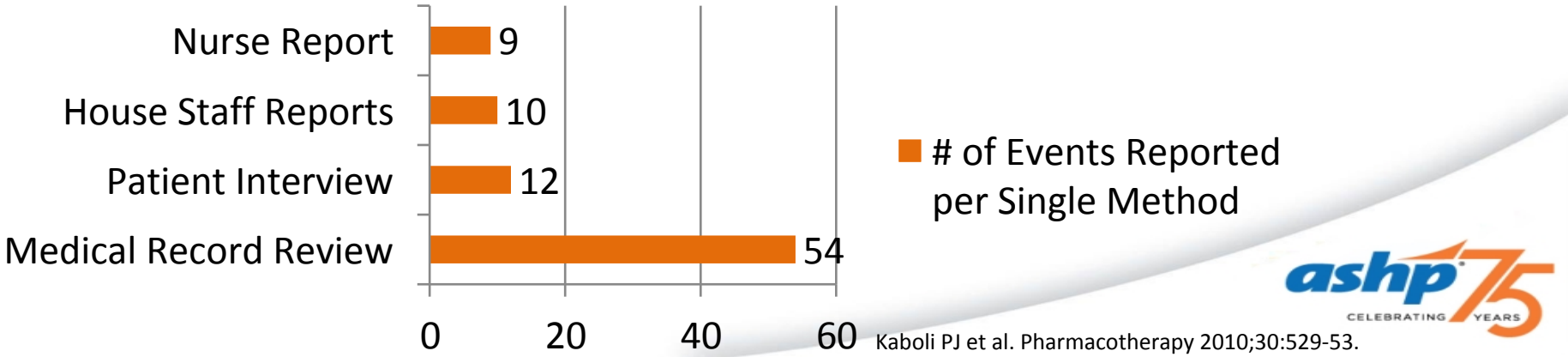
Supporting Data: Patient Interviews

- 48 bed general internal medicine ward
- 50% (63/126) patients with at least one medication error (ME)/ADE
- 106 events (37 ADEs, 69 MEs) with 80% reported via a single method



Kaboli PJ et al. Pharmacotherapy 2010;30:529-53.

Process

- Develop a standardized questionnaire to detect potential MEs or ADEs that occurred during the patient's ICU stay
- Questionnaire should be approved by an institutional patient safety committee or the equivalent
- Determine eligibility criteria for interviewing patients or family members
  - able to communicate in the ICU
- Establish a process for administering the standardized questionnaire
- Interview the patient, family member, or caregiver using the standardized questionnaire either close to the time of discharge or shortly thereafter

Which method of surveillance do you think identifies the most events?

A. Non-targeted chart review
B. Targeted chart review
C. Direct observation
D. Patient and family reporting

Key Takeaways and Application

- Key Takeaway #1
  - More than one surveillance method is needed because different approaches detect different events
- Key Takeaway #2
  - Evidence to support methods as illustrated in the clinical practice guideline but a lack of use other than voluntary reporting
    - Resources? Process?
- Key Takeaway #3
  - Need a commitment to improving surveillance so medication errors and adverse drug events can be prevented

- ***Practice Reflection Question (application):*** What are your current surveillance practices? Based on these data, what are areas for improvement?