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Actionable Patient Safety Solution (APSS) #3A: Medication Errors

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Comments

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Actionable Patient Safety Solution (APSS) #3A:
MEDICATION ERRORS

Executive Summary Checklist

Medication errors (wrong drug, wrong dose, wrong patient or route of administration) are a major cause of inpatient morbidity and mortality. An effective program to reduce medication errors will require an implementation plan to complete the following actionable steps:

▢ Hospital leadership must understand the medication safety gaps in their own system, and be committed to a comprehensive approach to close those gaps.

▢ Create a multidisciplinary team, including physicians, nurses, pharmacists, and information technology personnel to lead the project.

▢ Implement systematic protocols for medication administration, featuring checklists for writing and filling prescriptions, drug administration, and during patient transitions of care, as well as other quality assurance tools. These tools will include:
  - Installing the latest safety technology to prevent medication errors, such as the BD Intelliport™ Medication Management System and First Databank FDB MedKnowledge™ system or other drug dosing solutions for individual or categories of medications such as Monarch Medical Technologies solution for calculating IV & SubQ insulin doses.
  - Use barcoding for drug identification in the medication administration process.
  - Check patient's allergy profile before prescribing medication.
  - Ensure appropriate training and safe operation of automated infusion technologies.
  - Distinguish "look-alike, sound-alike" medications by labeling design and storage.
  - Implement a system for patient follow-up to ensure medication adherence.

▢ Implement technology that standardizes Computerized Physician Order Entry (CPOE), reporting systems and quality assurance reports to audit compliance with safe drug administration practices.

▢ Practice the Five Patient Rights on Medications: right patient, right drug, right dose, right route, and right time of administration. All care providers should use this simple checklist.

▢ Provide education of all hospital personnel in the principles above. Monitor the effectiveness of this education at regular intervals.

▢ Review monitoring/reporting results at medical staff meetings and educational sessions as a part of Continuous Quality Improvement (CQI).

The Performance Gap

Medical errors are defined as preventable adverse events or effects of care and are a major cause of death in the United States. 1 in 20 perioperative medication administrations, or every second operation, resulted in a medication error and/or an adverse drug event.[1] Healthcare leadership must be made fully aware of the significant improvements in quality and safety of healthcare, as well as cost savings, that can be realized by actively addressing medical errors.

Medical errors include inaccurate or incomplete diagnosis or treatment, as well as instances of an appropriate method of care being executed incorrectly.[2] The vast majority of medical errors result from faulty systems and poorly designed processes, rather than poor practices or incompetent practitioners.[3]

Medication errors are a form of medical error and a significant cause of adverse events. Medication errors can be categorized as: 1) wrong drug, 2) wrong dose, 3) wrong route, 4) wrong frequency and 5) wrong patient. For example, drug infusion pump errors related to programming and operation are common and may have catastrophic complications. These pumps are complex to operate and poorly designed user interfaces can lead to programming errors. Patients receiving infused medications are often critically ill and receiving multiple medications, which further increases the probability of error. Perioperative medication administration has challenges due to a lack of computerized order entry, pharmacy approval or oversight by a second person prior to administration. These challenges coupled with a high stress environment has higher rates of medication errors resulting in a higher severity level.[4] A variety of approaches are now available, to reduce these types of errors, including automated infusion and IV injectable technologies, integration of electronic medical records, continuous patient monitoring, predictive algorithms, checklists, and process of care advances.

Closing the performance gap will require hospitals and healthcare systems to commit to action in the form of specific leadership, practice, and technology plans.

Leadership Plan

Hospital governance, senior administrative leadership, and clinical/safety leadership must close their own performance gaps by implementing a comprehensive patient and medication safety approach. The process must include the fundamentals of change outlined in the National Quality Forum (NQF) safe practices.[4] Specifically, the plan must:
- have strong evidence that they are effective and reducing preventable deaths;
- are generalizable and may be applied in multiple care settings and for multiple patient types;
- are likely to have a significant impact on reducing preventable deaths if fully implemented; and
- provide knowledge that can be used to educate and empower patients, healthcare professionals, researchers, and insurers.
- be designed so that leadership and *all* healthcare professionals fully understand the performance gaps in their own area of care;
- include a firm target date for the implementation of the corrective plan, with measurable quality indicators and milestones. "Some is not a number. Soon is not a time"[5];

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[1] Nanji, K. C., Patel, A., Shaikh, S., Seger, D. L., & Bates, D. W. (2016). Evaluation of perioperative medication errors and adverse drug events. The Journal of the American Society of Anesthesiologists, 124(1), 25-34.

[2] Kerr, E. (2000). What is an error?. Effective Clinical Practice, 6, 261-269.

[3] Palmieri, P. A., DeLucia, P. R., Peterson, L. T., Ott, T. E., & Green, A. (2008). The anatomy and physiology of error in adverse health care events. Advances in Health Care Management, 7, 33-68.

[4] Meyer, G., Denham, C. R., & Battles, J. (2010). Safe practices for better healthcare–2010 update: A consensus report. In Washington, DC, National Quality Forum (p. 58).

[5] Institute for Healthcare Improvement. Overview of the 100,000 lives campaign. Retrieved from: https://www.ihi.org/Engage/Initiatives/Completed/5MillionLivesCampaign/Documents/Overview%20of%20the%20 100K%20Campaign.pdf

- budget allocations for the corrective plan should be evaluated by governance boards and/or senior administrative leaders;
- be endorsed by clinical/safety leadership to ensure implementation across all providers and systems; and
- include a standardized system for feedback so that work plans remain flexible and may be fine-tuned as implementation progresses.

Practice Plan

- Formally assess opportunities to reduce medication errors with a comprehensive self-assessment process.[6]
- Create a multidisciplinary team which includes physicians, nurses, pharmacists, and information technology personnel.
- Develop education on medication error and patient safety updates. Frequency can be monthly or quarterly. Systematize patient allergy and drug-drug interaction checks on every patient, CPOE, medication barcoding, as well as patient education and adherence tools for correct and timely medication administration.[7] This should include the use of checklists and other quality assurance tools.
- Universal checklist for drug administration must include: patient, drug, dose, route, frequency.
- Implement standardized order sets where possible.[8]
- Implement the Institute for Safe Medication Processes (ISMP) guidelines for training and safe operation of intravenous infusion pumps.[9]
- Implement Institute for Safe Medication Processes (ISMP) guidelines for the multidisciplinary use of medication dispensing cabinets.[10]
- Implement Institute for Safe Medication Processes (ISMP) guidelines for Adult IV Push Medications.
- Review medication labels and redesign as needed.[11]
- Implement a standardized process for compounding sterile medications.[12]
- Adhere to the Patient Safety Movement Actionable Patient Safety Solution guidelines for continuous monitoring of all patients who are receiving parenteral narcotics or other sedative drugs.[13]
- Implement CDC Guidelines for single use injections, one solution, one patient, one syringe.

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[6] Institute for Safe Medication Practices. (2011). 2011 ISMP medication safety self assessment® for hospitals. Retrieved from: http://www.ismp.org/selfassessments/Hospital/2011/Default.asp

[7] Institute for Safe Medication Practices. (2011). ISMP acute care guidelines for timely administration of scheduled medications. Retrieved from: http://www.ismp.org/Tools/guidelines/acutecare/tasm.pdf

[8] Institute for Safe Medication Practices. ISMP's guidelines for standard order sets. Retrieved from: http://www.ismp.org/Tools/guidelines/StandardOrderSets.asp

[9] Institute for Safe Medication Practices. Proceedings from the ISMP summit on the use of smart infusion pumps: Guidelines for safe implementation and use. Retrieved from: http://www.ismp.org/Tools/guidelines/smartpumps/default.asp

[10] Institute for Safe Medication Practices. Institute for safe medication practices (ISMP) guidance on automated dispensing cabinets. Retrieved from: http://www.ismp.org/Tools/guidelines/ADC/default.asp

[11] Institute for Safe Medication Practices. Label formats finalized versions. Retrieved from: http://www.ismp.org/Tools/guidelines/labelFormats/default.asp

[12] Institute for Safe Medication Practices. ISMP guidelines for safe preparation of compounded sterile preparations. Retrieved from: http://www.ismp.org/Tools/guidelines/IVSummit/IVCGuidelines.

[13] Weinger, M. B., & Lee, L. A. (2011). No patient shall be harmed by opioid-induced respiratory depression. APsF Newsletter, 26, 21-26.

To be successful in implementing this Actionable Patient Safety Solution, one should rely on implanting a technology plan using the following systems. Other specific strategies will be developed or become apparent as the above are implemented. This action plan will include careful observation of the consequences of each new strategy, which will in turn lead to additional novel ideas for further improvement in medication administration safety.

Suggested practices and technologies are limited to those proven to show benefit or are the only known technologies with a particular capability. As other options may exist, please send information on any additional technologies, along with appropriate evidence, to info@patientsafetymovement.org.

System or Practice	Available Technology
All Settings	
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: ● Computerized Physician Order Entry (CPOE) ● Drug-drug interaction check ● Drug-allergy interaction check ● Electronic Prescribing (eRx) ● Electronic Prior Authorization (ePA)	*The following EHR vendors have signed the Patient Safety Movement Open Data Pledge:[14]* ● Cerner ● GE Healthcare
Electronic Medication Administration Record (eMAR) system with pharmacy and bedside barcoding capabilities[15]	● First Databank FDB MedKnowledge system[16]
FDA approved clinical decision support solution for medication therapy recommendation.	● Monarch Medical Technologies Endotool® Solutions for insulin
Infusion pumps that wirelessly communicate data back to the electronic eMAR	● Alaris® ● Baxter® ● Hospira® ● Fresenius® ● B.Braun® I.V. pumps.
Patient and Medication barcoding system	● Codonics® Safety Labeling System; or ● BD Intelliport™ Labeler; or ● Single Use Injection Vials and Kits

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[14] Patient Safety Movement Foundation. Healthcare Technology Pledges. Retrieved from: http://patientsafetymovement.org/challenges-solutions/commitments-pledges/healthcare-technology-pledges/

[15] Institute for Safe Medication Practices. Reporting a medication or vaccine error or hazard to ISMP. Retrieved from: https://www.ismp.org/errorReporting/reportErrortoISMP.aspx

[16] First Databank. (2014) Case study: Enterprise EMAR, hospital [harmacy, barcoding meta healthcare IT solutions. Retrieved from: http://www.fdbhealth.com/~/media/downloads/form%20required/us/case%20study%20-%20fdb%20medknowledge%20-%20barcoding%20-%20meta%20healthcare.ashx

CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE[17,18]	• Leapfrog CPOE Evaluation Tool[19]
Drug Libraries	• Alaris® • Baxter® • Hospira® • Fresenius® • B.Braun® I.V. pumps • BD Intelliport™ Medication Management System for I.V. injectables, or comparable systems.
Pharmacy Workflow Manager	• DoseEdge® from Baxter Healthcare®
Perioperative Environment	
IV injectable doses, audible and visual feedback for each syringe attached with measurement of dose, allergy alerts and more accurate and timely documentation wireless to the anesthesia information system	• BD Intelliport™ Medication Management System.
Continuous physiologic monitoring on patients receiving IV medications to provide an early indication of deterioration due to a medication error	• Masimo rainbow® Acoustic Monitoring[20] • Side-stream end-tidal carbon dioxide monitoring ○ Oridion® ○ Masimo® ○ Respironics®
Pharmacy Environment	
Pharmacy robots to reduce safety problems associated with providers drawing up their own medications, and risks associated with contamination from outsourced compounders.	• BAXA® Intellifil Robot.

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[17] Metzger, J., Welebob, E., Bates, D. W., Lipsitz, S., & Classen, D. C. (2010). Mixed results in the safety performance of computerized physician order entry. Health Affairs, 29(4), 655-663.

[18] Leung, A. A., Keohane, C., Lipsitz, S., Zimlichman, E., Amato, M., Simon, S. R., ... & Seger, D. L. (2013). Relationship between medication event rates and the Leapfrog computerized physician order entry evaluation tool. Journal of the American Medical Informatics Association, 20(e1), e85-e90.

[19] The Leapfrog Group. (2016). Prepare for CPOE Tool. Retrieved from: http://www.leapfroggroup.org/survey-materials/prepare-cpoe-tool

[20] Mimoz, O., Benard, T., Gaucher, A., Frasca, D., & Debaene, B. (2012). Accuracy of respiratory rate monitoring using a non-invasive acoustic method after general anaesthesia. British Journal of Anaesthesia, 108(5), 872-875.

Utilize Single Use Injection Kits or Pre-mixed sterile solutions	● Asclemed USA Inc., Injection Kits ● Nubratori RX, Pre-mixed sterile solutions

Other Considerations
"End-to-end" smart pump system, or other electronic pump systems

Metrics

Topic:

Adverse Drug Event

Adverse drug event (ADE) with harm to patient (Category E or higher on NCC-MERP classification) that is preventable (i.e., not an unknown first-time reaction to a medication).

Outcome Measure Formula:

Numerator: Number of reported adverse drug events with harm (as defined above) – by class or medication
Denominator: Number of doses administered (by medication or class of medications)
* Rate is typically displayed as ADE with harm/1000 doses given

Metric Recommendations:

Indirect Impact (preventable rate):

All patients benefit from efforts such as CPOE, medication reconciliation (upon admission and discharge from the hospital), monitoring of drugs with therapeutic indexed levels (e.g., digoxin, phenytoin, warfarin), conversion of IV to PO meds once patient can tolerate oral liquids, and antibiotic stewardship.

Direct Impact (non-preventable rate):

All patients prescribed medications

Lives Spared Harm:

Lives = (ADE Rate $_{baseline}$ - ADE Rate $_{measurement}$) X Doses ┃┃ Patient Days $_{baseline}$

Notes:
Top Medication Classes/Triggers:

1. Opioids
2. Sedatives/Hypnotics (including propofol)
3. Anticoagulants
4. Antimicrobials (including antivirals and antifungals)
5. Anti-diabetic medications (including insulin, and other injectable and oral medications)
6. Injectable medications

Initial/Baseline measurement will show ability to capture ADE information, since most are voluntarily reported. Over time, decreases in this rate can show lives spared harm. To ensure that reductions are not due to decreased reporting, a control measure should also be measured:

Control Rate Calculation:

Numerator: Number of **ALL** reported errors and adverse drug reactions (including harm and NOT causing harm or "near misses")
Denominator: Number of doses administered over time period
Control ADE rate should be consistent or increase, with corresponding decrease in ADE with harm

Data Collection:

ADE reporting information is dependent on volunteer reporting and accuracy of people verifying reports (preferably from pharmacy and a medication errors reporting program, MERP).

Medication usage information is usually collected from billing information rather than medication orders (more accurate if patient received the dose or not).

If medication usage information is not available, denominator could be per 1000 patient days. This can track over time, especially for all ADE reporting, however, will not adjust ADE rate for high or low utilization medications.

Scales:

- The Adverse Drug Reaction Probability Scale (Naranjo) determines the causality of an ADR or how likely is the drug the true cause of the ADE.[21]

Mortality (will be calculated by the Patient Safety Movement Foundation):

The PSMF, when available, will use the mortality rates associated with Hospital Acquired Conditions targeted in the Partnership for Patients (PfP) grant funded Hospital Engagement Networks (HEN). The program targeted 10 hospital acquired conditions to reduce medical harm and costs of care. "At the outset of the Partnership for Patients initiative, HHS agencies contributed their expertise to developing a measurement strategy by which to track national progress in patient safety—both in general and specifically related to the preventable HACs being addressed by the PfP. In conjunction with CMS's overall leadership of the PfP, AHRQ has helped coordinate development and use of the national measurement strategy. The results using this national measurement strategy have been referred to as the "AHRQ National Scorecard," which provides summary data on the national HAC rate.[22] Adverse drug events was included in this work with published metric specifications. This is the most current and comprehensive study to date. *Based on these data the estimated additional inpatient mortality for Adverse Drug Events is 0.020 (20 per 1000 events).*

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[21] U.S. National Library of Medicine. (2015) Adverse drug reaction probability scale (Naranjo) in drug induced liver injury. Retrieved from: https://livertox.nih.gov/Narajo.html

[22] Agency for Healthcare Research and Quality. (2015). Efforts to improve patient safety result in 1.3 million fewer patient harms. Retrieved from http://www.ahrq.gov/professionals/quality-patient-safety/pfp/interimhacrate2013.html

Workgroup

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Revision History

Version	Primary Author(s)	Description of Version	Date Completed
Version 1	Paul Jansen	Initial Release	January 2014
Version 2	Jim Bialick, Ron Jordan, Jerika Lam, Laura Batz Townsend, Steven Barker, Thomas Corlett, Paul Jansen, Chris Jerry, Ariana Longley, Steve Mullenix, Robert Nickell, Rachael Raynes, Rochelle Sandell, Jason Yamaki	Workgroup Review	January 2016
Version 3	Michael Ramsay, Steven Barker, Joe Kiani, Jim Bialick, Ariana Longley	Executive Review	April 2016
Version 4	Jerika Lam, Ron Jordan, Nat Sims, Coco Yang, Celine Peters, Robert Nickell, Stuart Long, Steve Barker, Michael Ramsay, Ariana Longley, Joe Kiani	Workgroup and Executive Review	January 2017

Actionable Patient Safety Solution (APSS) #3B:
ANTIMICROBIAL STEWARDSHIP
THE ROLE OF PHARMACY AND THE MICROBIOLOGY LAB IN PATIENT SAFETY

Executive Summary Checklist

Inappropriate use of antimicrobial drugs (antibiotics, etc.) is a significant cause of patient morbidity and mortality. This risk can be greatly reduced by an Antimicrobial Stewardship Program (ASP), which requires an implementation plan that includes the following actionable steps:

☐ Commitment from institutional leadership (administration, medicine, pharmacy, nursing, microbiology, and technology) to develop and support an Antimicrobial Stewardship Program.

☐ Create a multidisciplinary Antimicrobial Stewardship Committee that includes infection prevention, infectious disease professionals from Medicine and Pharmacy, Microbiology Laboratory, Nursing, and Information Technology. This group will ensure the:
  ● accountability of ASP chair or co-chairs.
  ● development of protocols to support ASP initiatives and interventions.
  ● personnel training and support.
  ● necessary infrastructure for measuring antimicrobial use and outcomes.
  ● monitoring of microbial resistance and its effect on disease patterns.
  ● development of clear goals for the ASP, including timelines and metrics.
  ● delivery of regular updates to the institutional antibiogram and compliance with Clinical Laboratory Standards Institute (CLSI) guidelines.

☐ Implement Computerized Physician Order Entry (CPOE) with Clinical Decision Support (CDS) and computer-based surveillance software to provide real-time data at the point of care for ASP initiatives.

☐ Develop mechanisms to educate clinicians regarding ASP initiatives and progress. Identify and educate clinicians who exhibit outlying prescribing patterns. Monitor progress and include the results in staff educational sessions.

☐ All antimicrobial orders are reviewed by a hospital pharmacist

The Performance Gap

On September 29, 2014 California Governor Jerry Brown approved SB 1311 that will require all general acute care hospitals in California to establish a physician supervised multidisciplinary Antimicrobial Stewardship committee by July 1, 2015.[1] The overall objectives of the Antimicrobial Stewardship Program (ASP) committee are to identify and reduce risks of developing, acquiring, and transmitting infections; reduce healthcare costs and toxicities associated with antimicrobials and inappropriate therapy; and, most importantly, improve patient outcomes (e.g., reduced antimicrobial/antifungal/antiviral resistance rates, reduced *C. difficile* rates, and reduced hospital LOS). More importantly, an effective ASP committee or team is comprised of an ID-trained physician, pharmacist (preferably ID-trained), infection control personnel and microbiologist. Inappropriate use of antimicrobials can have unintended consequences on both the pathogen and patient. From the perspective of the pathogen, resistance may be acquired and spread within the healthcare system and into the community. From the patient perspective, adverse reactions, super-infections, selection of resistant pathogens, and poor clinical outcomes may occur. Hence, optimized and judicial use of antimicrobials is a critical component of patient safety. Any institution implementing an ASP must be able to measure two key variables: 1) antimicrobial use [to assess whether interventions lead to changes in use] and 2) outcomes associated with changes in antibiotic use. For instance, a metric that is used to determine the impact of the ASP is by calculating the defined daily doses (DDDs) of antibiotics per 1000 patient days (see under "Pharmacy Driven Interventions for ASPs" section). The cost per quality adjusted life-year (QALY) could also be used as another metric to measure the cost-effectiveness of the program in preventing specific infections (e.g., bloodstream infections).

While typically not thought of as an aid in patient safety, it should be apparent that one of the key components of the ASP is the prevention of adverse drug events by decreasing the indiscriminate use of antibiotics. According to a number of studies, approximately 25% of adverse drug events arise from antimicrobial use.[2,3] Antimicrobials in one study were responsible for 19% of emergency department visits (2004-2006), in which the majority were allergic reactions. Based on this data, the study found that risks for adverse events from antimicrobial therapy were three times higher than those reported for aspirin, phenytoin, and clopidogrel.[4] Another critical adverse outcomes associated with the use of antibiotics is *Clostridium difficile* colitis, often a complication associated with broad spectrum antibiotic use, but has also been reported to occur with almost any type of antibiotic. This type of infection carries an increased risk of readmission, as well as an increased risk for mortality. Hence, judicial and prudent use of antimicrobial therapy may prevent resistance, adverse drug events, and improve patient safety.

As antimicrobials are dispensed by the pharmacy, it is an important clinical responsibility of the pharmacist to ensure the optimal use of antimicrobial agents and educate healthcare professionals and patients within the hospital setting. Functions related to this responsibility of the pharmacist may include and are not limited to the interventions described below.

Pharmacy Driven Interventions for ASPs
- Protocols for changes from intravenous to oral antibiotic therapy in appropriate situations.
  - *Rationale: Decrease cost, decrease hospital stay, and reduce line infections.*
  - Clinical Stability Criteria for IV to PO:
    - Afebrile
    - Stable heart rate
    - Stable respiratory rate

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[1] California Legislative Information. (2014). SB-1311 hospitals: Antimicrobial stewardship. Retrieved from: http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140SB1311
[2] Bates, D. W., Cullen, D. J., Laird, N., Petersen, L. A., Small, S. D., Servi, D., ... & Vander Vliet, M. (1995). Incidence of adverse drug events and potential adverse drug events: Implications for prevention. Jama, 274(1), 29-34.
[3] Lesar, T. S., Briceland, L., & Stein, D. S. (1997). Factors related to errors in medication prescribing. Jama, 277(4), 312-317.
[4] Shehab, N., Patel, P. R., Srinivasan, A., & Budnitz, D. S. (2008). Emergency department visits for antibiotic-associated adverse events. Clinical Infectious Diseases, 47(6), 735-743.

- Systolic blood pressure >90mm Hg
- O2 saturation >90% (O2 partial pressure >60 mm Hg)
- Functional GI
- Normal mental status
- Dosage adjustments in cases of organ dysfunction.
  - *Rationale: Avoid toxicities.*
- Dose optimization (pharmacokinetics/pharmacodynamics) to optimize the treatment of organisms with reduced susceptibility.
  - *Rationale: Avoid toxicities, optimize PK/PD, improve patient outcomes.*
- Automatic alerts in situations where therapy might be unnecessarily duplicative.
  - *Rationale: Avoid toxicities and decrease costs.*
- Time-sensitive automatic stop orders for specified antibiotic prescriptions.
  - *Rationale: Decrease cost and unnecessary antimicrobial therapy, and decrease development of resistance.*
- Initiation of necessary treatment for patients who should be receiving antibiotics.
  - *Rationale:* With *no empiric or directed therapy against infecting or suspected organisms, the delay in time to an active antibiotic against the pathogen increases mortality.*
- Antimicrobial use and efficacy analysis
  - *Rationale: Need to determine the patient days for the hospital ward being analyzed for the time period of the data. The calculation is: (DDDs / patient days) * 1000. Recent guidelines from the Infectious Disease Society of America, recommend the use of days of therapy (DOT) per 1000 patient days over DDD, with DDD being an alternative at institutions that cannot collect DOT data.*

Microbiology Laboratory Contribution

- Providing at least yearly antibiograms (if possible twice a year). Antibiogram reporting should be location specific (e.g., ICU, general wards, or pediatric areas).
- Incorporate rapid diagnostics such as multiplex PCR and Matrix Assisted Laser desorption/ionization – time of flight (MALDI-TOF).
  - Rapid diagnostics have been demonstrated to decrease the time to appropriate antibiotics and decrease the time on unnecessary antimicrobial therapy.
- Incorporate Pro-calcitonin level measurement in the laboratory to aid in antibiotic initiation and discontinuation.
  - During bacterial infection, Pro-calcitonin is produced in large quantities by body tissues. Strong evidence supports its use in antibiotic management of infections, particularly, pneumonia or other lower respiratory tract infections, and has been demonstrated to significantly decrease unnecessary antibiotic use and shorten duration of therapy.
- Automatic testing and reporting of tigecycline and colistin for Carbapenem Resistant Enterobacteriaceae isolates.
  - As carbapenem resistance is increasingly reported, it is critical that alternative agent susceptibilities be made available. These alternative agents include tigecycline and colistin. While breakpoints for susceptibility are not available by CLSI, FDA breakpoints are available and should be used for interpretation.
- Reporting of minocycline susceptibility for *Acinetobacter* isolates.
  - Minocycline susceptibility remains high in most institutions against multi-drug resistant *Acinetobacter spp*, hence this should be taken advantage of as its resistance patterns allow.
- Selective reporting of susceptibilities of antimicrobials.
  - Selective reporting is a process of withholding susceptibility results from selected categories of antibiotics that may have deleterious effects on the hospital antibiogram/resistance rates, or financial cost that do not have a therapeutic advantage over other commonly used antimicrobial agents. For example, if an *E. coli* strain is isolated from a bloodstream infection and is not susceptible to a 1st generation cephalosporin but is susceptible to cefotaxime, other broader agents

such as cefepime, meropenem, or ceftaroline can be withheld and available upon the request of the physician.

Leadership Plan

Commitment from the hospital leadership is required for the successful implementation and progress of any clinical program, including the ASPs. Commitment and support of ASPs should not only come from the ASP committee or infectious diseases physicians, but also from the senior administration. Formal statements made at the administrative level in support of the program implementation and progression should be clear, in this way practitioners at the hospital will know and understand the importance of the ASP's presence and goals. Some approaches that hospital/facility leadership should include in support of the ASP are:[5,6]

- Financial support
- Formal statements supporting the ASP and optimal use of antimicrobials within the hospital
- Protected/acknowledged time for personnel from various departments to participate in the ASP.
- Provide training and support to personnel
- Provision of necessary infrastructure for tracking and measuring antimicrobial use and outcomes.

Practice Plan

Each hospital should create a multidisciplinary team that includes an ID physician, ID-trained or clinical pharmacist, microbiologist, infection control, and information technologists.[5] Depending on the size, type, and resources available to the hospital different strategies can be employed. In a large academic hospital it may be possible to form an antimicrobial stewardship committee and implement either a restrictive ASP or prospective audit with feedback.

In a restrictive program, select antimicrobials are placed on formulary restriction for use in only select indications. Dispensing of a restricted agent would require approval by designated personnel, usually an ID physician, ID fellow, or clinical pharmacist. The advantages of this program are:
>(a) the direct oversight in the use of targeted antimicrobials,
>(b) reduction of pathogen resistance within the hospital and communities,
>(c) reduced hospital LOS, and
>(d) reduced risks of antimicrobial-related side effects and drug-drug interactions.

The disadvantages may include:
>(a) the requirement of personnel availability around-the-clock,
>(b) physicians may perceive this as a loss of autonomy, and
>(c) review of appropriateness only occurs with targeted/restricted agent, but not for non-restricted agents which can also lead to problems.[7,8]

An alternative to the restrictive program is a prospective audit with feedback program. In this program, a retrospective (hours to days) review of antimicrobial orders takes place for targeted and in some institutions non-targeted antimicrobials for appropriateness. It is also common to find programs that use a hybrid approach in which

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[5] Centers for Disease Control and Prevention. (2015). Core elements of hospital antibiotic stewardship programs. Retrieved from: https://www.cdc.gov/getsmart/healthcare/implementation/core-elements.html

[6] Dellit, T. H., Owens, R. C., McGowan, J. E., Gerding, D. N., Weinstein, R. A., Burke, J. P., ... & Brennan, P. J. (2007). Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. Clinical Infectious Diseases, 44(2), 159-177.

[7] Goff, D. A., Bauer, K. A., Reed, E. E., Stevenson, K. B., Taylor, J. J., & West, J. E. (2012). Is the "low-hanging fruit" worth picking for antimicrobial stewardship programs?. Clinical Infectious Diseases, cis494.

[8] Dellit, T. H., Owens, R. C., McGowan, J. E., Gerding, D. N., Weinstein, R. A., Burke, J. P., ... & Brennan, P. J. (2007). Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America guidelines for developing an institutional program to enhance antimicrobial stewardship. Clinical Infectious Diseases, 44(2), 159-177.

audit and feedback are employed along with a restricted formulary. Advantages of the prospective audit with feedback are the avoidance of loss of autonomy and the opportunity to educate individuals rather than only restrict utilization. A disadvantage is compliance is often voluntary.[8]

Implementation of the above two strategies require personnel dedicated to the ASP. In most academic and medium-to-large community hospitals, formation of an ASP with either of these strategies would be possible. On the other hand, in smaller hospitals where dedicated personnel may not be available, some of the pharmacy driven interventions mentioned previously can be implemented, as they require less resources and effort. These have been referred to as "low hanging fruit" interventions as they are the simplest to implement and yet have been shown to have a positive impact.[7] Such interventions include intravenous-to-oral conversions, therapeutic substitutions, batching of intravenous antimicrobials, monitoring and discontinuing preoperative antibiotic prophylaxis.

The Centers for Disease Control and Prevention has provided recommendations on core elements that should be implemented for hospital ASPs.[5] These include:

- Commitment from institutional leadership (technology, personnel, finance)
- Accountability of ASP chair or co-chairs
- A clinician with drug expertise in antimicrobials [e.g., clinical pharmacist (Infectious Disease trained)]
- Actionable program components (e.g., prospective audit, automatic discontinuation orders)
- Monitoring of microbial resistance and infection patterns
- Reporting of and education about ASP findings to hospital staff (physicians, nurses, pharmacists, etc.)

Technology Plan

To be successful in implementing this Actionable Patient Safety Solution will rely on implanting a technology plan using the following systems. Other specific strategies will be developed or become apparent as the above are implemented. This action plan will include careful observation of the consequences of each new strategy, which will in turn lead to additional novel ideas for further improvement in medication administration safety.

Suggested practices and technologies are limited to those proven to show benefit or are the only known technologies with a particular capability. As other options may exist, please send information on any additional technologies, along with appropriate evidence, to info@patientsafetymovement.org.

System or Practice	Available Technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: ● **Computerized Physician Order Entry (CPOE)** ● **Drug-drug interaction check** ● **Drug-allergy interaction check** ● **Clinical Decision Support tools (CDS)**	*The following EHR vendors have signed the Patient Safety Movement Open Data Pledge:*[9] ● Cerner ● GE Healthcare
CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE[10,11]	● Leapfrog CPOE Evaluation Tool[12]
Drug Libraries	● Alaris® ● Baxter® ● Hospira® ● Fresenius® ● B.Braun® I.V. pumps ● BD Intelliport™ Medication Management System for I.V. injectables, or comparable systems.
Pharmacy Workflow Manager	● DoseEdge® from Baxter Healthcare®

Technology has significantly advanced in the last decade within the hospital setting with the development of Electronic Health Records (EHR) and computer physician order entry (CPOE) systems. The CPOE, in particular,

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[9] Patient Safety Movement Foundation. Healthcare Technology Pledges. Retrieved from:
http://patientsafetymovement.org/challenges-solutions/commitments-pledges/healthcare-technology-pledges/
[10] Metzger, J., Welebob, E., Bates, D. W., Lipsitz, S., & Classen, D. C. (2010). Mixed results in the safety performance of computerized physician order entry. Health Affairs, 29(4), 655-663.
[11] Leung, A. A., Keohane, C., Lipsitz, S., Zimlichman, E., Amato, M., Simon, S. R., ... & Seger, D. L. (2013). Relationship between medication event rates and the Leapfrog computerized physician order entry evaluation tool. Journal of the American Medical Informatics Association, 20(e1), e85-e90.
[12] The Leapfrog Group. (2016). Prepare for CPOE Tool. Retrieved from: http://www.leapfroggroup.org/survey-materials/prepare-cpoe-tool

has been identified as a potential key action in improving patient safety.[13] Computer clinical decision support programs exist that complement the EHR and CPOE, which can provide epidemiologic data (e.g., antibiogram), warnings (drug interactions, excess dosages), allergies, or therapy guidelines (drug-bug mismatches) in real-time during order entry or chart review. Such performance capabilities have demonstrated increases in patient safety, cost savings, and decreased time allotted to ASP activities.[14,15]

As a complement to EHRs, CPOE systems, and decision support software, computer-based surveillance programs have also been developed and implemented in the hospital settings and used specifically in ASPs. These programs have been used to collect data on hospital-acquired infections and adverse drug reactions.[8,16] Thus, incorporating surveillance programs and CPOE with decision support programs can likely benefit patient safety and the ASP by providing real-time data at the point of care, leading to improved clinical decisions and facilitating data collection for antimicrobial targeting or interventions.[8]

Conclusion

The ASP plays a critical role in patient safety. Hospitals in California are now required by law to have an antimicrobial stewardship committee comprised of at least an ID physician and clinical pharmacist, but should ideally also include a microbiologist, infection control and IT personnel. A number of interventions and different program types can make up the ASP, which includes actions from the pharmacy, microbiology, and IT departments. The resources required for implementing the ASP can range from minimal resources to dedicated resources (**Table 1**); however, once implemented ASP initiatives can increase patient safety, reduce resistance rates, decrease hospital costs, and improve patient clinical outcomes.

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[13] Kuperman, G. J., & Gibson, R. F. (2003). Computer physician order entry: Benefits, costs, and issues. Annals of Internal Medicine, 139(1), 31-39.

[14] Evans, R. S., Pestotnik, S. L., Classen, D. C., Clemmer, T. P., Weaver, L. K., Orme Jr, J. F., ... & Burke, J. P. (1998). A computer-assisted management program for antibiotics and other antiinfective agents. New England Journal of Medicine, 338(4), 232-238.

[15] Kullar, R., & Goff, D. A. (2014). Transformation of antimicrobial stewardship programs through technology and informatics. Infectious Disease Clinics of North America, 28(2), 291-300.

[16] Evans, R. S., Larsen, R. A., Burke, J. P., Gardner, R. M., Meier, F. A., Jacobson, J. A., ... & Hulse, R. K. (1986). Computer surveillance of hospital-acquired infections and antibiotic use. Jama, 256(8), 1007-1011.

Table 1: Interventions and required resources

Intervention/Program	Minimal resources required	Dedicated resources required
IV to PO conversion	Pharmacist	
Antimicrobial dosage adjustments	Pharmacist	
Automatic alerts	IT	
Automatic stop orders	IT	
Restrictive/Formulary ASP	ID physician, clinical pharmacist	
Prospective audit with feedback		ASP committee
Hybrid: Prospective audit with feedback & Restrictive ASP		ASP committee
Antibiogram (hospital-specific)	Micro lab	
Selective susceptibility reporting/SDD	Micro Lab	
EHR/CPOE		IT, funding
Decision support programs		IT, funding

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Version 1	Jerika Lam, Jason Yamaki, Ron Jordan	Initial Release	January 2016
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Actionable Patient Safety Solution (APSS) #3C:
IMPROVE PREVENTION OF SEVERE HYPOGLYCEMIA

Executive Summary Checklist

Severe hypoglycemia (SH) causes significant morbidity and occasional mortality in hospitalized patients. The establishment of an effective program to reduce errors in the recognition and treatment of SH requires an implementation plan that includes the following actionable steps:

☐ Establish a commitment from hospital administration and medical leadership to reduce SH.

☐ Raise institutional awareness of the issue by comparing hospital and nursing units based on performance quality scorecards.

☐ Create a multidisciplinary team that includes physicians, pharmacists, nurses, diabetic educators, medication safety officers, case managers, and long-term healthcare professionals. This team will:

- Develop a system to identify patients receiving anti-diabetic medications (sulfonylureas, insulins, etc.) in the Electronic Health Record (EHR).

- Implement real-time surveillance methods, analysis tools, and point-of-care blood glucose (BG) monitoring and reporting systems.

- Create insulin order sets that could be modified to reduce risks of hypoglycemia.

- Coordinate glucose monitoring, automate insulin dose calculations, insulin administration, and meal delivery during changes of shift and times of patient transfer.

- Develop a systematic approach to reduce SH and implement universal best practices.

☐ Continuously monitor the incidence of SH in the hospital, and use the results of this monitoring in medical staff education sessions as a part of Continuous Quality Improvement (CQI).

The Performance Gap

Hypoglycemia is a common problem for many patients with diabetes, and it can also occur in non-diabetics in a hospital setting. . Mild episodes can cause unpleasant symptoms and disrupt daily activities. Severe hypoglycemia (SH) can result in disorientation and unusual behavior, and may be life-threatening. Frequent hypoglycemia is associated with increased morbidity, length of stay, and mortality. Hypoglycemia has been associated with mortality in the intensive care units.[1] Moderate and SH are strongly associated with increased risk of death, especially from distributive shock.[2] This is by means of impairment of autonomic function, alteration of blood flow and composition, white cell activation, vasoconstriction, and the release of inflammatory mediators and cytokines.[3,4] The prevalence of hypoglycemia (serum glucose <70 mg/dL) was reported as 5.7% of all point-of-care blood glucose (BG) tests in a 2009 survey of 575 hospitals.[5] The definition of SH (a low BG level that requires the assistance of another person for recovery), is a level <40 mg/dL, has been adopted as the level likely to cause harm in the hospital setting.[6] SH is a preventable harm. Early therapeutic management of mild hypoglycemia can prevent more SH episodes. In addition, literature showed that clinicians do not consistently adjust their patient's anti-diabetic regimens appropriately following treatment of hypoglycemia, placing the patient at additional risk.[7,8]

Causative factors that may lead to the development of hypoglycemia for inpatients may include excessive insulin dose, inappropriate timing of insulin or anti-diabetes therapy, unaddressed antecedent hypoglycemia or changes in the nutritional regimen, creatinine clearance changes, or steroid dose (9).[9] Failure of effective BG monitoring and communication between physicians, pharmacists and nurses can also contribute to the problem. The diverse nature of potential errors in the treatment of inpatients with SH supports the need for a decision-making model that can be used to predict and prevent SH episodes and improve overall patient safety and outcomes.

Closing the performance gap will require hospitals and healthcare systems to commit to action in the form of specific leadership, practice, and technology plans.

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[1] Elliott, M. B., Schafers, S. J., McGill, J. B., & Tobin, G. S. (2012). Prediction and prevention of treatment-related inpatient hypoglycemia. Journal of Diabetes Science and Technology, 6(2), 302-309.

[2] NICE-Sugar Study Investigators. (2012). Hypoglycemia and risk of death in critically ill patients. New England Journal of Medicine, 2012(367), 1108-1118.

[3] Adler, G. K., Bonyhay, I., Failing, H., Waring, E., Dotson, S., & Freeman, R. (2009). Antecedent hypoglycemia impairs autonomic cardiovascular function implications for rigorous glycemic control. Diabetes, 58(2), 360-366.

[4] Wright, R. J., & Frier, B. M. (2008). Vascular disease and diabetes: is hypoglycaemia an aggravating factor?. Diabetes/Metabolism Research and Reviews, 24(5), 353-363

[5] Swanson, C., Potter, D., Kongable, G., & Cook, C. (2011). Update on inpatient glycemic control in hospitals in the United States. Endocrine Practice.

[6] Schwartz, A. V., Vittinghoff, E., Sellmeyer, D. E., Feingold, K. R., De Rekeneire, N., Strotmeyer, E. S., ... & Faulkner, K. A. (2008). Diabetes-related complications, glycemic control, and falls in older adults. Diabetes Care, 31(3), 391-396.

[7] Boucai, L., Southern, W. N., & Zonszein, J. (2011). Hypoglycemia-associated mortality is not drug-associated but linked to comorbidities. The American Journal of Medicine, 124(11), 1028-1035.

[8] DiNardo, M., Noschese, M., Korytkowski, M., & Freeman, S. (2006). The medical emergency team and rapid response system: Finding, treating, and preventing hypoglycemia. Joint Commission Journal on Quality and Patient Safety/Joint Commission Resources, 32(10), 591.

[9] Deal, E. N., Liu, A., Wise, L. L., Honick, K. A., & Tobin, G. S. (2011). Inpatient insulin orders: Are patients getting what is prescribed?. Journal of Hospital Medicine, 6(9), 526-529.

Leadership Plan

- The plan must include the fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, ability, and action.[10]
- Hospital governance and senior administrative leadership (medical, pharmacy, and nursing) must fully understand the performance gaps in their own healthcare system.
- Hospital governance, senior administrative leadership, and clinical/safety leadership must close their own performance gaps by implementing a comprehensive approach.
- Hospitals should set a goal date for the implementation of the corrective plan, with measurable quality indicators and milestones.
- Specific budget allocations for the plan should be evaluated by governance boards and senior administrative leaders.
- Clinical/safety leadership should endorse the plan and ensure implementation across all providers and systems.

Practice Plan

- Each hospital should create a multidisciplinary team, which includes physicians, pharmacists, nurses, diabetic educators, medication safety officers, case managers, and long-term healthcare professionals).
- Develop a systematic approach to reducing severe hypoglycemia:
    - Identify events and prioritize
    - Raise institutional awareness
        - Compare hospitals and nursing units based on performance quality scorecards (use harm rate for at-risk patient days: # of events/# of patient days during hospital stay when a diabetic agent is ordered at any time)
    - Encourage nurses to enter hypoglycemia into safety event self-reporting site
    - Communicate to the hospital leadership board
    - Send letters to physicians and providers (from case managers)
    - Educate hospital staff, providers and patients – hospital newsletter and posters made for each hospital/nursing unit listing known and assumed solutions to hypoglycemia (e.g., "STOP Hypoglycemia!")
    - Kickoff reception for safety initiative
    - Frequent monitoring of glucose levels in patients who are at risk.
- Implement foundational Best Practices and "Just Do Its" (**Appendices A and B**)
    - Establish a Hypoglycemia Task Force for the hospital
    - Propose multidisciplinary diabetes safety team at each hospital
    - Adopt foundational best practices (literature-based recommendations for all hospitals)
    - Implement "Just Do Its!" (or "Start Nows") – these should be safe and reasonable interventions tested internally
    - Adopt ISMP recommendations for U-500 insulin precautions (**Appendix C**)
- Event investigation and collect causative factors
    - Causative Factors (to consider as part of analysis tool):
        - Insulin stacking
        - Wrong drug, dose, route, patient, or time
        - Insufficient glucose monitoring
        - Basal heavy regimen
        - Decreased nutritional intake
        - Event related to outpatient or emergency department drug administration
        - Event while treating elevated potassium
        - Glucose trend not recognized
        - High dose sliding scale insulin

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[10] National Quality Forum. (2010). Safe practices for better healthcare–2010 update. Retrieved from: http://www.qualityforum.org/publications/2010/04/safe_practices_for_better_healthcare_%E2%80%93_2010_update.aspx

- Home regimen continued as inpatient
- Significant reduction in steroid dose
- Sulfonylurea-related hypoglycemia
- Insulin administration and food intake not synchronized
- POC glucose reading not linked to insulin administration
- POC glucose reading not synchronized with food intake
  - Analysis tool forms reviewed by either pharmacist and/or nurse in a timely manner (e.g., 72 hours) for causative factors; communicate findings with physician(s)
  - Results are collated and reported to Medication Safety Committee and the Pharmacy and Therapeutics Committee
  - Identify interventions (evidence-based and expert opinion) that are used to resolve the most common or most harmful causative factors
  - Track the interventions and create customized action plans based on an integrated results dashboard
  - Share best practices within hospital and to other hospitals
- Share strategies and implement informed interventions on target floors and patients.

Technology Plan

Suggested practices and technologies are limited to those proven to show benefit or are the only known technologies with a particular capability. As other options may exist, please send information on any additional technologies, along with appropriate evidence, to info@patientsafetymovement.org.

- Implement glycemic management clinical decision support for insulin therapy recommendation, based on individual responses to insulin and designed for mitigation of all types of hypoglycemia.
  - This would include all of the following bullet points with significant additional safety features.
- Implement real-time surveillance method for informatics alerts: "High-Risk Sulfonylurea Alert" and "Hypoglycemia Risk Alert".
- Implement an automated hypoglycemia event analysis tool (to discover local causes of hypoglycemia and guide future interventions).
- Implement point-of-care BG monitoring and reporting systems, including quality assurance reports to audit compliance with hypoglycemia management goals and restriction of insulin utilization.
- Implement automated triggers for most common causative factors of hypoglycemia, an electronic tracking system for SH events, interventions used and clinical outcomes.
- Implement a results dashboard for each nursing unit within the hospital and Best Practices used to resolve the hypoglycemic event(s).
- Set restrictions for the prescribing of U-500 Regular Insulin to only specialists and under special circumstances in CPOE.

System or Practice	Available Technology
ONC Meaningful Use Certified EHR system Electronic Health Record (EHR) System with the following capabilities: • Computerized Physician Order Entry (CPOE) • Drug-drug interaction check	*The following EHR vendors have signed the Patient Safety Movement Open Data Pledge:*[11] • Cerner • GE Healthcare

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[11] Patient Safety Movement Foundation. Healthcare Technology Pledges. Retrieved from: http://patientsafetymovement.org/challenges-solutions/commitments-pledges/healthcare-technology-pledges/

● Drug-allergy interaction check ● Clinical Decision Support tools (CDS)	
FDA approved glycemic management clinical decision support for insulin therapy recommendation, based on individual patient's response to insulin and designed for mitigation of all types of hypoglycemia.	● Monarch Medical Technologies Endotool® Solutions
CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE[12,13]	● Leapfrog CPOE Evaluation Tool[14]
Drug Libraries	● Alaris® ● Baxter® ● Hospira® ● Fresenius® ● B.Braun® I.V. pumps ● BD Intelliport™ Medication Management System for I.V. injectables, or ● comparable systems.
Pharmacy Workflow Manager	● DoseEdge® from Baxter Healthcare®

[12] Leung, A. A., Keohane, C., Lipsitz, S., Zimlichman, E., Amato, M., Simon, S. R., ... & Seger, D. L. (2013). Relationship between medication event rates and the Leapfrog computerized physician order entry evaluation tool. Journal of the American Medical Informatics Association, 20(e1), e85-e90.

[13] Metzger, J., Welebob, E., Bates, D. W., Lipsitz, S., & Classen, D. C. (2010). Mixed results in the safety performance of computerized physician order entry. Health Affairs, 29(4), 655-663.

[14] The Leapfrog Group. (2016). CPOE evaluation tool. Retrieved from: http://www.leapfroggroup.org/sites/default/files/Files/CPOE_Instructions_20160624_1.pdf

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Revision History

Version	Primary Author(s)	Description of Version	Date Completed
Version 1	Jerika Lam, Ron Jordan	Initial Release	January 2016
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Version 3	Jerika Lam, Steven Barker, Michael Ramsay, Ariana Longley, Joe Kiani	Workgroup and Executive Review	January 2017

Intervention	Rationale
Elevate awareness of hypoglycemia	Best in class and individual hospital initiatives to elevate awareness on preventable harm have improved patient care.
Real time analysis (48 hours)	Pharmacy surveillance system provides information of when and where these events occur, but not why they occur. Many hospitals have had success lowering harm rate using this intervention.
Create and utilize diabetes management team	AACE/ADA (American Association of Clinical Endocrinologists/American Diabetes Association) noted creation of a multidisciplinary steering committee guided by local diabetic experts can establish reasonable and achievable glycemic management goals.
Provide prescriber with tools to use as a dosing guide	- AACE/ADA suggests a systems approach for management of inpatient glycemic control. - Can establish reasonable and achievable glycemic management goals with use of protocols and order sets.
Nursing education process	- AACE/ADA noted a lack of ownership in diabetes care may be due in part to insufficient knowledge or confidence in diabetes management. - Improvements in care can be achieved by ongoing education and training.
Insulin dose timing coincide with food intake	- AACE/ADA noted many hospitals are challenged by poor coordination of meal delivery and prandial insulin administration. - A systems approach can promote the coordination of glucose monitoring, insulin administration, and meal delivery, particularly during change of shifts and times of patient transfer.
Improve POC glucose testing with the insulin administration time	- AACE/ADA stated that bedside BG monitoring with use of POC glucose meters should be performed before meals and at bedtime in most inpatients who are eating usual meals. - Important to avoid routine use of correction insulin at bedtime.
Utilize glucose management software	Collective evidence showed a reduction in hypoglycemic events through the use of glucose software management

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[15] Moghissi, E. S., Korytkowski, M. T., DiNardo, M., Einhorn, D., Hellman, R., Hirsch, I. B., ... & Umpierrez, G. E. (2009). American Association of Clinical Endocrinologists and American Diabetes Association consensus statement on inpatient glycemic control. Diabetes Care, 32(6), 1119-1131.

Just Do It!	Modify insulin order set to hold insulin only with MD order
	Modify insulin order set to match pending electronic order set to reduce doses of bedtime sliding scale (30% reduction)
	Modify insulin order set to avoid routine correction insulin at specific times (e.g., 0200 and 0400)
	Modify insulin order set to match pending electronic order set to state: Notify MD when hypoglycemic event occurs (2 levels <70 mg/dL or 1 level <50 mg/dL, or >300 mg/dL)
	Add Pharmacist and Endocrinologist on diabetes management team

Appendix C: Start Now: U-500 Regular Insulin Project[16]

Scope: Develop guidelines for injectable U-500 insulin to reduce ADE preventable harm. U-500 insulin is an uncommon concentration, which if given with syringes designed for U-100 insulin can cause serious harm.

Preventable Harm: Risk potential and risk severity are both high

Resources: Pharmacist(s) and nurse(s)

Deliverable Goals:

- Develop standard High Alert or High Hazard Medication or restrictions for U-500 insulin at all hospitals to prevent improper dosing and harm secondary to hypoglycemia.
- Develop policy that will safeguard or restrict the use of U-500 to specialists and special circumstances

Risks/Barriers:

- Hospitals that do not have the drug on formulary have not addressed patients using drug from home;
- Hospitals feel drug not on formulary will protect them from ADEs (Non-formulary does not equal no-risk of ADE)

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[16] Milligan, P. E., Blackburn, M. C., Dachroeden, R. R. (2014). Multi- faceted improvement initiative to detect and improve prevention of severe hypoglycemia. Retrieved from: http://www.ashp.org/DocLibrary/Abstract-Archive/SM14-Session-Abstracts.pdf

Actionable Patient Safety Solution (APSS) #3D:
PEDIATRIC ADVERSE DRUG EVENTS

Executive Summary Checklist

An effective program to reduce the incidence of pediatric adverse drug events (pADEs) and harm should be instituted and combine leadership strategies, software (healthcare IT), hardware (drug compounding systems, drug delivery technology, and physiological monitoring systems), and most importantly people (changes in clinical practice, protocols and education) in protecting pediatric patients by focusing on the following key tasks:

- ▢ Demonstrate board and executive leadership engagement and commitment by aligning hospital-wide strategic goals, accountability and systems to reduce pADEs.
- ▢ Create a multidisciplinary team specialized in neonatal and pediatric medicine that reports regularly to executive leadership, with a focus on pADE.
- ▢ Institute an effective software program for identifying, detecting, and reporting pADEs with analysis of the incidence and characteristics of pADEs and the near-misses.
- ▢ Deploy a closed loop medication administration system by implementing an electronic medication administration record (eMAR) and barcoding, or other auto identification technology with computerized provider order entry (CPOE) and pharmacy for medication administration.
- ▢ Institute proven interventional bundles for pADEs:
    - Standardized order sets and protocols for each admitting diagnosis;
    - CPOE with sophisticated decision support systems (DSS) including medication reconciliation, allergy checking, interaction checking, and dose range checking with alerts;
    - Enhanced pharmacy services including clinical pharmacists on rounds, implementing a double-check process as part of medication verification prior to dispensing high-risk medications, utilizing improved IV compounding tools such as bar code assisted medication preparation system (BCMP), and improving workforce skills to assure correct drug compounding and a pharmacy intervention database;
    - Ensure open communication and standardized medication handoff processes between healthcare teams at shift changes to verify medications are being administered correctly compared to the order, and that patient monitoring parameters for high alert medications are in place;
    - 'Smart' drug infusion pumps with drug libraries that are harmonized with order sets and enterprise formularies that include pediatric standardized drug concentrations addressing all weight ranges and are periodically updated based on review of an incident database, alert and override data;
    - Support tools to ensure that the correct concentration of drug in diluent is prepared, taking into account fluid balance for small patients and patients with fluid restrictions, and an infusion rate that is acceptable and within pump capabilities in all areas where children receive care.
- ▢ Select and implement new enterprise clinical information systems and electronic health records, verify and assess that the features of an organization's healthcare IT system includes full support for best practices in age- and weight-specific prescribing, compounding, dispensing, and administration of pediatric medications.
- ▢ Consider relevant improvement initiatives and opportunities for collaboration in pADE reduction outside of the hospital system.
- ▢ Disseminate pediatric-specific assistive technologies such as eBroselow (or equivalent) to assure that basic capabilities to stabilize and treat acutely ill or injured children are present 24/7 throughout all environments of care.

- Ensure that the FDA Safety Communication: "Syringe Pump Problems with Fluid Flow Continuity at Low Infusion Rates Can Result in Serious Clinical Consequences" is reviewed and understood by the team.
- Utilize Continuous Quality Improvement (CQI) software from infusion pump manufacturers to monitor drug library parameters on a routine basis and to report the frequency of command overrides and alerts triggered for unsafe practices.

The Performance Gap

As reported by the Institute for Safe Medication Practices (ISMP), during a 5-year span between 2008 and 2012, there were over 45,000 adverse drug events (ADEs) reported to the US Food and Drug Administration (FDA) in children aged less than 18 years old. Of these, approximately 64% of ADEs (29,298) involved reports of a serious injury, which included 2,935 (6%) deaths, 10,032 (22%) cases that required hospitalization, 1,430 (3%) cases considered life threatening, and 816 (2%) cases of disability.[1]

Preventing medication errors in pediatric patients poses unique challenges as children are particularly vulnerable to adverse outcomes from medication errors because of the need for weight-based drug dosing involving multiple calculations, dilution of stock drug solutions, immature renal and hepatic functions, and limited communication skills when experiencing side effects.[2,3,4] In addition, drugs may be approved for marketing with limited clinical trials in children. Greater than 70% of the drugs used in pediatrics have not been studied scientifically in age-specific populations to assess patient safety.[4,5] Most medications used in the care of children are formulated and packaged primarily for adults. The available dosage forms and concentrations appropriate for administration to neonates, infants and children are limited. Therefore, medications often must be prepared in different volumes or concentrations to accommodate delivery modalities that take into account fluid balance for small patients and patients with fluid restriction, and, if an infusion pump is required, provide an infusion rate that is acceptable and within pump capabilities. When drugs are not prepared centrally in the pharmacy (i.e., extemporaneous compounding by frontline caregivers), computational errors and admixtures that do not account stability, compatibility, or bioavailability data may represent additional challenges.[6]

Studies showed that medication errors in pediatrics are up to three times more likely to be associated with a potential ADE compared to those reported in adults.[2,7] Compared to other pediatric patient groups, the neonatal ICU patient group has the highest error and potential ADE rate.[2,8] As reported in an earlier study, ADE rates in hospitalized children were substantially higher (15.7 per 1000 patient-days) than previously described.[9] However, 22% of all ADEs could be preventable, and 17.8% could have been identified earlier.[9]

In 2001, the ISMP and the Pediatric Pharmacy Advocacy Group (PPAG) collaborated to produce the nation's first set of guidelines to reduce pediatric medication errors.[10] The American Academy of Pediatrics (AAP) has also taken a lead in making recommendations to reduce errors.[11]

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Closure of performance gaps and "getting to zero" medication errors will require the constant vigilance from all healthcare professionals and the commitment of hospitals and healthcare systems to implement action in the form of specific leadership, practice and technology plans. This will lead to a decrease in medication errors and a reduction in the occurrence of preventable ADEs in pediatric patients.

Leadership Plan

The hospital board, executives and other senior administrative leadership (medicine, pharmacy and nursing) must fully understand the performance gaps in reducing pADEs at their own healthcare systems. Commitment from all the leaders and stakeholders is necessary for the successful closure of these performance gaps. Leaders should endorse a comprehensive pADE reduction action plan and ensure implementation across all providers and systems. Strategic and tactical approaches that hospital leadership should endorse include the following:

- Establish pADE reduction as a strategic priority by creating a clear metric and goal that are included on the hospital-wide dashboard reviewed by the board and senior executives.
- Invest and allocate funds to:
  - Develop and maintain continuous education programs for healthcare providers with respect to pediatric clinical updates, high alert medications, pADEs monitoring and proper use of drug infusion pumps.[12,13,14,15,16]
  - Support clinical and research programs to develop an educational forum and "Best Practices" model for healthcare providers to expand the body of knowledge in pediatric medicine.
- Encourage and support the use of a simple, real-time pADE reporting system.[15]
- Review accurate, up-to-date pADE data at least monthly.[15]
  - Charter a committee or task force to review the reported data at the hospital and unit levels, generate and implement strategies for improvement, analyze barriers and regularly report to executive leadership.[15]
- Expect a comprehensive root cause analysis of all pADEs that involve serious patient harm. The analysis should include the root cause of the medication error, feedback to the individual linked to the error, implementation of time-bound and evidence-based changes to avoid similar pADEs, and widespread sharing of lessons learned.[15]
- Support the development of a lessons learned program to raise awareness among providers across the spectrum of medication delivery about pADE events, risks and improvement efforts using longitudinal data, individual events and near misses.
- Assess staffing and ensure an adequate number of medical, nursing and pharmacy staff specially trained to prescribe, prepare, dispense, and administer medications to children.[11,17]

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- Promote and enhance collaborative communication among all disciplines participating in neonatal and pediatric patient care, including pharmacy staff, patients and families.[7]
- Consider relevant improvement initiatives and opportunities for collaboration in pADE reduction outside of the pediatric hospital system such as ECLIPSE,[18] FDA-ASHP Standardize for Safety (S4S) Initiatives and OCHSPS.
- Implement and disseminate assistive technologies that support community practitioners as they stabilize, treat and transfer neonates and children in higher levels of care.

Practice Plan

- Standardize pediatric medication treatments and usage, as well as the processes for drug administration in pediatric patients. Some strategies include the following:
  - Establish and maintain a functional pediatric formulary system with policies for drug evaluation, selection and therapeutic use.[6,11]
  - Develop and optimize a smart infusion pump drug library with explicit support for intravenous therapy for pediatric patients.[19,20]
  - Prevent timing errors in medication administration by standardizing the number of days considered in all pediatric protocols upon deciding a treatment start date (e.g., Day 0 or Day 1).[6]
  - Weigh all pediatric patients in kilograms at the time of admission or as soon as possible (i.e., within four hours of admission) in an emergency situation since weight is used to calculate most dosing for children.[6]
  - Standardize and limit the number of concentrations and dosage strengths of high alert medications to the minimum needed to reduce potential medication errors.[6,21,22,23,24] High alert medications for pediatric patients should be generated by individual hospitals based on their types of pediatric population, infrastructure and unique features.[25,26]
  - Develop age-related treatment algorithms to guide providers to the correct dosing appropriate for the age of the pediatric patient.

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- Age- and weight-related developmental changes in pediatric patients affect the medication use process of specific drugs, and should be taken into consideration. The age-related treatment algorithms will be useful in preventing the use of medications outside the intended patient population.
    - Use reputable, reliable references and protocols to help standardize pediatric medication therapies.
    - Participate and track the progress of the FDA-ASHP Standardize for Safety Initiative.
    - Evaluate clinical guidelines and protocols on a routine basis for sustainability and safety, especially when limited safety and/or efficacy data are available in the pediatric population.
- Develop and implement a pediatric trigger toolkit that will electronically identify high risk medications based on the therapeutic levels, dosages and pADEs.
    - Alignment of the trigger toolkit with clinical protocols specific for the medication.
    - Utilization of an ADE trigger tool method to identify possible adverse events have been shown to ensure more patient safety events compared to voluntary reporting.[27,28]
    - The pediatric trigger toolkit is effective at identifying ADEs and reducing the frequency of sentinel events for hospitalized pediatric populations.[9]
- Create a pediatric multidisciplinary team. This team's responsibilities will include the following:
    - Achieve hospital-wide pADE reduction goals;
    - Monitor accurate, up-to-date pADE metrics;
    - Ensure outstanding event reporting systems, root cause analyses, lessons learned processes and improvement strategies for pADE reduction;
    - Benchmark the adequacy of the features of the individual hospital's medication safety practices and clinical information systems against the proven best practices, identify gaps, and make recommendations.
- Collaborate in a multidisciplinary team (e.g., physicians, pharmacists and nurses) to promote and endorse accountability and responsibility in reporting pADEs from all healthcare providers.[29,30]
    - For example, a pharmacy-driven ADE reporting approach, embraced by nurses and physicians, was shown to improve ADE reporting and avoid inconsistency in the information gathered.[29]
    - Develop and ensure comprehensive specialty training for all practitioners involved in the care of pediatric patients, as well as continuous education programs for healthcare providers to stay current and knowledgeable in medications and treatment of pediatric conditions, and be familiar with the ongoing pADE tracking and reporting systems.[6,11]
    - Collaborate with the Informatics Technology team to develop and customize CPOE order sets to help standardize care and medication therapy for specific pediatric disease states.[31]
    - Develop a team of experts (e.g., physician, pharmacist and nurse) to train healthcare providers at their hospital on how to use the smart infusion pumps with customized pediatric drug libraries.[20]

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- Develop and standardize a smooth and effective communication process for hand-offs (e.g. using a checklist)[32,33] upon patient transfer to a different unit within the hospital, and upon the transitions of care within and outside clinical settings.[34,35,36]
- Ensure adequate pharmacy services for pediatric patients to reduce medication errors and ADEs.[12] The strategies proposed by the American College of Clinical Pharmacy (ACCP) and PPAG include:[37]
  - Elevating the minimum expectations for pharmacists entering pediatric practice,
  - Standardizing pediatric pharmacy education,
  - Expanding the current number of pediatric clinical pharmacists,
  - And creating an infrastructure for development of pediatric clinical pharmacists and clinical scientists.
- Develop and implement pharmacist-managed admission medication histories and medication reconciliation process for pediatric patients, which have shown to prevent potentially significant adverse drug reactions and have a positive impact on patient care.[38]
- Develop and implement a discharge prescription review program, led by a clinical pharmacist (with pediatric training preferred), to ensure the medication doses are equivalent to those prepared in the hospital. This is an effective method for reducing prescribing errors in pediatric patients during transition of care.[39]
- Implement pharmacist-driven processes, such as developing a double- and triple-check system for high alert medications to ensure the "5 Rights", appropriate medication selection, and accurate excipients, dose and concentrations of liquid medications prior to compounding and dispensing them.
- Develop an education forum for community healthcare providers (e.g., physicians, pharmacists and nurses) about appropriate prescribing and dispensing medications for pediatric patients.[40]
- Disseminate pediatric-specific assistive technologies such as eBroselow (or equivalent) to assure that basic capabilities to stabilize and treat acutely ill or injured children are present 24/7 throughout all environments of care.[41]

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Technology Plan

Suggested practices and technologies are limited to those proven to show benefit or are the only known technologies with a particular capability. As other options may exist, please send information on any additional technologies, along with appropriate evidence, to info@patientsafetymovement.org.

Technology has significantly advanced in the last decade within the healthcare setting with development of Electronic Health Records (EHR), CPOE, barcode medication administration (BCMA), bar code assisted medication preparation system (BCMP) and smart pump infusion technology. Multiple studies in pediatrics have demonstrated a decrease in both prescribing errors and ADEs after implementing these technologies.[12,24,42,43,44,45,46,47,48,49,50] However, most of these systems are designed for use in adult patients and customization is often needed to ensure optimal use in pediatric patients.[31,51]

- Work with the multidisciplinary healthcare team to develop, improve and optimize the pADE reporting systems to identify, target, track and monitor pADEs.
- Embed a pediatric trigger toolkit in the CPOE as an alert system for prescribers when medications are ordered out of range or are duplicate therapies.[9,27,28]
- Develop and optimize real-time surveillance systems to identify high risk/high alert medications and to optimize pediatric patient outcomes via mitigation of pADEs.
- Standardize equipment and measurement systems throughout the institution, such as smart infusion pumps and accurate weight scales for pediatric patients.[11]

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- Ensure best practices are used for syringe pumps with medications requiring low infusion rates (<5 mL per hour) to prevent medication errors.[52,53]
- Ensure that the FDA Safety Communication: "Syringe Pump Problems with Fluid Flow Continuity at Low Infusion Rates Can Result in Serious Clinical Consequences" is reviewed and understood by pharmacists who dispense drugs for use in programmable syringe pumps, by clinical engineers and technicians who maintain programmable syringe pumps, and by caregivers who use or who train users on programmable syringe pumps.[52]
  - Promote eLearning modules on this topic,[54] prepared by Massachusetts General Hospital, are freely available at syringeinfusionsafety.org as referenced by the FDA in the Safety Communication.
- Implement and optimize bar coded medication process for pediatric medication products (e.g., multi-dose or unit-dose vials, compounded, and/or repackaged).[48,55]
  - Use a bar code assisted medication preparation system (BCMP) for intravenous sterile compounding in pharmacy, such as Baxter's DoseEdge Pharmacy Workflow Manager, BD's Cato™ Medication Workflow Solutions, and Omnicell's i.v.SOFT® Assist.
  - Use the eBroselow System (or equivalent) as an electronic aid to assist those who compound drugs extemporaneously, in achieving compliance with standardized concentrations that respect fluid balance considerations for small patients and patients with fluid restriction, and are compatible with the performance envelope of drug infusion pumps.[41]
  - Use the Codonics Safe Label System,[56] or the BD Intelliport Medication Management System, to assure correct source vial identification, container preparation, and Joint Commission- compliant labeling of drugs given by IV push or infusion in the perioperative environment.[57]
- Utilize Continuous Quality Improvement (CQI) software from infusion pump manufacturers to monitor drug library parameters on a routine basis and to report the frequency of command overrides and alerts triggered for unsafe practices.[58,59]
  - Analyze and proactively respond to identified issues from smart pump data to minimize use of basic mode.
- Develop systems to perform gap and root cause analyses to improve patient and medication safety.

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- With technology prevalent in healthcare, physicians, pharmacists and nurses should use both synchronous and asynchronous forms of communication to improve medication safety at the transitional points of care.[7,34]
- Develop and optimize communication technology across healthcare settings, providers and caregivers of the pediatric patients via secured HIPAA-protected lines (e.g., telemedicine and apps).

Workgroup

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Revision History

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