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

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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 transition 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™ Medication Management System and First Databank FDB MedKnowledge™ system
  - Use barcoding 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 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 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. In 20 perioperative medication administrations, and every second operation, resulted in a medication error and/or an adverse drug event. 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. The vast majority of medical errors result from faulty systems and poorly designed processes, rather than poor practices or incompetent practitioners.

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.

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. Specifically, the plan must:

1. have strong evidence that they are effective and reducing preventable deaths;
2. are generalizable and may be applied in multiple care settings and for multiple patient types;
3. are likely to have a significant impact on reducing preventable deaths if fully implemented; and
4. have knowledge available 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”\(^5\);
• include budget allocations for the 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.
• 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.\(^10\)
• 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.\(^13\)

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\(^5\) Overview of the 100,000 Lives Campaign. Institute for Healthcare Improvement.
\(^7\) [http://www.ismp.org/Tools(guidelines/acutecare/tasm.pdf](http://www.ismp.org/Tools(guidelines/acutecare/tasm.pdf)
\(^11\) [http://www.ismp.org/Tools(guidelines/labelFormats/default.asp](http://www.ismp.org/Tools(guidelines/labelFormats/default.asp)
\(^12\) [http://www.ismp.org/Tools(guidelines/IVSummit/IVCGuidelines.pdf](http://www.ismp.org/Tools(guidelines/IVSummit/IVCGuidelines.pdf)
\(^13\) Toelting RK et al. APSF. 2011.
# 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.

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<table>
<thead>
<tr>
<th>System or Practice</th>
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<tbody>
<tr>
<td><strong>All Settings</strong></td>
<td>The following EHR vendors have signed the Patient Safety Movement Open Data Pledge:14</td>
</tr>
<tr>
<td><strong>ONC Meaningful Use Certified EHR system</strong></td>
<td>Cerner</td>
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<tr>
<td>Electronic Health Record (EHR) System with the following capabilities:</td>
<td>GE Healthcare</td>
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<tr>
<td>- Computerized Physician Order Entry (CPOE)</td>
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<td>- Drug-drug interaction check</td>
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<td>- Drug-allergy interaction check</td>
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<td>- Electronic Prescribing (eRx)</td>
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<td>- Electronic Prior Authorization (ePA)</td>
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<tr>
<td>Electronic Medication Administration Record (eMAR) system with pharmacy and bedside barcoding capabilities15</td>
<td>First Databank FDB MedKnowledge system16</td>
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<tr>
<td>Infusion pumps that wirelessly communicate data back to the electronic eMAR</td>
<td>Alaris®</td>
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<td></td>
<td>Baxter®</td>
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<td>Hospira®</td>
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<td>Fresenius®</td>
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<td>B.Braun® I.V. pumps.</td>
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<tr>
<td>Patient and Medication barcoding system</td>
<td>Codonics® Safety Labeling System; or Single Use Injection Vials and Kits</td>
</tr>
<tr>
<td>CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE17,18</td>
<td>• Leapfrog CPOE Evaluation Tool19</td>
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14 [EHR companies that have signed Patient Safety Movement Open Data Pledge](https://www.ismp.org/orderForms/reporterrortoiISMP.asp)


| 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 | BD™ Medication Management System.  
| 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 |  
| Continuous physiologic monitoring on patients receiving IV medications to provide an early indication of deterioration due to a medication error | Masimo rainbow® Acoustic Monitoring  
| | Side-stream end-tidal carbon dioxide monitoring  
| | Oridion®  
| | Masimo®  
| | Respironics®  
| Pharmacy Environment | BAXA® Intellifil Robot.  
| Other Considerations | “End-to-end” smart pump system, or other electronic pump systems  

19 [https://leapfroghospitalsurvey.org/cpoe-evaluation-tool/](https://leapfroghospitalsurvey.org/cpoe-evaluation-tool/)  
20 Mimoz O et al. BJA. 2012.
Measurement Specifications

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:

\[ \text{Lives} = (\text{ADE Rate}_{\text{baseline}} - \text{ADE Rate}_{\text{measurement}}) \times \text{Doses} \times \text{Patient Days}_{\text{baseline}} \]

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:

The PSMF, when available, will use the mortality rates associated with Hospital Acquired Conditions targeted in the Partnership for Patient’s (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 “AHQR 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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**Workgroup**

Chair:

OPEN

Co-Leaders:

Ron Jordan, RPh, FAPhA, Dean, Chapman University School of Pharmacy  
Jerika Lam, PharmD, AAHIVP, FCSHP, Assistant Professor, Chapman University School of Pharmacy

Members:

Laura Batz Townsend, President and Co-founder, Louise Batz Patient Safety Foundation  
Steven Barker, PhD, MD, Chief Medical Officer, Masimo; Professor of Anesthesiology, University of Arizona  
Jim Bialick, Immediate Past President, Patient Safety Movement Foundation  
Thomas Corlett, Patient Advocate, Ehlers-Danlos Inspiration Community  
Paul Jansen, Vice President of Business Development, Masimo  
Chris Jerry, President, Emily Jerry Foundation  
Ariana Longley, MPH, Vice President, Patient Safety Movement Foundation  
Steve Mullenix, RPh, National Council for Prescription Drug Programs (NCPDP)  
Robert Nickell, Founder and CEO, Enovachem  
Celine Peters, Clinical Nurse Specialist, Becton Dickinson (BD)  
Rachael Raynes, JD, University of Vermont Medical Center  
Rochelle Sandell, Patient Advocate  
Jason Yamaki, PhD, PharmD, Chapman University’s School of Pharmacy

**Metrics Integrity:**

Nathan Barton, Statistical Data Analyst, Intermountain Healthcare  
Robin Betts, RN, Assistant Vice President of Quality and Patient Safety, Intermountain Healthcare  
Jan Orton, RN, MS, Clinical Operations Data Manager, Intermountain Healthcare

**Revision History**

<table>
<thead>
<tr>
<th>Version</th>
<th>Primary Author(s)</th>
<th>Description of Version</th>
<th>Date Completed</th>
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<tbody>
<tr>
<td>Version 1</td>
<td>Paul Jansen</td>
<td>Initial Release</td>
<td>January 2014</td>
</tr>
<tr>
<td>Version 3</td>
<td>Michael Ramsay, Steven Barker, Joe Kiani, Jim Bialick, Ariana Longley</td>
<td>Executive Review</td>
<td>April 2016</td>
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Actionable Patient Safety Solution (APSS) #3A:
ANTIMICROBIAL STEWARDSHIP
(THE ROLE OF PHARMACY AND THE MICROBIOLOGY LAB) IN PATIENT SAFETY

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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 an multi-disciplinary 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 to establish a physician supervised multidisciplinary Antimicrobial Stewardship committee by July 1, 2015. 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 \textit{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 judicious 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 indiscriminant use of antibiotics. According to a number of studies, approximately 25% of adverse drug events arise from antimicrobial use. 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. Another critical adverse outcome associated with the use of antibiotics is \textit{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, judicious 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.

\begin{enumerate}
\item \url{http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140SB1311}. Accessed 01/11/2015.
\item Lesar TS, Briceland L, Stein DS. Factors related to errors in medication prescribing. JAMA. 1997; 277:312–317.
\end{enumerate}
**Pharmacy Driven Interventions for ASPs**

a. 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  
   - Systolic blood pressure >90mm Hg  
   - O2 saturation >90% (O2 partial pressure >60 mm Hg)  
   - Functional GI  
   - Normal mental status  

b. Dosage adjustments in cases of organ dysfunction.  
   **Rationale:** Avoid toxicities.  

c. Dose optimization (pharmacokinetics/pharmacodynamics) to optimize the treatment of organisms with reduced susceptibility.  
   **Rationale:** Avoid toxicities, optimize PK/PD, improve outcomes.  

d. Automatic alerts in situations where therapy might be unnecessarily duplicative.  
   **Rationale:** Avoid toxicities and decrease costs.  

e. Time-sensitive automatic stop orders for specified antibiotic prescriptions.  
   **Rationale:** Decrease cost and unnecessary antimicrobial therapy, and decrease development of resistance.  

f. Initiation of necessary treatment for patients who should be receiving antibiotics.  
   **Rationale:** No empiric or directed therapy against infecting or suspected organisms.  
   Delay in active antibiotic against pathogen increases mortality.  

g. 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. When considering the impact of antimicrobial use in pediatrics, the calculation of days of therapy (DOT) per 1000 patient days is preferred, given that with pediatrics the dose is often adjusted according to weight there is no single DDD.  

**Microbiology Laboratory Contribution**  

1) Providing at least yearly antibiograms (if possible twice a year). Antibiogram reporting should be location specific (e.g., ICU, general wards, or pediatric areas).  
2) Reporting of Susceptible Dose Dependent (SDD) for Enterobacteriaceae on cefepime or other beta-lactams in culture and sensitivity reporting.  
   a. As CLSI breakpoints are based on specific daily doses of antibiotics (e.g., cefepime 1g q8h). A susceptibility of “I” for intermediate will be based off of this dose, thus the reported isolate based on PK/PD, could be susceptible at a dose of 2g q8h. This allows for use of cefepime and avoiding an escalation to a carbapenem. NOTE: As always therapy should be guided by patient response and not susceptibilities alone.  
3) Automatic testing and reporting of tigecycline and colistin for Carbapenem Resistant Enterobacteriaceae isolates.  
   a. 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.

4) Reporting of minocycline susceptibility for Acinetobacter isolates.
   a. 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.

5) Selective reporting of susceptibilities of antimicrobials.
   a. 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 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.)

\(^8\) Dellit et al. “Infectious Diseases Society of America and the Society for Healthcare Epidemiology of America Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship”; CID, 2007:44.
Technology Plan

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Hospira®  
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| Pharmacy Workflow Manager | DoseEdge® from Baxter Healthcare® |

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9 EHR companies that have signed Patient Safety Movement Open Data Pledge
12 https://leapfroghospitalsurvey.org/cpoe-evaluation-tool/
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, 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.\(^8\)

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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.

Table 1: Interventions and required resources

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

Chair:
OPEN

Co-Leaders:
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Revision History

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# Actionable Patient Safety Solution (APSS) #3B: IMPROVE PREVENTION OF SEVERE HYPOGLYCEMIA

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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, 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. 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 (<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.

Leadership Plan

The plan must include the fundamentals of change outlined in the National Quality Forum safe practices, including awareness, accountability, ability, and action.\(^\text{10}\)

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

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 Now’s”) – 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

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\(^{10}\) NQF Safe Practices for Healthcare. 2010 Update.
- 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
- 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@patientsafetysummit.org.*

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 Drug-allergy interaction check Clinical Decision Support tools (CDS) | The following EHR vendors have signed the Patient Safety Movement Open Data Pledge: 
- Cerner
- GE Healthcare

CPOE simulation tool to quantify the risk of serious ADEs with your current system CPOE | Leapfrog CPOE Evaluation Tool

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®

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11 EHR companies that have signed Patient Safety Movement Open Data Pledge
14 https://leapfroghospitalsurvey.org/cpoe-evaluation-tool/
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### Appendix A: Summary of Foundational Best Practices

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elevate awareness of hypoglycemia</td>
<td>Best in class and individual hospital initiatives to elevate awareness on preventable harm have improved patient care.</td>
</tr>
<tr>
<td>Real time analysis (48 hours)</td>
<td>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.</td>
</tr>
<tr>
<td>Create and utilize diabetes management team</td>
<td>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.</td>
</tr>
</tbody>
</table>
| 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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Appendix B: Just Do Its! Recommendations\textsuperscript{16}

<table>
<thead>
<tr>
<th>Just Do It!</th>
<th>Modify insulin order set to hold insulin only with MD order</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Modify insulin order set to match pending electronic order set to reduce doses of bedtime sliding scale (30% reduction)</td>
</tr>
<tr>
<td></td>
<td>Modify insulin order set to avoid routine correction insulin at specific times (e.g., 0200 and 0400)</td>
</tr>
<tr>
<td></td>
<td>Modify insulin order set to match pending electronic order set to state: Notify MD when hypoglycemic event occurs (2 levels &lt;70 mg/dL or 1 level &lt;50 mg/dL, or &gt;300 mg/dL)</td>
</tr>
<tr>
<td></td>
<td>Add Pharmacist and Endocrinologist on diabetes management team</td>
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Appendix C: Start Now: U-500 Regular Insulin Project\textsuperscript{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)

\textsuperscript{16} Milligan P, Blackburn C, Dachroeden R. Multi-faceted improvement initiative to detect and improve prevention of severe hypoglycemia. ASHP Summer Meeting 2014.