

Getting Started Kit:

Safe Administration of High-Risk IV Medications

Intra- and Inter-Hospital Standardization: Drug Concentrations and Dosage Units

How-to Guide

As part of continuing efforts to improve patient and medication safety, in January 2005 members of the San Diego Patient Safety Consortium (SDPSC) evaluated areas for local patient safety improvements. Standardization of intravenous (IV) infusion medication concentrations and dosage units with and across hospitals in San Diego County was identified as a significant opportunity to reduce morbidity and mortality due to preventable, high-risk IV-related adverse drug events. The 2006 Institute of Medicine (IOM) report, "Preventing Medication Errors," urges hospitals to take action to reduce the potential for errors. This toolkit provides the results of the work by the SDPSC IV Safety Task Force, along with tools and information to assist other acute care organizations in implementing this standard approach.

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Introduction

Goal:

Standardize high-risk IV drug concentrations and dosage units within and across hospitals area-wide to reduce the likelihood of adverse drug events (ADEs).

Standardization of Intravenous (IV) Medication Administration

- Clinical practice will always involve some degree of variability, given the inherent variability in patients' underlying pathophysiology and unique needs.
- Nevertheless, it is important to identify and reduce both unnecessary variability that increases opportunities for error and costs, and undesirable variability that reflects deviations from clinical guidelines and best practices.
- The challenge is to identify such variability, implement changes to reduce it, monitor the impact of those changes, and work to continuously improve patient safety and evidence-based care.
- The experience of the San Diego Patient Safety Consortium shows that area-wide standardization of high-risk IV drug concentrations and dosage units significantly reduces variability in IV therapy, helping to promote safer and more consistent practices in administering high-risk IV medications to patients.

Potential Benefits

- Improved patient safety due to reduced complexity, variability, and opportunities for high-risk IV medication errors.
- Improved compliance with best practices.
- Extension of institutional compliance with JCAHO and local IV medication safety goals area-wide, across all hospitals and related medical services (home health, long-term care, and paramedic services).
- Increased clinician satisfaction due to a less complex, safer environment that is also attractive to prospective employees.
- Opportunities to drive vendor standardization and other improvements to reduce IV-medication-related costs.
- Improved dose error reduction software (DERS) dataset for current or future "smart pump" and/or bar code administration systems.

Creating a Shared Need: The Case for Standardization

IV Medications Are Associated With the Highest Risk Of Harm

- In seeking to improve patient safety, the primary focus should be on preventing errors with the greatest potential for harm.¹
- Many of the highest risk medications—e.g., heparin, insulin, morphine, and propofol—are delivered by IV infusion.²⁻⁴
- 61% of the most serious and life-threatening potential adverse drug events (ADEs) are IV drug-related.⁵
- IV administration often results in the most serious outcomes of medication errors.⁶

The Administration Process Is Vulnerable to Error

- Relative to the other points along the medication-use continuum, the administration process has the fewest safeguards and fewest support mechanisms, and it often relies on a single healthcare professional for accuracy.⁷⁻¹⁰ This is because there is less opportunity to intercept these errors; administration is at the end of the process with no naturally occurring redundancies.
- ICU studies found high-alert IV medication administration error rates of 34%^{7,11} and 49%.^{7,12}
- 41% of drug-administration mortalities were associated with dosing errors.^{7,13}
- Dosing errors were by far the most common type of medication error—28%.¹⁴
- While 70% of ordering errors were intercepted, only 6% of the wrong dose errors occurring in the nurse administration stage were intercepted.¹⁴
- The second most common cause of nurse administration errors—13%—was infusion pump and delivery problems.¹⁴

Extensive Variability Increases Opportunities for Errors

- A key medication process problem related to administration and monitoring is incorrect dosing due to confusion among medications.⁷
- Nursing staff turnover rates are high: 21.3% per year for hospitals.⁷
- Many nurses now work in multiple settings, and both patients and nurses transfer among area hospitals.

Standardization Is Supported by Patient Safety Initiatives and Research

- Lack of standardization has been at least a partial cause of many cases of overly high doses, including a number of fatal overdoses.^{7,15,16}
- The need to reduce variability is a focus of Institute of Medicine (IOM, 1999) and Institute for Safe Medication Practices reports,¹⁷ and Institute for Hospital Improvement initiatives.¹⁸
- Substantial unnecessary variation in IV medication practices is associated with increased risk of harm; standardization has the potential to substantially improve IV medication safety.¹⁹
- JCAHO National Patient Safety Goal requires a hospital to...
 3. Improve the safety of using medications.
 - 3b. "Standardize and limit the number of drug concentrations available in the organization."²⁰

Management Support Is Essential

- These kinds of changes—e.g., hospital-wide standardization of doses—require top-level decisions.
- Frontline operators—those who make the errors in drug use—have limited ability to correct these systems problems on their own.¹⁹

Need to Go Beyond Drug Concentrations

- In many institutions the concentrations standardization is well on the way to full implementation. Moreover, in a 100-hospital sample, Bates et al found drug concentrations to be the least variable of the infusion parameters.¹⁹
- Extensive variability exists in drug dosing units, and selection of the wrong dosage unit can result in very large errors.
- For example, although most hospitals use only one concentration of heparin, they frequently use more than one dosage unit for heparin—e.g., units/hr and units/kg/hr—in the same patient care area. This creates opportunities for significant errors, e.g., a 68-kg patient could receive a 68-fold overdose.
- A standard approach to IV medications exists in many hospitals. But often the standard is not the same across all areas in a hospital, across hospitals in a system, or across all or even most hospitals in a given region where patients and staff may transfer.
- Policies, procedures, and standard work processes can provide a substantial margin of safety in minimizing variability in high-risk situations. Importantly, technology is not required to implement standardization of IV drug concentrations and dosage units.
- For institutions that do have or plan to implement smart pumps with DERS, standardization of drug concentrations and dosage units is an important first step in creating the necessary drug libraries. Standardization of drug dosing ranges is a logical next step in improving medication safety.

Mobilizing Commitment

Forming the Task Force

- Most healthcare facilities are probably already involved in efforts to standardize and limit the number of drug concentrations.
- The first step in developing an area-wide IV Safety campaign is to bring together the individual institutions in a geographic region to form a Task Force comprised of key individuals from each institution who are already involved in this effort.

Stakeholders (* = Task Force members)

<ul style="list-style-type: none"> ■ Critical Care Nurses* (from all institutions) ■ Clinical Pharmacists* (from all institutions) ■ Perinatal Nurses (from all institutions) ■ Process Improvement Department ■ CNS/Educators ■ IS/IT Pharm-IT Department ■ Pharmacy Buyers/Wholesaler Supplier ■ information ■ CNO/Nursing Leadership ■ Pharmacy Leadership ■ Intensivists 	<ul style="list-style-type: none"> ■ Neonatologists ■ Ob-Gyn Physicians ■ Anesthesia ■ Pharmacy and Therapeutics Committee ■ Policy and Procedure Committee ■ Those responsible for standard order sets ■ Others, as needed
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- An “Elevator Speech” can be used to quickly convey key elements of the campaign. For example:

What: We are creating area-wide standards for high-risk IV infusion concentrations and dosage units in ___(name of designated area)_____.

Why: This is important because there’s great risk of harm associated with variation in practice.

Success: Success in our region will be when a patient or nurse can transfer to any area or facility and the IV concentrations and dosing units will be the same. This will help reduce errors and confusion among clinicians.

Need: We need your institution’s support and participation in developing these community standards and rolling out the changes within your organization.

Creating a Project Charter and Plan

- Once the Task Force has been formed, it should develop a project charter. This is key to establishing the scope of the project, keeping the team moving in the same direction and preventing the goals and objectives from migrating during the course of the project.
- The goal and objectives should be time-specific and measurable.²¹
- *Sample Primary Goal:* Within one year, for selected common IV infusions, implement one community standard for each drug for 1) concentration and 2) dosing unit.
- *Sample Objective:* By ___ (date)___ identify and engage the process-change participants representing each site and its clinicians.
- Check individual calendars for 6 months to determine if adequate time is available for project-related activities. Schedule all bi-weekly or monthly meetings up front.
- *Identify roles*–Identify executive sponsor, process owner and change agents for each organization participating.

Managing Resistance

For each institution:

- Identify key stakeholders.
- Anticipate the amount of resistance they will have, what the fundamental concerns are, and how to minimize the barriers and maximize the benefits.
- Validate assumptions with each stakeholder.
- Obtain a coalition of committed supporters.
- Develop a strategy to secure the support of front lines and management personnel, for example: “We want our name to be on the list of the safest hospitals in the area.”

Communicating Effectively

Early and continuous communication is essential.

- Select the audience(s) within the hospitals, including the various disciplines’ leaders, especially nursing, as well as those involved with pre-hospital medication administration: home health, long-term care, and emergency medical services.
- Convince them of the problem and therefore the benefits to the end user of implementing change.

- Evidence-based selling works best, for example:
 - Your own knowledge of medication errors—the most important.
 - MEDMARX and other medication error databases
 - The medical literature
 - Guidelines—Society of Critical Care Medicine, others
- Here is what the change requires.
- Here are the benefits.
- We need your help and cooperation, and appreciate everybody's efforts.

Desired Outcomes

- Specific, identified sponsors—e.g., Chief Nursing Officers, Pharmacy Directors, and Pharmacy & Therapeutics Committees—are willing to give visible, active, and public commitment and support to the project.
- Stakeholders and task force members have the ability to direct resources to the project and are willing to provide leadership by example and to devote their personal focus, time, and passion to this effort.²³
- Stakeholders and task force members agree on the story they wish to tell and have a quick effective way to initially communicate that story.
- The task force has a clear goal, objectives, scope and set of operating norms; all meetings have been scheduled.
- The desired result—i.e., area-wide/regional standardization of IV medication concentrations and dosage units—is clear, widely understood and shared.

Tools

- *Invitation: Example*
- *Project Charter: Example*
- *Executive Sponsor, Process Owner, Change Agent Responsibilities*
- *Stakeholders' Support/Resistance Analysis Tool*
- *PowerPoint Presentation*

Developing a Standardized List

- Perform an area-wide inventory of medication concentrations and dosage units.
- Prioritize the high-risk medications: insulin, heparin, IIb/IIIa inhibitors, opioids, neuromuscular blockers, electrolytes (e.g., magnesium).
- Determine where variations exist in current practice.
- Identify by care area the drugs that need to be changed and consolidate the data to eliminate unnecessary variability.
- Through multiple iterations, develop an agreed-upon list of standardized concentrations and dosage units for common IV medications.
- In parallel with reviewing infusion standards, begin planning for education, training, and implementation (discussed below).
- Work with stakeholders at each institution to obtain agreement on consolidated list.
- Physicians may want to review and participate in standard-concentration changes, especially the anesthesia standards.
- Physicians likely will want to review and approve any changes to dosage units; Pharmacy and Therapeutics Committees (P&Ts) likely will be advised by relevant specialty subcommittees.

Desired Outcome

An agreed-upon list of standardized IV medication concentrations and dosage units.

Tools

- *Adult IV Infusions Survey Tool: Sample Page*
- *Standardized List of Adult IV Infusions: Example*

Planning for Implementation: Tips From the Field

Objective:

Error-free, synchronized system change implemented on a mutually determined change date/time.

- Standardization of high-risk IV medication concentrations and dosage units is a high-risk process change. If less than completely successful, it could result in dosage errors and serious, preventable harm to patients.
- Sufficient time and effort must be allocated to successfully implement the change, and activities must be well coordinated, so that end users will agree to make the changes and make the project succeed.²³

Identifying Process Owners

- Identify the existing organizational departments and interdisciplinary bodies owning all the various pieces of this complex implementation.
- Identify necessary, including as yet non-existent, interdisciplinary bodies needed to coordinate this complex process.
- For each site identify a site-specific, interdisciplinary, implementation management team, ideally to include:
 - Nurse Executive—executive sponsor
 - Pharmacist
 - Critical Care Nurse Leader
 - Perinatal Nurse Leader
 - Pharmacy technician(s) to support system monitoring and IV product change-out
 - Nurses from each affected unit
 - IT analyst(s) expert in the relevant IT systems that contain IV drug infusion dosing and concentration information such as standard orders

Synchronizing System Change Within and Across Sites

- Identify the stages of the medication-use process, tools, and users potentially most impacted by these changes.
- Identify the relevant change approval processes, including anticipated turnaround times for each process change, e.g., nursing and pharmacy leadership, P&T, critical care, IT, etc.
- Obtain an IV medication errors measurement baseline 3 to 6 months prior to the system change. This should be compared with a measurement with the same timeframe after go-live of the new standards. A 30-day transition between baseline and re-measure is reasonable.
- Ensure all owners/approvers are on the same page at the date/time of implementation of the new standards.
- Policy and Procedures Committees: Identify policies that need to be changed.
- Update IV Medication Guidelines and any other descriptors of new standards for IV medications.
- Formulary/compendium: Necessary updates may require involvement of IT leadership or dedicated committees to synchronize pharmacy, nursing, computerized prescriber order entry (CPOE), and other IT systems.
- Medication Order Processing System: IT leadership or dedicated IT committees may need to approve updates.
- Order Sets: Identify preprinted and CPOE orders that need to be changed to prevent conflicts in description of drug product and dosage units.
- Establish Pharmacy and Therapeutics Committee pre-approved change criteria (i.e., using “standard concentration” as defined in Standard Infusion Definitions, instead of in the order sets.) Thereafter this will prevent conflicts and asynchrony between medication standards and order sets, and avoid the time-consuming, tedious, and highly error-prone task of updating and maintaining order sets.
- Paper: find and replace all old order sets, often a low-yield process requiring multiple cycles.
- Electronic: Short of fully electronic documentation, print-on-demand electronic standard order forms facilitate achieving this standardization goal, with the added risk of each care area becoming its own print shop, creating stores of order forms.
- Nursing Documentation: Identify documentation forms (paper/computerized) that need to be changed, e.g., Nursing Medication Administration Record (MAR) and Input and Output documentation to be updated with new dosage units.
- Drug Product Availability: Pharmacy and vendors need to ensure that any necessary new products will indeed be available on the day of implementation of the new concentrations and reliably available thereafter through appropriate par levels.

- **Drug Packaging:** Ensure that the new concentration product is **OBVIOUSLY NEW** and **DIFFERENT**. A Pharmacy temporary “wrapper” should be used to alert nurses hanging the new drips.
- **Smart pumps (if applicable):**
 - Update datasets with a unique filename communicated in the change implementation campaign and on product alert wrappers.
 - Apply the pharmacy temporary “wrapper” or other product alert identifier for a long enough period after the change (e.g., 2-3 months, as negotiated with the nursing end-users) to catch smart pumps still without the new dataset (“closet” pumps, rentals, etc).
 - Ensure that software and experts are available to monitor updating of smart pump datasets with new standardized concentration and dosage units, as well as subsequent pump activation of new dataset.
 - If manual upload of the new data set is required, identify locations of all smart pumps.
 - If the upload is to be done wirelessly, test the integrity of the dataset updating functionality, wireless system integrity, and scope of coverage.

Communicating Start Date Clearly

- It is very important to reinforce the momentum of the project and announce clearly and with total management support its imminent implementation,²¹ e.g.,

“Effective ___(date)___(or “next Monday”), all employees will use the new system.”

Desired Outcomes

- A clear sense of the official start day for the new system.²¹
- A clear understanding in the organization of the new system and sufficient commitment to implement it successfully.²¹
- Integration of the new initiative with ongoing work activities.²¹

Tools

- *Implementation Timeline*
- *Implementation Checklist*
- *Temporary Pharmacy IV Wrapper*

Monitoring Change, Celebrating Success

- It is important to ensure that once the change is started, it endures and flourishes, and that necessary learning and skills are transferred throughout the organization.²¹

Reporting Results

- Perform baseline IV medication errors measurements 3 to 6 months prior to the system change. Later these should be compared with a same period of time after go-live of the new standards. A 30-day transition between baseline and re-measure is reasonable.

- Figures 1 and 2 show results obtained across all participating hospitals by the SDPSC.

Celebrating Success

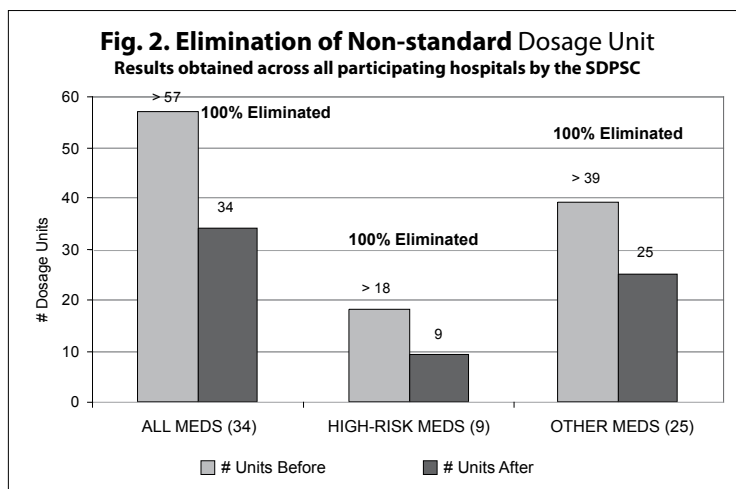
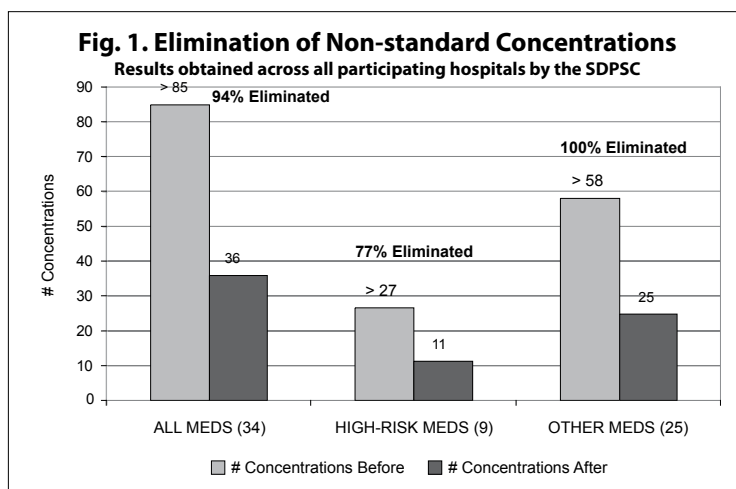
- Celebrate success of area-wide standardization in terms of satisfaction, service, and safety.
 - Formal report to stakeholders, e.g., site quality councils, nursing leadership, etc.
 - Public relations campaign –press release, newsletter article, posters, slides, website

Desired Outcomes

- Reduction in IV infusion medication errors.
- Consistent, visible and tangible reinforcement of the change initiative in the organization.²³
- Sense of accomplishment shared within and across institutions.
- A measurement and evaluation process is in place following the change.

Tools

- *Sample PowerPoint Presentation*
- *Sample Press Release*



Tools To Drive Success

The Toolkit with the following tools is available at www.cardinalhealth.com/clinicalcenter.

Invitation: Example

This letter can be customized to invite people to join your collaborative effort. The invitation presents the goal and the process that will be followed to achieve the goal. An "Agreement to participate" allows people to fax back their recommendations for task force members, so that

"Together we can make _____ (area name) _____ among the safest places in the US to receive critical healthcare."

Project Charter: Example

This tool can help your task force to specify critical project elements, e.g., project start and length, project owner, sponsor, team members, problem statement, what success will look like, and key measurements.

Executive Sponsor, Process Owners, Change Agent Responsibilities

This tool specifies the common and distinct responsibilities of various task force members.

Stakeholder Support/Resistance Analysis Tool

This brief process description and analysis template can be used to help identify resistance and gain support of key individuals for the project.

PowerPoint Presentation

This SDPSC presentation can be customized to present information at appropriate times during the project: the case for standardization, the task force's work, results and immediate benefits.

Adult IV Infusions Survey Tool: Example

This template can be used to help identify participating hospitals' current practices with regard to the administration of IV medications.

Standardized List of Adult IV Infusions: Example

This is the standardized list developed by the SDPSC.

Implementation Timeline

This SDPSC timeline can be customized to meet your hospitals' needs.

Implementation Checklist

This is another way to check that all necessary steps have been taken for implementation of the standardized list.

Pharmacy Temporary IV Wrapper

This should be used to ensure that a new concentration product is OBVIOUSLY NEW and DIFFERENT, i.e., to alert nurses hanging the new standardized drips.

Press Release: Example

This can be customized to communicate the task force's work to your wider community.

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