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ISMP An ECRI Affiliate

Acute Care
ISMP Medication Safety Alert!®
Educating the Healthcare Community About Safe Medication Practices

California Medication Error Reduction Plan: Time for regulators and accreditors to adopt similar initiatives

ISMP has always been an advocate for learning from the experiences of others—taking certain aspects of another's experience and incorporating it into your own work and life for the purpose of improvement. It is in this spirit of learning that we again share with readers our support of a 20-year statewide initiative in California (CA) to reduce medication-related errors, which we hope hospital regulators and accreditors, if not US hospitals themselves, will adopt. Since 2002, the California Department of Public Health (CDPH) has required every licensed general, acute care hospital in CA to establish a Medication Error Reduction Plan (MERP), referred to as the CA MERP (www.ismp.org/ext/1009). CDPH defines a medication-related error as any preventable medication-related event that adversely affects a patient and is related to professional practice, healthcare products, and organizational procedures and systems.

The CA MERP was developed under the leadership of Loriann De Martini, PharmD, MPH, BCGP, while serving as deputy director of the Office of Quality Performance and Accreditation at CDPH, and who is now the Chief Executive Officer of the California Society of Health-System Pharmacists (CSHP). When recently asked about the success of the program, Dr. De Martini said, *"Enactment of a CA statute requiring hospitals to proactively identify and implement methodologies to reduce the occurrence of medication errors has exponentially accelerated medication safety efforts in our state for our over 400 hospitals. All have benefited from these efforts, [including] patients and healthcare professionals, by reducing harm and improving the quality of care provided."* While we recognize that significant resources and expertise are necessary to design and execute a robust MERP, such an effort can significantly improve patient safety.

CA MERP Regulatory Requirements

The CA MERP requires each hospital to adopt a methodology to assess, improve, and evaluate medication safety. **Table 1** (page 2) provides details regarding the required components in each hospital's CA MERP, along with examples of self-assessment questions. An impactful MERP should focus on high-leverage systems and technologies to improve high-alert medication processes. Each initiative in the MERP should include the rationale for selection, a plan to measure effectiveness and outcomes, as well as follow-up steps.

Interdisciplinary Oversight

To oversee the CA MERP, each organization must designate an interdisciplinary medication safety committee comprised of pharmacists, nurses, physicians, and administrators. Other members may include respiratory therapists, safety/quality/risk management staff, educators, and informatics staff. Coordination of the committee's activities by a medication safety officer (MSO) is highly recommended. The committee must conduct a timely review of all medication-related errors submitted, including those that caused harm or have the potential to cause harm, and evaluate for actionable improvements, be empowered to make necessary changes to procedures and systems, and share the lessons learned and actions taken with frontline staff and leadership.

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SAFETY briefs

Using VIGIV for monkeypox? The concentration is not as it may seem. A prescriber ordered Vaccinia Immune Globulin Intravenous (Human) (VIGIV) (NDC 60492-0173-1) 6,000 units/kg for a hospitalized 3.49 kg neonate (total dose of 20,940 units) with monkeypox-like symptoms. A single-dose vial arrived from the national stockpile in an unlabeled carton without a package insert. The immediate vial label displayed, "greater than or equal to 50,000 units per vial," without listing a corresponding volume or concentration (**Figure 1**). When trying to determine how to prepare this product, a pharmacist found the package insert on DailyMed (www.ismp.org/ext/997), which states that VIGIV is provided in a 20 mL single-dose vial containing antibodies to vaccinia virus at greater than or equal to 50,000 units per vial. The package insert states to remove the entire contents of the vial to obtain the labeled dosage of VIGIV. Practitioners might assume the vial contains a total volume of 20 mL equaling 50,000 units, but 20 mL is the size of the glass vial! The actual volume in each vial is variable!

The pharmacist at the above hospital consulted with the Centers for Disease

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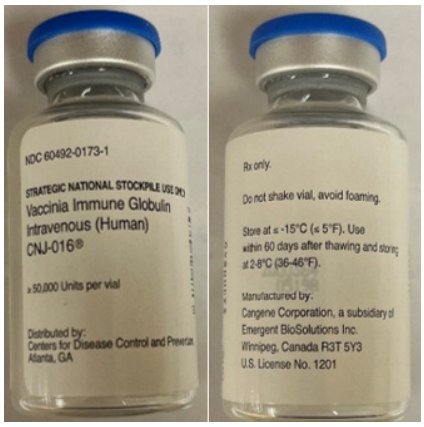

Figure 1. The Vaccinia Immune Globulin Intravenous (Human) CNJ-016 vial label displays greater than or equal to 50,000 units per vial, without a corresponding volume or concentration.

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Table 1. CA MERP Requirements and Examples of Self-Assessment Questions

CA MERP Requirements	Examples of Self-Assessment Questions
Evaluate, assess, and include a method to address each of the 11 procedures or systems associated with medication use to identify weaknesses or deficiencies that could contribute to errors. **11 procedures and systems** ■ Prescribing ■ Prescription order communications ■ Product labeling ■ Packaging and nomenclature ■ Compounding ■ Dispensing ■ Distribution ■ Administration ■ Education ■ Monitoring ■ Use	■ What committee/team oversees the MERP? ■ Have interventions to reduce medication errors been identified for each of the 11 procedures/systems? ■ How does the hospital determine effectiveness and identify weaknesses or deficiencies in the 11 procedures/systems? ■ Does the method include the use of metrics such as process measures? Aggregate trending reports? Failure mode and effects analysis (FMEA)? Self assessments? Root cause analysis (RCA)? Observation? Robust reporting system? ■ Does the method include analysis of all medication error data to identify problems? ■ How has the assessment process been used to address system deficits and reduce medication errors? ■ Were the implementation strategies used to address the system deficits effective in reducing medication errors?
Include an annual review to assess the effectiveness of the implementation of each of the procedures and systems listed in the first requirement.	■ How do you know that a specific intervention is working to reduce errors? ■ On an annual basis, did you assess the effectiveness of the plan for each of the 11 procedures and systems? ■ Did the annual review identify interventions that were ineffective? ■ Is the MERP effective in reducing errors?
Include modification as warranted when weaknesses or deficiencies are noted, to achieve the reduction of medication errors.	■ What method is used to identify weaknesses or deficiencies that could contribute to errors? ■ What weaknesses and/or deficiencies have the hospital noted upon review? ■ How was the plan modified to address the noted deficiencies? ■ Did the hospital reassess the MERP after it had been modified? ■ Was the revised plan or the modification effective in addressing the noted deficiencies?
Describe the technology to be implemented and how it is expected to reduce medication-related errors associated with one or more of the procedures and systems listed in the first requirement.	■ Does the MERP include an implementation plan for the technology? ■ Has the hospital implemented the technology specified in its plan? ■ How has the technology been effective in reducing medication errors?
Include a system or process to proactively identify actual or potential medication-related errors. The system or process shall include concurrent and retrospective review of clinical care. (The intent is for the hospital to have a robust medication error reporting system, identify medication system vulnerabilities, and develop corrective actions.)	■ What is the hospital's process to identify medication errors and risks? ■ Does the process include concurrent (e.g., observation) and retrospective (e.g., analysis of error reports, RCA) review of care? ■ Does the process include a proactive component? ■ Does it include a variety of methods to identify risks, errors, and harmful events, such as error reporting, process/outcome metrics, FMEA, self assessments, RCA, capture of pharmacy or nursing interventions, triggers, observation, chart review, and/or survey data? ■ Is the process effective? How do you know it's effective? ■ Is there a culture of safety that encourages reporting? How is reporting encouraged?
Include a multidisciplinary process, including healthcare professionals responsible for pharmaceuticals, nursing, medical staff, and administration, to regularly analyze all identified actual or potential medication-related errors and describe how the analysis will be utilized to change current procedures and systems to reduce medication-related errors.	■ How does your hospital analyze reported medication errors? Are pharmacists, nurses, physicians, and administrators part of the process? ■ Does the multidisciplinary group regularly analyze all identified actual or potential medication-related errors? ■ How has this analysis been used to change current procedures or systems? ■ What examples can you provide to demonstrate such a change in procedures or systems? ■ Were the changes in the procedure or system effective in reducing medication errors?
Include a process to incorporate external medication-related error alerts to modify current processes and systems as appropriate.	■ Does the plan include a review of external medication error alerts to modify current processes and systems? ■ What external sources does the hospital use for identification of potential/actual risks related to medication errors? ■ How has the hospital used these external alerts to modify processes and systems? ■ Were changes in the procedure or system effective in reducing medication errors?

Sources: Chapter 2.05 Minimization of Medication-Related Errors in the California Health and Safety Code Section 1339.63 (www.ismp.org/ext/1009); All Facility Letter from CDPH issued on August 10, 2009 (www.ismp.org/ext/1022); All Facility Letter from CDPH issued on December 9, 2008 (www.ismp.org/ext/1023); General Acute Care Hospital Relicensing Survey, Regulations with Survey Procedures revised March 2016 (www.ismp.org/ext/1028).

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Learning from External Reports

Another essential feature of the CA MERP requires establishing a process to incorporate and learn from *external* medication-related error alerts, and to take action to modify current processes and systems as needed to reduce the risk of similar errors internally. Organizations should be proactive in ensuring system safety and not wait until a tragic event happens to make changes. No news is *not* good news when it comes to patient safety. The CA regulation suggests that each organization needs to accurately assess how susceptible its systems are to the same errors that have happened in other organizations, and to acknowledge that the absence of similar errors is not evidence of safety.

Personal experience is a powerful teacher, but the price is too high to learn all we need to know from firsthand experiences. Learning from the mistakes of others is imperative, and ISMP is especially supportive and pleased that CA requires this component in its MERP regulations. Not learning from the mistakes of others serves as an existential risk to patient safety, yet its importance is almost universally overlooked by federal and state regulators and accreditors.

To include a review of *external* medication-related error alerts, we recommend identifying individuals, such as the MSO or members of the interdisciplinary medication safety committee, to regularly read various resources, including the following:

- ISMP newsletters (www.ismp.org/node/1003), *Action Agendas* (www.ismp.org/node/645), and ***Targeted Medication Safety Best Practices for Hospitals*** *(Best Practices)* (www.ismp.org/node/160)
- The Joint Commission *Sentinel Event Alert* newsletters (www.ismp.org/ext/1015)
- US Food and Drug Administration (FDA) drug alerts and statements (www.ismp.org/ext/1016)
- *National Alert Network* (NAN) alerts (www.ismp.org/ext/1017)
- National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) recommendations and statements (www.ismp.org/ext/1018)
- Medication Safety Officers Society (MSOS) list serve (www.medsafetyofficer.org)
- American Society of Health-System Pharmacists (ASHP) member list serve (www.ismp.org/ext/1020)
- ECRI (www.ecri.org)

Those individuals should be assigned to compile *external* alerts and bring them to the interdisciplinary medication safety committee to proactively review and identify issues that are pertinent to their organization so changes can be implemented prior to an event occurring. Organizations may also choose to collaborate with a Patient Safety Organization (PSO) (www.ecri.org/pso) to share adverse drug events or hazards and learn from other organizations.

Procedures and Systems

Below are examples of initiatives organizations might implement across the 11 MERP procedures and systems. Organizations should define/set goals to achieve based on measurable data (e.g., a 25% reduction).

Prescribing

- Reduce clinically insignificant computer alerts
- Verify and document a patient's opioid status (naïve versus tolerant) and type of pain (acute versus chronic) before prescribing extended-release and long-acting opioids
- Create and/or measure compliance with anticoagulant order sets and the appropriate use of reversal agents

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Control and Prevention (CDC) and was instructed to withdraw the total volume in the vial, then divide 50,000 units by the volume to determine the final concentration. The total volume was determined to be 11.5 mL and resulted in a concentration of 4,348 units/mL. Therefore, the patient-specific dose (20,940 units) was calculated to be 4.82 mL. If the CDC specialist had not been available, the pharmacist might have incorrectly determined the concentration to be 50,000 units/20 mL (2,500 units/mL), which would have resulted in a final dose of 36,436 units/8.38 mL (almost double the intended dose).

Also, before the pharmacist could verify the order in the electronic health record and generate a patient-specific label, which requires the volume and concentration, the technician had to first draw up the volume of the vial to determine the concentration (i.e., the technician had to manipulate the VIGIV before the label was printed). This is another opportunity for error because the technician will not have a printed label for the syringe.

ISMP has confirmed this unusual situation with the CDC. To provide clarity, the CDC went on to explain that the vials are filled from pooled plasma with a minimum of 50,000 units per vial, thus the volume and concentration vary per vial. When this medication is requested and approved to treat monkeypox, the CDC emails an investigational new drug (IND) protocol to the prescriber in advance, and this should be distributed to pharmacy staff to refer to for dose preparation and titration instructions (www.ismp.org/ext/1030).

In addition to the container label issue, the "administration" section of the package insert states that VIGIV should be given intravenously (IV) at an infusion rate no greater than 2 mL/minute. For patients weighing less than 50 kg, it should be administered at a rate no greater than 0.04 mL/kg/minute (133.3 units per kg/minute). However, when the pharmacist consulted with CDC, they learned about the IND protocol which indicated that for certain patients, VIGIV administration should be initiated at an infusion rate of 0.01-0.02 mL/kg/minute for the first

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Prescription order communications

- Reduce the number of parenteral nutrition (PN) transcription errors
- Reduce the number of verbal orders

Product labeling

- Use tall man (mixed case) letters on storage location (e.g., medication bins) labels
- Along with the full generic vaccine names and Centers for Disease Control and Prevention (CDC) standard abbreviation for vaccines, list vaccine brand names on computer-generated labels

Packaging and nomenclature

- Implement a process and track compliance with the timely addition and testing of new formulary medication barcodes

Compounding

- Assess compliance with the use of intravenous (IV) and/or oral liquid extemporaneously compounded master formulation records
- Track progress with implementation of USP General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings* requirements

Dispensing

- Use chart review to detect dispensing errors with high-alert medications (e.g., opioids, anticoagulants, chemotherapy, PN) and implement action plans to reduce errors

Distribution

- Reduce medication delays by refilling a sufficient quantity of medication in the automated dispensing cabinet (ADC)
- Improve barcode scanning compliance when refilling the ADC

Administration

- Increase smart pump dose error-reduction system (DERS) usage to greater than 95% (based on *Best Practice* #8) for applicable medications and infusions
- Expand barcode medication administration verification to outpatient care areas (e.g., emergency department, infusion center), achieving compliance with use of the technology
- Reduce ADC overrides for non-emergent high-alert medications

Education

- Provide discharge education for patients discharged home on anticoagulants
- Complete medication safety competency assessments during new staff orientation

Monitoring

- Implement capnography or end-tidal (exhaled) carbon dioxide monitoring for patients receiving IV or epidural patient-controlled analgesia (PCA)
- Document pain scores before and after administration of pain medications

Use

- Complete a medication-use evaluation (MUE) on a high-alert medication or a new formulary medication

Reporting Hazards and Errors

Prescribers, nurses, pharmacists, respiratory therapists, and other healthcare practitioners who identify medication-related hazards or errors must report them internally through the organizational reporting program. If you have an electronic error reporting system, consider configuring it with events categorized into the 11 CA MERP procedures and systems to trend the data and provide visibility to specific event types that

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30 minutes and then it can be increased by 0.01-0.02 mL/kg/minute from the initial infusion rate for the next 30 minutes. After that time, the remaining infusion may be administered at a rate of 2 mL/minute.

If a patient in your organization requires the use of VIGIV, obtain the current IND protocol from the prescriber or CDC, consider creating a worksheet to calculate the concentration of the vial in hand, include a label to use when drawing up the vial contents. Include complete titration instructions for the nurse so that VIGIV is administered at the correct rate.

Survey about NRFit transition. NRFit is the name selected by the Global Enteral Device Supplier Association (GEDSA; www.stayconnected.org) for ISO 80369-6-compliant neuraxial connectors, which are incompatible with the Luer system and other types of syringes (e.g., ENFit, oral syringes), thus preventing wrong route misconnections. We have previously shared information about NRFit devices and how they can safeguard neuraxial medication administration (www.ismp.org/node/18850).

Now that vendors have made more NRFit products available, please consider completing GEDSA's seven-question *NRFit Awareness and Adoption - Clinical Survey* (www.ismp.org/ext/1006) to provide GEDSA and your organization with a better understanding of the barriers and enablers to transition to NRFit.

In 2014, The Joint Commission (TJC) released its *Sentinel Event Alert 53: Managing Risk During Transition to New ISO Tubing Connector Standards* (www.ismp.org/ext/996), which you may find useful as a resource when planning for NRFit transition. We know that many organizations used this *Sentinel Event Alert* publication when planning their transition to ENFit devices.

We hope that the TJC resource, and the GEDSA website and information gathered from the survey results about NRFit awareness and adoption, will provide organizations with enough information to plan for transition to NRFit.

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require improvement. Assign each hazard or error reported to a responsible department leader for review and follow-up. Although not required by CA regulations, we hope hospitals will consider reporting medication hazards and errors (including harmful and potentially harmful events) to ISMP (www.ismp.org/report-medication-error) so we can alert the entire healthcare community about the risk. Besides voluntary reporting, consider reviewing medication-related triggers and markers (e.g., use of reversal agents) to identify risks or errors.

Annual Review of the MERP

In CA, regulations require hospitals to conduct an annual review of the MERP to assess its effectiveness. The interdisciplinary medication safety committee should direct this process, summarize all activities in the MERP, and add newly identified strategies during the year. If an outcome does not meet the goal defined in the selected metrics, discuss this during the annual review and decide if the initiative is still feasible, if it will require additional resources, or if the plan requires modification.

MERP in Other States

We were pleased to see that the Arkansas (AR) State Board of Pharmacy followed California's lead and, as of 2014, hospital pharmacy regulations require the pharmacy and therapeutics committee to perform the following functions: *Develop and routinely evaluate a hospital-wide MERP to identify actual or potential medication-related errors and perform a concurrent and retrospective review of clinical care. The MERP should address the areas of prescribing, prescription order communication, product labeling, product packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use* (www.ismp.org/ext/1010). This language is directly from the CA statute that formed the requirements for the CA MERP.

Conclusion

The CA MERP initiative provides a framework to advance many of the error-reduction strategies that we have advocated and supported over the years, including:

- Maintaining a robust medication error reporting system
- Interdisciplinary teams analyzing medication risks and errors
- Carefully planned technology implementation
- Effective and timely use of measurable assessments to evaluate the impact of selective error-reduction strategies
- A proactive approach to risk identification analysis
- Use of external information to improve medication safety
- Annual review of the strategic plan to reduce medication errors

For those working outside CA and AR, we encourage you to complete a gap analysis using the CA MERP framework (**Table 1**, page 2) and to develop a formal MERP. For those working in CA and AR, please be on the lookout for a survey that ISMP and CSHP are planning to conduct early in 2023 to help measure the effectiveness of the MERP and to better understand how the program has impacted medication safety.

If you would like to subscribe to this newsletter, visit: www.ismp.org/node/10

Report medication and vaccine errors to ISMP: Please call 1-800-FAIL-SAF(E), or visit: www.ismp.org/report-medication-error. ISMP guarantees the confidentiality of information received and respects the reporters' wishes regarding the level of detail included in publications.

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Special Announcements

FREE ISMP webinar

Join us on **November 30, 2022**, for a **FREE** webinar on ***Transitioning to Ready-to-Administer IV Medications: Can it be Both Safe and Affordable?*** Learn about key vulnerabilities when intravenous (IV) medications that require manipulation at the bedside have led to errors and patient harm. The speakers will also discuss cost and safety comparisons of manufacturer-prepared prefilled ready-to-administer (RTA) products versus traditional vial-to-syringe products. The program is supported by Fresenius Kabi, and continuing education (CE) credit is being offered for pharmacists, pharmacy technicians, and nurses. For more information and to register, please visit: www.ismp.org/node/45218.

Get intensive about medication safety

Don't miss our last ***ISMP Medication Safety Intensive (MSI)*** workshop of the year! This unique 2-day session is being held virtually on **December 1** and **2**! You won't want to miss this opportunity to maximize your error-prevention efforts and learn to look at your organization through the eyes of leading safety experts. For information and to register, please visit: www.ismp.org/node/127.

Take our survey on tall man letters!

ISMP is updating our list of ***Look-Alike Drug Names with Recommended Tall Man Letters*** (www.ismp.org/node/136). We are asking for your input by taking a short survey. Please submit your responses by **December 2, 2022**, online at: www.ismp.org/ext/1014.

CHEERS AWARDS event and raffle

Please register to attend **ISMP's 25th Annual CHEERS AWARDS** dinner on **December 6** at 6:00 p.m., in Las Vegas, NV, by visiting: www.ismp.org/node/34374. The **CHEERS AWARDS** are ISMP's only fundraising event, and as part of our fundraising efforts for this blockbuster year, we are hosting an online raffle with an amazing array of high-end prizes, from a Samsung 50-inch smart TV to a $200 Amazon gift card. To purchase your raffle tickets, visit: www.ismp.org/ext/1029.

Walk the Red Carpet with Safety Stars

ISMP 25th Annual Cheers Awards

Join Us on Tuesday, December 6, 2022

ISMP is recognizing medication safety leaders at the 2022 Cheers Awards dinner and we would love to see you there.

This is not only the **25th anniversary of the Cheers Awards**, but we are also honoring a true medication safety star, **Michael R. Cohen**, who is this year's Keynote Speaker and Lifetime Achievement Award winner.

Support Cheers During Our Blockbuster Year!

Keynote Speaker and Lifetime Achievement Award Winner:

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP

Michael R. Cohen, President Emeritus and co-founder of the Institute for Safe Medication Practices (ISMP), has dedicated his career to advocating for medication error prevention. His passion for medication safety began in 1974 when he saw the value in sharing the story of a serious adverse event that occurred at a local hospital to help prevent the same error from happening again. He founded ISMP in 1994 and launched the first of its newsletters in 1997. ISMP's publications now reach over a million health professionals in the US and over 30 foreign countries. Dr. Cohen also has helped bring about countless changes in clinical practice, public policy, and drug labeling and packaging that have impacted millions of patients and healthcare professionals. He has received numerous awards for his leadership and advocacy in medication safety.

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To register to attend or make a donation to show your support, visit: www.ismp.org/node/34185