

Acute Care ISMP Medication Safety Alert

Educating the Healthcare Community About Safe Medication Practices

Safety considerations for challenges when using smart infusion pumps



PROBLEM: Organizations must customize their smart infusion pump drug libraries and tailor each to their needs. However, drug library customization requires dedicated resources to review the literature, compare the parameters in the drug libraries with actual clinical practice, and determine safeguards for each infusion in the drug library. Organizations must also continually ensure that the library content is up to date and that the most recent version has been downloaded and is active on all of their smart

pumps. Unfortunately, ISMP has received reports related to safety risk and limitations that healthcare practitioners face when trying to optimize drug libraries and implement important safeguards to prevent catastrophic programming errors.

No Universal Maximum Dose

Several medications, including opioids, benzodiazepines, and anticoagulants, do not have a universal maximum dose published in the official prescribing information; instead, they have widely variable doses based on the medication's indication, patient-specific parameters, tolerability, or clinical response. Without a maximum dose built into the smart pump library, a programming error, including programming doses or rates 10-fold or greater than intended (e.g., entering 200 mg instead of 20 mg, 19 units/hour instead of 1.9 units/hour) could lead to significant patient harm. For example, if a heparin protocol does not include a maximum dose, the team that builds the smart pump drug library will need to achieve consensus to set it. While the smart pump team may try to capture most dose scenarios, they may not know where to draw the line for patients who receive doses that are higher or lower than typical doses for clinically appropriate reasons. Yet, if a smart pump issues a hard stop for a dose outside the limits but the dose is still clinically appropriate for the patient, the practitioner will likely need to revert to a risk-prone process of manually programming the heparin infusion without engaging the dose error-reduction system (DERS).

(Wide Dosing Parameters or Variable Rates

Medications with wide dosing parameters or variable rates of infusion cause added challenges when building dose range limits in drug libraries. The smart pump team may have difficulty building effective safeguards while accommodating the variable doses and infusion rates for medications titrated to patients' clinical responses, used for different indications, or based on the patients' tolerability. The following are examples that highlight these challenges.

Clinical response. Titratable medications, such as vasopressors, require prescribers to order an initial rate of infusion, titration parameters including the frequency of titration, the maximum dose or rate of infusion, and an objective clinical measure to guide changes. If the smart pump team setting the minimum and maximum dose limits does not consider the full range of the titration across all patients, the result is possible nuisance alerts or unnecessary hard stops for the practitioner programming the pump.

Indication. For mechanically ventilated patients in the intensive care unit (ICU), the typical dose of a ketamine continuous infusion for analgesia, sedation, agitation, or continued on page 2 — **Pump challenges** >

SAFETY brief

Paralytic cap warning is easily missed. Cisatracurium vials (20 mg/10 mL) from Teva display "Warning: Paralyzing Agent" in black print on a dark blue cap, making the warning difficult to visualize (Figure 1). The way the warning is printed

continued on page 2 — SAFETY brief >



Figure 1. Due to the dark print and cap color on the cisatracurium 20 mg/10 mL vial by Teva, practitioners can overlook the cautionary statement, "Warning: Paralyzing Agent," printed in black.

Please 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 (see page 6). Please submit your responses by December 2, 2022, online at: www.ismp.org/ ext/1014. Our list of drug name pairs with tall man letters was first compiled in 2008 to help healthcare organizations employ a standard set of tall man letters to differentiate lookalike drug names. We are considering adding a few name pairs that have been involved in errors, and we truly value your opinion! Meanwhile, ISMP is participating in a 4-year Northwestern University (Chicago) research project, led by Bruce L. Lambert, PhD, and funded by the US Food and Drug Administration (FDA), to assess the comparative effectiveness of various methods of drug name text enhancements and the ability of tall man (mixed case) lettering to reduce errors during drug selection.

chronic pain is much lower than the dose of this medication infusion used for refractory status epilepticus based on a goal of electrographic suppression. If only one option exists in the smart pump library for ketamine, which has up to a 10-fold difference in safe dosage ranges based on its indication, a practitioner who makes a programming error may not receive an alert.

Tolerability. Prescribers may incrementally increase the rate of certain chemotherapy and immunosuppressants based on the patient's tolerability, rather than titrating to a clinical endpoint. For example, when used for certain indications, ri**TUX**imab has an initial infusion rate with incremental increases every 30 minutes unless hypersensitivity or an infusion-related reaction occurs.

For each of these situations, practitioners who make programming errors will either not receive clinically important alerts if the dose limits are too wide, or will receive nuisance alerts or hard stops if the dose limits are too narrow. Nuisance alerts that happen regularly contribute to alert fatigue and workarounds that can result in administering the medication infusion without engaging the DERS.

(Large Dosing Differences in Opioid-Naïve and Opioid-Tolerant Patients

Patients may require a continuous opioid infusion or patient-controlled analgesia (PCA) for a variety of indications, including pain management or end-of-life care. There are large differences in opioid doses, rates, and concentrations used to treat opioid-naïve patients compared to opioid-tolerant patients. Like the scenarios described above, if there is only one option for each opioid medication infusion, nuisance alerts may fire for opioid-tolerant patients if the dose range limits are too narrow, or clinically important alerts may not fire for opioid-naïve patients if the upper limits are too high.

Bolus Doses Inappropriately Administered from Continuous Infusions

When patients receive a continuous infusion, practitioners may be required to directly administer a bolus dose of the same medication from the continuous infusion. This is only safe if the smart pump has a bolus dose feature that administers the correct dose and volume for the bolus dose at the correct rate, and then *automatically* resumes the continuous infusion at the earlier rate. Without prebuilt bolus options, an unsafe workaround occurs when a practitioner simply increases the rate of infusion to administer the bolus dose, and then must *remember* to manually return the infusion to the prior rate settings after the bolus dose has been administered. A second issue seen with bolus doses is when the volume of the bolus consumes a large amount of the infusion provided, which may cause confusion and delays. Consider these error-prone scenarios:

A prescriber ordered a bolus dose of 3,200 units of heparin for a 40 kg child receiving a heparin infusion via a syringe pump. To administer the bolus from the 100 units/mL infusion, it would require administration of 32 mL, more than half of the current syringe volume. The nurse assumed the pharmacy would dispense a more concentrated heparin syringe for the bolus dose. However, the pharmacy did not dispense a separate bolus dose because the heparin order set in the electronic health record (EHR) did not specify how to administer it, and pharmacy staff did not realize the bolus dose would consume more than half of the volume in the syringe already infusing, resulting in a delay in care.

A prescriber ordered an opioid bolus dose for a patient receiving an opioid infusion, but the bolus exceeded the maximum hard limit in the drug library. As a result, the practitioner bypassed the bolus dose feature and administered the bolus by increasing the rate of the continuous opioid infusion. Fortunately, this at-risk behavior did not adversely affect the patient, and the practitioner remembered to decrease the opioid infusion rate after the bolus dose had been administered. Unfortunately, this sent the wrong message to the practitioner, that taking this risk was an acceptable practice; sooner or later, someone will forget to adjust the rate.

continued on page 3 — Pump challenges >

> **SAFETY** brief cont'd from page 1 on the cap likely violates USP General Chapter <7> Labeling. USP Chapter <7> requires printing the cautionary statement, "Warning: Paralyzing Agent" or "Paralyzing Agent" (depending on the size of the closure system), in black or white font, whichever provides the greatest color contrast with the ferrule or cap color, and in a way that is

clearly visible under ordinary conditions of

ISMP has notified the US Food and Drug Administration (FDA), USP, and the manufacturer about this problem and has recommended using white print on the dark blue cap so that practitioners can clearly see the warning statement. For now, organizations should consider purchasing this medication from a different manufacturer, or if already purchased, add an auxiliary label with "Warning: Paralyzing Agent" or "Paralyzing Agent" over the cap.

Worth repeating...



Mix-ups between COVID-19 and influenza (flu) vaccines

Here we go again. It is that time when the flu season and the need for coronavirus disease 2019 (COVID-19) bivalent boosters are converging. We previously noted mixups between the COVID-19 and the flu vaccines in our newsletter, including in the Top 10 Medication Safety Concerns from 2021 (www.ismp.org/node/29473). Just like the previous flu season, we are now seeing a lot of similar mix-ups between these vaccines. Case in point: recently, a patient went to the pharmacy to receive both the flu vaccine and the bivalent Moderna COVID-19 booster. After a pharmacist administered the two vaccines, the pharmacy notified the patient that the pharmacist had inadvertently administered two doses of the bivalent COVID-19 booster. The patient later reported nausea, vomiting, headache, and joint pain. We anticipate more mix-ups to occur now that both the COVID-19 and flu vaccines are often given simultaneously.

To prevent mix-ups, handle one vaccine at a time, and provide separate areas for continued on page 3 — *Worth* repeating >



Untimely Library Updates

Some organizations lack the resources and/or expertise for ongoing maintenance, updating, and testing of the software and drug library for all smart infusion pumps. Smart infusion pumps are limited by the software version and drug library installed on the devices, making it imperative to regularly update the drug library in every device. For example, after changing a standard concentration of a medication infusion due to a drug shortage or formulary change, if organizations do not update the libraries on all the pumps, the practitioner may select an incorrect concentration resulting in a programming error. Or, if the practitioner cannot find the new concentration, it may delay patient care. We shared similar concerns with concentration errors in our June 16, 2022, feature article on safely transitioning to new drug concentrations (www.ismp.org/node/32208).

SAFE PRACTICE RECOMMENDATIONS: Consider the following recommendations to address the described smart infusion pump challenges:

Establish and approve dose limits. Establish and/or evaluate minimum and maximum dose limits for each medication infusion and bolus dose that requires infusion via a smart infusion pump. Determine if the dose limits should be weight-based or non-weight based, aligning the dose limits with organizational protocols, dosing references, literature, and clinical practice. Engage end users (e.g., nurses, anesthesia providers) when deciding if medication infusions and bolus doses need to have more than one drug library entry due to wide dosing parameters or variable rates. For example, consider providing two library options for opioid infusions and bolus doses based on the patient's opioid status (naïve versus tolerant). Also consider the full range of titration when setting dose limits for titratable infusions. Smart infusion pump dosing limits should not cause nuisance alerts or prevent the programming of incremental doses.

Reach a consensus on each medication infusion and bolus dose limits and determine soft and hard limits. This will require a search of the literature and analysis of organization-specific prescribing and pump data that reflect current clinical usage, doses, and practices. Be aware that continuous infusion units are generally dosed per hour while boluses may be dosed per minute. While reviewing past pump data, examine outliers to determine if they were planned or may have been errors. For example, if an order calls for a dose of up to 100 mcg/kg/hour but the patient is titrated up to 270 mcg/kg/hour, be suspicious of an error. Once the drug library parameters have been determined, require approval by an interdisciplinary committee before updating or creating the drug library. Also determine and communicate a process for practitioners to request changes to the set limits.

Use the EHR to drive safe practice. Because smart pump dose alerts or hard stops detect and/or prevent catastrophic programming errors and serve *only* as a final layer of protection against administering overdoses, establish dose range checking in the EHR to notify prescribers and pharmacists up front if it is likely that a medication infusion dose has been prescribed outside of a safe dose range. Also, configure the EHR to notify prescribers and pharmacists that a medication infusion requires a change in concentration if the dose falls outside of the capability of the organizational pumps (e.g., less than 0.1 mL/hour for a 50 mL syringe). Require all titratable medication orders to include the medication name; route; initial or starting rate; incremental units the rate can be increased or decreased; frequency of dose titrations; maximum rate of infusion; and an objective clinical measure to guide changes. Ideally, match medication names in the smart pump with the names in the medication administration record (MAR) and EHR.

Create drug libraries. Once the dose limits and hard stops have been established and approved, set soft dosing limits in the smart pump drug library that reflect the maximum continued on page 4 — Pump challenges >

> Worth repeating cont'd from page 2 vaccine preparation and administration, away from distractions and interruptions. Using manufacturer prefilled flu vaccine syringes may help distinguish them from the COVID-19 vaccines and boosters, which must be withdrawn from a vial into a syringe. Before vaccine administration, check the patient's vaccine card/medical record and the state/local immunization information system. Ask the patient which vaccine(s) they have requested and verify the vaccine(s) with a signed consent form(s). Only bring the intended vaccine(s) for one patient at a time into the vaccination area and include the parent/patient in verifying the prepared vaccine(s). Clearly label all syringes. During preparation and administration, use barcode scanning to confirm the correct vaccine. Document the lot number and expiration date prior to administration, and document administration afterward. Ensure adequate staffing and do not expect staff to accomplish both

If a mix-up occurs, notify the patient and provide the intended vaccine before they leave the vaccination area (or ask the patient to return to the vaccination site). Report any vaccination errors to the US Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (www.vaers.hhs.gov) – reporting is mandatory for vaccines authorized for emergency use – and also report the error to the ISMP Vaccine Errors Reporting Program (ISMP VERP) (www.ismp.org/report-medication-error).

vaccine administration and other respon-

sibilities simultaneously.



Naloxone syringe and Clave/MicroClave connector incompatibility

In a recent case, a practitioner connected an Aurobindo Pharma (Eugia Pharma Specialties Limited) naloxone syringe, distributed by AuroMedics Pharma, to a MicroClave (ICU medical) needlefree syringe connector on the intravenous (IV) tubing access port to administer the drug. They could not push the medication out of the syringe. When the practitioner detached the naloxone syringe from the MicroClave connector, they noted a piece

continued on page 4 — Worth repeating >





expected dose and rate prescribed as well as a buffer for patients who may require more or less than the typical default doses and rates. Set hard dosing limits as a forcing function to prevent catastrophic errors, while considering patients who may clinically require atypical doses, to prevent end users from needing to program the infusion without engaging the DERS. Incorporate a process to double check the drug library build prior to releasing it onto the pumps.

Limit multiple indication-based options. If different indication-based library entries are needed for certain medication infusions, determine if the infusion is only used for a single indication in a specific location, and limit the drug library for that location to only one option, when possible. Otherwise, let end users know about the infusions that have multiple indication-based options. If possible, clearly include the indication in the drug name selection on the pump.

Test the drug library. Test the drug library to ensure that soft and hard stops will capture a variety of prescribing and programming errors. Specifically test hard stops to ensure they will capture and prevent 10-fold under- and overdose errors. For medication infusions with two options in the drug library based on the indication, make it obvious to the end users which option to select, or this could lead to unintended downstream effects or programming errors. For example, if oxytocin has a peripartum option with a lower dose range limit for induction and a postpartum option with a higher dose range limit for bleeding, have end users review the naming convention used for each indication of oxytocin in the drug library as well as the associated workflow to ensure it is intuitive to select and switch between the two options.

Differentiate opioid status. In alignment with the ISMP Targeted Medication Safety Best Practices for Hospitals (www.ismp.org/node/160), verify and document a patient's opioid status (naïve versus tolerant) before prescribing and dispensing continuous infusions of opioids. Default order entry systems to the lowest initial opioid starting dose. Review the literature and analyze organization-specific prescribing and pump data to build order sets with dosing guidance that differentiate opioidnaïve versus opioid-tolerant patients. During opioid prescribing, automatically link products with the corresponding concentration that pharmacists will dispense. Design the drug library options and limits to reflect the order sets and to be intuitive for end users. Consider whether your patient population warrants having a separate palliative or end-of-life care drug library. Additionally, instead of relying on end users to select the correct opioid concentration from a menu of multiple options, consider establishing entries defined by a dose threshold (e.g., morphine less than or equal to 5 mg/hour or greater than 5 mg/hour), with specific concentrations restricted to opioid-tolerant patients.

Limit bolus doses from a continuous infusion. Only allow practitioners to administer a bolus dose from a continuous infusion if your infusion pump has a bolus feature that automatically resumes the continuous infusion rate once that bolus dose has been administered, and if your drug library includes bolus dose range limits. For large volume bolus doses or when several medications are running through the same line, consider dispensing and administering the bolus dose separately.

Communicate how end users should administer bolus doses. On the EHR/MAR. clearly show the route and rate of administration of the bolus, and whether the pharmacy will dispense a separate bolus (or verify a bolus dose from an automated dispensing cabinet [ADC]), or the practitioner should administer the bolus from the continuous infusion via a bolus infusion feature. If the pharmacy dispenses a separate bolus dose (or verifies removal from an ADC), specify on the EHR/MAR whether it will be in a syringe or a bag/bottle, which might require a different infusion pump or channel and a separate administration set. If dispensing a bolus dose in a syringe for pediatric

continued on page 5 - Pump challenges >

> Worth repeating cont'd from page 3 of jagged glass or plastic stuck in the tip of the syringe, which blocked the flow of medication. The organization replicated this issue several times using various lots of Aurobindo naloxone syringes and MicroClave devices. This situation is quite serious since the timely administration of a reversal agent is critical in preventing patient harm or even death.

We previously reported a similar issue with the use of Dr. Reddy's Laboratories prefilled naloxone syringes and Micro-Clave needlefree syringe connectors. Details of the event, including photos, can be found here: www.ismp.org/node/42880. Evidently, the action of inserting the glass syringe tip can cause the pin in the Micro-Clave access system to break off in the syringe tip, preventing delivery of the medication. In some events, a piece of plastic was found lodged inside Dr. Reddy's naloxone syringe tip, also effectively blocking the flow of medication. This could also compromise the MicroClave port and increase the risk of IV line contamination and infection.

We have reached out to the US Food and Drug Administration (FDA) and the manufacturers again. Aurobindo told us that, according to their syringe vendor (BD), the syringe is not compatible with any external devices, and practitioners must use the needle provided with the kit. For now, organizations should refrain from using Aurobindo and Dr. Reddy's prefilled naloxone syringes with a MicroClave connector and consider purchasing naloxone syringes from an alternative manufacturer. If incompatible prefilled glass syringes remain on the market, FDA and device/ drug manufacturers need to clearly communicate this potential problem and perhaps include prominent warnings on the packaging itself.

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October 16-22, 2022

patients, electronically determine the syringe size based on the volume of the dose and the required rate of infusion.

Track all smart pumps. Provide the necessary resources to track all smart infusion pumps, regardless of the location in the organization, to ensure timely software and drug library updates as well as ongoing biomedical inspections and maintenance. Some infusion pump vendors provide a central server to help track infusion pumps by serial number; others use radio frequency identification (RFID) tags on the devices to track the approximate physical location of infusion pumps, both of which can be used to help find missing infusion pumps that need to be inspected or updated.

Update drug libraries. Update drug libraries at least quarterly and establish criteria for off-schedule updates needed to address drug shortages, new drugs added to the formulary, new drug protocols, or concentration changes. Implement a standard process for communicating drug library content changes to end users, including the updated drug library go-live date, the modified information, and directions on how to ensure the infusion pump has the newest library version. Include the organization's name as part of the drug library name, so users can quickly identify whether an infusion pump is from an outside organization. Consider using the current month and year (e.g., September 2022) as a naming convention for library updates to inform the user that they are using the most current drug library. While we recommend the purchase or lease of smart infusion pumps capable of wireless drug library updates, some pumps require a physical connection to a computer to update the library. Whether you have wireless capability or a manual library update process, develop a method to track the update status of each pump and investigate pumps that have not been updated.

Review pump data. Have the smart infusion pump team regularly monitor drug library usage and alerts, including overridden soft alerts, and adjust the dose limits as needed based on current practice and the literature. If a patient's dose falls outside a defined hard limit and the practitioner must administer the medication outside of the DERS, require an independent double check. Consider using a checklist/form to standardize and document the process, ensuring all necessary steps are followed. Use this checklist/form to communicate the outliers to the smart pump programming team and the pharmacy. Also if there are any safety reports related to the use of the smart pump, notify the smart pump team for follow-up. Continuous monitoring and reevaluation of the data is imperative to determine warranted adjustments to the drug library and possibly hospital dosing protocols.

Plan for interoperability. Implement bi-directional (i.e., auto-programming and auto-documentation) smart infusion pump interoperability with the EHR to reduce the risk of infusion pump programming errors. Employ the above recommendations to prepare for a smooth interoperability implementation. To learn more about infusion pump and EHR interoperability, see our **Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps** at: www.ismp.org/node/972.

Work with pump vendors. Collaborate with your smart pump vendor and provide feedback for consideration for future upgrades. For example, share how character limits in the drug library might affect the display of the medication name, potentially increasing the opportunity for error as well as increasing the difficulty in finding a medication in the library. To cite another example, displaying options in a logical order for pediatric patients might require manipulating the weight or adding extra spaces or characters so doses for 1 kg patients appear before doses for 10 to 20 kg patients. Smart pump vendors must consider human factors to enhance the physical design of the pump and drug library, and to improve the programming experience for end users.

2023 Just Culture scholarship recipients

ISMP is pleased to announce the 2023 Judy Smetzer Just Culture Champion **Scholarship** recipients. The three individuals who were selected are the first to be awarded these annual scholarships, which are being offered in cooperation with The Just Culture Company. The recipients will be able to enroll in a live-hosted or online Just Culture Certification Course, after which they will be eligible to sit for the Just Culture Certification Exam. In addition, each recipient will receive a membership in the Just Culture Community of Learners (with live-hosted webinars) and a 2-year software license for the Just Culture Algorithm and supplemental learning materials. The recipients are:

- Nicole Chopski, PharmD, ANP, from the Idaho Division of Occupational and Professional Licenses, located in Boise, ID
- Kristin Neiswender, RN, MSN, CPPS, from the Children's Hospital of Philadelphia, located in PA
- Scott Possley, PA, MPAS, from the Hospital for Special Surgery, located in New York, NY

Please join us in congratulating these emerging safety leaders. To learn more about each recipient, the scholarship benefits, and the application process, please visit: www.ismp.org/node/44043.

To subscribe: www.ismp.org/node/10



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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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☐ Don't Know

☐ Yes **If Yes**, please describe:

ISMP survey on tall man (mixed case) lettering to reduce drug name confusion

In 2008, ISMP compiled a list of look-alike drug name pairs with suggested tall man (mixed case) letters to be used in ambulatory and inpatient healthcare organizations to differentiate these products on pharmacy-generated labels, documents, and computer screens. It has been 6 years since we last updated the list, so we are seeking your input regarding a few more drug name pairs we are considering for addition to the list. Also, we are interested in learning how useful you find tall man (mixed case) letters as an effective differentiating strategy and any other name pairs you believe we should consider for the list. Please submit your survey responses by **December 2, 2022**, online at: www.ismp.org/ext/1014.

KEY DK = Don't Know/Uncertain											
Question and Confused Drug Name Pairs or Groups	Aware of Confusion?		Add to List?			Proposed Tall Man (Mixed Case) Lettering?					Alternate
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Please tell us whether you are aware should be added to our list, and whet You can also provide alternative sugg	ther you a	agree o	r disag	ree wit	h the ta	ıll man (mixe	d case) lette	ers selected	to help differ		
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cyclo PHOS phamide (and cyclo SPORINE and cyclo SERINE , already on list)											
droPERidol and droNABinol											
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Please review the name pairs listed in additional name pairs that you feel sho							www.ismp	.org/node/13	6, and then l	et us know if	there are any
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7 Do you believe tall man (mixed case) le	ettering h	as prev	ented v	you fro	m pres	cribing, trans	cribing, dis	pensing, or a	ıdministering	the wrong r	medication?



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 **25**th **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.



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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