

# Proceedings of a summit on preventing patient harm and death from i.v. medication errors

JULY 14–15, 2008  
ROCKVILLE, MARYLAND

Am J Health-Syst Pharm. 2008; 65:2367-79

**A** summit on preventing patient harm and death from i.v. medication errors was convened on July 14 and 15, 2008, in Rockville, Maryland, by the American Society of Health-System Pharmacists (ASHP), ASHP Research and Education Foundation, Institute for Safe Medication Practices, United States Pharmacopeia (USP), Infusion Nurses Society, Joint Commission, and National Patient Safety Foundation. Participants included an expert panel comprising members of professional (i.e., pharmacy, medicine, and nursing), safety, quality, standards-setting, and accreditation organizations (Appendix A) and work groups consisting of other major stakeholders, including frontline practitioners, representatives of manufacturers of i.v. medications and administration devices, and vendors of automation, machine-readable coding, and information systems and technologies (Appendix B).

The goals of the summit were as follows:

- Achieve consensus on a set of essential safe practices for i.v. medication use that should be universally adopted to prevent patient harm,
- Identify barriers to the implementation of these safe practices and rec-

ommend specific actions to overcome these barriers,

- Prioritize the recommended safe practices into those that should be implemented immediately and other practices that may not be immediately feasible but could be part of a long-term organizational strategic plan, and
- Obtain stakeholder commitments to taking action to improve the safety of i.v. medication use.

## Background

The high potential for patient harm and death from errors involving i.v. medications is widely recognized.<sup>1-3</sup> Errors in the prescribing, storage, preparation, dispensing, administration, and monitoring of i.v. medications can be particularly dangerous because of the immediate onset of systemic effects, low therapeutic index of many i.v. medications, and difficulty reversing pharmacologic effects after i.v. administration.

The literature contains many reports of analyses of the nature and causes of i.v. medication errors.<sup>2,4-6</sup> Many i.v. medications commonly associated with patient harm have been identified and designated high-alert medications to ensure that these

medications are handled with extra caution.<sup>7</sup>

Data regarding parenteral medication errors from USP's Medmarx database were presented at the summit. These data were obtained from more than 1 million error reports from 850 hospitals between 2002 and 2006. Parenteral medication errors were nearly three times as likely to cause harm or death (3.0%) compared with other errors reported to Medmarx (1.2%). The majority (79%) of harmful or fatal parenteral errors involved the i.v. route of administration (other errors involved the subcutaneous, epidural, intravascular, or intrathecal route), and 58% of parenteral errors originated during the administration step of the medication-use process. The therapeutic categories most commonly associated with harmful or fatal parenteral medication errors were insulin, opioid analgesics, and blood coagulation modifiers.

Strategies have been devised to eliminate or minimize i.v. medication errors based on root causes and contributory factors identified from error analyses.<sup>1,8-15</sup> The effectiveness of these error-prevention strategies has been demonstrated, but this knowledge has not resulted in universal adoption by hospitals and

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Supported by grants from Baxter, Hospira, and Cardinal Health.

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DOI 10.2146/ajhp080406

health systems. Serious harm and death from medication errors involving i.v. medications continue to be reported.<sup>16,17</sup>

Three major barriers to safe i.v. medication use were identified by health care practitioners during the development of the summit agenda: (1) lack of standardization of and good process design for i.v. medication use, (2) lack of shared accountability for safety among members of different health care disciplines, and (3) high-volume, high-demand work environments where safety may be sacrificed for other priorities. The summit presented a rare opportunity for front line practitioners, health care thought leaders, and industry representatives to join together, candidly exchange ideas, and collaborate to develop an agenda for change.

### A consensus-building process

A framework of recommended safe i.v. medication practices was developed before the summit by an interdisciplinary focus group with content expertise. These safe practices were categorized by the part of the medication-use process to which they pertained. The focus group also drafted lists of proposed actions for regulatory, accreditation, and standards-setting groups (Appendix C); industry (Appendix D); and quality, safety, and professional organizations (Appendix E). Recommendations for priority safety features of infusion pumps (Appendix F) also were made by the focus group. As no limitations were placed on the focus group discussion, an extensive list of actions and practices was generated.

Comments about the recommendations in the framework were solicited from the ASHP Section of Inpatient Care Practitioners Advisory Group on Medication Safety, and revisions to the recommendations were made accordingly. A survey of summit participants was conducted before the summit to identify the three top-priority safe practices in

each step of the medication-use process and key discussion points.

Members of the expert panel used a consensus-building process during the two-day summit to identify and discuss criteria for selecting priority safe i.v. medication practices. The National Quality Forum criteria for specificity, benefit, evidence of effectiveness, generalizability, and readiness were used to evaluate the proposed practices.<sup>18</sup>

### Consensus on safe practices

Summit participants identified priority safe i.v. medication practices for each step of the medication-use process, critical barriers to these safe practices, and specific actions that could be taken by stakeholders to overcome the barriers (Table 1). Social-marketing concepts were used to select the actions most likely to be effective.<sup>22</sup> This approach focuses first on actions that are easy or inexpensive to implement or that are associated with proven benefits and goals. Summit participants proposed short- and long-term actions needed to implement the priority practices, recommended the major stakeholder groups who should be involved, and assigned an approximate time frame for completion (Tables 2 and 3). Short-term actions were defined as those that could be accomplished within three years.

### Barriers to implementation

Several barriers to the implementation of safe i.v. medication practices were identified in more than one step of the medication-use process. These barriers included cultural issues, a lack of resources (e.g., funds, equipment, staff), inadequate medication-safety education and training, and a lack of universal consensus on safe practices.

### Short-term actions

Summit participants recommended the use of drug information from authoritative sources to establish

national standards for i.v. medication use in hospitals and health systems, regardless of the availability of intelligent infusion devices. At a minimum, the standards would include the (1) drug name, (2) recommended minimum and maximum dosages, (3) upper and lower administration rate limits that may not be overridden (if applicable), and (4) standardized concentrations and dosing units.

The standards should address the needs of special patient populations and clinical conditions, such as neonates and patients with diseases in which fluid restriction is required. The standards should also accommodate a variety of i.v. medication administration techniques, including direct i.v. injection (i.e., i.v. push), intermittent and continuous i.v. infusion, as well as recommended rates of administration and any necessary precautions, such as monitoring requirements. If consensus on the standardized concentrations or other elements cannot be achieved for a particular medication, guidelines or boundaries for use of the medication should be established instead.

Participants recommended that the standards be developed by professional associations representing the health care disciplines and patient-safety organizations. An initial set of standards for at least 10 drugs would be identified, preferably high-alert products already available in ready-to-administer form. The list would then be expanded into a comprehensive reference that should be nationally adopted.

Summit participants called for expedited approval and marketing of new product concentrations of currently approved drugs if included in nationally standardized concentrations. Recommended stakeholders included patient-safety organizations in collaboration with the Food and Drug Administration (FDA) and pharmaceutical industry. Recognizing the effort required to achieve this change, participants recommended

Table 1. Priority I.V. Medication Safety Practices, Barriers to Implementation, and Actions To Overcome Barriers <sup>19-21</sup>			
Step in Medication-Use Process	Priority I.V. Medication Safety Practices	Barriers to Implementation	Recommended Action To Overcome Barriers
Formulary management and medication-use policy	<p>Implement standardized infusion concentrations (dose, rate, units) based on local and national practices that are appropriate for most practice settings and allow exceptions, if needed<sup>a</sup></p> <p>Use commercially available ready-to-administer i.v. medications if available (except parenteral nutrient solutions)</p> <p>Limit available concentrations of parenteral medications on the formulary</p> <p>Implement hospitalwide standardized processes for high-alert medications<sup>a</sup></p> <p>Prohibit use of patients' own parenteral medications or establish strict criteria for exceptions</p> <p>Establish comprehensive i.v. medication administration policies, with standardized administration times, upper and lower dosage limits, and administration rates (especially for i.v. push and adjusted medications); policies for special patient populations; and policies that specify any required monitoring, special equipment, or unique competencies for administration<sup>a</sup></p> <p>Establish communication procedures for product shortages, recalls, and safety advisories, including recommendations for alternative agents</p>	<p>Cultural barriers (e.g., failure of pediatricians to view and treat patients as individuals)</p> <p>Lack of resources (staff, equipment, and funds), limited capacity to accommodate increased workload, and the tradeoffs involved in decisions to assume additional responsibilities that compromise provision of services, especially in small institutions</p> <p>Focus on hospital inpatients with less consideration for patient care provided in other settings</p> <p>Difficulty standardizing concentrations of i.v. medications because of limited product availability from manufacturers and use of noncommercial sources (e.g., pharmacy compounding centers)</p> <p>Supply chain management issues</p> <p>Communication overload</p> <p>Risk of patient harm associated with work flow interruptions</p> <p>Practitioner reluctance to share drug libraries because of liability concerns or proprietary nature of libraries</p>	<p>Address safety culture issues with evidence and encourage health care providers to standardize treatment</p> <p>Prepare a tool kit to facilitate development of consensus on standardized i.v. medication concentrations</p> <p>Develop national drug reference or "library" of i.v. medications</p> <p>Identify best practices for i.v. medication use in a variety of care settings (not limited to the inpatient setting)</p> <p>Apply technology solutions to overcome limitations due to staff shortages and eliminate certain types of human error</p> <p>Prioritize communications and limit unnecessary information</p>
Prescribing and ordering	<p>Use standardized i.v. medication orders (paper or electronic format)<sup>a</sup></p> <p>Prescribe standardized infusion diluents, concentrations, and units (preferably commercially available products)<sup>a</sup></p> <p>Limit use of nonstandardized infusions to clinical indications in which benefits outweigh potential risks</p>	<p>Resistance to change, difficulty breaking established habits</p> <p>Local practices that differ from practices used elsewhere in nation</p> <p>Ordering practices in specialized practice settings where standardized orders are impractical (e.g., emergency situations)</p>	<p>Use CPOE<sup>b</sup> with standardized i.v. medication orders</p> <p>Consider nature and causes of local errors along with national recommendations in developing lists of high-alert drugs; develop standardized orders for most drugs</p> <p>Establish policies and procedures that address exceptions in specialized practice settings where the use of standardized orders may not be appropriate</p>

Table 1 (continued)

Step in Medication-Use Process	Priority I.V. Medication Safety Practices	Barriers To Implementation	Recommended Action To Overcome Barriers
	<p>Use hospitalwide standardized dosing protocols for emergency drugs and high-alert medications (e.g., heparin, insulin)<sup>b</sup></p> <p>Differentiate look-alike medications when ordering</p> <p>Use clinical decision support at the point of care (e.g., drug allergy and drug interaction alerts, dosage calculators).</p>		<p>Incorporate i.v. medication prescribing best practices into professional schools' curricula</p> <p>Provide education and training in health care institutions about proper i.v. medication prescribing practices</p> <p>Develop and provide resources for health care institutions to use in establishing standards for prescribing</p> <p>Establish and monitor measures of adherence to standards of prescribing and make unsafe prescribing actionable</p> <p>Promote collaboration among vendors of IT systems and health care providers to design systems that reinforce best practices for i.v. medication ordering</p>
Storage	<p>Stock commercially available ready-to-administer infusions for emergency use in patient care areas where possible</p> <p><i>Differentiate look-alike medications, including separate storage locations<sup>a</sup></i></p> <p><i>Prohibit or impose tight security precautions on stocking concentrated injectable products and more than one concentration of an i.v. medication on patient care units<sup>a</sup></i></p> <p>Designate storage locations of authorized medications on patient care units (i.e., minimize variability in storage locations)</p> <p><i>Adopt ISMP guidelines on interdisciplinary safe use of ADCs<sup>a</sup></i></p>	<p>Cultural issue and human factors</p> <p>Limited resources, especially funds for investment in costly storage equipment and technologies in small institutions</p> <p>Lack of national consensus on storage practices due to differences in professional regulations among states</p>	<p>Provide interdisciplinary education and training on i.v. medication safety and safe storage practices</p> <p>Develop best practices, tools, checklists, templates, and guidelines for i.v. medication safety</p> <p>Implement nationally standardized guidelines for heparin, insulin, and opioid analgesics and standardized concentrations for i.v. infusions</p> <p>Encourage collaboration with FDA to identify and market standardized concentrations for ready-to-administer i.v. products</p> <p>Collaborate with vendors to increase the affordability and availability of ADCs and other storage equipment and technologies for small institutions</p> <p>Organize consortium of professional, quality, and safety organizations to build a foundation for i.v. medication safety, starting with the development of guidelines, checklists, and data collection methods</p>
Preparation and Dispensing	<p><i>Dispense i.v. medications and admixtures in ready-to-administer form (i.e., a form that requires no manipulation prior to administration)<sup>b</sup></i></p>	<p>Insufficient staff education and training and lack of staff competence in safe i.v. medication preparation and dispensing practices</p>	<p>Promote use of national standardized concentrations that are based on evidence</p> <p>Request standards-setting organizations to establish an expectation for use of these standardized concentrations</p>

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Table 1 (continued)	Step in Medication-Use Process	Priority I.V. Medication Safety Practices	Barriers To Implementation	Recommended Action To Overcome Barriers
		<p>Standardize process for compounding sterile products, with procedures to minimize unnecessary interruptions and distractions, trace and verify the accuracy of compounding, and provide for pharmacist checking of compounding accuracy<sup>d</sup></p> <p>Label i.v. admixtures using standard format with information needed by staff who will administer admixtures prominently displayed</p> <p>Ensure competency of pharmacists and technicians who prepare i.v. medications</p> <p>Use best practices for preparation of i.v. admixtures in addition to practices for assuring stability and sterility in USP chapter 797<sup>a</sup></p> <p>Use machine-readable codes to verify accuracy of medication dispensing and filling of ADCs<sup>e</sup></p>	<p>Failure to appreciate value of and return on investment in safe i.v. medication preparation and dispensing processes</p> <p>Lack of culture of safety and lack of leadership</p> <p>Insufficient human resources</p> <p>Lack of research and evidence to support changes needed to improve safety in i.v. medication preparation and dispensing</p>	<p>Encourage manufacturers of ready-to-administer i.v. infusions and medications to standardize labeling</p> <p>Involve frontline practitioners in making decisions about new or revised processes</p> <p>Educate entry-level and senior practitioners and leaders about i.v. medication safety</p> <p>Encourage vendors of automation, machine-readable coding, and IT to design for interoperability and functionality of marketed products</p> <p>Eliminate archaic forms of expression for i.v. medication dosages and concentrations (e.g., epinephrine 1:1000)</p> <p>Recruit multiple stakeholders to leverage changes to improve i.v. medication safety, reaching consensus on safe practices</p> <p>Proactively consider legislative and regulatory solutions to safety problems</p> <p>Commit to a common goal of improved i.v. medication safety by setting competition aside</p> <p>Encourage collaboration among quality, safety, and professional organizations to fund research on effectiveness of i.v. medication safety practices and system changes</p>
	Administering	<p>Require independent double checks and documentation of administration of selected high-alert medications, including pump settings<sup>f</sup></p> <p>Standardize i.v. medication administration, with provisions to (1) minimize unnecessary interruptions and distractions, (2) focus on 1 patient at a time, (3) refer to an accurate medication administration record at the bedside, (4) engage the patient or parent and family members in medication administration process, (5) use 2 patient identifiers, (6) trace tubings to the body before administering medication into tubing,</p>	<p>Staffing and equipment shortages, large patient volume and workload, low staff:patient ratios</p> <p>Inappropriate use or procedure for double checks because of lack of understanding of the administration process and common causes of error in the process</p> <p>Failure to recognize workarounds as a symptom of poor system design and predictive of a safety problem</p> <p>Lack of understanding of reasons for workarounds</p> <p>Lack of staff skills and competence</p>	<p>Prioritize high-alert i.v. medications and administration scenarios for double checks</p> <p>Develop materials to educate staff about the effectiveness of double checks, other system redundancies, and safety measures for i.v. medication administration safety and the risks associated with workarounds</p> <p>Establish policies for scenarios when departure from standard operating procedure may be appropriate based on an analysis of risks and benefits</p> <p>Establish procedures for reporting workarounds in a nonpunitive climate and monitor and analyze workaround data to identify root causes and rectify poor system design</p>

Table 1 (continued)

Step in Medication-Use Process	Priority I.V. Medication Safety Practices	Barriers To Implementation	Recommended Action To Overcome Barriers
	<p>and (7) label distal and proximal infusion sites when using pumps with multiple channels or multiple pumps (e.g., for epidural medications, enteral nutrition)<sup>b</sup></p> <p>Ensure competency of staff who prepare and administer i.v. medications</p> <p>Involve patients and families in i.v. medication safety and provide written scripts to guide interactions between health care providers and parents</p> <p>Use clinical tools customized for high-risk patient populations (e.g., dose calculators for pediatric patients or patients with renal insufficiency)</p> <p>Limit the preparation of i.v. admixtures by nursing staff to life-threatening emergencies and preparations with limited stability</p> <p>Use intelligent infusion devices with dose-limiting feature enabled<sup>a</sup></p>	<p>Perceived need for speed that precludes following safe practices, especially preparing i.v. admixtures in pharmacy</p> <p>Lack of resources for standardizing i.v. administration practices</p> <p>Reluctance of others to share their policies, or perception that standardized concentrations are unnecessary in absence of intelligent infusion devices and technology</p> <p>Perception that standardization of i.v. medication administration processes is impossible because of the unique needs of the patient population or care setting</p> <p>Modeling of workarounds and other unsafe behaviors in i.v. medication administration for new staff by senior staff, resulting in normalization of deviance from safe practices</p>	<p>Commit to fix poorly designed systems to eliminate workarounds</p> <p>Notify vendors of systems that adversely affect patient safety</p> <p>Use technology (e.g., point-of-care machine-readable coding for medications, intelligent infusion devices) when possible to minimize the need for manual double checks</p> <p>Encourage manufacturers to design i.v. administration devices and information systems and technologies with interfaces to facilitate interoperability</p> <p>Identify best practices for i.v. medication administration and develop training materials to ensure staff competence</p> <p>Educate staff about risks associated with variance from safe practices in administering i.v. medications and train staff in safe practices</p> <p>Identify experienced nurses who follow safe i.v. medication administration practices to serve as mentors for entry-level nursing staff</p> <p>Develop drug administration policies through the formulary process that can be used with or without intelligent infusion devices and technologies, or compile drug policies and share them with others</p> <p>Provide incentives for institutions to adopt the standardized concentrations</p> <p>Collect and analyze medication administration error data and compare with national data to identify opportunities for improvement in safe practices</p> <p>Collect, analyze, and publish i.v. infusion device alert and override data to identify errors and near misses and strategies to eliminate them</p> <p>Use infusion pumps with the features listed in Appendix F</p> <p>Promote use of safe i.v. medication administration practices in all patient care settings</p>

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Table 1 (Continued)	Step in Medication-Use Process	Priority I.V. Medication Safety Practices	Barriers to Implementation	Recommended Action To Overcome Barriers
	Monitoring medication-use and medication-use processes	<p><i>Have antidotes, supportive medications, dosing and administration information, and resuscitation equipment immediately available in patient care areas<sup>a</sup></i></p> <p>Establish baseline and ongoing monitoring procedures for selected parenteral, high-alert medications (e.g., anticoagulants, insulin, vasopressors, oncologic agents) so that medication ordering is linked with appropriate laboratory test results</p> <p><i>Establish standard operating procedures for communication at the time of patient transition from one care setting to another to provide for continuity of care and medication reconciliation<sup>b</sup></i></p> <p>Establish standard operating procedures for communicating about and responding to actual or suspected medication errors</p> <p><i>Use data from intelligent infusion devices and information systems to improve medication-use processes<sup>a</sup></i></p>	<p>Lack of clarity, consensus, and objective monitoring parameters for medications and medication-use processes</p> <p>“Silos” with a lack of understanding, cooperation, collaboration, trust, and shared accountability among members of different health professions or practitioners in different practice settings</p> <p>Time constraints in medical academic institutions that preclude addressing safe practices in monitoring i.v. medication use and medication-use processes as part of the curricula</p> <p>Cultural issues (fear of blame and punishment for reporting errors or raising safety concerns)</p>	<p>Encourage manufacturers of i.v. administration devices to design fail-safe tubing connections to preclude opportunities for misconnections</p> <p>Appoint chief pharmacy officer, chief nursing officer, and chief medical officer to facilitate communication among the disciplines at a high level within the health system about safety concerns in monitoring i.v. medication use and medication-use processes</p> <p>Establish an institutional interdisciplinary medication safety team or committee with representation from medicine, pharmacy, nursing, and other disciplines as appropriate and a member from the board of trustees or directors and hold the team accountable to the board of directors</p> <p>Provide a model, tools, and training for i.v. medication safety team to use in analyzing existing medication-use processes to identify problems, root causes, and potential improvements</p> <p>Develop business case to educate the health system leadership about the benefits of i.v. medication safety measures, system vulnerabilities identified by risk managers, and potential costs of inaction; provide an action plan for key issues, including a call to action</p> <p>Educate senior leaders and middle managers about i.v. medication safety issues they should communicate to the board of trustees or directors</p> <p>Make an organizational commitment to safety</p> <p>Create a culture that empowers frontline health care practitioners to ask questions and raise concerns about i.v. medication safety without fear of retaliation or other repercussions</p> <p>Publish rationale for and role of the medication safety team</p> <p>Establish processes to hire qualified, competent staff and provide training as needed to ensure competency</p>

Table 1 (continued)			
Step in Medication-Use Process	Priority I.V. Medication Safety Practices	Barriers to Implementation	Recommended Action To Overcome Barriers
			Implement well-designed systems that increase understanding among health care practitioners about the importance of interdisciplinary communication; eliminate silos Identify appropriate measures (other than traditional productivity measures), collect data to evaluate the safety of medication-use processes, and provide these data to the medication safety team Educate physicians, pharmacists, and nurses about i.v. medication safety at student level to cultivate a fundamental culture of patient safety among future practitioners

<sup>a</sup>One of three top priority safe practices identified by summit participants prior to the summit (four safe practices were identified in preparation and dispensing because of a tie).

<sup>b</sup>CPOE = computerized prescriber order entry, IT = information technology, ISMP = Institute for Safe Medication Practices, ADC = automated dispensing cabinet, USP = United States Pharmacopeia.

that the collaboration should begin now without awaiting completion of the i.v. medication standards.

Summit participants recommended the development of a consensus statement that supports the preparation of i.v. products by the pharmacy department except for emergency situations when a delay could compromise patient safety. “Preparation of i.v. products” and “emergency” should be defined to facilitate common understanding of the intent of the statement.

Summit participants also encouraged the use of intelligent infusion devices and the development of a process to ensure that the full benefit is obtained from the devices and technology. This process should use tools to assist in selecting, implementing, and evaluating the safe use of pumps, and the development of a tool kit that includes these items was recommended.

The summit participants recommended developing a business case for safety to present to chief executive officers, other health care leaders, and payers about the need for action to improve i.v. medication safety. The business case would include a framework for a model institutional medication-safety committee or team based on best practices.

The establishment of an institutional interdisciplinary medication-safety committee, with administration (i.e., leadership or governance), physician, pharmacist, nurse, patient, and information technology representatives, was recommended by summit participants. Collaboration among members of this committee should increase understanding among disciplines and practice settings and promote shared accountability for safety. Professional organizations that represent hospital or health-system leaders or health care executives should be involved in this effort.

**Long-term actions**

Summit participants recommend-

Table 2.  
Short-Term Actions to Support Safe I.V. Medication Practices

Recommended Action	Proposed Primary Stakeholder Groups	Time Frame
Use drug information from authoritative sources to establish national standards for i.v. drug use, with the drug name, recommended minimum and maximum dosages, upper and lower administration rate limits that may not be overridden, standardized concentrations and dosing units, and commercially available strengths and concentrations, taking into consideration special patient populations and clinical conditions	Professional associations representing pharmacists and nurses, standards-setting organizations, patient safety organizations	12–24 mo
Request expedited process for approving and marketing new concentrations of existing products	Food and Drug Administration, patient safety organizations, pharmaceutical industry	12–36 mo
Develop a consensus statement that recommends preparation of i.v. products by the pharmacy department and allows appropriate exceptions (e.g., emergency situations when a delay could compromise patient safety)	Patient safety organizations and professional associations representing pharmacy, nursing, medicine, and others as appropriate	2–3 yr
Encourage use of intelligent infusion devices and create a mechanism to ensure that their full benefit is obtained; develop assessment tool kit and algorithm for use by the quality or safety committee in evaluating intelligent infusion device selection and use	Professional organizations representing pharmacists and nurses, patient safety organizations, intelligent infusion device manufacturers, organizations that evaluate such devices	12 mo
Evaluate intelligent infusion device use, use of national standards for i.v. medication use, use of commercially available ready-to-administer i.v. medications if available, and the practice of preparing i.v. admixtures in the pharmacy as part of quality-improvement activities	Hospital or health-system leaders	12 mo
Create business case for chief executive officer, health care leadership, and payers about the need to improve i.v. medication safety by providing a framework for a medication safety committee based on best practices	Professional organizations, health care executives, or hospital boards and trustees	12 mo
Establish institutional interdisciplinary medication safety committee, with administration and leadership, physician, pharmacist, nurse, patient, and information technology representatives, to increase understanding among and eliminate barriers between disciplines and practice settings	Professional organizations that represent hospital or health-system leaders or health-care executives	12 mo

ed requesting FDA to further require all drug labels to bear a single-format, machine-readable bar code that is easily integrated into patient care processes. The American National Standards Institute recently approved health industry bar-code standards, which should help to facilitate this action.<sup>23</sup> Recommended stakeholders in this process include FDA, pharmacy organizations, manufacturers of

pharmaceuticals and i.v. administration devices, and vendors of automation, machine-readable coding, and information systems and technologies. Frontline practitioners should be involved in the implementation of this recommendation because of the need to integrate the technology into patient care processes.

Education and training on medication safety issues and practices for

physicians, pharmacists, and nurses was recommended. Such education and training should be provided in both professional schools and postgraduate programs. A standardized curriculum addressing general medication safety issues that affect all three professions should be tested in a short-term pilot program. Academic organizations for these professions will be the key stakeholders in

Table 3.  
**Long-Term Actions to Support Safe I.V. Medication Practices**

Action	Proposed Primary Stakeholder Groups	Time Frame
Ask Food and Drug Administration to further require all drug labels to bear a single-format, machine-readable code that facilitates integration into patient care processes	Food and Drug Administration, manufacturers, and associations representing frontline practitioners	3 yr
Provide education and training on medication safety issues and practices for physicians, pharmacists, and nurses in professional schools and postgraduate programs	Pharmacy, nursing, and medicine academic organizations and professional associations	3–5 yr
Develop a resource kit for i.v. medication safety to facilitate implementation of national standard concentrations for selected drugs, standards for medication administration practices, standards for root cause analysis, and performance-improvement monitoring, with the consistent submission of i.v. medication variance data to a national database	Patient safety and quality organizations and pharmacy associations	3 yr and 1 day
Establish research agenda to answer questions about and develop best practices for i.v. medication safety	Organizations that conduct or fund research	3–5 yr
Compile a catalog or inventory of established practices for i.v. medication safety that are effective, identify the best practices, and develop mentoring or coaching programs for implementation of the best practices	Professional safety, quality, standards-setting, and accreditation organizations	1–3 yr

making curriculum changes. Professional associations will be involved in postgraduate educational programs.

The Institute for Healthcare Improvement (IHI) defines a bundle as a group of practices that, when performed collectively and reliably, have been shown to improve patient outcomes.<sup>24</sup> Summit participants recommended the development of a resource kit, similar to the IHI “bundle” of practices concept. This tool kit would include use of national, standardized concentrations, standards for medication administration practices, root-cause analysis and performance-monitoring recommendations. Participants recommended reporting i.v. medication variance data to a national database or program and sharing “lessons learned.” Patient safety and quality organizations and pharmacy associations would be key stakeholders in this effort.

Another long-term action recommended by summit participants is to establish a research agenda to answer

questions about and develop best practices for i.v. medication safety. The research agenda could be spearheaded by organizations that conduct or fund research. Obtaining funding and establishing a timeline for the research remain to be addressed.

Compiling a catalog or inventory of established and effective practices for i.v. medication safety, identifying best practices, and developing programs to mentor or coach practitioners in the implementation of these best practices also were recommended.

**Proposed follow-up action**

At the conclusion of the summit, 49 summit participants committed to specific actions they would be willing to take to improve i.v. medication safety. Summit organizers and participants recognized that, although considerable enthusiasm and momentum were generated and that some progress was made in achieving the goals of the two-day summit, much additional work is needed to

accomplish the ultimate goal of preventing death and harm from i.v. medication errors. Convening a follow-up meeting of the group to build on accomplishments of the summit was proposed. In the meantime, a Web page planned by ASHP to facilitate communication among summit participants and organizers about the actions to improve i.v. medication safety was suggested. This forum should help ensure that the enthusiasm and momentum generated during the summit do not wane and that action is taken. The ASHP Web page also will inform ASHP members and other interested persons about the goals and outcomes of the summit.

**Conclusion**

The interdisciplinary group of health care practitioners, medication safety experts, thought leaders, and industry representatives convened at the summit took preliminary steps to improve i.v. medication safety by prioritizing safe practices identified by content experts and identifying

actions that are feasible in the short- and long-terms. The work accomplished by the summit participants is only a beginning to what will be a lengthy process that requires follow-up to ensure that improvement in i.v. medication safety is achieved.

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## Appendix A—Expert panel participants in summit on preventing patient harm and death from i.v. medication errors

**Peter B. Angood, M.D.**, Vice President and Chief Patient Safety Officer  
Joint Commission

**Frederick Blum, M.D., FACEP**, Past President  
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**Carolyn M. Clancy, M.D.**, Director  
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**Diane D. Cousins, B.S.Pharm.**, Vice President,  
Center for Advancement of Patient Safety  
United States Pharmacopeia

**Gerald J. Dal Pan, M.D., M.H.S.**, Director,  
Office of Surveillance and Epidemiology  
Food and Drug Administration

**Cindy Dusik, Pharm.D.**, 2008 Chair  
Pediatric Pharmacy Advocacy Group

**Frank Federico, B.S.Pharm.**, Content Director  
Institute for Healthcare Improvement

**Mary Ann Gibbons, B.S.N., RN**, Member  
National Association of Neonatal Nurses

**Paul A. Gluck, M.D.**, Chair  
National Patient Safety Foundation

**Karl F. Gumpfer, B.S.Pharm., BCNSP, BCPS, FASHP**, Director, Section of Pharmacy Informatics and Technology  
American Society of Health-System Pharmacists

**Lisa Hines, B.S.N., M.S.**, Senior Project Director  
National Quality Forum

**Patricia L. Holbrook, B.S.Pharm.**, Inpatient Pharmacy Supervisor  
Veterans Healthcare System

**Beverly J. Holcombe, Pharm.D., BCNSP, FASHP**, Chair, Clinical Practice Committee  
American Society for Parenteral and Enteral Nutrition

**Henri R. Manasse, Jr., Ph.D., Sc.D.**, Executive Vice President and Chief Executive Officer  
American Society of Health-System Pharmacists

**Donald E. Martin, M.D.**, District Director  
American Society of Anesthesiologists

**Denise Maxwell-Downing, B.S.N., M.S., RN, CNOR**, Perioperative Nursing Specialist  
Association of Operating Room Nurses

**Virginia R. McCann, M.S., M.A., RNC**, Member  
Academy of Neonatal Nurses

**Kathleen M. McCauley, Ph.D., RN-BC, FAAN, FAHA**, Past President  
American Association of Critical Care Nurses

**Janet M. Nagamine, M.D.**, Chairperson, Quality and Patient Safety Committee  
Society of Hospital Medicine

**Richard B. Osteen, D.Ph.**, Sterile Products Manager  
Vanderbilt University Medical Center

**Jack M. Percelay, M.D., M.P.H., FAAP**, Immediate Past Chairperson, Section on Hospital Medicine  
American Academy of Pediatrics

**Jeffrey M. Rothschild, M.D., M.P.H.**, Assistant Professor of Medicine  
Brigham & Women's Hospital

**Matt Scanlon, M.D.**, Associate Professor of Pediatrics—Critical Care  
Medical College of Wisconsin

**Lisa Schulmeister, M.N., RN, APRN-BC, OCN, FAAN**, Director-at-Large  
Oncology Nurses Society

**Rowena N. Schwartz, Pharm.D., BCOP**, Director

Oncology and Weinberg Pharmacy  
The Johns Hopkins Hospital

**Scott R. Smith, B.S.Pharm., Ph.D.**, Director,  
Pharmaceuticals Outcomes Research  
Agency for Healthcare Research and Quality

**Erin Sparnon, B.S.E.**, Senior Project Engineer  
ECRI Institute

**Allen J. Vaida, Pharm.D., FASHP**, Executive Vice  
President  
Institute for Safe Medication Practices

**Cora Vizcarra, M.B.A., RN, CRNI**, President-  
Elect  
Infusion Nurses Society

**Appendix B—Work group participants  
in summit on preventing patient harm  
and death from i.v. medication errors**

**Mary Alexander, M.A., RN, CRNI, CAE**, Chief  
Executive Officer  
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**Mary Baker, Pharm.D., M.B.A.**, Medical  
Manager and Clinical Fellow  
Hospira Worldwide, Inc.

**Magda Barini-García, M.D., M.P.H.**, Senior  
Medical Advisor  
Health Resources and Services Administration  
Center for Quality

**Debra K. Bello, Ph.D., RN**, Senior Director,  
Global Medical Affairs  
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**Ginny Blocki**, Global Director Marketing  
Baxter Healthcare Corporation

**Jeffrey Carlisle, Sc.B.**, Chief Executive Officer  
Fluidnet Corporation

**Kevin J. Colgan, B.S.Pharm., M.A., FASHP**,  
Senior Vice President  
EPI-Q, Inc.

**Jeffrey B. Cooper, Ph.D.**, Executive Vice  
President  
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**Charles E. Daniels, B.S.Pharm., Ph.D.**,  
Pharmacist-In-Chief  
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**Cheryl Graziano, M.S.N., RN**, Vice President,  
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**Peggi Guenter, Ph.D., RN, CNSN**, Director for  
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Nutrition

**Nancy Hedlund, B.S.Pharm., M.B.A.**, Director,  
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**Harry Jablonski, Pharm.D.**, Senior Manager,  
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**Nancy J. Kramer, B.S.N., RN, CRNI**, Interim  
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**Ronda K. Lehman, Pharm.D., M.B.A.**,  
Administrative Director of Pharmacy and  
Disease Management  
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**Stephen R. Lewis, M.D.**, Chief Medical Officer  
Cardinal Health, Inc.

**Michelle M. Mandrack, B.S.N.**, Director of  
Consulting Services  
Institute for Safe Medication Practices

**James C. McAllister III, B.S., M.S.**, President  
CardeaRX

**Robert B. Meek, Jr.**, Director, Advanced  
Automation Solutions  
McKesson Automation

**William F. Minogue, M.D., FACP**, Executive  
Director and President  
Maryland Patient Safety Center, Inc.

**Brent Nibarger, B.S.**, President  
Fluidnet Corporation

**Jeffrey S. Nordquist, M.S., M.B.A.**, Vice-  
President, Marketing  
Baxter Healthcare Corporation

**Shawn O'Connell, M.S., RN**, Director, Clinical  
Value Marketing  
B. Braun Medical, Inc.

**Nelson R. Patterson, B.S., M.B.A.**, Senior  
Director, Global Infusion Systems  
Baxter Healthcare Corporation

**Kelly L. Podgorny, B.S., M.S., RN, CPHQ**,  
Project Director  
Joint Commission

**Deb R. Saine, B.S.Pharm., M.S.**, Medication  
Safety Manager  
Winchester Medical Center

**Kevin A. Scheckelhoff, B.S.Pharm., M.B.A.**,  
Vice President, Medication Safety Solutions  
McKesson Corporation

**Janet A. Silvester, B.S.Pharm., M.B.A., FASHP**,  
Director of Pharmacy Services  
Martha Jefferson Hospital

**Nathaniel M. Sims, M.D.**, Physician Advisor,  
Biomedical Engineering, Partners  
Healthcare  
Massachusetts General Hospital

**Christine Snyder, B.S., M.B.A.**, Director,  
Pharmaceutical Franchise Marketing  
Baxter Healthcare Corporation

**May-Britt Sten, M.S.N., RN-BC**, Manager,  
Process Improvement  
Children's National Medical Center

**Marc Stranz, B.S., Pharm.D.**, Vice President,  
Operations  
Critical Homecare Solutions

**John P. Straumanis, M.D.**, Medical Director,  
Pediatric Intensive Care Unit  
University of Maryland School of Medicine

**Dennis K. Tribble, Pharm. D.**, Chief  
Technology Officer  
ForHealth Technologies, Inc.

**Tim Vanderveen, Pharm.D., M.S.**, Vice-  
President, Center for Safety and Clinical  
Excellence  
Cardinal Health, Inc.

**John VanEeckhout, Pharm.D.**, Vice President,  
Clinical Services  
Child Health Corporation of America

**Billie Whitehurst, M.S., RN-BC**, Vice President  
and Chief Nursing Officer  
McKesson Corporation

**Appendix C—Proposed actions for  
regulatory and statutory groups<sup>a</sup>**

1. Require nationally standardized infusion concentrations for medications most frequently associated with harm or death
2. Require labeling that clearly and prominently communicates essential information for administration
3. Prohibit concentration expressions associated with harm (e.g., epinephrine 1:1000)
4. Require standardized readable bar codes that include the lot number and expiration date on all unit doses<sup>b</sup>
5. Require total content and volume on all immediate containers of i.v. medications
6. Standardize location of information on labels of immediate containers
7. Clearly and prominently distinguish concentrated injections from those in diluted (ready-to-administer) form
8. Establish minimum standards for technology systems such as electronic medication administration records for i.v. infusions
9. Achieve national consensus on clinical decision support<sup>b</sup>
10. Change the name of hydromorphone
11. Require standardized and distinct connections for enteral, i.v., epidural, and intrathecal administration devices
12. Request expedited process for Food and Drug Administration approval of additional infusion concentrations for currently approved drugs
13. Implement nationally standardized guidelines for
  - a. Anticoagulation with i.v. heparin
  - b. Tight glycemic control with i.v. insulin
  - c. Dosing and dose expressions for advanced life-support and pediatric advanced life-support drugs
14. Require bar-code verification of medication administration at the point of care<sup>b</sup>
15. Require cross-disciplinary education in medication safety in professional school curricula (medical, nursing, pharmacy) as well as residency and other postgraduate training (Accreditation Council for Pharmacy Education, Accreditation Council for Graduate Medical Education)<sup>b</sup>
16. Require continuous multidisciplinary, interactive, professional development in pa-

tient safety (professional associations, state boards)

<sup>a</sup>Includes the Joint Commission, standards-setting organizations, state regulatory organizations, national and federal government agencies, Centers for Medicare and Medicaid Services, Food and Drug Administration, and Agency for Healthcare Research and Quality.

<sup>b</sup>Denotes priority recommendations.

**Appendix D—Proposed actions for industry<sup>a</sup>**

1. Standardize machine-readable codes on unit doses that include the lot number and expiration date and a standardized location for the code
2. Redesign intelligent pumps with user-defined, rather than vendor-defined, features (see Appendix F)
3. Design automated dispensing cabinets for large-volume parenteral products with single-dose dispensing functionality
4. Test and release only fully functional pro-

grams (such as electronic medication administration records for i.v. fluids) or designate them alpha or beta products for testing

5. Include pharmacists on technology and automation development and implementation teams
6. Manufacture infusions of commonly used medications in a range of standardized concentrations appropriate to selected populations
7. Design labels for immediate containers that make the identity of the medication and content of the container obvious at a glance
8. Standardize label format and placement of information, including placement of machine-readable codes
9. Standardize information systems to be interoperable with pumps, machine-readable coding systems, automated dispensing cabinets, robots, and other technology

<sup>a</sup>Includes manufacturers of pharmaceuticals, parenteral products, i.v. administration devices, and automation, machine-readable coding, and information systems.

**Appendix E—Proposed actions for quality, safety, and professional organizations**

1. Develop best practices, tools, templates, checklists, and guidelines where required
2. Support or conduct research on the incidence, nature, and causes of i.v. errors and effectiveness of error prevention strategies and best practices
3. Facilitate change by assisting stakeholder groups in future meetings (e.g., future summits, task forces, expert panels)
4. Promote individual practitioner and interdisciplinary team medication safety training
5. When a patient dies from an i.v. drug error, initiate a process for a national call to action with lessons learned
6. Develop measures of success for adoption of summit recommendations; monitor and act on results

**Appendix F—Recommended priority safety features for infusion pumps**

<u>Feature</u>	<u>Impact</u>
Wireless technology	Integration between communication systems, real-time (automatic) updates; automatic programming based on computerized physician order entry with verification; ordering systems that have been tested and verified; ensures consistent medication rate menu information on pumps
Bar-code medication verification	Automatically matches the drug and pump settings, reducing human errors and number of steps in the medication administration process
Hard stops	Reduces catastrophic overdoses
Programming and documentation of independent verification (e.g., biometrics); integration with medication administration record	Forced function (e.g., prompt)
No rollover (up/down arrows stop at high or low setting)	Avoids programming errors
Mandatory programmed medication rate menus (e.g., default setting) that must be actively overridden; controlled access to selected libraries; reason required for override	All safety features are active; recommendations for “hard stops” with error data to support
Increased library capacity	Library can contain more specific medications for the patient population; eliminates need to select
Ability to bolus medications using the pump’s upper and lower dose/rate-monitoring software; limits in the medication rate menus around the bolus and maintenance dose	Safer medication administration; more rapid administration of the medication; potential decreased risk of nosocomial infection
Standardized, useful, and easily retrievable reports of data for quality improvement	Drives continuous improvement
Other recommendations	Better usability testing by vendors (including programming for special populations and worst-case scenarios); allows user to build and update medication administration rate menu; effective education and competency assessment on technology for providers; teaching features embedded in the pump; all settings are zeroed out at the end of an infusion; demonstrated return on investment in pumps; independent check; design forcing function (e.g., two nurses must completely program the pump correctly for infusion to initiate); uses biometric identification