Standardizing i.v. infusion concentrations: The time has come

Errors involving i.v. medications long have been known to carry high risks of patient harm and death.[1-8] Several factors contribute to the danger of i.v. medication errors, including the rapid onset of effects and narrow therapeutic indexes of infused drugs.[1] In addition, several characteristics of i.v. dosing and administration, such as variability in available concentrations for the same drug during transitions within the same institution and among facilities and settings, can increase the likelihood of errors. The need to perform calculations to guide extemporaneous preparation or to calculate administration rates also creates opportunities for errors.[1]

In this issue of *AJHP*, Walroth et al.[2] report on a consensus-driven process undertaken by the Indiana Hospital Association, using an initial framework developed by the Indiana Coalition for Patient Safety medication safety work group, to standardize drug concentrations for infusions in adults. This is just one of several initiatives that have addressed this problem over the past 2 decades.[1]

In 2006, local hospitals throughout San Diego County, the San Diego Patient Safety Consortium, and the Cardinal Health Center for Safety and Clinical Excellence announced the formation of a first-of-its-kind regional task force to improve patient safety by eliminating variation in i.v. medication practices among county hospitals.[3] The resultant San Diego Patient Safety Council IV Safety Task Force identified an important opportunity to reduce morbidity and mortality attributed to preventable, high-risk i.v. drug–related adverse events, issuing a tool kit to assist other acute care organizations in implementing a standardized approach. The principal goal was to standardize high-risk i.v. drug concentrations and dosages within and across hospitals areawide as a strategy for reducing the risk of adverse events.

These San Diego–area initiatives[4-6] set the groundwork for infusion standardization initiatives, including that described in this issue of *AJHP*.[2] In June 2008, the American Society of Health-System Pharmacists (ASHP) House of Delegates approved a policy statement supporting establishment of "nationally standardized drug concentrations and dosing units for commonly used high-risk drugs that are given via continuous infusions."[7] As a result, in July 2008 ASHP and the ASHP Research and Education Foundation along with the Institute for Safe Medication Practices (ISMP), United States Pharmacopeial Convention (USP), Infusion Nurses Society, Joint Commission, and National Patient Safety Foundation conducted a landmark national summit (the IV Safety Summit) aimed at preventing patient harm and death from i.v. medication errors.[1] One of the goals of the summit was to achieve broad-based consensus on a set of essential safe practices for i.v. medication use that should be universally adopted to prevent patient harm.[1] A proposed effort for establishing national standards for i.v. medication use in support of this goal was to initiate a process for standardizing i.v. concentrations and dosing units.[1]

After the IV Safety Summit, the USP Safe Medication Use Expert Committee established as a priority advocacy efforts to promote increased use of standardized i.v. concentrations, particularly for pediatric patients.[6] A basic tenet of the USP panel's approach was recognition that standardization and simplification are often-overlooked methods for risk reduction associated with several key activities within the medication-use cycle and that an important medication safety strategy to achieve such reductions was use of standardized i.v. concentrations.

Another recent regional effort to promote the use of standardized concentrations for i.v. infusions was launched in Indiana and focused on adult patients.[2] A final list of 28 concentrations for a total of 26 medications was culled from lists drawn principally from regional patient safety coalitions, published literature, and publicly available lists. The final list was developed through a consensus-based process by a statewide interprofessional group of representatives of safety coalitions and 9 health systems (representing 81 hospitals); a checklist of considerations for implementation was also developed. This work serves as an important model for other regional i.v. standardization efforts and contributes yet another standardized i.v. concentration list as part of a broader national standardization effort.

Despite these initiatives over the years, the needle still has moved little in terms of establishing national standards for i.v. medication safety, including those for drug concentrations. Most standardization efforts to date have focused principally on local and regional initiatives rather than national ones.[2,3,9] But things are about to change. The Food and Drug Administration's (FDA) Safe Use Initiative recently awarded ASHP a 3-year contract, one component of which will support development and implementation of nationally standardized i.v. drug concentrations.[10] The ASHP-directed Standardize 4 Safety initiative is the first national interprofessional effort to standardize i.v. medication concentrations as a strategy for reducing medications errors and improving transitions of care.[10] ASHP has partnered with national patient safety organizations, including the Pediatric Pharmacy Association, ISMP, the Association for the Advancement of Medical Instrumentation, and re-

gional and local healthcare organizations to further this work.[10] Working with partner organizations, hospitals, and pharmacist, nurse, and physician experts from across the care continuum, participants in the Standardize 4 Safety initiative are creating, testing, publicizing, and supporting nationwide adoption of standardized medication concentrations.

Standardize 4 Safety is a dual-arm project, with each arm having 3 phases. One arm is focused on development of standardized concentrations and dosing units for i.v. continuous infusions for adult patients (i.e., those weighing at least 50 kg) and pediatric patients (i.e., those weighing less than 50 kg) in addition to standardized concentrations of i.v. intermittent medications, agents used in patient-controlled analgesia, and epidural infusions. The other arm of the project focuses on oral liquids; its 3 phases will entail development of standard concentrations of compounded oral liquid medications, standard doses of all oral liquids (commercial and compounded), and standard doses of oral chemotherapy solid dosage forms. Similar methods will be used in both arms of the project.

Standardization of i.v. concentrations is just one component, albeit a critical component, of an i.v. infusion medication safety strategy. IV Safety Summit participants recommended that, at a minimum, national i.v. medication safety standards be developed for drug-naming practices and to delineate recommended minimum and maximum dosages, upper and lower administration rate limits that may not be overridden, and standardized concentrations and dosing.[1] The encouraging development is that local initiatives like those by the Indiana Hospital Association reported in this issue of *AJHP* (i.e., development of "the Indiana List")[2] continue to promote a concerted effort to develop national standards, which, because of FDA's Safe Use Initiative support and under ASHP's direction,[10] is poised to take an initial giant leap forward on a national level, affirming that the time has, indeed, finally come.

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