



## **Webinar: Background and Purpose of the Standardize 4 Safety Initiative: Let's Go Back in Time (#1 in series)**

Thursday, July 14, 2022 from 12:30-1:00pm Eastern

### **Answered Questions**

#### ***1. What has been the feedback from hospitals in standardizing their IV infusions?***

In general standardizing concentrations has received positive feedback from hospitals. With the use of smart pumps, and the need to create infusion libraries, standardization is a goal for most organizations. Most feedback that we receive at ASHP are questions regarding how certain concentrations were chosen, adding or considering a different concentration, or adding a medication to the standards. There have been only a handful of such requests. These will be considered moving forward.

The ultimate goal moving forward will be to use ASHP survey data and data from the Bainbridge Health Infusion pump network to create a reliable feedback loop from hospitals back to these standards.

#### ***2. How are you addressing the high volume of drug shortages? Use of standardized concentrations is great until the product is unavailable.***

Drug shortages were one of the elements the expert panels used in their deliberations. Because shortages are so variable over time, deliberations from several years ago may not reflect current issues. With the start of the Standardize 4 Safety Advisory panels, whose role is to maintain and update the standards, the opportunity exists to address in a timelier manner drug shortages that may affect the standard concentrations.

#### ***3. How often is the S4S list updated to reflect market changes?***

To date the S4S lists have been updated only when an error has been noted or brought to our attention. Updating the list was not a part of the original grant. ASHP however is committed to updating and maintaining the standard lists. Plans began last year to appoint multidisciplinary Advisory Panels to, on a quarterly basis, review and maintain the lists, address recommendations and comments. The first meetings of the panels will be later this summer.

#### ***4. What has been the role of the USP?***

USP has had no role in development of the standards.

#### ***5. Will the diluent for drug be a focus? Meaning 0.9% NaCl vs D5W?***

Providing recommended diluents was not within the scope of this project as that information is available in many drug information sources.

**6. What data will be required to be shared? Pump library/data sets? Or data use data? Is this for concentrations only, or alerts also? Thanks! (I had previously been in communication with the REMEDI folks).**

Bainbridge Health will provide summary data on all concentrations used across the infusion pump network to the S4S advisory panel. Organizations who are currently in the network and those that wish to join and submit data will have access to additional data including pump library elements and details on alerting patterns.

ASHP on the Standardize 4 Safety Website has provided a [checklist](#) for organizations to compare their practices and their alignment with Standardize 4 Safety concentrations. No identifying data is collected. That data will help guide the advisory panels, help give us insight as to which concentrations are being or not being adopted. This data right now will be disseminated via educational S4S offerings.

**7. Do we know how the groups defined pediatric vs adult?**

Pediatrics standards are intended for children less than 50Kg. Adults are 50 kg and higher. This information is included under [Considerations in Using the Pediatric Standards](#) (front material to the tables).

**8. Is there any reliable data on the percentage of facilities across the US that have adopted S4S to this point?**

The data we are collecting from the [Checklist](#), and the collaboration between ASHP and Bainbridge Health, is to evaluate gathered smart pump data that will help us determine a reasonably good approximation of adoption. The checklist is voluntary and the smart pump data are from those hospitals that use Bainbridge Health services. We believe the data to be reliable, but it will not provide an exact number across the US.

**9. Pharmacy practice has resisted FDA oversight of practice in favor of regulation through state Boards of Pharmacy and has used validation by JCAHO or other groups for demonstration of quality. Is there danger in collaborating with the FDA? Is this work a first step toward FDA impingement on practice and limitations on manufacturers?**

My apologies if the relationship with FDA was not clear on the presentation. FDA did not participate in any of the work or decisions made on the standards. FDA provided an opportunity to submit for grant money and chose this project as meeting the intentions of the grant. In this capacity their involvement was only as a grant funder. They requested accounting of the monies spent for the grant and requested regular updates on progress. A criterion for the grant was that this information be fully available to the public. There was no influence on decisions.

**10. One of the limitations of widespread adoption was HPLC based chemical stability. Previously the USP was willing to perform HPLC tests if we had prioritized specific concentrations to be tested. Is that door still open?**

We could not agree with you more on this comment. There are gaps in what may be considered a gold standard for stability data for many of these concentrations. You will note that for a number of concentrations “bracketing” was used when concentrations had stability data for lower and higher concentrations than the recommended standard. The assumption is that in-between concentrations should be equally stable. Where this was used is included in the front material for the standards. We are hoping by identifying these gaps this can lead to colleges of pharmacy and others to perform the needed research.

**11. Are minimum deliverable volumes (pump limitations) considered when selecting these standards?**

Yes the minimum deliverable concentration was routinely a part of the deliberations in choosing the standard concentrations. However, experience of the expert panel with certain pumps was primarily the source of these deliberations. There may be less widely used pumps that have different minimum concentrations which may not have been noted.

**12. What are the next steps with the ASHP and Bainbridge partnership?**

The collaboration between Bainbridge and ASHP will continue to evolve. Presently we are working on the following:

1. Education webinars to enhance adoption of the standards including a session at the upcoming ASHP midyear.
2. Sharing of data to inform standard concentrations for the standards that are being worked on currently (intermittent infusions) and for the ongoing evaluation of the advisory panels.
3. Sean O’Neill, Bainbridge Health’s Chief Clinical Officer, will serve in an ex-officio capacity on the advisory panels.
4. ASHP and Bainbridge Health are collaborating together to invite more hospitals into the network to increase the size and the validity of the dataset used to drive these standards.

**13. Where can we find the list of standard concentrations so we can compare with ours?**

You may find the standards on the Standardize 4 Safety web page: [www.ashp.org/standardize4safety](http://www.ashp.org/standardize4safety)

**14. During our conversion of the pumps, we were mandated to enter most of these standardized data into our own library, including ceiling doses. Are you looking into starting these changes with the pump manufactures?**

Yes we are interested in adoption of these concentrations by all stakeholders to reduce any change of errors that spurred the creation of the standards. That would include pump manufacturers.