Standardize 4 Safety and Its Importance for Your State's Practitioners

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Presenter

My educational background includes B.S.Pharm, Pharm.D., MHA, and a 2 year research fellowship. I have been a pharmacist since 1996. I am currently the Director of Medication Safety and Quality at ASHP. My current professional interests are IV and oral liquid standardization, naloxone usage and safety, Enfit connector and syringe design, opioid use/abuse, and antimicrobial resistance.

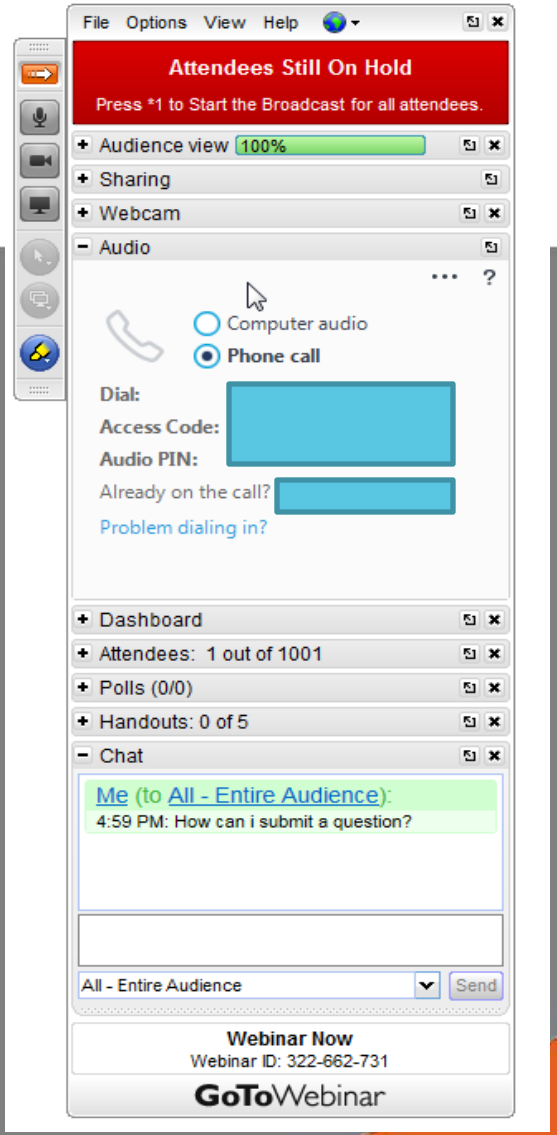
My expertise includes being a PICU pharmacy specialist, pharmacy clinical coordinator, medication safety chair/leader, and senior project manager overseeing large clinical, operational, and technology initiatives. I am LEAN certified and act as a LEAN coach at ASHP and previously at the University of Michigan.

Deborah Pasko

Expand or Collapse

To Ask a Question and Collapse Control Panel

Type your question here



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Conflict of Interest

- Funding for Standardize 4 Safety is a three year contract with the FDA under the Safe Use Initiatives Section 8.5
- The PI has no other conflicts of interest

Objectives

- Describe how standardization can be used as an error prevention tool
- State the importance of the Standardize 4 Safety project
- Present the most current versions of the standard concentrations for IV adult continuous, pediatric continuous, and oral compounded liquids
- State how to support the project and start implementation of the standard concentrations
- Describe the potential role of vendors and pharmaceutical companies in the project

Partners

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Back to the beginning

- **Henry Ford first developed standard work for car production lines in the early 1900s**
  - First time standardization used to ensure quality of work
- **LEAN concepts carried into the 1950s with the Toyota way**
- **LEAN enters healthcare in the late 1990s**
- **Smart infusion devices enter the marketplace in the late 1990s, but robust adoption started in 2000. Some hospitals still do not use this technology**
- **High reliability**

IV Summit 2008

- **The effort to standardize IV concentrations started in 2008, when a multi-stakeholder IV summit was held in Maryland to address preventing patient harm and death from IV medication errors. Three main barriers were identified at the summit:**
  1. Lack of standardization and good process design for IV medications
  2. Lack of shared accountability for safety among members of different healthcare disciplines
  3. High-volume, high-demand environments in which safety may be sacrificed for other priorities

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

Statement of the problem

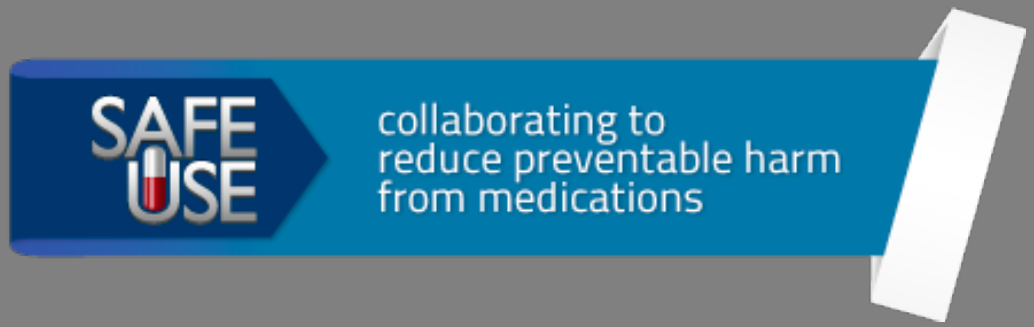
- **Currently, no national consensus for standard concentrations of IV medications (continuous, intermittent, etc.)**
- **Patients are transferred between patient care areas**
  - Within each hospital
  - Within same city
  - Within same state
  - Out of state
- **Each time a patient needs an IV medication, there is potential for error if a concentration different from that in the previous patient care area is used**
- **Often vulnerable patient populations involved**
  - Critically Ill
  - Pediatric, neonate
  - Geriatric

Standardize 4 Safety

https://www.ashp.org/Pharmacy-Practice/Standardize-4-Safety-Initiative

Standardize 4 Safety

- **Standardize 4 Safety is the first national, interprofessional effort to standardize medication concentrations in order to reduce errors and improve transitions of care**
- **Standardize 4 Safety is creating, testing, publicizing, and supporting the adoption of these national standardized medication concentrations**
- **Key partners include AAMI, PPAG, and ISMP**



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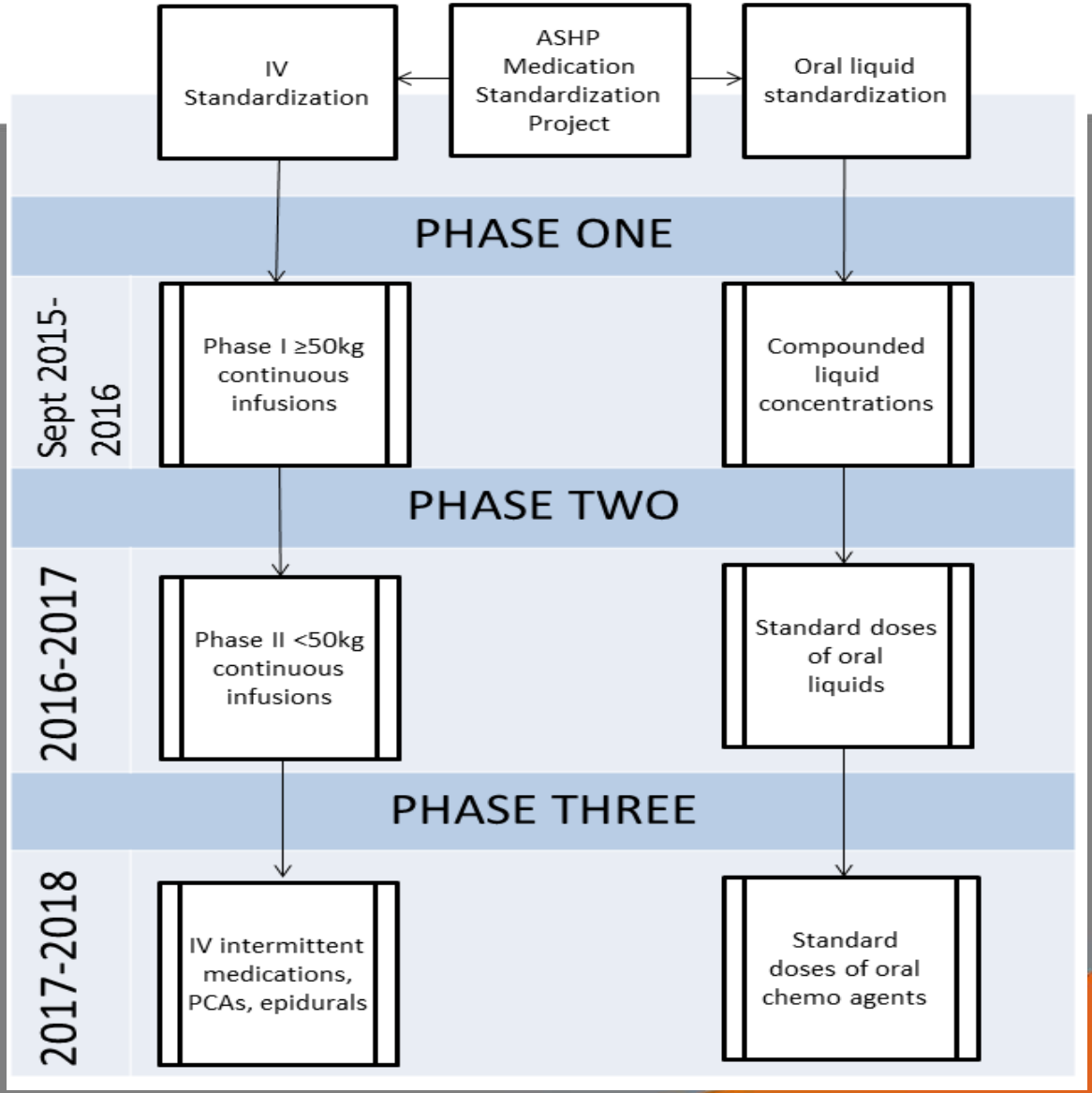
Project overview



Phases of the IV project

- **Phase I – Adult (≥50kg) continuous infusions. There will be two versions of this list, 1.01 and 1.02.**
  - Version 1.01 has been finalized and includes 32 of the most commonly used or high-alert medications administered via continuous IV infusion. Chemotherapy agents will not be included in the project
- **Phase II – Pediatric (<50kg) continuous infusions. There will be two versions of this list, 1.01 and 1.02. These will be available in 2017**
- **Phase III – IV intermittent, PCA/epidural medications. This is the final phase of the IV arm of the project.**

Exclusions for IV project

- Infusions related to extracorporeal modalities (Extracorporeal Membrane Oxygenation, Continuous Renal Replacement Therapies, etc.)
- Concentrations for non-treatment indications (i.e., heparin for line patency, etc.)
- Compounded infusion final volumes
- Diluents – selection of dextrose, saline, or a combination
- Library nomenclature and profile naming
- Chemotherapy drugs

Goals for Standardize 4 Safety

- Goal 1: Form a nationwide expert faculty panel
- Goal 2: Create the standards
- Goal 3: Disseminate the standards and assess their adoption

Methods: Formation of expert panels

- **IV panel**
  - 7 pharmacists
  - 3 nurses
  - 3 physicians
  - 1 consultant
  - 2 informaticists (ASHP)
- **Oral panel**
  - 7 pharmacists
  - 3 nurses
  - 3 physicians
  - 1 parent
  - 2 informaticists (ASHP)

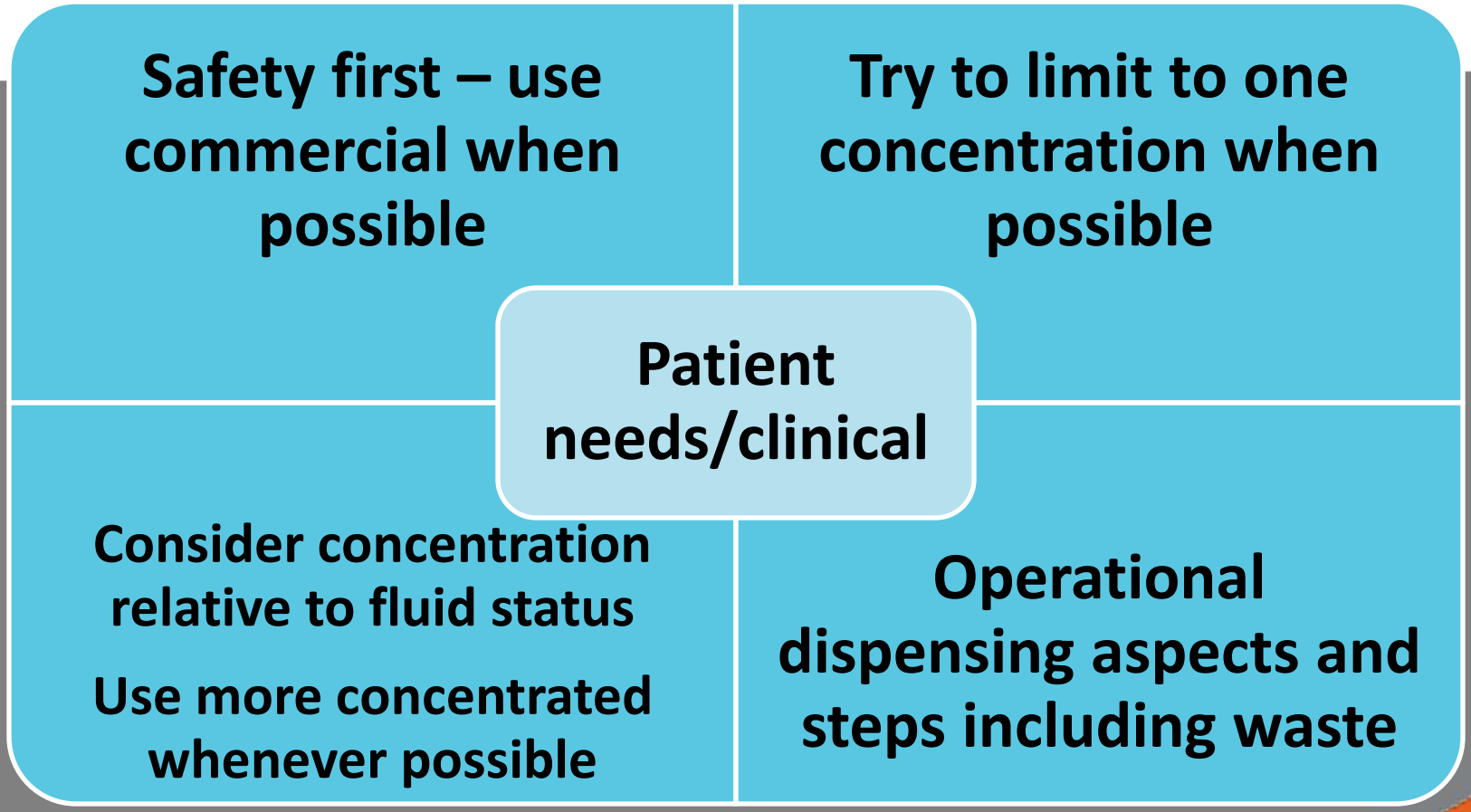
Methods: Data analysis

- **Data was collected from a variety of diverse sources:**
  - Standardized lists from state and regional efforts in Maine, Indiana, North Carolina, and San Diego
  - Information gathered from the 2008 IV Summit
  - Information gathered by the University of Utah Drug Information Service
  - Expert panel members' lists from their organizations
  - De-identified information from 503b companies
  - Other offerings from large health systems nationwide
- **A draft list was released for public comment, then revisions were conducted based on feedback collected.**

Methods: Meetings

- The expert panel convened in March 2016 to review the list and narrow the scope for Version 1.01 to 32 drugs
- Expert panel members continue to have one to two calls per month to continue their work

Methods: Guiding principles for IV



Methods: Quality assurance

- **The finalized list has been reviewed by expert panel members, internal ASHP staff, and ISMP for accuracy of drug name, concentration, and dosing units**
  - ASHP used the FDA and ISMP recommendations for tallman lettering
- **ASHP validated with the FDA that it is permissible to recommend a concentration other than that stated in the package insert (PI), given the inclusion of a disclaimer statement and the existence of evidence-based published literature for the concentration recommended**

Disclaimers

- This project is supported by a contract with the FDA, Safe Use Initiative, FDA-BAA-15-00121, Section 8.5

- This document is a working draft. Additional sections and lists will be added as the project moves forward

- Suggested concentrations may differ from the package insert (PI) information for a drug. This is due to clinical needs that may have transpired postmarket. When this is the case, studies are available to support the use of a concentration different than what the parent company specified.

Disclaimers

- **Dosing units were derived from**
  - PI information
  - Commonly used drug reference guides and clinical practice guidelines
  - Of special note, the expert panel is recommending that weight-based dosing be used for vasopressors (i.e., per kg, per minute), which may differ from institution-specific guidelines
- **These concentrations are *guidelines only and are not mandatory***
  - It is the vision of this project that organizations will voluntarily adopt these concentrations and join a national movement to use standardization across the care continuum as an error-prevention strategy for patient safety

Results for IV Version 1.01

Version 1.01 IV drug list

(see excel file for specifics)

Alteplase
Amiodarone
Argatroban
Bumetanide
Cisatracurium
Dexmedetomidine
Diltiazem
Dobutamine
Dopamine
Epinephrine
Esmolol
Fentanyl
Furosemide
Heparin
Hydromorphone
Insulin

Isoproterenol
Labetolol
Lidocaine
Lorazepam
Morphine
Midazolam
Milrinone
Nicardipine
Nitroglycerin
Nitroprusside
Norepinephrine
Phenylephrine
Propofol
Rocuronium
Vasopressin
Vecuronium

Compounded Oral Liquids

Statement of problem

- **Currently, no national standard concentrations**
- **Hospital pharmacies and community pharmacies use different recipes**
  - Why?
    - Availability of recipes
    - Availability of ingredients
    - Ease of preparation
    - Reimbursement
- **Medication errors occur through improper med rec**
  - Caregivers usually know doses in mLs, not mg
  - Concentrations are not readily known unless bottle present for verification or pharmacy is contacted (difficult during non-business hours)

Statement of problem (continued)

- **Nearly 75% of the drugs available in the US for adults have not been labeled for use in infants and children <12 years old**
- **Off-label drug use results in:**
  - Using drugs that have not been adequately tested
  - Using dosage forms that are not suitable for administration to infants and children
  - Using a portion of a solid dosage form
  - Increased demand for extemporaneous liquid formulations

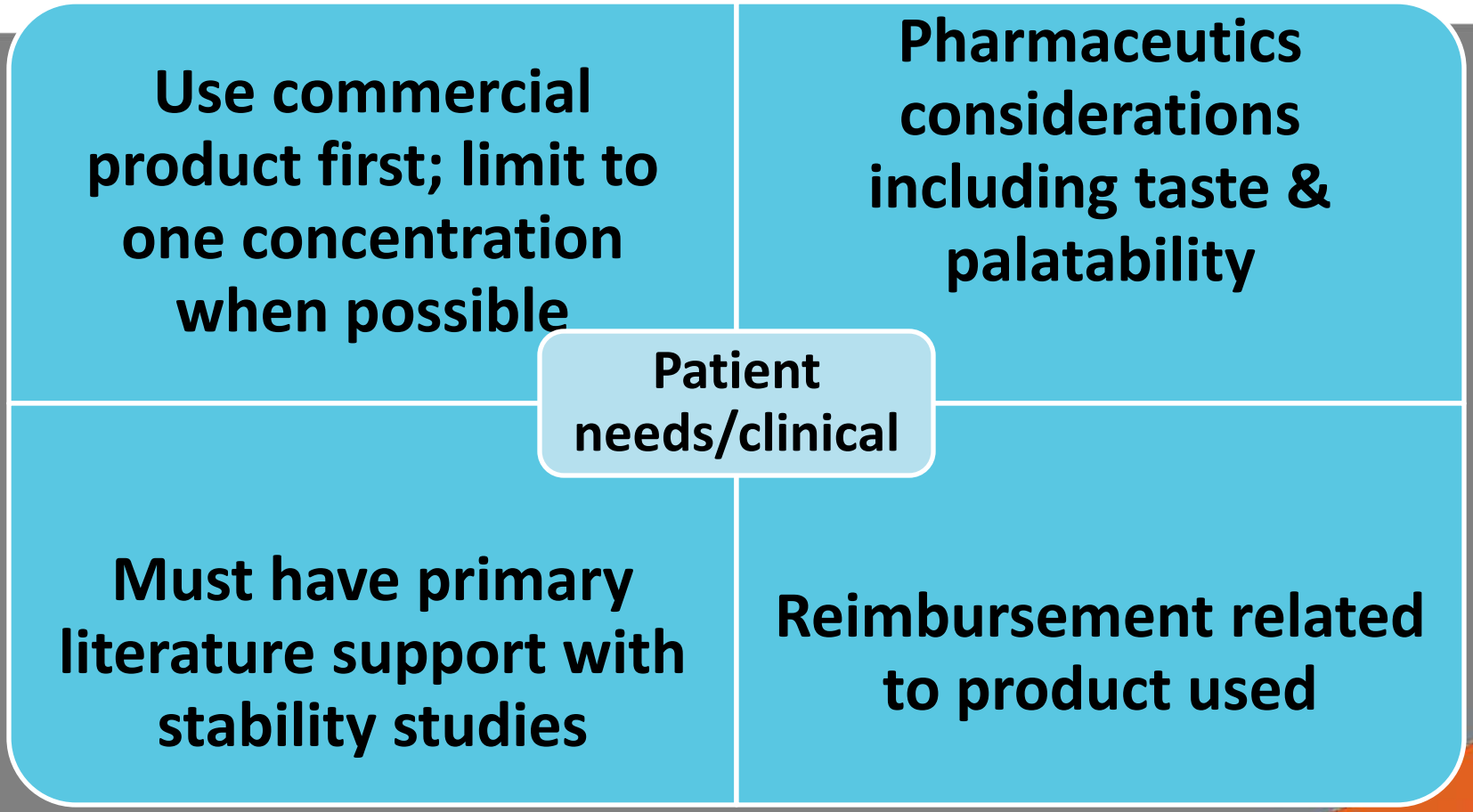
Oral compounded liquid medication arm

- **Standardized list of oral compounded liquid medications**
  - For all patients needing a liquid dosage form
  - Will use the Michigan effort as a starting point
    - www.mipedscompounds.org
- **Accurate measurement and measurement literacy**
  - Smart phone app to show consumer a visual display of an oral syringe and appropriate measurement for patient specific dose
- **What products could be commercially produced and how to keep costs down?**
- **Standardize liquid doses (ex: amoxicillin 256.5mg to 250mg)**
- **What other dosage forms could be developed (more solutabs, etc)?**

Challenges in using oral compounded medication formulations

- Lack of stability and sterility studies
- Short shelf-life
- Lack of pharmacokinetic/dynamic studies
- Efficacy and safety
- Palatability and compliance
- Variations in compounding practice

Oral compounded liquid medication decision matrix



Methods: Guiding principles

- **Version 1.01 is the first draft of the ASHP expert panel**
- **These are recommended/highly suggested concentrations at this time**
  - For a recipe to be considered, there must be a peer-reviewed published article
    - Abstracts are considered on a case-by-case basis
  - Stability needs to be longer than seven days to accommodate reasonable patient refill schedule

Methods: Guiding principles (cont.)

- Ease of compounding: simple ingredients that are readily available, doesn't require pH testing or addition of multiple complex ingredients
- Ease of measurement: for example, if the concentration is 1mg/mL, then dose=mL
- Concentration can be used for the majority of doses and won't result in doses less than 0.1mL
- Can be used for ketogenic diets (preference for sugar-free ingredients when possible)

Methods: Guiding principles (cont.)

- Preference for dye-free compounding ingredients when possible
- Preference for commonly used and accepted concentrations
- Existing USP monograph
- Avoid potential for tenfold dosing errors
- Cultural considerations related to ingredients

Methods for oral compounded liquids

- **Creation of expert panel**
  - Differs from IV panel, inclusion of parent member
- **Create the standards (remember, Easy Peasy!)**
  - ***Extensive*** work for recipe review
  - Currently in this stage
- **Stay tuned for the final list!**

Methods: Open comment periods

- **Will be done via ASHP Connect community**
- **Postings will be internally moderated**
  - Please use professional language
  - If you or the organization you represent feel strongly opposed to a particular concentration, please respond with a suggested alternative concentration, literature support, and patient clinical indication
    - The reason “we’ve always done it this way” is not evidence-based

Talking Points

Project talking points

- **Why use these concentrations?**
  - **It's the right thing to do for the patient** (HPI®)
    - Don't harm me
    - Heal me
    - Be nice to me
  - Error prevention strategy, especially given transitions of care and staff variation
- **National standards have been discussed for the past 10 years, don't you want to be part of the effort?**
- **National standards will lead to data sharing and enable clinical decision support at a national level instead of every hospital trying to do it on their own.**
  - **We can help you!!!!!**

IV talking points

- **How to prepare / considerations with IV continuous infusions:**
  - Do we have smart infusion pumps with libraries?
    - Don't necessarily need a pump to have standard concentrations
  - Do we have an inter-professional decision-making team?
  - Who are our key stakeholders? (Consider all sister hospitals and satellites, including offsite operating areas)
    - Providers – ED, OR, ICU, cardiac, general care
    - Pharmacists
    - Nurses
    - Informatics teams (drug records, order sets, etc.)
    - Administrators
    - Biomed / central distribution
    - Patients

IV talking points (cont.)

- **Gap analysis – how do the proposed standards compare with our own?**
  - Safety committee
  - P&T committee
- **How do we do library pushes – do you have a process?**
  - Wired
  - Wireless
- **When we implement changes, how will pharmacy operationalize, how will IT operationalize?**
  - One large push
  - Staged process

IV talking points (cont.)

- **Ordering Team**
  - Have providers been educated?
  - Are the dosing units different, education needs done?
    - Mcg/kg/min vs. mcg/min
    - Units/kg/min vs. units/min
- **Clinical considerations for patients**
  - Is the new concentration less or more concentrated?
  - Is the patient unstable at the time of the push so that a change can't be made?

Oral Liquid talking points

- Working with ambulatory care
- Working with community pharmacies
- Involving informatics teams
- Discussion with third-party payers
- Ongoing research needed
- Need for commercially available affordable liquid preparations

What you can do

- **START TALKING!!!!**
- **Be a champion, cheerleader, sponsor**
- **Don’t just get buy-in, take ownership**
- **Remember to take an inter-professional approach**
- **Start talking to the informatics team now**
- **Everyone can make a difference**
- **Resources: IPI, ASHP, new potential tools in the pipeline**

Early Adopters

- **Already having hospitals asking to be early adopters**
- **Why?**
  - It's the right thing to do for your patients
  - ASHP will promote early adopters on website, press releases, and communications to our partners and other agencies
  - Promote your hospital as leading medication safety efforts in your area
- **What?**
  - Adopt at least 26 of the 32 medications on the version 1.01 list
  - At least one of the concentrations for each medication
- **How?**
  - ASHP will assist
  - Toolkit, gap analysis will be coming soon

Communication methods

- **Sign up for informational pushes on the website**
  - Will be open for general public
  - Will post supporter list on the site for everyone to view (competition is good)
- **ASHP Connect community**
  - Moderated, interactive discussion
  - Updates on the initiative
- **ASHP meetings**
  - Anyone is welcome to presentations for own organizational meetings (contact me for content)
- **Vendors**
- **Change management experts**

Questions?

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