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Who Moved My Cheese? Standardization of the Pharmaceutical Supply Chain & Variation Reduction

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Trinity Health

Disclosures

• The presenters have no real or perceived conflicts of interest related to this presentation

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Learning Objectives

At the end of this session, participants should be able to:

- 1. Outline tactics for engaging key stakeholders in pharmacy medication cycle change management
- 2. Recognize initiatives that can be applied in individual hospitals or health systems and explain success in measuring change management initiatives
- 3. Identify key compliance opportunities within the pharmaceutical supply chain
- 4. Describe methods to reduce variation in pharmaceutical procurement practices





Trinity Health

- 90 Acute Care Hospitals
- Colleagues: 123,000
 - Employed Physicians and Clinicians: 6800
 - Affiliated Physicians: 27000
- Continuum of Care Services
 - 18 Clinically integrated networks
 - 13 PACE center programs
 - 100 continuing care locations
- Single Electronic Medical Record (EMR): Epic



Who Moved My Cheese?





Who Moved My Cheese?

What it means?

- Fable about change
- Cheese = what you want
- Maze = where to spend time looking for what you want



https://www.washingtonpost.com/entertainment/books/who-moved-my-cheese-became-a-monster-hit-twenty-years-later-were-still-wondering-why/2018/09/05/89a6e9aa-ac5e-11e8-8a0c-70b618c98d3c story.html Accessed 6-15-21



Pathways to Change



Trinity Health Clinical Framework



- Clinical Excellence Councils (CEC): Interprofessional team to replicate clinical excellence best practices and standards. The Councils focus on specific cohorts of patients in a service line (i.e. Orthopedics, Cardiovascular, Oncology and Emergency Care)
- Clinical Leadership Groups (CLG): Decision-making teams that have clinical and operational expertise and accountability that span numerous clinical areas. Leadership Groups are represented by their respective functions, such as pharmacy or radiology and or business units, such as medical groups.
- Clinical Services Groups (CSG): Teams which enable the work of care delivery that span multiple disease states and specialties.
 CSG are represented by services such as Patient Experience, Clinical Informatics, Clinically Driven Supply Chain and Zero Harm.



Pharmacy & Clinical Excellence Councils—Pathways for Change



Pharmacy & Therapeutics — Formulary or Medication Use





Formulary Standardization



Audience Poll Question: #1 of 5

Health System Level Formulary

Does your health system have a System Medication Formulary?

- a. Yes, we only have a system medication formulary
- b. No, formularies are determined by local sites
- c. We have both a system formulary as well as local site formularies



Trinity Health Pharmacy & Therapeutics Committee

Goals & Objectives

- Evaluate formulary status of new chemical entities
- Complete therapeutic class reviews
- Establish therapeutic interchange lists
- Perform Medication Utilization Evaluations (MUE)
- Work with clinical pharmacy committee, clinical excellence council (CEC) as well as P&T steering committee to develop and approve guidelines for the safe and effective use of medications
- Coordinate enterprise P&T functions with local P&T committees
- Monitor use of non-formulary items
- Develop methods for identifying and requesting drugs for formulary listing and/or removal
- Develop educational and training materials
- Be good stewards of our resources and be an advocate for evidence-based medicine and reduced variation where appropriate. Products should be evaluated with context of total clinical and financial or cost-effective outcomes
- Benchmark and ensure compliance with appropriate standards and regulations
- Provide recommendation for clinical content for the medical records



Trinity Health Pharmacy & Therapeutics Committee

Authority & Team Guiding Principles

- Authority
 - System P&T decisions will go to each local site P&T committee for presentation to local staff and gain approval of local Medical Executive Committee (MEC)
- Team Guiding Principles
 - Keep an open mind and a big picture view
 - Represent viewpoints across the System and across the continuum of care
 - Represent Trinity Health Guiding Behaviors
 - Active and regular participation in meetings and activities



Does your health system Pharmacy & Therapeutics Committee decisions require local approval by Medical Executive Committee (MEC)?

- a. Yes, we require local Medical Executive Committee (MEC) approval for system decisions
- b. No, our system P&T committee has delegated authority from local MEC
- c. Other



Formulary Standardization Process

Initial Work

<u>2016:</u>

- 1 electronic medical record (EMR) had 9658 line items
 - Trinity Health had at least 8 unique EMR's
- Compiled a list of medication from one electronic medical record (EMR)
- Evaluated list based on cost, purchases, duplicates utilization
- List of necessary class reviews drafted systematically reviewed at P&T



Formulary Standardization Process—Initial Class Reviews Identified

Hyponatremia Agents	Topical Corticosteroids
Emergency Contraceptives	Topical Beta Blockers
IV NSAIDs	Long Acting Antipsychotic Agents
Erythropoiesis-Stimulating Agents (ESAs)	Oral Cephalosporins
Ophthalmic Fluoroquinolones	Contrast Media
Thrombin	NK-1 Receptor Antagonist
MRSA Agents	Phosphate Binders
Ophthalmic Beta Blockers	Azole Antifungal Agents
IV acetaminophen (Ofirmev)	Liposomal Bupivacaine (Exparel)



Formulary Standardization Process

Continued Work

<u>2018</u>

- Draft formulary list was distributed to sites evaluate based on what patients need
- Evaluation was completed by sites (1 month)
- Feedback was evaluated
 - All feedback added to master document and distributed to sites
 - Missing "necessary" medications were added to TH formulary
 - Additional gaps identified, specifically controversial topics determined these would be addressed through additional SBAR, monographs and class reviews
- Arrived at "final" Trinity Health formulary January 2019



Formulary Standardization Process—Additional Gaps Identified

NICU Formulary	Ophthalmic Beta Blockers	Phosphate Binders
Topical Antifungals	Epidural Concentrations	Azole Antifungal Agents
Standard Concentrations & Pump library	Oral Vancomycin	PCA Concentrations
Electrolyte Replacement	Fluoroquinolones (IV and Oral)	Delivery of IV mixtures (Always/Sometimes/Never)
Pancreatic Enzymes	IV push medications	Insulin (including U-500 insulin)
Topical anesthetics	Alcohol and Wine on formulary	
Buprenorphine oral formulations	Ophthalmic sympathomimetics	







Delivery of IV Mixtures

Always/Sometimes/Never List

- Trinity Health never conducted a comprehensive review of how medications were delivered and supplied
- Why?
 - Adopting standard EMR
 - Decrease unnecessary variation: Wide variation in how medications were purchased and supplied for patients
 - Cost savings opportunity: decreasing variation and optimizing contracts
 - Opportunity to evaluate safety literature: align with safety best practice
 - Give sites flexibility: staffing, resources and cost savings



Historical State: IV Medication Delivery



Additional variations between methods and medications Site of assembly of Mini-Bag Plus, Add-Vantage, IV push Source of premix (Contract versus non-contracted, 503b)



Delivery of IV Mixtures—Standardization process

Compile background: Assessment of how products are available (using purchases) – Included all IV sets

- Utilized standing clinical workgroups: Medication Management
- -Worked to understand build in Epic as well as need for flexibility
- -Reviewed safety sources (ISMP, ASHP) what is best practice

Partnered with supply chain to understand overall impact of proposal

Proposal through approval process with feedback Communicate decisions (source) and change management around decision





Nicardipine premix versus compounding – Operational Implications

- Stability Information
- Alternate preparations for hospitals without 24-hour pharmacies on sites Vial to bag or emergency compounding
- Cost of labor and waste
 - Assumed uncomplicated compounding
 - Compounding = 50 bags per hour
 - Checking = 60 bags per hour
 - Shift in labor study from AJHP noted that unless there is a shift of approximately 25% of volume in compounded admixtures, staff labor would not need to shift
 - Waste several published studies noted waste of 2.5-8% waste depending on number of IV batches at site

Sources:

- <u>http://online.lexi.com/lco/action/ivcompatibility/trissels</u> Accessed 6-17-19.
- Witte LW, Eck TA, Vogel DP. Decision analysis applied to the purchase of frozen premixed intravenous admixtures. Am J Hosp Pharm. 1985:42;835-9.
- Clinical and Economical Considerations For IV Push Drug Delivery" technical paper -- authored by Industry Expert Richard Rosenfeld, RPh, MBA, for Baxa Corporation. December 2009.
- Flynn Ea, Pearson RE. Observational study of the accuracy in compounding IV admixutres at five hospitals. Am J Health-Sytem Pharm. 1997; 54: 904-12.
- Skibinski KA, White BA, Lin LIK, et al. Effects of technological interventions on the safety of a medication <u>http://www.healthmark.ca/DATA/DOCUMENT/HEALTHMARK_VIAL2BAG_sept_2017_ENG4.pdf Accessed 1-14-18</u>
- <u>https://etd.ohiolink.edu/!etd.send_file?accession=ucin1397736409&disposition=inline</u> accessed 6-17-2019



Delivery of IV Mixtures—Always/Sometimes/Never (ASN List) Nicardipine premix versus compounding – Impact of proposal

	Cost Premix	Purchased Units (Historical)	Total Cost (based on historical)	Cost Pharmacy Compound	Purchased Units (Historical)	Total Cost (based on historical)
Medication	\$85.25	22740	\$1,938,585	\$21.02	22740	\$477,994
Minibag				\$2.90	22740	\$65,946
Medication Costs		22740	\$1,938,585	\$23.92	22740	\$543,940
Vial adaptor, needle, syringe, alcohol swab	NA			\$1.57	22740	\$35,701
Tech time (Tier 1)	NA			\$0.41	22740	\$9,323
Pharmacist time (Tier 1)	NA			\$1.31	22740	\$29,789
Total cost preparation				\$1.89	22740	\$39,112
Total Cost			\$1,938,585			\$618,914



ALWAYS

Pharmacy will always compound medication (will not use premix) OR will load a vial and either a bag with vial adaptor or minibag plus in Automated Dispensing Machine

SOMETIMES Pharmacy will either compound or purchase premix *Allows sites to flex based on needs* **NEVER** Pharmacy will never compound this medication – will only purchase a premix



Medication Validated	Premix Available	Load premix in Pyxis (real or dummy)	Custom Simple (incl CNR and non-CNR)	Mini-bag Plus	Dispensing system adapter	Dispense components	Commercially available / 503b	IV Set Description	Cost Impact (increase) not 340b
never	yes	yes	premix only	premix only	premix only	premix only	premix only	clindamycin 300 mg/50 mL D5W	-\$29,403.00
never	yes	yes	premix only	premix only	premix only	premix only	premix only	clindamycin 600 mg/50 mL D5W	(see clindamycin 300 mg)
never	yes	yes	premix only	premix only	premix only	premix only	premix only	clindamycin 900 mg/50 mL D5W	(see clindamycin 300 mg)
always	no	no	yes	no	no	yes	Do not configure	DAPTOmycin mg/50 mL NaCl 0.9%	neutral
always	yes	yes	yes	no	No	yes	Do not configure	niCARdipine 25 mg/250 mL	\$2,161,965
always	yes	yes	yes	no	no	yes	Do not configure	niCARdipine 50 mg/ 250 mL	(see above)
never	yes	premix only	premix only	premix only	premix only	premix only	DOBUTamine 1,000 mg/250 mL D5W	Do not configure	neutral
never	yes	premix only	premix only	premix only	premix only	premix only	DOBUTamine 500 mg/250 mL D5W	Do Not configure	neutral



Medication Validated	Premix Available	Load premix in Pyxis (real or dummy)	Custom Simple (incl CNR and non-CNR)	Mini-bag Plus	Dispensing system adapter	Dispense components	Commercially available/ 503b	IV Set Description	Cost Impact (increase) not 340b
never	yes	yes	premix	premix	premix	premix	premix	potassium chloride 10 mEq/100 mL	Do not configure
never	yes	yes	premix only	premix only	premix only	premix only	premix	potassium chloride 20 mEq/100 mL	Do not configure
never	yes	yes	premix only	premix only	premix only	premix only	premix	potassium chloride 20 mEq/50 mL	Do not configure
never	yes	yes	premix only	premix only	premix only	premix only	premix	potassium chloride 20 meq/50 ml	Do not configure
always	yes	yes	yes	yes	yes	yes	Do not configure	piperacillin-tazobactam 3.375 g/100 ml NS	\$1,091,762.11
always	yes	yes	yes	yes	yes	yes	Do not configure	piperacillin-tazobactam 3.375 g/100 ml NS	see zosyn 3.375
always	yes	yes	yes	yes	yes	yes	Do not configure	piperacillin-tazobactam 4.5 g/100 mL NS	see zosyn 3.375
always	yes	yes	Yes	yes	yes	yes	Do not configure	piperacillin-tazobactam 4.5gm/100 mL NaCl 0.9%	see zosyn 3.375
always	yes	no	no	yes	yes	yes	Do not configure	piperacillin-tazobactam 2.25 gram/100 ml NaCl 0.9%	see zosyn 3.375





Who Moved My Cheese?

Always/Sometimes/Never (ASN List) Change Management

- Communication of background, process and why
- Operational concerns addressed when necessary
- Built changes in legacy electronic medical records where possible
- Only included allowable options in new EMR
- Block from wholesaler (when possible)
- Monitor outcomes



https://www.washingtonpost.com/entertainment/books/who-moved-my-cheese-became-a-monster-hit-twenty-years-later-were-still-wondering-why/2018/09/05/89a6e9aa-ac5e-11e8-8a0c-70b618c98d3c_story.html Accessed 6-15-21



Always/Sometimes/Never Outcomes

Nicardipine Premix versus Compounding



Nicardipine Units Purchased – Trinity Health



Always/Sometimes/Never Outcomes

Piperacillin/Tazobactam (Zosyn) Premix versus Compounding



Piperacillin/Tazobactam Spend (Dollars) – Trinity Health



Insulin Standardization



Formulary Standardization Process—Additional Gaps Identified

NICU Formulary	Epidural Concentrations	PCA Concentrations
Topical Antifungals	Oral Vancomycin	Delivery of IV mixtures (Always/Sometimes/Never)
Standard Concentrations & Pump library	Fluoroquinolones (IV and Oral)	Insulin (including U-500 insulin)
Electrolyte Replacement	IV push medications	
Pancreatic Enzymes	Alcohol and Wine on formulary	
Topical anesthetics	Ophthalmic sympathomimetics	
Buprenorphine oral formulations	Phosphate Binders	
Ophthalmic Beta Blockers	Azole Antifungal Agents	



Insulin Standardization Considerations

One Scenario

- Informatics
 - Less formulary build
 - Less formulary maintenance (avoids site specific virtualizations)
- Distribution
 - Less vendors to manage
 - Less SKUs to warehouse
- Future Contract Negotiations
 - Leverage pricing/market share (decrease cost)

Multiple Scenarios – State of Trinity Health

- Informatics
 - Site specific build (more complex)
 - Increased maintenance (resource strain)
 - Not aligned with overall goal for Trinity Health
- Distribution
 - More vendors to manage
 - More products to carry and manage
- Future Contract Negotiations
 - Less savings



Insulin Standardization—Process

Insulin Standardization Workgroup formed – safety and cost/waste pens versus vials Developed FMEA and cost analysis of Insulin Standardization ISMP publishes Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults



Insulin Standardization—Process 2





Insulin Standardization

Nursing & Pharmacy Implications

	Scenario 1 Community Floor Stock Vials	Scenario 2 One patient, one pen	Scenario 3 Short acting insulin - pen Basal insulin- centralized unit dose*	Scenario 4 Short acting insulin: floor stock vials Basal insulin – centralized unit dose [*]
Informal Time study (work time) ^{&}	Nursing: 2 min Pharmacy: 1 min 30 sec	Nursing: 1 min 14 sec Pharmacy 1 min 17 sec	Short acting Nursing: 1 min 14 sec Pharmacy 1 min 17 sec Basal Nursing: 57 sec Pharmacy: 3 min 53 sec	Short Acting Nursing: 2 min Pharmacy: 1 min 30 sec Basal: Nursing: 57 sec Pharmacy: 3 min 53 sec
Product Waste	Medium	Highest	Medium	Lowest

[&]Internal Trinity Health analysis

*Basal Insulin – drawn up as patient specific syringes in pharmacy


Audience Poll Question: #3 of 5

How does your health system deliver insulin?

- a. Community floor stock vials
- b. One patient, one pen
- c. Short acting insulin pen, Basal insulin drawn up in pharmacy
- d. Short acting insulin community floor stock vials, basal insulin drawn up in pharmacy
- e. One patient, one vial
- f. Other



Insulin Standardization—Safety

Pens

- Pros:
 - Labeled by the manufacturer with product name and product barcode
 - Individually labeled with patient's name
 - Provides insulin in a ready for administration form and less time to prepare
 - Can reduce waste when compared to dispensing 10 ml sized insulin vials
- Cons:
 - Post injection leaking from needle if not left in place for 5-10 seconds
 - Needlestick injuries from misaligning the angle of injection
 - Insulin cartridges have been misused as multiple-dose vials
 - Improper sharing of pens among multiple patients

Vials

- Pros:
 - Sharing of syringes and needs used for administration of insulin from vials is less likely than with the pens
 - Compatible insulins can be mixed in a syringe for a single injection
 - Insulin doses removed from vials may be less costly than doses using insulin pens, there may be less waste
- Cons:
 - Inaccurate dosing when using an insulin syringe for measurement, as units have been mistaken as milliliters and u-100 designation on insulin vials misunderstood
 - Confusion with look-alike vials of various types or concentrations of insulin





Safety – 2017 ISMP Insulin Guidelines

- Insulin Vials
 - Insulin vials should be removed from the carton prior to dispensing
 - Insulin vials in patient care areas have ready-to-apply barcoded labels for all clinician-prepared syringes
 - Pharmacy prepares and dispenses basal insulin in patient specific prefilled syringes
- Insulin Pens
 - Ideally, insulin pens should be dispensed to units with a patient-specific barcode label AND steps taken to ensure that only the correct patient-specific label can be scanned at the bedside without obscuring important information
 - Patient-specific insulin pens are stored on clinical units in a manner that prevents their inadvertent use on more than one patient
 - An insulin pen is never used as a vial
- Concentrated Insulin
 - Concentrated insulins are dispensed in patient-specific, labeled pen devices or in patient-specific, pharmacy-prepared syringes
 - U-500 insulin vials are only stored in the pharmacy

Institute for Safe Medication Practices (ISMP). ISMP Guidelines for Optimizing Safe Subcutaneous Insulin Use in Adults; 2017. https://www.ismp.org/guidelines/subcutaneous-insulin.





Safety-CDC

Questions about Multi-dose vials

1. What is a multi-dose vial?

A multi-dose vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that contains more than one dose of medication. Multi-dose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria. The preservative has no effect on viruses and does not protect against contamination when healthcare personnel fail to follow safe injection practices.

2. Can multi-dose vials be used for more than one patient? How?

Multi-dose vials should be dedicated to a single patient whenever possible. If multi-dose vials must be used for more than one patient, they should only be kept and accessed in a dedicated medication preparation area (e.g., nurses station), away from immediate patient treatment areas. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment that could then lead to infections in subsequent patients. If a multi-dose vial enters an immediate patient treatment area, it should be dedicated for single-patient use only.

3. What are examples of the "immediate patient treatment area"?

Examples of immediate patient treatment areas include operating and procedure rooms, anesthesia and procedure carts, and patient rooms or bays.

4. Our hospital uses bar code technology that requires scanning of medication vials and drawing up medication in the patient room. If multi-dose vials (e.g., insulin) are dedicated for single-patient-use only, can they be accessed in the patient room?

Ideally, from an infection control perspective, all medication preparation should occur in a dedicated medication preparation area (e.g., nurses station), away from immediate patient treatment areas. However, if there is a need to access multi-dose vials in the patient room (e.g., for the purposes of barcoded medication administration) the vial must be dedicated for single-patient-use only, the patient should be housed in a single-patient room, and all medication preparation should be performed in a designated clean area that is not adjacent to potential contamination sources (e.g., sink, used equipment). Following medication preparation, the vials should be stored, in accordance with manufacturer's instructions, in a manner to prevent inadvertent use for more than one patient and/or cross-contamination.

Source: <u>https://www.cdc.gov/injectionsafety/providers/provider_faqs_multivials.html</u>



Cost Implications

BEFORE DELIVERY SYSTEM	AFTER DELIVERY SYSTEM	COST ADJUSTMENT FACTOR	UNITS ADJUSTMENT FACTOR	REFERENCE
RAPID ACTING INSULIN				
10 ml vial FS	floor stock 3 ml vial	0.89	0.88	1,2
3 ml vials FS	Pens	1.70	1.61	1,2
10 ml vials	Pens	1	1	
3 ml pens	3 ml vials (FS)	0.30	0.39	1,2
BASAL INSULIN				
insulin pens	10 ml FS	0.93	1.12	2
insulin pens	insulin drawn up in pharmacy (cud)	0.39	0.45	3
10 ml FS	insulin pens	1.07	0.88	2
10 ml FS	insulin drawn up in pharmacy (cud)	0.39	0.45	3,4

Sources:

1. Lee LJ, Smolen LJ, Klein TM, et al. Budget impact analysis of insulin therapies and associated delivery

systems. Am J Health Syst Pharm 2012;69:958-65

2. Edmondson G, Criswell J, Krueger L, et al. Economic impact of converting from 10-mL insulin vials to

3-mL vials and pens in a hospital setting. Am J Health-Syst Pharm 2014;71:1485-9

3. Mount Sinai Hospital, internal communication 5/8/15, accessed 3-23-18.



Cost Implications

	Current state	Scenario 1	Scenario 2	Scenario 3	Scenario 4
	Using 3/18 contract prices	New Spend - All FS vials	New Spend - All pens	New Spend - Short Acting Insulin One Patient, One Pen Centralized Unit Dose Basal (CUD) Insulin	New Spend - Short acting insulin: Floor stock vials Centralized Unit Dose Basal (CUD) Insulin*
Total Savings from current state		-\$921,715.66	\$336,060.14	-\$603,889.31	-\$2,119,093.47
Total TH Projected Spend	\$4,597,395.91	\$3,675,680.25	\$4,933,456.06	\$3,993,506.60	\$2,478,302.44
New projected spend 340b	\$144,040.55	\$215,153.00	\$39,038.61	\$86,096.91	\$123,938.92
New projected spend non- 340b	\$4,453,355.36	\$3,460,527.26	\$4,894,417.45	\$3,907,409.69	\$2,354,363.52
Additional Consideratio ns					
Waste - Cost		Ļ	↑↑	↑	₩
Supply (needles, etc)		Ļ	Ŷ	Ŷ	Ţ
Labor (pharmacy)		-	-	↑	1



Recommendations

- Insulin delivery (pens versus vials) from a safety, nursing, pharmacy impact are equivalent with appropriate mitigating factors as recommended by ISMP
- Scenario 1 is NOT recommended by ISMP
- Most cost-effective insulin delivery method using evidence-based cost assumptions is Scenario 4: Floor stock vials and patient specific basal insulin is drawn up in pharmacy using vials
- Adoption of Scenario 4 across Trinity Health: complies with ISMP, CDC, Joint Commission and will provide cost savings of \$2 million dollars annually
- Coordinated multidisciplinary change management and operational discussions will be necessary for Trinity Health to arrive at "one way" for insulin delivery



Who Moved My Cheese?

Insulin Standardization – Change Management

- Communication of background, process and why
- Operational concerns addressed tool kit

12. Q: Who will be responsible for labeling the insulin vial with expiration date?

A: Pharmacy will date the short acting insulin vials when they stock it in the cubie pocket in automated dispensing cabinets (e.g. Pyxis).

13. Q: How will you be able to tell the vials apart? Do they look similar?

A: As with all medications, nurses should read the medication label on the vial. Many insulin vials look alike. Stocking of each type of insulin is in its own cubie pocket, therefore decreasing the risk of selecting the wrong insulin.

- Built changes in legacy electronic medical records
- Only included allowable options in new EMR
- Monitor outcomes



https://www.washingtonpost.com/entertainment/books/who-moved-my-cheese-became-a-monster-hit-twenty-years-later-were-still-wondering-why/2018/09/05/89a6e9aa-ac5e-11e8-8a0c-70b618c98d3c_story.html Accessed 6-15-21



Outcomes





Formulary Standardization Process—Additional Gaps Identified

IV Push Medications	What medications will be given IV Push when either intermittent infusion or IV push are acceptable administration strategies
Standardized Infusions	What are the concentrations, dosing units and instructions for titration for continuous infusion medications
Bolus from Infusion	When a bolus of a continuous infusion medication is needed, will the bolus given as a volume from the infusion or from a separate vial
Infusion Pump Library	Establish safety guardrails for infusions given via large volume infusion pumps



IV Push Medications



Which of the following is recommended as part of the ISMP Safe Practice Guidelines for Adult IV Push Medications

- Adult IV push medications should be provided in a ready-to-administer form to the greatest extent possible
- b. Instructions for proper reconstitution should be provided when dilution is necessary outside of the pharmacy sterile compounding area
- c. Initial and ongoing competency assessments for IV push medication preparation and administration are recommended
- d. All of the above



Advantages & Risks of IV Push Administration

Advantages of IV Push Administration

- Possible lower pharmacy preparation time
- A decreased time to administration of antibiotics in the emergency department
- Reduced administration time
- Increased nursing satisfaction
- Lower demand for large volume pump and supplies (i.e., tubing)
- Less fluid
- Reduce hidden medication loss from small-volume intermittent infusions (increased dose accuracy)
- Lower cost

Disadvantages of IV Push Administration

- IV medications prepared in syringes but left unlabeled and unattended
- IV push medications that are reconstituted in commercially available flush syringes of 0.9% sodium chloride and then remain mislabeled
- Reconstitution of a medication using the incorrect type and/or amount of diluent
- Failure to follow appropriate infection control standards associated with IV injection preparation and administration

https://www.ismp.org/resources/hidden-medication-loss-when-using-primary-administration-set-small-volume-intermittent

Gupta A, Mang N, Wei W, et al. Supply Shortages: A Silver Lining. Am J Med. 2018;131(6):630-632. doi:10.1016/j.amjmed.2018.01.029

ISMP Safe Practice Guidelines for Adult IV Push Medications <u>https://www.ismp.org/sites/default/files/attachments/2017-11/ISMP97-Guidelines-071415-3.%20FINAL.pdf</u>



IV Push & Intermittent IV Piggyback Administration



* For closed system IVPB

A time motion study has demonstrated similar time total nursing time for IV push administration (3.6 minutes) versus IVPB (4.74 minutes).

Garrelts J.C., Smith D.F., Ast D., "A Comparison Of The Safety, Timing And Cost-Effectiveness Of Administering Antimicrobials By Intravenous Bolus (Push) Versus Intravenous Piggyback (Slow Infusion) In Surgical Prophylaxis," PharmacoEconomics, 1992;2:1116-23.



Recommendation	ns Regarding the Preparation of Intravenous Push Medications
Institute for Safe Medication Practices (ISMP)	 Commercially available, prefilled syringes of medications that are already labeled should be used when possible To the greatest extent possible, provide adult IV push medications in a ready-to-administer form (to minimize the need for manipulation outside of the pharmacy sterile compounding area)
The Joint Commission	• Medications in patient care areas are available in the most ready-to-administer forms commercially available or, if feasible, in unit-doses that have been repackaged by the pharmacy or a licensed repackager.
American Society of Health-System Pharmacists	• Whenever possible, medications shall be available for inpatient use in single-unit packages and in a ready-to-administer form. Manipulation of medications before administration (e.g., withdrawal of doses from containers, reconstitution of powdered drug products, labeling of containers and splitting of tablets) by final users should be minimized
United States Pharmacopeia (USP) 〈797〉 Pharmaceutical Compounding of sterile preparations	• Limit syringe preparation outside of the pharmacy compounding area to emergency situations to minimize the risk of contamination. When necessary, storage of these drugs in syringes is limited to a one-hour period.

https://www.jointcommission.org/-/media/tjc/documents/standards/field-reviews/hap_field_review.pdf



Cost Comparison IVPB & IV Push

- <u>Cost Comparisons</u>
- Cost comparisons including total labor and supplies show the IV push route to be more cost effective compared to IV piggyback administration.

IV Push Cost

Preparation	Administration				
Cefazolin Vial = 1.00	RN Labor 2.10				
SWFI Diluent=0.70					
Syringe/needle =0.08					
Tech labor = 0.2					
Total Cost = \$ 4.08					

IVBP Costs

Preparation	Administration				
Cefazolin Vial = 1.00	RN Labor = 2.76				
Minibag = \$2.90	Tubing Set = ~2.00				
Syringe/needle=0.08					
Tech Time = 0.41					
Total Cost = \$9.15					



	IV Push Medication	Administration Consi	iderations	
	Lacosamide	Levetiracetam	Thiamine	Folic Acid
IV Push Dosing	≤ 400 mg	≤ 1500 mg	≤ 100 mg	< 5 mg
IVP Administration Rate	≤ 80 mg/minute	≤ 500 mg/minute	≤ 80 mg/minute	≤ 5 mg/minute
IVP Administration Time	Slow IV push ≤ 5 minutes	Slow IV push ≤ 5 minutes	IV push over 1 minute	IV push over 1 minute
Final Concentration (Undiluted Vial)	10 mg/mL	100 mg/mL	100 mg/mL	5 mg/mL
Age Considerations	\geq 18 years old	\geq 1 year old	\geq 18 years old	\geq 18 years old

https://www.jointcommission.org/-/media/tjc/documents/standards/field-reviews/hap_field_review.pdf



Standardization Decision—IV Push Medications

- Standardize to the IV push route for all adult doses of cefazolin, ceftriaxone and cefepime
 - Establish that a "ready to use" prepared syringe format as the standard method for dispensing IV push medications in Trinity Health
 - Deviation from the prepared syringe format may be applied for low-use products at remote sites without 24hour pharmacy services (i.e. cefepime at an off-site urgent care center). In these situations, a "kit" with label, diluent and drug vial to mitigate safety concerns will be the standard enterprise solution.
- Establish the IV push administration for the following medications
 - Thiamine (Doses of 100 mg or less)
 - Folic Acid (Doses less than 5 mg)
 - Levetiracetam (Doses of 1500 mg or less)
 - Lacosamide (Doses of 400 mg or less)





Who Moved My Cheese?

IV Push – Process & Change Management

- CEC Process
- Nursing engagement
 - Presented at Nursing Clinical Leadership Group
- Adoption with conversion to system standard EMR
- Option to convert prior (legacy systems have compatible buil
- Partner with nursing IV Push Safety Education



https://www.washingtonpost.com/entertainment/books/who-moved-my-cheese-became-a-monster-hit-twenty-years-later-were-stillwondering-why/2018/09/05/89a6e9aa-ac5e-11e8-8a0c-70b618c98d3c_story.html Accessed 6-15-21





Cefazolin IV Push





Standard Concentrations



Standard Concentrations of IV Infusions

Why? Rationale for Standard Concentrations Initiative

- Safety Benefit
 - Reduce errors resulting from confusion over non-standardized drug concentrations differences when patients transition their care from one setting to another
- Operational Benefit
 - Simplified ordering to decrease provider uncertainty and reduce electronic health record build and maintenance
 - Increased opportunity for contracting large volume of standard premixed medications
 - Reduces operational variations and enhances efficiency







Process

Standard Concentration Initiative

Goal: Reduce extensive variation

А	н	I	J	κ	L	м	N	0	Р	Q	R	s		U	v	w	x
IV Set Description		RIA 💌			DB		ED V			П 💌	MC	MIV		SA 💌	sc 🔻	SS ¥	GT 💌
EPINEPHrine 1 mg/250 ml D5W (std2)		0	0	0	0	0		0	0	0	0	0		0		1	1
EPINEPHINE 1 mg/250 mL D5W (std2)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
EPINEPHrine I mg/250 mL D5W (std2)	U	0	U	0	0	U	U	U	U	U	0	U	U	0	0	1	1
EPINEPHrine 2 mg/250 mL D5W (std)	0	0	0	0	0	0	0	1	0	1	0	1	1	0	0	0	0
EPINEPHrine 2 mg/250 mL D5W (std)	0	0	0	0	0	0	0	1	0	1	0	1	1	0	0	0	0
EPINEPHrine 2 mg/250 mL NS (std)	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0
EPINEPHrine 2 mg/250 mL NS (std)	0	0	0	0	0	0	0	0	0	1	1	0	1	0	0	0	0
EPINEPHrine 4 mg/250 mL D5W (std)	1	0	0	0	0	0	0	0	1	1	0	0	1	1	0	0	0
EPINEPHrine 4 mg/250 mL D5W (std)	1	0	0	0	0	0	0	0	1	1	0	0	1	1	0	0	0
EPINEPHrine 4 mg/250 mL NS (std)	1	1	1	1	1	1	0	0	1	1	0	0	1	1	0	1	0
EPINEPHrine 4 mg/250 mL NS (std)	1	1	1	1	1	1	0	0	1	1	0	0	1	1	0	1	0
EPINEPHrine 4 mg/250 mL NS (std3)	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0
EPINEPHrine 4 mg/250 mL NS (std3)	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0
EPINEPHrine 8 mg/250 mL D5W (std)	1	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0
EPINEPHrine 8 mg/250 mL D5W (std)	1	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0
EPINEPHrine 8 mg/250 mL NS (std)	1	0	0	0	1	1	0	0	1	0	0	0	0	1	0	0	0
EPINEPHrine 8 mg/250 mL NS (std)	1	0	0	0	1	1	0	0	1	0	0	0	0	1	0	0	0
EPINEPHrine 8 mg/500 mL NS	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
EPINEPHrine 8 mg/500 mL NS	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0

Guiding Principles

- ASHP Recommendations
- Default concentration
- 0.9% Normal Saline as default diluent
- Establish normalized rate and titration comments



Standard Titration Comments

Requirements for a Complete Medication Order – The Joint Commission

- For medication titration orders:
 - Medication name
 - Medication route
 - Initial rate of infusion (i.e., dose/minute)
 - Incremental units to which the rate or dose can be increased or decreased
 - How often the rate or dose can be changed
 - Maximum rate or dose of infusion
 - Objective clinical measure to be used to guide changes
 - Note: Examples of objective clinical measures to be used to guide changes include blood pressure, Richmond Agitation–Sedation Scale (RASS) and the Confusion Assessment Method (CAM)



Standard Titration Comments

- Default titration comments for most
 - Vasopressors, antihypertensives, critical care opioid infusions
- Indication specific titration comments for some

Titration Comments

Ketamine Based on Indication/Ketamine orderable comments

Refractory Status Asthmaticus: GOAL EFFECT: Ventilator compliance-adequate oxygenation/ventilation; INITIAL RATE: 0.5 mg/kg/hr; USUAL DOSE RANGE: 0.5 mg/kg/hr to 2.5 mg/kg/hr; TITRATION DOSE: 0.25 mg/kg/hr; TITRATION FREQUENCY: Q15 min; CONTACT PRESCRIBER: HR<60 BPM or >120 BPM, SBP>180 mmHg or <90 mmHg; for delirium, confusion, or hallucinations * Individual cases may deviate from parameters and would require an order from the provider documented in the patient record

Refractory Status Epilepticus: GOAL EFFECT: Burst suppression-termination of seizure activity; INITIAL RATE 1 mg/kg/hr; USUAL DOSE RANGE: 1 mg/kg/hr to 10 mg/kg/hr; TITRATION DOSE: 0.5 mg/kg/hr; TITRATION FREQUENCY: Q15 min; CONTACT PRESCRIBER: HR<60 BPM or >120 BPM, SBP>180 mmHg or <90 mmHg; for delirium, confusion, or hallucinations * Individual cases may deviate from parameters and would require an order from the provider documented in the patient record

Sedation, Analgesia ICU (PADIS): GOAL EFFECT: To RASS goal -1 to +1; INITIAL RATE: 0.06 mg/kg/hour; USUAL DOSE RANGE: 0.06 mg/kg/hr to 2 mg/kg/hr; TITRATION DOSE: 0.1 mg/kg/hr; TITRATION FREQUENCY: Q15 min; CONTACT PRESCRIBER: HR<60 BPM or >120 BPM, SBP>180 mmHg or <90 mmHg; for delirium, confusion, or hallucinations *Individual cases may deviate from parameters and would require an order from the provider documented in the patient record

Refractory Pain or Palliative Care: GOAL EFFECT: Patient pain/functional goal; INITIAL RATE 0.2 mg/kg/hr; USUAL DOSE RANGE: 0.2 mg/kg/hr to 0.5 mg/kg/hr; TITRATION DOSE: Per Physician Order; TITRATION FREQUENCY: Per Physician Order; CONTACT PRESCRIBER: Discuss needs for vital sign monitoring with ordering physician; *Individual cases may deviate from parameters and would require an order from the provider documented in the patient record

Multimodal Pain: GOAL EFFECT: Patient pain/functional goal; INITIAL RATE 0.1 mg/kg/hr; DOSE RANGE: 0.1 mg/kg/hr to 0.25 mg/kg/hr; TITRATION DOSE: Per Physician Order; TITRATION FREQUENCY: Per Physician Order; CONTACT PRESCRIBER: HR<60 BPM or >120 BPM, SBP>180 mmHg or <90 mmHg; for delirium, confusion, hallucinations or nystagmus; Respiratory Rate <10 BPM, Oxygen Saturation <90%; *Individual cases may deviate from parameters and would require an order from the provider documented in the patient record



Comprehensive Standards

	Concentration	IV Set Builds	Bolus from Infusion?	Continuous Normalized Rate	Titration Comments
EPINEPHrine	20 mcg/mL	EPINEPHrine 5 mg/250 mL NaCl 0.9%	NO	mcg/kg/min	GOAL EFFECT: SBP greater than 90 mmHg or MAP greater than 65 mmHg* INITIAL RATE 0.01 mcg/kg/min* USUAL DOSE RANGE: 0.01 - 0.5 mcg/kg/min * TITRATION DOSE: 0.01 mcg/kg/min * TITRATION FREQUENCY: 5 min * CONTACT PRESCRIBER: HR less than 60 or greater than 120 BPM; SBP less than 80 or greater than 140 mmHg * Individual cases may deviate from parameters and would require an order from the provider
EPINEPHrine	40 mcg/mL	EPINEPHrine 10 mg/250 mL NaCl 0.9%	NO	mcg/kg/min	documented in the patient record

EPINEPHrine infusion	✓ <u>A</u> ccept
GOAL EFFECT: SBP GREATER than 90 mmHg or MAP GREATER than 65 mmHg INITIAL RATE: 0.01 mcg/kg/min USUAL DOSE RANGE: 0.01 - 0.5 mcg/kg/min TITRATION DOSE: 0.01 mcg/kg/min TITRATION FREQUENCY: 5 min CONTACT PRESCRIBER: -HR LESS than 60 BPM -HR GREATER than 120 BPM -SBP LESS than 80 mmHg -SBP GREATER than 140 mmHg	
Individual cases may require deviation from parameters (with prescriber approval)	
 EPINEPHrine HCl in 0.9 % NaCl 5 mg/250 mL infusion (\$\$\$) 0.01-0.5 mcg/kg/min × 60.8 kg (1.824-91.2 mL/hr, rounded to 1.82-91.2 mL/hr), intravenous, Continuous, Starting today at 1700 GOAL EFFECT: SBP GREATER than 90 mmHg or MAP GREATER than 65 mmHg INITIAL RATE: 0.01 mcg/kg/min USUAL DOSE RANGE; 0.01 - 0.5 mcg/kg/min TITRATION DOSE: 0.01 mcg/kg/min TITRATION FREQUENCY: 5 min CONTACT PRESCRIBER: -HR LESS than 60 BPM -HR GREATER than 120 BPM -SBP LESS than 80 mmHg -SBP GREATER than 140 mmHg *Individual cases may require deviation from parameters (with prescriber approval)* 	
Next Required	✓ <u>A</u> ccept







Who Moved My Cheese?

Standard Concentration Process & Change Management

- P&T Process
- Adoption with conversion to system standard EMR
 - Changes site specific
 - Conversion processes performed near go-live
- Pump library development to assist with conversion



https://www.washingtonpost.com/entertainment/books/who-moved-my-cheese-became-a-monster-hit-twenty-years-later-were-stillwondering-why/2018/09/05/89a6e9aa-ac5e-11e8-8a0c-70b618c98d3c_story.html Accessed 6-15-21



Bolus from Infusion



Which of the following is an ISMP recommended pump functionality for performing bolus from infusion?

- a. Separate dosing limits for bolus dose
- b. Automatically switches back to continuous infusion rate after bolus is administered
- c. Both A and B
- d. None of the above

Institute for Safe Medication Practices (ISMP). ISMP Guidelines for Optimizing Safe Implementation and Use of Smart Infusion Pumps; 2020



Bolus From Infusion

Workflow Options

- Bolus doses can be programmed into the smart infusion pump to be given from the continuous infusion bag "bolus from infusion"
- Bolus doses can be drawn up from a separate vial and administered independently from the infusion

Standardization Opportunity

- Variation exists in smart pump manufacturers, models and functionality across Trinity Health
- EMR functionality made documentation of bolus from infusion cumbersome to use in some legacy systems
- Both the variation in smart pumps and electronic health record challenges has resulted in variation in pump library settings including utilization of "bolus from infusion" features
- Standardizing the use of bolus from infusion will allow standardization of electronic health record order set build and pump library settings across Trinity



Bolus from Infusion Decision

- Trinity Health sites will ensure that smart infusion pumps meet ISMP safety criteria when procuring new equipment
- The standard in Trinity Health will be to use bolus from infusion for the following defined list of adult, pediatric and neonatal continuous infusions if infusion pumps meet ISMP criteria for safely performing this function:
 - <u>Requires nurse Double Check</u>: Bivalirudin, cisatracurium, heparin, fentanyl, hydromorphone, insulin regular, 3% Saline, ketamine, magnesium sulfate for OB (20 gm/500 mL), morphine, rocuronium, vecuronium
 - <u>Does not require nurse double check:</u> Aminocarproic acid (CT Surgery bolus), amiodarone, bumetanide, Calcium Chloride infusion for renal replacement therapies, diltiazem, esmolol, furosemide, IV fluid bolus without added potassium (i.e. NS, D5W, LR, D10) less 500 mL, labetalol, lidocaine, lorazepam, midazolam, milrinone, octreotide, pentobarbital, procainamide
- Sites with non-ISMP compliant smart infusion pumps should work with supply chain to develop a plan and timeline to sunset and move to compliant smart infusion pumps.







Who Moved My Cheese?

Bolus from Infusion Process & Change Management

- P&T Process
- Nursing engagement
 - Presented at Nursing Clinical Leadership Group
- Sites continue with current practice
- Adoption with conversion to system standard EMR
 - Changes site specific
 - Conversion processes performed near go-live
- Pump library development to assist with conversion



https://www.washingtonpost.com/entertainment/books/who-moved-my-cheese-became-a-monster-hit-twenty-years-later-were-stillwondering-why/2018/09/05/89a6e9aa-ac5e-11e8-8a0c-70b618c98d3c_story.html Accessed 6-15-21



Large Volume Infusion Pump Library



Pump Library Standardization

Comprehensive Standard Initiative

• Pump library reflects standards established

Challenges

- Server hosting
 - Local v Central
 - Different library capacities depending on pump manufacturer and software
- EMR Variation
 - Significant variation in IV set builds by site
- Pump variation
 - Manufacturer and Model
 - Sunset dating
- Standardized Care Areas
 - Unit configurations
 - Reporting functionality



Care Areas—Infusion Pump Library

Standard Care Areas – Adult Hospital

- Adult
- Labor and Delivery
- Infant (10 kg or less)
- Pediatrics (10.1 kg to 49.9 kg)
- NICU
- Anesthesia
- Chemo/Infusion Center
- Training





Who Moved My Cheese?

Pump Library Process & Change Management

- Workgroup process
 - Pump implementation workgroup engagement of multidisciplinary group review
- Nursing engagement
 - Nurse educators at each site
- Adoption with conversion to system standard EMR
 - Tool provided as reference
 - Depending on server hosting, can choose local CCA



https://www.washingtonpost.com/entertainment/books/who-moved-my-cheese-became-a-monster-hit-twenty-years-later-were-stillwondering-why/2018/09/05/89a6e9aa-ac5e-11e8-8a0c-70b618c98d3c_story.html Accessed 6-15-21


Assessment Question #1 of 4

Which of the following is a strategy for engaging key stakeholders in pharmacy medication cycle change management?

- a. System level Pharmacy and Therapeutics Committee initiatives
- b. Establish a health system level medication formulary
- c. Clinical Framework with engaged clinician leaders
- d. All of the above



Which of the following are examples of a change management initiative and an appropriate strategy for monitoring success of that initiative?

- a. Implement a bolus from infusion standard and ask nurses how they give these boluses after a month
- b. Establish IV set compounding standards via the Pharmacy and Therapeutics committee and monitor purchases of non-formulary premix medications
- c. Construct a system standard for insulin delivery and poll pharmacy directors on compliance
- d. All of the above



Assessment Question #3 of 4

Which of the following represent key compliance opportunities within in the pharmaceutical supply chain?

- a. Insulin delivery
- b. IV set compounding and premade purchases
- c. Medication class reviews
- d. All of the above



Assessment Question #4 of 4

A method to reduce variation in clinical procurement practices would be_____

- a. Establishing a system level medication formulary
- b. Implementing IV set compounding standards
- c. Ensuring electronic medical record build matches formulary and system standards
- d. All of the above



Summary & Conclusions

- 1. Change is hard
- 2. Standardization of operational and clinical processes across a large health system requires engaging key stakeholders
- 3. Success is possible with an armamentarium of tools
- 4. Standardization increases safety, reduces unnecessary variation and provides cost savings



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Thank you...

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