Policy & Procedure

Policy Title:	Infusion Pump Data Set (Drug Library) Development and Maintenance	
Applies To:	Medical Staff, Nursing, Pharmacy, Clinical Engineering	
Location Applicability:	Children's Health Program, Women's & Newborn Health Program, Department of Pharmacy, Department of Clinical Engineering	
Approved: August 31, 2023	**Effective:** September 5, 2023	**Next Review:** September 2027
Sponsor:	Clinical Manager of Pharmacy	
Approval Authority:	Director of Pharmacy	
Number: 1.50	**Manual:** Medication Management	

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PURPOSE

This policy provides direction on the management of Data Sets and Dose Error Reduction Systems (DERS) for the following pumps:

- Large volume pumps – B Braun Infusomat®
- Syringe Pumps – B Braun Perfusor®

- Computerized ambulatory drug delivery (CADD®) pumps
- CADD Solis® (Patient Controlled Analgesia for Pediatrics and Women's Health)
- CADD Solis VIP® (Pediatric Advanced Care Team & Pediatric Oncology)

POLICY STATEMENTS

The IWK Health Centre, specifically the Pharmacy Department, maintains an infusion pump data set (drug library) consisting of a compilation of medications that are administered parenterally via continuous infusion or intermittent infusions infused over a duration of longer than 5 minutes.

Formulary medications, as well as commonly prescribed *Special Access Programme Drugs* and non-formulary medications, are included in the data set where appropriate and when requested by the care team.

Requests for entries intended for routes other than parenteral are approved on an individual basis, weighing risks and benefits. The intended route must be clearly indicated in the drug long name or clinical alert.

Standard concentrations and medication specific infusion limits must be approved for use within the Health Centre and reflect current clinical judgement and evidence.

- Standard concentrations are determined based on current clinical practice and chosen based on a goal of avoiding infusion rates below 0.05 mL/hour and avoiding continuous infusions that run above 10 mL/hour. The concentrations must be isotonic or if not, be clearly identified as hypotonic or hypertonic.

- The number of concentrations for each medication is limited to no more than two for a specific patient care area, with an exception made for Pediatric Advanced Care Team and the Pediatric OR
    - Avoidance of tenfold differences in concentrations for the same medication in the same care area *(example: morphine 1 mg/mL and morphine 10 mg/mL)* is the goal. Exceptions shall be only on the approval of D&T Committee.

Soft limits are set for all medications and soft and hard limits are set for high alert medications.

- The limits set for soft and hard limits shall be tested regularly by the SACA pharmacist to ensure that they are functioning appropriately.
- Limits shall be reviewed regularly to ensure consistency with current practice and as drug monographs and clinical order sets are revised.

Pharmacy emails reminders for large volume and syringe pump data set additions or changes to clinical staff quarterly (Refer to Procedure – Large Volume and Syringe Pump Data Sets). Updates are completed quarterly or more frequently, as required.

Ambulatory Pump Protocol changes or additions are initiated by contacting the Systems Analyst – Clinical Applications Pharmacist or a care area's Clinical Pharmacist.

PROCEDURE

Large Volume and Syringe Pump Data Sets

1. Nursing or Pharmacy identify that an addition or change to the Data set is required.
2. Refer to Appendix B: Guidelines for Completing Application for Additions / Changes to Drug Library Data Set for Large Volume or Syringe Pumps.
3. The Drug Library Addition/Change Form for Large Volume and Syringe Pumps, (available via Pulse under Pharmacy – General Drug Information) must be completed by Medical Staff/Clinical Manager/Clinical Leader/Clinical Nurse Specialist/Clinical Leader of Development or Pharmacist .
    - 3.1.1. The level of urgency for each request must be indicated.
    - 3.1.2. A list of references must be included for each submission.
    - 3.1.3. The request must be forwarded to the Clinical Pharmacist of that care area or, for care areas that don't have a designated Clinical Pharmacist, the request must be forwarded directly to the Systems Analyst – Clinical Applications (SACA) Pharmacist and IWK Drug Information.
4. Clinical Pharmacists and SACA Pharmacist must:
    - 4.1. Thoroughly review requests and the references provided.
    - 4.2. Confer with the care team to determine that the request is clinically significant and a change in prescribing or a change of practice is required
        - 4.2.4. If the request is a valid request but will have no impact on prescribing practice or nursing practice and deemed of minimal clinical significance, the change can be approved by the Pharmacy Director.
    - 4.3. Liaise with the Chief(s) of Anaesthesia (Pediatric / Women) prior to any changes affecting medications in the anaesthesia data sets.
5. Once changes or additions have been approved, SACA pharmacist will update data set.
    - 5.1. All changes or additions to the drug library are double checked by another pharmacist and/or Health Care Professional prior to upload.
    - 5.2. A detailed list of changes will be shared with Clinical Leaders, Clinical Leaders of Development, Pharmacists, Chief(s) of Anesthesia, to be distributed to front line staff who use the large volume and syringe pumps.
6. New drug library file will be shared with Clinical Engineering and prepared to be uploaded wirelessly to the pumps on a predetermined date.

REFERENCES

Accreditation Canada. (2021). *Medication management standards*. Page 40
https://pulse.iwk.nshealth.ca/subsites/page/view/?id=18976

Building a Smart Infusion System Drug Library (2017)
https://www.ismp.org/resources/building-smart-infusion-library

Forms

Application for Additions / Changes to Drug Library Data Set or see Appendix C

APPENDICES

APPENDIX A: Definitions

Dose Error Reduction System (DERS)	Electronic infusion pumps manufactured with drug libraries containing drug name, Soft and Hard infusion limits; they are designed to prevent errors in solution and mediation delivery, often called “smart pumps”
Drug Library	A comprehensive list of medications and fluids that are to be delivered using the infusion pump. This library includes any dose, volume, or rate limitations that are programmed into the software
Parenteral	Administered by any route other than the alimentary canal, such as the intravenous, subcutaneous, intramuscular, or mucosal route (Infusion Nurse Society, 2016).
Health Care Professional (HCP)	A member of a regulated health care profession, or a student of a recognized health profession program
Continuous infusion	The infusion of a medication over several hours (continuous drip) to days. It involves hanging the IV solution as a primary infusion
Intermittent infusion	A medication dose meant to be delivered over a relatively short period.
Hard Limit	A dose limit programmed into a pump; the pump cannot be programmed lower than a lower “Hard” limit or higher than a upper “Hard” limit.
Soft Limit	A dose limit programmed into a pump; the pump will alert the user that the dose is unusually low (or high); however, the user can still proceed

APPENDIX B: Guidelines for Completing Application for Additions / Changes to Drug Library Data Set for Large Volume or Syringe Pumps

- If there is more than one indication or patient population for a medication AND the dosing is unique to each indication/patient population, complete a separate form for each.
- If there is more than one standard concentration requested for a medication, indicate what concentration should be available to which patient population.
- **Loading Dose** can be the first dose of an intermittent medication that is then followed by lower maintenance doses OR it can be a dose that is administered prior to a continuous infusion. Loading doses that are administered over 60 minutes or under can be programmed using the loading dose or bolus settings. Loading doses that are administered over more than 60 minutes will be programmed using Dose Over Time mode.
- **Bolus settings** encompass loading doses that are administered in 60 minutes or under as well as breakthrough/procedural doses. Indicate the time frame of the bolus where possible.
- **Soft minimum** refers to the lowest dose below which the pump will display the dosing range or rate and ask if you would like to continue. It does not stop the user from proceeding but will record that a dose lower than recommended has been given and the pump will indicate during infusion that the dose is below the limits set within the drug library.
- **Standard Starting Dose** should be the dose/rate that you would like the pump to default to when the drug library entry is chosen.
- **Soft Maximum Dose** is the high end of the dosing range for the medication. It does not stop the user from proceeding but will record that a dose higher than recommended has been given and the pump will indicate during infusion that the dose is above the limits set within the data set.
- **Hard Limit** is set to stop the user from infusing outside the set parameters. The pump will alert the user that the maximum has been reached and it will NOT let the user enter data outside the set limits. **Hard MAXIMUM Limits are required for all HIGH ALERT MEDICATIONS.** Be sure that if you indicate a Hard Limit that a dose/rate above the Hard Limit should **NEVER** be administered.
- **Continuous Infusion** can be used for infusions that are ordered with a dose rate or intermittent infusions that have a maximum dose rate (example mg/kg/min).
- **Intermittent Dose** should be used for medications that are ordered as a total dose administered over a certain time i.e. 10 mg/kg over 30 minutes. If you are unsure of the recommended administration times, leave the Administration Time fields blank.

APPENDIX C: Application for Additions / Changes to Drug Library Data Set for Large Volume or Syringe Pumps

Care Team		Date submitted			
Submitted by		Title		Phone #	
Clinical Leader Approval (Signature required)					
Priority of Request	☐ Urgent (ASAP)	☐ Routine (Next scheduled update)			
Type of Request	☐ Addition	☐ Change /Edit			
Other Care Areas Possibly Affected?		Have they been consulted?	Yes / No		
Reason for Request					
Categories involved (may check more than one category for a single entry)	☐ All standard meds ☐ Antidotes ☐ Anti-infectives ☐ Blood Products	☐ Fluid and nutrition ☐ Chemo and related ☐ Pain Team ☐ Pediatric Advanced Care Team	☐ Hypnotics (Ped-OR only) ☐ Vaso actives (Ped-OR only) ☐ Fluid Restricted		
Generic Name					
Indication					
Standard Concentration(s)					
Is this a pharmacy prepared admixture?	Yes / No	If Yes, have the Pharmacy Sterile Services been consulted around stabilities and compatibilities?	Yes / No		
Clinical Notes or Alerts Max: 3 lines (18-24 characters each line)					

■ Loading Dose

Dosing units	Hard Minimum	Soft Minimum	Standard Dose	Soft Maximum	Hard Maximum
	N/A				
Administration Time	Shortest Duration (Hard Limit)	Shortest Duration (Soft Limit)	Standard Duration	Longest Duration (Soft Limit)	Longest Duration (Hard Limit)
Indicate Hours or Minutes					

■ Continuous Infusion

Dosing Units		Hard Minimum	Soft Minimum	Standard	Soft Maximum	Hard Maximum
		N/A				
Allow Bolus?	Bolus Units	Hard Minimum	Soft Minimum	Standard	Soft Maximum	Hard Maximum
Yes / No						

Bolus should be administered over _____ minutes.

■ Intermittent Dose

Dosing units	Hard Minimum	Soft Minimum	Standard	Soft Maximum	Hard Maximum
Administration Time	Shortest Duration (Hard Limit)	Shortest Duration (Soft Limit)	Standard Duration	Longest Duration (Soft Limit)	Longest Duration (Hard Limit)
Indicate hours or minutes					

Application for Additions / Changes to Drug Library Data Set for Large Volume or Syringe Pumps (cont'd)

References	**Attach hard copies of all indicated references.	Edition &/or Year
☐	Up-To-Date/Lexicomp	
☐	Pediatric Injectable Drugs (Teddy Bear)	
☐	ASHP Handbook of Injectable Drugs (powered by Trissels)	
☐	Micromedex/Neofax	
☐	British National Formulary (BNF)	
☐	Product monograph	
☐	In house protocol **(Requires physician approval and signature, attached)**	
☐	Other (specify):	

Additional Notes:

This Section For Pharmacy Use Only:	
Received by:	Date received:
Draft Reviewed by: / /	Final review date:
Drug Library version:	Date of scheduled Drug Library Update:
Pump setting confirmed by:	/ /
Date Update Completed:	Final Update Version:

IWK/NSH Policy Documents Being Replaced

(Please List)

Version History

(To Be Completed by the Policy Office)

Major Revisions (e.g. Standard 4 year review)	Minor Revisions (e.g. spelling correction, wording changes, etc.)