FAILURE MODE EFFECT ANALYSIS (FMEA) PROJECT ON ADMINISTRATION OF CONCENTRATED KCL INFUSION IN CICU

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INTRODUCTION

Intensivists, Cardio-thoracic surgeons and Cardiologists all agree that correction of hypokalemia is crucial in critically ill children. Therefore, in the Children Intensive Care Unit (CICU), concentrated KCL 1:1 dilution is commonly prescribed for cardiac patients for correction of low serum potassium. When fluid intake is restricted, small volume infusions are necessary and KCL will be diluted with minimal diluent. However, any medication error related to concentrated KCL infusion can be potentially fatal. This concern was raised to the Patient Safety Council. A taskforce was formed to review this process and to look for solutions to prevent fatal errors related to administration of concentrated KCL.

OBJECTIVE

The objective was to minimize the chance of any loopholes within the KCL administration process which might potentially compromise patient safety. We also aim to quantify the risk involved in control failure so as to enable us to provide the correct type of damage control.

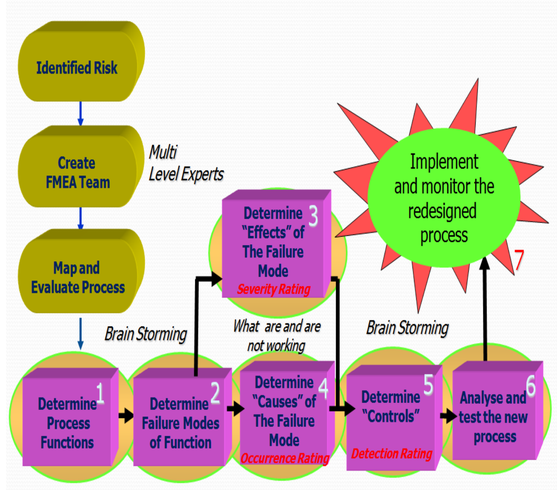
METHODOLOGY: FAILURE MODE EFFECT ANALYSIS (FMEA)

FMEA is a prospective risk assessment tool designed to promote patient safety by mapping out the process of care, follows by identifying potential failures that may occur in this process, in order to understand how and why errors or failures occur (Shebl et al, 2012). Using the FMEA model, the group analysed the entire administration process of IV KCL. Potential failure modes that might impact on patient safety in the various sub-processes were identified as requiring improvements. The group then listed the appropriate safety measures that was necessary to prevent potential medication errors pertaining to these processes.

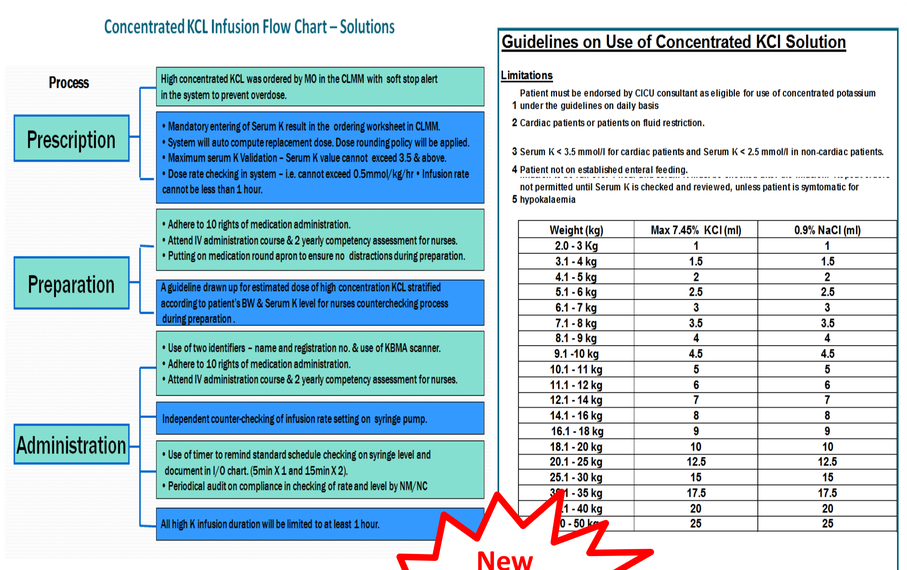
CONCLUSION

The new process allows CICU doctors to place high-risk KCL 7.45% (1mmol/mL) Injection (1 in 1 dilution) order with automatic calculated dosage and dose rate checking function in place. With the development of safety guidelines on the use of concentrated KCL, we have achieved our goal of eliminating the potential risks that can result in fatal error in this group of patients.

FMEA Methodology



New Processes



New Guidelines

START

Potential Risk Identified: medication error arising from concentrated KCL can be FATAL

Worksheet

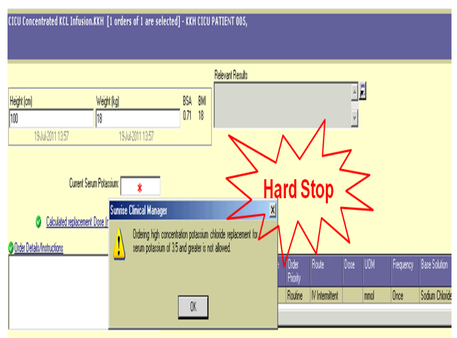
Failure Mode and Effect Analysis Worksheet

Processes & Subprocesses	Potential Failure Modes	Potential Causes	Potential Effects	Severity	Probability	Detection	RPN	Actions to Reduce Failure Mode
Prescription	• Wrong dose	1. Knowledge deficit 2. Wrong selection from drug list. 3. Not timely verified by pharmacist.	• Overdose or underdose • ADR • Lethal cardiac arrhythmias • Death	10	3	5	150	• Approval by senior doctor. • Timely verification by pharmacist before admin. • High concentration potassium infusion to be incorporate into CICU order set in CLMM • There will be soft stop using a maximum infusion rate of 0.4 mmol/kg/hr
	• Prescribe on wrong patient	1. Similar patient name. 2. Patient identifier not clear 3. Name does not appear on screen when ordering med.	• Wrong patient receives inappropriate drugs and dose. • ADR •Allergic response. • Death	9	3	4	108	• Continue to practise strictly using 2 patient's identifiers.
	• Inappropriate entering of order in CLMM	1. Lack of knowledge. 2. Verbal orders 3. Unclear order 4. Unfamiliar with ordering system. 5. Order into wrong patient	• Arrhythmias • Seizures • Death	9	3	4	108	• Medical officer to enter correct Serum K result in CLMM order entry worksheet (OEW) to allow system to auto compute replacement dose. • Adequate Physician coverage and communication channels.

Failure Mode and Effect Analysis Worksheet

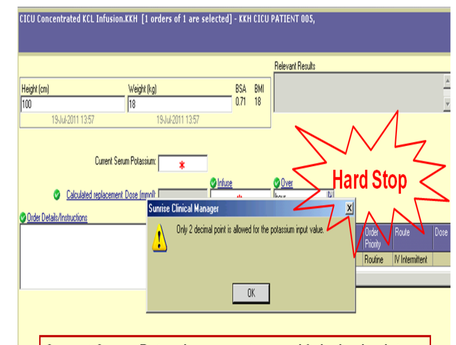
	Potential Failure Modes	Potential Causes	Potential Effects	Severity	Probability	Detection	RPN	Actions to Reduce Failure Mode
Preparation of medications	• Wrong drug, • wrong dose, • wrong diluent. •inadequate check	1. Failure of double checking 2. Knowledge deficit 3. Environment factors: distractions.	• Overdose or underdose • ADR • Lethal cardiac arrhythmias • Death	9	3	3	81	• Adhere to 10 rights of medication administration. • Ensure independent counter-checking. • Refer to reference chart. • In-house orientation program on drug dilution for nurses.
Admin. of drugs	•Wrong pump rate set	1. Knowledge deficit in the use of the pump. 2. Distraction during pump rate setting.	• Overdose or underdose • Lethal cardiac arrhythmias • Death	10	3	6	180	• Independent counterchecking of rate setting on syringe pumps. • Use timer to remind staff the standard interval check on syringe level at 5min X 1 and 15min X 2 and document in I/O chart.
	•Wrong patient	1. Failure to identify correct patient. 2. Ordered on wrong patient eMAR.	• ADR • Death	10	3	6	180	• Use of two identifiers. • Adhere to 10 rights of medication administration. • Use of KBMA scanner to identify correct patient.

Maximum Serum Potassium Validation



Serum Potassium value cannot exceed 3.5mmol and above

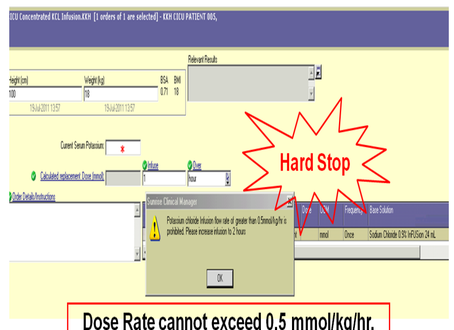
Serum Potassium Entry Validation



Current Serum Potassium cannot exceed 3 decimal points.

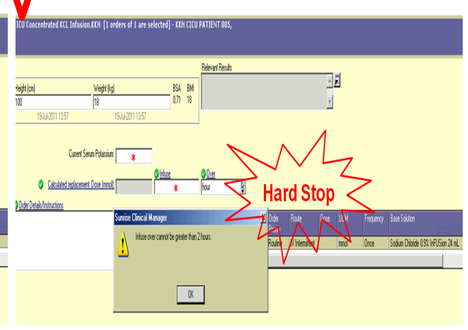
Ordering Safety Check

Dose Rate Checking



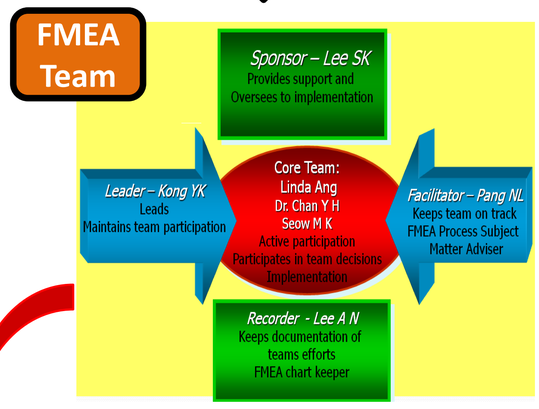
Dose Rate cannot exceed 0.5 mmol/kg/hr.
To proceed, doctor need to increase Infusion to 2 hours.

Infuse Over Validation



Infuse duration cannot be < 1 hour

Process Function & Failure Mode



Concentrated KCL Infusion Flow Chart

Processes	Sub-process Control Gap	Potential Failure
Prescription	High concentrated KCL was ordered by MO in the CLMM without soft stop alert to prevent overdose.	Wrong dose, Wrong patient, Inappropriate entering of order in CLMM
	No guidelines and criteria reference chart for doctors to refer when ordering.	
	• No entry of Serum K result in CLMM ordering worksheet. • No max. serum K validation prior to prescribing. • No dose & infusion rate checking during prescribing.	
Preparation	• Adhere to 10 rights of medication administration. • Attend IV administration course & 2 yearly competency assessment for nurses. • Putting on medication round apron to ensure no distractions during preparation.	Wrong drug, Wrong dose, Wrong diluent, Inadequate check
	No guideline on maximum infusion rate and criteria for staff to refer during preparation.	
	• Use of two identifiers – name and registration no. • Adhere to 10 rights of medication administration. • Attend IV administration course & 2 yearly competency assessment for nurses.	
Administration	No counter-checking of infusion rate setting on syringe pump.	Wrong pump rate set, Wrong patient
	No periodical checking of syringe level during infusion	
	No limitation to infusing duration.	

Scoring

FMEA Scoring - Severity

	Severity of Effect	Rating
Extreme	Catastrophic effect; death	10
	Major Injury; required life support intervention	9
High	Fairly major injury; required additional stay in ICU monitoring	8
	Moderate injury; required additional stay in High Dependency	7
Moderate	Minor injury; required additional monitoring	6
	No patient harm but required monitoring for possible side effect	5
	No patient harm but affect treatment regime	4
Low	No patient harm, resume normal treatment regime	3
	No patient harm	2
None	No effect	1

FMEA Scoring - Detection

	Likelihood that control will detect failure	Rating
Very Low	No known control(s) available to detect failure mode.	10
Low	Controls have a remote chance of detecting the failure.	9
		8
Moderate	Controls may detect the existence of a failure	7
		6
		5
High	Controls have a good chance of detecting the existence of a failure	4
		3
Very High	The process automatically detects failure	2
	Controls will almost certainly detect the existence of a failure.	1

FMEA Scoring - Occurence

	Likelihood of Occurrence	Rating
Very High	Failure is almost certain to occur	10
	Failure is almost inevitable	9
High	Process is not in statistical control	8
	Similar processes have experienced problems	7
Moderate	Process is in statistical control but with isolated failures	6
	Previous processes have experienced occasional failure	5
	Previous processes have experienced out-of-control conditions	4
Low	Process is in statistical control	3
	Process is in statistical control. Only isolated failures associated with almost identical processes	2
Remote	Failure is unlikely. No known failures associated Identical processes	1

Frequent checking during administration

Date	Checking of KCL infusion syringe level 5 min X 1 and 15 min X 2 post commencement of infusion & documentation in IO chart.				Signature / Name	Follow-up Action by HOD /Remark
	5 min X 1		15 min X 2			
	YES	NO	YES	NO		

RESULTS

With no wrong dose errors reported under the old system, we have no data to support our claim of quality and safety improvement. However, looking at errors that have been reported in the literature and reviewing our own processes before and after the change, we felt that we have taken a giant step in reducing our risk of concentrated KCL administration errors in CICU.

References
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