

Neonatal Total Parenteral Nutrition: Initiative and implementation of standardized formulation in Saudi Arabia

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Abstract

The total parental nutrition considered as high alert medications for neonates population and others. Several medications safety institutions and international with national accreditation organization recommended setting prevention measure of medical error events. The new medications safety project initiative was neonates standardized parental nutrition formulation. The formulation contained all requirements of American Parenteral and Enteral Nutrition and European Parental and Enteral Nutrition standard. Also, to the United State Pharmacopeia 797 stranded. The formulation is suitable for neonates with formal renal and hepatic functions with common neonate's requirements Parenteral Nutrition in Saudi Arabia. The new initiative's project may implement through explored project management tools with close measurements of performance indicators outcome. The neonate's standardized formulation of parental nutrition new programs at Ministry of Health hospitals in the Kingdom of Saudi Arabia with Gulf and Middle East counties.

Keywords: Adult total parenteral nutrition, formulation, Pharmacy, Ministry of Health, Saudi Arabia.

INTRODUCTION

The national total parental nutrition at Ministry of health hospitals founded in 2013 as part of pharmacy strategic plan in Kingdom of Saudi Arabia [1-2]. The plan consisted of several parts including the standardized formulation of neonatal Total Parenteral nutrition (TPN). Some hospitals in Saudi Arabia with an emphasis in the capital Riyadh designed new formulation of standardized co traction of neonates. The projects were part of medication safety and quality management in the pharmacy practice [3]. Several counties with various publication showed the benefit of high alert TPN components in improving clinical patient outcomes and reducing cost burden in the healthcare system [4-7]. The neonatal standardized concentration formulation system does not exist at more than 50% at Ministry of Health hospitals in Saudi Arabia and Europe countries [8-9]. Also, the most TPN related problems prevented by the pharmacist was dosing errors and omission of drug therapy. The new

initiatives projected to improve clinical outcomes and prevent nutritional related mistakes during prescribing, preparations and administration of total parental nutrition with neonates in Kingdom of Saudi Arabia. The author is not familiar with any published literature at in Saudi Arabia, and Gulf countries or the Middle East described the standardized formulation of neonatal Total Parenteral nutrition.

NEONATAL TOTAL PARENTERAL NUTRITION STANDARDIZED FORMULATION IN SAUDI ARABIA

It is standardized formulation of total parental nutrition for neonates. The formulation is derived from current literature and American Society for Parenteral and Enteral Nutrition (ASPEN) guidelines for neonates 's population with an average of one-kilogram body weight [5,10]. The formulation consisted of several parts demographic data of the patients, total macronutrients, total micronutrients, the calculated total calories and non-protein calories over nitrogen ratio,

and pharmacy preparation part. The formulation consisted of first three consequence days of starting TPN through central line administration. Each day contained one-third of the quantities of the total fluid requirements, total calories, carbohydrates, protein, electrolyte, trace elements and multivitamins as explored in appendix 1, 2 and 3.

SWOT ANALYSIS

The SWOT (Strength, Weakness, Opportunities, and Threats) analysis used for the project. The strength of the neonates formulations including all information of starting total parental nutrition is available, dosing of TPN component is available, prevent mistakes in writing TPN neonates orders are available. The weak points are including the formulation is not individualized for all patients, it cannot apply for several disease renal or hepatic failure. It does not contain the TPN administration instruction. The opportunity that is including it is straightforward to form to convert them as computerized, and physician order entry; it can calculate all TPN statistical information. The threat point is including the physician or pharmacist not used the formulation.

Implementations steps of Neonatal Total Parenteral Nutrition Standardized Formulation

The pharmacy department Organize Consultation Committee from expert pharmacist especially from Intravenous admixture and total parental nutrition services and clinical pharmacists inside the pharmacy department. The committee should extensively review then approve the standardized formulation of neonatal total parenteral nutrition. The head of the committee will contact with the surgical and medical department for final revisions of the drafting and approval. The head of pharmacy services will submit the final draft of the formulation to Pharmacy and Therapeutic committee for review and approval. The head of the committee will arrange with Computer department to make as electronic order forms. The pharmacy education coordinator arranges with all department including nursing, surgical and medical department to Educate and train the medical staff of using the formulation with additional to pharmacy staff. The pharmacy quality management will set up the key performance indicators (KPI) to measure the impact of the project. All pharmacy concern team including TPN Preparation, clinical pharmacist will Collect the KPI of the project retrospectively in the past three to six months, and then collect the data prospectively in the coming months. The head of the committee will contact with musing and surgical departments to start with one surgical department as the pilot trial. The pharmacist will Review the pilot trial and correct the form according to the pharmacy consultation committee. The team will expand to all surgical department and medical department. Review and alter the shape accordingly

through committee. The head of the committee will Expand to all hospital department including neonates critical care, Review and adjust the formulation accordingly. The pharmacy quality management coordinator will measure the impact of the project by comparing the KPI before and after starting the project. The head of the committee will analyze the results and review by the consultation committee. The head of pharmacy will submit the final report to Pharmacy and therapeutic committee for final touch and comments. The consultation team will Review the last comments on the project, update it accordingly, and continue the project for the next year.

CONCLUSION

The neonatal Parenteral Nutrition standardized formulation is new initiative project to prevent attributable medications errors related issues, improve patient clinical outcome and avoid the economic burden on the healthcare system in Kingdom of Saudi Arabia.

Acknowledgment: None

Conflict of Interest: None

Abbreviation Used: TPN: Total parental nutrition, ASPEN: American Society for Parenteral and Enteral Nutrition, SWOT: Strength, Weakness, Opportunities, and Threats. KPI: Key Performance Indicators

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TOTAL PARENTERAL NUTRITION NEONATAL FORM				
PRESCRIBER TO COMPLETE NOS. 1 UP TO 8				
NO. 1	Date: / / 200... Day(s) of TPN: (Begin with 1) <input type="checkbox"/> Central <input type="checkbox"/> Peripheral			
NO.2	Dextrose: 3 gm/day (start with 5-7mg/kg/min & increases up to 13-16mg/kg/min)			
NO.3	Amino Acids: 0.5 gm/day (start with 1gm/kg/day, increment with 0.5 gm/kg/day, up to 3gm/kg/day)- Monitor BUN			
NO.4	Fat 20% : 0.5 gm /day (start 1gm/kg/day, increment with 0.5gm/kg/day, up to 3gm/kg/day, 2 gm/kg/day in mildly jaundiced pts)- Monitor TGs			
NO.5	Total volume of TPN: 100 mL/day Total volume of FAT: 2.5 mL/day Total volume of IVF: mL/day (Type of IVF:) Total volume of PO: mL/day Total fluid intake: mL/day			
NO.6	TPN rate: mL/hr FAT rate: mL/hr over hrs (max. rate: 0.11 gm/kg/hr)			
NO. 7				
Additives	Prescribed amt/day	Maintenance Range	Notes	FOR PHARMACY ONLY
Sodium	1	2-4 Mmol/kg/day		<ul style="list-style-type: none"> • Base Solution: _____ ml Dextrose 50% _____ % _____ ml Amino A 10 _____ % _____ ml Sterile Water
Potassium	1	2-4 Mmol/kg/day		
Calcium	0.5	0.7-1.4 Mmol/kg/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	
Magnesium	0.15	0.15-0.25 Mmol/kg/day		
Phosphate		0.5-1.5 Mmol/kg/day	Na PO4(1mL= 3 Mmol PO4 & 4 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	<ul style="list-style-type: none"> • Additives: _____ mL Sodium _____ _____ mL Potassium _____ _____ mL Calcium _____ _____ mL Magnesium So4 _____ _____ mL Potassium _____ _____ mL _____ _____ mL _____
Chloride	2	2-4 Mmol/kg/day		
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	
Fat soluble vit.	1.5	Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day (Vitalipid N Infant®)*	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	
Water soluble vit.	1.5	>10kg: 10 mL/day <10kg:1mL/kg (Solutiv ®N)*	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	
Trace Elements	0.1	0.1 mL/kg of Multitrace™. 4 Pediatric*	-Contains: zinc, cooper, manganese & chromium -Caution: in renal dysf., biliary tract obstruction	
Insulin, regular		As needed		
Heparin		0.5-1 unit/ each mL of TPN	USED FOR PERIPHERAL TPN, Check PT/PTT, avoid in case of HIT or thrombocytopenia	
Hydrocortisone		5mg/ each liter of TPN	USED FOR PERIPHERAL TPN and to prevent thrombophlebitis	
				<ul style="list-style-type: none"> • Fat: Fat 20% _____ % Volume 2.5 _____ mL
* Check with IV Room for brand changing				
Prescriber name & sign.		Bleep of prescriber		RPh name
Prescriber ID		Nurse name		Technician

Appendix 2

KINGDOM OF SAUDI ARABIA
MINISTRY OF HEALTH
PHARMACEUTICAL SERVICES
IV ADMIXTURE AND TPN DEPARTMENT

**TOTAL PARENTERAL NUTRITION
NEONATAL FORM**

PRESCRIBER TO COMPLETE NOS. 1 UP TO 8

NO. 1	Date: / / 200... Day(s) of TPN: 2nd (Begin with 1) <input type="checkbox"/> Central <input type="checkbox"/> Peripheral
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NO.2	Dextrose: 6 gm/day (start with 5-7mg/kg/min & increases up to 13-16mg/kg/min)
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NO.3	Amino Acids: 1 gm/day (start with 1gm/kg/day, increment with 0.5 gm/kg/day, up to 3gm/kg/day)- Monitor BUN
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NO.4	Fat 20% : 1 gm /day (start 1gm/kg/day, increment with 0.5gm/kg/day, up to 3gm/kg/day, 2 gm/kg/day in mildly jaundiced pts)- Monitor TGs
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NO.5	Total volume of TPN: 125 mL/day Total volume of FAT: 5 mL/day Total volume of IVF: mL/day (Type of IVF:) Total volume of PO: mL/day Total fluid intake: mL/day
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NO.6	TPN rate: mL/hr FAT rate: mL/hr over hrs (max. rate: 0.11 gm/kg/hr)
-------------	--

NO. 7

Additives	Prescribed amt/day	Maintenance Range	Notes	FOR PHARMACY ONLY
Sodium	1.5	2-4 Mmol/kg/day		<ul style="list-style-type: none"> Base Solution: _12_ ml Dextrose _50%_ % _10_ ml Amino A _10_ % _____ ml Sterile Water Additives: _3_ mL Sodium _____ _0.75_ mL Potassium _____ _4_ mL Calcium _____ _____ mL Magnesium So4 _____ mL Potassium _____ _____ mL _____ mL Fat: Fat _20%_ % Volume _5_ mL
Potassium	1.5	2-4 Mmol/kg/day		
Calcium	1	0.7-1.4 Mmol/kg/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	
Magnesium	0.2	0.15-0.25 Mmol/kg/day		
Phosphate		0.5-1.5 Mmol/kg/day	Na PO4(1mL= 3 Mmol PO4 & 4 Mmol Na) KPO4(1mL= 3 Mmol PO4 & 4.4 Mmol Na)	
Chloride	3	2-4 Mmol/kg/day		
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	
Fat soluble vit.	1.5	Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day (Vitalipid N Infant*)*	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	
Water soluble vit.	1.5	>10kg: 10 mL/day <10kg:1mL/kg (Soluvit TMN)*	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	
Trace Elements	0.1	0.1 mL/kg of Multitrace™. 4 Pediatric*	-Contains: zinc, cooper, manganese & chromium -Caution: in renal dysf., biliary tract obstruction	
Insulin, regular		As needed		
Heparin		0.5-1 unit/ each mL of TPN	USED FOR PERIPHERAL TPN, Check PT/PTT, avoid in case of HIT or thrombocytopenia	
Hydrocortisone		5mg/ each liter of TPN	USED FOR PERIPHERAL TPN and to prevent thrombophlebitis	

* Check with IV Room for brand changing

Prescriber name & sign.	Bleep of prescriber	RPh name
Prescriber ID	Nurse name	Technician

Name: _____ **N2**
Hospital No: _____
Nationality: _____
Treating physician: _____
(TPN Formula for Neonates 1 kg Non-diabetic normal kidney & liver function)

Ward		Age	
Wt.	1 kg	Height	cm
Diagnosis			
TPN indication(s)			

NO. 8	Daily Calories intake
Dextrose (gm/day) × 3.4 = (6) × 3.4 = 20.2 Kcal/day	
Fat (gm/day) × 10 = (1) × 10 = 10 Kcal/day	
Total = 30.2 Kcal /day	
Total/Wt = 30.2 Kcal /kg/day	
Non Protein Calories/ Nitrogen : 190 / 1 (Recommended ratio = 150 / 1)	

Appendix 3

KINGDOM OF SAUDI ARABIA
MINISTRY OF HEALTH
PHARMACEUTICAL SERVICES
IV ADMIXTURE AND TPN DEPARTMENT

**TOTAL PARENTERAL NUTRITION
NEONATAL FORM**

PRESCRIBER TO COMPLETE NOS. 1 UP TO 8

NO. 1	Date: / / 200...
	Day(s) of TPN: 3rd (Begin with 1)
	<input type="checkbox"/> Central <input type="checkbox"/> Peripheral

NO.2	Dextrose: 9 gm/day (start with 5-7mg/kg/min & increases up to 13-16mg/kg/min)
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NO.3	Amino Acids: 1.5 gm/day (start with 1gm/kg/day, increment with 0.5 gm/kg/day, up to 3gm/kg/day)- Monitor BUN
-------------	---

NO.4	Fat 20% : 1.5 gm /day (start 1gm/kg/day, increment with 0.5gm/kg/day, up to 3gm/kg/day, 2 gm/kg/day in mildly jaundiced pts)- Monitor TGs
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NO.5	Total volume of TPN: 150 mL/day Total volume of FAT: 7.5 mL/day Total volume of IVF: mL/day (Type of IVF:) Total volume of PO: mL/day Total fluid intake: mL/day
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NO.6	TPN rate: mL/hr FAT rate: mL/hr over hrs (max. rate: 0.11 gm/kg/hr)
-------------	--

NO. 7

Additives	Prescribed amt/day	Maintenance Range	Notes	FOR PHARMACY ONLY
Sodium	2	2-4 Mmol/kg/day		<ul style="list-style-type: none"> Base Solution: 18 ml Dextrose 50% % 15 ml Amino A 10 % ml Sterile Water
Potassium	2	2-4 Mmol/kg/day		
Calcium	1.5	0.7-1.4 Mmol/kg/day	Give as Calcium Gluconate PHARMACY: check Ca/PO4 compatibility	
Magnesium	0.25	0.15-0.25 Mmol/kg/day		
Phosphate		0.5-1.5 Mmol/kg/day	Na PO4(1mL= 3 Mmol PO4 & 4 Mmol Na) KPO4(1 mL= 3 Mmol PO4 & 4.4 Mmol Na)	<ul style="list-style-type: none"> Additives: 4 mL Sodium 1 mL Potassium 6.5 mL Calcium mL Magnesium So4 mL Potassium mL mL
Chloride	3	2-4 Mmol/kg/day		
Acetate		As needed	Acetate and Cl should be in 1:1, unless it is indicated	
Fat soluble vit.	1.5	Neonates, <2.5kg: 4 mL/kg Children, >2.5kg:10 mL/day (Vitalipid N Infant®)*	-Max dose=10 mL/day (1mL contains 20 mcg Vit K1) - Use this brand for age of ≤ 11 years.	
Water soluble vit.	1.5	>10kg: 10 mL/day <10kg: 1mL/kg (Solvivit™)*	Contains: Vit. B1, B2, nicotinamide, B6, pantothenic acid, C, biotin, folic acid & B12	
Trace Elements	0.1	0.1 mL/kg of Multitrac™. 4 Pediatric*	-Contains: zinc, cooper, manganese & chromium -Caution: in renal dysf., biliary tract obstruction	
Insulin, regular		As needed		
Heparin		0.5-1 unit/ each mL of TPN	USED FOR PERIPHERAL TPN, Check PT/PTT, avoid in case of HIT or thrombocytopenia	
Hydrocortisone		5mg/ each liter of TPN	USED FOR PERIPHERAL TPN and to prevent thrombophlebitis	
				<ul style="list-style-type: none"> Fat: Fat 20% % Volume 7.5 mL

* Check with IV Room for brand changing

Prescriber name & sign.		Bleep of prescriber		RPh name	
Prescriber ID		Nurse name		Technician	

Name: _____ **N3**
Hospital No: _____
Nationality: _____
Treating physician: _____
(TPN Formula for Neonates 1 kg Non-diabetic normal kidney & liver function) **N3**

Ward		Age	
Wt.	1 kg	Height	cm
Diagnosis			
TPN indication(s)			

NO. 8	Daily Calories intake
Dextrose (gm/day) × 3.4 = (9) × 3.4 = 30.6 Kcal/day	
Fat (gm/day) × 10 = (1.5) × 10 = 15 Kcal/day	
Total = 45.6 Kcal /day	
Total/Wt = 45.6 Kcal /kg/day	
Non Protein Calories/ Nitrogen : 190 / 1 (Recommended ratio = 150 / 1)	