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

REFERENCES


Table 1: Total Parenteral Nutrition Formulation

<table>
<thead>
<tr>
<th>Additives</th>
<th>Prescribed amount/day</th>
<th>Maintenance Range</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>1</td>
<td>2-4 mEq/kg/day</td>
<td></td>
</tr>
<tr>
<td>Potassium</td>
<td>1</td>
<td>2-4 mEq/kg/day</td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>0.7-1.4 mEq/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium</td>
<td>0.15</td>
<td>0.15-0.25 mEq/kg/day</td>
<td>Give as Calcium Gluconate PARENTERAL, check Ca/Po4 compatibility</td>
</tr>
<tr>
<td>Phosphate</td>
<td>0.5-1.5 mEq/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chloride</td>
<td>2</td>
<td>2-4 mEq/kg/day</td>
<td></td>
</tr>
<tr>
<td>Acetate</td>
<td>As needed</td>
<td>Acetate and Cl should be in 1:1, unless it is indicated</td>
<td></td>
</tr>
<tr>
<td>Fat soluble vitamins</td>
<td>1.5</td>
<td>Neutrals, &gt;2.5 mg/kg or 10 mg/day (oral)</td>
<td>- Max dose=10 mL/day (1mL contains 50 mg Vit K1) - Use this brand for age &lt;11 years</td>
</tr>
<tr>
<td>Water soluble vitamins</td>
<td>1.5</td>
<td>&gt;10 mg/kg 10 mL/bottle</td>
<td>Contains: Vit. B1, B2, niacinamide, B6, pantethenic acid, C, biotin, folic acid &amp; B12</td>
</tr>
<tr>
<td>Trace Elements</td>
<td>0.1</td>
<td>0.1 mL/kg of dry solids</td>
<td>Contains: zinc, copper, magnesium &amp; chromium</td>
</tr>
<tr>
<td>Insulin, regular</td>
<td>As needed</td>
<td></td>
<td>Calcium</td>
</tr>
<tr>
<td>Heparin</td>
<td>0.5-1 unit/mL of TPN</td>
<td>USED FOR PERIPHERAL TPN, Check PE/PIT, avoid in case of HIT or thromboembolism</td>
<td></td>
</tr>
<tr>
<td>Hydrocortisone</td>
<td>5mg/each liter of TPN</td>
<td>USED FOR PERIPHERAL TPN and to prevent thrombophlebitis</td>
<td></td>
</tr>
</tbody>
</table>

Additives: 2 mL Sodium, 0.5 mL. Magnesium, 3 mL. Calcium, 3 mL. Potassium

** Base Solution:**
- _6_mL Dextrose _50%_ %
- _5_mL Amino A _10%_ %
- _5_mL Sterile Water

** Additives:**
- _2_mL Sodium
- _0.5_mL Magnesium
- _3_mL Calcium
- _3_mL Potassium

** Fat:**
- Fat _20%_ %
- Volume _5_mL

Ward | Age | Wt. | Height cm | Diagnosis | TPN indication(s) | Daily Calories intake |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1 kg</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Non Protein Calories/ Nitrogen:
- Recommended ratio = 150 / 1

Name: [N1]
Hospital No: ____________________________
Nationality: ____________________________
Treatng physician: ____________________________

(TPN Formula for Neonates 1 kg Non-diabetic normal kidney & liver function)
### TOTAL PARENTERAL NUTRITION NEONATAL FORM

**PRESCRIBER TO COMPLETE NOs. 1 UP TO 8**

<table>
<thead>
<tr>
<th>NO.</th>
<th>Date: / / 200... Day(s) of TPN: 2nd (Begin with 1)</th>
<th>Central</th>
<th>Peripherally</th>
</tr>
</thead>
</table>

**NO. 2**

Dextrose: 6 gm/day (Start with 5-7mg/kg/min & increases up to 13-16mg/kg/min)

**NO. 3**

Amino Acids: 1 gm/day (Start with 1gm/kg/day, increment 0.5 gm/kg/day, up to 3gm/kg/day) - Monitor BUN

**NO. 4**

Fat 20%: 1 gm/day (Start 1gm/kg/day, increment 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: 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

**NO. 6**

TPN rate: ml/hr

FAT rate: ml/hr over hrs (max rate: 0.11 gm/kg/hr)

---

### NO. 7

<table>
<thead>
<tr>
<th>Additives</th>
<th>Prescribed amount/day</th>
<th>Maintenance Range</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>1.5</td>
<td>2.4 Mmol/kg/day</td>
<td></td>
</tr>
<tr>
<td>Potassium</td>
<td>1.5</td>
<td>2.4 Mmol/kg/day</td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>1</td>
<td>0.7-1.4 Mmol/kg/day</td>
<td></td>
</tr>
<tr>
<td>Magnesium</td>
<td>0.2</td>
<td>0.15-0.25 Mmol/kg/day</td>
<td></td>
</tr>
<tr>
<td>Phosphate</td>
<td>0.5-1.5 Mmol/kg/day</td>
<td>Na PO4 (1ml = 3 Mmol PO4 &amp; 4 Mmol Na) KPO3 (1ml = 3 Mmol PO3 &amp; 4.4 Mmol Na)</td>
<td></td>
</tr>
<tr>
<td>Chloride</td>
<td>3</td>
<td>2.4 Mmol/kg/day</td>
<td></td>
</tr>
<tr>
<td>Acetate</td>
<td>As needed</td>
<td>Acetate and Cl should be in 1:1, unless it is indicated</td>
<td></td>
</tr>
<tr>
<td>Fat soluble vit.</td>
<td>1.5</td>
<td>Neonates, ≤2.5kg: 4 mL/kg Children, ≥2.5kg: 10 mL/kg (oral use per 10 mL/11 years)</td>
<td>Max dose 10 mL/day (1ml. contains 20 mcg Vit K1) Use this brand for age of &lt; 11 years</td>
</tr>
<tr>
<td>Water soluble vit.</td>
<td>1.5</td>
<td>&gt;10kg: 10 mL/day ≤10kg: 10 mL/kg Solvent 100%</td>
<td>Contains: Vit B1, B2, niacinamide, B6, pantotethenic acid, C, biotin, folic acid &amp; B12</td>
</tr>
<tr>
<td>Trace Elements</td>
<td>0.1</td>
<td>0.1 mL/kg of Multivit. 4 Pediatric</td>
<td>Contains: iron, copper, magnesium &amp; chromium</td>
</tr>
<tr>
<td>Insulin, regular</td>
<td>As needed</td>
<td>As needed</td>
<td></td>
</tr>
<tr>
<td>Heparin</td>
<td>0.5-1 unit/mL of TPN</td>
<td>USED FOR PERIPHERAL TPN, Check PT/PTT, avoid in case of HIT or thrombocytopenia</td>
<td></td>
</tr>
<tr>
<td>Hydrocortisone</td>
<td>5mg/each liter of TPN</td>
<td>USED FOR PERIPHERAL TPN and to prevent thrombophlebitis</td>
<td></td>
</tr>
</tbody>
</table>

---

**FOR PHARMACY ONLY**

- **Base Solution:**
  - _12_ mL Dextrose 50% %
  - _10_ mL Amino A
  - _3_ ml Sterile Water

- **Additives:**
  - _3_ mL Sodium
  - _0.75_ mL Potassium
  - _4_ mL Calcium
  - _3_ mL Magnesium S04
  - _1__ mL Potassium
  - _1__ mL
  - _1__ mL

- **Fat:**
  - Fat 20%
  - Volume 5 mL

---

### Ward

<table>
<thead>
<tr>
<th>Age</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Wt.</th>
<th>1 kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>cm</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
</tr>
<tr>
<td>TPN indication(s)</td>
<td></td>
</tr>
</tbody>
</table>

---

<table>
<thead>
<tr>
<th>NO. 8</th>
<th>Daily Calories intake</th>
</tr>
</thead>
</table>

Dextrose (gm/day) = (6) x 3.4 = 20.2 Kcal/day

Fat (gm/day) = 10 = (1) x 10 = 10 Kcal/day

Total = 30.2 Kcal/day

Total = 30.2 Kcal/kg/day

Non Protein Calories/ Nitrogen: 190 / 1

(Recommended ratio = 150 / 1)
**TOTAL PARENTERAL NUTRITION NEONATAL FORM**

**PRESCRIBER TO COMPLETE NO. 1 UP TO 8**

**NO. 1**
- Date: / / 200...
- Day(s) of TPN: 3rd (Begin with 1)
  - Central
  - Peripheral

**NO. 2**
- Dextrose: 9 gm/day (start with 5-7mg/kg/min & increases up to 13-16mg/kg/min)

**NO. 3**
- Amino Acids: 1.5 gm/day (start with 1mg/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

**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

**NO. 6**
- TPN rate: mL/hr
- FAT rate: mL/hr over hrs (max. rate: 0.11 gm/kg/hr)

---

**NO. 7**

<table>
<thead>
<tr>
<th>Additives</th>
<th>Prescribed unit/day</th>
<th>Maintenance Range</th>
<th>Notes</th>
<th>FOR PHARMACY ONLY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>2</td>
<td>2-4 Mmole/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potassium</td>
<td>2</td>
<td>2-4 Mmole/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td>1.5</td>
<td>0.7-1.4 Mmole/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium</td>
<td>0.25</td>
<td>0.15-0.25 Mmole/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phosphate</td>
<td>0.5-1.5 Mmole/kg/day</td>
<td></td>
<td>Nu PO4 (1mL=3 Mmole PO4 &amp; 4 Mmole Na) RPO4 (1mL=3 Mmole PO4 &amp; 4.4 Mmole Na)</td>
<td></td>
</tr>
<tr>
<td>Chloride</td>
<td>3</td>
<td>2-4 Mmole/kg/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acetate</td>
<td>As needed</td>
<td></td>
<td>Acetate and Cl should be in 1:1, unless it is indicated</td>
<td></td>
</tr>
</tbody>
</table>
| Fat soluble vit.   | 1.5                | Neumonat 2.25g: 4 mL/kg Child/Neumonat 2.25g: 10 mL/kg (Vitapul N infant)* | Max dose: 10 mL/day (1mL contains 20 mcg Vit K1) Use this brand for age of ≤11 years | • **Base Solution:**
|                    |                    |                   |                   | _18 _ml Dextrose 50%_%
|                    |                    |                   |                   | _15 _ml Amino A 10%
|                    |                    |                   |                   | _ml Sterile Water
| Water soluble vit. | 1.5                | >100g: 10 mL/day   | Contains: Vit B1, B2, niacinamide, B6, pantothenic acid, C, biotin, folie acid & B12 | • **Additives:**
|                    |                    | >100g: 1 mL/kg    |                   | _4 _ml Sodium
|                    |                    | (Solubly P N)†    |                   | _1 _ml Potassium
| Trace Elements     | 0.1                | 0.1 mL/kg of      | Contains: zinc, copper, manganese & chromium | _6.5 _ml Calcium
|                    |                    | Mestranol 4% & Podiatric* |                   | _ml Magnesium So4
| Insulin, regular   | As needed          |                   | Caution: in renal dys, bilary tract obstruction | _ml Potassium
| Heparin            | 0.5-1 unit/each mL of TPN | USED FOR PERIPHERAL TPN, Check PT/PTT, avoid in case of HIT or thrombocytopenia |                  | • **Fat:**
| Hydrocortisone     | 5mg/each liter of TPN | USED FOR PERIPHERAL TPN and to prevent thrombosis |                  | Fat 20% _%

* Check with IV Room for brand changing

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Name: ___________
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**

**NO. 8**

<table>
<thead>
<tr>
<th>Daily Calories intake</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Dextrose (gm/day) x 3.4 = (9) x 3.4 = 30.6 Kcal/day</td>
<td></td>
</tr>
<tr>
<td>Fat (gm/day) x 10 = (1.5) x 10 = 15 Kcal/day</td>
<td></td>
</tr>
<tr>
<td>Total = 45.6 Kcal/day</td>
<td></td>
</tr>
<tr>
<td>Total Wt = 45.6 Kcal/kg/day</td>
<td></td>
</tr>
<tr>
<td>Non Protein Calories/ Nitrogen : 190 / 1 (Recommended ratio = 150 / 1)</td>
<td></td>
</tr>
</tbody>
</table>

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