KK WOMEN'S AND CHILDREN'S HOSPITAL

Work Instruction

Title/Description:	THERAPEUTIC PLASMA EXCHANGE VIA PRISMAFLEX MACHINE		
Department:	Children's Intensive Care Unit Effective Date: 01-04-2017		01-04-2017
Procedure No:	61220-3008 Revision No.: -		-
Revision Date:	-	Approved by:	Chief Nurse
Applies To:	All healthcare members	Approved by:	Office Harde

Amendments:		
⊗ New document	content change	□Reviewed with no changes on DD/MM/YY

1.0 PURPOSE

To provide guidelines on therapeutic plasma exchange (TPE) for children in CICU.

2.0 POLICY

This policy defines the indications of TPE, the procedures involving the operation of the Prismaflex machine as well as the care and monitoring of patients on TPE

The decision to initiate TPE is made by the patient's primary physician, based on the indication outlined in 4.0.

- 2.1 Doctor in charge (Associate Consultant and above) in CICU prescribes the TPE order.
- 2.2 Staff Nurse in CICU will prepare, prime, initiate and terminate the therapy via the PRISMAFLEX machine using the filtration method.
- 2.3 CICU trained Nurse will perform nursing management and monitor patient on TPE
- 2.4 Each patient is assessed, on an individual basis, to the need for starting TPE, the number and frequency of sessions, by the intensive care physician with the primary doctor

3.0 DEFINITION

TPE is an extracorporeal blood purification technique designed for the removal of large molecular weight substances from the plasma. TPE involves the separation of plasma from the whole blood and the infusion of a replacement fluid in equal volume to the plasma that is removed. The replacement fluid can be in the form of 5% albumin, a mixture of albumin and 0.9% saline or fresh frozen plasma (FFP). With TPE, red blood cells, white blood cells and platelets are returned to the patient

- 3.1 The mechanisms by which TPE exerts its therapeutic effects are summarized as:
 - 3.1.1 Removal of abnormal circulating factor
 - Antibody (anti-GBM disease, Myasthenia gravis, Guillain-Barré syndrome)
 - Monoclonal protein (Waldenstrom's macroglobulinemia, myeloma protein)
 - Circulating immune complexes (cryoglobulinemia, SLE)
 - 3.1.2 Replenishment of specific plasma factor
 - thrombotic thrombocytopenic purpura

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- 3.1.3 Other effects on immune system
 - Improvement in function of reticuloendothelial system
 - Removal of inflammatory mediators (cytokines, complement
 - Shift in antibody-to-antigen to more soluble forms of immune complexes
 - Stimulation of lymphocyte clones to enhance cytotoxic therapy
- 3.2 TPE have been shown in the following diseases to be of clinical benefit either as a primary or an adjunctive therapy
 - Goodpasture's syndrome (anti-GBM disease)
 - Thrombotic thrombocytopenic purpura syndrome
 - Hemolytic uremic
 - Cryoglobulinemia
 - Hyperviscosity syndrome
 - Myeloma cast nephropathy
 - Acute demyelinating polyneuropathy (Guillain-Barré)
 - Chronic inflammatory demyelinating polyneuropathy
 - Homozygous familial hypercholesterolemia (selective adsorption)
 - Myasthenia gravis crisis
 - Chronic inflammatory demyelinating polyneuropathy
 - Eaton-Lambert myasthenic syndrome
 - Post-transfusion purpura
 - Refsum's disease
 - Cutaneous lymphoma (photopheresis
 - HIV-related syndromes (polyneuropathy, hyperviscosity, thrombotic
 - Coagulation factor inhibitors
 - Paraproteinemic peripheral neuropathy
 - Systemic vasculitis associated with ANCA
 - Rapidly progressive glomerulonephritis (without anti-GBM)
 - SLE (in particular SLE cerebritis
 - ABO-incompatible marrow transplant
 - Bullous pemphigoid
 - Pemphigus vulgaris
 - Immune thrombocytopenia (Staph protein A adsorption)
 - Hemolytic disease of the newborn

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3.3 EQUIPMENT

PRISMAFLEX machine

The dialysis machines which are able to perform the TPE using the 'TPE' function The method uses plasma separation by a highly permeable membrane, TPE 1000 or TPE2000.

Plasma Membrane

	TPE1000	TPE2000
Membrane	polypropylene	polypropylene
Surface area	0.15m ²	0.35m ²
Wall thickness	150 µm	150 µm

Extracorporeal volume

	Blood line (ml)	Plasma filter (ml)
TPE1000	71	23
TPE2000	125	41

Filter size

	TPE 1000	TPE 2000
Patient's weight	<30kg	>30kg

Blood flow rate (Qb)

TPE1000: minimum blood flow rate 50ml/min, maximum blood flow rate TPE2000: minimum blood flow rate 100ml/min, maximum blood flow rate

	Maximum Plasma filtration rate (ml/min)	
QB (ml/min)	TPE1000	TPE2000
50	16	-
100	29	42
180	49	-
200	-	79
250	-	97

3.4 SITE OF VASCULAR ACCESS

Vascular access is achieved by the insertion of a dual-lumen catheter into the femoral,i nternal jugular or subclavian veins. Femoral catheter is preferred especially with the use of citrate anticoagulation, as the return of hypocalaemic blood near the AV node may cause arrhythmia when using the neck veins

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3.5 SIZE OF VASCULAR ACCESS

As the minimum blood flow of 50ml/min is required, a catheter size of <7F may not support this flow. The table below serves as a guide to the size of catheter based on body weight.

Weight of patient (Kg)	Cannula size	
Neonate	Single lumen 5F	
	Double lumen 6.5F	
3-6	Double lumen 6.5F, 7F	
6-15	Double lumen 8F, 9F	
15-30	Double lumen 10F	
>30	Double lumen 11.5F	
	Triple lumen 12F	

3.6 VOLUME EXCHANGE

3.6.1 Estimated plasma volume (EPV)

The estimated plasma volume (EPV) can be calculated by the following formulae:

$$EPV (ml) = (1 - HCT) (b + cW)$$

W = lean body weight,

b = 1530 for males, 864 for females and

c = 41 for males, 47.2 for females

HCT = haematocrit

3.6.2 **OR**

EPV (ml) = [TBV (ml/kg) \times body weight (kg)] \times (1 – HCT)

Where TBV is the total blood volume

TBV = 80ml/kg in children <10kg

TBV = 70ml/kg in children ≥10kg

3.6.3 Relationship of plasma exchange volume with removal

PV Equivalents	Substance removed (%)	Post-exchange level (%)	
0.5	35	65	
1.0	55	45	
1.5	65	35	
2.0	70	30	

The kinetics of immunoglobulin removal by TPE follows an exponential relationship $C_t = \text{Coe}^{\text{-x}}$

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where Co is the initial concentration of the substance, Ct is its concentration at time t, and x depends on the volume of distribution of the substance in question

The first plasma volume removed results in 55% of the substance removed and the second plasma volume removed results in an additional 15% of the substance being removed. At most two, plasma volumes are removed at each TPE session

Rate of plasma removal should be <50 ml/kg/hr

3.7 REPLACEMENT FLUIDS

Colloidal agents are used as replacement solutions in the form of 5% albumin, 5% albumin with normal saline or FFP.

Albumin	5% Albumin	
FFP	Indications for FFP as partial or total replacement fluid:	
	TTP/HUS	
	 preexisting coagulopathy, 	
	 risk of cholinesterase depletion 	
	 when the fibrinogen level is low (< 1.25g/L) 	

If albumin is used as the replacement fluid:

Plasmapheresis depletes coagulation factors, replacement by albumin and crystalloids alone may deplete these factors. If there are multiple sessions over short periods, FFP should be used for the last 1/3 of replacement fluid.

3.8 COMPLICATIONS

Complications can classified as:

- 3.8.1 Related to vascular access
 - Hematoma
 - Pneumothorax
 - Retroperitoneal bleed

3.8.2 Related to the procedure

- Hypotension from externalization of blood in the extracorporeal circuit
- Hypotension due to decreased intravascular oncotic pressure
- Bleeding from reduction in plasma levels of coagulation factors
- Oedema formation due to decreased intravascular oncotic pressure
- Loss of cellular elements (platelets)
- Ethylene oxide-associated hypersensitivity reactions

3.83 Related to anticoagulation

- Bleeding, especially with heparin
- Hypocalcaemic symptoms (with citrate)
- Metabolic alkalosis (with citrate)

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3.9 STRATEGIES TO PREVENT SOME OF THESE COMPLICATIONS

3.9.1 Hypocalcaemia

10% calcium chloride (0.2ml/kg, max 10ml) or 10% calcium gluconate (0.5ml/kg, max 20ml) is given as an infusion for the duration of the therapy, with iCa monitoring.

3.9.2 Hypokalaemia

Serum potassium should be monitored and replaced accordingly.

3.9.3 Sensitivity to replacement fluids

If there is transfusion reactions to FFP that is used as replacement fluid, evaluation should be done as per the hospital's transfusion reaction protocol If repeated TPE sessions are required for sensitized individuals, premedications may be considered:

- PO prednisone or IV hydrocortisone (for patients who are nil by mouth),
- PO or IV diphenhydramine
- PO or IV ephedrine
- 3.9.4 Infections post TPE

IVIG (0.5g/kg) infusion can be considered for infections, especially if the serum IgG level is low

3.9.5 ACE Inhibitor

Consider stopping ACE inhibitors 24-48 hours prior to TPE

3.9.6 Haemorrhage

Use FFP as replacement fluid at the last 1/3 of session

3.10 MONITORING

- 3.10.1 Vital signs
 - Continuous heart rate and ECG monitor
 - Hourly BP

3.10.2 Blood investigations

Baseline (before TPE)	PT/PTT, ACT, FBC, Blood gas, ME/iCa
During TPE	ACT, ME/iCa
(hourly)	
Post TPE	PT/PTT, ACT, FBC, ME/iCa

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3.10.3 Monitor for haemolysis

Monitor access transmembrane pressure (TMPa). TMP should not be higher than the maximum shown in the table for the blood flow rate

Qb	Maximum TMPa (mmHg)		
(ml/min)	TPE1000 TPE2000		
50	100	-	
100	140	120	
180	190	-	
200	-	171	
250	-	193	

Check effluent for red or pink tinge

4.0 PROCEDURE

4.1 Informed consent (TPE info sheet)
Informed consent must be obtained before the implementation of TPE- Refer to Annex 1

4.2 Vascular access

Vascular access is obtained by the intensive care registrar, associate consultant or consultant by aseptic technique

4.3 TPE Order Sheet

The intensive care physician inputs the TPE orders into the TPE order sheet- Refer Annex 2

4.4 Medications

All medications should be reviewed by pharmacist. Medications that are highly protein-bound should preferably be given after plasmapheresis

4.5 Priming of TPE circuits using PRISMA machine Requisites

- TPE set (select according to patient's weight)
- Normal Saline 0.9% 1000ml soft bag x 3 or 2 (for TPE 1000)
- Injection Heparin Sodium 1000unit / ml X 10 vials
- Syringe 10mls x 1
- Syringe 50ml x 1Needle 23G x 1
- Sterile gloves
- Sterile towel
- Alcohol swabs x 5

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4.6 Steps in Procedure

- Perform medical hand washing
- Counter-check doctor's order in TPE order sheet
- Prime set when ready to start treatment
- Perform medical hand washing
- Open TPE set

4.7 On the PrismaFlex machine

- Select new or same patient
- When choosing therapy, select TPE mode
- Load the TPE set onto the machine and follow the step-by-step instructions on the screen.
- **TPE 1000** 1st prime with Normal Saline 0.9% 1000ml then add 10,000 units to 2nd Normal Saline 0.9% 1000ml priming bag
- **TPE 2000** 1st and 2nd prime with Normal Saline 0.9% 1000ml then add 10,000 units to 3rd Normal Saline 0.9% 1000ml priming bag
- Inspect the set for air and observe closely for leakage at joints and connections within the system during priming.
- Once the priming process is completed and the "self-test" is passed, the machine is ready for use.
- Press "CONTINUE" key ONLY when patient is ready to start TPE

4.8 Initiation of TPE via central venous catheter (Vascath)

- Doctor to be present before initiating treatment
- Before the procedure, the nurse should
 - Counter-check and key-in TPE order on the PrismaFlex machine with another RN.
 - Assess and record patient's haemodynamic status
 - Assess catheter site for redness and swelling
- Put on mask and apron
- Perform medical hand washing
- Prepare the following in a sterile dressing set:-
 - Don on sterile gloves
 - Pour normal saline 0.9% into the compartment
 - Pour in cleansing solution
 - Add in the syringes and gauze
- Drape catheter site with sterile towel.
- Scrub the arterial and venous lumen of the catheter access ports one at a. time with chlorhexidine 2% with alcohol 70% for one minute
- Remove catheter caps and discard
- Connect a 3ml syringe filled with 1ml 0.9%NaCl to arterial port (red).

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- Aspirate 1.5 ml of blood and spread the blood onto a piece of gauze to check for blood clots.
- Flush with 3ml of 0.9%NaCl into the catheter and clamp with positive pressure.
- Repeat steps for the venous port (blue).
- Connect arterial and venous lines and ensure that there is no air bubble within the line.
- Release all clamps on access lines.
- Initiate TPE treatment as per Doctor's order.
- Secure lines with micro-pore tape.

4.9 Set Prismaflex settings

- Patient's haematocrit
- Start blood flow 50mls/min and increase slowly to target (Inform Dr if not possible)
- Enter Total Replacement volume= Total Plasma volume to be exchanged
- Replacement flow ml/hr will be total replacement volume divided by the number of hours to complete.
- Plasma loss rate and pre blood rate should be kept at 0 ml/hr
- Anticoagulant rate to refer to TPE order sheet (Annex 2) anticoagulant guideline
- During change of Albumin bottle/FFP
 - Key bag change
 - At the Change Bags/Containers screen, key the volume at Allowed Volume Replacement- ml
 - If 500ml of 5%Albumin use, to set rate at 480ml
 - If FFP use, to set 10-20ml less than volume shown on the FFP bag

4.10 Termination of TPE from PRISMA machine

- Put on mask and apron.
- Prepare the followings in a sterile dressing set:-
 - Open and put in all stopcocks, syringes, needles and transparent dressing.
 - Perform handwashing before putting on sterile glove
 - · Prepare heparinised saline to heparin lock lumens of dialysis catheter
 - < 5kg -330 units in 10mls normal saline (33u/ml)
 - > 5kg 1000units in 10mls normal saline (100u/ml)
 - Prepare 2 x 3ml syringes with the prepared heparinsed saline
 - Filled the 2 x 5m syringes with 0.9% NaCl
 - Termination is operated through the interactive display screen
 - Standby mode is automatically entered when pressing the stop button on. the Status screen
 - Select "END TREATMENT" from the screen
 - To return blood to the patient, select "RETURN BLOOD" from the next screen
 - Follow the instruction on the "RETURN BLOOD" screen
 - Select "DISCONNECT" if end treatment without returning blood. Follow instruction
 - on the "DISCONNECT PATIENT" screen

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- Hang the bag of 0.9% NaCl at lower left corner of PrismaFlex machine
- Clamp the access port (red) of patient's catheter
- Clean connecting section with chlorhexidine 2% with alcohol 70% for one minute
- Disconnect access line from patient
- Attach 5ml syringe to access port
- Unclamp the access port
- Aspirate 2 3 mls of blood from the lumen
- Squelch aspirate on gauge to check for any blood clot
- Flush access port with 0.9% NaCl and clamp with positive pressure
- Check patient's catheter to determine the amount of heparin to be
- injected. The volume should not exceed the amount indicated on the lumen
- Heparin lock lumen and clamp port
- Cap lumen with stopcock
- Connect access line (from PrismaFlex machine) to the bag of saline using spike
- Hold down "START RETURN" key on the screen to return desired amount
- WARNING: Do not return blood if clotting is present in blood
- of blood lines or filter
- Repeat steps with the venous port (blue
- Change dressing at exit site if soiled or wet
- Secure the catheter down with micropore tape to keep it from dangling and to prevent dislodgement
- Press "CONTINUE" key on screen
- Press "UNLOAD" to unload pump segments from pump raceways from the next screen
- Clamp all lines attach to bags
- · Disconnect lines from all bags.
- Remove and discard the set, solution bags and effluent bag
- Press "TREATMENT HISTORY" to view treatment history data from the last 24 hours.
- Record post TPE parameter
- Turn off machine and power point
- Wipe the machine with medic wipe before storage

5.0 REFERENCE

Prisma Education Programme Student Handbook

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6.0 RECORDS

No.	Records	Filed By	Retention	Disposal Method
1	PrismFlex TPE flowsheet (printed)	File in	Follow DDMS	Follow DDMS
2	24 hours Fluid schedule checklist (printed)	patient records	patient record disposal	patient record disposal
3	Nursing Progress notes (printed)			
4	TPE Ordersheet (printed)			

7.0 ANNEXES

Annex 1- Informed Consent (TPE info sheet)

Annex 2- TPE Order Sheet

8.0 SPECIAL INSTRUCTION

NIL

9.0 DISTRIBUTION LIST

As per 'Applies To'

Annex 1

Children's Intensive Care Unit

THERAPEUTIC PLASMA EXCHANGE (TPE)

This leaflet serves to provide parents with some general information on therapeutic plasma exchange (TPE) for children who are critically ill at our Intensive Care Unit.

Parents are encouraged to discuss any concerns or doubts regarding their child's condition with the doctor-in-charge.

What is TPE?

Therapeutic plasma exchange (TPE) is an extracorporeal blood purification technique designed for the removal of large molecular weight substances from the plasma.

How does TPE work?

This involves the insertion of a dialysis catheter into a big vein – the femoral vein in the groin or the subclavian/ internal jugular veins in the neck.

In the intensive care unit where the patients are critically ill, TPE is done via the PRISMAFLEX machines using the membrane method, where blood is drawn from one lumen of the catheter, the plasma is "exchanged" in the circuit and blood returned to the patient in the second lumen of the catheter, over a period of between 2 to 4 hours.

What are some of the risks associated with TPE?

- 1. To prevent blood in the TPE circuit from clotting, the medications are given to the patients. This is usually done by giving a medication, heparin, which is used to prevent blood from clotting. This may also cause the patient to bleed more easily. The choice of the anticoagulant is based on the medical condition of the patient. Blood tests are done on a regular basis to ensure adequate anticoagulation and safety of the exchange.
- 2. Whenever a tube is inserted into a blood vessel there is an increased risk of infection. Signs of infection are watched for carefully and antibiotics given if needed.
- 3. During initiation, instability of the blood pressure is sometimes encountered. This will be monitored closely and the necessary action taken.
- 4. As the catheter is relatively large, it can sometimes impair the blood flow in the limb (if inserted in the leg) or clots can form in the vein.

Annex 1

Children's Intensive Care Unit

THERAPEUTIC PLASMA EXCHANGE (TPE)

How long will your child be on TPE?

Each patient is assessed, on an individual basis, the frequency and number of exchanges needed.

Care for patients under TPE

During the course of TPE treatment, the patient will be reviewed daily and his condition monitored closely by the team. Blood tests to monitor the electrolyte status and clotting time will be done regularly during the TPE session.



Annex 2

PRISMA TPE ORDER SHEET

· · · - o -	ht (kg)		Height (cm)		BSA (m ²)	
Allo	ergy		Date			
Catl	heter	1	Fr	cm	Site	
Fi	lter	TPE 1000	TPE 2000			
Me	ode	TPE				
	1 161 / 1	, • >		T		T
BI	lood flow (ml		Start at		Torgot	
TDE1000	4-5ml/kg/mi 50ml/min,ma		Start at		Target	
		ax 250ml/min				
1PE2000:	1001111/111111; 111	ax 250IIII/IIIII				
Estimated	l Plasma Vol	ume (EPV) =	ml	I		I
W b = c =	= lean body v = 1530 for ma	les, 864 for fema s, 47.2 for female	les and			
OR EF W	PV (ml) = [TB here TBV is t BV = 80ml/kg		g	1 – HCT)		
OR EF W TF TF	PV (ml) = [TB here TBV is t BV = 80ml/kg BV = 70ml/kg	V (ml/kg) × bod he total blood vo in children <10k in children >10k cchanged =	lume ggX EPV ml	1 – HCT)		
OR EF W TF TF	PV (ml) = [TB] here TBV is t BV = 80ml/kg BV = 70ml/kg lume to be ext t do more than	V (ml/kg) × bod he total blood vo in children <10k in children >10k schanged = =	lume ggX EPV ml		Albumin wi	

Indications for FFP as partial or total replacement fluid:

- TTP/HUS
- Pre-existing coagulopathy
- risk of cholinesterase depletion
- when the fibrinogen level is low (< 1.25 g/L)

Priming solution (Avoid blood prime)	TPE 1000	1 st prime: 1000ml x1 normal saline	2 nd prime: 1000 ml normal saline (Add 10,000U heparin)	
	TPE 2000	1 st and 2 nd prime: 1000 ml Normal saline 0.9%	3 rd prime: 1000 ml Normal Saline 0.9% (Add 10,000U heparin)	
Anticoagulation		DiluteU heparin in 50ml N/S (Amt= Wt(kg)x2.5Ux50) 1ml/hr=2.5U/kg/hr		
Loading Maintenance ACT Monitoring (baseline, 1hr and 4-6hrly)	Continuou Baseline A Keep ACT	Bolus 20U/kg; 8ml of 50ml syringe Continuous infusion atml/hr (start at 10U/kg/hr) Baseline ACT (normal 80-120) Keep ACT between and Increase or decrease by 10%		
Calcium infusion		IV 10% calcium gluconate (0.5ml/kg; max 20ml) ml over 2 hours		
Heparin Lock		Heparin locked lumen; < 5kg -330 units in 10mls NS(33u/ml) > 5kg - 1000units in 10mls NS (100u/ml) To lock the catheter according to manufacturer advice.		
	Baseline (1	pre-plasmapheresis) P	T/PTT	

Duration (min) = {Plasma volume x exchange (1 or 1.5times)} / Plasma filtration rate

During plasmapheresis every

Post plasmapheresis

hour

Blood investigations

ACT (Low range)

ACT (Low range) ME Q 2 hourly/PRN

ACT (Low range)

FBC ME/iCa ABG

iCa

PT/PTT

FBC ME/iCa