Supplementary material Patient Record Sheet

Name-	Age/Sex-	Date/ Time-
CR No.-	IPD No-	Group- A/B
Chief complaints-		
History of presenting illness-		
Past history-		
History of previous treatment-		
Family history-		
Personal history-		
Immunisation history-		
Drug allergy-		

Airway-	Intervention-
Breathing- RR- Retractions- Air entry- Added sounds- SpO2%-	Intervention- Ventilator requirement- yes/no ? Mode PIP PEEP RR I:E FiO2
Circulation- HR- CRT- Core to peripheral temperature-	Intervention- Group A/B IVC collapsibility index-

Pulse volume-

Blood pressure-

ECG-

JVP-

RBS-

centile	SBP	DBP	MAP
5th			
50th			
90th			
95th			
99th			

CNS examination-

GCS-

Pupils-

Active seizures-

Focal deficit-

DTRs-

Plantars-

Neck rigidity-

Anterior fontanelle (if applicable)-

Intervention-

Exposure –	Intervention-
Other system examination-	
Anthropometry- Weight- Height/length- Weight/height- Mid upper arm circumference- Head circumference- Interpretation-	
Whether included in the study? Included / Excluded	
If excluded- reason for exclusion 1. Hypovolemic shock – haemorrhagic shock, gastroenteritis, burns, trauma, diabetic ketoacidosis 2. Conditions in which volume expansion is guarded- severe anaemia eg due to sickle cell anaemia, malaria, cardiogenic shock with congestive heart failure, acute kidney injury, dengue shock 3. Severe acute malnutrition (SAM) 4. Patients who have already received some form of treatment in the form of fluid boluses or inotropes from other hospital 5. Patients who are terminally ill and will require cardiopulmonary resuscitation at presentation to PEM.	

Date/ time				
Heart rate				
CRT				
Core/peripheral temperature				
Pulse volume				
Blood pressure				
Respiratory rate				
Retractions				
Crepts				
SpO2				
JVP				
Liver span				
GCS				
Urine output				
IVC collapsibility index				
Intervention				
Supportive management				

Date/ time				
Heart rate				
CRT				
Core/peripheral temperature				
Pulse volume				
Blood pressure				
Respiratory rate				
Retractions				
Crepts				
SpO2				
JVP				
Liver span				
GCS				
Urine output				
IVC collapsibility index				
Intervention				
Supportive management				

Arterial/venous blood gas

	Initial	At 1 hour	At 6 hours	At 48 hours
pH				
pCO2				
HCO3				
pO2				
FiO2				

PaO2/FiO2				
Lactate				
Interpretation				

Renal function test

Sodium- Potassium- Chloride-	Urea- Creatinine- Uric acid-

Complete blood count

Haemoglobin- Platelet count-	TLC- DLC- ANC-

PT/INR-

Liver function test

Bilirubin- Direct/indirect- AST- ALT- ALP- GGT-	Total protein- Albumin- Globulin-

C-reactive protein-

Erythrocyte Sedimentation Rate-

Blood culture and sensitivity-

Urine routine and microscopy-

Urine culture and sensitivity-

CSF/ Pleural fluid/ Ascitic fluid/ Pus (if applicable)-

Supplementary material Consent Form

Chest X-ray-
Other investigations-
Final diagnosis-

Total number of fluid boluses required-
Any signs of fluid overload-
Total number of inotropes required-
Time of resolution of shock-
Total duration of inotropes required-
Total duration of ventilation required-
Length of hospital stay-
Final outcome – discharge/ death
Multiple organs involved-
pSOFA-L score-

Variables		Score				
		0	1	2	3	4
Respiratory	PaO_2:FiO_2 or	≥400	300-399	200-299	100-199 with respiratory support	<100 with respiratory support
	SpO2:FiO_2	≥292	100-149	50-99	20-49	<20
Coagulation	Platelet count (x10^3 /µL)	≥150	100-149	50-99	20-49	<20
Hepatic	Total bilirubin (mg/dL)	<1.2	1.2-1.9	2.0-5.9	6.0-11.9	>12.0
Cardiovascular - MAP by age group or vasoactive infusion, mmHg or µg/kg/mind	<1 mo	≥46	<46	Dopamine hydrochloride ≤ ordobutamine hydrochloride (any)	Dopamine hydrochloride >5or epinephrine ≤0.1or norepinephrine bitartrate ≤0.1	Dopamine hydrochloride >15or epinephrine >0.1or norepinephrine bitartrate >0.1
	1-11 mo	≥55	<55			
	12-23 mo	≥60	<60			
	24-59 mo	≥62	<62			
	60-143 mo	≥65	<65			
	144-216 mo	≥67	<67			
	>216 mo	≥70	<70			
Neurologic	Glassgow coms score	15	13-14	10-12	6-9	<6
Renal - Creatinine by age group	<1 mo	<0.8	0.8-0.9	1.0-1.1	1.2-1.5	≥1.6
	1-11 mo	<0.3	0.3-04	0.5-0.7	0.8-1.1	≥1.2
	12-23 mo	<0.4	0.4-0.5	0.6-1.0	1.1-1.4	≥1.5
	24-59 mo	<0.6	0.6-0.8	0.9-1.5	1.6-2.2	≥2.3
	60-143 mo	<0.7	0.7-1.0	1.1-1.7	1.8-2.5	≥2.6
	144-216 mo	<1.0	1.0-1.6	1.7-2.8	2.9-4.1	≥4.2
	>216 mo	<1.2	1.2-1.9	2.0-3.4	3.5-4.9	≥5
Lactate level		<2 mmol/	>2 mmol/lt			

Consent Form for participants Less than 18 years of age and participants above 18 years who are not in a condition to give consent (Form 3B)

Patient Information Sheet

Introduction :

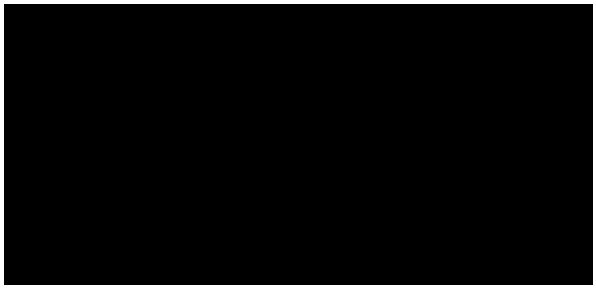
This information sheet is for the parents of children aged 1 month to 14 years in Paediatric Emergency, AIIMS Raipur presenting with septic shock. I, Dr. Swasti Keshri, Post Doctoral student of Paediatric Emergency Medicine under the guidance of Dr. (Professor) Anil Kumar Goel and co-guides, Dr. Santosh Rathia and Dr. Varun Anand are conducting a reasearch in requirement of fluid boluses in the initial resuscitation of septic shock in children. I shall explain to you the condition of the patient and the nature of illness and you are free to ask questions at any point of time. Septic shock is a serious situation where infection causes poor pulses and low blood pressure. It can damage multiple organs of the body due to poor blood supply. It also poses a risk to the life of your child despite all treatment and your child is in a serious condition.

Latest research has found out that fluid restriction in management of septic shock in children has better outcomes in terms of recovery, mortality, number of days of ventilation, number of days of hospital stay. We would conduct a research where we will straightaway start medicines to increase the blood pressure of your child without giving fluid boluses. All other medications and routine care will be provided in a timely fashion. In the meanwhile, we will closely monitor your child and also do bedside ultrasound of your child and if any need of fluid arises, we will give fluids as per the existing protocol and the need of the patient. The safety of the patient will be of utmost concern to us and we will give fluid bolus to the patient if we clinically feel the need to do so. Also, your child will be properly followed up and monitored throughout the hospital stay. Kindly go through the study details and decision for your child to participate in the research is completely at your discretion.

Title of the study- **"Initial Fluid Bolus Versus No Bolus in the resuscitation of septic shock in children. A randomised control trial."**

Principal Investigator- Dr. Swasti Keshri,

M.B.B.S, M.D. (Paediatrics), D.N.B. (Paediatrics),



Guide – **Dr. Anil Kumar Goel**

Professor and head of Department,
Department of Paediatrics,
AIIMS Raipur

Purpose of study: To analyse the outcome of initial resuscitation of septic shock without giving fluid bolus with early inotropic support.

STUDY DESIGN : Randomized Controlled Trial, open label trial

Inclusion criteria: Children of age group 1 month to 14 years presenting to paediatric emergency and fulfilling the case definition of septic shock.

Study procedure :

Once the child is enrolled in this study, the detailed history and clinical examination will be done. As your child is very sick, we will first do the needful initial resuscitation and in the meanwhile, you will be informed about the condition of your child and about the research study. Your child has equal chances to be allotted to either of the two groups : first group where medicines to increase blood pressure will be started immediately without giving fluid bolus and the second group where fluid bolus will be given first and then inotropes will be given as per the traditional management of septic shock. We have the safety of your child as our utmost concern. If participants of the first group require fluid boluses by clinical examination or by bedside ultrasound, we will do the needful.

Possible risks to your child:

Septic shock is itself a serious condition that poses life risk to your child and may cause multiple organ damage like respiratory failure, kidney injury, liver injury, brain injury. 2nd group is managed in the traditional way, so no additional risks will be imposed to your child because of enrolling in the study. 1st group which is being given inotropes directly, some patients have may fluid deficit and may require fluids later on (intention to treat) causing delay in response. But we

have the safety of your child as our utmost concern and we will not withhold fluid boluses if your child needs it. Other routine care like fluids, antibiotics, nursing care, etc will be provided to either group.

Possible benefits to your child:

The patient will be under close monitoring of the study investigator in AIIMS paediatric emergency.

The alternatives you have:

Even if you don't enroll in the study, the patient will be managed in the same lines as of 2nd group. However, if you do not wish to participate, you have the alternative of refusing participation at any point of this study.

Confidentiality of the information obtained from you:

Individual information will not be revealed.

Right to new information:

If the research team gets any new information during this research study, you will be told about that information.

For any complaint or clarification, please feel free to contact institute Ethics Committee:

Dr. P K Patra