COMPONENTS OF SYSTEMIC INFLAMMATORY RESPONSE AS PREDICTORS OF MORTALITY IN CHILDREN PRESENTING WITH FEVER AT THE EMERGENCY MEDICAL DEPARTMENT, MUHIMBILI NATIONAL HOSPITAL.

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By

Upendo George

A dissertation submitted in (partial) Fulfillment of the Requirements for the Degree of Master of Medicine (Emergency Medicine) of Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled, **components of systemic inflammatory response as predictors of mortality in children presenting with fever at emergency medical department, Muhimbili National Hospital** in (partial) fulfillment of the requirements for the degree of Master of Medicine (Emergency Medicine) of Muhimbili University of Health and Allied Sciences.



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DECLARATION

AND

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I, **Upendo George**, declare that this dissertation is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

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DEDICATION

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LIST OF ABBREVIATIONS

CBC	Complete Blood Count
CRP	C- Reactive Protein
ED	Emergency department
EMD	Emergency Medical Department
LOS	Length of stay
MNH	Muhimbili National Hospital
MODS	Multiple Organ Dysfunctional Syndrome
MUHAS	Muhimbili University of Health and Allied Sciences
PALS	Pediatric Advanced Life Support
SBI	Severe Bacteria infections
SIRS	Systemic Inflammatory Response Syndrome
WBC	White Blood Cell
WHO	World Health Organization

ABSTRACT

Introduction: Sepsis is defined as a known or suspected infection in a patient with elements of the systemic inflammatory response syndrome (SIRS). Septic patients present with a variety of clinical manifestations, but temperature dysregulation, tachycardia, tachypnea, and an abnormal white blood cell (WBC) count are considered cardinal components of SIRS. We investigated the predictive value of SIRS criteria for in-hospital mortality among febrile children under 5 years old presenting to the Emergency Department (ED) at Muhimbili National Hospital in Dar-es-Salam, Tanzania.

Methods: This was a descriptive cohort study of febrile children under 5 years, presenting to our ED. Providers prospectively completed a standardized data sheet. Outcome data was obtained from hospital records and telephone follow-up. Study data were entered into Excel (Microsoft, Redmond, WA, USA) and analyzed in SAS 9.3 (Cary, North Carolina, USA).

Results: We enrolled 105 patients between August and November 2012. The median age was 14 months, with 80% over 6 months old, and 63.8% were male. 57 (54.3%) children were referred from outside facilities. The overall mortality rate was 19%, and 90% of children who died had ≥2 SIRS criteria. Mortality in children with ≥2 SIRS criteria (in addition to fever) was significantly higher (27.7% versus 5%) than in those with 0-1 SIRS criteria, and children with fever and >2 SIRS criteria were seven times more likely to die (OR 7.05, p=0.01). 85 children were discharged from the hospital, and of the 64 (75.3%) children we were able to reach after discharge, all were alive at 14 day

telephone follow-up. 19/85 children who survived to hospital discharge were lost to follow up.

Conclusion: SIRS criteria may be helpful to predict febrile children at high risk of mortality. Further studies are needed to validate these findings in larger cohorts.

INTRODUCTION AND LITERATURE REVIEW:

Fever is among the most common chief complaints in paediatric patients, accounting for approximately 20 – 30% of emergency department (ED) visits and is one of several inflammatory signs that may result from systemic infection(1)(2). Sepsis is defined as the presence of two or more criteria for systemic inflammatory response syndrome (SIRS) accompanied by known or suspected infection. SIRS signs include abnormal temperature, tachycardia, tachypnoea, and abnormal white blood cell count(3)(4). Clinical syndromes range from occult bacteremia, SIRS, sepsis, severe sepsis, septic shock and finally multiple organ dysfunction syndrome (MODS) and death (3)(4). Septic shock is defined as severe sepsis plus hypotension despite fluid resuscitation. Septic shock is further divided into warm and cold shock with mortality in cold shock being 50% of the presenting population(4). Males tend to have a higher mortality rate when compared to females in a similar age group(5)(6), despite that no statistical significance was found when analysis was done based on sex(7)(8), and overall mortality varies substantially by age, with the highest rate among neonates(4)(6).

Several studies done on the epidemiology of sepsis show high mortality rate in septic individuals(7)(9)(10), with highest mortality in severe sepsis and MODS(7)(8)(11)(12). SIRS was found to be prevalent in hospital admissions with 82% of all admissions(12). Having organ dysfunction is associated with increased chances of death(7)(8)(9)(12), with multiple organs dysfunction carries higher mortality compared to single organ dysfunction(11)(12).

Age significantly influences the epidemiology of severe sepsis worldwide with the perinatal population accounting for a vast majority of cases(3). According to a study

done at MNH on maternal and neonatal infections, 23% of pregnant women and 8.9% of neonates were colonized with Group B streptococcus, one of the main bacteria causing sepsis in the neonatal age group(13). All isolates in this study were found to be sensitive to vancomycin and ampicillin while showing resistance to clindamycin, erythromycin and penicillin G. Another study done in a tertiary teaching hospital in South India showed significantly higher mortality in septic neonates who were culture positive(14). In addition, this study identified other peri-natal factors associated with culture positivity and sepsis, including premature rupture of membranes, low APGAR score, and mechanical ventilation.

Preliminary studies in Tanzania have also documented that among children with a diagnosis of sepsis who were at least 60 days of age, streptococcus pneumonia, non-typhoidal salmonellae, hemophilusinfluenzae, and Escherichia coli accounted for more than 70% of isolates(15). This study also identified salmonellae as the most common cause of bacteremia and sepsis in children between 2 months and 14 years of age. Malaria was associated with increased risk of severe non- typhoidal salmonellae bacteremia(15).

Another Tanzania study conducted in Mwanza in 2010 reported that meningococcal infections in young infants may be difficult to distinguish from viral syndromes and may rapidly progress to clinical deterioration(16). This study demonstrated that these infections have also been associated with prolonged antibiotic regimens, requiring an extended hospital stay and increased risk of permanent neurological deficit(16).

Despite our knowledge on sepsis and treatment available, the burden of sepsis is still huge and some studies have shown an increase in sepsis associated hospital admission and mortality(10)(17).

Multiple studies have demonstrated that early treatment has resulted in significant reduction of mortality from sepsis, so early diagnosis is crucial(18)(19). Several studies have identified effective and efficient protocols for the rapid evaluation and treatment of children with suspected sepsis(18)(19), but the utility of these protocols may be setting dependent. Since childhood vaccination and disease prevention programs impact which pathogens are likely to cause disease in a given population, setting may change the appropriateness of both diagnostic and treatment strategies. In addition, the processing of laboratory samples including cultures can be time-consuming and expensive, and availability of medications, supplies and equipment will influence workup and management.

Emergency medicine physicians, especially in limited resource settings, are often required to manage patients with limited information. There are several studies done in developing countries that use modified scoring systems based on simple physical exam characteristics and basic laboratory tests in order to identify children at high risk of poor outcome. One prospective observational study done in India was designed in order to develop a simple clinical score to help prioritize care and predict mortality amongst paediatric patients. The clinical criteria used were temperature, oxygen saturation, pulse rate, respiratory rate, sensorium changes and seizures (TOPRS). Abnormalities in temperature, oxygen saturation and respiratory rate were associated with a significant risk of mortality(20). Another study done in two centers in India and United Kingdom

aimed to externally validate the "signs of inflammation in children that kill" (SICK) score, originally designed for use in low-resource settings. The seven parameters included heart rate, respiratory rate, temperature, oxygen saturation, capillary refill time and level of consciousness. This study proved that physical characteristics can be used to predict morbidity and mortality in emergency departments(21). Thorough history and physical examination is of great importance in detecting the seriousness of infection(22). Another study on whether it is possible to determine febrile infant with serious bacterial illness based on thorough history, physical examination, vital signs and laboratory test showed that source of infection is important in determining the seriousness of the illness(23).

This study aims to identify the factors available at or near the time of presentation that contribute to mortality in febrile children arriving at the EMD at Muhimbili National Hospital.

2.0: PROBLEM STATEMENT AND RATIONALE

There is a lack of regionally-relevant data to stratify risk in septic patients or to guide evidence-based management of sepsis in the emergency setting in Sub-Saharan Africa. Evaluating the prognostic impact of SIRS in children presenting with fever may improve sepsis- associated morbidity and mortality by identifying a cohort of children at higher risk for poor outcomes that may be targeted for aggressive early intervention, and by providing a basis for future management algorithms.

3.0: OBJECTIVES

3.1: Broad Objective

To investigate whether SIRS criteria are predictive of mortality amongst febrile children under 5 years of age presenting to the EMD at Dar es Salaam, Tanzania.

3.2: Specific Objectives

1. To investigate whether SIRS criteria predict in-hospital mortality among febrile children under 5 years of age presenting to EMD.

2. To investigate the relationship between patient demographics and medical history and SIRS signs amongst febrile children under 5 years of age presenting to the EMD

3. To identify top EMD diagnoses and final hospital diagnoses in febrile children under 5 years of age presenting to the EMD.

4. To identify the concordance between EMD diagnoses to final hospital diagnoses in febrile children under 5years of age presenting to the EMD.

4.0: METHODOLOGY

4.1: Study design and Setting

This descriptive cohort study was conducted from August through November 2012 at the Muhimbili National Hospital Emergency Medical Department (EMD), a tertiary care center with approximately 36,000 EMD visits per year.

4.2: Ethical Clearance

The Institutional Review Board of the Muhimbili University of Health and Allied Sciences approved the study protocol.

4.3: Sample size and Data collection

We enrolled a convenience sample of 105 children under 5 years of age presenting with fever or reported fever to the MNH EMD during the times when the research personnel were available. We defined fever as axillary temperature of ≥37.5°C as rectal temperatures are not routinely performed in our department and rectal thermometers are not available. Children who presented with cardiac arrest were excluded. No children were excluded. All children with fever or reported fever with this current illness were included

We were interested in children 5 years of age group since they are in greater risk of developing infectious disease processes if not well immunized.

The parents of eligible children were approached and offered the opportunity to participate. Written informed consent was obtained from those who agreed. No children were excluded. The treating physicians prospectively completed a standardized data collection form, including demographic data, vital signs, immunization history, pertinent data from the history and physical examination, laboratory results, treatment delivered,

and the final EMD diagnosis. Patients were tracked in terms of death within the EMD, hospital length of stay and mortality within the ward. Post discharge telephone follow up was done.

4.4: Data analysis

To define our variables, we used SIRS criteria derived from The Surviving Sepsis Campaign 2012(24) and International Paediatric Sepsis Consensus Conference 2005(25) and our specific age-based parameters are described in table 1. Laboratory abnormalities were those considered to be potentially relevant for sepsis evaluation and included hypoglycemia, hyperglycemia, low platelet levels and WBC abnormalities. Abnormal WBC was defined as leukocytosis, leukocytopaenia, predominant neutrophilia and/or bandemia by the ranges listed in table 1. Any number of laboratory abnormalities was counted as 1 SIRS criteria. Having AMS and /or hypotonia was counted as 1 SIRS criteria. We considered patient with 2 or more SIRS criteria (in addition to fever, which was an inclusion criteria for the study) to have SIRS. This was one more criteria than required in Surviving Sepsis Campaign 2012 and International Paediatric Sepsis Consensus Conference 2005.

The study data were entered into an Excel database (Microsoft Corporation, Redmond, WA, USA) and analyzed in SAS Version 9.3 (Cary, North Carolina, USA). Logistic regression analysis was performed to assess the odds ratio for mortality for SIRS criteria <2 compared to ≥ 2, age of one year or less versus >1 year, as well as the presence versus absence of chronic disease.

Table 1: Age appropriate abnormal vital signs and laboratory values.

Variable		**Abnormal values**
Pulse rate		<1 year: >180bpm 1 – 5 years: >140bpm
Respiratory rate		<1year: >34 breaths/min 1 – 5 years: >22 breath/min
Laboratory abnormalities	WBC	<1year: >17.5 or <5 1 – 5 years: >15.5 or <6
	RBG	>7.7mmol/L <4mmol/L
	Thrombocytopaenia	< 150000
Neurological abnormalities	AMS	
	Hypotonia	

5: RESULT

5.1: Patients characteristics

Data was collected in 105 children under 5 years of age who had reported or documented fever on arrival to EMD. We had three groups of children with fever; fever at presentation 64 (61.0%), documented fever 24 (22.9%) and reported fever 17 (16.2%). The median age was 14 months, with 80% of children over 6 months of age, and 63.8% were male. Fifty seven (54.3%) children were referred from outside hospitals or health centers, and 84 (80%) received treatment prior to arrival at the EMD.

Children were divided into two main groups namely children who met our SIRS criteria (had ≥ 2 criteria in addition to fever) and children who did not.

Table 2: Patient Characteristics by SIRS Criteria

	All (N=105)	**Children not meeting SIRS criteria (N=40)**	**Children with SIRS (N=65)**
Age			
1-3 months	9 (8.6%)	2 (5%)	7(10.8%)
4-6 months	12 (11.4%)	5 (12.5%)	7 (10.8%)
>6 months	84 (80.0%)	33 (82.5%)	51 (78.4%)
Gender			
Female	38 (36.2%)	13 (32.5%)	25 (38.5%)
Male	67 (63.8%)	27 (67.5%)	40 (61.5%)
Birth history			
Abnormal birth history	12 (11.4%)	1 (2.5%)	9 (13.8%)
Chronic disease			
Any chronic disease	14 (13.3%)	1 (2.5%)	13 (20%)
Immunization			
Fully immunized	71 (67.7%)	28 (70%)	43 (66.2%)
Partially immunized	34 (32.3%)	12 (30%)	22(33.8 %)
No immunization	0 (0%)	O (0%)	0 (0%)
Referral from other facilities	57 (54.3%)	19 (47.5%)	38 (58.5%)
Mortality	20 (19%)	2 (5%)	18 (27.7%)

Among the children who met this SIRS criteria as compared to those who did not, there was a higher rate of female gender (38.5% versus 32.5%), abnormal birth history (13.8% versus 7.5%), and chronic diseases (20% versus 2.5%). The mortality in children with SIRS was significantly higher at 27.7% versus 5% in children not meeting SIRS criteria. Additionally, when odds ratios were calculated, children with fever and 2 or more SIRS criteria were seven times more likely to die than those with fever and 1 or no SIRS criteria. Age of greater than or less than one, gender, and chronic disease were not significant predictors of mortality. Overall, 90% of children who died met our SIRS criteria.

5.2: Mortality in Febrile children

Two main groups are found in Table 3, comparing outcomes amongst children who survived to hospital discharge and those who did not. The overall mortality of patients in the study was 19%.

Out of all children enrolled in the study 94 (89.5%) had abnormal physical examination. This group is further divided into those children who died and those who did not. In the group where the children died, 9 (45%) of children who died had ≥ 3 organ system abnormalities on physical examination, while only 15% of surviving children had ≥ 3 organ system abnormalities on exam.

Additionally, when odds ratios were calculated, children with fever and 2 or more SIRS criteria were seven times more likely to die than those with fever and 1 or no SIRS criteria. Age of greater than or less than one, gender, and chronic disease were not

significant predictors of mortality. Overall, 90% of children who died met our SIRS criteria.

Table 3 – Survival status

	All patients	**Patients who survived to hospital discharge (N=85)**	**Patient who died (N=20)**
Age			
1 -3 months	9 (8.2%)	7 (8.2%)	2 (10%)
4 -6months	12 (11.4%)	9 (10.6%)	3 (15%)
>6months	84 (80.0%)	69 (81.2%)	15 (5%)
Chronic disease			
Absent	91 (86.7%)	74 (87.1%)	17 (85%)
Present	14 (13.3%)	11 (12.9%)	3 (15%)
Immunization status			
Fully immunized	71 (67.7%)	58 (68.2%)	13 (65%)
Partially immunized	34 (32.3%)	27 (31.8%)	7 (35%)
Not immunized	0 (0%)	0 (0%)	0 (0%)
Referred from other facilities	57 (54.3%)	42 (49.4%)	15 (75%)
Any physical exam abnormality	94 (89.5%)	75 (88.2%)	19 (95%)
1 organ system	35 (33.3%)	32 (37.6%)	3 (15 %)
2 organ systems	37 (35.2%)	30 (35.3%)	7 (35%)
≥ organ systems	22 (21.0%)	13 (15.3%)	9 (45%)
SIRS criteria			
Any vital sign abnormality	74 (70.5%)	56 (65.9%)	18 (90%)
1 VS	37 (35.2%)	31 (36.5%)	6 (30%)
2 VS	31 (29.5%)	24 (28.2%)	7 (35%)
≥3 VS	6 (5.7%)	1 (1.2%)	5 (25%)
Any observed or reported change in mental status	34 (32.4%)	25 (29.4%)	9 (45%)
SIRS laboratory abnormalities	51 (48.6%)	34 (44.7%)	13 (65%)
Patient meeting SIRS criteria	65 (61.9%)	47 (55.3%)	18 (90%)

Table 4: Odds ratios for Mortality

	Odds Ratio	Standard Error	P
SIRS <2 vs. >2	7.05	5.57	0.01
Age <1 vs. >1	0.85	0.45	0.76
Gender	1.55	0.84	0.42
Presence of any chronic disease	1.12	0.76	0.87

5.4: Differential Diagnoses

Table 5: EMD Diagnosis vs. Hospital Diagnosis

	Top EMD impression	Top hospital diagnoses	Cause of death
1	Malaria (26)	Septicemia (15)	Septicemia (8)
2	Pneumonia (16)	Acute watery diarrhea (13)	Pneumonia (3)
3	Septicemia (16)	Pneumonia (10)	Surgical emergencies (2)
4	Urinary tract infection (8)	Malaria (7)	Cardiac arrest 2° Congenital Heart Disease (1)
5	Acute watery diarrhea (7)	Sickle cell disease (6)	Tuberculosis (1)
6	Meningitis (5)	Congenital disorders (5)	Hepatitis (1)
7	Anemia (5)	Urinary tract infection (4)	Anemia (1)
8	Skin and soft tissue infections (5)	Febrile seizure (3)	Malignancy (1)
9	Intestinal obstruction (4)	Meningitis (3)	Meningitis (1)
10	Tuberculosis (3), Sickle cell disease (3), Hepatitis (3)	Skin and soft tissue infections (3)	Accidental death (1)
Overall EMD differential diagnoses concordance with hospital discharge diagnoses or cause of death: 84 (80%)			
Overall top EMD clinical impression concordance with hospital discharge diagnoses or cause of death: 54 (51.4%)			

Top EMD and hospital diagnoses are listed in table 5. Infectious causes accounted for the majority of deaths.

5.5: Follow Up

Table 6: Follow up

	Patients with SIRS	**Patient without SIRS**
Number surveyed	N=32	N=33
Alive at follow up time	32 (100%)	33 (100%)
Return to baseline	24 (75%)	27 (81.8%)
Still have symptoms	8 (25%)	6 (18.2%)
Unscheduled hospital visit	1 (3.1%)	2 (0.1%)
Deceased	0 (0%)	0 (0%)
Lost to follow up	15 (23.1%)	5 (12.5%)

During follow up, we were able to survey 64 (75.3%) children. The rest of the study population was lost to follow up due to the fact that some the guardians/parents did not have phones. The rate of successful follow up was higher amongst the patients who met SIRS criteria than those without. In surviving patients who had met SIRS criteria, 75% were back to their baseline at the time of follow up, while 25% had continued symptoms, but only 3.1% had unscheduled hospital visits. In those who had not meet SIRS criteria, 66.7% were back to baseline by the time of follow up, 15.2% had continued symptoms and 6.1% had unscheduled hospital visits.

6.0: DISCUSSION:

To our knowledge, this is the first regional study that describes clinical risk factors predictive of poor outcomes in the children presenting with fever in an emergency setting. The goal of the study was to be able to recognize signs and symptoms which are associated with increased mortality in children with fever. It is often difficult to predict which children with fever have serious bacterial infection (SBI) or septicemia and are at risk for poor outcome. The presence of fever itself causes heart rate and respiratory rate changes. We adopted previously published SIRS criteria, requiring 2 criteria in additional to fever in our study in order to identify the highest risk cohort.

This study validates the use of SIRS criteria in resource-limited areas, by comparing febrile children who have ≥2 SIRS criteria with those who have fewer. These criteria take into consideration the availability of tests in our setting, by making the use of physical signs and symptoms and simple tests available. As our study demonstrated, there was a significant difference in mortality amongst children meeting SIRS criteria as compared to those who did not.

The male to female ratio of our sample reflects the same male to female ratio of the entire patient population arriving at our EMD(26). Our study found that overall mortality in children with fever arriving at the EMD was 19%, with mortality in children with SIRS being 27.7%, compared with 5% in those who did not meet our criteria for SIRS. In comparison to a study done in the USA in 1995 (before implementation of sepsis protocols for children), the in-hospital mortality in septic children was 10.3%(5). As in our study there was increased mortality in children with SIRS. The markedly

higher overall mortality in our study may be attributed to several factors: real disease burden and vaccination patterns, socioeconomic status, delay to presentation (54.3% are referred from different facilities), and lack of a pediatric intensive care unit and pediatric ventilators at our hospital. In study done at Boston Children's Hospital, pneumococcal infections had highest rates of mortality in children with fever(2). Tanzania has only recently implemented the pneumococcal vaccine, and it is unlikely that any of the children included in our study had been vaccinated against this pathogen.

When we looked into physical characteristics associated with mortality, 90% of our cohort had vital sign abnormalities apart from fever, with 30%, 35% and 25% corresponding to 1, 2 and ≥3 vital sign abnormalities respectively. Amongst the children who died, 90% met SIRS criteria and 45% had abnormalities in ≥3 organ systems. The prevalence of febrile children meeting SIRS criteria in our study 65 (61.9%) is comparable to the rate of 72% from a study done in Latvia to determine the prevalence of SIRS in children aged 2 -5 years(27).

Factors like tachycardia and AMS that have been shown to be predictors of mortality in prior studies(21)(28), were also more common among children who died compared with children who lived. In our study tachycardia was present in 50% of who died and 34.1% of survivors; AMS in 45% of died children versus 29.4% in survivors.

We also followed simple laboratory result in determining if the child has SIRS, and these were age specific. These tests include WBC count, platelets, and blood sugar levels. These laboratory findings have been used in explaining the morbidity and mortality in children. In our study presence of one or more than one abnormal laboratory results were scored as one in SIRS criteria. Due to the limited availability of CRP,

lactate, and creatinine clearance in our facility these variables were not included in the study, despite the fact that they have been used as predictors of severity of illness in febrile children(29)(30). Abnormal laboratory tests were correlated with increased mortality in children in our study, and 65% of those did not survive to hospital discharge had laboratory abnormalities compared to 45% of the children who survived. There is a tendency towards increased mortality in the presence of abnormal WBC, which is similar to the findings of prior studies done on febrile children(25)(31).

Thrombocytopenia was observed in about 9.5% of the study population, and there was no significant difference in the rate of thrombocytopaenia between those who died and those who survived. Thrombocytosis was observed in about 30% of the children who died and 27.4% of those who survived to hospital discharge date. Perhaps the most important demographic characteristic observed in this study was the referral status of febrile children. Children referred from peripheral health facilities were sicker compared to those who came directly from home. This is supported with the fact that 75% of children who died were referred from peripheral hospitals as compared to 49.4% of children who survived. Being referred with a primary care physician is associated with increased mortality(32) despite the fact that majority of these children were given antibiotics at the referral sites. The increased mortality however can not necessarily be attributed to the referral system process or delay as the children presenting directly to the EMD are more likely to be children of hospital personnel and urban dwellers, which may independently impact their outcomes. Further studies should be done to evaluate the impact of referral and delay to care.

During follow up we found that none of the children who were discharged directly from the EMD died. Overall on follow up, 20.3% of the children were reported as not back to baseline activities though only 4.7% of them had unscheduled hospital visits. This is difficult to compare with other studies done on readmission and sepsis survival, since the follow up time was short compared to those studies(33)(34).

7.0: LIMITATIONS

We had a small sample size which made it difficult for us to find potentially small but statistically significant differences amongst the patients. In addition, capillary refill was not recorded in data collection although prior studies have identified it to be an important marker of volume status and prolonged capillary refill as a risk factor for sepsis. The inability to reach a significant minority of discharged patients may limit the utility of hospital follow up data.

8.0: CONCLUSION

SIRS was found to be prevalent in febrile children less than five years of age. Having SIRS increases the odds of dying in febrile children less than five years of age. Abnormal physical findings such as pulse rate, respiratory rate and level of consciousness, and abnormal laboratory findings correlates with increased mortality in children with fever. Signs of systemic inflammation can be used to predict morbidity and mortality in febrile children who presents to an emergency department in Sub-Saharan Africa.

9.0: RECOMMENDATIONS:

Our results should be prospectively validated in a larger cohort and in other settings. In addition, further studies are needed on the predictive value of additional demographic factors, other laboratory tests, referral status, and delay to care for febrile children in our region.

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APPENDICES:

CONSENT FORM

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATIONS, MUHAS

Informed Consent form

ID-NO [ ]

Consent to participate: Factors predicting in hospital mortality and duration of stay of septic children aged 2months to 5years presenting at EMD-MNH.

Greetings! My name is ……..and I am a Doctor working on this research project with the objective of investigating the above subject.

Purpose of the Study

We are conducting this study in order to know the conditions that have poor prognosis in the children with sepsis.

What Participation Involves

If you agree to join the study, you will be required answer the question on the illness of your child faithfully also allowing physical examination and management of your child to be done.

Confidentiality

All information we collect on forms will be entered into computers with only the study identification number.

Risks

We do not expect that any harm will happen to you because of joining this study. Sometimes, a small bruise may occur after giving blood.

Rights to Withdraw and Alternatives

Taking part in this study is completely your choice. If you choose not to participate in the study or if you decide to stop participating in the study you will continue to receive all services that you would normally get from this hospital. You can stop participating in this study at any time, even if you have already given your consent. Refusal to participate or withdrawal from the study will not involve penalty or loss of any benefits on which you are otherwise entitled.

Benefits

If you agree to take part in this study you will benefit by knowing about the condition of your child and its management.

In Case of Injury

We do not anticipate that any harm will occur to your child as a result of participation in this study. However, if any physical injury resulting from participation in this research should occur, we will provide you or your child with medical treatment according to the current standard of care in Tanzania. There will be no additional compensations to you.

Who to contact

If you ever have questions about this study, you should contact the study Coordinator or the Principal Investigator DrUpendo George (Muhimbili University of Health and Allied Sciences, P.O. Box 65001, Dar es Salaam). If you ever have questions about your rights as a participant you may call Prof. V. Mwafongo, Head of Department-EMD. P.O. Box 65001, Dar es Salaam. Tel: 2150302-6

Signature:

Do you agree?

Participant agrees……..Participant does NOT agree……

I,_____ have read the contents in this form. My questions have been answered. I agree that my child will participate in this study.

Signature _____

Signature of witness (if mother/caretaker cannot read)___

Signature of research assistant_____

Date of signed consent_____

CONSENT FORM: (SWAHILI)

FomuyaridhaakatikaUtafitijuuyavituvinavyoashiriavifonakulazwakwamudamrefukwawa totowenye "sepsis" walionaumriwamiezimiwilihadimiakamitanowanaowasilikatikaidarayamagonjwayadharurakatikahospitaliyataifayamuhimbili.

Utambulisho

Habari za saa hizi,

Jina langu ni **Dr. Upendo George** na ninafanya kazi katika hospitali ya muhimbili na pia ni mtafiti katika utafiti wa "Tathmini juu ya vitu vinavyoashiria vifo na kulazwa kwa muda mrefu katika watoto wenye "sepsis" walio na umri wa miezi miwili hadi miaka mitano wanaowasili katika idara ya magonjwa ya dharura katika hospitali ya taifa ya muhimbili. Sasa nitakupa maelezo ya kina kuhusu utafiti huu na kasha nitakuomba ridhaa yako ya kushiriki katika utafiti huu. Endapo utakuwa na maswali yoyote nitafurahi kukujibu.

Malengo ya utafiti.

Utafiti huu unafanyika kwa nia ya kuchunguza viashiria mbalimbali vya vifo na kulazwa kwa muda mrefu kwa watoto wenye magonjwa ya "sepsis" wanaowasili katika idara hii mpya ya ajali na dharura muhimbili hosipitali.

Ushiriki unahusisha nini

Watakaokubali kushiriki tutawahoji maswali kadhaa, kisha kupimwa kwa taratibu zote za kidaktari na kupewa matibabu husika

Usiri

Jina lako litaonekana katika fomu moja tu kwa ajili ya kutengeneza namba yako ya utambulisho wa siri. Ni namba hii tu itakayotumika katika fomu za maabara na katika komputa mahali ambapo maelezo haya yote yatahifadhiwa.

Taarifa zote utakazotupa ni siri na zitatumika tu kwa ajili ya utafiti huu na kuboresha huduma ya afya katika mazingira ya kazi na elimu ya utoaji wa huduma bora za matibabu ya mwili kuwa na joto kwa watoto walio chini ya umri wa miaka mitano kwa wafanyakazi wetu na wagonjwa na sio vinginevyo**.** Hakuna mtu mwingine zaidi ya wanaohusika wa utafiti huu ,atakayesoma/kupata maelezo yako.

Faida na Athari

Faida utakayopata katika utafiti huu ni kujua mtoto wako anaumwa nini pamoja na aina ya matibabu atakayopata. Pia utaelewa madhara mbalimbali yatokanayo na ugonjwa wa mtoto wako.

Uhuru wa kushiriki na haki ya kujitoa

Ushiriki wako katika utafiti huu ni kwa hiari kabisa na pia unayo haki ya kujitoa katika utafiti huu wakati wowote ule utakapojisikia kufanya hivyo. Uamuzi wako wa kushiriki katika utafiti huu ama la, hautaadhiri hata kidogo haki yako kama mgojwa ya kupata huduma na tiba.

Nani wa kuwasiliana naye.

Iwapo utakuwa na swali lolote kuhusu utafiti huu , unaweza kuwasiliana na

Dr Upendo George; Chuo kikuu Cha Afya na Sayansi za tiba Muhimbili; Idara ya tiba; S.L.P 65001 Dar es Salaam. Simu 0784 684 333

AU

Professa .V.Mwafongo: Msimamizi wa utafiti huu :Chuo kikuu Cha Afya na Sayansi za tiba Muhimbili; S.L.P 65001 Dar es Salaam

Mimi _____

Nimeelewa maelezo yaliyoandikwa hapo juu na kuridihika na majibu niliyopewa kwa maswali yangu yote. Ninakubali kushiriki katika utafiti huu.

Jina la mshiriki: _____

Sahihi ya mshiriki: _____

Sahihi ya Shahidi: (kama mshiriki hawezi kusoma): _____

Tarehe ya kusaini ridhaa: _____

DATA SHEET

Pt initials:

FEBRILE CHILD STUDY

ANY QUESTIONS CALL: UPENDO GEORGE 0784 684 333, FAITH RINGO 0715 942 246

INCLUDE ANY CHILD WHO:

Age ≤5years T ≥ 37.5C **or** T ≤35Cduring stay at EMD **or** Reported fever with THIS illness Not in cardiac arrest on arrival

PERSONAL INFORMATION

Name:	**Medical record number:**
Age (months/years):	**Date seen:**
Sex (M or F):	**Time arrived @ EMD:**
Address:	**Time seen:**
Phone no. 1:	**By Dr. :**
Phone no. 2:	**Responsible person:**

INFORMATION FROM REFERRING HOSPITAL

Referred from another facility? **Circle: Y or N.If NO, skip this box.**
Referral hospital: Number of days of admission **or** Admission date:
Referral diagnosis (list all):
List any prior facilities patient visited during this illness?
Treatment received prior to arrival at EMD **(mark Y, N or unk**), **if YES, name them**: - Antibiotics: - Anti-malarial: - Anti-pyretic: - Other medications: - IV fluids prior to arrival at MNH -> Type: Amount:

HISTORY OF PRESENT ILLNESS

CHIEF COMPLAINT		
____mo/yo M/F w/ _____ for ___ days w/ associated: **[ ] cough x ____ days** **[ ] fever x ____ days** **[ ] AMS x ____ days** **[ ] Poor feeding x ____ days** **[ ] Other:**		
ROS (check all that apply)		
[ ] cough **[ ] dyspnea/SOB** **[ ] cyanosis** **[ ] other (list):**	**[ ] AMS** **[ ] seizures/convulsions** **[ ] fever** **[ ] rash** **[ ] swelling?**	**[ ] vomiting** **[ ] diarrhea** **[ ] abdominal distension** **[ ] jaundice** **[ ] decreased urine output** **[ ] not passing stool** **[ ] poor feeding**
PMH		
[ ] Term [ ] Preterm [ ] Unk **Complications with birth (describe):** **Chronic/congenital disease (check):** **[ ] Congenital heart disease [ ] Sickle cell anemia [ ] Asthma [ ] HIV/AIDS**		

[ ] Other (list all):
Last antibiotic use (date):
Hospitalization history (date and dx): **Surgical history (date and operation):**
Immunizations per [ ] parent/guardian OR [ ] HPI card (check all that apply)
[ ] DPT-Hb **[ ] Polio (OPV)** **[ ] Measles** **[ ] Hemophilus** **[ ] Others (list):**
Current home medications (list all)
Prescription by doctor: **Bought at pharmacy w/o prescription:** **Local herbs:**

PHYSICAL EXAM

Triage VS: BP	HR	T (axillary/rectal)	RR	Sp02	% (RA/ __L NC/ __L NRB).
Resus VS: BP	HR	T (axillary/rectal)	RR	Sp02	% (RA/ __L NC/ __L NRB).

HEENT:

[ ] Bulging fontanelle [ ] Other:

[ ] Sunken eyes

[ ] Ear discharge / hyperaemic tympanic membrane

[ ] Stiff neck

[ ] Hyperaemic oropharynx

Neurology:

- Mental status: [ ] Alert [ ] Drowsy [ ] Irritable [ ] Stupor [ ] Coma

- Tone: [ ] Decreased [ ] Flaccid [ ] Hypreactive [ ] Hypertonia

[ ] Other:

Chest: [ ] RRR [ ] no murmur/rub/gallop Abnormal: [ ] tachycardic [ ] other:

[ ] NL effort, CTAB, no wheezes/rales/rhonchi Abnormal: [ ] wheezes, R/L

[ ] rales, R/L

[ ] rhonchi, R/L

[ ] increased

WOB/retracting [ ] tachypnea

[ ] other:

Abdomen: Distended

Bowel sounds: absent/ reduced/ increased

Palpable organs/ masses.....

Skin / soft tissue

Rash.....

Cellulitis.....

Abscess.....

FEBRILE CHILD STUDY

ANY QUESTIONS CALL: UPENDO GEORGE 0784 684 333, FAITH RINGO 0715 942 246

Pt initials:

DIFFERENTIAL DIAGNOSIS (List):

#

#

#

#

#

#

INVESTIGATIONS

X-ray /CT-scan: done at EMD / prior to arrival

Findings:

Laboratory results

RBG.....

RDT.....

Rapid HIV test.....

B/S for mps.....

FEBRILE CHILD STUDY

ANY QUESTIONS CALL: UPENDO GEORGE 0784 684 333, FAITH RINGO 0715 942 246

Pt initials:

CBC; WBC..... N .....M..... B..... E .....Bands.....

Hb..... Hct..... Platelets.....

Chemistry: Na..... K..... Cl..... BUN..... Cr .....Glucose..... Ca..... Lactate.....

ABG/VBG: pH ..... pCO2..... pO2 .....HCO3 .....An Gap.....

UA.....

CSF: clear / traumatic / purulent

Micro:

Cultures: urine / blood / CSF

TREATMENT

MEDICATION	DOSE	ROUTE	TIME GIVEN
IVF	AMOUNT	TIME	NOTES

FEBRILE CHILD STUDY

ANY QUESTIONS CALL: UPENDO GEORGE 0784 684 333, FAITH RINGO 0715 942 246

Pt initials:

BLOOD PRODUCTS	AMOUNT	TIME	NOTES
OTHER INTERVENTIONS (Intubation, procedures, etc)			

Repeat VS						
Time	BP	PR	RR	Sp02	Temp	RBG

FEBRILE CHILD STUDY

ANY QUESTIONS CALL: UPENDO GEORGE 0784 684 333, FAITH RINGO 0715 942 246

Pt initials:

DISPOSITION

[ ] WARD A [ ] WARD B [ ] MAKUTI A [ ] MAKUTI B [ ] MORGUE
Time the patient leave EMD
Is the patient alive at disposition YES / NO If NO: Date of death Cause of Death
Is the patient alive at hospital discharge: YES /NO If YES: Date of discharge Discharge diagnosis If NO: Date of death Cause of death

FOLLOW UP AFTER DISCHARGE (at 14 days)

Date
Person reached / relationship to the patient
Is patient alive YES / NO If NO: Date of death

FEBRILE CHILD STUDY

ANY QUESTIONS CALL: UPENDO GEORGE 0784 684 333, FAITH RINGO 0715 942 246

Pt initials:

If alive, has patient returned to baseline activities/ school? YES/ NO If NO, explain
Has patient has unscheduled hospital / doctor visit since discharge? YES/ NO If YES, explain

PROVIDE ANY OTHER INFORMATION

FEBRILE CHILD STUDY

ANY QUESTIONS CALL: UPENDO GEORGE 0784 684 333, FAITH RINGO 0715 942 246

Pt initials: