



Easy Protocol Assessment in Children Emergency Room, Irrua Specialist Teaching Hospital Nigeria

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Aim: To determine the effect of the EASY (Early Attention to Sepsis in the Young) protocol on sepsis outcomes in children admitted into the children's emergency unit.

Methodology: Sixty participants (24 males and 36 females) aged 1 month - 16 years were recruited into two arms- The EASY protocol and the non-EASY protocol (control) arm. The researchers obtained relevant treatment history and clinical and laboratory data, which were analyzed statistically using SPSS version 25.

Results: Twenty-five (80%) patients on EASY protocol received saline boluses compared to 5 (16.7%) in the control group. The difference was significant: $\chi^2 = 24.09$, $p < .001$. Similarly, more patients on EASY (10; 33.3%) than the control (3; 10.0%) received continuous positive airway pressure: $\chi^2 = 4.81$, $p = .03$.

Where the symptoms were predominantly restricted to one organ system, those on EASY protocol spent less time in the emergency unit (0.98 ± 0.43 days) than the control (1.87 ± 0.97 days): $F = 13.02$, $p = .001$. However, there was no statistically significant difference in the overall duration of

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hospital admission in both groups: $t = 1.33$, $p = 0.20$.
In the EASY arm, the particular EASY treatment used correlated with the presence of underlying chronic disease and the approximate duration of current illness; $p = 0.001$, $R^2 = 0.37 - 0.59$; as well as the presence of abnormal blood cell counts; $p = 0.022$, $R^2 = 0.39 - 0.64$.
Conclusion: The EASY protocol increased the intensity of treating children with sepsis in the emergency unit and reduced the critical phase.

Keywords: Sepsis; protocol; children; emergency; critical; EASY; ISTH; Nigeria.

ABREVIATIONS

AIDS : Acquired immune deficiency syndrome
CPAP : Continuous positive airway pressure
EASY : Early attention to sepsis in the young
ED : Emergency department
ECMO : Extra Corporeal Membrane Oxygenation
ICU : Intensive care unit
MODS : Multiple organ dysfunction syndrome
SICM : Sepsis induced cardiomyopathy
SIRS : Systemic Inflammatory Response Syndrome

1. INTRODUCTION

Sepsis is a life-threatening organ dysfunction caused by a dysregulated host response to infection. [1] It is a syndromic response to infection and is frequently a common final pathway to death from many infectious diseases worldwide. [2] Infectious diseases constitute one of the most common causes of death in infants and children worldwide, particularly in developing countries. [3,4] In 2017, almost half (20 million) of all estimated sepsis cases worldwide occurred in children under 5 years of age. [5] About 80% of deaths related to infectious diseases occur in low- and middle- income countries.[6] Recent studies done in Nigeria have reported high sepsis mortality rates in admitted patients: 53% in Jos University Teaching Hospital [7], 28.8% in the paediatric unit of University of Nigeria Teaching Hospital,[8] and 21.8% in University of Benin Teaching Hospital paediatric unit. [9] The spectrum of disease caused by infectious diseases may start with Systemic Inflammatory Response Syndrome (SIRS) and progress to severe sepsis, Multiple Organ Dysfunction Syndrome (MODS), septic shock and death. Often, the preceding and reversible warm phase of septic shock is unfortunately unrecognized until it progresses to irreversible cold shock. [10] This is due to the dearth of specific or pathognomonic clinical signs associated with warm shock, which latter is often a retrospective diagnosis. [10]

Due to the global burden and high mortality arising from sepsis, consistent efforts have been made to develop sepsis care bundles aimed at reducing the mortality rates of sepsis. Care bundles are a group of simple and practical interventions which when administered together on the septic patient, yields maximum outcome benefit [11] In 2004, the surviving sepsis campaign (SSC) was launched aiming to improve the survival of patients with sepsis and in 2008, SSC guidelines incorporated two sepsis care bundles.[12] Further revisions of SSC guidelines have been done over the years and other sepsis bundles have also been launched in several settings globally including “sepsis six” in the UK. [13] However, sepsis bundles designed specifically for use in children and the adequacy of their implementation are still limited [14,15]

Yet, several observational studies support the concept that sepsis bundles play an important role in improving the outcomes from sepsis. Gao and colleagues [16] carried out the first study to demonstrate the impact of compliance after adopting 6-h and 24-h sepsis bundles on hospital mortality in patients with severe sepsis and their findings revealed that noncompliance with the 6-h bundle was associated with a more than twofold rise in hospital mortality. In addition, there was a 76% increase in the risk of hospital death if the 24-h bundle targets were not achieved.

Though beneficial, international sepsis guidelines cannot be adequately implemented in most parts of Africa due to the shortage of requisite resources such as skilled manpower, adequate equipment and drugs. [17] Furthermore, African children may respond differently when such international guidelines such as bolus resuscitation used as a life-saving intervention, are applied directly on them without modification, leading to high rates of mortality in children with sepsis. [18]

In Nigeria in particular, the treatment of children with sepsis is largely uncoordinated among

medical practitioners.[19] This is due to the absence of national guidelines for the treatment of sepsis in the country. [19] Hence, the EASY protocol was developed to address this gap. We proposed a protocol that can be applied at almost all levels of health care in Nigeria and across the continent (as well as in other low- and middle-income countries). It requires very minimal equipment, and can be learned by medical practitioners with different levels of specialization.

The EASY protocol is adapted to Nigeria's unique rural and resource limited settings with the fundamental principle of early identification of sepsis (even in the warm phase) and vigorous treatment to prevent deterioration to a more critical phase of sepsis. This timely intervention is cost-effective as it avoids the deployment of sophisticated medical equipment which are scarce and largely unaffordable in Nigeria.

Prior to the introduction of the EASY protocol, the children emergency unit of the setting where it was implemented had no sepsis bundle but had some general, but undocumented treatment guidelines. However, there were repeated adoptions of varying treatment practices in the ED, by resident doctors at different levels of training who rotate through the ED as a requirement for their training. Hence, the EASY protocol was introduced to serve as a uniform guideline and standard for first responders in the ED, aiming to improve the outcome of sepsis in children.

As part of its precepts, the EASY protocol emphasizes triaging patients with sepsis into groups that receive different treatment options depending on their history and clinical findings at presentation. The method includes:

- 1- identifying patients with infections who have abnormal vital signs
- 2- separating these patients into 2 groups: those who require fluid resuscitation and those in whom fluid resuscitation may be detrimental
- 3- timely institution of treatment items for each group according to the EASY algorithms
- 4- and frequent clinical reviews and monitoring using the monitoring flow chart.

The EASY protocol consists of three components:

- 1- a set of instructions/ bundle (which every patient gets) - Appendix 1
- 2- stepwise algorithm – Appendix 2 and
- 3- a monitoring flow chart – Appendix 3

The two algorithm-groups are: (i) the group that would require fluid bolus(es) and Oxygen therapy/ CPAP; and (ii) the group that would require diuretics, inotropes and Oxygen therapy/ CPAP.

The indications for administering the EASY protocol are: SIRS of infectious aetiology with abnormal vital signs, sepsis, severe sepsis, septic shock and MODS (i.e. patients with infections who show signs of compensatory cardiorespiratory hyperactivity or overt clinical decompensation).

The study aimed to evaluate the effect of the EASY protocol on the outcome of sepsis in the children's emergency unit of the study site.

The specific objectives were:

- 1- To determine the effect of the EASY protocol on the mortality rate of children with sepsis admitted into the ED
- 2- To evaluate the efficiency of the EASY protocol administered without invasive medical equipment in the treatment of sepsis
- 3- To determine the effect of the EASY protocol on the duration of the critical phase of sepsis
- 4- To evaluate the effect of the EASY protocol on the total duration of the hospital admission

The primary outcome measures of this study were all-cause mortality from sepsis in children admitted into the paediatric ED and the duration of management of sepsis.

2. MATERIALS AND METHODS

2.1 Study Design

The study was retrospective study.

2.2 Place and Duration of Study

Children Emergency Unit, Department of Paediatrics, Irrua Specialist Teaching Hospital (ISTH) Edo State Nigeria; April to July 2019.

ISTH is one of the three Federal teaching hospitals in Edo State, Nigeria, and is situated in a rural community with most of its patient-clientele coming from neighbouring communities. However, the hospital also receives referral cases from other parts of Edo State and neighbouring states, including Kogi, Delta and Ondo states. The setting is the referral centre for children and adults with Lassa fever and other hemorrhagic fevers in the South-South geopolitical zone of Nigeria.

The children emergency unit is a 17-bedded unit. It is the first point of call of children aged one month to 16 years who present with medical emergencies. Patients that present to the unit are either treated on an outpatient basis or admitted if they are determined to require inpatient care. Indications for admission into the unit include:

1. The presence of abnormal vital signs,
2. Others are inability to eat or drink, convulsions, severe pallor, jaundice, hematuria, altered consciousness and coma, moderate or severe dehydration, difficulty with breathing of different aetiologies, shock, anaphylaxis, sickle cell crises, meningitis, moderate to severe pneumonia, acute glomerulonephritis intestinal obstruction/ paralytic ileus, and other infectious or non-infectious diseases with features of hemodynamic or systemic compromise.
3. Children referred from other health facilities due to the suspicion of viral hemorrhagic fevers are first resuscitated and treated in an isolation room in the children emergency unit before the results of the definitive investigations are obtained. Thereafter, they are transferred to the appropriate isolation wards if the results are positive. On the other hand, if the results are negative, like the other patients admitted to the ED, they continue to receive treatment in the ED until they are clinically stabilized and transferred to the paediatric ward.

The paediatric ED also serves as a mini-ICU. Hence, the duration of hospitalization in the ED before transfer to the paediatric ward can be regarded as the severe/ critical phase of the illness.

We conducted this study two months after EASY became operational in the children's ED. Prior to

this, the EASY protocol had been introduced to all the doctors working in the department in several departmental seminars and clinical meetings. Further bedside demonstrations were done in the emergency unit during routine work hours and call hours.

The content of the trainings included:

- 1- identifying indications for administering the EASY protocol
- 2- how to administer the algorithms in a stepwise manner
- 3- adhering to the frequency of clinical reviews/ monitoring
- 4- the exit point of the protocol

Copies of the protocol were printed out and placed on the noticeboards in the paediatric ED for the resident doctors to refer to as needed. As the EASY protocol is comprised of standard treatment procedures which were already operational in the ED (but now put together in an organized, stepwise and goal-oriented manner), the doctors were already familiar with the individual components of the protocol. This facilitated the smooth uptake of the protocol. The antibiotics choices for patients who received the EASY protocol were guided by the existing regimen in the ED and was not altered by the protocol. The trainings and demonstrations were conducted in the preceding two months before the protocol became operational.

The protocol was administered by the junior or senior resident doctor who first evaluated the patient in the ED after the nurses had obtained their vital signs. The criterion for administering the protocol was the presence of abnormal vital signs in a patient with a disease of infectious nature. These abnormal vital signs were: tachycardia, bradycardia, tachypnea, bradypnea, hypotension, abnormal oxygen saturation and subnormal temperature, with or without fever. Table 1 below illustrates the patient selection process for the EASY protocol and how it was administered.

Thus, the inclusion criteria was the presence of abnormal vital signs in children that presented with infections.

We obtained the data retrospectively from the patients who got the protocol in the first two months of introducing the EASY protocol into the emergency unit. Of the 156 patients who were admitted into the ED during this period, 30

patients received the intervention and were recruited. In a rearward manner, we also consecutively recruited 30 patients treated for sepsis (i.e who had abnormal vital signs and infections) in the preceding months before we introduced the protocol, to serve as the comparison group. Thus, half of the study participants were admitted after the EASY protocol institution and benefited from the protocol (group A). In contrast, the other 30 patients (group B) did not have the EASY intervention.

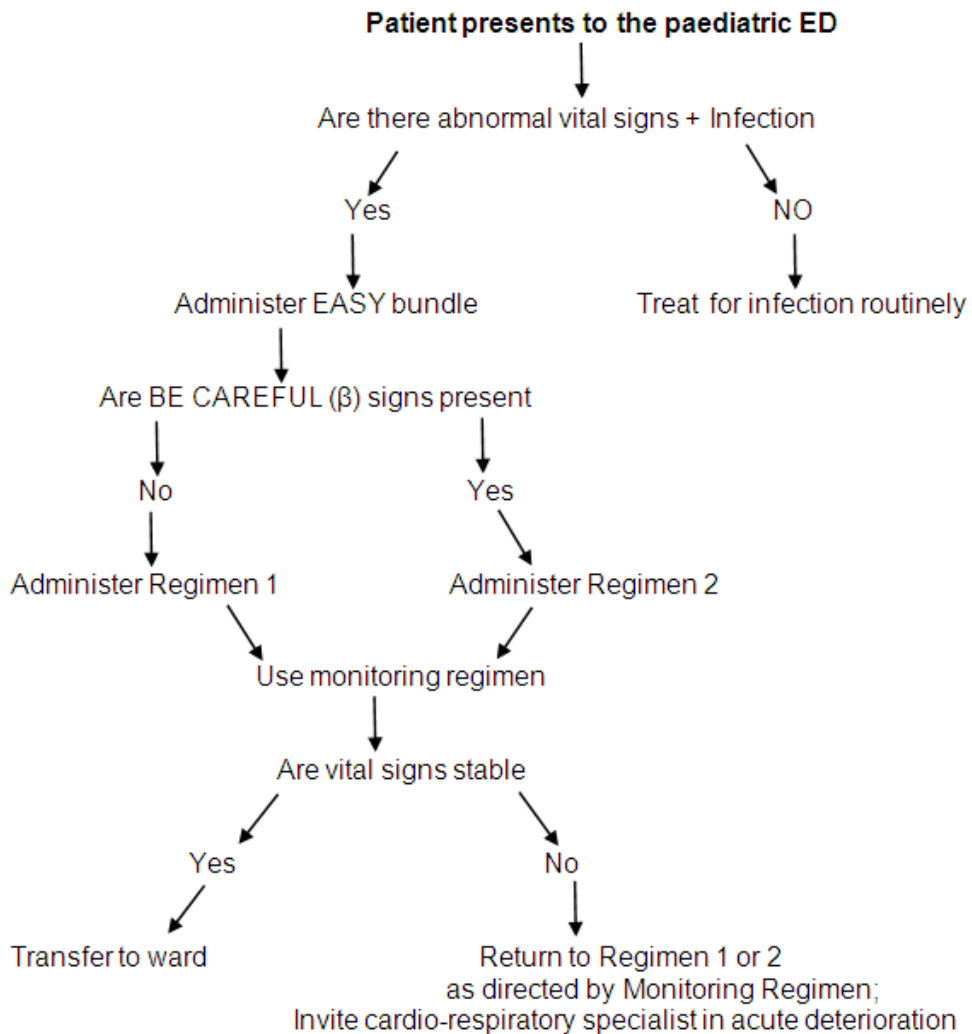
Total enumerative sampling was employed such that every patient who met the criteria of inclusion during the period of the study was selected i.e. consecutive recruitment method.

This was applied for both groups of the study. This sampling method was used to prevent sampling bias.

The data obtained from each group were:

1. their demographic variables,
2. presenting complaints,
3. duration of symptoms before presentation,
4. clinical signs at presentation,
5. admitting diagnosis
6. the results of their complete blood count and differentials,
7. the duration spent in the ED
8. and the total duration of hospital admission.

Table 1. Patient selection for EASY protocol



We also obtained the patients' data from the individual triage cohorts of group A patients. The clinical signs at presentation determined the triage cohorts and the particular algorithm of the EASY protocol that the physician administered.

The data were analyzed using the Statistical Package for Social Sciences (SPSS) version 25. Chi-square test was used for group comparisons, while ANOVA was utilized for comparing means and logistic regression for determining predictive values. The results are presented in tables and graphs.

3. RESULTS AND DISCUSSION

The mean age of group A was 4.46 years (Range: 2 months - 16 years ± 4.31) while that of group B was 4.66 years (Range: 5 months - 14 years ± 4.49), and they were not statistically different; $t = 0.17, P = .87$. Group A had 19 females and 11 males, while group B had 17 females and 13 males. Again, this difference was not significant, $\chi^2 = 0.28, P = .60$. This is shown in Table 2 below.

At presentation, 21 patients in group A had abnormal pulse rates compared to 13 in group B, while 14 patients in group A had abnormal respiratory rates compared to 20 in group B. However, these differences were also not statistically significant. Similarly, the majority of the patients in both groups had signs restricted to a single organ system, and their numbers were not significantly different.

The majority of the patients in both groups had no underlying chronic disease. Table 3 shows the prevalence of chronic illnesses in the two groups and the number of organ systems manifesting with clinical symptoms at the presentation time.

The mean duration of the acute illness (before presentation) for groups A and B were 8.30 (1 - 35) days and 7.07 (1 - 60) days, respectively, and the difference was not statistically significant; $t = 0.472, P = .64$. The admitting diagnoses of the patients in both groups were also similar and are illustrated in Fig. 1

Table 2. Age and gender distribution of the study population

Age group	Group A (%)	Group B (%)	
0 - 11 months	8 (26.7)	5 (16.7)	$\chi^2 = 0.91$ $P = .64$
1 - 4.9 years	11 (36.7)	13 (43.3)	
≥ 5 years	11 (36.7)	12 (40.0)	
Total	30 (100.0)	30 (100.0)	
Gender			
Male	11 (36.7)	13 (43.3)	$\chi^2 = 0.28$ $P = .60$
Female	19 (63.3)	17 (56.7)	
Total	30 (100.0)	30 (100.0)	

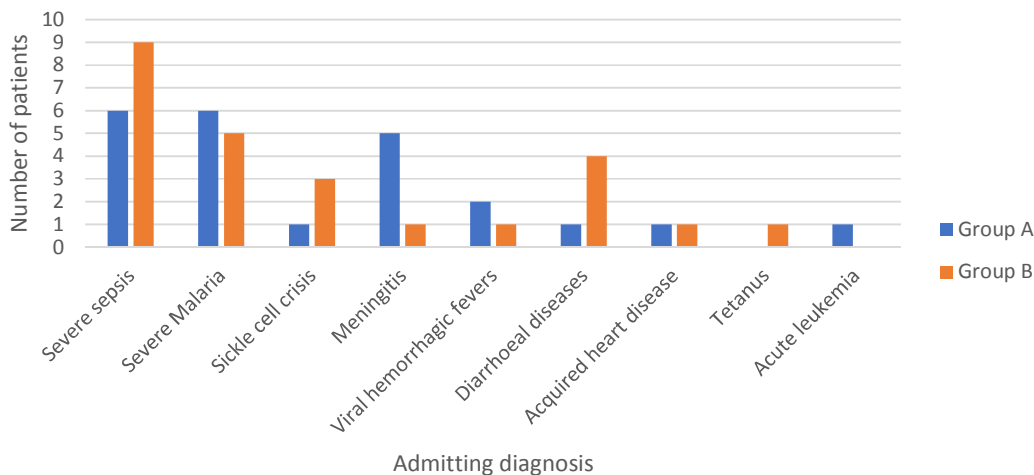


Fig. 1. Diagnosis at admission into the ED

Table 3. Presence of underlying chronic disease

Chronic disease (%)	Group A (%)	Group B (%)	
None	23 (76.67)	22 (73.3)	
Sickle cell anemia	3 (10.0)	4 (16.7)	
AIDS	1 (3.33)	2 (6.67)	
Acquired heart disease	1 (3.33)	1 (3.33)	
Asthma	1 (3.33)	0 (0.0)	
Acute leukemia	1 (3.33)	0 (0.0)	
Obstructed hernia	0 (0.0)	1 (3.33)	
Total	30 (100.0)	30 (100.0)	
Number of systems affected			
One	18 (60.0)	23 (76.67)	
Two	10 (33.33)	6 (20.0)	$\chi^2 = 1.27, P = .53$
Three	2 (6.67)	1 (3.33)	
Total	30 (100.0)	30 (100.0)	

Table 4 shows the frequency of administering saline boluses, oxygen therapy and bubble continuous positive airway pressure (Bubble-CPAP) ventilation. Again, significantly more group A patients had saline boluses and Bubble-CPAP compared to group B. However, the difference in frequency of direct oxygen therapy was not significant across the groups.

Group A patients who had symptoms in one organ system spent significantly less time in the ED (0.98 ± 0.43 days) than group B patients (1.87 ± 0.97 days) who similarly had symptoms restricted to one system; $F = 13.02, P = .001$. There was, however, no significant difference in the mean ED stay of patients with two and three systems involved across both groups. Overall, the mean ED stay of group A patients was 1.26 days while that of group B was 2.27 days, but this difference was not statistically significant; $t = 1.83, P = .09$.

The particular EASY algorithm used strongly correlated with the presence of underlying chronic disease and the duration of acute illness

(both obtained from history) when evaluated together; $P = .001, R^2 = 0.37 - 0.59$. It also predicted the presence of abnormal blood counts (low packed cell volume/ hemoglobin, leukocytosis and absolute neutrophilia or neutropenia); $P = .02, R^2 = 0.39 - 0.64$.

Further logistic regression showed that the particular algorithm used could predict the presence of abnormal blood counts, the presence of underlying chronic disease and the duration of acute illness when evaluated collectively; $P = .001, R^2 = 0.63 - 1.00$.

There was no (0%) mortality in group A while one patient (3.33%) died in group B. The patient who died had symptoms in 2 organ systems and died after 21 hours on admission from complications of acute kidney injury from sepsis. In addition, one patient in group B was discharged against medical advice by the parents due to financial constraints. Hence, 28 patients (93.3%) in group B were discharged home after treatment, while all 30 patients (100%) in group A were discharged home after treatment.

Table 4. Frequency of saline boluses, oxygen therapy and continuous positive airway pressure

Saline boluses	Group A (%)	Group B (%)	
Yes	24 (80.0)	5 (16.7)	$\chi^2 = 24.09$ $p < .001$
No	6 (20.0)	25 (83.3)	
Total	30 (100.0)	30 (100.0)	
Oxygen therapy			
Yes	15 (50.0)	10 (33.3)	$\chi^2 = 1.71$ $p = .15$
No	15 (50.0)	20 (67.7)	
Total	30 (100.0)	30 (100.0)	
BCPAP			
Yes	10 (33.3)	3 (10.0)	$\chi^2 = 4.81$ $p = .03$
No	20 (67.7)	27 (90.0)	
Total	30 (100.0)	30 (100.0)	

4. DISCUSSION

As EASY is an indigenous sepsis protocol designed for use with minimal need for medical equipment and relying almost exclusively on clinical signs, laboratory classifications of multiple organ dysfunction in sepsis were not required for this study. This is particularly relevant as there is a dearth of invasive and technological facilities to investigate these parameters at the study site, and at other resource-constrained settings. [20] As an alternative, the number of body systems with clinical signs at presentation was used as an index of disease severity. The total number of days spent in the ED is used in this study as an indicator of the duration of the acute/ critical phase of the disease in the patients. The cohort of patients in both groups were similar with respect to their baseline characteristics.

The results of the study show that the cohort that got the EASY protocol received significantly more saline boluses than the control group. This was also the case with assisted ventilation, in this case bubble continuous airway pressure Bubble-CPAP. These results show that with the use of the EASY protocol, the initial resuscitative treatment on arrival at the ED is more intense and proactive. Similar findings are observed with the use of sepsis bundles in general. [21,22]

Majority of the patients in group A without multiple organ dysfunction (i.e. those who had signs limited to a single organ system) responded more rapidly to initial resuscitative treatment and required less time in the ED, compared to the control group. Thus, EASY shortened the duration of the acute phase of illness in patients with early stages of sepsis and thus, may have prevented progression to severe sepsis and MODS. This can be explained by the early anticipation of lactic acidosis and subsequent timely proactive management with crystalloid boluses. Severely elevated lactic acid levels can have profound hemodynamic consequences and lead to death. [23]

On the other hand, in patients with multiple organ involvement requiring more intensive care, EASY did not significantly shorten the critical stage of illness but tended to improve the overall survival rate. However, a larger sample size is required to establish this observation.

The study demonstrated a strong correlation between the presence of abnormal blood counts and the particular algorithm used. This is

particularly noteworthy as the results of these investigations were obtained after the algorithm had been instituted, and thus the selection of the appropriate algorithm could not have been influenced by the blood counts. This indicates the credibility of the EASY protocol, signifying that it upholds scientific and logical processes.

No patient in the study who had the EASY protocol deteriorated clinically or progressed from a less severe to a more severe stage of sepsis. This may be because frequent clinical reviews form the cornerstone of EASY, and help to detect the earliest signs of deterioration, thereby allowing for early modification of treatment choices as directed by the algorithms, as soon as the vital signs of the patients are noticed to be worsening.

A unique feature of the EASY protocol is that it gives room for physicians to individualize the algorithms according to the index patient's clinical status and needs. This, therefore, reduces the risk of increased morbidity and mortality caused by administering the same treatment to every child with sepsis as was observed in a randomized control trial on children with sepsis in East Africa. [18]

This unique feature accounts for the potential advantage of the EASY protocol over other sepsis guidelines as the protocol identifies clinical signs of Sepsis Induced Cardiomyopathy (SICM) right from the point of presentation, and immediately administers drugs that support the heart: cardiac inotropes, slow infusion of diuretics, CPAP and no crystalloid boluses. SICM is a very severe complication of sepsis, is difficult to treat and is associated with mortality rates as high as 70%. [24] In SICM, crystalloid boluses are detrimental and should be avoided. [25] This critical knowledge is incorporated into the EASY protocol. Thus, the EASY protocol is a merger of critical care and emergency medicine, administered to patients with sepsis at the beginning of their treatment.

Another unique feature of the EASY protocol is that it does not require any invasive procedure. Prompt respiratory support with Bubble-CPAP in dyspneic patients rather than routinely placing them on Oxygen helps to forestall the need for mechanical ventilation which is fraught with several risks and complications. [26] Similarly, identifying patients in acute cardiac failure/ SIMD and prompt institution of specific treatment, may prevent the need for invasive cardiac monitoring

and eventual Extra Corporeal Membrane Oxygenation (ECMO) which is a very invasive procedure. Invasive procedures are associated with increased morbidity, prolonged recovery time from complications and death [27] In best practices, they are best avoided wherever possible. In this respect, the EASY protocol is relevant even in advanced countries and other medical settings where the absence of sophisticated invasive equipment is not a constraint. In addition, highly skilled manpower and manhours to administer such invasive procedures are not required, further reducing the cost to the health care system and the overall burden of sepsis.

Not only are the EASY algorithms structured to suit different sepsis patterns, the EASY bundle is also flexible and allows for testing according to local disease epidemiology. For instance, rapid tests for Malaria, Dengue, Lassa Fever, rapid streptococcal tests etcetera can be incorporated into the bundle according to the epidemiology of disease in the locality. This is at the discretion of the doctors practicing in a given locality. Thus, the EASY bundle does not require modification in the event of an epidemic/ pandemic and can be readily used in a sudden disease outbreak. The need for physicians to be able to adjust sepsis guidelines according to their unique environment allows for better compliance with guidelines, and this is a cornerstone of the EASY protocol.

A further invaluable advantage of the EASY protocol is that it ultimately improves the clinical skills of physicians by emphasizing detailed attention to clinical signs and promoting frequent reviews, an advantage that is very useful in reducing sepsis morbidities and mortality in low resource settings and indeed, all over the world. Clinical signs form the bedrock of clinical practice and are very pertinent in achieving prompt and accurate diagnosis which in turn improve patient safety and survival in all facets of medical practice [28]

4. CONCLUSION

The EASY sepsis protocol is a useful and efficient tool for the management of sepsis in children. Very importantly, it does not cause harm, increased morbidity or death. In addition, the EASY protocol can be effectively administered on patients by using mainly clinical signs and symptoms and no sophisticated medical facilities. EASY reduces the duration of the acute phase of sepsis in the children without

multiple organ dysfunction and accurately triages patients to receive different treatment choices. The incorporation of a triage system into a sepsis protocol/ bundle is novel and this study demonstrates its feasibility and efficacy, making the protocol useful even in settings with adequate resources.

CONSENT

This was a retrospective chart review of participants who received standard and new treatment (EASY) protocol used for patients in an emergency unit. So, no informed consent was obtained from the parents. However, to ensure anonymity, the data was de-identified.

ETHICAL APPROVAL

All authors hereby declare that all procedures have been examined and approved by the Irrua Specialist Teaching Hospital ethics committee (ISTH/HREC/20190205/012) and have therefore been performed in accordance with the ethical standards laid down in the 1964 "Declaration of Helsinki."

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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