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RESEARCH ARTICLE

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Clinical Features, Antibiotic Resistance, and Management of Bacterial Meningitis in Children Under Five at Nakuru Level 5 Hospital

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ABSTRACT

Bacterial meningitis is a severe condition contributing to high morbidity and mortality among children under five years in low-resource settings. This study assessed the clinical management of bacterial meningitis at Nakuru County Referral Hospital (NCRH) in Kenya, focusing on antimicrobial therapy appropriateness and factors influencing treatment outcomes. A cross-sectional study based on retrospective data of hospital records was conducted, including data on clinical features, laboratory results, and antimicrobial sensitivity patterns. The study aimed to evaluate the appropriateness of antimicrobial therapy and its adherence to culture and sensitivity results. The study included children with a mean age of 2.03 years and a mean weight of 1.48 kg. Streptococcus pneumoniae (42.9%) and Haemophilus influenzae (30.5%) were the most prevalent pathogens. Antimicrobial sensitivity revealed that *Streptococcus pneumoniae* was most responsive to Ceftriaxone (70.8%) and Vancomycin (60%). Despite this, the appropriate use of Ceftriaxone was low (16%), while Vancomycin was administered correctly in 60% of cases. Incomplete vaccination status and daycare attendance were significant risk factors for poor outcomes (p < 0.05). The findings highlight challenges in the clinical management of bacterial meningitis at NCRH, particularly in the selection and application of antimicrobial therapies. The low rate of appropriate antimicrobial use suggests gaps in following sensitivity results, potentially compromising patient outcomes. The predominance of Streptococcus pneumoniae underscores the need for improved vaccination strategies. Additionally, younger age, lower weight, and male gender were identified as key factors associated with increased risk, necessitating targeted interventions in these groups. In conclusion, enhancing adherence to antimicrobial guidelines and strengthening vaccination efforts are crucial for improving the clinical management of bacterial meningitis in children under five at NCRH. Further research should explore additional factors affecting treatment outcomes in this population.

Keywords Bacterial Meningitis; Antimicrobial Sensitivity; Clinical Management; Streptococcus pneumoniae; Pediatric Infection

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INTRODUCTION

Bacterial meningitis (BM) is a critical public health disproportionately affects young children, particularly those under five years of age (Duke et al., 2003). Globally, it is a leading cause of mortality and severe morbidity, with significant consequences such as cognitive impairment, hearing loss, and other neurological deficits. The disease is characterized by rapid onset and progression, which, if not promptly managed, can result in fatal outcomes or irreversible damage (Wendon et al., 2017). In low-resource settings, such as many regions in sub-Saharan Africa, the challenge of managing BM is compounded by limited access to advanced diagnostic tools, delayed healthcare-seeking behavior, and the increasing threat of antimicrobial resistance (Thizy et al.,

Nakuru County, located in the Rift Valley region of Kenya, is a rapidly growing area with a diverse population, including a significant number of young children (Gevera et al., 2019). The Nakuru County Referral Hospital (NCRH) serves as the primary healthcare facility for the region, handling a high volume of pediatric cases. Despite advancements in healthcare, bacterial meningitis remains a significant concern in Nakuru, as it does in many other parts of Kenya. The hospital's pediatric department frequently manages cases of BM, yet there is limited data on the clinical management practices and outcomes specific to this setting. This gap in knowledge is critical, as understanding local epidemiology, risk factors, and treatment efficacy is essential for improving patient outcomes and developing targeted interventions.

The burden of bacterial meningitis in Nakuru is reflective of broader challenges faced across sub-Saharan Africa, where the disease continues to cause significant morbidity and mortality. In this region, BM is primarily caused by Streptococcus pneumoniae. Neisseria meningitidis. Haemophilus influenzae type b (Hib) (Amin et al., 2016). The introduction of vaccines has reduced the incidence of Hib-related meningitis, but S. pneumoniae and N. meningitidis remain prevalent (Slack et al., 2021). Moreover, the high prevalence of antimicrobial resistance further complicates treatment, necessitating the use of empirical therapy often before definitive laboratory results are available. This practice, while sometimes concerns about necessary, raises appropriateness and effectiveness of antimicrobial therapy, particularly in a setting where access to advanced diagnostic tools and laboratory facilities may be limited.

The clinical management of bacterial meningitis at NCRH involves a combination of empirical antimicrobial therapy, supportive care, and, when possible, treatment tailored to culture and sensitivity results. However, the effectiveness of these management strategies has not been comprehensively evaluated. Factors such as delayed presentation, misdiagnosis, and suboptimal adherence to treatment guidelines may contribute

to poor outcomes (Sloan et al., 2022). In addition, socio-demographic factors like age, nutritional status, and vaccination history are likely to influence the course and prognosis of the disease.

In many cases, the diagnosis of BM is based on clinical signs and symptoms, such as fever, neck stiffness, and altered mental status (Sheybani et al., 2016). However, in younger children, these symptoms may be nonspecific, leading to diagnostic challenges. Cerebrospinal fluid (CSF) analysis remains the gold standard for diagnosing bacterial meningitis, but in resource-limited settings like Nakuru, the availability and timely processing of CSF samples can be inconsistent (Gomes, 2022). This situation often results in reliance on clinical judgment and empirical treatment, which may not always align with the actual causative pathogen or its antimicrobial susceptibility profile.

The management of bacterial meningitis in this context is further complicated by the need to balance the urgency of treatment with the risks of antimicrobial resistance (van de Beek et al., 2016). The increasing incidence of resistant strains of *S. pneumoniae* and other pathogens in Kenya and the broader region underscores the importance of ongoing surveillance and judicious use of antibiotics. Additionally, while vaccination has significantly reduced the incidence of meningitis caused by Hib and certain serogroups of *N. meningitidis*, gaps in vaccination coverage remain, particularly in rural and underserved populations.

Given these challenges, there is a pressing need for studies that evaluate the current clinical management practices for bacterial meningitis at Nakuru County Referral Hospital. We evaluated clinical management of bacterial meningitis in children under five at Nakuru County Referral Hospital, Kenya.

METHODS

Study Design

This was a cross-sectional study based on retrospective data according to (Algahtani et al., 2020). The primary variables of interest included the clinical management practices, outcomes of the treatment administered, and the adherence to clinical guidelines in treating BM. The cross-sectional design was selected to allow for the assessment of data from a specific time frame, providing a comprehensive overview of management approaches and effectiveness. This design was chosen for its ability to efficiently utilize existing records to evaluate clinical practices and outcomes without the need for prolonged data collection periods.

Study Location

The study was conducted at Nakuru County Referral Hospital (NCRH), located in Nakuru County, Kenya, approximately 2 kilometers north of Nakuru town's commercial center in the Rift Valley . NCRH is a major healthcare facility that serves as a referral center for multiple sub-county hospitals and health centers across the region, Sampling Technique including Molo, Njoro, Olenguruone, Ol-Kalau, and Naivasha. Its strategic location comprehensive services make it an essential hub for pediatric care, including the management of severe infections like bacterial meningitis. The hospital's diverse patient population and wide catchment area provided a rich context for studying the clinical management practices and outcomes of BM in children.

Target and Study Population

The target population for this study consisted of children under the age of five years who were diagnosed with bacterial meningitis at Nakuru County Referral Hospital between 2016 and 2021. The study specifically focused on those children admitted to NCRH during this period. The choice of this age group was based on their heightened vulnerability to BM and the associated risks of severe complications. The study population represented a critical demographic for assessing the effectiveness of clinical management practices in a high-risk, resource-limited setting.

Inclusion and Exclusion Criteria

Inclusion criteria for the study were children under five years of age who were diagnosed with bacterial meningitis and admitted to NCRH between 2016 and 2021. The medical records of these patients needed to be complete, containing all necessary information on diagnosis, treatment, and outcomes relevant to the study. Exclusion criteria included cases where cerebrospinal fluid (CSF) analysis was not performed, or records were incomplete or missing essential data. This ensured that only cases with a confirmed diagnosis of bacterial meningitis were included, enhancing the reliability of the study's findings regarding clinical management.

Sample Size and Sampling Technique Sample Size

The sample size was determined using Fischer's formula (1978) for calculating sample sizes in cross-sectional studies. Assuming a 10% prevalence of positive CSF culture results among pediatric admissions, the initial calculated sample size was

138. However, due to the finite population size of pediatric BM cases at NCRH during the study period, a reduction formula was applied, resulting in a final sample size of 112. This sample size was considered sufficient to provide statistically significant insights into the clinical management practices at the hospital.

Given the retrospective nature of the study, purposive sampling (Campbell et al., 2020) was used to select patient files that met the inclusion criteria. This method, particularly criterion-i purposive sampling, ensured that the study concentrated on those pediatric patients who had a confirmed diagnosis of bacterial meningitis and were treated at NCRH. The purposive selection of records was critical for focusing on clinically relevant cases, thereby improving the study's ability to assess the management practices and outcomes.

Data Collection Instruments and **Procedure**

A data abstraction tool was specifically designed to collect detailed information on clinical management practices, including the types of antimicrobials used, dosing regimens, duration of treatment, and patient outcomes (Appendix After obtaining the necessary ethical approvals, the researcher accessed and reviewed patient files from the hospital's records department, focusing on those that met the study's inclusion criteria. Data were abstracted from these files and entered into the data abstraction forms. To ensure data quality, each form was checked for completeness and accuracy at the end of each data collection day before being transferred to a password-protected Microsoft Excel database, accessible only to the Principal Investigator (PI).

Data Analysis, Interpretation, and Presentation

Data were analyzed using SPSS, version 20.0. Descriptive statistics were used to summarize clinical management practices, including the types of antibiotics administered, dosing strategies, and treatment outcomes. Continuous variables such as age and weight were expressed as means and standard deviations, while categorical variables were summarized as proportions and percentages. The study also assessed the adherence to clinical guidelines by

protocols. established between clinical outcomes and variables like status, treatment regimens and patient demographics malnourished. This indicates that a significant were analyzed using Fischer's exact test and portion of the children were in a good nutritional logistic regression analysis. A p-value of less than state, although nearly half faced nutritional 0.05 was considered statistically significant.

Ethical Considerations

Kabarak University Research Committee (KUREC) KABU01/KUREC/001/01/10/22), Nakuru the County Referral Hospital Research Department, 55.24% of the children, while 44.76% had and the National Commission for Science, Technology and Innovation (NACOSTI) (License No: NACOSTI/P/22/20918). To ensure patient potential gaps in immunization, which may confidentiality, no unique identifiers were recorded on data collection forms. All paper documents were securely stored in a locked accessible only to the Principal Investigator, while electronic data was protected with password security.

RESULTS

Clinical characteristics of children admitted to NCRH

Out of the total cases, 47.62% of the children were delivered through spontaneous vaginal delivery (SVD), while 52.38% were delivered via cesarean section (CS). This near-equal distribution suggests a balanced representation of both delivery modes among the study population. Nutritional Status:

comparing the observed management practices The majority of the children (57.14%) were Associations reported to be healthy in terms of nutritional while 42.86% were identified challenges. More than half of the children (53.33%) had a history of delayed developmental milestones, with 46.67% having no such history. Ethical approval for the study was obtained from This highlights that developmental delays were Ethics relatively common in this population, possibly (Ref: influencing their susceptibility to bacterial meningitis. Vaccination status was incomplete in complete vaccination records. The higher prevalence of incomplete vaccination suggests contribute to the incidence of bacterial meningitis. A significant proportion of the children (60%) attended daycare, while 39.05% did not. This indicates that daycare attendance was common among the children, which might relevant considering the potential for increased exposure to infections in such settings.

> Regarding serostatus, 33.33% of the children were reactive, 36.19% were non-reactive, and 30.48% had no serostatus test performed. The diverse serostatus results indicate varying levels of exposure or immune response among the children, with a substantial proportion lacking this crucial diagnostic information.

Table 1: Clinical characteristics of Children Admitted to NCRH

Characteristic	Category	Count	Percent
Mode of delivery	SVD	50	47.62
	CS	55	52.38
Nutritional status	Healthy	60	57.14
	Malnourished	45	42.86
History of delayed milestones	Yes	56	53.33
	No	49	46.67
Vaccination status	Complete	47	44.76
	Inomplete	58	55.24
Day care	Yes	63	60
	No	41	3905
Sero Status	Reactive	35	33.33
	No-reactive	38	36.19
	not done	32	30.48

Antimicrobial sensitivity patterns of the isolates among children under five in NCRH

The findings revealed that Amoxicillin-clavulanic acid (Augmentin®) had a sensitivity rate of 57.5%, with 30 out of 52 isolates responding positively to the drug, while 22 were resistant. This indicates a moderate level of effectiveness for Augmentin® in treating bacterial meningitis in this population. Ceftriaxone, a commonly used antibiotic, demonstrated a higher sensitivity rate of 70.8%. Out of 24 isolates tested, 17 were sensitive to Ceftriaxone, while only 7 showed resistance. This suggests that Ceftriaxone remains a relatively

effective option for managing bacterial meningitis in the studied population. exhibited Gentamicin, however, lower sensitivity rate of 42.9%. Among the 14 isolates tested, 6 were sensitive, while 8 were resistant. This lower sensitivity indicates that Gentamicin may be less effective as a first-line treatment for bacterial meningitis in this setting, necessitating careful consideration when prescribing this drug. Vancomycin showed a sensitivity rate of 60%, with 9 out of 15 isolates responding positively to the treatment, while 6 were resistant. This suggests that Vancomycin is moderately effective treating bacterial meningitis in population, although resistance is still a concern.

Table 2: Antimicrobial Sensitivity Patterns of Drugs Used in the Treatment of Bacterial Meningitis Caused by Streptococcus pneumoniae in Children Under Five at Nakuru County Referral Hospital

Drug	Resistant	Sensitive	Total	% Sensitivity
Amoxycillin-clavulanic acid (Augmentin®)	22	30	54	57.5
Ceftriaxone	7	17	24	70.8
Gentamicin	8	6	14	42.9
Vancomycin	6	9	15	60
Total	43	62	105	

The results showed that Amoxicillin-clavulanic In contrast, Gentamicin had the lowest acid (Augmentin®) had a sensitivity rate of 69.2%, sensitivity rate at 28.6%. Out of 14 isolates with 36 out of 52 isolates responding positively, tested, only 4 were sensitive, while 10 were while 16 were resistant. This indicates that resistant. Augmentin® is relatively effective in treating Gentamicin's limited effectiveness in this context, bacterial meningitis population. in this Ceftriaxone demonstrated the highest sensitivity among the tested antibiotics, with an impressive population. Vancomycin showed a sensitivity rate of 83.3%. Out of 24 isolates, 20 were sensitive, rate of 73.3%, with 11 out of 15 isolates and only 4 showed resistance. This suggests that responding positively to the drug and 4 showing Ceftriaxone is highly effective and remains a resistance. This indicates that Vancomycin is strong choice for managing bacterial meningitis in generally the studied children.

This low sensitivity suggesting it may not be the best option for firstline treatment of bacterial meningitis in this effective for treating bacterial meningitis, although resistance remains consideration.

Table 3: Antimicrobial Sensitivity Patterns of Drugs Used in the Treatment of Bacterial Meningitis Caused by Hemophilus influenza in Children Under Five at Nakuru County Referral Hospital

Drug	Resistant	Sensitive	Total	% Sensitivity
Amoxycillin-clavulanic acid (Augmentin®)	16	36	52	69.2
Ceftriaxone	4	20	24	83.3
Gentamicin	10	4	14	28.6
Vancomycin	4	11	15	73.3
Total	26	79	105	

Amoxicillin-clavulanic acid showed a high sensitivity rate of 78.8%, with 41 86.7%, with 13 out of 15 isolates responding out of 52 isolates responding positively, and only positively and only 2 showing resistance. This 11 displaying resistance. This suggests that indicates that Vancomycin is highly effective in Augmentin® is generally effective for treating managing bacterial meningitis in the studied bacterial meningitis in this population.

Ceftriaxone, another commonly used antibiotic, demonstrated a sensitivity rate of 70.8%. Of the 24 isolates tested, 17 were sensitive, while 7 were resistant. While still effective, Ceftriaxone's sensitivity is slightly lower than that of Augmentin®, indicating its potential as a reliable treatment option, though resistance should be monitored. Gentamicin exhibited a sensitivity rate of 50%, with an equal number of isolates (7 out of 14) being sensitive and resistant. This moderate sensitivity suggests that Gentamicin's effectiveness is limited, and it may not be the best choice for first-line treatment of bacterial meningitis in this setting.

(Augmentin®) Vancomycin had the highest sensitivity rate at population, making it a strong candidate for treatment.

Table 4: Antimicrobial Sensitivity Patterns of Drugs Used in the Treatment of Bacterial Meningitis Caused by Neisseria meningitis in Children Under Five at Nakuru County Referral Hospital

Drug	Resistant	Sensitive	Total	% Sensitivity
Amoxycillin-clavulanic acid (Augmentin®)	11	41	52	78.8
Ceftriaxone	7	17	24	70.8
Gentamicin	7	7	14	50
Vancomycin	2	13	15	86.
Total	22	83	105	

Appropriateness of therapy given culture and sensitivity results among children admitted for treatment of bacterial meningitis in NCRH

Amoxicillin-clavulanic acid (Augmentin®) had an appropriate use rate of 44%, with 22 instances of appropriate use compared to 28 cases of inappropriate use. This suggests a moderate level of adherence to proper use guidelines for Augmentin®. Ceftriaxone showed the lowest rate of appropriate use at just 16%, with only 7 cases deemed appropriate out of 43 total uses.

This indicates a significant challenge in ensuring application Ceftriaxone, correct of highlighting the need for better adherence to treatment protocols. Gentamicin had appropriate use rate of 42%, with 18 appropriate uses out of 43 instances, similar to Augmentin®. This reflects a moderate level of proper use but suggests room for improvement. Vancomycin demonstrated the highest rate of appropriate use at 60%, with 26 instances of appropriate use versus 17 inappropriate uses. This indicates that Vancomycin was generally well-utilized according to clinical guidelines.

Table 5:

Appropriateness of Antibiotic Use in the Treatment of Bacterial Meningitis in Children Under Five at Nakuru County Referral Hospital

Medicine	Appropriate Use	Inappropriate use	Percent appropriate use
Amoxycillin-clavulanic acid (Augmentin®)	22	28	44%
Ceftriaxone	7	36	16%
Gentamicin	18	25	42%
Vancomycin	26	17	60%

DISCUSSION

The clinical characteristics of the children admitted to NCRH with bacterial meningitis provide a valuable context for understanding the disease burden in this population. The nearly equal distribution of delivery modes, with 47.62% delivered via spontaneous vaginal delivery (SVD) and 52.38% via cesarean section (CS), suggests that mode of delivery may not be a significant factor in the development of bacterial meningitis in this population. However, it is notable that cesarean section deliveries are slightly more prevalent, which might reflect broader trends in obstetric practices in the region rather than a direct association with bacterial meningitis.

Nutritional status emerged as a critical factor, with 57.14% of children being healthy and 42.86% identified as malnourished. Malnutrition is a known risk factor for increased susceptibility to infections, including bacterial meningitis, due to its impact on immune function. The presence of nearly half of the children being malnourished underscores the need for integrated nutritional interventions as part of comprehensive care for children at risk of bacterial meningitis.

Developmental delays were reported in 53.33% of the children, which aligns with the understanding that such delays can be associated with increased vulnerability to infections. The high prevalence of delayed milestones in this population suggests that these children may have underlying conditions or vulnerabilities that predispose them to severe infections like bacterial meningitis (Patil, 2015). This finding emphasizes the importance of early developmental screening and intervention to mitigate such risks.

Vaccination status revealed that 55.24% of the children had incomplete vaccination records. Incomplete vaccination is a critical concern, as it leaves children vulnerable to vaccine-preventable diseases, some of which can lead to secondary bacterial infections, including meningitis. This finding is consistent with other studies that have highlighted the role of incomplete vaccination in the incidence of bacterial infections in children. **Improving** vaccination coverage could significantly reduce the burden of bacterial meningitis in this population. Daycare attendance was common among the children,

with 60% attending daycare. Daycare settings are known for higher transmission rates of infectious diseases due to close contact among children (Collins and Shane, 2018). This finding suggests that daycare attendance may be a relevant factor in the spread of bacterial pathogens, further emphasizing the need for stringent infection control measures in such settings.

The serostatus results were varied, with 33.33% of the children being reactive, 36.19% non-reactive, and 30.48% untested. The diverse serostatus findings highlight the complexity of the patient population and the importance of thorough diagnostic workups in managing bacterial meningitis. The significant proportion of children without serostatus testing points to gaps in diagnostic practices that could impact the effective management of the disease.

The antimicrobial sensitivity patterns observed in this study provide critical insights into the effectiveness of commonly used antibiotics in the treatment of bacterial meningitis in children under five. Amoxicillin-clavulanic acid (Augmentin®) showed a moderate sensitivity rate of 57.5%, with 30 out of 52 isolates responding positively. This indicates that while Augmentin® is effective in some cases, there is a substantial proportion of resistance (42.5%). The findings are consistent with other studies that have reported varying degrees of resistance to beta-lactam antibiotics, particularly in settings with high antibiotic use. Ceftriaxone, a third-generation cephalosporin, demonstrated a higher sensitivity rate of 70.8%, making it a relatively effective option for treating bacterial meningitis in this population. This finding is supported by numerous studies that have identified Ceftriaxone as a cornerstone in the management of bacterial meningitis due to its broad spectrum of activity and good penetration into the cerebrospinal fluid (CSF) (Nau et al., 2013; Nau et al., 2015). However, the presence of resistant isolates (29.2%) underscores the need for continuous surveillance and judicious use of antibiotics to prevent further resistance development.

Gentamicin exhibited the lowest sensitivity rate at 42.9%, indicating its limited effectiveness in treating bacterial meningitis in this population. This result is concerning, given that Gentamicin is often used in combination with other antibiotics for treating severe infections (Gonzalez-Padilla et al., 2015). The high level of resistance observed suggests that Gentamicin may not be suitable as a first-line treatment in this setting. Similar findings

have been reported in other studies, where increasing resistance to aminoglycosides has been attributed to their extensive use in both human and veterinary medicine. Vancomycin, with a sensitivity rate of 60%, presents a effective moderately treatment particularly for resistant Gram-positive organisms such as Streptococcus pneumoniae. The findings align with global trends where Vancomycin is often reserved for severe cases or when resistance to other antibiotics is suspected. However, the presence of resistant isolates indicates the need for careful consideration of its use to avoid the emergence of Vancomycinresistant strains.

The assessment of the appropriateness of antibiotic use revealed significant challenges in the management of bacterial meningitis at Amoxicillin-clavulanic NCRH. (Augmentin®) had an appropriate use rate of only 44%, suggesting that more than half of the prescriptions were not aligned with sensitivity results. This finding raises concerns about potential overuse or misuse of antibiotics, contributing to the development of resistance. Ceftriaxone had the lowest rate of appropriate use at just 16%, indicating a widespread issue with its application in clinical practice. The between sensitivity discrepancy rates appropriate use highlights the need for improved diagnostic support and adherence to treatment guidelines. The misuse of Ceftriaxone, despite its high sensitivity, suggests that clinicians may not be fully utilizing culture and sensitivity data in their prescribing decisions.

Gentamicin, with an appropriate use rate of also reflects challenges in 42%, treatment with sensitivity results. The moderate rate of appropriate use suggests that while some clinicians are adhering to guidelines, there is still significant room for improvement. Gentamicin's lower sensitivity, its use should be more carefully considered, particularly in light of the high resistance rates observed. Vancomycin, with a 60% rate of appropriate use, performed better than the other antibiotics but still leaves considerable room for improvement. relatively higher rate of appropriate use suggests that clinicians may be more cautious in prescribing Vancomycin, possibly due to its status as a last-resort antibiotic. However, the 40% rate of inappropriate use indicates that even for critical antibiotics, there are gaps in practice that need to be addressed.

CONCLUSIONS

The study highlights significant issues in the management of bacterial meningitis in children under five at Nakuru County Referral Hospital, particularly in the areas of antibiotic sensitivity and appropriate use. The findings underscore the need for improved diagnostic practices, better adherence to treatment guidelines, and continued surveillance of antibiotic resistance patterns. Addressing these challenges is critical to improving outcomes for children with bacterial meningitis and preventing the further spread of antibiotic resistance. Future efforts should focus on strengthening antibiotic stewardship programs, enhancing the use of culture and sensitivity testing decision-making, and comprehensive vaccination coverage to reduce the incidence of bacterial meningitis.

RECOMMENDATIONS

We recommend implementation of a robust antibiotic stewardship program at NKRH, prioritizing the integration of routine culture and sensitivity testing in clinical practices and Nau, R., Djukic, M., Spreer, A., & Eiffert, H. adherence to treatment guidelines to improve outcomes for children with bacterial meningitis and combat antibiotic resistance.

CONFLICT OF INTEREST

Authors declare no conflict of interest.

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