Recent trends in the microbiology and antimicrobial susceptibility patterns of deep neck space infections, a descriptive analysis.

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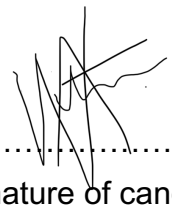
Declaration

I, Werner André Rossouw, declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the department of Otorhinolaryngology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.



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Presentations and publications arising from the research project

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Abstract

Deep Neck Space Infections (DNSI) present healthcare institutions with a significant clinical conundrum and an ever-present public health concern. Rapid progression of disease and potential for immediate life-threatening complications warrants an aggressive approach to diagnostic and therapeutic interventions in DNSI. The current standard of care involves securing the airway, incision and drainage of collections and source control. Broad-spectrum empiric antibiotics needs to be initiated at first contact with healthcare services and continued until culture identification and sensitivity results allows for de-escalation, or clinical improvement is noted. Unfortunately, antimicrobial susceptibility among organisms commonly implicated in DNSI are shifting under pressure. Current literature reports an observed absolute increase in the prevalence of resistant bacterial strains, especially in lower socioeconomic environments. Recommendations regarding choice of empiric agents should be informed by observing locoregional trends. In their pursuit of enhancing clinical outcomes and curbing the emergence of resistant pathogens the authors sought to determine the profile of organisms currently encountered in DNSI and whether co-amoxiclav still constitutes an effective choice. A retrospective review is presented, reporting on the organisms identified and their antimicrobial susceptibility trends over five years within four tertiary hospitals in Johannesburg, South Africa. Basic demographic indicators and specimen references were obtained by perusing theatre records for procedures related to “incision and drainage of neck abscess.” Findings within the cohort are congruent with previous literature on the topic and co-amoxiclav may still be recommended as an effective first-line empiric agent in DNSI. However, a subtle shift toward increasing antimicrobial resistance is noted in the susceptibility trends, indicating a substantial evolving future public health concern.

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CHAPTER 1

INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

The emergence of the antibiotic era has revolutionized treatment of infections in the head and neck, significantly reducing overall morbidity and mortality(1,2). However, Infections of the deep neck spaces still present a significant clinical conundrum with recent literature reporting an increase in prevalence and a shift in antimicrobial susceptibility of pathogens(3,4).

Deep Neck Space Infections (DNSI) may be described as inflammation with or without purulent organization involving the potential spaces formed by cervical communicating fascial planes. This may manifest clinically as cellulitis, phlegmon or abscess formation and constitutes a medical and surgical emergency(5,6). Each cervical space is unique in its anatomical relations and therefore the clinical presentation and tendency towards various complications may differ.

1.2 Deep neck space anatomy

Superficial and deep layers of fascia envelop the structures of the neck to form cervical spaces. The superficial layer extends from the cranium down to the thorax, shoulders, and axilla. It contains adipose tissue, superficial blood vessels, sensory nerves, lymphatics as well as the platysma muscle and muscles of facial expression. Infections contained only within the superficial layer are not termed DNSI's, but this layer may contain the pressure exerted by infections of the deeper spaces leading to compressive complications(7,8).

The potential deep neck spaces are formed by three layers (superficial, middle, deep) of deep cervical fascia. The superficial layer of deep cervical fascia (also called the investing layer) attaches to the mandible, zygomatic arches, mastoid processes, hyoid bone, scapulae, and sternum. Along its course it splits to encase the sternocleidomastoid muscles, trapezius muscles, parotid and submandibular glands to attach posteriorly to the ligamentum nuchae(7,8). The middle layer courses from the skull base superiorly to the mediastinum inferiorly. It contains the anterior structures of the neck and has visceral and muscular divisions. The visceral division contains the larynx, trachea, pharynx, oesophagus, thyroid gland, parathyroid glands, recurrent

laryngeal nerves, and lymph nodes. It courses inferiorly to blend with the fibrous pericardium and great vessels in the mediastinum, and posteriorly to blend with the prevertebral fascia. The muscular division originates from the hyoid bone, splits to contain the infrahyoid strap muscles (sternohyoid, sternothyroid, thyrohyoid, omohyoid) and inserts into the sternum and clavicles(8,9).

The deep layer of the deep cervical fascia also courses from the skull base to the mediastinum. It contains the posterior structures of the neck and has alar and prevertebral divisions. The alar fascia connects the transverse processes of the cervical vertebrae down to the second thoracic vertebra. It forms the posterior boundary of the retropharyngeal space and the anterior boundary of the prevertebral space, in-between which the danger space exists down to the diaphragm. Posteriorly, the prevertebral fascia attaches to the vertebrae creating the prevertebral space from the skull base down to the coccyx. The prevertebral fascia contains the paraspinal muscles, phrenic nerves, brachial plexus, vertebral vessels, and the cervical sympathetic trunk(7–9). The deep neck spaces are bounded by these fascial layers but when their natural resistance has been overcome by infection, predictable pathways of spread are created.

The deep neck spaces may be divided into those cranial to the hyoid bone (buccal, masticator or temporal, parotid, peritonsillar, submandibular, sublingual, parapharyngeal), caudal to the hyoid bone (anterior visceral or pretracheal) and those that traverse the length of the neck (carotid, retropharyngeal, prevertebral)(2,6). Recent literature in our region reports the peritonsillar and submandibular spaces to be the most affected, alone or in combination with other spaces(6).

Odontogenic and pharyngotonsillar sepsis appears to be the most common precipitants, but the source might also be idiopathic in 8-57% of cases(4,6). Odontogenic sepsis of the mandibular dentition is likely to lead to collections in the submandibular space. The submandibular space extends from the mucosa of the floor of the mouth and mandible superiorly, to the hyoid bone inferiorly. It is divided by the mylohyoid muscle into supramylohyoid and inframylohyoid compartments, also referred to as sublingual and submaxillary compartments respectively. These compartments communicate along the posterior free border of the mylohyoid muscle, meaning that sepsis from the roots of dentition can spread from the sublingual to the submaxillary compartments. The roots of the second and third molars extend directly into the submaxillary compartment. Furthermore, there exists no true posterior barrier, which allows for communication with the parapharyngeal space. Pharyngotonsillar sepsis may result in spread of sepsis to

the peritonsillar space. The peritonsillar space is bounded medially by the capsule of the palatine tonsil, laterally by the superior pharyngeal constrictor muscle, and anteroposteriorly by the palatine arches. Further spread of infection may occur laterally into the parapharyngeal space(7–9).

1.3 Microbiology and Antimicrobial susceptibility trends in DNSI

Most DNSI's are polymicrobial in nature, with pathogenic organisms forming part of the commensal upper aerodigestive tract flora(6). *Streptococci* species*, Staphylococcus aureus* and anaerobes are the most common causative organisms(10). The role of Gram-negative aerobic bacteria is limited. The most common isolated gram negative is *Klebsiella pneumoniae*(11)*. Actinomyces, Mycobacterium,* and fungi are also potential causative organisms but are rarely encountered(12)*.* Low oxygen tension in the loose areolar tissues of the deep neck spaces create an ideal environment for synergistic growth of aerobic and anaerobic organisms(13). Recent evidence indicates the stage at presentation may also influence the pattern of organism load, which initially favours aerobe growth followed by gradual increase in anaerobe load(14).

A recent retrospective review of microbiological trends in DNSI observed culture yields in the South African setting to be 69% positive cultures and 31% negative cultures(6). This is consistent with previous observations in the literature citing 27-40% sterile cultures(15). Of all the organisms identified, 92% were aerobic and 8% anaerobic(6). These findings are concordant with previous data.

Most available literature describe Gram-positive aerobic cocci as the most frequently isolated organisms in the setting of DNSI(1,6). *Viridans* group *streptococci* (VGS) are the most common organism cultured in odontogenic infections. Keeping in mind that odontogenic infections may also be characterised by polymicrobial growth and greater load of anaerobic organisms(14). The *Streptococcus anginosus* group (formerly milleri) includes anginosus, intermedius and constellatus species(4). They form part of the commensal flora of the oral cavity and oropharynx with the potential to cause suppurative infection after mucosal disruption(16). Group A Beta-haemolytic *Streptococci* (GABHS) like *Streptococcus pyogenes* is a common causative organism in tonsillar and pharyngeal sepsis(5,14). The *Streptococcus* species are generally sensitive to co-amoxiclav, which is the current first choice empiric agent in our region(1).

In a South African case series that evaluated DNSI in the HIV-infected paediatric

population, *Streptococcus* and *Prevotella* was identified as prevalent organisms. Antibiograms in this study revealed almost universal resistance to penicillin and ampicillin(17). In another local study comparing adult and paediatric DNSI's, *Staphylococcus aureus* was found to be the most prevalent organism in the paediatric population (defined as age <16yrs), with a prevalence of 65% in positive cultures. Out of all the cultured organisms in the paediatric group, 67% was sensitive to cloxacillin, while 76% of positive cultures conferred resistance to penicillin/ampicillin. These findings suggest a different approach to empiric coverage of DNSI in the paediatric population, such as starting cloxacillin earlier. This was shown to be more clinically- and cost efficient(3).

Anaerobes are rarely cultured in isolation but rather as part of a polymicrobial infection. *Prevotella* species appear to be the most frequently isolated anaerobe(4,6). *Prevotella* is a Gram-negative member of the *Bacteroides* phylum that is part of the commensal flora of the oral cavity. Recent locoregional susceptibility trends point to persistent susceptibility to metronidazole(6). *Bacteroides* species, *Peptostreptococcus* species and *Fusobacterium* species are also commonly isolated as pathogens in the oral cavity(6). Culture identification of anaerobic organisms may take 6 to 8 days, which further emphasises the importance of correct choice of empiric antimicrobials(18).

The findings of studies incorporating molecular sequencing techniques in organism identification recommend that clinicians should suspect the presence of anaerobic organisms in DNSI regardless of disease severity and culture findings. Drugs with anaerobe cover should be included in empiric regimes(18). The recommendation based on local epidemiology was also co-amoxiclav. Metronidazole or clindamycin should be additionally considered in selected cases such as in immunocompromised patients(5). This stands in line with current locoregional practise.

1.4 Diagnosis and Management of DNSI

Contrast Enhanced Computed Tomography (CECT) constitutes the golden standard in diagnosis of DNSI(2). The principles of management include providing a secure airway, surgical incision and drainage of collections with source identification and control, as well as administration of systemic antimicrobial treatment(4,15). Rapid progression of disease and potential for complications warrants an aggressive approach to diagnostic and therapeutic interventions in DNSI(5). Complications of DNSI include jugular vein thrombophlebitis, descending mediastinitis with potential for pleuropulmonary collections, pericarditis, septic shock, disseminated intravascular coagulation as well as

posing an imminent threat to the integrity of the airway(2,19). Coexisting medical disorders including Diabetes Mellitus (DM), Human Immunodeficiency Virus (HIV), End Stage Renal Disease (ESRD), anaemia, obesity, and advanced age (>65years) are known to increase the incidence of complications, length of hospital stay, as well as mortality(14,17,19).

Initial administration of broad-spectrum empiric antibiotics, followed by culture-guided therapy with de-escalation to the narrowest effective agent constitutes the universally adopted standard of care(18). Cultures of purulent material have a relatively low yield, blood cultures even lower (15,5%). Furthermore, at least 48 hours is needed until organism identification and antibiograms becomes available to the clinician(6,18). These factors emphasise the importance of prompt initiation of appropriate antimicrobial therapy. It is therefore prudent that the choice of empiric treatment be informed by data obtained from observing locoregional trends(12).

Current literature reports an observed absolute increase in the prevalence of resistant bacterial strains, especially in lower socioeconomic environments(3,6). Therefore, regular observation of local community and hospital acquired pathogens and their antimicrobial susceptibility patterns should inform decision making with regards to empiric antibiotic choices(6). With this retrospective analysis, the authors wish to analyse and describe the distribution of microbes and antimicrobial susceptibility patterns encountered in DNSI. The findings of this study should inform effective use of empiric antimicrobial drugs – which will enhance clinical outcomes, reduce the emergence of resistant pathogens, and shorten duration of hospital stay(18).

CHAPTER 2

METHODOLOGY

2.1 Research question

What are the microorganisms and their antimicrobial susceptibility patterns cultured from DNSI, and are the trends changing over time?

2.2 Research design

A descriptive retrospective review of records over 5 years from January 2018 to December 2022. Sites under investigation included four tertiary referral centres in Johannesburg, South Africa – namely Chris Hani Baragwanath Academic Hospital, Charlotte Maxeke Johannesburg Academic Hospital, Helen Joseph Hospital and Rahima Moosa Mother and Child Hospital.

2.3 Materials and Methods

Inclusion criteria:

- All patients that underwent surgical management of DNSI at tertiary referral centres in Johannesburg. Diagnosis of DNSI was made on clinical and radiological assessment.
- Cases were identified by perusing the emergency and elective theatre records for procedures designated “incision and drainage of neck abscess” and related terms.
- Cases were included regardless of age and gender.
- The National Health Laboratory Services (NHLS) database was then audited to extract the results from microscopy, culture and sensitivity (MC&S) that was published related to specimen obtained from the surgical procedures.

Exclusion criteria:

- Cases where no specimen was submitted for MC&S evaluation.
- Cases where records are found to be incomplete.

2.4 Data collection

Collection of data was performed by the principal investigator alone. This was achieved by visiting each site, obtaining access to theatre records with the appropriate permission, and capturing the specimen episode number, age, gender, and procedure number of each case on a data collection sheet. Ethical clearance was obtained from the Human Research Ethics Committee (HREC), clearance certificate number: M231065 M240506-B-0001. Data was captured on the principal investigator's personal password protected laptop and included no identifiers._See "Appendix A" for the tick sheet that was used during data collection.

2.5 Data analysis

- Basic demographic descriptors including the mean and median age of cases were determined and reported on. Specimens were broadly divided according to their origin from index or revision surgeries to improve accuracy of clinical recommendations.
- The profile of microorganisms encountered per year in review is depicted and broadly discussed.
- Antimicrobial susceptibility trends over the years in review is depicted and discussed for the current empiric agent of choice – co-amoxiclav.
- The probability of dependent events were calculated using Fisher's exact and Pearson's chi-squared tests on Stata software. Categorical variables such as the influence of age, gender, and number of surgical procedures on culture findings and antimicrobial susceptibility was tested.
- The Cochrane-Armitage trend test was utilised to detect a monotonic trend in the antimicrobial susceptibility proportions over the years in review.
- Statistical significance was set at a threshold of $p \leq 0,05$.

2.6 Limitations

- The accuracy of culture yields was a limiting factor as patients receive empiric antibiotics whilst awaiting theatre, before samples are collected intra-operatively.
- Sampling conditions are generally unsuitable for fastidious anaerobic organisms, lowering the perceived incidence.
- Fungal culture is not routinely performed and therefore fungal causes of DSNI may be underestimated.
- Viral causes of DNSI was not analysed as molecular testing is not routinely

performed.

- DNSI caused by Mycobacterial organisms was not represented in this study as these patients tend to present with a more insidious clinical course and rarely require surgical intervention in our centres. Should suspicion arise, the result of a Mycobacterial Polymerase Chain Reaction (PCR) test is awaited before planning surgery. Unfortunately, investigations for mycobacterial organisms were inconsistently reported on in the sample.
- The paediatric population was not well represented in this sample as most cases are successfully managed with systemic antibiotics and needle aspiration in our setting. Needle aspiration is not performed in theatre and therefore this data was not available in the theatre records.
- Accessibility of theatre records at the time of data collection presented a substantial limitation. Records are captured manually on hard copy books. Unfortunately, these books have degraded over time, making some entries illegible. There were also records missing at most institutions, resulting in an incomplete representation of the period in review.
- This report did not include further descriptions of the anatomical neck spaces involved as well as the medical comorbidities of each case.
- Inconsistent availability of antibiotic disks in the lab. Every positive culture was therefore not consistently tested for sensitivity against the same antibiotics. Ampicillin/Amoxicillin and Co-amoxiclav was found to be the most consistently reported on. Recommendations regarding other agents could not be made with similar accuracy.

CHAPTER 3

RESULTS

The period in review yielded a total of 310 cases. 12 cases had to be removed after the exclusion criteria was applied. These were all cases that had undergone incision and drainage in theatre, but no specimen could be found on the NHLS database. Therefore, 298 cases were left for further analysis. Of these cases, there were 226 (76%) males and 72 (24%) females. Paediatric cases are defined as those patients younger than 16 years of age and adult cases 16 years of age and older, this age cutoff was chosen based on previous studies on the topic and is due to differences in maturation of lymphatic structures(3,17). A total of 23 (8%) children and 275 (92%) adults were included. The sample includes cases aged 7 months to 82 years old. The mean age is

38,2 years, and the median is 36 years. Of all the cases analysed, 201 (67%) specimens were obtained from index surgery and therefore reflects community-acquired pathogens, whereas 97 (33%) specimens were obtained from revision surgery representing nosocomial pathogens.

There were 3 types of specimens that was collected in the operating theatre, namely abscess aspirate, swab and tissue. Abscess aspirate represents fluid or pus that was aspirated into a syringe from the surgical site, transferred to a sterile specimen container, sealed and submitted to the lab. Swab represents a pus swob taken in theatre from the surgical site, and tissue represents a biopsy that was taken from the surgical site and submitted to the lab. A total of 68 (23%) specimens yielded no growth, whilst 5 (2%) specimens yielded a mixed growth. These reports could not isolate a single organism and therefore did not include bacterial culture or sensitivity findings. Out of the remaining 225 specimens, 47 different organisms were identified and are summarised in according to each year in review in figures 1 to 5.

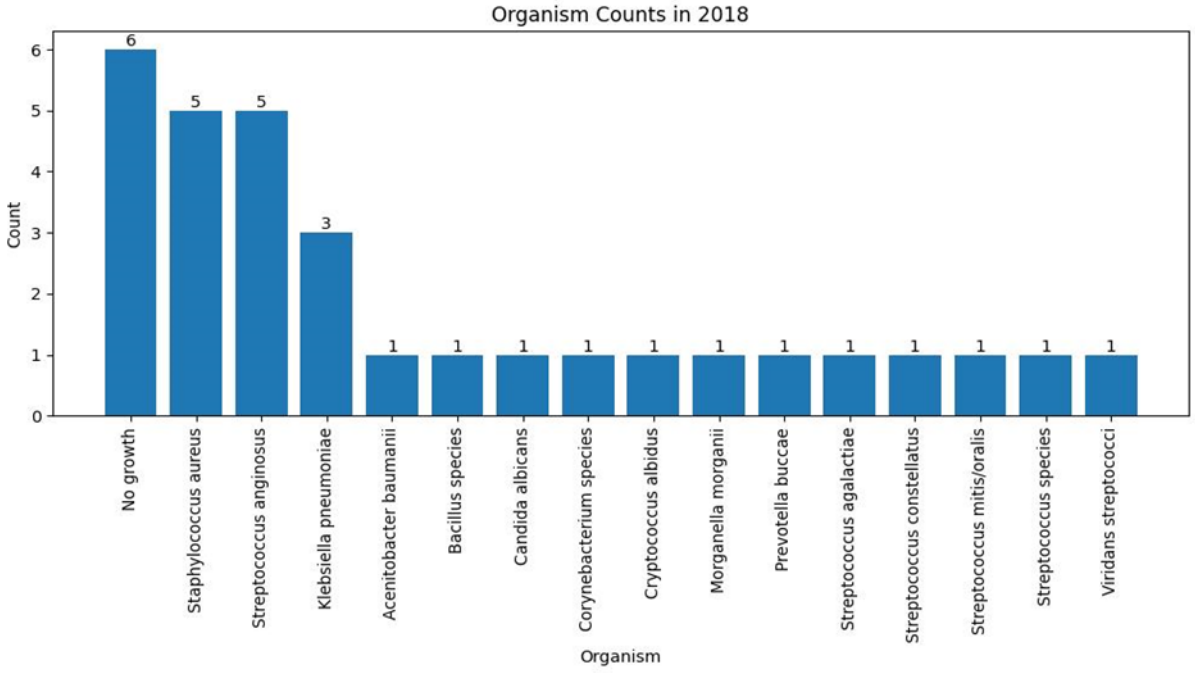

Figure 1: Organism counts in 2018 (n=31)

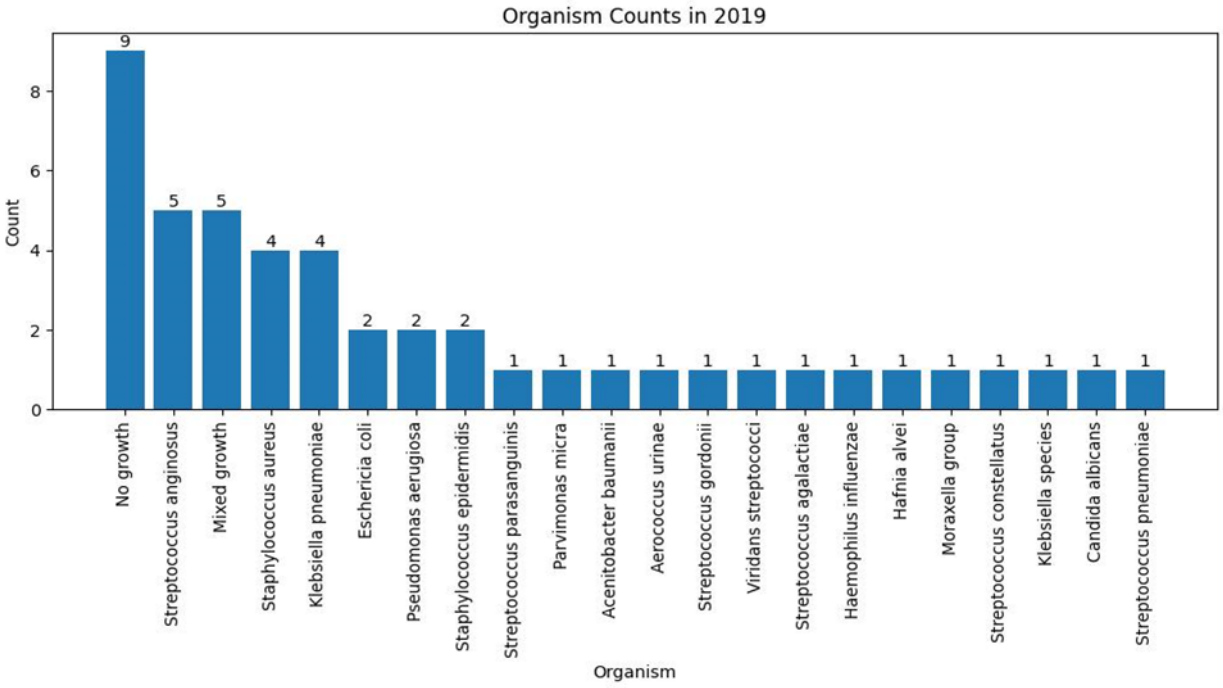

Figure 2: Organism counts in 2019 (n=47)

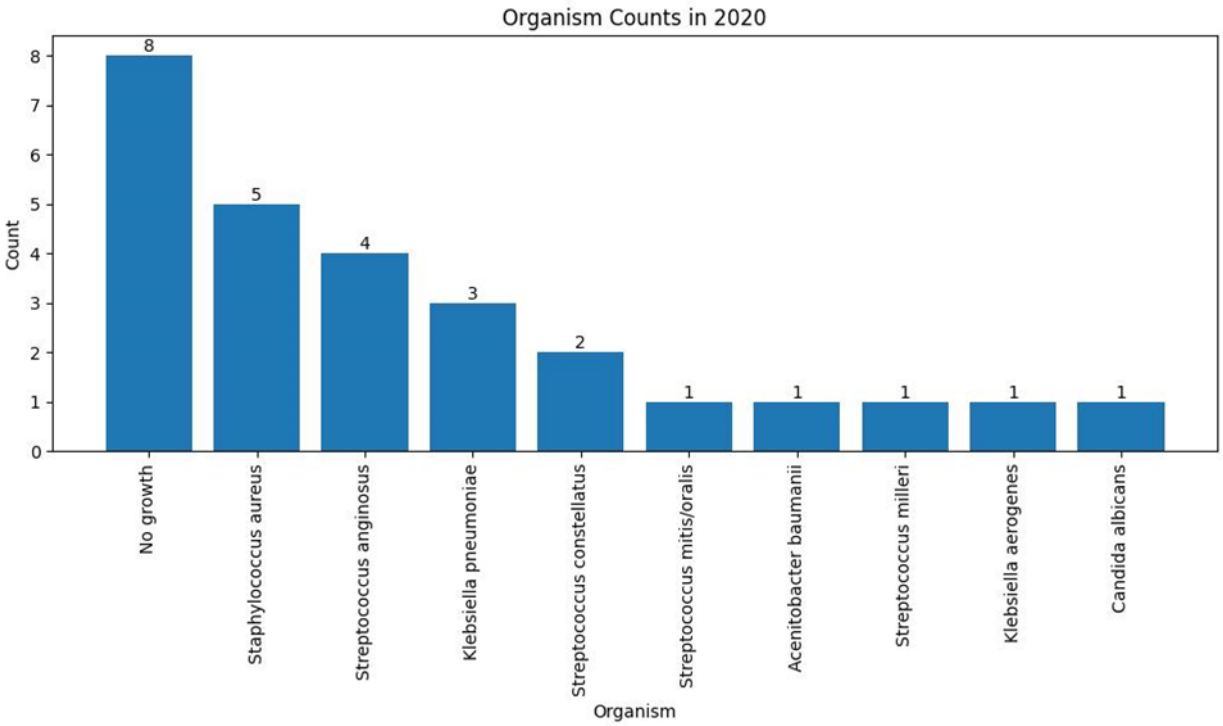

Figure 3: Organism counts in 2020 (n=27)

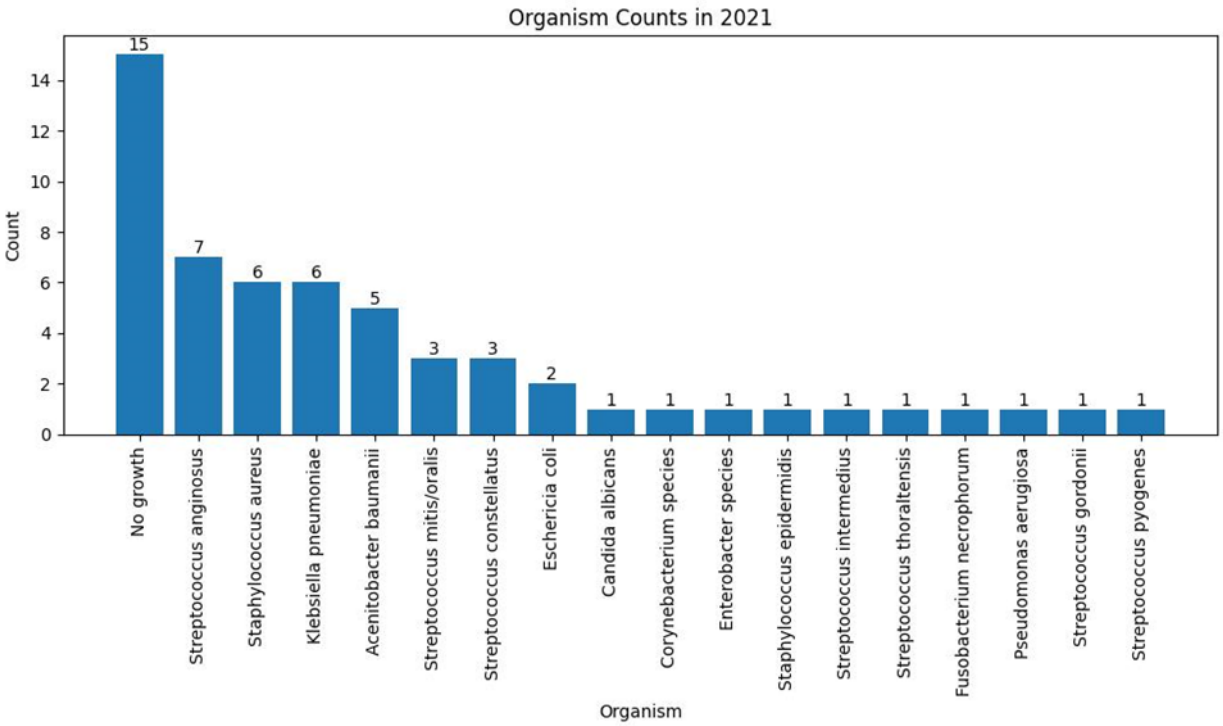

Figure 4: Organism counts in 2021 (n=57)

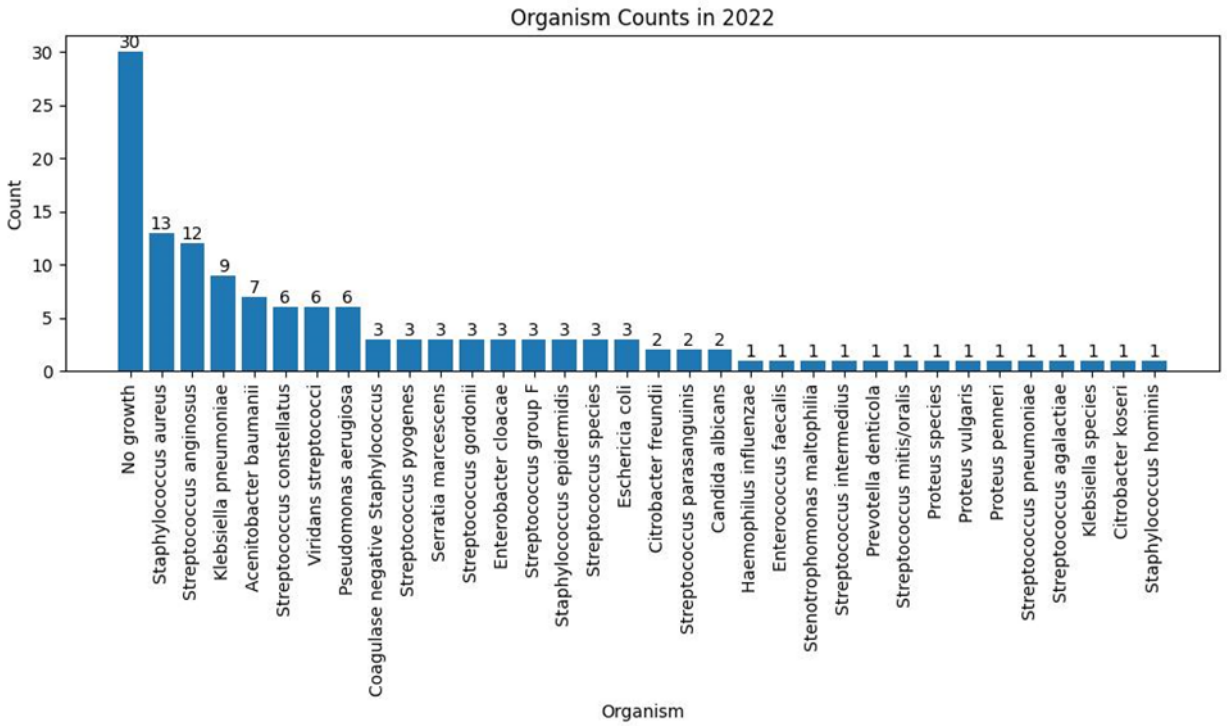

Figure 5: Organism counts in 2022 (n=136)

The most commonly identified organisms included both *Streptococcus anginosus* and *Staphylococcus aureus*, each identified from a total of 33 (15%) positive cultures. *Klebsiella pneumoniae* (11%) was the most commonly cultured gram-negative pathogen and was mostly associated with specimens obtained from revision surgery. There was a total of 6 (3%) cultures that yielded a yeast in the form of Candida Albicans, all of them were from adults. True anaerobes represented only 2% of the sample with 4 species cultured from a total of 225 positive culture specimens. These include *Prevotella buccae*, *Prevotella denticola*, *Parvimonas micra* and *Fusobacterium necrophorum*. *Staphylococcus aureus* was the most common organism cultured in children with a total of 15 out of 23 (65%). Other organisms identified in children included *Streptococcus parasanguinis*, *Citrobacter freundii*, *Klebsiella pneumoniae*, *Staphylococcus hominis* and *Fusobacterium necrophorum*.

Findings in terms of antimicrobial sensitivity were broadly divided into specimens obtained during index surgery and those obtained during revision surgery. The most common organisms encountered during index surgery was *Streptococcus anginosus*

and *Staphylococcus aureus*, each accounting for 33 out of the 107 index organisms (31% each). Other organisms encountered on index surgery are summarised in figure 6. Included in the bar graph are the percentage of organisms that are sensitive to ampicillin/amoxicillin and co-amoxiclav respectively. The most common organisms encountered in revision surgery are also demonstrated as such in figure 7.

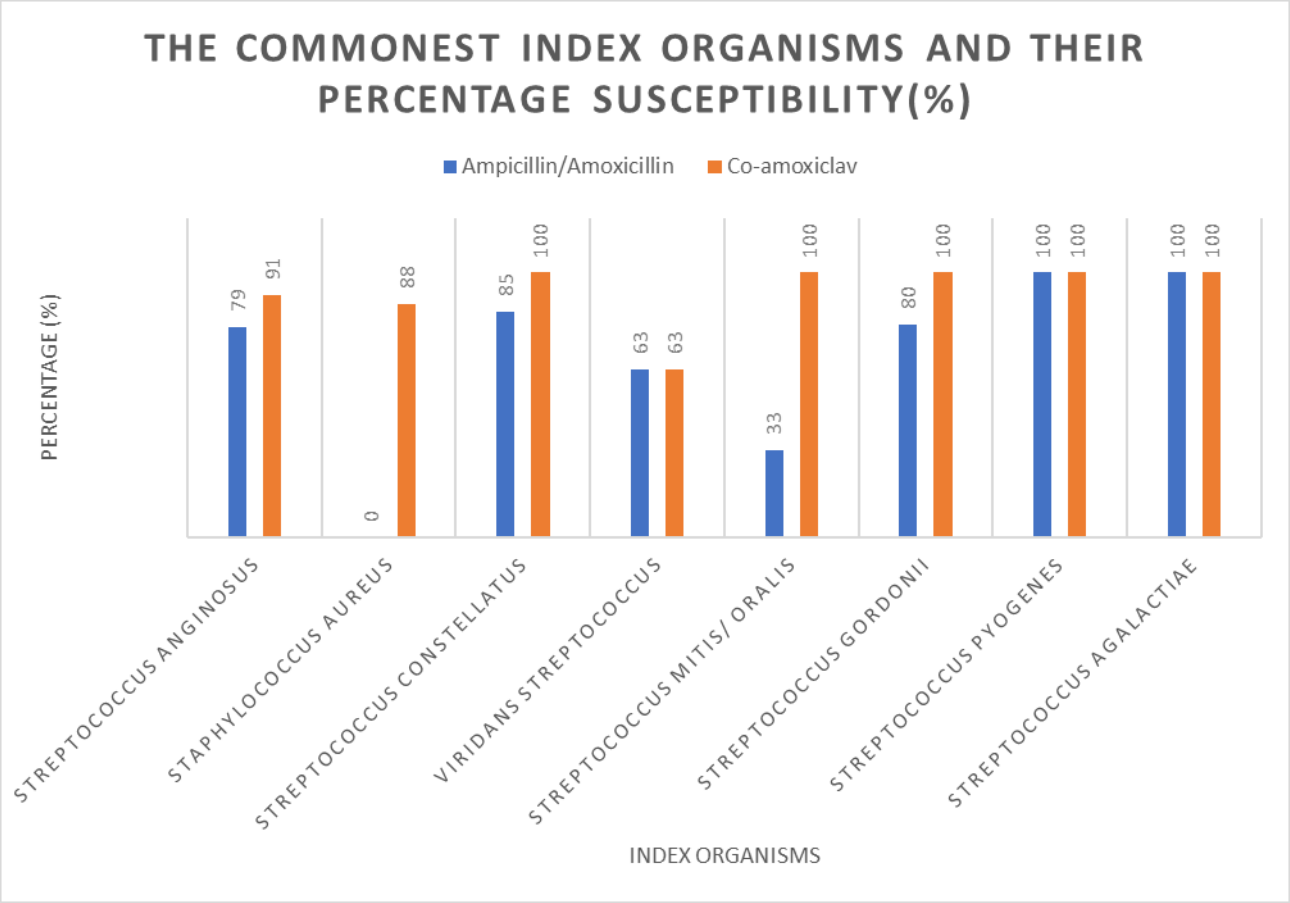

Figure 6: Organisms cultured from index surgery and their susceptibility to first-line empiric antibiotics.

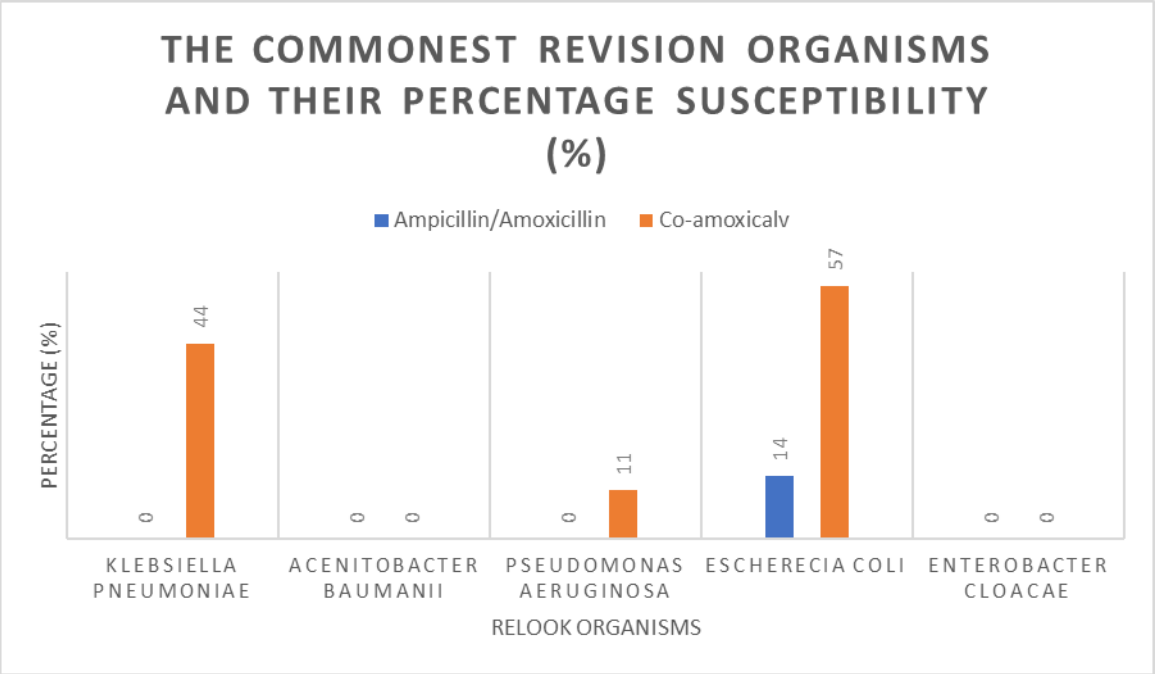

Figure 7: Organisms cultured from revision surgery and their susceptibility to first-line empiric antibiotics.

DISCUSSION

The findings above stand in line with previous literature on the topic, supporting data validity (10,11). Due to the varying availability of antibiotic disks, the lab was not able to publish antibiograms which consistently tested the same antibiotics for susceptibility in every culture. This presented a limitation because not all culture positive organisms could be directly compared during the analysis. In the index surgery group, there were 9 different species totalling 107 specimens that consistently reported susceptibility to co-amoxiclav, which is the current empiric drug of choice. Susceptibility to ampicillin/amoxicillin was also consistently reported. The same was done for the revision surgery group, which yielded 5 different species totalling 59 specimens. Antibiotic susceptibility is depicted as sensitive or resistant. A total of 4 cases were published as intermediate sensitivity to ampicillin/amoxicillin, these were categorised with resistant organisms to facilitate ease of data interpretation.

The analysis of index organisms in this study stands to represent the current trend of community-acquired pathogens involved in DNSI. Among pathogens cultured from index surgery over the 5 years in review, a total of 91% (97/107) of organisms are sensitive to co-amoxiclav with only 9% (10/107) resistant. This indicates that co-amoxiclav can still serve as an efficient drug for use in the empiric management of DNSI. Utilising the Cochrane-Armitage test for trend, susceptibility to co-amoxiclav over the years in review among pathogens cultured from index cases revealed no significant change (p=0.21). Illustrated in figure 8. However, there were some outliers in the data worthy of discussion. In the paediatric population 65% (15/23) of culture positive specimens yielded *Staphylococcus aureus*, all isolates were methicillin-sensitive. Therefore, cloxacillin/flucloxacillin would be a viable alternative in the management of paediatric DNSI. The most commonly reported alternative antibiotic choice in this group was the third-generation cephalosporins including ceftriaxone and cefotaxime. Combined with metronidazole to extend anaerobe cover, this offers an efficient alternative.

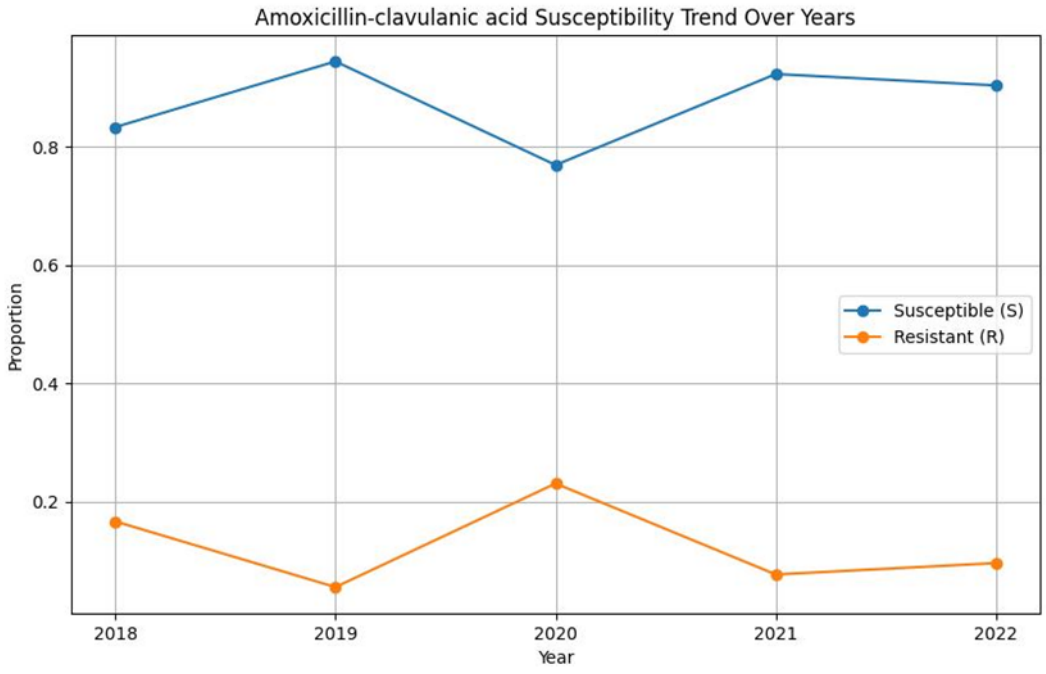

Figure 8: Trend of the proportion of organisms cultured from index surgery susceptible and resistant to co-amoxiclav

Sensitivity to ampicillin/amoxicillin were poor among pathogens cultured from index cases, with only a total of 53% (57/107) of organisms sensitive and 47% (50/107) of organisms resistant. Ampicillin/amoxicillin therefore represents a poor choice of empiric agent in the context of community-acquired DNSI.

The pathogens isolated from specimens collected during revision surgery represents the current trend of nosocomial organisms. These patients would've been admitted for at least 48 hours. These pathogens are almost universally resistant to ampicillin/amoxicillin (98%). Co-amoxiclav does not represent an efficient choice of cover as 43 out of 59 isolates (73%) are resistant. There is also a grossly visible trend of increasing resistance to co-amoxiclav among nosocomial pathogens that can be observed over the years in review, as demonstrated by figure 9. The Cochrane-Armitage test for trend revealed no statistical significance (p=0.55). No single agent may be recommended to provide cover for these cases as antimicrobial cover should be dictated by antibiograms at this point in care. Of note were some of the mechanisms of resistance published in the reports. Out of the 25 specimens that cultured *Klebsiella pneumoniae*, 10 (40%) were classified as Carbapenem Resistant Enterobacteriaceae (CRE) and 3 (12%) produced Extended-Spectrum Beta-Lactamase (ESBL). Out of the 15 specimens that cultured *Acenitobacter baumanii*, 11 (73%) were classified as Extremely Drug-Resistant (XDR). Another 2 out of 7 (29%) cultures positive for *Escherichia coli* produced ESBL.

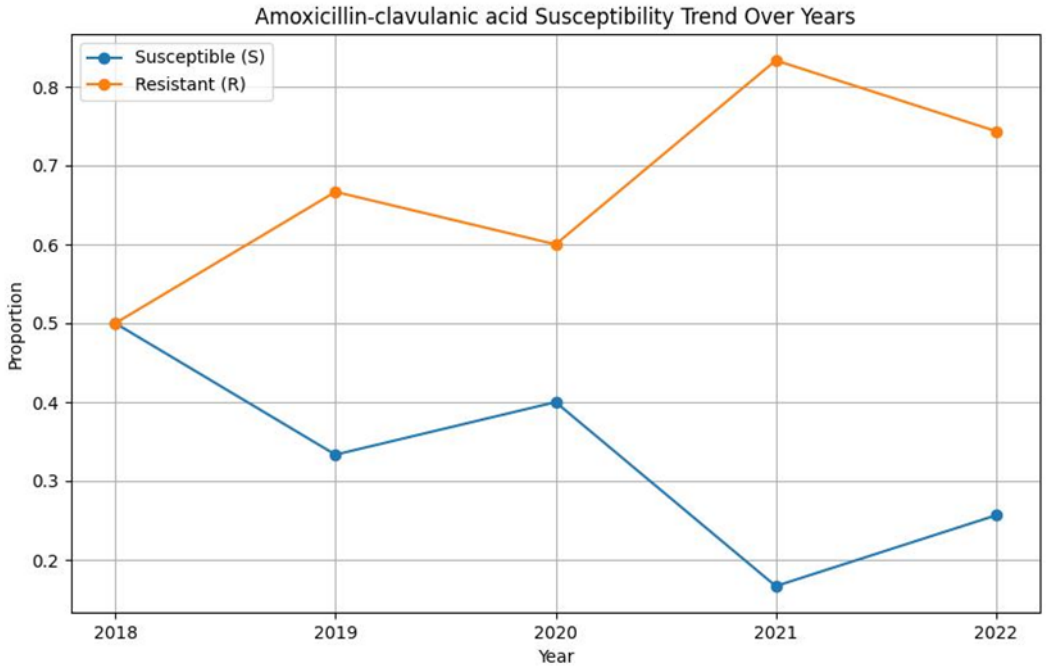

Figure 9: Trend of the proportion of organisms cultured from revision surgery susceptible and resistant to co-amoxiclav

When the index and revision organisms were pooled together and tested for their susceptibility to co-amoxiclav over the years in review, a concerning trend of increasing resistance could be observed. This is depicted in figure 10. Further analysis revealed no significant change in trends over the years in review ($p=0.52$). Although statistical significance was not achieved, this finding supports existing literature reporting the emergence of increasing bacterial resistance in DNSI. Regular locoregional surveillance is required to ensure public safety and optimal outcomes for those afflicted by the condition.

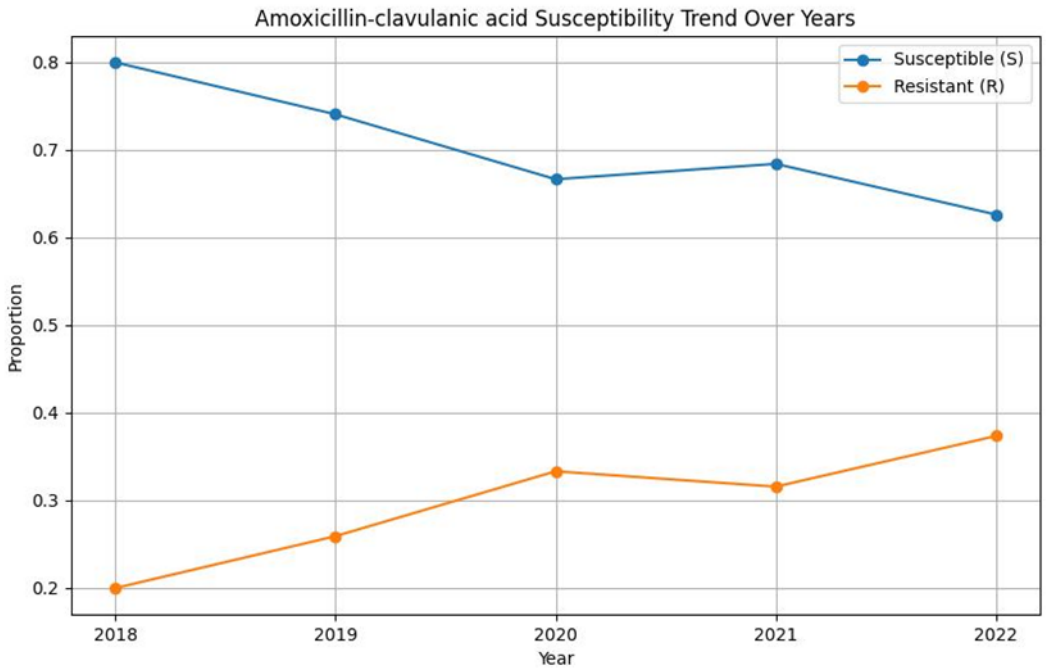

Figure 10: Pooled trend of the proportion of organisms susceptible and resistant to co-amoxiclav

The paediatric population was not well represented in this report as outlined above. From the data that was available it was determined that flucloxacillin would constitute a fair empiric choice as most DNSI are caused by MSSA.

CONCLUSION

Based on the trends observed in the recent locoregional data presented in this retrospective review, co-amoxiclav still represents a good choice for empiric cover in DNSI. However, there appears to be a shift towards increasing resistance in the susceptibility trends. Follow-up studies and continued observation are needed to ensure optimal clinical outcomes in our patients. The utility of monitoring the trends of locoregional pathogens and their antimicrobial susceptibility patterns in the context of DNSI cannot be understated. Early findings indicate that a third-generation cephalosporin with metronidazole may be considered as an alternative, should resistance to co-amoxiclav continue to rise. In the paediatric population, flucloxacillin represents a good empiric choice. Early appropriate antimicrobial cover with timeous

surgical intervention and source control should avoid the need for revision surgery. In cases requiring revision surgery the choice of antimicrobial should be revised and tailored to antimicrobial sensitivity reports as a rising trend of resistance to commonly used empiric agents now represent a public health concern.

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FACULTY OF HEALTH SCIENCES

ETHICS CLEARANCE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr Werner André Rossouw

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M231065 M240506-B-0001

NAME: (Principal Investigator)	Dr Werner André Rossouw
DEPARTMENT:	School of Clinical Medicine Charlotte Maxeke Johannesburg Academic Hospital Chris Hani Baragwanath Academic Hospital, Helen Joseph Hospital, Rahima Moosa Mother and Child Hospital
DEGREE:	Master of Medicine in Otorhinolaryngology
PROJECT TITLE:	*Recent trends in the microbiology and antimicrobial susceptibility patterns of deep neck space infections, a descriptive analysis*
DATE CONSIDERED:	27/10/2023
DECISION:	Approved unconditionally
CONDITIONS:	
NOTE:	HREC (Medical) Application Number: MED23-09-121
SUPERVISOR:	Prof S. Maharaj and Dr L. Mothibi
APPROVED BY:	Prof. Yasmin Adam, Co-Chairperson, HREC (Medical)
DATE OF APPROVAL:	06/05/2024 **EXPIRY DATE:** 06/05/2029

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATOR(S)

I/we fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit the application to the Committee. **I agree to submit a yearly progress report** in the month date of convened meeting each year until study is closed. Failure to submit annual report will result in ethics clearance certificate suspension. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. Unreported changes to the application may invalidate the clearance given by the HREC (Medical). Login to upload signed copy of this ethics clearance certificate prior to commencing with the study https://www.witsethics.co.za/login.aspx. Email a signed copy of ethics clearance certificate to HREC-Medical.ResearchOffice@wits.ac.za.

Principal Investigator Signature

07/05/2024
Date

APPENDIX A

Add header

Case Number	Date	Age	Gender	Specimen ref no	Procedure #	Specimen type
1						
2						
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Add header

Organism	Gram stain	Metabolism	Organism code	Growth comment	Organism comment	