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Establishment of an antimicrobial stewardship strategy on the surgical NICU at Cairo University specialized pediatric hospital

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ABSTRACT

Purpose: Antimicrobial resistance is a major concern that we are facing nowadays. This is due to antibiotic misuse and bacteria developing resistance to the commonly used antibiotics. This may lead to increased mortality and consumption of country resources. Implementation of an antimicrobial stewardship program [ASP] can limit the use of unnecessary antibiotics and subsequently decrease the infection rates with better patient outcome. We aimed to control antibiotic misuse, reduce infection rate, decrease drug costs, and reduce length of hospital stay in the ICU.

Methods: We conducted a prospective study on the surgical neonatal ICU [SNICU] over a period of 6 months divided into pre-implementation phase, followed by an ASP phase, in which we applied the antibiotic guidelines approved by the ASP committee. Data were collected in the two phases and analyzed for demographics, compliance with guidelines, prescribed antibiotics, lab investigations, surgical site infection [SSI], length of stay and patient outcome.

Results: Compliance to the guidelines was encountered in 86% and SSI rate decreased to 20%. Days of Therapy (DOT) per 1000 patient days showed a significant decrease in Ampicillin Sulbactam by 296 ($p = 0.024$), Imipenem by 220.34 ($p = 0.024$) and Vancomycin by 287.34 ($p = 0.048$). Drug cost showed a 1185.97 EGP decrease in the ASP period compared to the pre-implementation period ($p = 0.714$). Average LOS decreased in the ASP period by a mean difference of 2.5 ($p = 0.027$).

Conclusion: ASP implementation can control antibiotic misuse, decrease the medical care expenses and improve patient outcome.

Type of study: Clinical research paper.

Level of evidence: Level one.

Antibiotics are considered a double-edged sword because if used properly they can treat a lot of infections; on the other hand, if they are used inappropriately, they lead to emergence of new bacterial strains that are resistant to the available agents [1]. One of the drawbacks of antibiotic misuse is the increasing rate of infections. Surgical site infections are one such example, with dire consequences [2].

Several antibiotics are now ineffective for specific infections such as pneumonia [3]. Resistant microorganisms are emerging at a rate exceeding the development of new drugs [2].

Implementing an effective antimicrobial stewardship program is an attempt at controlling antibiotic misuse with subsequent decrease of resistance and improvement of patient outcome [4].

The present study aimed to apply a stewardship strategy on the surgical neonatal ICU to control antibiotic misuse. The main outcomes were SSI rate, drug cost, resistance patterns and LOS.

We based our protocol on Great Ormond Street Hospital antimicrobial guidelines, which are in turn based on guidance from the British National Formulary for Children (BNFc), the Manual of Childhood Infections and the Scottish and Intercollegiate Guidelines Network (SIGN) on Antibiotic prophylaxis in surgery. A NICU-specific antibiogram was also compiled and included [5–7].

We hypothesize that:

- Antimicrobial stewardship program can positively affect surgical patient outcome and save hospital resources
- Advanced methods of bacterial cultures can positively impact cases' outcome with faster choice of appropriate antibiotics and consequently better outcome

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1. Materials and methods

1.1. Setting

On the surgical neonatal ICU, an 18 incubator ICU, in Cairo University Specialized Pediatric Hospital (CUSPH).

1.2. Inclusion and exclusion criteria

We conducted a prospective study over a period of nine months divided into two phases during which we monitored all neonates admitted to the ICU for surgical interventions.

1.3. Program Design and Implementation

The design process for this ASP began in May 2016 when there was no documented policy for antibiotic prescription except microbiological culture and sensitivity results. A multidisciplinary team was formed consisting of a neonatologist, a pediatric clinical pharmacist, a pediatric surgeon, a quality member, a microbiologist and an infection control practitioner. Participation was voluntary, and no funding was directly applied to the design, implementation, or maintenance of the program.

Our protocol was based on Great Ormond Street Hospital antimicrobial guidelines, which are in turn based on guidance from the British National Formulary for Children (BNFc), the Manual of Childhood Infections and the Scottish and Intercollegiate Guidelines Network (SIGN) on Antibiotic prophylaxis in surgery [5–7]. A review of medical literature and a CUSPH NICU-specific antibiogram were also considered in the guidelines development process. Recommendations focused on evaluation of cases according to type of operation and presence of risk factors for sepsis, or documented infection at the time of admission and prophylactic postoperative antibiotics. A draft of the guidelines was distributed to staff for feedback and, once finalized, the new guidelines were approved by the ASP team and distributed to all ICU staff members for implementation (Fig. 1). To facilitate implementation and reinforce key concepts, a pediatric clinical pharmacist attended patient care rounds.

The program was officially launched in October 2016 as the first ASP on the SNICU at CUSPH. The ASP team has met every 3 months to review data, discuss feedback, address program issues, and make modifications.

1.4. Study design

We conducted a quasi-experimental study that aimed at determining the impact of an ASP on controlling antibiotics misuse, decreasing the infection rate and drug costs in the hospital. The two phases of the study were: Pre-implementation phase, phase one, or “observational period” and the ASP period, phase two, or “implementation period”.

Data were collected daily from patients' files for antibiotic prescriptions, infections (clinically and/or lab confirmed), days of therapy, length of hospital stay, lab results and justifications for each step. Follow up data was reviewed regularly to allow for timely prescriber audit, feedback and outcome. In the ASP Period, monitoring compliance to the guidelines was added.

A daily stewardship follow-up sheet was made based on WHO criteria for surgical site infection surveillance merged with prescribed perioperative antibiotics and subsequent antibiotic modifications. An additional simpler antibiotic follow-up sheet was designed and attached to each patient file.

1.5. Outcome measures

These were divided into primary and secondary. Primary measures included compliance to the applied guidelines; days of therapy (DOT) per 1000 patient days (PD), compiled monthly; rate of infection; drug cost;

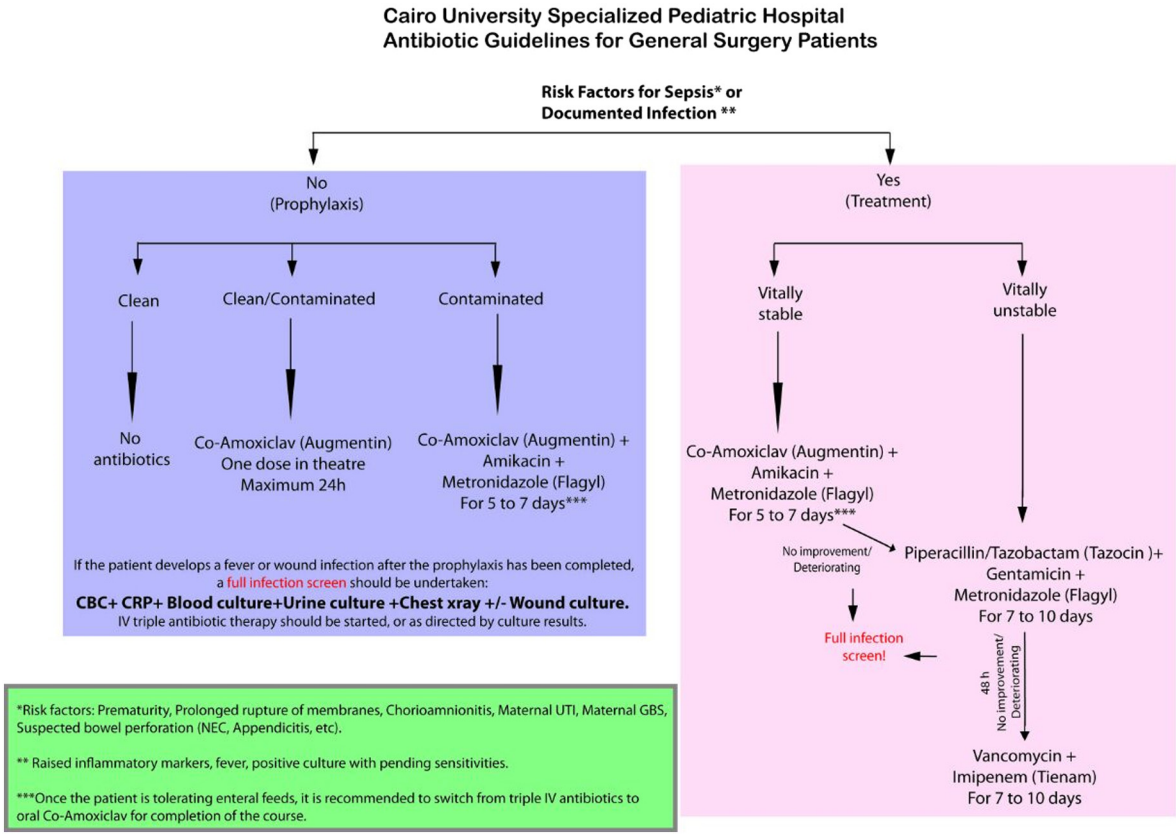

Fig. 1. Cairo University Specialized Pediatric Hospital Antibiotic Guidelines for General Surgery Patients.

Table 1
Total Admissions Correlation between pre-implementation and ASP Periods.

		Phases						P value
		Pre-implementation period (60 patient)			ASP period (150 patient)			
		Mean (Standard Deviation)	Number (%)	Sum	Mean (Standard Deviation)	Number (%)	Sum	
Total admissions		20 (4)		60	25 (7.4)		150	0.262
Drug cost		4838.40 (3063.85)			3652.43 (2258.68)			0.714
Length of hospital stay in days (LOS)		15.15 (11.38)			11.94 (10.71)			0.027
Outcome	Discharged		40 (66.7%)	60		119 (79.3%)	150	0.053
	Died		20 (33.3%)			31 (20.7%)		

turnaround time (TAT) of lab results, defined as time from sample delivery to the lab to reporting of the results [8]; and prescribed antibiotics.

Certain steps taken to improve TAT included: Training of the ICU staff on good sampling to avoid poly-microbial nature of the samples; preliminary reporting of direct gram stained films before final reporting of sensitivity results and introduction of automation to decrease TAT.

The aggregate sum of antimicrobial use in our NICU included: All antibacterial and antifungal agents administered intravenously, intramuscularly, or orally and excluded antivirals, topical, ophthalmic, and nebulized antimicrobials.

Secondary measures included assessing the antimicrobial resistance pattern; length of hospital stay; rate of infections primarily surgical site infection and rate of MRSA in the admitted patients (as balancing measures, each infection was reviewed in detail for timeliness of recognition); rate of MRSA colonization and effect of decolonization on MRSA infection rate; role of automated expert systems in more accurate and timely antibiotic susceptibility results.

1.6. Microbiological workup

Wound swabs, pus, blood, urine, sputum and other samples were processed in the lab by conventional culture with subsequent identification using biochemical reactions and antimicrobial susceptibility testing using the modified Kirby Bauer disc diffusion method [9].

The percentage of resistant organisms was calculated. Multidrug resistance (MDR) was defined as acquired resistance to at least single agent in three or more categories of antimicrobials. Extensive drug resistance (XDR) was defined as non-susceptibility to at least a single agent in all but two or fewer categories of antimicrobials. Pan-drug resistance (PDR) was defined as acquired resistance to all agents in all antimicrobial categories [10].

1.7. Screening for MRSA

All neonates of phase 2 were screened on admission then re-swabbed after one week in case of delay of surgery. Swabs were taken from nasal, axillary and groin areas and inoculated on Mannitol salt agar (BIO-RAD#11350) and DNA agar (BIO-RAD#31257) followed by Cefoxitin (Thermo- scientific Oxoid code: (DD0026) testing for positive cases [11].

1.8. Automated minimal inhibitory concentration (MIC) testing

Isolates were collected from selected critical cases from wound, blood and sputum specimens and subjected to Automated MIC testing for better evaluation of the resistance patterns, precise antibiotic sensitivity results by the more accurate MIC and shorter turnaround time (TAT) [12].

Antibiotic susceptibility testing cards for Gram negative bacilli, Gram positive cocci and yeasts; were stored at 2–8 °C and used according to manufacturer instructions.

Results were analyzed regarding resistance patterns and phenotype detections obtained by the Advanced Expert System (AES) and compared with disc diffusion results to check the agreement between both methods.

1.9. Statistical Methods

Data were coded and entered using the Statistical Package for the Social Sciences (SPSS) version 25. Data were summarized using mean, standard deviation in quantitative data and using relative frequency (percentage) and frequency (count) for categorical data. Comparisons between quantitative variables were done using the non-parametric Mann–Whitney *U* test**.** Chi square (χ^2) test was performed for comparing categorical data. We used the Fisher's exact test when the expected frequency was less than 5. p-Values that were less than 0.05 were considered as statistically significant.

2. Results

The observational period ran from July 1st, 2016 till September 30th, 2016. The ASP period ran from October 1st, 2016 to March 31st, 2017. The study included 210 surgical neonates. There were 60 neonates in the pre-implementation phase and 150 neonates in the ASP period (Table 1). Demographic showed admission of 68.3% (41/60) Males and 31.7% (19/60) Females in phase 1 and 62% (93/150) Males and 38% (57/150) females in phase 2.

2.1. Types of operations

Clean contaminated operations predominated in phase 1 and 2 with the percentages of 78.3% and 81.9% respectively while clean operations constituted 21.7% and 18.1% respectively.

2.2. Days of Therapy per 1000 Patient Days

Correlation between phase 1 and phase 2 regarding days of therapy (DOT)/1000 patient days of each antimicrobial is shown in Table 2.

2.3. Therapeutic interventions

During the ASP period, Stewardship interventions were applied. These interventions were collected monthly with estimation of percentage of physician acceptance (Table 3).

2.4. Perioperative compliance to the guidelines

Guidelines were applied starting October 2016 with a compliance of 86%.

Correlation between compliance to the guidelines and outcome showed no statistically significant difference; 26/127 (20.5%) of patients died who were treated by physicians following guidelines, while 6/21 (28.6%) died who were treated by physicians not following guidelines ($p = 0.557$).

Table 2
Days of Therapy of each antimicrobial used in the study.

	Phases				p Value
	Pre-implementation		ASP Period		
	Mean	Standard Deviation	Mean	Standard Deviation	
Augmentin	16.67	28.87	299.83	95.26	.024
Ampicillin Sulbactam	318.33	85.45	22.33	21.12	.024
Gentamycin	146.33	125.68	382.33	101.75	.048
Amikacin	241.67	141.57	139.00	171.47	.548
Cefotaxime	28.67	37.42	.00	.00	.167
Imepenem	310.67	57.98	90.33	32.20	.024
Meropenem	109.00	176.81	70.00	91.52	1.000
Metronidazole	204.00	172.72	575.00	173.03	.048
Fluconazole	118.67	77.11	115.33	80.49	.905
Vancomycin	448.67	141.80	161.33	70.81	.024
Polymixin	83.33	63.89	87.50	121.05	.905
Cefuroxime	44.33	40.70	11.17	10.57	.381
Ciprofloxacin	96.67	73.70	83.33	51.98	1.000
Teicoplanin	50.33	8.74	2.00	4.90	.024
Linezolid	4.33	4.04	.00	.00	.167
Levofloxacin	10.00	13.23	12.83	28.15	.714
Piperacillin-tazobactam	39.67	19.50	244.67	61.07	.024
Fungizone	14.33	24.83	2.00	4.90	.714
Ceftriaxone	22.00	38.11	.50	1.22	.714
Trimethoprime-sulfamethoxazole	16.67	28.87	22.00	24.34	.548
Cefepime	.00	.00	1.83	4.49	.714

2.5. Surgical site infection surveillance

The percentage of surgical site infections was estimated using the number of operations as the denominator (Table 3).

2.6. Microbiological workup

2.6.1. Conventional Methods

All samples obtained from patients for conventional culture and antimicrobial susceptibility testing were grouped and analyzed. All wound cultures were positive in the pre-implementation and ASP periods: 17 and 67 cultures respectively. Blood cultures were positive in 95% of the requested blood cultures in the pre implementation period (n = 19/20) and in 81% (n = 47/ 58) of those requested in the ASP period. Other cultures were positive in 75% (n = 6/8) in the pre-implementation period and 90.9% (n = 30/33) in the ASP period. The percentage of each organism in wound and blood samples is shown in Table 4. Cultures other than wound and blood revealed the following organisms in Phase 1: 50% *Klebsiella* spp. (n = 5), 10% *Acinetobacter* spp. (n = 1), 10% *Pseudomonas* spp. (n = 1), 20% *E coli* (n = 2) and 10% CONS (n = 1), while cultures of phase 2 revealed 48% *Klebsiella* spp. (n = 20), 7.3% *Acinetobacter* spp. (n = 3), 39.3% *Pseudomonas* (n = 12), 4.9% *Candida* spp. (n = 2), 2.4% *E coli* (n = 1), 2.4% MRSA (n = 1), 2.4% *Proteus* spp. (n = 1) and 2.4% alpha hemolytic streptococci (n = 1). The turnaround time of conventional cultures was statistically different between the 2 phases (p = 0.024). Isolated organisms were categorized into resistant and susceptible strains in both the pre-implementation and ASP periods. Susceptible organisms represented a higher percentage in the ASP period than resistant ones, isolated from all sample types (Fig. 2). MRSA screening on admission for the patients included in the ASP was negative for MRSA carriage (0%).

Table 3
Physician acceptance to ASP therapeutic interventions and SSI rate of clean contaminated operations.

	Number of interventions	Physician acceptance (%)	SSI Rate (%)
July/2016	---*	---	**54.2**
August/2016	---*	---	**38.50**
September/2016	---*	----	**47.4**
October/2016	84	85.5%	**17.1**
November/2016	16	100%	**37.5**
December/2016	83	84.4%	**21.1**
January/2017	51	80.3%	**28.6**
February/2017	65	98.5%	**31.8**
March/2017	159	89.3%	**20**

• Therapeutic interventions were first started in the ASP period.

2.6.2. Automated Microbiological workup

Forty isolates, subjected to conventional culture and antimicrobial susceptibility testing, were also subjected to automated quantitative MIC testing. Thirty-five Gram-negative isolates and 5 Gram-positive isolates were tested for a specific panel of antimicrobials. The total number of MIC was 560 MIC result.

Table 4
Percentage of Organisms in Wound Cultures and Blood cultures.

		Phases			
		Pre-implementation		ASP	
		Count	%	Count	%
Wound cultures' organism	*Acinetobacter spp.*	11	42.3%	13	12.4%
	E coli	4	15.4%	13	12.4%
	Klebsiella spp.	3	11.5%	43	41.0%
	Pseudomonas spp	3	11.5%	8	7.6%
	CONS	3	11.5%	10	9.5%
	Enterobacter	1	3.8%	4	3.8%
	Enterococcus	0	.0%	6	5.7%
	MRSA	0	.0%	4	3.8%
	Serratia	1	3.8%	0	.0%
	Candida	0	.0%	2	1.9%
	Alpha and beta hemolytic Streptococcus	0	.0%	2	1.9%
Blood culture organisms	*Klebsiella spp.*	8	44.4%	12	22.6%
	Candida spp.	8	44.4%	3	5.7%
	Acinetobacter spp.	1	5.6%	8	15.1%
	CONS	1	5.6%	14	26.4%
	E coli	0	.0%	4	7.5%
	Enterobacter spp.	0	.0%	4	7.5%
	MRSA	0	.0%	4	7.5%
	Alpha and beta hemolytic Streptococcus spp	0	.0%	2	3.8%
	Enterococcus spp.	0	.0%	1	1.9%
	Pseudomonas spp.	0	.0%	1	1.9%

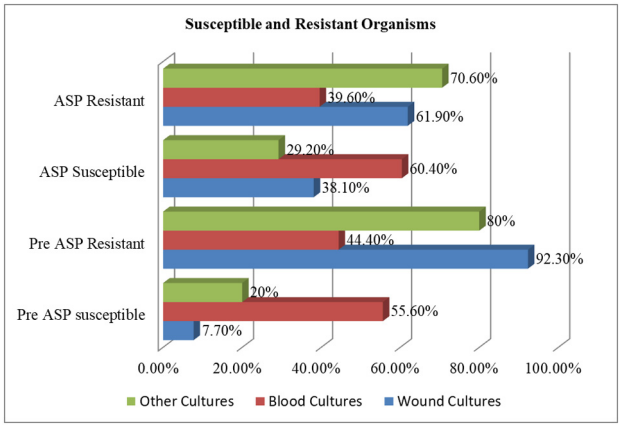

Fig. 2. Resistant and Susceptible strains in Pre-implementation and ASP Phases.

2.6.3. Automated vs. Conventional AST testing

Results of the disc diffusion and MIC were compared to detect the role of automated AES in interpretation of the result. The two methods showed matched results in 80% of the isolates regarding break points and mismatch in 20%; 10% showing minor errors and 10% showing AES therapeutic changes. The two methods showed agreement 99.28% (n = 556/560) regarding CLSI breakpoints.

Eighteen antibiotic results (3.2%) were modified by AES interpretative ability out of which 66.7% (n = 12/18) were Beta lactam drugs, 11.1% (n = 2/18) were combined inhibitor beta lactam drugs and 22.3% (n = 4/18) were Flouroquinolones.

AES and disc diffusion showed 100% agreement in phenotypic detection of ESBL, resistance to high level Aminoglycoside in *Enterococcus spp.* and methicillin resistance of *Staphylococcus aureus* (100% agreement in Cefoxitin screening).

The turnaround time of 40 cultures processed by both automated and conventional methods was calculated and compared showing an average TAT of conventional methods for non-blood and blood cultures of 75 and 144 h respectively decreasing to 43.4 and 115 h with automated methods.

3. Discussion

Antibiotics constitute a big part of the most commonly prescribed medications in the NICU. The right timing of therapeutic intervention for a true infection is critical in some cases however unnecessary exposure to antibiotics can result in the development of antimicrobial resistance, as well as an increased risk of candidemia, hospital-acquired infections, necrotizing enterocolitis, and death [13].

Our study showed 86% perioperative compliance to the applied SNICU guidelines in the ASP Phase, near to the 98.9% compliance of the ASP conducted by Yale New Haven Children's Hospital NICU (YNHCH) in the USA [14]; and better than the study conducted by Tamma et al. which applied two approaches: Pre prescription authorization (PPA) and post prescription review with feedback (PPRF) which showed guideline-compliance in 66% of patients in the PPA group and 43% in the PPRF group [15].

Our DOT/1000 patient days showed significant decrease in mean DOT/1000 patient days with a statistically significant difference in some of the antibiotics used such as Ampicillin Sulbactam which showed a decrease in mean DOT/1000 patient days by 296 (p = 0.024), Imepenem by 220.34 (p = 0.024), Vancomycin by 287.34 (p = 0.048), Teicoplanin by 48.33 (p = 0.024).

Other antibiotics showed a decrease in mean of DOT/ 1000 patient days during the ASP period such as Meropenem by 39 days, Amikacin by 102, Cefotaxime by 28.1, Cefuroxime by 33.16, Ceftriaxone by 21.5, Ciprofloxacin by 13.43 but with a non-significant difference (p = 1, 0.548, .167, 0.381, 0.714, 1.000 respectively). A similar study conducted in YNHCH showed an overall DOT per 1000 PD decrease in ASP by 14.7 days but this decrease was not statistically significant (p = 0.669) [14].

Antibiotics introduced as part of the new SNICU guidelines showed an increase in mean use with a statistical significance indicating commitment to the applied guidelines such as Piperacillin-Tazobactam (p = 0.024), Augmentin (p = 0.0240 and Gentamycin (p = 0.048).

The drug cost was 1185.97 EGP less in the ASP period compared to the pre-implementation period (p = 0.714) with an average monthly cost of 3652.4 EGP (210.6 $), which is less than similar studies that showed a cost of stewardship program implementation was in average 4305 $ per month [16].

The average LOS decreased in the ASP period by a mean difference of 2.5 which was statistically significant (p = 0.027). This was quite similar to a study conducted in 2015 that showed a median length of hospital stay that was significantly reduced post ASP (p < 0.01) [4].

There was no correlation between the commitment to the applied guidelines and patient outcome (alive or dead) (p = 0.557). The patient outcome changed slightly between the pre-implementation period and the ASP period with an increase in survival rate in the ASP period by a difference of 13.4% however this did not reach statistical significance (p = 0.05). This increase in survival rate is higher than a study conducted by the Palestinian Medical Complex that showed no significant difference in overall 30-day mortality or readmission between the pre-ASP (26.9% vs. 23.9%; p = 0.1) and post-ASP groups (26.1% vs. 24.6%; p = 0.54) respectively [4].

First month of the pre-implementation period of the current study showed an SSI rate of 54.2% which subsequently showed a monthly decrease after starting the ASP, ending with 20% SSI. This is in contrast to a conducted study in a tertiary care center in New York City which showed no difference in SSI rates between pre-implementation and ASP periods [17].

In our study Gram-negative organisms were the most common SSI pathogens in both phases with a percentage of 88.3% and 77.1% respectively. On the other hand, a similar study conducted on neonates undergoing cardiac surgery found *methicillin-susceptible Staphylococcus aureus* (MSSA) as the most common SSI pathogen in both study periods with percentages of 67% and 38% respectively [17]. This difference in the causative organisms could be attributed to the type of patients and type of surgery as patients included in our study underwent gastrointestinal (GIT) procedures. The wounds were therefore more liable to get infected by the Gram-negative flora of the GIT.

Our results regarding the most common pathogens isolated from surgical sites were similar to a study conducted **at Gaziantep University Hospital which showed a 74.6% predominance of Gram-negative organisms** [18]. **All (100%) of our** *Staphylococcus aureus* **showed methicillin resistance** which is comparable to the 83.3% reported by Namiduru et al. [18].

Culture and sensitivity results from the current study revealed a decrease in extended and multidrug resistant organisms when comparing pre-implementation and ASP periods: 74% and 57.8% respectively. Similarly, a study conducted on a neonatal intensive care unit showed a decrease in multidrug-resistant organisms between two periods with percentages of 4.7% and 1.6% respectively [19].

One of the essential elements of an ASP is to study how laboratory technologists can provide the fast and accurate results to the physicians as reference for antibiotic prescription. In our study the TAT of microbiological cultures showed improvement over time with a significant improvement in the ASP period. This began with an average TAT of wound cultures' reports 96 h to reach an average of 76 h by the end of the study period. Similarly blood cultures' TAT started with an average of 188 h to reach 164 h. This improvement in TAT was more obvious than that of a similar study conducted in Taiwan in 2013 which showed a decrease in average TAT of blood cultures from 96 h to 87.5 h [20].

Automated MIC testing and disc diffusion showed 100% agreement in Cefoxitin screening of *MRSA* and ESBL detection, unlike another

study conducted at Sao Joao Hospital to detect the efficiency of automated systems in detection of ESBL in *E Coli, Klebsiella pneumoniae and Klebsiella Oxytoca* in which there was disagreement in 23.9% of cases with disc diffusion method [21].

Limitations faced by this study included

- Conduction over a period of 9 months with different seasons included however; type of patients did not differ significantly with nearly equal percentages of surgical conditions
- ASP period was twice as long as the preimplementation period because no modifications were done to the guidelines all through the ASP phase and we calculated all the percentages and made correlations according to the denominator of each phase.
- Single institutional application as it was a pilot study to encourage introduction of ASP in CUSPH

4. Conclusion

In a multidisciplinary team setting we implemented an ASP that achieved an 86% compliance rate and was successful in decreasing the DOT, LOS, medication costs and the number of antibiotic-resistant organisms. Both SSI rate and TAT were concomitantly ameliorated due to ongoing quality improvement efforts.

A long-term ASP should be applied on a wider scale to get the targeted outcome. We recommend introduction of automated techniques to shorten the turnaround time of lab investigations as an essential factor for correct implementation and achievement of the ASP goals.

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Declarations of interest

None.

Ethical approval

Study was approved by the ethical committee of Cairo University Faculty of Medicine.

Informed consent

An informed consent was taken from all participants' parents, as the participants were surgical neonates, to participate in the study to be published.

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