

Implementation Of 5s PDCA Methodology to Assess and Improve Antimicrobial Stewardship Practices in A Tertiary Trauma Care Centre In Tamilnadu, India

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ABSTRACT

Background: Antimicrobial effectiveness is in jeopardy because of the worldwide rapid development of bacterial resistance. The crisis of antimicrobial resistance has been ascribed to the overuse and abuse of these drugs as well as the lack of innovation by the pharmaceutical industry, thereby necessitating the requirement for antimicrobial preservation. This study focuses on assessing the rationality and effectiveness of the prescription of antimicrobials.

Objective: The study mainly focuses on the assessment of antimicrobial stewardship using 5S PDCA (Plan, Do, Check and Act) methodology by observing the antimicrobial prescribing practices, comparing them to established hospital standards, and identifying appropriate elements that are contributing to antimicrobial stewardship program deviance.

Methods: A prospective observational study using 5S PDCA methodology to assess antimicrobial stewardship was conducted in the department of orthopedics and plastic surgery in a major trauma care centre in Tamil Nadu, India over a period of one year.

Result: In our study, implementation of the 5S PDCA methodology showed a marked reduction of deviations in antibiotic practices. The antimicrobial usage pattern has been improved and the study helped in updating institutional antibiotic policy. The major problems that are creating a subsequent deviation from the proper conductance of antimicrobial stewardship programs have been sorted out by the study effectively.

Conclusion: The study concludes that there is a need for antimicrobial stewardship and the application of 5S PDCA methodology is beneficial as the tool for improving every step in reducing the antimicrobial practice deviations and improving the patient outcomes. The problems identified have been sorted out and improvement strategies have been implemented which have helped in improving the patient outcomes. Correspondingly, inappropriateness of antibiotic usage was reduced in sort phase from 53% to 25%, set in order phase from 48% to 17 %, shine phase from 45% to 16%, standardize phase from 25% to 15% and sustain phase from 38% to 18%.

Keywords: Antimicrobials, Resistance, Stewardship, 5S PDCA

INTRODUCTION

The middle of the 1950s marked the beginning of the antibiotic development era with the discovery of penicillin. The advent of antimicrobials for clinical purposes was unquestionably the major healthcare accomplishment of the twentieth century [1]. In just more than a century, antibiotics have revolutionized modern medicine dramatically and extended relative lifespan of humans. Though, drug discovery has seen many advancements

in its technology, including rational drug design, but has not resulted in development of novel antimicrobials [2].

The present predicament of antimicrobial resistance (AMR) emanates from gradual decline in discovery and development of antibiotics along with advent of drug resistance in several human diseases [1]. It is rare and hard to anticipate that evolutionary processes give rise to new pathogen resistance factors but may be attributed to enormous ramifications [3].

India was the biggest country to utilize antibiotics in field of healthcare in 2010, consuming 12.9×10^9 units of antibiotics. The steadily rising percentage of methicillin-resistant staphylococcus aureus isolates in India is a sign of growing AMR epidemic. Methicillin-resistant Staphylococcus aureus (MRSA) accounted for roughly 29% of isolates in 2008; by 2014, that number had increased to 47% [4]. The World Health Organization along with various organizations, and research scholars all concur that public distribution of resistance is a critical challenge that requires a worldwide organized plan of action to deal with, despite criticisms levelled at these comb forecasts by others [5].

A coordinated initiative known as the Antimicrobial Stewardship Program (ASP) aims to enhance health of patients, minimize microbial resistance, and stop spread of diseases caused by multidrug-resistant microorganisms while also encouraging appropriate use of antimicrobials, including antibiotics. It can have a greater advantage in critical care situation and drastically reduces cost and utilization of antibiotics. Moreover, ASPs may minimize hospital stays generally and enhance management of infections driven by particular microorganisms resistant to antibiotics [6, 7].

5S method is part of lean manufacturing methodology. In 1980s, Hiroyuki Hirano created technology in Japan. According to Ho et al. (1995), 5S is an industrial approach that sets a company apart from opposition [8].

5 S indicates sort, set in order, shine, standardize, and sustain obtained from Japanese words *Seiri*, *Seiton*, *Seiso*, *Seiketsu*, and *Shitsuke*.

➤ *Seiri* (Sort)

Making a distinction between what is necessary and what is not is the first step in 5S. After a clear distinction has been made, deleting extraneous elements and handling them correctly can remove impediments and facilitate manpower. Therefore, it will be better for any organization to start using 5S if they evaluate necessary things about cost or other associated variables and designate spaces with red tags to hold needless items.

As regards our study, sort phase entails identifying deviations in antibiotic practices and their eradication by considering assessment of antimicrobial stewardship.

➤ *Seiton* (Set in order)

Seiton, translated as "Set in Order" or "Streamline," means to make stewardship process methodically. As a result, guidelines must be established to guarantee that each step in process is ensured. The orderly placement of each step strives to enhance a seamless process of antimicrobial stewardship. Antibiotic usage is coordinated in this period to minimize already resolved differences in first phase.

➤ *Seiso* (Shine)

The term "*seiso*" (meaning "clean") refers to eliminating defects in stewardship process that improve overall efficiency of it. ASPs were made more effective by resolving discrepancies in multiple ways; discussing issues with appropriate healthcare professionals, presenting in committee meetings, and reporting discrepancies proactively.

➤ *Seiketsu* (Standardize)

Seiketsu mandates that all procedures created by previous 3S be standardized and recorded. *Seiketsu* asked for establishment of a cozy stewardship process to uphold a high quality of antibiotic practices in organization.

By creating protocols, running public education campaigns, amending regulations, and presenting observation studies in medical audit meetings, stewardship process can be made more uniform.

➤ *Shitsuke* (Sustain)

The idea of on-site management is simple to put into practice, but it is still important to keep an eye on whether personnel can carry out these tasks for an extended period. Sustainable development is referred to as *shitsuke*.

The required discipline and training can assist in carrying out 5S steps and through routine auditing, point prevalence investigations, and analysis of healthcare practitioners' adherence to protocol, ASPs can be achieved [9].

MATERIALS AND METHODS

Aim of the study

To assess and improve antimicrobial stewardship practices by using the 5S PDCA methodology in a major trauma care center.

Objective

- To observe and assess the effectiveness of antimicrobial stewardship practices within the hospital.
- To measure the deviations from standards in the antibiotic usage pattern according to the institutions policy.
- To identify the root causes and eliminate the factors leading to discrepancies in the antimicrobial stewardship practices.
- To improve the antibiotics utilization pattern by implementing 5S PDCA principles.

Study design: A prospective interventional study

Inclusion criteria

- All patients receiving antimicrobials irrespective of age, gender, type of infection, and type of wound admitted for surgery.
- In-patients who stays not less than 24 hours

Exclusion criteria

- Patients who were not prescribed antimicrobials during hospitalization.
- Out-patients with antimicrobials.
- Patients admitted for other than surgical procedures.

Study site: Department of orthopedics, trauma, plastics, hand and micro surgery, in Ganga Hospital Coimbatore, Tamilnadu, India.

Study duration: 12 months

Study population: Sample size: 1000

Data collection

Cases collected from different wards and high-risk areas such as ICU, and HDU and followed entire patients who met an inclusion criteria from day one to till the day of discharge. The study period was divided into four phases according to study methodology (5S PDCA). The data was collected using a well-structured data collection form.

Data analysis

The collected data were analyzed by using 5S – PDCA assessment checklist.

Study procedure

The study is conducted in four phases - Plan, Do, Check and Act.

Plan Phase:

Primary assessment of the current situation of ASP (Antimicrobial Stewardship Practices) is a part of this phase. The areas of enhancement were identified and selected. This phase includes a review of various literature related to antimicrobial stewardship with 5S PDCA, then forming a data collection form for pilot study. The pilot study took place in a small-scale setting where 100 cases were collected to observe appropriate usage of antibiotics which stated few deviations in antimicrobial stewardship practices.

Do Phase:

Out of 1000 cases, 500 cases were collected in DO phase. The deviations of ASPs such as failing to adhere to hospital antibiotic policy, inappropriate usage of higher-end antibiotics, administration of antibiotics for a longer or shorter duration and insufficient knowledge on administration of loading and maintenance dose of antibiotics

were observed which required further improvement. The assessment of improvement can be done by implementation of 5S as a quality assessment tool.

Check Phase:

A vital stage in making decisions and determining next course of action is the check step. Checking of improvement in antimicrobial stewardship was done by using the 5S checklist which was made according to different phases of the 5S tool. Implementation of proposed action plan such as continuous training and education to healthcare professionals, persistent auditing on antibiotics usage, and analyzing inappropriateness of antibiotic usage were done and then 500 cases were collected in this phase.

Act Phase:

During the Act phase, crew records the findings and decides whether to accept or reject modifications. Preceding check phase, additional action plans such as conducting regular meetings and discussions with antimicrobial stewardship team, informing team physicians whenever a higher-end antibiotic is prescribed, following up on stop orders of antibiotics to be followed to obtain a better improvement, results were compared using radar chart.

A **radar chart** displays multiple data piled at same focal position along an axis. This makes it simple to compare and assess several entities such as data obtained in Phase II and Phase III to obtain significant information. Additionally, simple structure of the chart makes it extremely easy to create a complex, multivariate data display.

RESULTS

Phases Description

In the planning phase, literature review and preparation of data collection form was done and data were collected from patient's case sheets and laboratory reports. The 5S Checklist for Monitoring ASP is depicted in the table 1.

Table 1. 5S Checklist for Monitoring Antimicrobial Stewardship Program

SORT	
<input type="checkbox"/>	Antibiotic selection without considering
<input checked="" type="checkbox"/>	Spectrum
<input checked="" type="checkbox"/>	Site of infection
<input checked="" type="checkbox"/>	Wound
<input checked="" type="checkbox"/>	Surgery
<input checked="" type="checkbox"/>	Antibiogram

✓	Culture report review
❑	Justification for usage of antibiotic
▪	Prescribing antibiotics without infection or for a condition that doesn't need antibiotic
❑	Culture sensitivity report processing
▪	Improper review of c/s report
▪	Lag time
▪	Information sharing that is impartial between nurses and doctors
▪	Insufficient sophisticated reporting (MIC, zone of Inhibition)
▪	Improper rationale for sample request
▪	Insufficient knowledge regarding hospital antibiogram
❑	Guideline non-adherence
❑	Administration error
❑	Wrong selection of drug, dose, duration, and frequency
SET IN ORDER	
❑	Proper selection of antibiotic
Prophylactic	
✓	Type of surgery
✓	Type of wound
	Nature of suspected infection
Empirical	
✓	Antibiogram review
✓	Spectrum
Specific	
✓	C/S review

✓	Drug selection based on the patient's clinical condition
<input type="checkbox"/>	Processing of culture sample
•	Justification for sample request
•	Aseptic sample collection method
•	Proper sample collection
•	Sample transportation time
•	Proper sample storage
<input type="checkbox"/>	Processing of culture report
•	Proper reporting of culture –EMR method
•	On-time report generation
<input type="checkbox"/>	Improved communication between nurses and doctors
<input type="checkbox"/>	Proper history documentation
<input type="checkbox"/>	Dose adjustment-iv to oral conversion, pk consideration
<input type="checkbox"/>	Escalation/De-escalation
SHINE	
<input type="checkbox"/>	Presented in PTC
<input type="checkbox"/>	Tracking the antibiotic practice discrepancies
<input type="checkbox"/>	Tracking the adverse effects of antibiotics
<input type="checkbox"/>	Education to healthcare professionals

<input type="checkbox"/> Active participation of clinical pharmacists in antibiotic stewardship activities
STANDARDISE
<input type="checkbox"/> Preparation of protocol
<input type="checkbox"/> Antibiotic observation studies presented in medical audits
<input type="checkbox"/> Updation of antibiotic prophylaxis guidelines
<input type="checkbox"/> Classes for doctors
<input type="checkbox"/> Education program for laboratory staff
<input type="checkbox"/> Regular training classes enabled
SUSTAIN
<input type="checkbox"/> Regular auditing
<input type="checkbox"/> Antibiotic Stewardship Committee meeting
<input type="checkbox"/> Multiple antibiotic observational studies by trainees
<input type="checkbox"/> Monitoring clinical outcome
<input type="checkbox"/> Nurses' adherence to protocol
<input type="checkbox"/> Monitor doctor's adherence to protocol

The usage of various antibiotic classification such as cephalosporins, aminoglycosides, fluoroquinolones, macrolides and carbapenems in phase II and phase III are depicted in table 2.

Table 2. Distribution of antibiotics based on usage (n=1000)

ANTIBIOTIC	PHASE II		PHASE III	
	No. of cases	Percentage	No. of cases	Percentage
Cefuroxime	401	80.2	445	89

Cefoperazone/sulbactam	59	11.8	31	6.2
Amikacin	84	16.8	43	8.6
Clindamycin	26	5.2	13	2.6
Piperacillin/tazobactam	92	18.4	74	14.8
Ofloxacin	19	3.8	7	1.4
Levofloxacin	6	1.2	3	0.6
Meropenem	30	6	19	3.8
Ciprofloxacin/tinidazole	2	0.4	3	0.6
Colistin	4	0.8	3	0.6
Vancomycin	2	0.4	4	0.8
Teicoplanin	11	2.2	5	1
Linezolid	26	5.2	13	2.6
Nitrofurantoin	4	0.8	4	0.8
Cephalexin	35	7	16	3.2
Ceftriaxone/sulbactam	3	0.6	3	0.6
Moxifloxacin	3	0.6	2	0.4
Metronidazole	16	3.2	9	1.8
Augmentin	33	6.6	26	5.2
Erythromycin	1	0.2	1	0.2
Doxycycline	3	0.6	1	0.2
Cefotaxime	0	0	1	0.2
Tigecycline	0	0	1	0.2

Cefoperazone	1	0.2	1	0.2
Cephazolin	6	1.2	2	0.4
Ciprofloxacin	8	1.6	1	0.2
Cefixime	1	0.2	1	0.2
Imipenem	0	0	2	0.4
Ceftriaxone	1	0.2	1	0.2
Rifaximin	0	0	1	0.2
Clarithromycin	4	0.8	0	0
Cefuroxime axetil	4	0.8	0	0
Roxithromycin	1	0.2	0	0
Total	886	100	736	100

The antibiotic usage is followed on basis of culture reports, escalation or de-escalation after a positive culture reports and to continue the same antibiotic when empirical antibiotic prescribed falls sensitive to the isolated microorganism. This distribution in phase II is depicted in table 3 and figure 1.

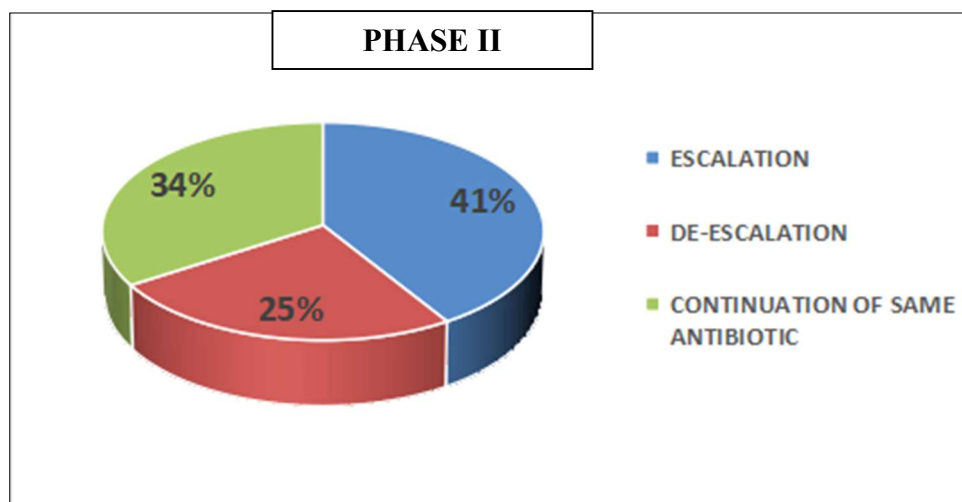


Figure 1. Escalation/De-Escalation Pattern in Phase II

Implementation of the proposed action plan such as continuous training and education to healthcare professionals, persistent auditing on antibiotics usage, and analyzing inappropriateness of antibiotic usages were done after which data were collected in phase III which is demonstrated in table 3 and figure 2.

Table 3. Escalation/De-Escalation pattern in Phase II (n= 500) and Phase III (n= 500)

	PHASE II		PHASE III	
	No. of Cases	Percentage	No. of Cases	Percentage
Escalation	205	41%	229	45.90%
De-Escalation	125	25%	114	22.8%
Continuation of the same antibiotic prescribed	170	34%	157	31.14%

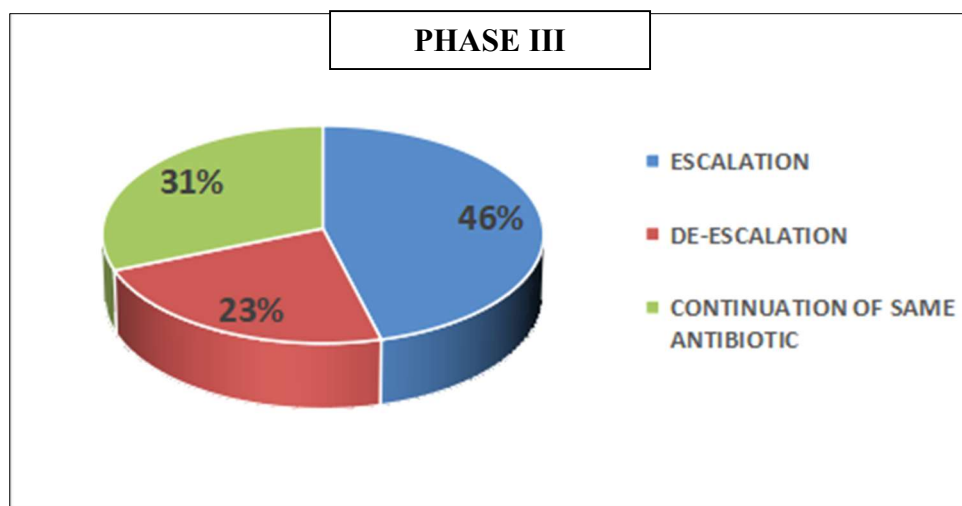


Figure 2. Escalation/De-Escalation Pattern in Phase III

The data distribution of antibiotic utilization pattern such as prophylactic use, empirical use and specific use in phase II and phase III are illustrated in below table 4.

Table 4. Antibiotic utilization pattern

ANTIBIOTIC USAGE	PHASE II	PHASE II (%)	PHASE III	PHASE III (%)
Prophylactic	633	71.04	556	75.5
Empirical	184	20.6	137	18.61
Specific	43	5.8	74	8.3
Total	891	100	736	100

The data collected in phase II and phase III were implemented in 5S - sort, set in order, shine, standardize and sustain to develop a radar chart which is illustrated in table 5 and figure 3.

Table 5. 5S Radar Chart

5 S	PHASE II	PHASE III
SORT	53	25
SET IN ORDER	48	17
SHINE	45	16
STANDARDISE	25	15
SUSTAIN	38	18

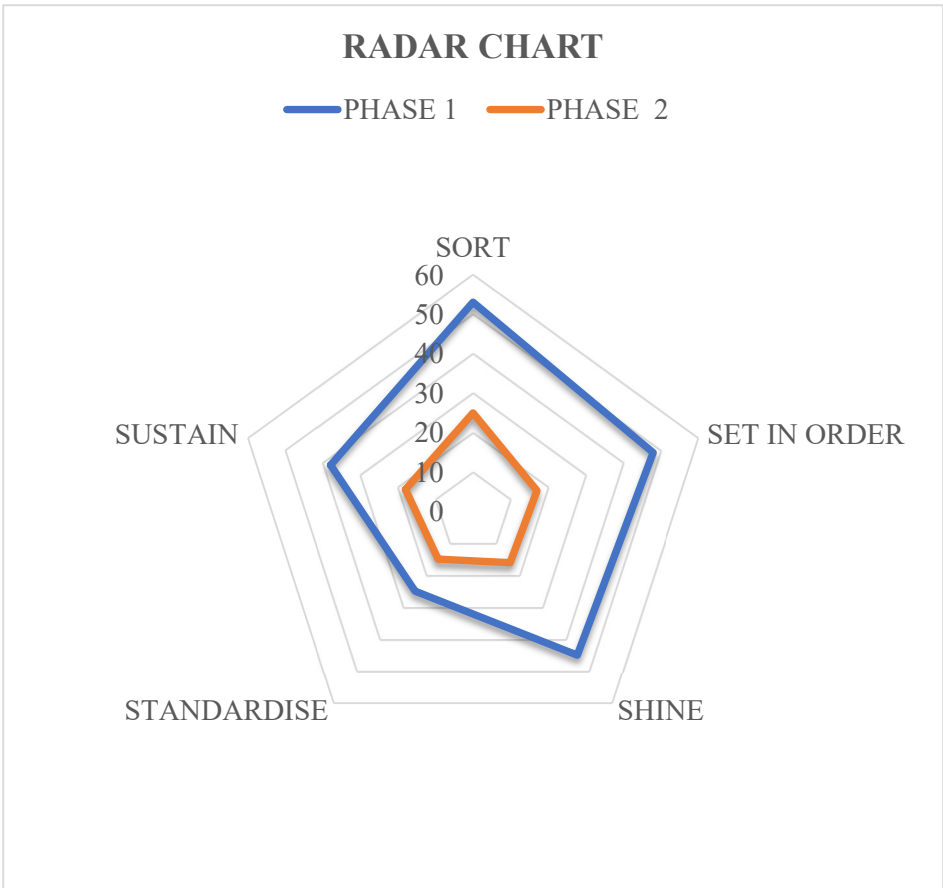


Figure 3. 5S Radar Chart

DISCUSSION

Clinical pharmacy services provided by hospitals often include regular ward visits, medication assessment of patient charts, individual suggestions on medication utilization, and involvement of pharmacists in providing professional guidance on medication handling during interdisciplinary visits to hospital wards. It has been suggested that increased clinical pharmacy efforts in field of antimicrobial agents could help with improving outcomes, encouraging antibiotic prescribing, reducing improper usage, and potentially slowing emergence and distribution of resistance in context of the rising antimicrobial resistance [10 -14].

Similar to ASP activities, pharmacists examine medications as part of routine practice to confirm dosage, diagnosis, consistency with standards, and interactions between drugs. Healthcare professionals such as physicians and clinical pharmacists play a major role in improving ASPs by building greater communication between them and having an understanding that ASPs are multi-focal which requires frequent monitoring and consistent follow-up to create a stable standardization. The model would be one in which pharmacists lead and carry out day-to-day activities, while physicians support their stewardship program from standpoint of community wellness, available for regular patient evaluation and assistance as required [15].

- The most commonly used antibiotic was Cefuroxime (80.2% in Phase I and 89% in Phase II),
- Followed by Amikacin (16.8 % in Phase I and 8.6 in Phase II.) Piperacillin/Tazobactam (18.4% in Phase I and 14.8% in Phase II) and Cefoperazone/Sulbactam (11.8% in Phase I and 6.2% in Phase II) respectively.

Cefuroxime and Amikacin were prophylactic antibiotics of choice according to local surgical prophylaxis antibiotic guidelines of the tertiary trauma care center. Piperacillin/Tazobactam and Cefoperazone/Sulbactam were used in cases of re-infection or in cases that required a broader antibiotic coverage or as an empirical therapy for infection cases.

The cases in which previous antibiotic selected and dose given were either not sensitive enough for infection drug was found to be resistant or clinical scenario demanded an escalation. Efforts such as continuous training and education to healthcare professionals, persistent auditing on antibiotics usage, analyzing inappropriateness of antibiotic usage conducting regular meetings and discussions with antimicrobial stewardship team, conducting regular meetings and discussion with antimicrobial stewardship team, informing team physicians whenever a higher-end antibiotic is prescribed, follow up on stop orders of antibiotics were made to control escalation rates and also to reduce usage of higher end antibiotics.

As the study was carried out in a prominent surgical setting, rise of prophylactic usage of antibiotics is undoubtedly practiced followed by empirical usage in both phases for suspected infections. Our study aided in the improvement of antibiotic utilization patterns which included strengthening the usage of prophylactic antibiotics and an increase in selection of specific antibiotics after detecting specific micro-organism thereby reducing the empirical usage of higher end antibiotics which turned out to have a major impact on hospital antimicrobial stewardship practices.

CONCLUSION

The use of 5S PDCA approach in the study shows a significant decrease in deviations in good antibiotic practices. The usage percentage of prophylactic antibiotics was strengthened from 71.04% (Phase II) to 75.5% (Phase III), a reducing trend in empirical antibiotic usage was observed from 20.6% (Phase II) to 18.61% (Phase III) and consistent improvement in usage of specific antibiotic was noticed from 5.8% (Phase II) to 8.3% (Phase III). Through the implementation of 5S PDCA methodology, inappropriateness of antibiotic usage was reduced in sort phase from 53% to 25% which is a 28% reduction in total deviations, set in order phase from 48% to 17 %, shine phase from 45% to 16%, standardize phase from 25% to 15% and sustain phase from 38% to 18%.

We deduced underlying causes and issues with antibiotic stewardship program from the study. Regular auditing, point prevalence studies, observational audits, stewardship committee meetings, and other activities helped to enhance the process.

As part of the study, effectiveness of antibiotic practice guidelines in the hospital was evaluated, and this

evaluation assisted in updating antimicrobial policies. A significant improvement was observed in antibiotic prescription patterns, usage patterns, policy adherence, and drug administration protocols.

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