



Rational use of antibiotics for major elective gynaecological and obstetrical surgical procedures: quality improvement journey from a tertiary care public facility

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ABSTRACT

Background Antibiotic resistance is a global problem. Irrational use of antibiotics is rampant. Guidelines recommend administration of single dose of antibiotic for surgical antimicrobial prophylaxis (SSAP) for elective obstetrical and gynaecological surgeries. However, it is not usually adhered to in practice. Majority of women undergoing elective major gynaecological surgeries and caesarean sections in the department of obstetrics and gynaecology of our tertiary level heavy case load public health facility were receiving therapeutic antibiotics (for 7–10 days) instead of recommended SSAP. Our aim was to increase the SSAP in our setting from a baseline 2.1% to more than 60% within 6 months.

Methods After root cause analysis, we formulated the departmental antimicrobial policy, spread awareness and sensitised doctors and nursing officers regarding antimicrobial resistance and asepsis through lectures, group discussions and workshops. We initiated SSAP policy for elective major surgeries and formed an antimicrobial stewardship team to ensure adherence to policy and follow processes and outcomes. The point of care quality improvement (QI) methodology was used. Percentage of patients receiving SSAP out of all low-risk women undergoing elective surgery was the process indicator and percentage of patients developing surgical site infection (SSI) of all patients receiving SSAP was the outcome indicator. The impact of various interventions on these indicators was followed over time with run charts. **Results** SSAP increased from a baseline 2.1%–67.7% within 6 months of initiation of this QI initiative and has since been sustained at 80%–90% for more than 2 years without any increase in SSI rate.

Conclusion QI methods can rapidly improve the acceptance and adherence to evidence-based guidelines in a busy public healthcare setting to prevent injudicious use of antibiotics.

PROBLEM

Surge in antimicrobial resistance (AMR) is a global threat. By 2050, approximately 10 million people will die annually because of

AMR, with most of these deaths happening in Africa and Asia. AMR along with the discovery void of antibiotics makes it imperative to address this problem at the earliest. One of the reasons for emergence of AMR is injudicious use of antibiotics. Indian Council of Medical Research (ICMR) issued guidelines to tackle AMR in 2017 and initiated antimicrobial stewardship in India.¹

Lady Hardinge Medical College and associated Shrimati Sucheta Kriplani Hospital is a public tertiary care health facility and department of obstetrics and gynaecology conducts approximately 13 000 deliveries, 600 elective caesarean sections and 400–450 major surgeries annually. We did not have an antimicrobial policy and women undergoing elective major gynaecological surgeries and caesarean sections were routinely prescribed preoperative prophylactic antibiotic (usually within 2–4 hours before surgery), and postoperative antibiotics for 7–10 days. The choice of antibiotic and its duration was decided by the treating consultant and included multiple type of regimens.

AVAILABLE KNOWLEDGE

Rational use of antibiotics is imperative to thwart AMR. International and ICMR guidelines on antimicrobial use recommend use of surgical antimicrobial prophylaxis (SSAP) by administering a single dose of antibiotic in women undergoing elective surgeries.^{2–5} The SSAP ensures effective tissue concentration of antibiotics to protect against any intraoperative bacterial contamination. There is no evidence to support prolonged use of antibiotics postoperatively in clean or clean-contaminated surgeries for prevention

of post-operative infections. A recent meta-analysis of 83 trials compared the practice of 1–5 days of postsurgical antibiotics versus no antibiotics. Authors concluded that prescribing antibiotics in postoperative period does not provide any added benefit.⁶ Irrational antibiotic use might be harmful by altering the resident flora from susceptible to resistant strains.⁷

Most national and international committees recommend cefazolin as the drug of choice for SSAP.⁸ Research has also shown that amoxicillin–clavulanate (AMX/CL) have comparable efficacy to cefazolin for prevention of postoperative infections. A prospective study in India concluded that both AMX/CL and cefazolin seem to be equally effective.⁹

RATIONALE

The quality improvement (QI) initiative was conceptualised on the basis of literature evidence supporting the need for rational use of antibiotics, with an aim to reduce AMR. A similar QI intervention was done in a secondary care maternity unit in Pakistan and they were able to reduce the percentage of patients receiving extended duration antibiotics in up to 92% of women.¹⁰ The latter study proved that even in low-income and middle-income countries, QI methods are successful in implementing the good clinical practices and evidence-based guidelines.

A study done in 2016 suggested that involvement of all levels of stakeholders through regular team meetings and individual discussions as well as incorporating their inputs in the QI process helped to sustain the new system.¹¹ Different activities like departmental conferences and small group discussions play a big role in educating and motivating the team members. Coding and documentation is also essential to capture the correct information regarding implementation of the change idea. Use of brochures, newsletters or technology aid in dissemination of information. Similar QI intervention to ensure appropriate antibiotic prescription in childhood pneumonia was carried out in Ohio in 2011 which focused on these educational methods to improve compliance to guidelines.¹²

We performed a root cause analysis to identify gaps in rational use of SSAP in the department under four domains—policy, people, procedure and place (figure 1). These gaps were then plugged one by one with multiple Plan-Do-Study-Act (PDSA) cycles to accomplish our aim.

SPECIFIC AIMS

Aim of our QI initiative was to implement ‘ICMR antimicrobial use guidelines’ for prescribing SSAP as a single dose antibiotic (within 15–60 min) before incision to low-risk patients undergoing elective gynaecological surgery, and caesarean sections. Our Specific, Measurable, Applicable, Realistic and Timely aim was to increase the percentage of patients receiving SSAP from a baseline of 2%–60% within 6 months.

METHODS

Context

Our department has five units with a team of 20 consultants, 32 senior residents and 48 postgraduate students. It conducts approximately 400 elective major gynaecological surgeries and 600 elective Caesarean sections annually. Our patients usually belong to lower or low-middle socioeconomic strata. The major gynaecological procedures included hysterectomy, myomectomy, ovarian cystectomy, surgeries for uterovaginal prolapse, vaginoplasty, tuboplasty, vesicovaginal fistula repair, rectovaginal fistula repair, complete perineal tear repair, endoscopic procedures and oncosurgeries. All women admitted in our department for elective surgery were included in the QI initiative.

The admitted patients were categorised in two groups (1) low-risk group : patients without any risk factors which increase susceptibility to infection (2) high-risk group : patients with risk factors for infection like diabetes mellitus, anaemia, poor nutritional status, malignancy, prior radiation or chemotherapy, presence of indwelling urinary catheter for a prolonged period, extremes of age, prolonged tobacco use, coexistent remote body-site infections, immunocompromised status, prolonged preoperative hospitalisation.¹³

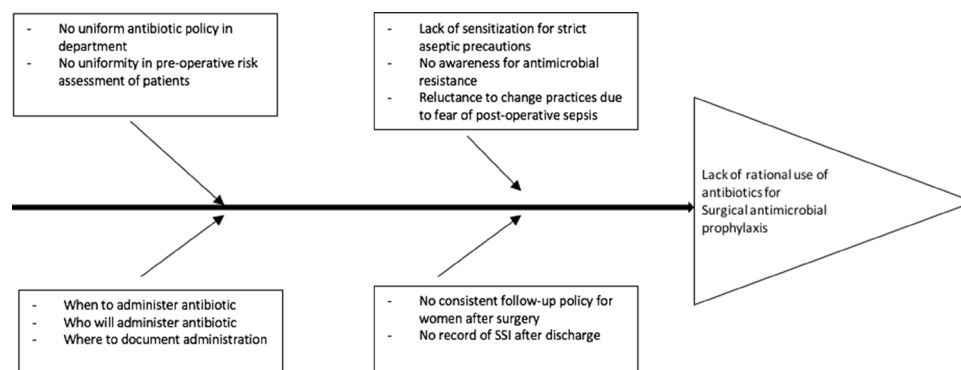


Figure 1 Fishbone analysis to identify gaps in rational use of prophylactic antibiotics under four domains—policy, people, procedure and place. SSI, surgical site infection.

Interventions

The study was conducted in three sequential phases over a period of 41 months from July 2017 to November 2020.

Phase 1: pre-intervention phase

This phase lasted for 1 month, 1 July 2017 to 31 July 2017. We performed three activities in this phase 1 (PDSA cycle 1) (online supplemental table):

1. Baseline data collection: It was collected for 1 month to understand the existing antibiotic practises and sepsis rates. The data were collected for all patients undergoing elective surgery with respect to type of surgery, risk factors, antibiotic administration (type and duration) and development of surgical site infection (SSI).
2. Review of literature and development of draft antibiotic policy: A detailed review of literature of existing guidelines on SSAP was performed by a designated nodal officer. The initial draft of guideline was prepared in consultation with microbiologist to factor in

for the common microorganisms detected from the swabs received from postoperative patients with SSI and their antibiogram.

3. Formulation of antimicrobial stewardship performa: We designed a form for preoperative risk assessment as described above, and to record the details of antibiotics prescribed (figure 2). This form was attached in front of the patient's case record at the time of pre-operative evaluation and collected at discharge. Preoperative risk assessment was done by the consultant in charge, SSAP was administered in operation theatre by the resident doctor and any SSI was documented and reported by the resident in charge to the nodal officer.

Phase 2: interim phase

This phase lasted for next 6 months from 1 August 2017 to 31 January 2018. This phase was driven by the gaps identified in the fishbone analysis and included finalisation of

NAME	CRNO -	DATE OF SURGERY -	UNIT -
Risk Factors			
Age	<18 / 19-59 / >60	Co-existing infection	Yes / No
Anaemia	Mild / mod / severe	Diabetic	Yes / No
Preoperative BT	Yes / No If yes, specify no.		
BMI 18-22.9 23 -27.9 >28	Normal Overwt Obese	Immunocompromised	Yes / No
Prolonged Pre-op stay >7 days	Yes / No If yes, specify days	Preop shaving	Yes / No
For Obstetric Patients	Membranes status +/-	Duration of LPV- hrs	No. of PV examinations-

Name of Surgical procedure-	Type of surgery	Prophylactic Antibiotic	Name - Dose - Route -
	Elective / Emergency		
Duration of Surgery	Hrs min	Inj. - Incision Interval	Hrs min
Intraoperative complication	Yes / No If yes, specify	Repeat dose	Yes / No If yes specify interval from first dose
BT	Yes / No If yes specify no. of units	Maintainence drug	Name- Dose- Route- Duration-
Foreign Body at surgical site (Mesh, surgical etc)	Yes / No If yes specify	Antibiotic Changed	Name - Dose- Route- Duration-
Drains	Yes / No	Reason for change of antibiotic	Raised Counts / fever / wound infection / chest infection / UTI / as per culture report
If changed more than once, please give details overleaf			

Sepsis	Discharge (serous / purulent) Wound disruption(Superficial / Deep / Burst) Septicaemia / Septic shock		
Organisms grown		Antibiotic Sensitivity	
Duration of hospital stay		Outcome	Discharged healthy / Adverse outcome
Any repeat surgical intervention			

Figure 2 Antimicrobial stewardship form. BT, Blood Transfusion, BMI, body mass index, LPV, Leaking Per Vaginum, PV, per vaginum, UTI, Urinary tract infection.

antibiotic policy guidelines and development of training structure for healthcare workers.

- ▶ As a pilot intervention (PDSA cycle 2), we rolled out the draft guidelines in one of the units headed by the team leader. The unit team consisted of five consultants and they all agreed to follow the proposed guidelines. The data were collected in the pilot unit for 1 month (1 August 2017–31 August 2017) with respect to type of surgery, risk factors, antibiotic administration and SSI.
- ▶ Simultaneously meetings were conducted with all faculty members of the department to discuss recommendations, reach a consensus and finalise the policy. We held four departmental meetings over a period of 1 month. We shared the baseline data of the existing practices of SSAP and SSI rates and presented our experience from pilot unit. The suggestions were incorporated, and guidelines were finalised.
- ▶ The following antibiotic strategy was adopted:
 - SSAP was defined as single dose of antibiotic given within fifteen to sixty minutes prior to surgical incision. Repeat dose was recommended in case of blood loss more than 1500 mL, or surgery lasting more than 4 hours after the initial dose.
 - We recommended a single dose of injection AMX/CL 1.2 g intravenously. Antibiotic sensitivity test was done on admission.
 - All low-risk women undergoing surgery were expected to receive SSAP.
 - The operating surgeon decided for choice and duration of antibiotic in high-risk patients. All patients were monitored during the postoperative period for any evidence of SSI. The SSI was defined as infection that occurs within 15 days of the surgical procedure and involves the skin and subcutaneous tissue of the incision (superficial incision) and/or deep soft tissue (fascia, muscle) of the incision (deep incision) and/or any part of the anatomy (organs and spaces) other than the incision that was opened or manipulated during an operation (organ/space).
 - Patients developing postoperative temperature of more than 38°C were systematically examined and investigated for any focus of infection. Their complete blood count and urine for routine and microscopic examination were sent. Antibiotics were prescribed postoperatively in patients where infection was suspected. The treating clinician decided for the type of antibiotic.
 - At the time of discharge, patients were instructed to contact the hospital in case of any symptoms suggestive of infection. Patients were followed up till 15 days after surgery by the operating team to detect any SSI.
- ▶ We performed multiple PDSA cycles (PDSA cycles 3–7) to fine tune our improvement strategies (online supplemental table 1):

- Implementation of policy in all units (PDSA cycle 3) was done. Multiple interactive sessions for the residents were conducted on the topics of normal skin and vaginal flora, common pathogenic microorganisms, universal precautions, importance of practicing asepsis, the departmental antibiotic policy and diagnosis of SSI and collection of wound swabs.
- Unitwise nodal officers were appointed and included in Antimicrobial Stewardship Task Force (ASTF) and a social media group was created for regular sharing of collected data (PDSA cycle 4).
- A 2-day intensive workshop of residents and consultants was held on AMR (PDSA cycle 5) under the aegis of ‘AMR week’ in November 2017.
- Subsequently sensitisation and training of nursing officers was done for flagging irrational use of antibiotics in the wards (PDSA cycle 6). They were advised to inform the nodal officer if they observed any patient receiving antibiotics for an extended duration. They were also trained on basic aspects of asepsis and antibiotic stewardship.
- The data of SSAP and SSI rates was presented every month during the monthly statistics meeting of the department (PDSA cycle 7).
- The antimicrobial stewardship programme was then integrated as a part of induction training programme for every new batch of residents (PDSA cycle 8).

Phase 3: post intervention phase

This phase started from 1 February 2018 and was continued as a departmental policy. This phase assessed the impact of interventions introduced in phase 2. We collected monthly data and continued presenting it in monthly departmental meeting to follow the trends.

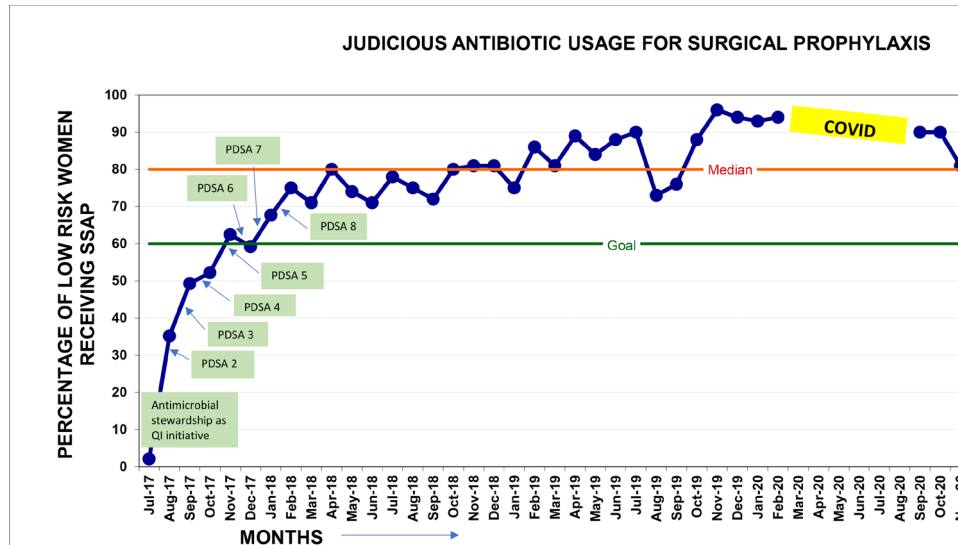
MEASURES

We decided to use the percentage of patients receiving SSAP without postoperative antibiotic continuation in all low-risk women undergoing elective surgeries as the process indicator. The percentage of patients developing SSI out of those receiving SSAP was recorded as the outcome measure. The overall SSI rate in all the patients undergoing elective surgery was also recorded every month for comparison. The data was collected every month by the nodal officers from all five units and entered in Microsoft excel sheets and compiled by the recorder.

RESULTS

Phase 1: preintervention phase (July 2017)

A total of 52 low-risk patients were admitted in the department for elective surgical procedure during baseline data collection phase, and 46 were found to be low-risk women. SSAP was received by only one (2.1%) patient. Total five (9.6%) patients developed SSI.



PDSA 1: Antimicrobial stewardship as QI initiative; **PDSA 2:** Implementation in one unit; **PDSA 3:** Implementation in all units; **PDSA 4:** Expansion of team to increase ownership; **PDSA 5:** Educational training through AMR week workshop; **PDSA 6:** Inclusion of Nursing officers for monitoring; **PDSA 7:** Sharing monthly data during monthly meetings and through technology; **PDSA 8:** Integration of antimicrobial policy in induction training program for new residents

Figure 3 Run-chart depicting SSAP% in low-risk group and SSI % in all SSAP group during and after the QI initiative. SSAP usage raised from 2.1% in baseline month (preintervention) to 54.3% in intervention phase (August 2017–January 2018) and further rose to 84.6% in postintervention phase. The median SSAP usage was 80%. PDSA, Plan-Do-Study-Act cycle, QI, quality improvement; SSAP, single-dose surgical antimicrobial prophylaxis.

Phase 2: interim phase (August 2017–January 2018)

SSAP was administered to 35.2% (18/51) low-risk women undergoing elective surgery in August 2017. Overall sepsis was reported in 3.9% (2/51). It was noted that of all 18 women administered SSAP in the pilot unit, none had SSI. Two cases with SSI were in the extended antibiotic group.

The policy was thereafter accepted by all consultants and SSAP rates gradually showed an upward trend (figure 3) and gradually increased to 67.1% in January 2018 after multiple PDSA cycles (190 out of 337 low-risk women received SSAP during interim phase). However, intermittent variations in the process indicator were observed which was attributed to rotation of the consultants in the concerned ward every 3–4 months.

The SSI rates in these women receiving SSAP ranged from 0% to 3.5% (3 out of 190 women receiving SSAP

had SSI) and showed similar trends as the overall SSI rates in the department in patients receiving extended antibiotics (figure 4).

Phase 3: post-intervention phase (February 2018–November 2020)

We performed 2257 surgeries in the postintervention phase. A total of 1971 women were low risk among these women. Of these, 1669 (84.6%) women received SSAP with SSI in 11 (0.65%) women. Overall SSI occurred in 47 (2.08%) women operated in the department.

DISCUSSION

Summary

Clinicians often overprescribe antibiotics presurgery and postsurgery sometimes for several days after surgery to

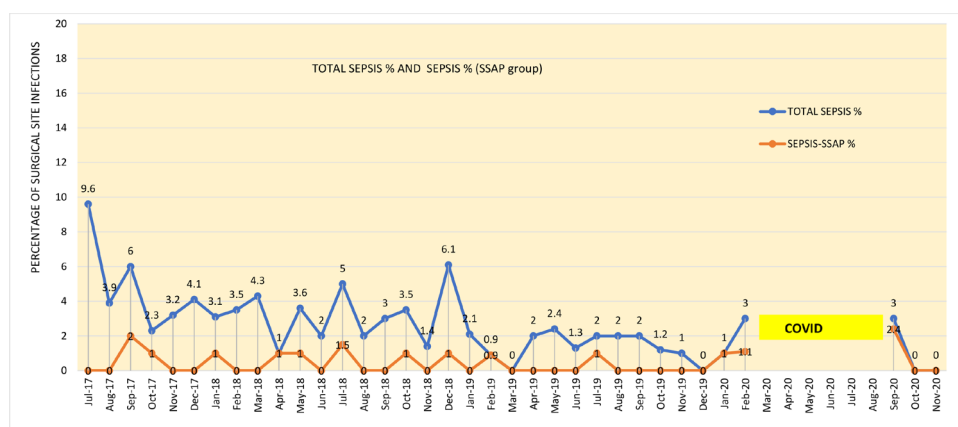


Figure 4 Trends of SSI as percentage in all postoperative women and SSAP group before, during and after the QI initiative. QI, quality improvement; SSAP, surgical antimicrobial prophylaxis; SSI, surgical site infection.

overcome the fear of breach in asepsis during surgery and resultant SSI. However, given the growing awareness of antibiotic resistance and potential toxicities, an ASTF was constituted in our department to implement good clinical practice guidelines for SSAP. We used point-of-care QI methodology to rapidly adopt evidence-based national guideline for appropriate antibiotic therapy in low-risk women admitted for elective surgeries.¹⁴ Over a period of 3 years, the department increased the practice of administration of SSAP from baseline negligible to near 90% and has successfully sustained it over 70% without any increase in SSI rate. The data, however, could not be collected for a period of 6 months from March 2020 to August 2020 due to COVID-19 pandemic as elective surgeries were withheld. Routine operative procedures resumed only in September 2020.

Strengths

The strength of this project is that despite being a heavy load, public sector hospital catering to patients from lower socioeconomic strata, we were able to adopt best practices for women undergoing elective surgeries. This project has continued over a long time and involved many units with different consultants. It also captured the challenges of maintaining the change ideas despite change in operating surgeons every 3–4 months in the concerned wards. This gives insight in managing QI projects in heavy load departments. We managed to convince most of those involved in decision making and worked together as a team. This project shows the importance of recording the outcome measure in the non-intervention conventional group in addition to the intervention group for comparison to convince low performers.

Interpretations

Administration of SSAP is a rational, evidence-based recommendation made by various national and international organisations like WHO, Center for Disease Control and Prevention, American College of Obstetricians and Gynecologists, Society of Obstetricians and Gynaecologists of Canada and ICMR. By adopting these, we were able to implement SSAP from 0% to nearly 90% at the end of 2 years of implementing the policy.

The Antimicrobial Stewardship Form played a pivotal role in our QI initiative. We were able to introduce consistency in preoperative risk assessment and SSAP. This was useful in uniform data collection and tracking deviations.

International guidelines may be modified or adapted according to the country and institution. We chose to adapt the guidelines provided by the ICMR with respect to the antibiotic choice based on availability of antibiotic in our hospital drug formulary and the inputs by the microbiologist based on the hospital antibiogram. We used AMX/CL 1.2 g for SSAP and found no increase in the postoperative infections. Larger randomised controlled trials may be required to assess comparative efficacy of AMX/CL and cefazolin for SSAP.

We observed that as the need for injectable antimicrobials decreased, the patients were discharged earlier

and the risk of nosocomial infections decreased. Itskovitz J also concluded that shorter courses of antimicrobial prophylaxis effectively decrease fever, serious postoperative infections and hospital stay.¹⁵

Hence, we have clear evidence supporting effectiveness of QI methodology to increase appropriate antimicrobial prescription in agreement with a national guideline in a public sector institution. Overcoming fear of sepsis is a challenge requiring multidisciplinary effort. Regular sensitisation by workshops and regular audits are required to ensure acceptance, compliance and adherence. Monitoring the process and outcome measures and sharing of data helped in sustaining changes.

Limitations

The major limitation of this study is the nonavailability of data on economic impact of implementation of SSAP in terms of average cost of antibiotic use per patient and average hospital stay for calculation of cost-effectiveness of this intervention. Due to the heavy patient load, suboptimal support staff and free healthcare for all, we were unable to capture these important outcome indicators. Cost of care is an important measure to evaluate the success of a policy change, however, the current study focused on the potential success of using QI methodology in implementation of appropriate national guideline.

Inclusion of data on reduction in the therapeutic antibiotics would have made the study robust. However, the study only focused on the low risk group where only prophylactic antibiotics were given, hence, data for therapeutic antibiotics could not be collected. Although, reduction of antibiotics for therapeutic purpose was a subjectively perceived effect of rational use but could not be measured objectively due to non-availability of a trained antibiotic surveillance team. We did do a sample retrospective analysis for average hospital stay and antibiotic usage from the concerned wards for 1 month each before and after intervention for comparison which suggested reduced consumption of antibiotic in the postoperative ward.

Another limitation was regarding the duration of follow-up of postoperative patients. We followed our patients only till 2 weeks postsurgery for development of SSI whereas in actual definition, patients need to be followed till 30 days after surgery.

Future work should evaluate whether the adherence to the guidelines is cost-effective and results in equivalent or improved outcomes for the patient.

Lessons learnt

A stepwise approach can facilitate achieving goals which may initially appear non-achievable. Changing the behaviours and practices is difficult but not impossible. Focused group discussions are very useful in sensitisation and identifying barriers. Early identification and troubleshooting prevent slowing down of the projects and keeps the momentum. It is always good to start small and avoid giant steps. We started the change in one unit, shared the results with others and motivated them to adopt and test the change. Generating

competition among different units was very effective in maintaining the enthusiasm. Regular watch on the outcome measures is essential for sustenance.

This initiative resulted in appropriate risk assessment of pre-operative patients, uniformity in antimicrobial prescription, decreased antibiotic usage and reduced hospital stay without any increase in SSI. We assume that this QI initiative was not only economical but also decreased the workload of nursing staff, saved patients of the discomfort of getting injectable antibiotics for prolonged periods and related side effects of unnecessary administration of antibiotics.

Trying out the different change ideas helped us to reach the final goal of improving the prescription protocol in low risk women planned for elective surgery. Leading by example (initiating the QI initiative in pilot unit of the team leader), encouraging attitude (regular communication with all surgeons and discussing with the hesitant ones), inclusiveness of all (taking inputs from nursing personnel and residents improved data collection) and periodic sharing of data (during monthly statistical meeting) helped us in allaying fears and moving ahead towards improved practices for antimicrobial stewardship.

CONCLUSION

QI methodology is exceedingly effective in increasing judicious antimicrobial prescription in agreement with national guidelines in a public sector facility. SSAP is an evidence-based practice which should be followed in all patients undergoing elective surgeries. Overcoming fear of sepsis is a challenge requiring multidisciplinary effort. Regular sensitisation by workshops and audits are required to ensure acceptance, compliance and adherence. Continuous monitoring of the process and outcome measures and sharing of data helped in sustaining the changes.

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Contributors All made substantial contributions to the conception or design of the work and/or the acquisition, analysis or interpretation of data for the work. MP as team leader and SN as recorder drafted the paper. SN and AG collected the baseline data. VC, NJ, DM, MS, KC and TG as unitwise nodal officers collected the monthly data and helped in sensitising residents. AG, PS and EC analysed the data and ensured correctness. PS, EC, HV and RM helped in monitoring antibiotic consumption and postoperative hospital stay of patients and notified extension of antimicrobials to nodal officers (MP and SN). SN as guarantor takes full responsibility of the work. All authors critically appraised, reviewed and approved the final version of the paper. All agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval This project was designed to improve the service for patients. It was undertaken using improvement science methodology and was not deemed to

require ethics approval. The interventions made were designed to standardise and optimise routine accepted good practice.

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