

Article type : Clinical Article

CLINICAL ARTICLE

Antibiotic use during repair of obstetrical anal sphincter injury: a quality improvement initiative

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Keywords

antibiotic prophylaxis, OASIS, obstetric anal sphincter injury, postpartum infection, quality improvement, sphincter repair

Synopsis

Following implementation of a quality improvement intervention aimed at increasing antibiotic administration at the time of obstetric anal sphincter injury repair, antibiotic use increased 13-fold.

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1002/IJGO.13623](https://doi.org/10.1002/IJGO.13623)

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Abstract

Objective: To evaluate the effects of a quality improvement initiative regarding the administration of antibiotics at the time of obstetric anal sphincter injury (OASIS) repair.

Methods: At University of Michigan—a tertiary care center in Ann Arbor, MI, USA, we implemented a quality improvement intervention aimed at administering a single dose of broad-spectrum antibiotics at the time of OASIS repair. Best practice recommendations and reminders were presented to the department. Cefazolin plus metronidazole or clindamycin plus gentamycin were the recommended antibiotics. The effects of this intervention were assessed based on a chart review of deliveries between January 4, 2014 and February 13, 2019, which included patient data both pre-initiative and post-initiative to compare the prevalence of antibiotic use at the time of OASIS repair.

Results: Recommended antibiotic use increased from 0.3% (1/372) pre-initiative to 75.7% (106/140) post-initiative ($P < 0.001$), and any antibiotic use increased from 6.5% (24/372) to 82.9% (116/140, $P < 0.001$). The proportion of cases complicated by wound infection/breakdown decreased by 55% after the quality improvement intervention (3.2% pre-intervention vs 1.4% post-intervention, $P = 0.22$).

Conclusion: Following a departmental quality improvement intervention aimed at increasing antibiotic administration at the time of OASIS repair, antibiotic use increased 13-fold. Although underpowered to detect a significant difference in wound complications, our study showed a clinically meaningful decrease in wound infection/breakdown with antibiotic administration.

1 INTRODUCTION

Obstetric anal sphincter injuries (OASIS), also known as third- and fourth-degree perineal lacerations, involve injury to the anal sphincter complex and are a well-known complication of vaginal delivery [1-3]. While the true incidence of OASIS is unknown, it is estimated to occur in 11% of all vaginal deliveries [4]. Postpartum wound infection following OASIS is common, with a prevalence of up to 20% [5,6]. Antibiotics, given either during labor or at the time of OASIS repair, have been shown to decrease postpartum perineal wound complications [5,6]. In 2015, the Royal College of

Obstetricians and Gynaecologists published a guideline recommending the use of broad spectrum antibiotics following OASIS repair [7]. Later in 2018, the American College of Obstetricians and Gynecologists published a Practice Bulletin indicating that this is a reasonable practice [8]. In an effort to increase adherence with this recommendation at our institution, we designed and implemented a quality improvement intervention aimed at increasing the administration of antibiotic prophylaxis at the time of OASIS repair. The primary objective of this study was to evaluate the efficacy of a departmental quality improvement intervention aimed at increasing the proportion of women receiving antibiotics at the time of OASIS repair. The prevalence of perineal wound infections/breakdown and reoperation for wound-related complications were analyzed as secondary outcomes.

2 MATERIALS AND METHODS

The quality improvement initiative focused on administering a single dose of broad-spectrum antibiotics at the time of OASIS repair was implemented on December 14, 2017 at the University of Michigan—a tertiary care center with over 4,500 deliveries per year. All deliveries complicated by OASIS between January 4, 2014 and February 13, 2019 were included, and cases before and after the initiative were compared. It is standard practice at our institution for all OASIS repairs to be performed by obstetrical faculty and residents.

On December 14, 2017, a department-wide Grand Rounds presentation was given outlining best practices for managing OASIS and introducing the new institutional perinatal practice guideline on this topic (University of Michigan Perinatal Joint Practice – Third and Fourth Degree Laceration Repair; Carolyn Swenson and Roger Smith, authors; posted December 11, 2017, Appendix S1). The primary recommendation was to give a single dose of broad-spectrum antibiotics at the time of OASIS repair.

Recommended antibiotics were cefazolin 2 g intravenous plus metronidazole 500 mg intravenous or oral. Cefazolin was selected based on the only published randomized controlled trial of antibiotic prophylaxis for OASIS repair [6], while metronidazole was included based on extrapolation of evidence for decreasing surgical site infection after hysterectomy [9] and colorectal surgery [10]. For patients with a severe penicillin

allergy, gentamycin 5 mg/kg plus clindamycin 900 mg were recommended. Additional best practices included guidelines for repair technique, when to perform the repair in the operating room, and recommendations for postpartum care.

Recommended best practices for laceration repair technique included the following: full thickness closure of the rectal mucosa with 3-0 or 4-0 polyglactin suture, re-approximation of the internal anal sphincter with interrupted or mattress sutures using 2-0 or 3-0 polydioxanone suture, and end-to-end closure of the external anal sphincter with interrupted sutures of 2-0 or 3-0 polydioxanone. End-to-end rather than overlapping closure was recommended due to evidence suggesting equal long-term efficacy of both procedures but increased dyspareunia with the overlapping technique [11,12].

Performing the repair in the operating room was recommended for all fourth-degree lacerations, and if general anesthesia or improved exposure of the laceration was required. Postpartum recommendations included the use of a daily bowel regimen of polyethylene glycol 3350 to maintain toothpaste-like stool consistency for at least six weeks postpartum; use of ice packs and scheduled ibuprofen and acetaminophen; warm water sitz baths; and referral to our postpartum pelvic floor specialty clinic (Michigan Healthy Healing After Delivery), where patients are typically seen within 2-3 weeks of delivery [13].

Implementation of this practice was multi-modal. In addition to the Grand Rounds presentation, the departmental perinatal practice guideline on OASIS repair and information about all recommended best practices were distributed electronically to faculty members and residents. Furthermore, summaries of this information were displayed on printed posters throughout the labor and delivery unit. The specific antibiotic recommendations and a summary of the recommended repair techniques were both added to every delivery cart and printed on small cards for residents to keep in their badge holders. In addition, residents underwent a hands-on OASIS repair session facilitated by one of the authors (CWS), during which they practiced the recommended repair techniques using appropriate suture on porcine anal sphincters. In order to identify women whose vaginal delivery was complicated by an OASIS (including 3a, 3b, 3c, and fourth-degree lacerations) from January 2014 to February 2019, the electronic medical record was queried using the laceration type recorded in

the delivery summary. Laceration types were classified as follows: 3a is a tear involving <50% of the external anal sphincter (EAS), 3b involves $\geq 50\%$ of the EAS, 3c extends through both the EAS and internal anal sphincter (IAS), and a fourth-degree laceration extends through both the EAS, IAS, in addition to the anal mucosa [8]. Patient information including demographic characteristics, medical co-morbidities (diabetes including pre-existing and gestational and hypertension including pre-existing and hypertensive disorders of pregnancy/pre-eclampsia), parity, delivery details (gestational age, birthweight, length of second stage), antibiotic type and timing of administration, and postpartum complications were extracted using a combination of our departmental quality improvement database and chart review. Chart review was performed to determine the presence of postpartum wound infection or breakdown, which were defined as the diagnosis of either “wound infection” or “wound breakdown” in any postpartum visit encounter within three months of delivery. These wound complications were combined for analysis because the terms were used interchangeably in the medical record.

The proportion of women receiving antibiotics, both recommended and non-recommended, at the time of OASIS repair before and after the quality improvement initiative was compared as the primary outcome. Rates of OASIS repair in the operating room and wound complications, including wound infection/breakdown and reoperation, were also compared between the two time periods.

Statistical analyses were performed using Student *t*-test and Chi-square test for continuous and categorical variables, respectively. A *P*-value of <0.05 was considered significant. A single-intervention interrupted time series analysis using Ordinary Least Squares estimation was performed to analyze the quarterly rate of change in utilization of antibiotics before and after the quality improvement intervention. Interrupted time series analysis is a quasi-experimental design utilizing linear regression to investigate the longitudinal effects of an intervention and is generally unaffected by confounding variables [14]. For the purposes of this analysis, the “pre-intervention” period is from the third quarter of 2014 through the fourth quarter of 2017 and the “post-intervention” period is from the first quarter of 2018 through the first quarter of 2019. Statistical analyses were conducted with SPSS V24.0 (IBM Corporation, Armonk, NY).

The evaluation of this quality improvement project was deemed 'not regulated' by the University of Michigan institutional review board (HUM00163625) and was written in accordance with the SQUIRE 2.0 (Standards for Quality improvement and Reporting Excellence) guidelines [15]. Informed consent was waived, as this is a retrospective review of existing data included in the standard care of patients. The data was de-identified, and the results will not negatively or positively affect the patients or their offspring.

3 RESULTS

All 512 patients with OASIS at time of delivery during the study period were included in the analysis. Table 1 shows the demographics and obstetrical variables of women included. The majority of patients were white, non-Hispanic, and primiparous. Spontaneous vaginal delivery occurred in 80% of deliveries, and the episiotomy rate was 9% among women with OASIS. The pre-intervention time period spanned approximately three years, during which time 372 deliveries had OASIS compared to 140 in the post-intervention period, which was just over one year. Groups did not differ significantly in terms of race, parity, medical comorbidities, mode of delivery, episiotomy incidence, laceration type, or birthweight (Table 1). The post-intervention group was on average one year older (31.2 years [21-42 interquartile range] post-intervention vs 30.2 years [16-43] pre-intervention, $P = 0.03$).

Following the quality improvement intervention, the proportion of patients receiving any antibiotics at the time of OASIS repair increased 13-fold (6.5% pre-intervention vs 82.9% post-intervention, $P < 0.001$). In the post-intervention period, over 90% of patients who received antibiotics received those recommended in the institutional guideline (106/116, 91.4%; Figure 1) and about half of them received the antibiotics within two hours of delivery (74/140, 52.9%). Figure 2 shows the interrupted time series analysis for change in utilization of antibiotics at the time of OASIS repair. In the pre-intervention group, average utilization of any antibiotic increased by 8% per quarter (i.e., slope of the trend line=0.08) compared to 30% per quarter in the post-intervention period (slope=0.30). During the fourth quarter of 2018, 100% of women with OASIS (N = 26) had the recommended antibiotics administered at the time of repair. The overall

difference in slopes (i.e., the change in average quarterly utilization) before and after the intervention did not reach statistical significance ($P = 0.60$) — likely due to the high and sustained uptake in administration of antibiotics in the first quarter after the quality improvement intervention was implemented (2018 Q1). There were no serious adverse events attributable to antibiotic administration.

The proportion of cases complicated by wound infection/breakdown decreased by 55% after the quality improvement intervention (3.2% pre-intervention vs 1.4% post-intervention, $P = 0.22$). Our study was not powered to detect a statistically significant difference in wound complication. According to a post hoc calculation, a sample size of 2175 women in each group would be required to detect a 40% change in wound infection/breakdown rate (80% power, $\alpha = 0.05$). Patients who received the recommended antibiotics had a lower wound infection/breakdown rate than those who received any antibiotics, but this did not reach statistical significance (0.9% with correct antibiotics vs 3.2% with any antibiotics, $P = 0.17$). Women with a fourth-degree laceration had a four-fold higher wound infection/breakdown rate than those with third-degree lacerations (10.3% with fourth-degree vs. 2.3% with-third degree, $P = 0.04$). Neither diagnosis of diabetes nor operative delivery had an effect on the wound infection/breakdown rate (Table 2). Operative deliveries included vacuum and forceps deliveries, and there was one wound complication in each of these groups. Additionally, there was no significant difference in mean length of second stage of labor between women who did and did not develop a wound complication (151.0 ± 108.2 minutes with wound infection/breakdown vs. 129.9 ± 112.6 minutes without, $P = 0.49$) Following the intervention, no significant change was observed in the proportion of patients whose laceration was repaired in the operating room nor in the rate of unplanned return to the operating room for wound complication within three months of delivery (Table 2). Reasons for return to the operating room included wound breakdown, laceration revision/excision of granulation tissue, lysis of adhesions for vaginal agglutination, and anal sphincteroplasty.

4 DISCUSSION

Following implementation of a quality improvement intervention aimed at increasing antibiotic administration at the time of OASIS repair, antibiotic use increased

from 6.5% to 83.0% and was sustained at >70% in each quarter for 13 months of follow-up. Although the study was underpowered to detect a significant difference in wound complications, the rate of wound infection/breakdown decreased by over 50% in the post-intervention period.

Existing studies on antibiotic use at the time of OASIS repair are mostly either retrospective case series or randomized controlled trials, both study designs with limitations—the former limited by unmeasured confounders and the latter limited by lack of reproducibility in real-world clinical practice. Our paper extends the literature by using interrupted time series analysis, providing a quasi-experimental study design to test the effectiveness of our intervention in a real-world setting rather than that of a clinical trial. Furthermore, we describe a reproducible quality improvement intervention successful in modifying physician practice, which is notoriously difficult to change. Many theories have been promoted about how to choose a successful intervention, but no single theory has been identified as the most widely applicable [16]. A Cochrane review evaluated the effectiveness of interventions to change clinical practice and found that interventions designed based on investigations into the reasons for resistance to change can be effective, but the effects are generally small to moderate [17]. The team that designed our intervention identified the main barriers to guideline adherence in this case as clinicians either being unaware of the recommendation to give antibiotics or simply forgetting to give them. We attempted to overcome these barriers by disseminating the guidelines in multiple forms, as explained previously. The fact that the intervention had such a large effect on clinical practice may be attributed to the involvement of residents, who provide consistency by spending a month at a time on the labor and delivery floor. We identified one resident champion (author MB) who was critical to ensuring uptake of the new practice recommendations by the obstetrics and gynecology residents.

In our study, the wound complication rate including infection/breakdown and reoperation was 2.7%, which is lower than rates reported in the literature. Studies of wound complications following OASIS report complication rates ranging from 7-44% overall and 6-29% with antibiotics [5,6,18]. The discrepancy in rates between the current and existing studies may be related to differences in use of operative delivery

and prevalence of fourth-degree perineal lacerations, both of which are risk factors for wound complications [5,18]. The aforementioned studies report operative delivery rates of 35-72%, whereas it was only 12% in our cohort. Furthermore, 14-19% of women with OASIS in the referenced studies had fourth-degree lacerations, compared to only 6% in our study population. Variations in how “wound complication” is defined may also account for some differences in interpretation. For example, Lewicky-Gaupp et al. defined wound breakdown as a wound separation of at least 1 cm, but the studies by Stock and Duggal did not specify how wound breakdown was defined. The objective criteria for diagnosing wound complications were not standardized in our study; however, chart review was used to identify specific diagnoses of “infection” and “breakdown” in addition to reoperation for OASIS wound complications, which should account for the clinically relevant complications. While we did see a 55% decrease in wound infections/breakdown in our study, we were underpowered to detect a significant difference. Therefore, we cannot make any definitive conclusions about the efficacy of antibiotic prophylaxis at the time of OASIS repair in decreasing wound complications. To our knowledge, our study is the first to include metronidazole in the antibiotic regimen for OASIS repair, so further investigation could compare the effectiveness of metronidazole plus cefazolin to cefazolin alone.

The greatest strength of our study is that it demonstrates the effectiveness of a quality improvement initiative to change provider practice in a widespread manner that was sustained in short-term follow-up. This initiative could potentially be reproduced and implemented in other labor and delivery units. Our study had several limitations in addition to those inherent to retrospective data collection. We had a relatively short follow-up time after the intervention. We do not yet know if portions of the intervention will need to be repeated at certain intervals to maintain the shift in practice. In addition, the study was underpowered to detect a change in wound complications.

After implementation of a department quality improvement initiative aimed at increasing compliance with the recommendation to give broad-spectrum antibiotics at the time of OASIS repair, we observed a 13-fold increase in administration of antibiotics and a non-statistically significant reduction in postpartum wound complications.

AUTHOR CONTRIBUTIONS

CC, MB, and CS designed the study. CC, MB, RS, and CS designed and implemented the quality improvement initiative. CC and CS did the chart review. CC and CS did the data analysis. CC drafted the manuscript. DF, RS, and CS revised the manuscript. All authors reviewed and approved the manuscript.

ACKNOWLEDGMENTS

The authors thank Sarah Block for her assistance with manuscript preparation. Investigator support for CWS was provided by the National Institute of Child Health and Human Development (NICHD) WRHR Career Development Award K12 HD065257.

CONFLICTS OF INTEREST

The authors have no conflicts of interest.

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Figure Legend

Figure 1. Percentage of OASIS treatment and wound complications in the pre- and post-intervention periods

* $P < 0.001$

Abbreviations: OASIS, obstetric anal sphincter injury

Figure 2. Proportion of OASIS repairs receiving antibiotics before and after quality improvement policy implementation

Abbreviations: OASIS, obstetric anal sphincter injury; QI, quality improvement

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TABLE 1. Patient characteristics

Variable	Total Cohort (N=512)	Pre-Intervention (n=372)	Post-Intervention (n=140)	<i>P</i> value
Age, years ^a	30.48±4.3 (16-43)	30.2±4.3 (16-43)	31.2±4.2 (21-42)	0.03
Body Mass Index, kg/m ² ^a	30.1±5.3 (20-56)	30.1±5.4 (20-56)	30.1±4.9 (21-47)	0.99
Race				0.11
White	343 (67.0)	248 (66.7)	95 (67.9)	
Black/African American	25 (4.9)	24 (6.5)	1 (0.7)	
Asian	105 (20.5)	75 (20.2)	30 (21.4)	
American Indian and Alaska Native	1 (0.2)	1 (0.3)	0 (0)	
Bi/Multi Racial	8 (1.6)	5 (1.3)	3 (2.1)	
Unknown/Other	30 (5.9)	19 (5.1)	11 (7.9)	
Ethnicity				<0.001
Non-Hispanic	357 (69.7)	231 (62.1)	126 (90.0)	
Hispanic	10 (2.0)	1 (0.3)	9 (6.4)	
Unknown	145 (28.3)	140 (37.6)	5 (3.6)	
Diabetes	36 (7.0)	26 (7.0)	10 (7.1)	0.95
Hypertension	71 (13.9)	47 (12.6)	24 (17.1)	0.19
Current Smoker	7 (1.4)	7 (1.9)	0 (0)	0.20

Parity				0.91
1	400 (78.1)	288 (77.4)	112 (80.0)	
2	96 (18.8)	72 (19.4)	24 (17.1)	
3	13 (2.5)	10 (2.7)	3 (2.1)	
4	3 (0.6)	2 (0.5)	1 (0.7)	
Delivery Type				0.17
SVD	408 (79.7)	288 (77.4)	120 (85.7)	
VBAC	44 (8.6)	37 (9.9)	7 (5.0)	
Vacuum	41 (8.0)	33 (8.9)	8 (5.7)	
Forceps	19 (3.7)	14 (3.8)	5 (3.6)	
Length of Second Stage, minutes	130.5±112.4 N=478	133.4±115.2 N=353	122.2±104.3 N=125	0.34
Episiotomy				0.86
No	468 (91.4)	339 (91.1)	129 (92.1)	
Yes	44 (8.6)	33 (8.9)	11 (7.9)	
Laceration Type				0.20
3a	346 (67.6)	254 (68.3)	92 (65.7)	
3b	90 (17.6)	68 (18.3)	22 (15.7)	
3c	47 (9.2)	28 (7.5)	19 (13.6)	
4	29 (5.7)	22 (5.9)	7 (5.0)	

Birthweight, g ^a	3525.7±505.4 (2110-5279)	3512.5±500.6 (2159-5279)	3561.4±518.5 (2110-4880)	0.33
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Data reported as n (%) unless otherwise noted

^aMean±SD (range)

Abbreviations: SVD, spontaneous vaginal delivery; VBAC, non-operative vaginal birth after cesarean

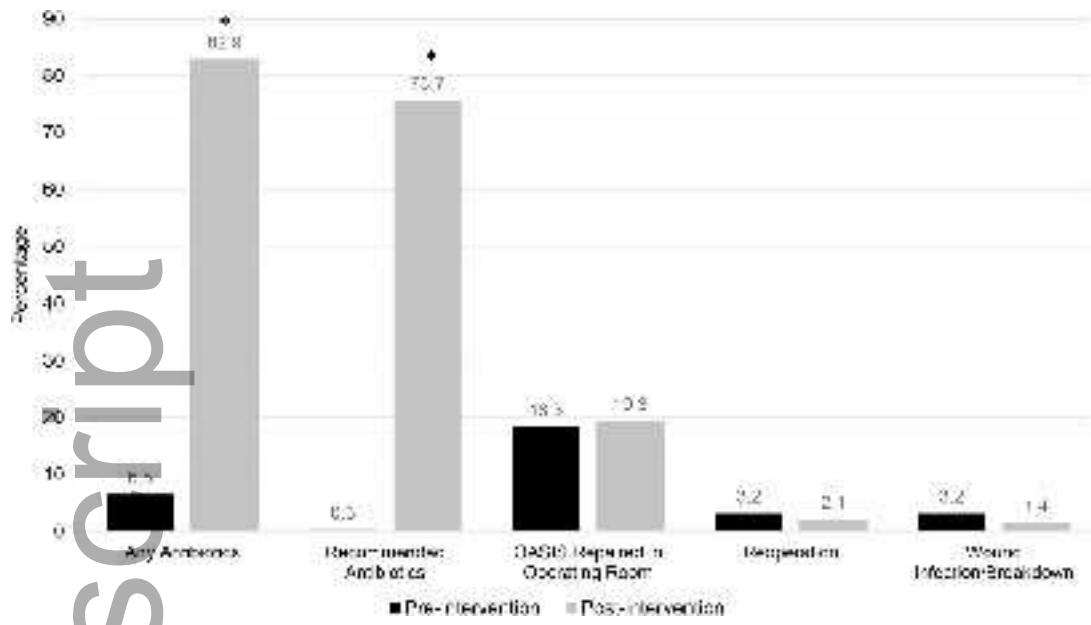
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TABLE 2. Wound complications by predisposing factor

Predisposing Factor	Wound Infection or Breakdown	<i>P</i> value
Any Antibiotics Given		0.44
No	11/372 (3.0)	
Yes	3/140 (2.1)	
Correct Antibiotics Given (any time)		0.17
No	13/405 (3.2)	
Yes	1/107 (0.9)	
Correct Antibiotics Given (within 2 hours of delivery)		>0.099
No	13/437 (3.0)	
Yes	1/75 (1.3)	
Laceration Type		0.009
3a	6/346 (1.7)	
3b	5/90 (5.6)	
3c	0/47 (0)	
4	3/29 (10.3)	
Operative Delivery		0.50
No	12/452 (2.7)	
Yes	2/60 (3.3)	
Diabetes		0.61
No	14/476 (2.9)	
Yes	0/36 (0.0)	

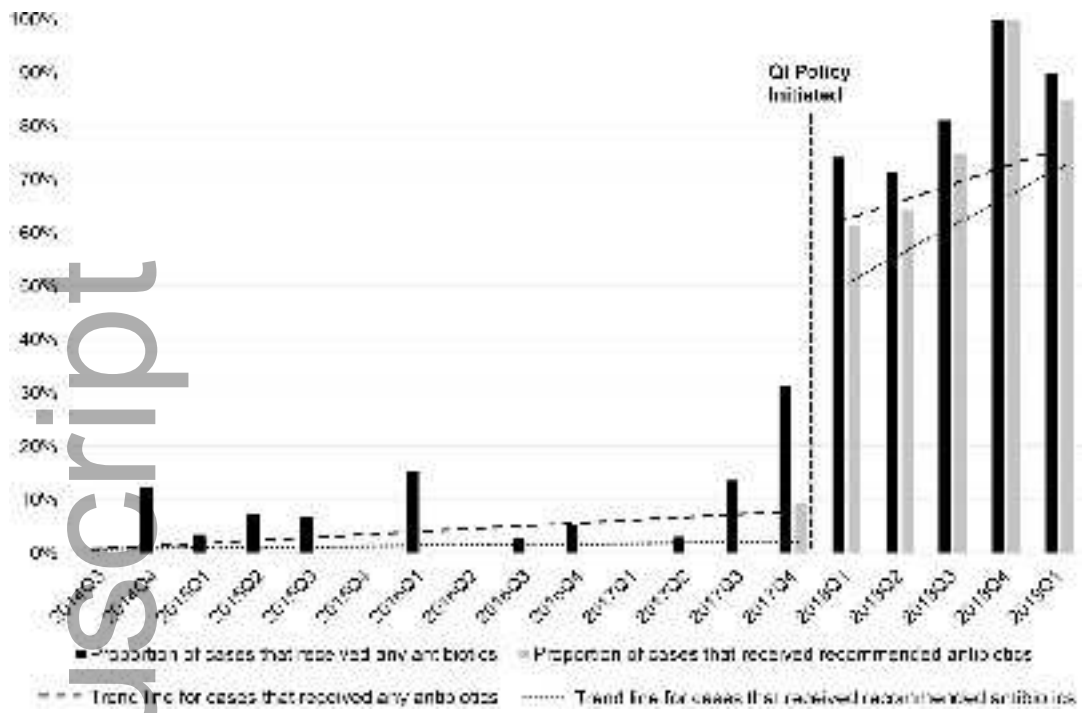
Data presented as n/N (%)

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