


BMJ Open Quality **Impact of a quality programme on overindication of surgeries for endometriosis and cholecystectomies**

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ABSTRACT

Approximately 45% of patients receive medical services with minimal or no benefit (low-value care). In addition to the increasing costs to the health system, performing invasive procedures without an indication poses a potentially preventable risk to patient safety. This study aimed to determine whether a managed quality improvement programme could prevent cholecystectomy and surgery for endometriosis treatment with minimal or no benefit to patients.

This before-and-after study was conducted at a private hospital in São Paulo, Brazil, which has a main medical remuneration model of fee for service. All patients who underwent cholecystectomy or surgery for endometriosis between 1 August 2020 and 31 May 2021 were evaluated. The intervention consisted of allowing the performance of procedures that met previously defined criteria or for which the indications were validated by a board of experts. A total of 430 patients were included in this analysis. The programme prevented the unnecessary performance of 13% of cholecystectomies ($p=0.0001$) and 22.2% ($p=0.0006$) of surgeries for the treatment of endometriosis. This resulted in an estimated annual cost reduction to the health system of US\$466 094.93.

In a hospital with a private practice and fee-for-service medical remuneration, the definition of clear criteria for indicating surgery and the analysis of cases that did not meet these criteria by a board of reputable experts at the institution resulted in a statistically significant reduction in low-value cholecystectomies and endometriosis surgeries.

PROBLEM

A young woman at our institution underwent multiple interventions for endometriosis. From the first to the third day after surgery, she presented with moderate hypotension, abdominal pain and low fever, which were attributed to intraperitoneal haemorrhage and blood reabsorption by the surgeon. On the fourth postoperative day, when the patient's blood pressure decreased to 80/40 mm Hg, perforation was hypothesised and subsequently confirmed during exploratory laparoscopy. Cavity cleaning and drainage,

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Literature on effective programmes to reduce surgeries for which the risks and costs outweigh the benefits is scarce.

WHAT THIS STUDY ADDS

⇒ The results revealed that even in a private practice hospital where the fee-for-service medical remuneration model prevails, prevention of low-value surgery is possible.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Adopting such programmes can save resources and reduce adverse events.

Hartman rectosigmoidectomy and a colostomy of the terminal sigmoid colon were performed. The patient developed sepsis, requiring prolonged mechanical ventilation and drainage of collections by interventional radiology on two occasions, drainage of pleural effusions and exploratory laparotomy to clean the cavity. The patient's hospital stay exceeded one month.

Most shamefully, the patient had no formal indication for surgical treatment of endometriosis.^{1 2} Effectiveness, that is, the provision of services only to those who could benefit, which was not respected in this case, is one of the attributes of a quality healthcare system according to the Institute of Medicine definition.³ This case represents an instance of low-value care, which can be defined as the use of healthcare services when the risks and costs outweigh the benefits.⁴ In a sample of 4 million Medicare fee-for-service beneficiaries, 45.6 out of 100 received medical services that provided minimal clinical benefit.⁵ Low-value care is a common practice, even in systems that do not use fee-for-service remuneration.⁴



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BACKGROUND

Substantial variation occurs in the use of low-value care among medical service providers, but a tendency to maintain this organisational profile over time persists, suggesting that organisations can shape the practice patterns of their affiliated physicians.⁴ Thus, to increase the safety of care, avoid unnecessary use of resources and contribute to the sustainability of the health system, in July 2020, Hospital Israelita Albert Einstein started the Adequacy of Care Management Program. In this study, we discuss the implementation, main results and potential impacts of this programme on patients and the healthcare system. Since a large number of cholecystectomies and endometriosis surgeries are performed in our hospital, and many of these procedures are empirically perceived to be unnecessary, these surgeries were chosen for management in this programme.

Between 10% and 15% of patients develop cholelithiasis.⁶ Approximately 80% of these patients are asymptomatic and remain asymptomatic throughout their lives.⁷ Although complications are frequent in symptomatic patients, they are very rare in patients without symptoms.⁶ Complications associated with gallstone disease only occur after an episode of biliary colic. Thus, cholecystectomy is only indicated for patients with symptomatic gallstones or sludge.⁸ Performing cholecystectomy only in symptomatic patients is one of the recommendations based on the consensus opinion of the medical literature on the Choose Wisely movement.⁹

The outcomes of endometriosis surgery are highly variable, and disease recurrence is frequent. While 20–30% of patients present with symptomatic improvement after diagnostic laparoscopy, manifestations persist in 20–40% of those who undergo surgical treatment of the disease.^{10 11} This strongly suggests that drug treatment should be attempted before surgery. For this reason, the Practice Committee of the American Society for Reproductive Medicine asserts that ‘*endometriosis should be viewed as a chronic disease that requires a lifelong management plan with the goal of maximising the use of medical treatment and avoiding repeated surgical procedures*’.² The same guidance is recommended by other consensus.¹²

We were unable to find scientific studies that analysed the magnitude of low-value cholecystectomies, endometriosis surgeries or interventions to reduce their frequencies.

The primary objective of this programme was to reduce the overindication of cholecystectomies and surgeries for endometriosis when unvalidated by a board of experts. The secondary objectives were to assess whether a programme of this nature is effective in saving the health system’s financial resources, reducing the number of complications and improving the quality of the medical information recorded in patients’ electronic medical records. We also analysed the patient-reported outcome measures (PROMs) to quantify the impact of these surgeries on patients’ quality of life.

METHODS

Design

The study design was a preintervention and postintervention time series performed at a private Brazilian hospital with a capacity of >700 beds, which predominantly used the fee-for-service payment model. This intervention, the Adequacy of Care Management Program, aimed to limit the performance of procedures without formal indications (low-value surgeries).

Population

The study population included all patients who underwent elective cholecystectomy procedures and surgical treatment of endometriosis between 1 August 2020 and 17 January 2021, the period prior to the implementation of the Adequacy of Care Management Program, and from 18 January to 31 May 2021 after the start of the programme.

These patients were referred to the institution by the surgeons themselves, who were registered physicians with previously defined privileges to perform these types of procedures. Urgent surgeries or surgeries associated with other procedures (eg, endometriosis surgery and hysterectomies) were excluded from the analysis.

Adequacy of Care Management Program

The Hospital Israelita Albert Einstein has a sector titled the Department of Medical Practices, which is responsible for managing and regulating medical practices, the curatorship of care pathways and protocols and the performance evaluation of physicians. This division was tasked with creating a workflow to survey and limit low-value surgeries for the treatment of endometriosis and cholecystectomies, titled the ‘Adequacy of Care Management Program’. The programme aims to ensure that healthcare is safe (ie, patients are not harmed by care designed to help them), effective (ie, services are provided to those who would benefit rather than to those who would not), timely and efficient (ie, waste of equipment and supplies is avoided).

The implementation of this programme was based on three steps: (1) creation of a board of experts; (2) provision of gynaecologists and general surgeons with information about the beginning of the audit related to the correct indication of endometriosis and cholecystectomy surgeries, respectively; and (3) limitation of the performance of procedures that do not meet previously defined criteria or for which indication was not validated by a board of experts.

The practice of each physician in our hospital is evaluated on approximately 70 quality indicators, such as surgical complications and readmission rates, in a programme called Medical Segmentation. The best ranked physicians in this programme and those recognised by the Department of Medical Practices for providing effective care (only performing procedures for those who could benefit from them) were invited to form a board of experts. The board was initially asked to

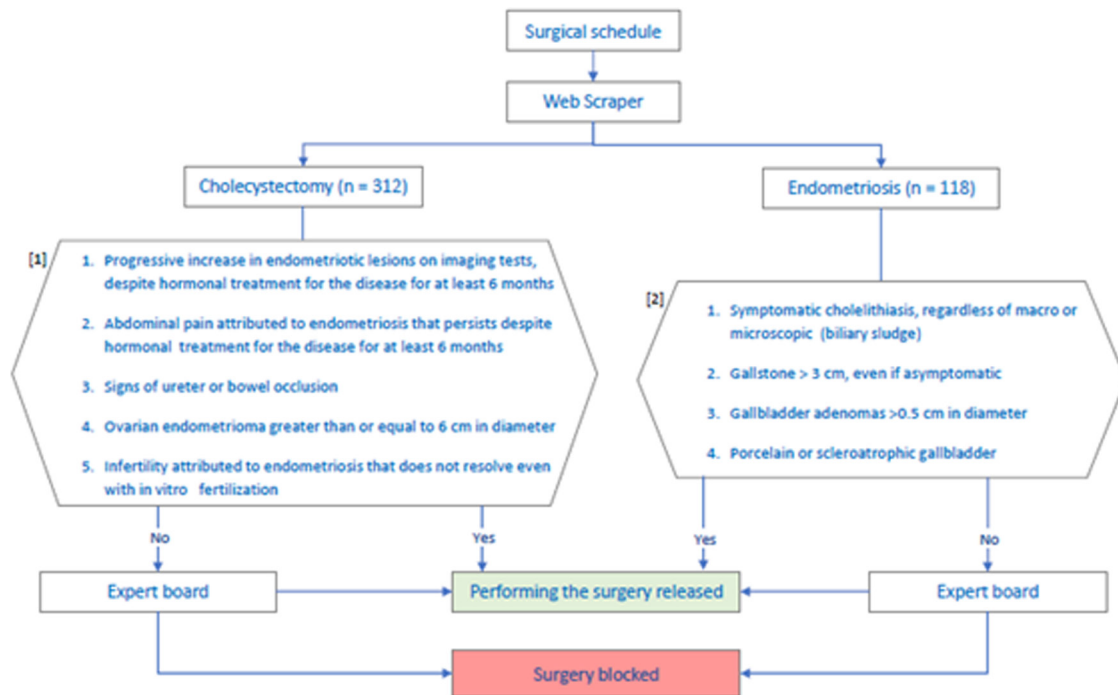


Figure 1 Surgery release flow. ¹Soper.²⁷ ²Abrão *et al*¹; Practice Committee of the American Society for Reproductive Medicine.²

write care pathways that defined clear criteria for surgical indications based on the best evidence in the literature (figure 1). These guidelines were disseminated, made accessible and made known to all hospital physicians. The board experts were also called on to resolve doubts related to the indications for the scheduled procedures.

Intervention

For the elective scheduling of the studied surgeries, a detailed description of the clinical picture and a copy of the imaging examination were uploaded to the electronic system. As our institution performs an average of 10 000 surgeries or invasive procedures per month, a web scraper was created to automate the identification of the surgeries of interest. When information was incomplete, a team from the Department of Medical Practices contacted the appropriate surgeon to complete the data. If the criteria for surgery were not met, the patient was referred to an expert council after concealing the identities of the physician and patient. Procedures without formal indications were excluded. Despite these efforts, low-value surgeries may occur due to a lack of time for analysis by the Department of Medical Practices and the board of experts, if the symptoms or clinical treatments described in the medical report, which justified the authorisation to perform the procedure, were not confirmed by the patient in the post-operative period or if the patient did not answer the questionnaire after surgery (see below).

Study of the intervention

Preintervention and postintervention data were collected prospectively by two dedicated research nurses from the Department of Medical Practices. Information regarding

the clinical condition, indication criteria for surgery, surgical complications and completeness of medical information was extracted from the electronic surgical scheduling system and electronic medical records of the patient Cerner Millennium. Confirmation of the clinical condition described by the physician in the report that was sent to the system and PROMs were collected through telephone calls and/or questionnaires sent to patients during the postoperative period. The financial costs of the surgeries and complications were provided by the institution's Office of Value-Based Health Care.

Measures

The rate of surgeries performed without indication validity by the board of specialists, rate of medical reports with clinical pictures, number of copies of the imaging examination uploaded to the electronic system, length of hospital stay, rate of surgical complications and costs were measured. All measurements were performed during the pre-implementation and post implementation periods of the Adequacy of Care Management Program.

All data were prospectively collected and recorded on a preformatted spreadsheet to ensure completeness and accuracy.

Statistical analysis

The comparison between the groups of patients before and after the Adequacy of Care Management Program was implemented using the χ^2 test for categorical variables, Student's t-test for continuous variables with normal behaviour (with analysis of means and SDs) and the non-parametric Wilcoxon test for non-normal variables (comparing medians and IQRs). To infer the normal

behaviour of the variables, the Shapiro-Wilk test was applied, considering a value of $p < 0.05$ to conclude the non-normality of the analysed variable. The software used for statistical analysis was R V.3.6.0. Statistical significance was considered at 5%.

RESULTS

Patients

During the study period (1 August 2020 to 31 May 2021), 430 consecutive patients were analysed, of which 264 were analysed prior to the implementation of the Adequacy of Care Management Program and 166 after its implementation.

The baseline characteristics of the patients who underwent cholecystectomy and endometriosis surgeries are presented in [table 1](#).

Sex, age and diagnoses that motivated the performance of cholecystectomies were similar between the groups. However, in the preintervention period, the number of cholangiographies performed was statistically higher than that in the postintervention period. Regarding endometriosis, the only difference between the preintervention and postintervention populations was in the International Classification of Diseases, which became more specific with more precise indication of the disease site ([table 1](#)).

Primary and secondary outcomes

The primary and secondary outcomes are presented in [table 2](#). Prior to implementation of the Care Adequacy Management Program, a considerable number of low-cost procedures were performed (13% cholecystectomies and 24.3% endometriosis surgeries). After implementation of the programme, no cholecystectomies and only 2.1% of endometriosis surgeries were performed without formal indications validated by expert advice. Thus, the programme was associated with a reduction in the unnecessary performance of 13% of cholecystectomies ($p=0.0001$) and 22.2% of surgeries for the treatment of endometriosis ($p=0.0006$).

Over the past 5 years, the annual costs of elective cholecystectomies and surgeries for endometriosis in our hospital were US\$1 577 380.57 (1170 surgeries per year) and US\$1 175 835.43 (380 surgeries per year), respectively. These surgeries were associated with 1.9% and 3.4% of complications requiring readmission within 30 days, which resulted in annual costs of US\$80 815.66 and US\$34 934.14, respectively. The programme also facilitates avoiding approximately three complications, with readmissions per year for each procedure. Thus, financial savings provided by low-value surgeries can lead to an annual cost reduction for the health system, estimated at US\$466 094.93. This value corresponds to the cost savings resulting from avoiding low-cost surgeries (13% fewer cholecystectomies and 22.2% fewer endometriosis surgeries).

The annual cost for Hospital Israelita Albert Einstein to maintain this programme was approximately US\$3703.00. The monthly time consumed by nurses and physicians to carry out the activities was 9 and 1.7 hours, respectively.

The programme required surgeons to send medical reports with descriptions of the clinical cases and copies of imaging examination results to the electronic scheduling system in 100% of cases, activities which previously occurred in 88% of cholecystectomies ($p=0.0002$) and 92% of surgeries for the treatment of endometriosis ($p=0.0042$). In the early days of the programme, several contacts with surgeons were required to request reports with more detailed descriptions.

A questionnaire evaluating symptoms related to the diseases studied and PROMs was administered to 278 patients. After cholecystectomy and surgical treatment of endometriosis, 15.7% and 11.9% of patients, respectively, developed long-lasting adverse symptoms ([table 3](#)). Regarding quality of life after surgery, 42.2% and 11.9% reported that quality of life remained unchanged, and 6.8% and 7.6% reported that it worsened, respectively.

DISCUSSION

In this study, we found that a managed programme with clearly defined criteria can prevent the occurrence of low-value surgery. Pre-implementation and post implementation analyses of the programme showed that it is possible to reduce unnecessary cholecystectomies and endometriosis surgeries to virtually zero at the local level, resulting in reduced costs for the health system and increased patient safety. The primary strength of our programme is that it was performed in a real-world setting and is therefore likely to be generalisable at least to other Brazilian settings.

The explicit definition of the institutional criteria for performing these surgeries, approval by the expert council and postoperative confirmation of the clinical picture described by physicians requesting the procedures may be responsible for the changes observed in the physician practice patterns in our study.

In a recent review, Colla *et al*¹³ suggested that patient education or cost sharing, pay for performance, insurer restrictions, clinical decision support (clinical pathway and point-of-care decision support), physician education or feedback and the association of these interventions may be effective in reducing low-value care. However, almost all interventions aimed to reduce the overuse of antibiotics, acid-suppressive medications, blood transfusions and diagnostic tests. However, these interventions cannot be easily adapted to perioperative workflows.

In the systematic reviews cited above, only 10% of the studies evaluated strategies aimed at the deimplementation of surgical procedures. One such study was conducted by Wong *et al*,¹⁴ who mailed the results of an audit on the appropriateness of this procedure to all surgeons performing carotid endarterectomies in a Canadian city, along with clinical practice guidelines on the

Table 1 Characteristics of the analysed patients

Characteristics	Cholecystectomy			Endometriosis		
	Preimplantation (n=194)	Postimplantation (n=118)	P value	Preimplantation (n=70)	Postimplantation (n=48)	P value
Female sex, n (%)	121 (62)	68 (58)	0.4764	70 (100)	48 (100)	0.999
Age						
Age, mean (SD), year	45.0 (13.6)	43.8 (12.2)	0.4733	34.7 (6.6)	35.9 (6.5)	0.328
Distribution, n (%)						
<45 years	102 (53)	68 (58)	0.5473	66 (97.1)	46 (92.0)	0.399
45–59 years	65 (34)	38 (32)		2 (2.9)	4 (8.0)	
≥60 years	27 (14)	12 (10)		–	–	–
Diagnosis (ICD), n (%)						
K80.1, cholelithiasis	98 (51)	59 (50)	0.2868	36 (51.4)	16 (33.3)	0.012
K80.2, cholelithiasis without cholecystitis	11 (6)	2 (2)		5 (7.1)	7 (14.6)	
K80.4, cholelithiasis with cholecystitis	2 (1)	0 (0)		6 (8.6)	4 (8.3)	
K80.5, cholelithiasis without cholangitis or cholecystitis	1 (1)	1 (1)		4 (5.7)	5 (10.4)	
K80.8, other cholelithiasis	2 (1)	0 (0)		0 (0.0)	7 (14.6)	
K81.1, chronic cholecystitis	79 (41)	56 (48)		5 (7.1)	1 (2.1)	
K82.8, other gallbladder diseases	1 (1)	0 (0)		14 (20.0)	8 (16.7)	
Surgery performed, n (%)						
Laparoscopic cholecystectomy with operative cholangiogram	160 (82)	81 (69)	0.0176	23 (32.9)	9 (18.8)	0.137
Cholecystectomy without operative cholangiogram	0 (0)	1 (1)		13 (18.6)	7 (14.6)	
Laparoscopic cholecystectomy without operative cholangiogram	33 (17)	36 (31)		12 (17.1)	7 (14.6)	
Cholecystectomy with choledochostomy	1 (1)	0 (0)		22 (31.4)	25 (52.1)	
ICD, International Classification of Diseases.						

Table 2 Primary and secondary outcomes

Outcomes	Cholecystectomy			Endometriosis		
	Preimplantation (n=194)	Postimplantation (n=118)	P value	Preimplantation (n=70)	Postimplantation (n=48)	P value
Surgery with board-validated indication, n (%)	169 (87)	118 (100)	0.0001*	53 (75.7)	47 (97.9)	0.0006*
Hours of stay, μ (δ)	27.6 (13.6)	22.4 (10.4)	0.0005†	43.6 (24.2)	44.9 (24.0)	0.7661†
Readmission within 30 days, n (%)	4 (2)	1 (1)	0.6533*	3 (4.3)	3 (6.2)	0.6861*
Emergency room visit in 30 days, n (%)	19 (10)	13 (11)	0.8477*	7 (10)	9 (18.7)	0.1844*
Medical report sent to electronic scheduling system, n (%)	171 (88)	118 (100)	0.0001*	67 (95.7)	48 (100)	0.2699*
Image examination sent to electronic scheduling system, n (%)	178 (92)	118 (100)	0.0008*	67 (95.7)	48 (100)	0.2699*
Total cost (median, IQR)	US\$1306.77 (US\$306.29)	US\$1255.16 (US\$228.19)	0.07‡	US\$2620.19 (US\$1414.34)	US\$2353.86 (US\$1871.30)	0.3490‡

*Fisher's exact test.
†Student's t-test.
‡Mann-Whitney U test.

subject and a notification that prospective surveillance of the use of this procedure was to commence. Appropriate indications for surgery increased from 22% to 49%, and inappropriate surgeries decreased from 18% to 4%.

These findings suggest that active interventions and those with multiple components, such as ours, are more successful in producing deimplementation or deadoption of low-value care,¹⁵ although the subject still requires further research.¹⁶

We were unable to identify interventions with characteristics similar to those of our programme (institutional definition of surgical appropriateness criteria, third-party analysis of medical history and imaging studies to assess inclusion in these criteria, discussion and definition of the best conduct by a council of specialists in atypical cases and postoperative confirmation of the clinical picture).

In many cases, insurers' preauthorisation programmes lack the detailed clinical discrimination required to contraindicate low-value procedures. Therefore, <2% of

surgeries are refused by payers,¹⁷ which is much lower than that observed in the present study.

The interventions that most closely resemble our programme are mandatory second-opinion policies that have proven effective. An example of this type of intervention was a randomised multicentre study carried out in 36 hospitals in Latin America that followed 149 276 deliveries and induced a reduction in hospital caesarean section rates of 7.3% (95% CI 0.2%–14.5%).¹⁸ Since 2011, our hospital has been developing a second-opinion project to perform spine surgeries for one of the health plans served by the institution. This resulted in a recommendation for conservative treatment in 55.3% of the cases, and 11.1% of the patients were not considered to have a spinal disease.¹⁹

Mandatory second-opinion policies have the disadvantage of introducing a second doctor into patient care, which can compromise the physician–patient relationship with the first professional. In our intervention, the

Table 3 Patient-reported outcome measures (PROMs)

	Cholecystectomy	Endometriosis
How are your symptoms after surgery?		
Had no symptoms before surgery, n (%)	88 (53.3)	15 (12.8)
Improvement of pain, n (%)	51 (30.9)	88 (75.2)
Worsening of previous symptoms, n (%)	3 (1.8)	3 (2.5)
I developed new symptoms, n (%)	23 (13.9)	11 (9.4)
Total, n (%)	165 (100)	117 (100)
How is your quality of life after surgery?		
Improved, n (%)	82 (50.9)	94 (80.3)
Got worse, n (%)	11 (6.8)	9 (7.6)
Unchanged, n (%)	68 (42.2)	14 (11.9)
Total, n (%)	161 (100)	117 (100)

patient is only approached after the procedure has been performed, when confirmation of the clinical condition described by the physician and the collection of PROMs are carried out. Since January 2022, the Adequacy of Care Management Program has included all spinal surgeries performed at our institution.

Less invasive interventions for medical autonomy may also be effective. In a randomised controlled trial, local opinion leader education was an effective method of encouraging a trial of labour and vaginal birth for women with previous caesarean deliveries.²⁰ Since 2014, our hospital has carried out a programme called Adequate Childbirth, which with a multicomponent approach (creation and training of a multidisciplinary team, education of pregnant women, improvements in infrastructure and audits of delivery types) achieved an increase in the vaginal delivery rate of 27.5% and reduced neonatal intensive care unit admissions by 31.2%.²¹

The US healthcare system wastes \$760 billion to \$935 billion annually, representing 25% of total healthcare costs.²² In 2012, the American Board of Internal Medicine Foundation started a campaign called 'Choosing Wisely', which aimed to reduce low-value care services.²³ Although the USA undertook this and other national campaigns aimed at reducing low-value care, from 2014 to 2018, the cost of healthcare among individuals for fee-for-service Medicare remained virtually unchanged.²⁴

Local policies that limit inappropriate care, in addition to economic appeal, could improve the quality and safety of care because they minimise iatrogenic diseases caused by unnecessary interventions. From both patient and health system perspectives, programmes of this type can improve the quality and safety of care and have positive economic implications. Preventing the performance of procedures that may not be beneficial for patients can lead to cost savings for the healthcare system and reduce the occurrence of a significant number of complications.

By providing perverse incentives for the overuse of procedures, the fee-for-service model is an additional complicating factor for the success of a low-value care deimplementation programme.²⁵ In this payment system, surgeons earn higher profits for the performance of more surgeries. This is the case for surgeons who work at our hospital but are not hired by the institution. In fact, these physicians are the hospital's main clients, as they bring patients from their offices to undergo surgery at the institution. In this model, the financial sustainability of institutions largely depends on the clinical and surgical admissions generated by the open clinical staff. In a relationship of this type, harmony between the medical staff and the organisation greatly depends on the financial relationship between the parties. The adoption of measures that limit the performance of surgical procedures recommended by physicians from the clinical staff and consequently reduce their financial gains is a difficult task that may repel surgeons. While this reduction in physicians' autonomy to recommend surgery is a reason for discontent, doctors and patients are attracted to hospitals with

good reputations, which is generally built through the adoption of strict safety protocols. This is the case with Hospital Israelita Albert Einstein, which occupied the 34th position among the best hospitals in the world in the 2023 ranking in *Newsweek*. A programme such as this does not seem to be viable in many institutions, as it may induce physicians to operate on their patients in other hospitals where their practice does not suffer any kind of interference.

In a value-based payment model, providers receive adjusted reimbursements based on quality and cost efficiency. In this context, PROMs can be a very useful metric.²⁶ Among the patients who responded to the survey, almost half of those who underwent cholecystectomy and one-fifth of those who underwent surgery for endometriosis did not seem to have improved quality of life.

Moreover, this programme was only possible because of the institutional regulations of our organisation, whose articles are validated by a simple majority of votes in an assembly held with medical staff and establishes that the physicians' practices must be based on the best available evidence and the institution reserves the right not to carry out procedures that could jeopardise patient safety.

Since programme implementation, these interventions in endometriosis surgery and cholecystectomy have continued. Currently (May 2023), in addition to the aforementioned spinal surgeries, the programme also manages operations for nephrolithiasis and venous stent implantation in Cockett syndrome, and it is being structured to include tonsillectomy and spinal infiltration.

Our study had several limitations. For ethical reasons, the team responsible for the programme did not approach the patients before performing the surgeries to confirm the details of the surgeon's clinical history. However, all patients with endometriosis and most patients who underwent cholecystectomy answered a questionnaire containing relevant data from the clinical history and PROMs via telephone call or electronically during the postoperative period. In only one case of endometriosis, the information differed from the medical report required to schedule the surgery. As those in our hospital, many scheduled surgeries are suspended because of issues related to the patients (ie, withdrawal) or healthcare providers (ie, non-authorisation). Whether the reduction in low-value surgeries was motivated by the approach taken by the team responsible for the programme remains uncertain. We cannot state that the surgeries cancelled after the programme's intervention did not occur in another hospital.

CONCLUSION

Even in a private practice hospital where the fee-for-service medical remuneration model prevails, prevention of low-value care is possible. The definition of clear criteria for indicating surgery based on scientific evidence and the analysis of cases that did not meet these criteria

by a board of reputable experts at the institution proved to be effective in reducing the number of cholecystectomies and endometriosis surgeries from which the patients could not possibly benefit to practically zero.

Contributors MDCdO had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Concept and design: MDCdO, HdSF, MCN, SK. Acquisition, analysis or interpretation of data: MDCdO, ALV, FAdPR. Drafting of the manuscript: MDCdO, FGdM. Critical revision of the manuscript for important intellectual content: HdSF, ALV, FAdPR, DTM, GC, OB, VT, AM, MCN, SK. Statistical analysis: DTM. Administrative, technical or material support: MDCdO, HdSF. Supervision: MDCdO, HdSF. Guarantor, MDCdO.

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Patient consent for publication Not applicable.

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Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information.

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