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Development and external validation of the 'Global Surgical-Site Infection' (GloSSI) predictive model in adult patients undergoing gastrointestinal surgery

NIHR Global Research Health Unit on Global Surgery and GlobalSurg Collaborative

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Abstract

Background: Identification of patients at high risk of surgical-site infections may allow surgeons to minimize associated morbidity. However, there are significant concerns regarding the methodological quality and transportability of models previously developed. The aim of this study was to develop a novel score to predict 30-day surgical-site infection risk after gastrointestinal surgery across a global context and externally validate against existing models.

Methods: This was a secondary analysis of two prospective international cohort studies: GlobalSurg-1 (July–November 2014) and GlobalSurg-2 (January–July 2016). Consecutive adults undergoing gastrointestinal surgery were eligible. Model development was performed using GlobalSurg-2 data, with novel and previous scores externally validated using GlobalSurg-1 data. The primary outcome was 30-day surgical-site infections, with two predictive techniques explored: penalized regression (least absolute shrinkage and selection operator ('LASSO')) and machine learning (extreme gradient boosting ('XGBoost')). Final model selection was based on prognostic accuracy and clinical utility.

Results: There were 14 019 patients (surgical-site infections = 12.3%) for derivation and 8464 patients (surgical-site infections = 11.4%) for external validation. The LASSO model was selected due to similar discrimination to extreme gradient boosting (AUC 0.738 (95% c.i. 0.725 to 0.750) versus 0.737 (95% c.i. 0.709 to 0.765)), but greater explainability. The final score included six variables: country income, ASA grade, diabetes, and operative contamination, approach, and duration. Model performance remained good on external validation (AUC 0.730 (95% c.i. 0.715 to 0.744); calibration intercept -0.098 and slope 1.008) and demonstrated superior performance to the external validation of all previous models.

Conclusion: The 'Global Surgical-Site Infection' score allows accurate prediction of the risk of surgical-site infections with six simple variables that are routinely available at the time of surgery across global settings. This can inform the use of intraoperative and postoperative interventions to modify the risk of surgical-site infections and minimize associated harm.

Lay summary

This study is about finding ways to predict if someone will get an infection after having surgery on their stomach and intestines. If doctors know who is at high risk of getting an infection, they can take steps to prevent it and help the patient recover faster. The researchers used information from patients who had surgery all over the world to try to make a way to score how likely someone is to get infection in their wound from surgery. They did this in two different ways, then picked the one that was best at picking up infections, while still being easy to use. They then compared the new score against older scores to check if it really was better or not. The researchers found that their new score was good at predicting who might get an infection using just six bits of information on the patient. This new score worked even better than older scores when these were compared all together. This means that doctors can use this new score to check who is most likely to get an infection after surgery and so can take extra steps during and after the surgery to try and stop these from happening. Because the score is so simple, this is easy to use all around the world.

Introduction

Surgical-site infections (SSI) are among the most common postoperative complications in patients undergoing gastrointestinal surgery, with the associated postoperative morbidity and mortality posing a significant burden to both patients and health systems^{1,2}. There has been a marked reduction in the incidence of SSI as a result of the introduction of

numerous perioperative interventions that can reduce the risk and associated harm of SSI^{3–5}. Nonetheless, these infections continue to affect 10% of patients in high-income countries and one-third of patients in low- and middle-income countries (LMIC)⁶. To provide an evidence-based approach to allocation of these perioperative interventions, there needs to be better understanding of the patients at greatest risk. Furthermore, the earlier this can be

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determined in the perioperative care pathway, the more effectively interventions for treatment and surveillance can be provided.

Efforts to develop predictive tools for SSI have been ongoing for decades⁷; however, many do not align with current methodological recommendations⁸ and the few that have been externally validated outside the original cohorts typically display only moderate discrimination⁷. None has been widely adopted in clinical practice³⁻⁵, reflecting that the feasibility and clinical utility of these models continues to remain uncertain outside of their original contexts. This is particularly important for LMIC, which experience the greatest burden of SSI and stand to benefit most from direction of limited resources towards patients at most risk of SSI⁶. Therefore, the aim of this study was to develop and validate a prognostic score based on data available at the time of operation to predict 30-day SSI risk after gastrointestinal surgery across a global context. Subsequently, the aim was to perform external validation across global data in comparison with existing prognostic models.

Methods

This study reports the derivation and validation of the 'Global Surgical-Site Infection' (GloSSI) risk prediction model to stratify patients by their 30-day SSI risk after major gastrointestinal surgery. This study is reported according to the 'Transparent reporting of a multivariable prediction model for individual prognosis or diagnosis' (TRIPOD) statement⁹.

Data sources

This was a secondary analysis of two independent prospective multicentre international studies conducted by the GlobalSurg Collaborative (www.globalsurg.org). Eligible patients were identified by local collaborators at each participating hospital during 2-week data collection intervals within the respective data collection windows: July–November 2014 ('GlobalSurg-1'¹⁰) and January–July 2016 ('GlobalSurg-2'¹¹). These studies collected routine anonymized data with no change to clinical care pathways. Both were registered according to the appropriate local or national approval pathways in each participating country (audit approval, ethical or institutional review board). This secondary analysis was not pre-registered in an independent institutional registry.

Consecutive patients undergoing a broad range of gastrointestinal surgical procedures were eligible. However, each study focused on different cohorts of patients: GlobalSurg-1 focused on those undergoing emergency gastrointestinal surgery for any indication¹⁰; and GlobalSurg-2 focused on those undergoing emergency and elective gastrointestinal surgery¹¹. A full description of methods and primary findings of each of these studies has been previously described^{6,12}. Any centres on a global basis that routinely performed these surgeries were eligible to participate in the respective studies. For the purposes of this analysis, only adult patients (greater than or equal to 18 years old, with no upper age limit) undergoing gastrointestinal surgery were included across both studies. This included relevant procedures with no entry of the gastrointestinal tract (for example diagnostic laparotomy/laparoscopy, adhesiolysis, and hernia repair).

Data collection

Data in both studies were collected using a collaborative research methodology¹³, engaging clinicians, medical students, and allied healthcare professionals at sites around the world to collect data according to pre-published study protocols^{10,11}. Anonymized data

were submitted and stored on secure research electronic data capture (REDCap) servers¹⁴. Data collection teams were unaware of the predictors that would be included in the development or external validation of scores and therefore no blinding to outcomes or other predictors was deemed necessary.

Data were collected related to baseline demographics, perioperative care, and 30-day outcomes for each patient using a pre-specified case report form^{10,11}. Both data sets were standardized based on variables that shared a common definition and a complementary data structure. Data dictionaries from both studies were extracted directly from the REDCap platform and cross-referenced to identify these variables. These pairings were cross-tabulated before and after combination to ensure consistent order and encoding within the combined data set. These data were further supplemented using country-level World Bank income data for the year of data collection¹⁵ and BUPA Schedule of Procedures classifications of operative complexity¹⁶.

Outcome definition

The primary outcome in this analysis was 30-day SSI. In all GlobalSurg studies, this was defined according to the Centers for Disease Control and Prevention (CDC) definition¹⁷ (including all superficial, deep, and organ-space infections). All SSI events were recorded at 30 days after surgery either through in-person or health record review. However, in locations where it was not possible to conduct 30-day follow-up due to resource limitations, SSI was measured at the point of discharge, with a pragmatic assumption that SSI would not occur post-discharge. This CDC definition of SSI was used for all external validation models, irrespective of the exact definition used in the original derivation models.

Model derivation

The GlobalSurg-2 data set was selected as the derivation cohort due to having the broadest inclusion criteria and the primary outcome being 30-day SSI¹¹. The minimum sample size required for developing a multivariable prediction model was explored across a range of plausible scenarios based on the number of parameters, event rates, and expected model discrimination¹⁸ (Fig. S1). Based on the event rate previously reported for the GlobalSurg-2 data set⁶, the sample size was anticipated to be adequate for a model with an area under the curve (AUC) greater than or equal to 0.65. Candidate variables were considered from those previously included in prognostic models identified in a systematic review⁷. Additional variables were considered based on potential relevance and appropriateness to resource-limited environments. Candidate variables were discarded if: there was no clear clinical rationale for an influence on the outcome; they were not generalizable to all patients undergoing gastrointestinal surgery; or they would not be expected to be accessible across income settings. A priori, it was decided that any missing data would be handled using multiple imputation with chained equations, under the 'missing-at-random' assumption¹⁹. A total of ten data sets were imputed using available explanatory variables and the outcome variable, with patients clustered by country. Modelling was performed on imputed data sets, with Rubin's rules used to combine results²⁰.

A four-stage model building process was used, in line with best practice²¹ (Fig. 1). First, a criterion-based approach with a generalized additive model was used for initial variable selection²². Each variable was omitted from the complete model in turn ('leave-one-out' approach), with the decision to retain a variable based on the change in either the deviance explained (greater than

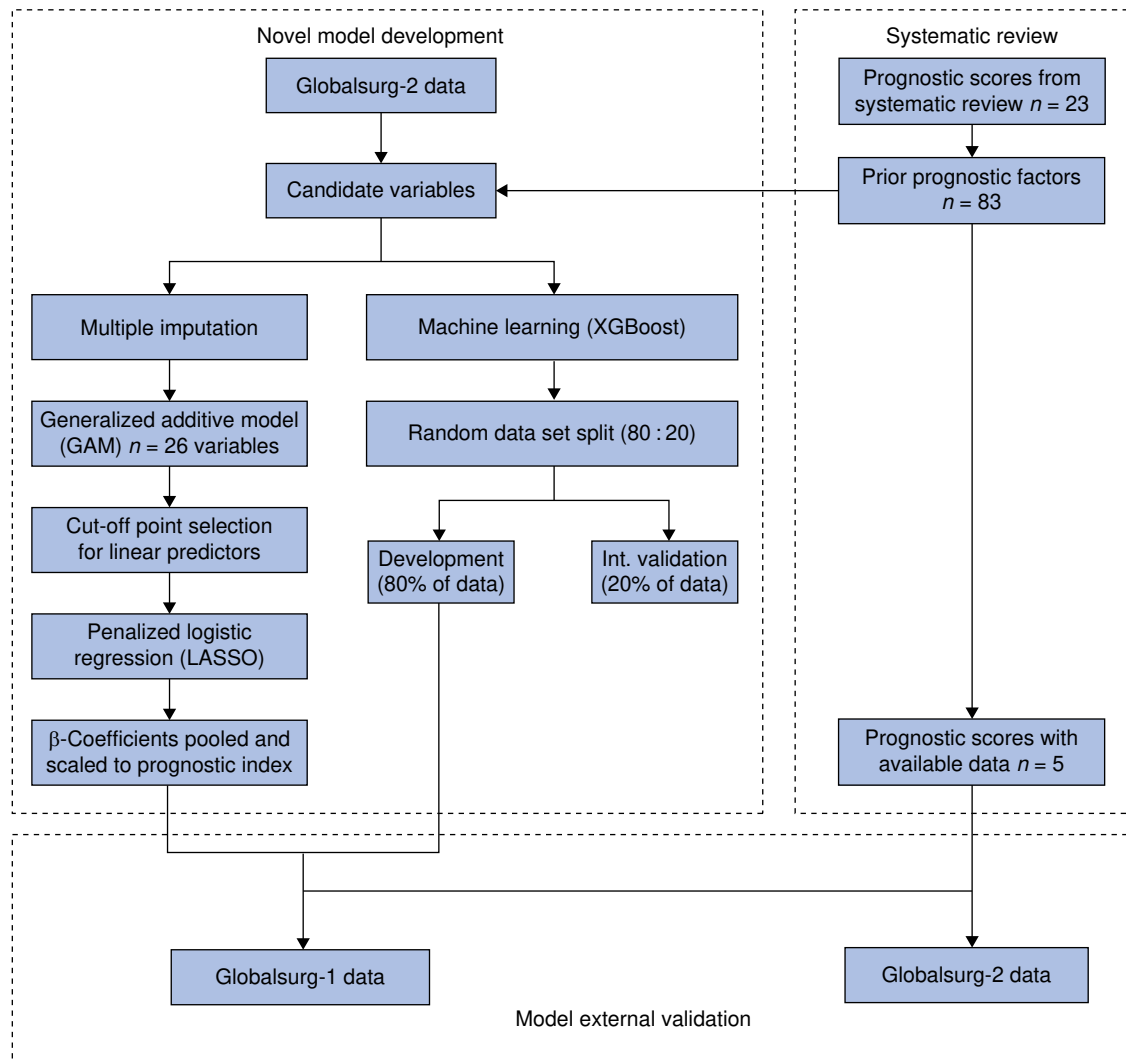


Fig. 1 Flow chart of modelling process

XGBoost, extreme gradient boosting; Int., Internal; LASSO, least absolute shrinkage and selection operator.

1%) or unbiased risk estimator (greater than 10%) compared with the complete model. Second, any continuous variables were categorized to facilitate clinical utility based on the observed relationship with SSI in the generalized additive model using an approach previously shown to maintain discriminative performance²². Third, a least absolute shrinkage and selection operator (LASSO) logistic regression model was used to establish the simplest model with the highest predictive potential. The final variables included were selected based on being retained in the majority (greater than five) of imputed data sets. Fourth, these selected variables were entered into a mixed-effects logistic regression model, with patients clustered by country. The fixed-effects coefficients across the models were pooled using Rubin's rules²³ and scaled to create the GloSSI prognostic index. As disparities in outcomes at country income level are due to systematic country differences, rather than being relevant at an individual level, these differences were instead accounted for by model intercepts specific for income level.

To provide a comparison of the predictive potential of the available data by accounting for any complex underlying interactions, an alternative machine-learning approach was explored (extreme gradient boosting (XGBoost))²¹. This included all candidate predictor variables from the development data set that

were present within the external validation data set. The development data set was randomly split into training and testing sets in an 80:20 ratio, with models fitted through ten-fold cross-validation, minimizing the binary classification error rate (the proportion of errors in classification of patients with SSI). Hyperparameters were also tuned via grid search to maximize the AUC in the test set.

External validation

External validation of the final GloSSI model was performed using the GlobalSurg-1 data set¹². Furthermore, all previous prognostic models identified in a systematic review were externally validated when the corresponding clinical parameters were available in the GlobalSurg data sets⁷. Where appropriate, clinical parameters that were aligned, but not exactly equivalent, in the GlobalSurg data sets were rationalized on a pragmatic basis. Operative duration is a key variable used in previous prognostic models and was collected in GlobalSurg-2, but not GlobalSurg-1. Therefore, a separate multivariable linear regression model was developed using GlobalSurg-2 data and used to estimate operative duration in the validation data set based on all patient and operative characteristics common across both data sets (Table S1). Missing

data were handled in the validation data set as per the derivation cohort, except the outcome variable was excluded as a predictor.

Statistical analysis

Model performance was compared using the AUC and prognostic accuracy summary statistics calculated for a range of cut-off values (sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV)). An AUC with a lower confidence interval of 0.5–0.59 was considered to indicate ‘poor’ model discrimination, 0.6–0.69 was considered to indicate ‘moderate’ model discrimination, 0.7–0.79 was considered to indicate ‘good’ model discrimination, and greater than or equal to 0.8 was considered to indicate ‘excellent’ model discrimination²⁴. Calibration was assessed through visual inspection and the calibration intercept (calibration-in-the-large) and slope²⁵ (an intercept of 0 and slope of 1 indicates ‘perfect’ calibration). No recalibration was planned or performed to allow determination of whether these models were ‘transportable’ in their original iteration²⁶ (for example continue to produce accurate predictions in a related, but different, population). Finally, a decision curve analysis was performed, which can allow determination of the clinical utility of a prognostic model through comparison of the relative value of benefits (treating a true positive) and harms (treating a false positive)²⁷. All statistical analyses were performed in R Studio version 4.1.1 (R Foundation for Statistical Computing, Vienna, Austria), with packages including tidyverse, finalfit, and predictr²⁸.

Results

Cohort characteristics

Data for 22 483 patients were eligible to be included in modelling (Fig. 1): 14 019 patients (62.4%) in the derivation cohort (GlobalSurg-2) and 8464 patients (37.6%) in the validation cohort (GlobalSurg-1).

Within the development cohort, the overall SSI rate was 12.3% (1730 patients), including 488 patients (3.5%) with organ-space infections (Table 1). The median age of patients in the cohort was 47.0 (interquartile range 32.0–63.0) years; 7051 patients (50.3%) were female and 8089 patients (57.7%) had at least one co-morbidity (ASA grade II–V). Half of the development cohort (6877 patients; 49.1%) were from LMIC. However, there were substantial differences in sociodemographic and clinical characteristics between the surgical populations in the derivation cohort and the validation cohort (Table 1). GlobalSurg-1 only included patients requiring emergency procedures, who were substantially more co-morbid and undergoing procedures that were technically less complex, yet often more contaminated and performed using an open approach. The overall SSI rate observed was broadly consistent between the cohorts (12.3% (1730 of 14 019) in the derivation cohort versus 11.4% (965 of 8464) in the validation cohort).

Development of a novel model

A total of 23 candidate predictor variables were identified within the development data set that were assessed before surgery or intraoperatively (Table S2). A further four variables were derived from existing variables (operative duration and specialty) or linked from external data sets (World Bank income level and operative complexity (BUPA Schedule of Procedures)). Data on these candidate variables were complete for 9762 patients (69.6%) and

the pattern of missing data was consistent with a ‘missing-at-random’ assumption (Fig. S2a). Due to small numbers within the development data set, co-morbidities describing the characteristic of immunosuppression (human immunodeficiency virus or malarial infection, corticosteroid or other immunosuppressant use, and recent chemotherapy) were collapsed into a single binary variable.

Generalized additive models were applied to the imputed data sets then pooled, with eight meeting the a priori threshold to be considered as important predictors of SSI (Table S3). Component smoothed functions generated were used to select informative cut-off values to categorize continuous variables (age and operative duration) (Fig. S3). On entering these variables into a penalized logistic regression model (LASSO), all variables were retained within the final model. Penalized regression coefficients of the final model (Table 2) were scaled into a prognostic index (GloSSI score: range 0–74).

The pooled LASSO model demonstrated good discrimination (AUC 0.738 (95% c.i. 0.725 to 0.750)) and calibration (intercept 0.044 and slope 0.995) for 30-day SSI within the derivation cohort (Table 3 and Fig. 2). This was similar to the XGBoost model within the internal validation (test) data set, which also showed good discrimination (AUC 0.737 (95% c.i. 0.709 to 0.765)) and high calibration (intercept –0.046 and slope 0.995) across the range of risk (Fig. 2). However, both models underestimated the probability in those at highest risk of SSI (Table 3 and Fig. 2b). Using the GloSSI prognostic index (Table 2 and Table S4), the prognostic accuracy was investigated across a range of values to provide flexibility in adapting to different clinical use cases (Table 4). With a ‘rule in’ approach, to exclude ‘low-risk’ patients (GloSSI score less than or equal to 5), a NPV of 95.9% (sensitivity 89.9% and specificity 33.5%) can be achieved. In contrast, with a ‘rule out’ approach, to select only ‘high-risk’ patients (GloSSI score greater than 50), an PPV of 36.2% (sensitivity 12.9% and specificity 96.8%) can be achieved.

External validation of the novel model and comparison with previous predictive models

There were 23 previous models identified in a systematic review⁷. All common model parameters (identified in greater than or equal to three models) were present in one or more GlobalSurg data set (Fig. S4), apart from BMI (n=10/23). Overall, five prior models were able to be externally validated using one or both of the GlobalSurg data sets. Of the 18 models that could not be validated due to a lack of prerequisite clinical parameters being present, this was predominantly due to an absence of preoperative blood test results or other infrequently identified predictors not being present (Fig. S4). Only four additional models could have been externally validated if BMI had been present in these data sets^{29–32}.

There were substantial differences between the surgical populations in the GlobalSurg cohorts and cohorts used to derive the previous scores undergoing external validation, with comparisons limited by the data reported (Tables S5, S6). Most notably, 40% (two of five) of previous scores were developed using data from patients undergoing non-abdominal procedures, with up to 70% of procedures reported to be classified as clean surgery. Furthermore, all previous scores were developed in cohorts from upper-middle- or high-income countries only.

On external validation using the GlobalSurg data sets, all models demonstrated a consistent performance across both data sets (Table 3 and Fig. S5a). The GloSSI score and XGBoost comparator demonstrated consistently superior discrimination across the validation data set compared with previous models (Table 3,

Table 1 Characteristics of the development and external validation cohorts

Characteristic	Derivation cohort (GlobalSurg-2)	Validation cohort (GlobalSurg-1)	P
Age (years), mean(s.d.)	47.9(18.6)	46.1(20.3)	<0.001
Sex			
Male	6184 (44.1)	4461 (52.7)	<0.001
Female	7051 (50.3)	4000 (47.3)	
Missing	784 (5.6)	3 (0.0)	
History of smoking			
Non-smoker	8538 (60.9)	4883 (57.7)	<0.001
Ex-smoker	1643 (11.7)	978 (11.6)	
Current smoker	2248 (16.0)	1616 (19.1)	
Missing	1590 (11.3)	987 (11.7)	
History of diabetes			
No	12 653 (90.3)	7495 (88.6)	<0.001
Diet controlled	120 (0.9)	166 (2.0)	
Medication (non-insulin) controlled	801 (5.7)	371 (4.4)	
Insulin controlled	376 (2.7)	210 (2.5)	
Missing	69 (0.5)	222 (2.6)	
ASA grade			
I	5544 (39.5)	3438 (40.6)	<0.001
II	5486 (39.1)	2692 (31.8)	
III	2162 (15.4)	1418 (16.8)	
V	94 (0.7)	178 (2.1)	
Missing	386 (2.8)	264 (3.1)	
History of immunosuppressive medication			
No	13 739 (98.0)	–	–
Yes	195 (1.4)	–	
Missing	85 (0.6)	–	
History of HIV			
No	12 701 (90.6)	–	–
Yes	83 (0.6)	–	
Missing	1235 (8.8)	–	
History of corticosteroid use			
No	13 571 (96.8)	–	–
Yes	333 (2.4)	–	
Missing	115 (0.8)	–	
History of chemotherapy (<6 weeks)			
No	13 646 (97.3)	–	–
Yes	293 (2.1)	–	
Missing	80 (0.6)	–	
Preoperative antibiotic treatment			
No	10 383 (74.1)	–	–
Yes	3385 (24.1)	–	
Missing	251 (1.8)	–	
Operative pathology			
Benign	11 233 (80.1)	7460 (88.1)	<0.001
Trauma	259 (1.8)	488 (5.8)	
Malignant	2523 (18.0)	516 (6.1)	
Missing	4 (0.0)	0 (0.0)	
Operative contamination			
Clean-contaminated	11 032 (78.7)	6907 (81.6)	<0.001
Contaminated-dirty	2835 (20.2)	1557 (18.4)	
Missing	152 (1.1)	0 (0.0)	
Intraoperative perforation			
No	13 617 (97.1)	6879 (81.3)	<0.001
Yes	402 (2.9)	1557 (18.4)	
Operative urgency			
Elective	7653 (54.6)	0 (0.0)	<0.001
Emergency	6366 (45.4)	8464 (100.0)	
Operative duration (min), mean(s.d.)	117.4(88.1)	–	–
Operative speciality			
UGI	2182 (15.6)	1150 (13.6)	<0.001
HPB	5074 (36.2)	1211 (14.3)	
Colorectal	5663 (40.4)	4291 (50.7)	
Other*	1100 (7.8)	1812 (21.4)	
Intraoperative stoma formation			
No	13 647 (97.3)	7592 (89.7)	<0.001
Ileostomy	135 (1.0)	359 (4.2)	
Colostomy	237 (1.7)	441 (5.2)	
Other	0 (0.0)	65 (0.8)	

(continued)

Table 1 (continued)

Characteristic	Derivation cohort (GlobalSurg-2)	Validation cohort (GlobalSurg-1)	P
Operative complexity			
Intermediate	2528 (18.0)	2983 (35.2)	<0.001
Major	7468 (53.3)	3554 (42.0)	
Major+	2614 (18.6)	1159 (13.7)	
Complex major	1393 (9.9)	762 (9.0)	
Missing	16 (0.1)	6 (0.1)	
Operative approach			
Minimally invasive	6960 (49.6)	2791 (33.0)	<0.001
Open	7059 (50.4)	5668 (67.0)	
Country World Bank income			
Low/lower-middle	4072 (29.0)	1928 (22.8)	<0.001
Upper-middle	2805 (20.0)	1254 (14.8)	
High	7142 (50.9)	5282 (62.4)	
30-day SSI rate			
No	11 545 (82.4)	7452 (88.0)	0.001
Yes	1730 (12.3)	965 (11.4)	
Missing	744 (5.3)	47 (0.6)	

Values are n (%) unless otherwise indicated. *Procedures with no entry of the gastrointestinal tract. HIV, human immunodeficiency virus; UGI, Upper gastrointestinal; HPB, Hepato-Pancreato-Biliary; SSI, surgical-site infection.

Table 2 'Global Surgical-Site Infection' score for prediction of surgical-site infections in adults undergoing gastrointestinal surgery

Variable	Level	β -Coefficient	Points
Co-morbidities	ASA grade	I	0
		II	0.245
		III	0.517
		IV	0.633
		V	0.291
	History of diabetes	No	0
		Diet controlled	0.591
		Medication (non-insulin) controlled	0.334
		Insulin controlled	0.354
			7
Operative	Operative approach/contamination	Minimally invasive/clean-contaminated	0
		Open/clean-contaminated	1.014
		Minimally invasive/contaminated-dirty	0.422
		Open/contaminated-dirty	1.968
			39
	Operative duration (min)	<200	0.000
		≥ 200	0.501
			10

Model intercept by country income level: high income = -70 ($\beta = -3.49$), upper middle income = -63 ($\beta = -3.15$), and low and lower middle income = -60 ($\beta = -2.98$). To generate the final scaled score, mean coefficients were multiplied by 20 and rounded.

Table 3 Model performance of the 'Global Surgical-Site Infection' score and previous predictive models across the GlobalSurg data sets

Model	Status	GlobalSurg-1		GlobalSurg-2	
		AUC (95% c.i.)	Calibration intercept and slope	AUC (95% c.i.)	Calibration intercept and slope
GloSSI (LASSO)	Derivation	–	–	0.738 (0.725,0.750)	0.044 and 0.995
	External validation	0.730 (0.715,0.744)	–0.098 and 1.008	–	–
XGBoost	Derivation	–	–	0.783 (0.770,0.796)	–0.002 and 1.192
	Internal validation	–	–	0.737 (0.709,0.765)	–0.046 and 0.940
	External validation	0.728 (0.713,0.743)	–0.298 and 0.926	–	–
Grant et al.⁴¹ (2019)	External validation	0.696 (0.680,0.711)	–	0.696 (0.683,0.710)	–
	NNIS (1986)	External validation	0.617 (0.600,0.635)	0.789 and 1.007	0.627 (0.614,0.640)
RSSIC (2012)	External validation	–	–	0.605 (0.592,0.618)	–
SENIC (1985)	External validation	0.635 (0.617,0.653)	0.362 and 0.688	0.659 (0.646,0.673)	0.461 and 0.882
Updated NNIS (2001)	External validation	0.687 (0.673,0.702)	0.969 and 1.445	0.698 (0.686,0.711)	1.203 and 1.308

GloSSI, 'Global Surgical-Site Infection'; LASSO, least absolute shrinkage and selection operator; XGBoost, extreme gradient boosting; NNIS, National nosocomial infections surveillance system; RSSIC, Risk of Surgical Site Infection in Cancer; SENIC, Study on the Efficacy of Nosocomial Infection Control.

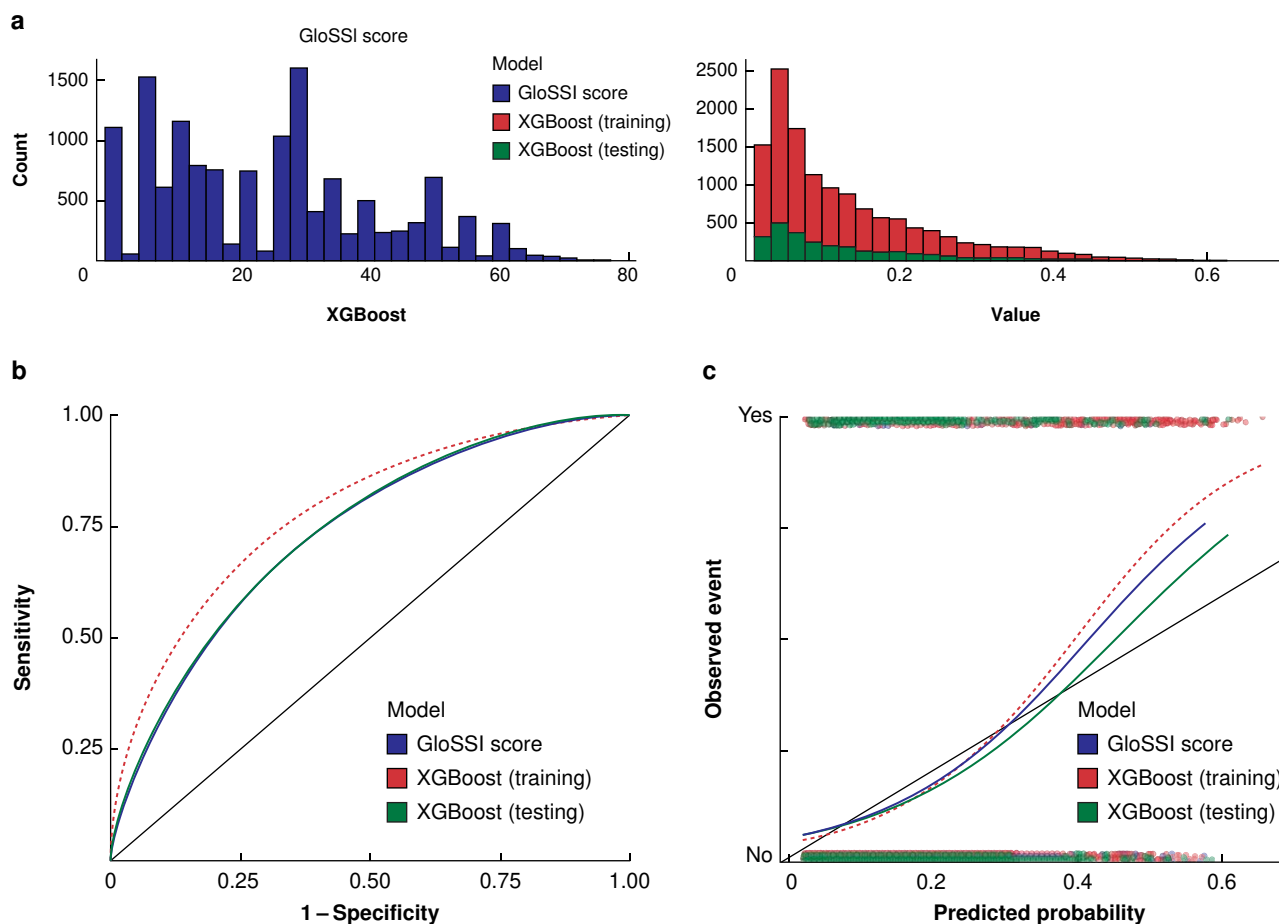


Fig. 2 Comparison of the performance of the least absolute shrinkage and selection operator and the extreme gradient boosting modelling approaches in the development cohort (GlobalSurg-2)

a Model prediction distribution. **b** Receiver operating characteristic (ROC) curves. **c** Calibration curves. GloSSI, 'Global Surgical-Site Infection'; XGBoost, extreme gradient boosting.

Table 4 'Global Surgical-Site Infection' score cut-off values and prognostic accuracy using the derivation data set

Cut-off value	Surgical-site infection rate (%)		Prognostic accuracy using the GlobalSurg-2 data set			
	'Low' risk (<cut-off)	'High' risk (\geq cut-off)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
5	4.1 (n = 175/4282)	16.1 (n = 1566/9737)	89.9	33.5	16.1	95.9
10	4.5 (n = 240/5384)	17.4 (n = 1501/8635)	86.2	41.9	17.4	95.5
15	4.9 (n = 308/6323)	18.6 (n = 1433/7696)	82.3	49.0	18.6	95.1
20	6.4 (n = 547/8532)	21.8 (n = 1194/5487)	68.6	65.0	21.8	93.6
30	7.7 (n = 820/10 659)	27.4 (n = 921/3360)	52.9	80.1	27.4	92.3
40	9.6 (n = 1182/12 336)	33.2 (n = 559/1683)	32.1	90.8	33.2	90.4
50	11.3 (n = 1516/13 398)	36.2 (n = 225/621)	12.9	96.8	36.2	88.7

PPV, positive predictive value; NPV, negative predictive value.

Fig. 3a, and Fig. S5a) and remained statistically significant 'good' discrimination for SSI. Sensitivity analysis to explore the results of external validation using only LMIC data showed that the GloSSI score and XGBoost comparator performed best among the scores evaluated, although with a reduction in discrimination compared with the full data sets (Fig. S5b).

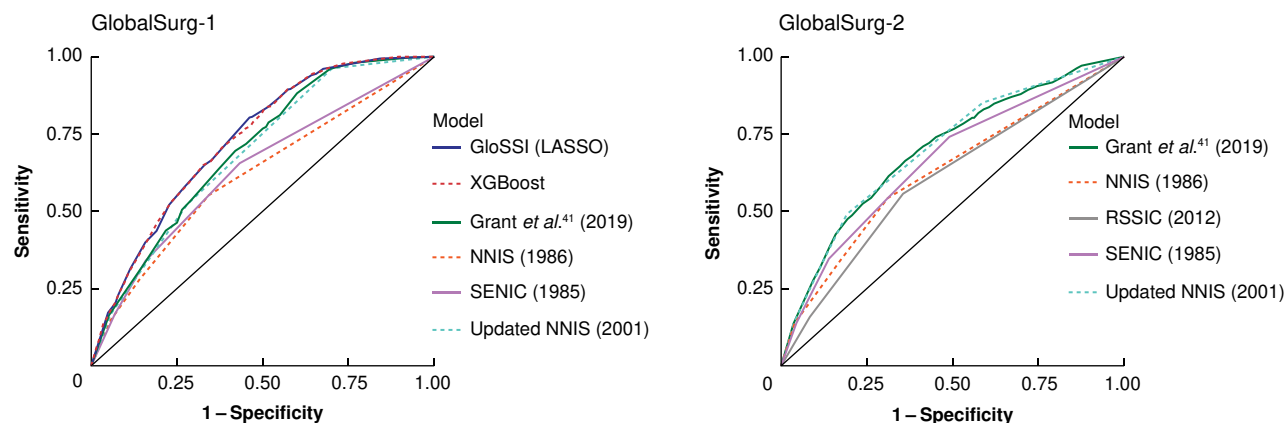
Nevertheless, the GloSSI score and XGBoost comparator appeared to remain well calibrated across a wide spectrum of risk on external validation (Table 3 and Fig. 3b). For the three models with sufficient information to determine calibration, these had a narrower spectrum of predicted probabilities with typically poor calibration demonstrated across the GlobalSurg data sets (Table 3

and Fig. 3b). Subsequent decision curve analysis showed that the GloSSI and XGBoost models had better clinical utility across a wider range of threshold risks compared with prior prognostic scores for the GlobalSurg data sets (Fig. 3c).

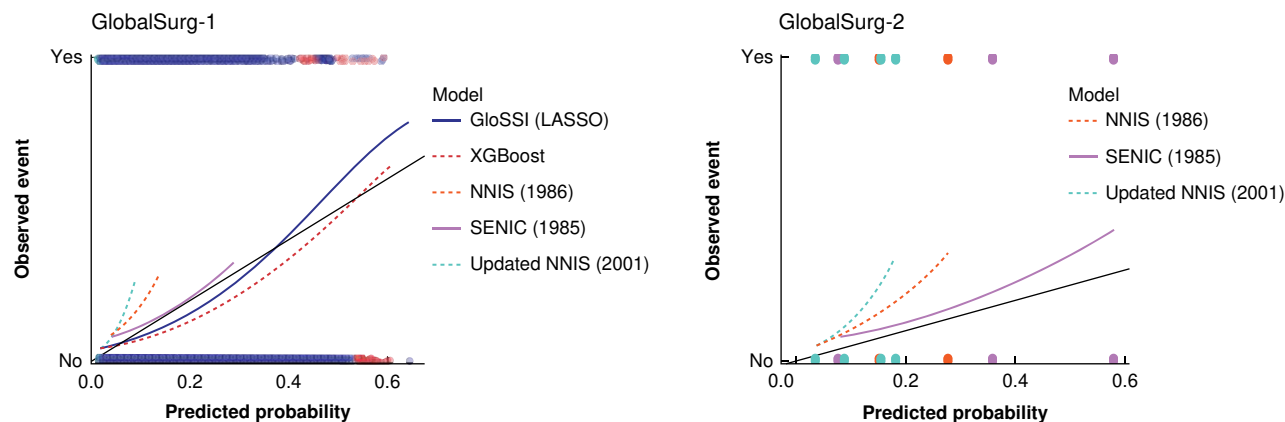
Discussion

This analysis used robust and well-established modelling techniques to derive a novel prognostic model (GloSSI score) to predict the likelihood of SSI within the first 30 days after surgery in those undergoing gastrointestinal surgery. This was developed using prospective data from an observational study conducted on

a ROC curves



b Calibration plots



c Decision curve analysis

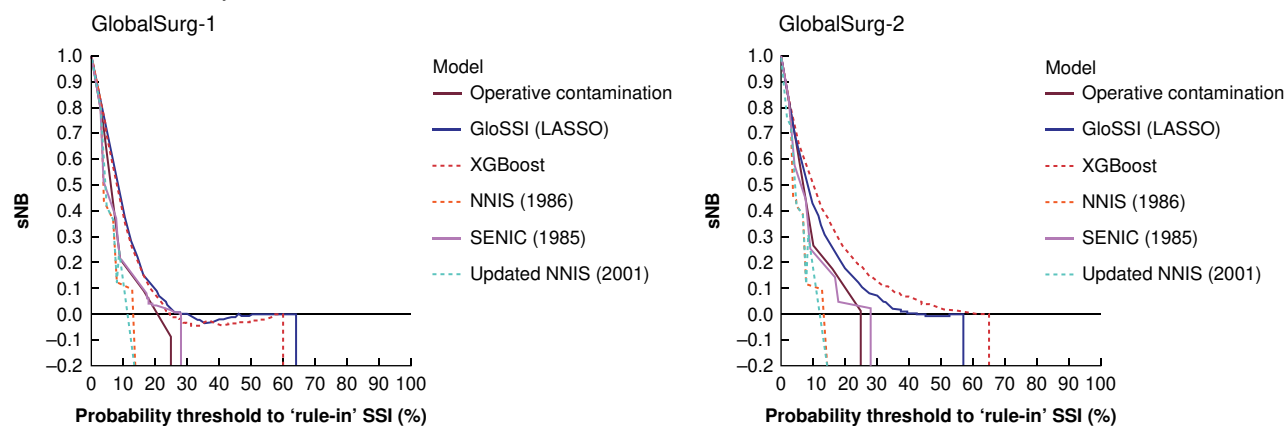


Fig. 3 External validation of the 'Global Surgical-Site Infection' score and previous predictive models across the GlobalSurg data sets

ROC, receiver operating characteristic; GloSSI, 'Global Surgical-Site Infection'; LASSO, least absolute shrinkage and selection operator; XGBoost, extreme gradient boosting; NNIS, National nosocomial infections surveillance system; SENIC, Study on the Efficacy of Nosocomial Infection Control; RSSIC, Risk of Surgical Site Infection in Cancer; sNB, standardised net benefit.

a global basis and incorporates predictor variables that are accessible to clinicians across all settings and at the time of surgery. On external validation in an emergency surgery population, the GloSSI score was demonstrated to be well calibrated across a wide spectrum of risk, with superior discrimination and clinical utility on decision curve analysis when compared with existing prognostic models. Furthermore, of the five prognostic models able to be externally validated using the large prospective GlobalSurg data sets, none was significantly higher than the a priori threshold for 'good' discrimination in the

cohort (AUC greater than or equal to 0.7) or consistently acceptable calibration.

Prediction of the risk of SSI at the point of surgery remains a challenging task, with a breadth of prognostic factors previously identified⁷. However, methodological issues in previous models have made it difficult to determine the true importance of these factors in the development of SSI. The variable selection process for the GloSSI score prioritized several of the co-morbidities and operative factors most commonly identified in previous models (Fig. S4), emphasizing their importance in a global context.

However, the combination of variables and weightings in the GloSSI score remains distinct from all pre-existing scores developed. Furthermore, these were a limited number of simple variables that are routinely available across income settings, increasing the clinical utility within routine practice. It was also notable that the effects of factors commonly highlighted in past models (for example patient age, history of smoking, and operative urgency) were largely explained by the contributions of other factors within the model. While this does not exclude an effect from these variables, it suggests that the factors included in the GloSSI model have a far greater value in the prognosis of SSI. Country income level was also identified as a significant prognostic factor for SSI (Table 2). This is a crude surrogate for a multitude of potentially causal factors, including differences in surgical practice, access to surgical care, presentation of pathologies, and availability of resources³³⁻³⁵. This may account for the lower performance on external validation in the LMIC subgroups, despite the incorporation of this factor into the model (Fig. S5).

The GloSSI score demonstrated consistently superior discrimination and clinical utility on decision curve analysis across the external validation data set compared with previous models, which were typically aligned with those reported in previous validation studies⁷ (Fig. S5). However, regarding the previous scores for which calibration was able to be evaluated (Fig. 3b), poor calibration was generally observed. This may be in part due to an earlier ceiling to the predicted probabilities compared with the GloSSI score, which demonstrated good calibration across a range of risks of SSI. This indicates that the GloSSI score is suitable for the reliable prediction of SSI in a broad cohort of undifferentiated patients undergoing gastrointestinal surgery, particularly those undergoing emergency procedures. However, further external validation using other data sets, particularly elective surgery populations, would be beneficial.

In recognition of the theoretical benefits of machine-learning approaches for clinical prediction³⁶, an XGBoost model was also developed as a best-in-class alternative of the primary modelling approach used in this paper. While this demonstrated superior performance within the development cohort, there was equivalent performance to the GloSSI model on external validation (AUC ~0.73) (Table 3). This indicates an element of overfitting in the original data set, but also potentially a limit to the capabilities of prediction of SSI using data that are routinely available at the time of surgery. While further improvement in the predictive potential via machine-learning approaches may be achievable, there is an inherent trade-off in the clinical utility. For example, including a greater number and complexity of variables would increase the burden and barriers to completion, integrating data on the postoperative journey of patients may prevent early intervention, and reduced transparency in the prediction process may reduce explicability and so the willingness of clinicians and patients to use³⁷.

This work presents the most comprehensive analysis to date of risk scoring systems for the prediction of SSI after gastrointestinal surgery, with several notable advantages to the approach used to develop and validate the GloSSI score. First, the data sets used throughout these analyses are from among the largest prospective studies of postoperative outcomes and were conducted on a global basis across a spectrum of income settings. This facilitated generalizability of the work to include LMIC settings, which have been overlooked in this area, yet have the highest burden of disease^{6,7}. Furthermore, the data collected across the GlobalSurg studies represent almost all common prognostic factors available at the time of surgery previously identified (Fig. S4) and so

maximized the likelihood of developing an accurate prognostic model. Second, the methodology to develop the GloSSI score was consistent with current best practice. It was determined a priori that there was suitable statistical power for model development, with the low rates of missing data in the GlobalSurg data sets being handled via multiple imputation to maintain this. Candidate variables considered were those with a clear potential role in the causal pathway for the development of SSI and only those available at the time of surgery were considered, increasing the applicability to clinical care. Robust modelling approaches for variable selection were subsequently utilized (including penalized regression and machine-learning approaches), avoiding the issues in using statistical significance as the decision criteria and accounting for collinearity in variables considered⁸. Finally, the largest external validation of prognostic models for SSI in gastrointestinal surgery to date was conducted, including the majority of scores previously externally validated^{32,38-40}, as well as two additional scores^{41,42}. This allowed a direct and fair comparison of their respective performance alongside the GloSSI score for broad cohorts of patients undergoing gastrointestinal surgery, allowing determination of the improved performance.

However, there are also several important limitations to this analysis. First, not all variables identified as predictors in previous scores were collected within the GlobalSurg studies, for example BMI (Fig. S4). This was a pragmatic decision to ensure these studies could be feasibly delivered across a range of income settings, where additional tests or equipment required for collecting data for other variables may not be available. Within this analysis, this limited the data available for score development and to conduct external validation, with the majority of previous scores (17 of 23) remaining unvalidated⁷. However, these unvalidated models had other methodological or practical challenges that limited their suitability in this context of undifferentiated patients undergoing gastrointestinal surgery⁷. This is reflective of broader issues with reproducibility across the prediction literature⁴³. Second, the discrimination observed on external validation of models may have been influenced by pragmatic decisions to derive additional variables that were essential to the model. Operative duration was frequently identified as a key prognostic factor across previous models (Fig. S4) and was an important feature in the context of the development of the GloSSI score (Table 2). However, this variable was only collected for the derivation cohort (GlobalSurg-2) and not the validation cohort (GlobalSurg-1). In the absence of alternative public sources of data on operative duration that were relevant in a global context, data from GlobalSurg-2 were used to predict operative duration in the validation data set (Table S1). While this may theoretically reduce discrimination for previous models, all scores bar one (Grant *et al.*⁴¹) categorize operative duration into broad intervals and so would not explain the typically poor discrimination observed. In contrast, there is a risk of information leakage from the derivation cohort to the validation cohort, given that the operative duration was predicted using variables shared with the GloSSI model. As such, it is possible that the performance of the GloSSI model in the validation cohort was overestimated and further external validation would be needed to explore this. Third, several pragmatic decisions were made regarding variables in the GlobalSurg data set to facilitate the modelling process. Where exposure rates were low for individual predictors in the GlobalSurg studies, but a common mechanism was shared, these were combined into a composite variable. In the case of 'history of immunosuppression', these included variables involving different immunosuppressive mechanisms and so may have different individual contributions to SSI that therefore were not observed.

However, none of these variables has been observed to have a strong association with SSI in prior prognostic models⁷ and so would be expected to require significantly larger data sets to determine whether a statistically significant association was present. Similarly, where the data collected in the GlobalSurg data sets did not exactly match the original study, variables were equated where appropriate (Tables S5, S6). Therefore, this may have also contributed to reduced discrimination observed on external validation for these models. Fourth, while inclusion of World Bank income status was identified as an important predictor of SSI, this is a surrogate measure that is reflective of potential differences in access, pathology, and clinical practice between regions rather than being reflective of intrinsic risk. Furthermore, there can also be substantial variation between countries and between hospitals within countries regarding these factors⁴⁴, which may influence the risk of SSI. Therefore, while differences between World Bank income status are accounted for within the GloSSI score, emphasis is placed on the patient-level factors for clinical decision-making (Table 2). Finally, the GlobalSurg studies used the same standard CDC diagnostic criteria for SSI; however, in global settings where it was not possible to conduct outpatient follow-up, the outcome was determined at the point of discharge. Increasingly, SSI has become a complication of the post-discharge interval⁴⁵ and so the true 30-day SSI rate may have been underestimated. This may explain the reduced discrimination in SSI recorded post-discharge within LMICs (Fig. S5). Therefore, while the SSI recorded here represents only those that came to the attention of hospitals, this is nonetheless reflective of clinical practice, particularly for areas of poor community healthcare access.

The GloSSI score allowed accurate prediction of the risk of SSI across an undifferentiated cohort of patients undergoing gastrointestinal surgery. It used six simple variables that are routinely available at the time of surgery across global settings and demonstrated superior performance on external validation in an emergency surgery population to all previous models evaluated to date and equivalent performance to a machine-learning-based comparator. It has a clear clinical application to inform intraoperative and postoperative interventions that can modify the risk of SSI and minimize associated harm³⁻⁵. Without a substantial change in the type and/or modality of data collected during hospital admission, it is unlikely that high discrimination can be achieved using data routinely available at the time of operation. Therefore, if a prognostic score is to be used in clinical care, there must be a pragmatic trade-off between sensitivity and specificity depending on the specific intervention and clinical context being considered. For interventions such as antibiotic prophylaxis, a low sensitivity may be acceptable so long as there remains a high NPV. However, for interventions that are resource-intensive (for example enrolment in clinical trials or enhanced postoperative surveillance programmes), a higher sensitivity may be prioritized to ensure an evidence-based approach to direct these towards patients at highest risk^{3,46}. Score cut-offs to facilitate the use of the GloSSI score for these different clinical purposes are provided (Table 4). Nonetheless, it should be noted that there has been increasing interest in the use of a dynamic risk model for prognosis in other clinical contexts⁴⁷. Unlike traditional modelling methods, the likelihood of SSI could instead be updated at pre-specified time points (for example before surgery, intraoperatively, and on discharge) to guide evidence-based decision-making throughout the clinical pathway. As surgical demand continues to grow in light of efforts to provide universal healthcare coverage and to address

the post-pandemic elective surgical backlog^{48,49}, the burden posed by SSI to health systems is expected to continue to scale accordingly. Therefore, there becomes an even greater clinical need for the use of prognostic tools to allow the modifiable risk of SSI to be mitigated. However, while there are clear cases of clinical use for numerous predictive models published, model performance is not a guarantee of clinical adoption⁵⁰. Further studies on the clinical impact or on how clinical prediction tools can be sustainably implemented within care pathways are warranted, rather than reliance on gradual diffusion and uptake into clinical practice.

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The authors declare no conflict of interest.

Supplementary material

Supplementary material is available at BJS online.

Data availability

The data sets generated during and/or analysed during the present study are available from the corresponding author on reasonable request.

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