
Development and Validation of the Ventral Hernia Repair Outcomes Reporting App for Clinician and Patient Engagement (ORACLE)



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- BACKGROUND:** Patient engagement is an increasingly important component of surgical decision making. Given the many factors associated with successful ventral hernia repair (VHR), we developed and validated the Outcomes Reporting App for Clinical and Patient Engagement (ORACLE) tool to help facilitate preoperative surgeon-patient discussions about VHR.
- METHODS:** All patients undergoing elective, VHR with 30-day follow-up data available within the Americas Hernia Society Quality Collaborative were eligible for study inclusion. Using bootstrapping and bias-corrected calibration, predictive models were generated and validated for 5 quality measures after VHR, including postoperative wound events, estimated length of hospital stay, unplanned 30-day readmission to the hospital, and risk of hernia recurrence at 1 year postoperatively.
- RESULTS:** A total of 10,690 patients met inclusion criteria. Based on comparison of the theoretical best to the observed calibration curves, the models for each of the 5 outcomes of interest have strong predictive strength as reflected in the Brier score for surgical site infection, surgical site occurrence requiring procedural intervention, and 30-day hospital readmission, the c-index for 1-year hernia recurrence and the R^2 value for the model for predicted hospital length of stay.
- CONCLUSIONS:** Using a national data set for development, ORACLE can be used to facilitate patient engagement, with the goal of tailoring interventions for VHR given each patient's unique factors. With ongoing data input into the Americas Hernia Society Quality Collaborative and a continuous re-evaluation of these risk models, it is our intention that this tool will serve as an up-to-date resource for hernia surgeons and ventral hernia patients. (J Am Coll Surg 2019;229:259–266. © 2019 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)
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The practice of medicine was founded on the idea of “provider paternalism” with clearly defined roles for the physician and the patient.¹ Within this model, physicians were solely responsible for the decision making and outcomes of their patients and their illnesses, and the patient assumed the “sick role.”^{1,2} Although the idea of provider paternalism was successful in the earlier centuries of medicine, this practice model has largely been replaced with

the idea of shared decision making between physicians and patients.¹ Within this new model, responsibility for patient outcomes is a collaboration between the physician and their patients through patient activation and engagement.^{1,3}

Patient activation refers to the ability for a patient to manage their own health, and patient engagement refers to the process by which patients acquire the knowledge

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Abbreviations and Acronyms

AHSQC	= Americas Hernia Society Quality Collaborative
LOS	= length of stay
ORACLE	= Outcomes Reporting App for Clinician and Patient Engagement
SSI	= surgical site infection
SSOPI	= surgical site occurrence requiring procedure intervention
VHR	= ventral hernia repair
VHWG	= Ventral Hernia Work Group

and skills to manage their own health.³ Ventral hernia repair (VHR) is one of the most commonly performed general surgery operations in the US.⁴⁻⁶ Nevertheless, the field of hernia surgery lacks reliable basic information about the underlying disease process, its management, and its prevention, resulting in significant confusion from both physicians and patients alike.⁷ Because of the prevalence of ventral hernias and the variation within this field of surgery, patient activation, and patient engagement are critical tenants to preoperative patient evaluation and to ensure long-term durability of repair. Therefore, the purpose of this study was to develop and validate a patient engagement tool that can be used to help guide preoperative decision making for patients undergoing VHR.

METHODS

Study population/data source

The Americas Hernia Society Quality Collaborative (AHSQC) was established in 2013 in an effort to improve the value of hernia care by using real-time continuous quality improvement principles.⁸ The AHSQC includes surgeons that practice in academic, community, and academic-affiliated institutions. As such, it is thought to be more representative of current hernia practice compared with single-institution experiences. In addition, it contains hernia-specific variables, including hernia size and location of mesh placement, that have been shown to be associated with hernia repair outcomes and are not available in larger national databases.⁸ For these reasons, we sought to develop and validate a ventral hernia patient engagement tool using the AHSQC. At the time of this study, the AHSQC had data available from 237 surgeons.

Inclusion and exclusion criteria

All patients who underwent an elective abdominal wall hernia repair with mesh who had at least 30-day and/or 1-year follow-up data available within the AHSQC

from January 2012 through October 2017 were eligible for study inclusion. This included patients who underwent epigastric hernia repair, umbilical hernia repair, or incisional hernia with or without concomitant parastomal hernia repair using either an open, laparoscopic, robotic, or hybrid surgical approach. Patients who underwent emergency VHR and those who underwent abdominal wall hernia repair without the use of mesh were excluded from this analysis. Patients who did not have 30-day follow-up data available were excluded from analysis of the 30-day outcomes of interest, and patients who did not have 1-year follow-up data available were excluded from analysis of the 1-year outcomes of interest.

Outcomes measures of interest

Five quality measures were chosen based on input from the AHSQC leadership team, which included risk of surgical site infection (SSI) within 30 days of VHR, risk of surgical site occurrence requiring procedure intervention (SSOPI) within 30 days of VHR, unplanned 30-day hospital readmission; risk of hernia recurrence within 1 year after VHR, and predicted hospital length of stay (LOS). Within the AHSQC, SSI, SSOPI, unplanned hospital readmission, and LOS are outcomes reported by the operating surgeon, and hernia recurrence is a composite patient- and surgeon-reported end point.⁹ Hospital LOS was calculated as the number of days from the index hernia repair operation to the date of discharge from the hospital. Surgical site infection and SSOPI were defined using the standardized definitions for postoperative wound events after VHR as follows: An SSI is an infection that occurs in the part of the body where the operation took place (ie abdominal wall) and is further defined as superficial, deep, and organ space SSIs.¹⁰⁻¹² An SSOPI is any surgical site occurrence (including SSI) that requires opening of the wound, wound debridement, suture excision, percutaneous drainage, or partial or complete mesh removal.¹⁰

Finally, ventral hernia recurrence was identified based on physical examination, radiographic assessment, or the Ventral Hernia Recurrence Inventory at 1 year after VHR.¹³

Statistical analysis

A predictive model for each of the outcomes of interest was generated using logistic regression for the binary outcomes of interest (SSI, SSOPI, and 30-day readmission), Cox proportional hazards regression for 1-year hernia recurrence, and quasi-Poisson generalized linear regression for predicted LOS. The strength of the models was determined by evaluating the bias-corrected calibration, which was calculated using bootstrap internal validation. The

Table 1. Population Characteristics and Operative Details

Variable	Data (n = 10,690)
Age, y, median (IQR)	58 (48–67)
Female sex, n (%)	5,378 (51.3)
Race, n (%)	
American Indian or Alaskan Native	23 (0.2)
Asian or Pacific Islander	44 (0.4)
African American	987 (9.2)
Hispanic	412 (3.9)
Middle Eastern	79 (0.7)
Caucasian	9,145 (85.5)
BMI, kg/m ² , median (IQR)	31.7 (27.8–36.4)
Current nicotine use, n (%)	1,161 (10.9)
Current steroid/immunosuppression use, n (%)	521 (4.9)
American Society of Anesthesiologists class, n (%)	
1	661 (6.2)
2	4,561 (42.7)
3	5,196 (48.6)
4	261 (2.4)
None assigned	10 (0.1)
Functional status, n (%)	
Independent	10,393 (97.2)
Partially dependent	272 (2.6)
Totally dependent	25 (0.2)
COPD, n (%)	737 (6.9)
End-stage renal disease on dialysis, n (%)	66 (0.6)
Diabetes mellitus, n (%)	2,032 (19.0)
Hernia type, n (%)	
Epigastric	504 (4.7)
Incisional	7,848 (73.4)
Incisional and parastomal	344 (3.2)
Lumbar	37 (0.3)
Spigelian	92 (0.9)
Umbilical	1,865 (17.4)
History of open abdomen, n (%)	1,054 (9.9)
Recurrent hernia, n (%)	3,352 (31.4)
Primary indication for hernia repair, n (%)	
Obstructive symptom	542 (5.1)
Enlarging hernia	6,978 (65.3)
Fistula	114 (1.1)
Infected mesh	136 (1.3)
Pain	8,686 (81.3)
Surgical approach, n (%)	
Open	6,891 (64.5)
Laparoscopic	2,024 (18.9)
Laparoscopic hybrid	168 (1.6)
Robotic	1,399 (13.1)

(Continued)

Table 1. Continued

Variable	Data (n = 10,690)
Robotic hybrid	131 (1.2)
MIS converted to open, unknown initial approach	77 (0.7)
Myofascial release, n (%)	43,36 (40.6)
Stoma present, n (%)	532 (5.0)
Planned concomitant procedure, n (%)	2,220 (20.8)
Mesh location, n (%)	
Inlay	337 (3.2)
Onlay	653 (6.1)
Sublay	9,700 (90.7)
Hernia width, cm, median (IQR)	5 (3–10)

IQR, interquartile range; MIS, minimally invasive surgery.

potential covariates for model inclusion were selected a priori from the available preoperative and intraoperative variables within the AHSQC. The decision to include each covariate was determined based on expert consensus, surgeon experience, and review of the literature, which revealed some association between each covariate and at least 1 of the outcomes of interest. The potential covariates for model inclusion were patient age, sex, race, BMI, nicotine use within 1 month of operation, steroid/immunosuppression use within 1 month of operation, American Society of Anesthesiologists class, functional status, COPD, end-stage renal disease requiring dialysis, diabetes mellitus, hernia type, primary or recurrent hernia, history of open abdomen, primary indication for hernia repair, myofascial release, presence of a stoma, planned concomitant procedure, mesh location, and hernia width. As this tool is intended for patient engagement and not to help direct surgeon decision making, surgical approach (ie open, laparoscopic, etc) and type of mesh used (ie synthetic, biologic, etc) were considered in the development of each model but are not available as modifiable variables.

After fitting the initial model for each of the outcomes of interest, the bootstrap distribution of the parameters in each model was examined to identify model instability and the need for collapsing levels of categorical variables or shrinkage of continuous variables. Bias-corrected estimates of model calibration were then generated to determine out-of-sample performance, strength of each prediction model, and to internally validate each prediction model. The measure of the calibration and goodness of fit for the binary outcomes (ie SSI, SSOPI, and 30-day unplanned hospital readmission) were assessed using the optimism corrected Brier score. Optimism is a bias in predicted probabilities that is typically caused by overfitting of a model, resulting in predictions that are too high for

positive outcomes and too low for negative outcomes.^{14,15} The Brier score measures the accuracy of the predicted probabilities and ranges from 0 to 1, where a measure closer to 0 indicates better calibration.^{14,15} The strength of the model for 1-year hernia recurrence was measured using the *c*-statistic. The *c*-statistic measures the predictive accuracy of logistic regression models for binary outcomes, with scores close to 1 indicating better goodness of fit.¹⁶ Finally, the strength of the model for predicted LOS was measured using R^2 . R^2 measures how much variability of a population's data is explained by the linear regression model. Ideally, R^2 would have a value close to 1.¹⁷ However, for models predicting human behavior, an R^2 value of 0.5 is considered strong.¹⁷

Based on the input of the available preoperative and intraoperative variables, the models can be used to generate the estimated probabilities and 95% CIs for each of the 5 outcomes of interest. These models were then converted to a web-based application, as we will describe, to facilitate use by surgeons and their patients. All statistical analyses were performed using the R software in addition to *rms*, *mice*, *stats*, *graphics*, *data.table*, *dplyr*, and *dtplyr* software packages (R Foundation for Statistical Computing).¹⁸

RESULTS

A total of 10,690 patients were identified within the AHSQC who met the inclusion criteria. Patient demographic data and operative characteristics are outlined in Table 1. Table 2 details the incidence of each of the 5 outcomes of interest. Due to the large number of hernia repairs captured within the AHSQC, there were enough outcomes events to facilitate the development of the 5 risk models, despite the low overall frequency of each of the 5 outcomes of interest.

Figures 1 through 5 illustrate the strength of each risk model. Ideally, a well-calibrated model has an observed, bias-corrected calibration curve that falls down the diagonal, along the theoretical best calibration curve. When the observed, bias-corrected calibration curve aligns with the theoretical best calibration curve, it means that there is concordance between the model predictions and the estimated out-of-sample observed event rate.¹⁹ Deviation from the theoretical best calibration curve represents model predictions that are too high or too low. In the foot of each plot, a histogram is provided, which displays the distribution of the predicted probabilities of the outcomes occurring, which were generated using the study population.

The models for SSI, SSOPI, and 30-day hospital readmission had strong optimism corrected Brier scores of

Table 2. Thirty-Day and 1-Year Outcomes

Variable	Incidence (n = 10,690)
Surgical site infection, n (%)	371 (3.5)
SSOPI, n (%)	553 (5.2)
30-day unplanned hospital readmission, n (%)	571 (5.3)
1-year hernia recurrence, n (%)	702 (6.6)
Length of hospital stay, d, median (IQR)	2 (0–5)

IQR, interquartile range; SSOPI, surgical site occurrence requiring procedural intervention.

0.038 (SSI), 0.053 (SSOPI), and 0.058 (30-day readmission). The *c*-statistic for the 1-year hernia recurrence model had a *c*-statistic value of 0.600. Lastly, the R^2 value for predicted hospital LOS was 0.471. Overall, each of the models have good calibration, with SSI, SSOPI, and 30-day hospital readmission having the strongest co-linearity between the theoretical best and the observed calibration curves, and the risk of 1-year hernia recurrence and predicted hospital LOS had the biggest difference between the theoretical best and the observed calibration curves.

A web-based tool for deploying our tool, known as the Outcomes Reporting App for Clinician and Patient Engagement (ORACLE), was developed using the validated models for each of the 5 clinical outcomes of interest. An adaptive web design using R Shiny was used, making the tool easily accessible by phone, tablet, or computer. The clinical factors important to preoperative VHR decision making, as described, are displayed in the web-based tool as radio buttons for discrete variables and slide bars for continuous variables. The tool is freely accessible to both patients and surgeons alike at www.ahsqc.org. Once the preoperative variable inputs are entered, predicted values and 95% CIs for these values are updated interactively and shown visually and numerically. In addition, users have the option of printing the results in hard-copy form that can be provided to the patient and placed into their medical record. It is our intention that the ability to visualize improvements in the predicted outcomes of interest and to print these predictions pre- and post-patient engagement will facilitate preoperative optimization of patients being considered for VHR operations.

DISCUSSION

Herein, we detail the development and validation of the ORACLE tool using the AHSQC database. This tool can be used to predict 5 outcomes of interest after VHR with reasonable accuracy. Within a quality-based model of healthcare, the tenants of patient-centered outcomes, patient activation, and patient engagement are emphasized. Interestingly, recent studies have shown that activated

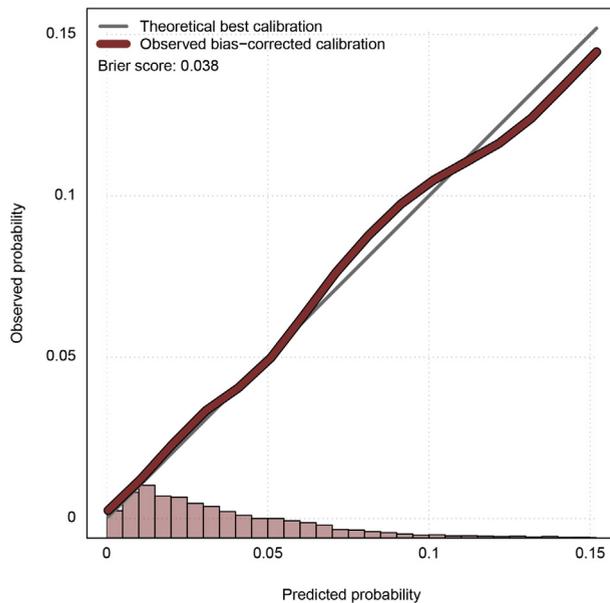


Figure 1. Calibration plot for 30-day surgical site infection logistic model. Solid gray line indicates the theoretical best calibration, and the bold, solid red line indicates the observed bias-corrected calibration. A well-calibrated model will produce a plot where the observed bias-corrected calibration line lies close to the theoretical best calibration line. The Brier score for this model is 0.038, with a score that approaches 0, indicating strong predictive value of the model.

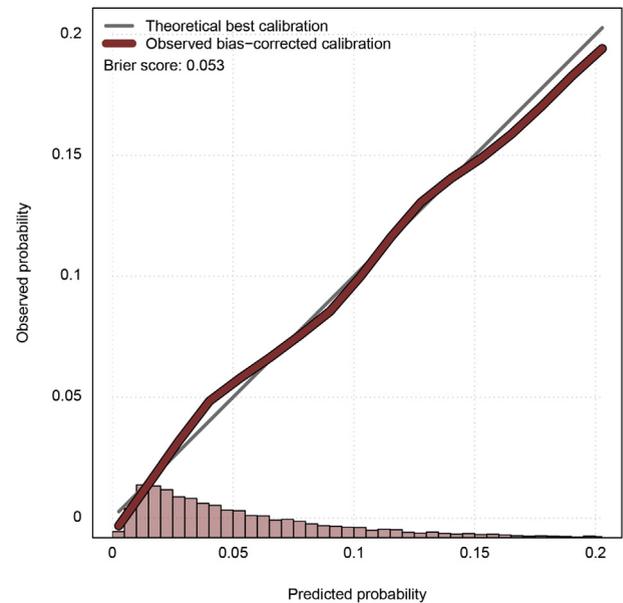


Figure 2. Calibration plot for 30-day surgical site occurrence requiring procedural intervention logistic model. Solid gray line indicates the theoretical best calibration, and the bold, solid red line indicates the observed bias-corrected calibration. A well-calibrated model will produce a plot where the observed bias-corrected calibration line lies close to the theoretical best calibration line. The Brier score for this model is 0.053, with a score that approaches 0, indicating strong predictive value of the model.

patients are more satisfied with the healthcare that they receive and that they are less likely to use more expensive healthcare resources.^{3,20-22} It is our intention that the ORACLE tool will be used during patient-physician interactions as one way to improve quality in hernia surgery.

The 2 most commonly used measures used to assess quality of VHR are the incidence of postoperative wound events and the long-term durability of the repair.⁶ Before the development of the ORACLE tool, there were 6 hernia-specific tools and 1 general surgery tool available to surgeons to help guide the management of ventral hernias. The hernia-specific tools include the CEDAR application, the European Hernia Society Hernia Classification System, the Ventral Hernia Work Group (VHWG) Grading Scale, the modified VHWG grading scale, the Hernia Risk Score, and the Ventral Hernia Staging System, and the general surgery tool is the American College of Surgeons NSQIP Risk Calculator. All of these tools have been adopted to a variable extent by hernia surgeons throughout the world. Nevertheless, 2 of these hernia staging systems are based on expert opinion (European Hernia Society and VHWG Staging System) only, and the 3 remaining hernia-specific tools (modified VHWG, Hernia Risk Score, and the Ventral Hernia Staging System) and the CEDAR application are based on data

from a single institution.^{5,6,23-26} In addition, only 1 of these classification systems (Ventral Hernia Staging System) attempts to predict hernia recurrence.²⁵ With respect to the general surgery risk calculator, the American College of Surgeons NSQIP Risk Calculator does not include important hernia-specific variables, including indication for hernia repair, size of the hernia defect, type and location of mesh used, and number of previous VHRs.⁴ The ability to predict a limited number of important outcomes, use of single-institution data, and use of overly simplistic models are inherent weaknesses of these tools. With the use of the AHSQC, we believe that some of these limitations are overcome with ORACLE. Specifically, the use of a national database that captures surgeons and patients who provide and receive care, respectively, in a variety of clinical settings can make this tool more applicable to a larger population of VHR patients and the use of bootstrap internal validation allows for flexible risk model development, which might more accurately predict the outcomes of interest.²⁷⁻²⁹

To facilitate patient activation and patient engagement, we have launched a website in which hernia surgeons and patients can access the ORACLE tool. By modifying

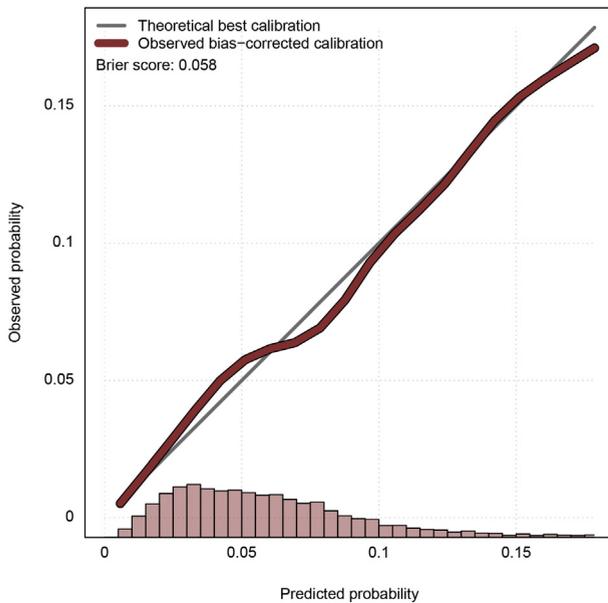


Figure 3. Calibration plot for 30-day unplanned hospital readmission logistic model. Solid gray line indicates the theoretical best calibration, and the bold, solid red line indicates the observed bias-corrected calibration. A well-calibrated model will produce a plot where the observed bias-corrected calibration line lies close to the theoretical best calibration line. The Brier score for this model is 0.058, with a score that approaches 0, indicating strong predictive value of the model.

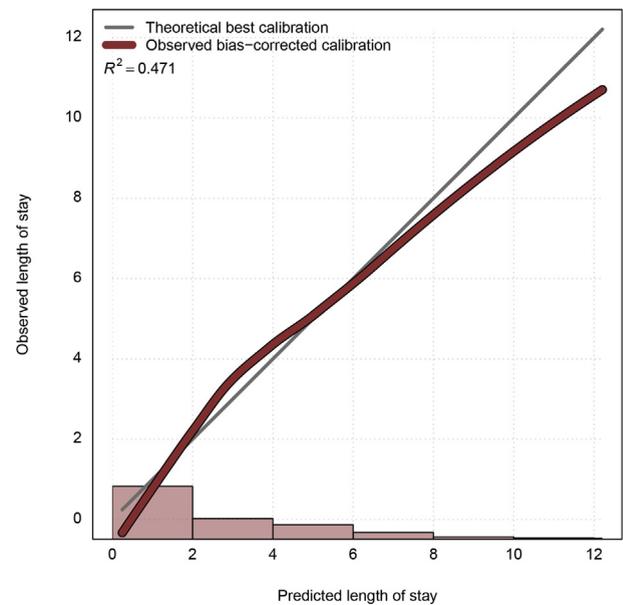


Figure 5. Calibration plot for predicted length of hospital stay quasi-Poisson model. Solid gray line indicates the theoretical best calibration, and the bold, solid red line indicates the observed bias-corrected calibration. A well-calibrated model will produce a plot where the observed bias-corrected calibration line lies close to the theoretical best calibration line. The R^2 value for this model is 0.471, with a score near 0.5, indicating strong predictive value of the model.

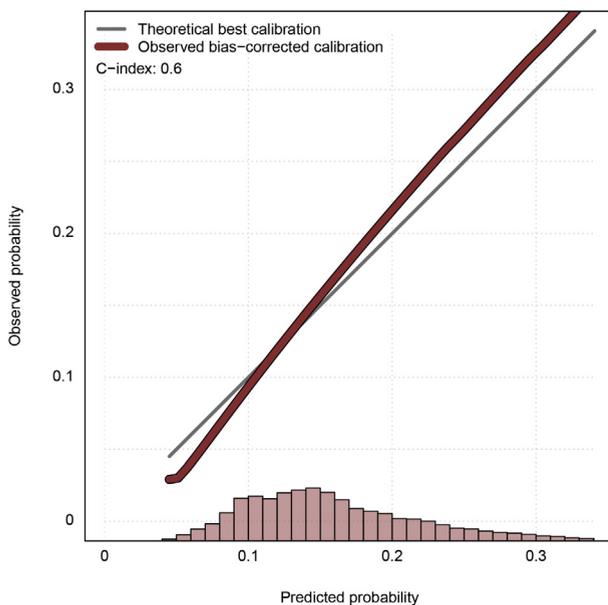


Figure 4. Calibration plot for 1-year hernia recurrence Cox model. The solid gray line indicates the theoretical best calibration, and the bold, solid red line indicates the observed bias-corrected calibration. A well-calibrated model will produce a plot where the observed bias-corrected calibration line lies close to the theoretical best calibration line. The c-statistic for this model is 0.600, with a score that approaches 1, indicating strong predictive value of the model.

preoperative and intraoperative variables, hernia surgeons can demonstrate how the risk of any of the 5 outcomes of interest can change based on preoperative optimization of modifiable patient risk factors. In addition, the patient-specific generated risk models can be printed from the website and given to patients for their review. It is our intention that through demonstration of the ORACLE tool and visual representation of the direct effect that a patient's modifiable risk factors can have on their VHR outcomes, patients will be empowered to take a more active role in their VHR procedure. Through patient activation and engagement with the ORACLE tool, it is our hope that both patient experience and the value of VHR surgery will improve.

Although there are several advantages to our patient engagement tool, there are also some limitations. First and foremost, it is important that the predictions from our tool are interpreted within the context of the CI for each of the outcomes measure. Although it is our hope that the data within the AHSQC database is representative of the more general hernia patient population, we recognize that there will be some patients and clinical scenarios for which this tool is used that result in outlier scenarios. In these cases, the predictive ability of our calculator will not be as accurate, which will be reflected by a wide CI for the

predicted values of each of the outcomes of interest. When using the ORACLE tool, CIs are defaulted to appear in green. To ensure that the users of our tool interpret potential outlier scenario results with caution, any predictive outcomes result that has a CI >10 percentage appears in purple rather than in green. The significance of these colors for the CIs is explained in the ORACLE user instructions on the ahsqc.org website. In a recent study by Holihan and colleagues,²⁷ 2 multicenter hernia databases in which a model for hernia recurrence was developed were compared and noted to have strong internal validation but not external validation. Although we performed our analysis using bootstrapping, which is a method of internal resampling that helps to reduce overfitting of models, the external validation of our risk models requires additional investigation.²⁷⁻²⁹ In addition, the number of events and patients available for 1-year hernia recurrence were lower than the number of events and patients available for the other outcomes of interest. This is likely one explanation as to why the 1-year hernia recurrence model does not have as strong of a predictive ability compared with the other risk models. Additionally, the strength of the model for predicted hospital LOS was measured using R^2 . Although R^2 values closer to 1 are typically considered stronger models, predicting human behavior is more complicated than predicting physical processes, which is why a value near 0.5 is considered good.¹⁷ Nevertheless, alternative models to predict these outcomes do not currently exist and we anticipate that the strength of our models will continue to improve as our models will undergo continuous data input and re-evaluation on a fixed cycle to ensure that the predictive strength of this tool remains optimized and reflective of the current AHSQC hernia patient population. Finally, although we intend for this tool to be used for patient activation and patient engagement, the direct impact that the use of this tool might have on patients and the ability to use this tool for these purposes requires additional investigation. As we continue to collect data on the number of times our tool is accessed online and through the feedback of the members of the AHSQC, we hope to determine future directions and applications of our tool, including the possible development of a mobile version of our application.

CONCLUSIONS

The current healthcare landscape is evolving from a paternalistic model to a shared responsibility model in which patient outcomes are optimized through physician counseling and patient activation and engagement. With the use of the AHSQC, we propose the ORACLE tool, as a resource for patient activation and engagement for VHR.

Author Contributions

Study conception and design: Haskins, Rosen, Poulouse
 Acquisition of data: Haskins, Olson, Stewart, Poulouse
 Analysis and interpretation of data: Haskins, Olson, Stewart, Rosen, Poulouse
 Drafting of manuscript: Haskins, Rosen, Poulouse
 Critical revision: Haskins, Olson, Stewart, Rosen, Poulouse

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