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Original Research Article

How surgeons use risk calculators and non-clinical factors for informed consent and shared decision making: A qualitative study

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ABSTRACT

Background: The discussion of risks, benefits, and alternatives to surgery with patients is a defining component of informed consent. As shared-decision making has become central to surgeon-patient communication, risk calculators have emerged as a tool to aid communication and decision-making. To optimize informed consent, it is necessary to understand how surgeons assess and communicate risk, and the role of risk calculators in this process.

Methods: We conducted interviews with 13 surgeons from two institutions to understand how surgeons assess risk, the role of risk calculators in decision-making, and how surgeons approach risk communication during informed consent. We performed a qualitative analysis of interviews based on SRQR guidelines.

Results: Our analysis yielded insights regarding (a) the landscape and approach to obtaining surgical consent; (b) detailed perceptions regarding the value and design of assessing and communicating risk; and (c) practical considerations regarding the future of personalized risk communication in decision-making. Above all, we found that non-clinical factors such as health and risk literacy are changing how surgeons assess and communicate risk, which diverges from traditional risk calculators.

Conclusion: Principally, we found that surgeons incorporate a range of clinical and non-clinical factors to risk stratify patients and determine how to optimally frame and discuss risk with individual patients. We observed that surgeons' perception of risk communication, and the importance of eliciting patient preferences to direct shared-decision making, did not consistently align with patient priorities. This study underscored criticisms of risk calculators and novel decision-aids – which must be addressed prior to greater adoption.

1. Introduction

Discussing risks, benefits, and alternatives to surgery with patients is a defining component of preoperative informed consent.[1] As shared decision-making becomes central to surgeon-patient communication, risk calculators have emerged as a tool to aid physician communication and support patient decision-making by providing quantitative assessments of postoperative outcomes. "All-procedure" risk calculators, such as the American College of Surgeons (ACS)-NSQIP Surgical Risk Calculator,[2] leverage post-operative data from health centers nationwide to estimate the likelihood of universal adverse events such as pneumonia, cardiac complication, renal failure, readmission and death among patients undergoing a particular procedure.

With the increasing prevalence of all-procedure risk calculators, surgeons have identified weaknesses with all-procedure risk calculators, including limited perceived benefit of all-procedure risk calculators in decision-making, overemphasis on physiologic measurements, perceived barriers to implementation or regular use, and lack of applicability for surgical subspecialties and

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operations with critical procedure-specific outcomes, such as anastomotic leak following esophagectomy or recurrent laryngeal nerve injury after thyroidectomy.[3–8] These challenges highlight a potential gap between the current use of all-procedure risk calculators and their ideal use. They also highlight a need to better understand how surgeons use risk assessments to aid in their decision-making and patient communication, and create risk calculators that more aptly fulfill their workflow needs.

In this study, we conducted a series of semi-structured qualitative interviews with surgeons to understand how surgeons perceive the role of risk assessment and risk calculators in their practice and to learn how they utilize these tools during preoperative informed consent. We invited surgeons to test a novel Visual Consent Tool, designed by our team to address reported challenges with risk calculators, in order to gain further insight into how risk communication tools can be optimized to support preoperative risk assessment, communication, and shared decision-making.[9]

2. Methods

2.1. Conceptual framework and study design

To address limitations in both communicating risk and achieving appropriate informed consent, our group designed a Visual Consent Tool (VCT), which incorporates patient preferences and incorporates validated visuals to standardize personalized risk communication (**Document 1**). The design and development of the VCT prototype has been described in prior studies.[9,10] Our group previously conducted semi-structured interviews and prototype testing with a convenience sample of 20 patients, and found that patients preferred many aspects of the novel VCT over current methods of risk communication and visualization.[10] As part of our iterative design process, we next sought to interview key clinician stakeholders regarding their perception and approach to obtaining informed consent, their perspective on the use and value of risk calculators in surgical decision-making, and their assessment of the prototype's design and potential utility.

2.2. Study participants and recruitment

We recruited academic surgeons from Beth Israel Deaconess Medical Center in Boston, MA and Dartmouth-Hitchcock Medical Center in Lebanon, NH. With regard to participant recruitment, purposeful sampling was completed to identify and recruit a representatively diverse cohort, particularly with respect to experience, gender, race, ethnicity, and surgical subspecialty. We contacted a designated subset of surgeons at each institution via email using a standardized template. A single follow-up email was sent to each potential participant. 75 surgeons (28 female [36%]; 47 male [64%]) were contacted during recruitment (July 2020–August 2020). This study was approved by the Institutional Review Board for Beth Israel Deaconess Medical Center. The study was conducted according to guidelines established by the Standards for Reporting Qualitative Research (SRQR) from the Equator Network (**Document 2**).[11]

2.3. Data collection

Two-part surgeon interviews were conducted from August to September 2020 using a semi-structured interview guide **(Document 3)**.[12] Participants were interviewed by study author JAP, a medical student trained in qualitative methods. Part 1–2 of the interview consisted of an overview of our project's scope and a conversation about informed consent; we sought to gain insight into surgeon's overarching experiences garnering consent and also learn about perceived pain points, barriers, and areas for disruption and improvement. Part 3 of the interview consisted of a demonstration of our Visual Consent Tool prototype, as well as a conversation about the value of risk calculators and how risk communication tools align with their needs and preoperative workflows. As part of the VCT demonstration, we utilized a series of urologic cases (i.e., laparoscopic prostatectomy). At the end of the interview, participants in a demographic survey (**Document 4**). Participants were consented verbally prior to the interview. Due to COVID-19 restrictions, interviews were conducted via video using Zoom, recorded with subject consent, and manually transcribed and de-identified by one researcher (JAP) using Microsoft Word. Interviews lasted a mean (SD) of 37 (4.2) minutes. Real-time field notes were taken by JAP.

2.4. Qualitative and statistical analysis

Between September 2021 and November 2021, we performed a thematic qualitative analysis of interview transcripts with the assistance of Computer-Assisted Qualitative Data Analysis Software, ATLAS.ti (Version 9.1.3).[13] Transcripts and field notes synthesized during interviews were reviewed; using a grounded theory approach, inductive coding was employed by one primary coder (JAP) to develop a preliminary codebook. Intercoder agreement was calculated among two independent coders (BRB and JSM) using the preliminary codebook. Quantitative reliability of the codebook was calculated using Krippendorff's Family of Alpha Coefficients, enumerating a c-alpha binary of 0.826.[14] This suggested the preliminary codebook was reliable and could be applied to the remaining interviews by independent coders. Subsequently, each transcript was coded independently by two coders (BRB and JAP). Codes were analyzed to establish themes related to the process of obtaining informed consent; the use of risk calculators and other tools to assess and communicate risk; and feedback on the visual consent tool. Thematic saturation was obtained after completing 12 interviews. Themes were analyzed for key insights, with results reported per SRQR guidelines (**Document 2**).

3. Results

3.1. Participants

A total of 13 surgeons were enrolled and interviewed (Table S1). 10 participants (77%) were male. Participants' median age was 46 years (IQR 39–50). Participating surgeons represented nine subspecialties including otolaryngology (N = 1), neurosurgery (N = 1), orthopedics (N = 1), trauma and acute care surgery (N = 1), surgical oncology (N = 4), pediatric surgery (N = 1), thoracic surgery (N = 1), colorectal surgery (N = 2), and plastic and reconstructive surgery (N = 1). Participants represented both institutions in roughly equal proportions (54% vs. 46%). Median years as a practicing attending was 11 (IQR, 6–15).

3.2. Summary of findings

Our thematic analysis yielded insights regarding (a) the current landscape and approach to obtaining informed consent in surgery; (b) detailed perceptions regarding the value and design of assessing and communicating surgical risk; and (c) practical considerations regarding our VCT and how to improve the future of risk visualization and shared decision-making in the informed consent process. A summary of the themes is presented in Table 1. Each of the following sections provides additional context on each theme. An aggregate summary of individual provider responses is included in Table S2 and Table S3.

Table 1
Summary of thematic analysis of provider interviews.

Domain	Summary Themes
Informed Consent	Surgeon's Approach to Informed Consent Blends the Pillars of Medical Ethics (i.e., Autonomy) with Medicolegal Requirements, Detailed in Standardized Consent Forms
	Surgeons Use Clinical and Non-Clinical Judgment to Risk Stratify Patients
	Surgeons Focus Risk-Benefit Discussion to Balance Understanding of Risk with Expectation
	Surgeons Use Adjunct Tools for Information-Sharing and Risk Communication
	Discerning Patient Understanding and Desire for Information Are Key Challenges
Risk Assessment and Communication	Current Use of Risk Calculators Is Variable and often Reserved for High-Risk Settings
	Surgeons Prefer Risk Tools that Supplement Judgment with Objective Analysis
	Individualized Data and Procedure-Specific Calculator Increase Value of Risk Calculators
Visual Consent Tool	Eliciting Patient Preferences Is Valuable to Surgeons, with Caveats
	Risk Visualization May Overemphasize Role of Quantitative Data in Clinical-Decision Making
	Accessibility and Efficiency are Necessary Attributes of Future Consent Tools

3.3. Part 1: informed consent process

In discussing the surgeon's approach and perceptions of the informed consent process, five major themes emerged, as outlined in Table 1: (A) surgeons endorsed an informed consent workflow and approach that combines the fundamental principles of medical ethics[15] with the medicolegal requirements for consent as detailed in the standardized consent form; (B) surgeons used several clinical and non-clinical factors to tacitly risk-stratify patients; (C) surgeons focused the risk-benefit discussion in an attempt to achieve satisfactory understanding of risk, while also conveying realistic expectations of surgical outcomes; (D) surgeons endorsed employing adjunct tools to convey surgical risks; (E) surgeons' ability to discern patient comprehension and patient's desire for information were two key challenges during informed consent.

Surgeon's Workflow and Approach to Informed Consent Blends the Pillars of Medical Ethics with Medicolegal Requirements Detailed in Standardized Consent Form.

Nearly all surgeons (12/13, 92.3%) evoked core principles of medical ethics (autonomy, beneficence and nonmaleficence) in describing the function of informed consent in surgery. More than half of surgeons (7/13, 53.8%) reported that patient consent should be designed to achieve awareness and fundamental understanding of pertinent risks and benefits, such that patients can appropriately make an informed decision regarding their care. A smaller group (5/13, 38.5%) asserted that preoperative consent served to provide awareness, rather than comprehensive understanding, of the indications for surgery and associated risks and benefits.

Despite varying perceptions of the objective of surgical consent, all participating surgeons (N = 13, 100%) reported using the structure of standard institutional consent forms, and the associated medicolegal framework, as a scaffold to obtain informed consent. While four surgeons used the consent form itself to guide the process, all 13 surgeons grounded the consent process by providing an overview of the surgical operation and a discussion of the risks, benefits and alternatives to surgery. The granularity of these discussions varies based on a number of clinical and non-clinical factors, as described in detail below, including the complexity of the procedure, the severity of the risks, the availability of alternatives, the surgeon's assessment of the patient's understanding and desire for information, and the surgeon's perception of the potential added value of more granular discussions.

Less than half (5/13, 38%) of surgeons discussed incorporating "fine print" into their consent, which included provisions such as permission to send specimens to pathology and have surgical trainees in the operating room. These surgeons emphasized these details to varying degrees, with 2 of 5 discussing these components in detail and 3 of 5 endorsing mentioning these items superficially, only elaborating if necessary based on patient preference.

Several surgeons (5/13, 38%) described obtaining informed consent as a "process" distinct from the actual medicolegal signage. The act of achieving informed consent was less discrete and occurred throughout the preoperative consultation, including the history, review of diagnostics and imaging and discussion of treatment options and management. For this group of surgeons, the process of obtaining informed consent was intrinsically related to their medical evaluation and discussion of treatment recommendations, and involved ensuring the patient understood their diagnosis and its likely trajectory, possible operative and non-operative treatment options, and anticipated short- and long-term implications of different management strategies. By incorporating education and counseling throughout the clinical encounter(s), the physician and patient collaboratively determined the preferred management strategy, and the critical aspects of achieving informed consent were performed at the time of medical decision-making. The actual process of completing and reviewing the consent form provided an opportunity for the provider to emphasize important details and verify patient understanding.

3.3.1. Surgeons use clinical and non-clinical judgment to tacitly risk stratify patients

Due to the time constraints of clinical practice, surgeons asserted that communicating a patient's most pertinent specific risks as efficiently and coherently as possible is one of their primary goals. The scope of the risk-benefits conversation is patient and practice dependent. Surgeons described using a range of clinical (Table S4) and non-clinical (Table S5) factors to decide which risks to highlight to the patient and how to present the information. Relying on both clinical judgment and their experience, most surgeons establish individual patient personas based on a combination of the distinct clinical and non-clinical factors; these factors dictate how surgeons assess and communicate risk, and differ from the standard clinical inputs of traditional risk calculators, as shown in Fig. 1. Surgeons then use these personas to mentally distinguish patients in order to tailor the discussion of risks and benefits accordingly, and incorporate each patient's unique clinical and non-clinical characteristics into the shared decision-making process.

As outlined in detail in Table S4, participants cited using clinical factors such as the patient's overall health, the case acuity, procedure complexity, and clinical context to risk stratify patients. Using these factors, surgeons assessed the patient's personal risk in the context of other patients' risks in order to individualize and contextualize postoperative risks.

Attending surgeons also described using non-clinical factors such as their assessment of the patient's health literacy, risk literacy, desired levels of decision engagement, risk engagement, and overall understanding, as shown in Table S5. By making these tacit

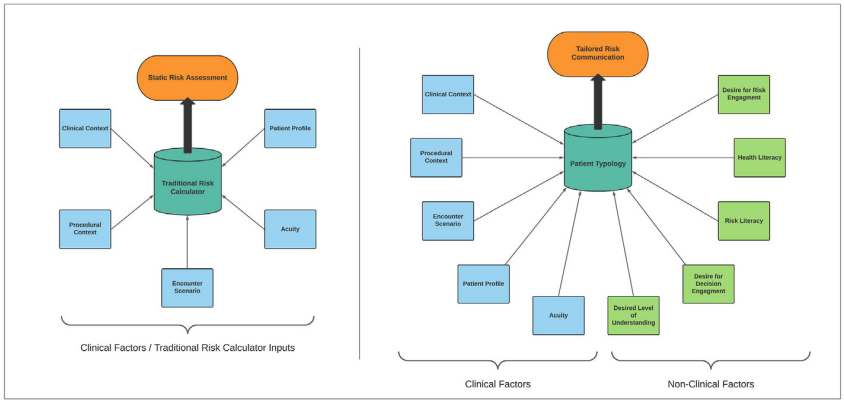

Fig. 1. Inputs Used in Surgeons' Tacit Risk Assessment vs Traditional Risk Calculators
Legend: Surgeons described using a range of clinical and non-clinical factors to decide which risks to highlight to the patient and how to present the information. Relying on both clinical judgment and their experience, most surgeons establish individual patient personas based on a combination of the distinct clinical and non-clinical factors; these factors dictate how surgeons assess and communicate risk, and differ from the clinical inputs of traditional risk calculators. Surgeons then use these personas to mentally distinguish patients in order to tailor the discussion of risks and benefits accordingly, and incorporate each patient's unique clinical and non-clinical characteristics into the shared decision-making process.

judgments, surgeons are able to tailor risk communication according to their assessment of a patient's needs.

3.3.2. Surgeons focus risk-benefit discussion to balance understanding of risk with expectation

All surgeons reported that contextualizing risk was key to effectively obtaining informed consent. Above all, surgeons sought to highlight the pertinent risks that were most "realistic", meaning most likely to occur, as well as a subset of complications that were, from the surgeon's perspective, key takeaways for patients, often due to their severity and/or impact on functional status or quality of life. One surgeon summarized this aspect of risk communication, stating it is necessary to prioritize "complications that are common even if they are minor; serious even if they're rare." Surgeons aim to optimize awareness and understanding, without providing a level of detail and complexity that leads to uncertainty, confusion and even emotional distress.

Depending on the clinical and procedural context, many surgeons reported that they might choose to emphasize procedural risks more than broader perioperative risks, or vice versa. For planned or routine procedures in healthier patients, all 13 surgeons described focusing on procedure-specific complications when discussing risks and benefits. On the other hand, surgeons acknowledged that for more complex procedures — more technically or anatomically challenging procedures — or more complex patients — higher acuity or greater comorbidities and baseline operative risk — explicit discussions would additionally occur regarding the patient's above average risk of perioperative morbidity and mortality.

In low-risk specialties and/or procedures, where there is minimal case-by-case variation in the risk of perioperative morbidity and mortality, surgeons felt it was most critical to emphasize long-term outcomes and those related to quality of life. For example, a urologist performing a routine radical prostatectomy might highlight potential complications such as erectile dysfunction or urinary incontinence rather than delve into the patient's risk of suffering from a myocardial infarction, acute renal failure, or deep venous thromboembolism. A surgical oncologist performing a planned thyroidectomy might take time to highlight the risks of short-term hypocalcemia or recurrent laryngeal nerve injury, rather than the risk of perioperative mortality. Surgeons sought to create a realistic view of surgery and the likely postoperative course, focusing the conversation on key takeaways, life-altering outcomes and notable common complications. As a result of advances in modern anesthesia and surgical practice, some surgeons asserted that some operations, especially in the elective or outpatient setting, do not warrant a deep-dive into inherent surgical risks, especially those that are "non-life changing."

3.3.3. Surgeons use adjunct tools for information-sharing and risk communication

All 13 surgeons reported using resources beyond only verbal discussion to communicate the risks associated with a given procedure. These included self-drawn sketches and diagrams, imaging, risk calculators, videos, and their institution's informed consent form, as outlined in Table S4. Some clinical tools, including sketches or imaging, were specific to the patient, while other adjuncts, such as videos and brochures, were procedure-specific, and made available to all patients undergoing a particular procedure. Principally, surgeons sought to use adjunct clinical tools which could be readily individualized to patients. A few surgeons cited "back of the napkin"-type sketches or anatomic diagrams that they could evoke in real-time—and adapt according to the direction of discussion. Several surgeons reported using the patient's imaging as a wireframe to discuss relevant anatomy, pathology, course of treatment, and related risks.

A detailed discussion of how surgeons use risk calculators follows in Part 2.

3.3.4. Discerning patient understanding and desire for information are key challenges

In discussing the consent process, surgeons highlighted common challenges to achieving and obtaining informed consent. Nearly all surgeons (12/13, 92.3%) noted the difficulty in accurately gauging a patient's understanding of the presented information. This potential gap in comprehension undermined shared decision-making and discussions of patient preference, as a patient's level of health literacy and risk tolerance was often uncertain. In addition, almost half of surgeons (6/13, 46%) described difficulty gauging how much information to communicate. Despite acknowledging these challenges, surgeons generally felt confident that they overcome these challenges by using the tacit reasoning and non-clinical factors described earlier to tailor the risk-benefit discussion

according to patient-specific characteristics. Several surgeons added that these challenges are exacerbated when caring for non-English speaking patients and patients with limited English proficiency; however, this important domain was incompletely discussed.

3.4. Part 2: perceived role of risk data and calculators in consent process

As part of our semi-structured interviews, surgeons shared their perception of the role of risk assessment in the consent process and provided commentary on the perceived added value of risk calculators to preoperative consent. Discussion about risk communication and the use of risk calculators enumerated three key insights and practical considerations for the implementation of risk calculators and decision aids in surgical practice: (A) surgeons' current use of risk calculators is variable and often reserved for high-risk patients or operations; (B) surgeons prefer risk tools that supplement their own clinical judgment with objective analysis; and (C) surgeons report that individualized data and procedure-specific risk calculators increase value of risk calculators and are more useful for risk communication.

3.4.1. Surgeons' current use of risk calculators is variable and reserved for high-risk patients

While nearly two-thirds of surgeons (9/13, 69%) reported routine use of data to aid risk communication, only about 50% (7/13) endorsed regular use of risk calculators. About one third of all participants (4/13, 31%) surgeons specifically described using all-procedure risk calculators such as the American College of Surgeons NSQIP risk predictor to provide quantitative risk assessments for high-risk patients (either patients with multiple comorbidities or undergoing relatively high-risk procedures). In this setting, participants described using clinical judgment to stratify the patient into low, average or high risk and then using the NSQIP surgical risk output to support this reasoning. Most frequently, this data was beneficial for communicating risk to patients, providing objective data to patients. Of note, these surgeons reported focusing less on the calculated risk of individual outcomes, and more on communicating an overarching narrative that the patient was at risk for postoperative complications, and that consideration of alternative treatments may be warranted. Despite its potential value in providing patients with a measured perception of risk, most surgeons reported that the output of the risk calculator rarely altered the treatment decision, and specifically whether to operate or not.

3.4.2. Surgeons prefer risk tools that supplement judgment with objective analysis

In describing the value of risk calculators, surgeons emphasized the capacity of risk calculators to efficiently provide objective reasoning to support surgeons' clinical judgements and goals for patient education. For example, one surgeon cited using Carolinas Equation for Determining Associated Risks (CeDAR) in their informed consent for patients undergoing open ventral hernia repairs, which is a publicly-available mobile and online application to predict the risks and financial impact of wound-related complications following ventral hernia repair.[16] The surgeon valued this tool, as it provided an objective, personalized and data-driven assessment of how a patient could leverage preoperative rehabilitation to directly attenuate their risk of postoperative complications and the estimated related cost of complications.

3.4.3. Individualized data and procedure-specific outcomes increase value of risk calculators

Several surgeons reported that their use of all-procedure risk calculators was limited by the fact that the outcomes of such calculators are drawn from nationally aggregated, heterogeneous data. Participants reported that the denominators used by all-procedure risk calculators may inflate or overestimate complication rates that are lower in the surgeon's practice. In addition, the NSQIP risk predictor offers a non-precise mechanism to adjust for patients who are perceived by the end-user to be higher risk than average, specifically increasing the estimate by one standard deviation. One surgeon summarized their concerns: *"The NSQIP tool has that adjuster to adjust for a more complicated presentation or a more complicated patient that crudely tries to inflate some of those projected rates. I always found those outputs are part of the reason I don't like this tool … I always found that some of the outputs just seem off as I've used them."*

Surgeons expressed a keen interest in procedure-specific and institution-specific risk calculators, in which the outputs accurately pertained to and reflected their patients, both with regard to the local context of care and the outcomes of greatest importance to a particular operation (i.e., hypocalcemia after parathyroid surgery or pancreatic leak after pancreatectomy). Surgeons noted that such attributes would substantially increase the use and value of risk calculators in surgical risk assessment, risk communication and shared decision-making. To address current gaps, several surgeons (3/13, 23%) described using their own outcomes data when communicating with patients to establish more accurate expectations for the patient. In their experiences, surgeon-specific and procedure-specific data, rather than data from national databases, served a more impactful role in weighing risks and benefits and discussing treatment options.

3.5. Part 3: visual consent tool

In the final part of our interviews, surgeons provided feedback on the design and utility of our novel Visual Consent Tool prototype. Three primary themes emerged: (A) eliciting patient preferences is valuable to surgeons, but calculators should highlight postoperative outcomes that are implicitly and explicitly important to patients; (B) risk visualization may overemphasize the role of quantitative data in clinical-decision making; and (C) accessibility and efficiency are necessary attributes of future consent tools.

3.5.1. Eliciting patient preferences is valuable to surgeons, with caveats

Surgeons reported that eliciting patient preferences is a difficult aspect of shared decision-making and valued how the design of the VCT preemptively requires patients to identify their most salient postoperative concerns. However, some surgeons expressed concern that the VCT primed patients to consider postoperative outcomes that are not implicitly important to the patient or relevant to the clinical setting. Several surgeons emphasized that it is the responsibility of the surgeon to bring patient-relevant concerns into focus, noting that *"… the patient is only worried about whatever the doctor tells him to be worried about."*

Similarly, several surgeons asserted that most patients do not have the background to engage meaningfully with many of the perioperative complications included in all-procedure risk calculators, such as myocardial infarction, urinary tract infection, or ileus. Several surgeons suggested that rather than inviting patients to rank or contemplate the same perioperative outcomes provided in clinician-facing risk calculators, patients should be asked about outcomes that have more bearing on postoperative functional status, satisfaction, and quality of life. Non-procedure-specific

adverse events, such as venous thromboembolism or urinary tract infection, may distort decision-making, as they ultimately have less relevance on long-term outcomes and competing treatment options. Surgeons reported that quality-of-life outcomes, such as urinary incontinence or erectile dysfunction after prostatectomy, are likely more implicitly important to patients, more central to patient education and decision-making, and, critically, more closely reflective of the specific risks the surgeon might emphasize in a typical risk-benefits discussion.

After viewing data on perioperative outcomes as part of the VCT, one surgeon responded:

> "But for prostatectomy you know those [quality-of-life] data points are way more important, way more important, for making a choice regarding surgery and in particular when you have other options like pharmacotherapy or observation. So I'm not at all critical of the data you're showing. But I am saying in real life, that's not the data – if I were [the] patient – I would want to hear about. And if I were the surgeon, I don't think it's the data I would want to focus on."

In addition, participants noted that if patients are asked to rank postoperative outcomes that require clinical knowledge to interpret, contextualize, or factor into a decision-making calculus, the tool may create more questions than it answers, subsequently adding time to the process and limiting the tool's usability in clinical practice.

3.5.2. Risk visualization May overemphasize the role of quantitative data in decision making

Surgeons reported that the prototype's three distinct risk visualizations – bar graph, logarithmic scale, and an icon array – made it possible to appeal to a range of patients, with varying health and graphical literacy levels, and might enhance patients' comprehension of quantitative data.

However, despite the appeal of visualizations, most surgeons ultimately questioned the necessity of offering such granular risk data to patients, and its role in shared decision-making. First of all, most surgeons felt that the majority of patients did not seek the granular outcome data that was captured in the VCT. One surgeon summarized this point, stating "*It's very rare that a patient says, "Wait a minute, exactly how often does this complication happen?" Hardly ever do they want that information. If they want it, fine I'll give it to them. But I don't think it really helps the conversation at all.*" Rather, surgeons believed that patients preferred data to be processed by surgeons and then communicated in mechanisms that were succinct, prioritized and easily understood. Even when augmented by evidence-based visualizations, surgeons reported that the quantitative data rarely aligned with how patients preferred to be educated about treatment options. In this gist-based decision-making calculus, in which patients rely on physicians to provide education, guidance and reassurance, surgeons asserted that their role was to establish realistic expectations for future outcomes, not offer exact percentages about morbidity risk.

> "Even mortality - most people do not ask, "What's the likelihood of death associated with an operation?" They say, am I going to die? And I say, "No, you're not gonna die." … They don't want to know if they have a 37% chance of death. So the biggest thing I'm struggling with right now is sort of the patient-side need, for me to say that I think this is valuable or not valuable."

Furthermore, some surgeons questioned whether it was appropriate or realistic to ask patients to use quantitative risk assessments to aid their decision-making. In their opinion, having patients interpret the risk of postoperative morbidity burdens them with data they lack the clinical knowledge and experience to contextualize, especially when considering patients often rely on the surgeon's interpretation of that data to ultimately make a decision. Ultimately, several surgeons expressed that patients expect them to elicit relevant patient preferences, guide clinical decisions based on their expertise, and the identified patient preferences, and then communicate accurate assessments of risk to achieve general awareness and understanding.

3.5.3. Accessibility and efficiency are necessary for successful VCT implementation

In considering whether they would use the VCT, surgeons reported that the tool would need to complement the consent process, rather than serving as an additional component of the consultation and decision-making. Surgeons reported that an ideal digital consent tool would be readily incorporated into current clinical workflows, without adding time, clicks or cognitive load. An ideal tool would offer both a patient-facing and clinician-facing platform, enabling clinician-independent educational functions, granular clinician-facing outputs and efficient integration of the tool itself in consultation, decision-making and the consent process. Surgeons suggested that a successful tool would need to support EHR integration, use of pre-populated patient-specific data and automated generation of relevant consent documentation. Given the demands of clinical practice, any inefficiencies or added provider burden would represent significant barriers to the use and implementation of an additional decision-tool.

4. Discussion

We conducted semi-structured interviews with surgeons at two institutions to understand how we might advance risk assessment and risk communication during the informed consent process. Our qualitative analysis identified important insights regarding surgical consent, risk communication and the future of data integration and visualization in surgical decision-making and the informed consent process. Principally, we found a discrepancy between how surgeons approach communication about risk and how current risk calculators frame risk. Surgeons incorporate a range of clinical and non-clinical factors to determine how to approach risk communication and shared decision-making with individual patients. Critically, in comparing surgeons' responses to patient perspectives, as elicited in prior interviews with patients,[9,10] we observed that surgeons' perception of risk communication, and the importance of eliciting patient preferences to direct shared decision-making, did not consistently align with patient priorities. Lastly, this study elucidated key barriers to use of risk calculators in general and our novel VCT tool specifically, which must be addressed prior to greater adoption.

4.1. Principal findings

We found that non-clinical patient factors affect how surgeons approach risk communication and informed consent. In particular, our study identified a discordance between how surgeons report assessing risk and how current risk calculators assess risk, as outlined in Fig. 1. Surgeons described using a rubric of clinical and non-clinical factors to tacitly risk stratify patients and communicate risk effectively to individual patients in a way that conforms to ethical tenets of informed consent. This approach is distinct from standard risk calculators, which use patient demographics, patient and procedural characteristics and clinical context to assess risk. By considering additional patient-specific factors, and establishing a more comprehensive patient identity, we found that surgeons

leverage clinical and non-clinical inputs in a calculus that answers two major questions: (1) Is this patient high, average, or low risk?; and, (2) What is the most effective and efficient way to communicate this patient's risk to them?

Our findings about surgeons' approach to risk assessment and risk communication aligns with other reported findings in the literature. For example, one study argued that traditional all-procedure risk calculators fail to take into account surgeons' ability to optimize surgical technique for midline ventral hernia repairs. Other studies examining surgical risk assessment have indirectly referenced this concept by trying to apply all-procedure calculators to niche subspecialty surgical care, with more universalized tools such as NSQIP failing to accurately predict post-operative complications for conditions like pancreaticoduodenectomy, oncologic proximal femoral replacement, flap reconstruction following soft tissue sarcoma resection, and sacral tumor resection for chordoma.[17–23] While the mathematical validity of all-procedure risk calculators has been proven, these findings in the literature and conclusions from our study suggest that there is room to incorporate other inputs that may contribute to patient morbidity.

Surgeons' perception of risk and personalized risk communication significantly diverged from how patients value personalized risk communication as part of shared decision-making and their overall surgical care. Previous work by our group examined how patients perceive risks before surgery and how personalized risk communication, via the VCT, may advance the informed consent process.[10] In interviewing surgical patients, we observed a broad range of priorities and risk communication preferences; however, patients universally reported that the VCT, in which surgeons were not the sole driver of the discussion, increased their knowledge of procedure-specific complications, awareness of relevant risks and overall comfort with decision-making. Ultimately, patients report that by eliciting their priorities regarding their care, the VCT led to a deeper discussion of risk and greater understanding. Surgeons expressed concerns regarding the practical utility and added-value of highly-granular risk communication tools, featuring patient-curated outcome data. Surgeons noted that highly granular data may obscure the decision-making process, and that by aiming to elicit patient priorities, the VCT may prime patients to consider postoperative outcomes that are not implicitly important. While surgeons aim to understand patient preferences and advance patient knowledge, surgeons assert that contextualizing risk and prioritizing different potential outcomes remains their expertise – and the value of tailoring risk communication and decision-making based on their perception of a patient's non-clinical factors cannot be paralleled by a clinical tool alone.

Furthermore, we identified that all-procedure risk calculators may not advance real-world needs. There is a reluctance to use all-procedure risk calculators in clinical practice, given concerns regarding their applicability to individual procedures and patients, and their lack of data on functional outcomes and patient-centered metrics. Surgeons expressed a strong preference for procedure-specific risk calculators, which might reflect more relevant metrics and thereby add important, objective insights to the decision-making process. Current use of risk calculators in shared decision-making and the consent processes is limited by data availability, and appropriate procedure-specific and patient-specific benchmarks. In addition, surgeons questioned the value of all-procedure risk calculators in decision-making, indicating that the output rarely alters the decision to proceed with surgery or not. This sentiment is supported by the results of one study showing that surgeons' decision making did not change with and without the use of the ACS-NSQIP risk calculator.[3] Some surgeons in our study noted that in high-risk patients, all-procedure risk calculators may provide objective evidence that the patient is high risk, and thereby, support a decision to pursue non-surgical intervention. However, among average-risk and low-risk patients, most surgeons reported that the outputs of all-procedure risk calculators rarely impact patient decision making, and poorly advance patient awareness and understanding of relevant and realistic outcomes, due to the lack of procedural specificity.

4.2. Moving forward and broader context

Our interviews with surgeons revealed that surgeons are not relying on risk calculators to make clinical recommendations and navigate shared decision-making with patients. This supports our finding that surgeons are using non-clinical factors, such as health and risk literacy, to determine how to communicate risk and achieve shared decision-making. However, our knowledge of how surgeons identify and employ non-clinical factors remains limited, and thus, there is a gap in our understanding of how to optimally support surgeons in this process. While this study provides a suitable foundation, additional research is needed to characterize the clinical and non-clinical factors which contribute to a surgeon's risk assessment and their process for using this information to advance patient-specific risk communication and ultimately informed consent.

Future risk calculators and clinical decision tools should incorporate a broader approach to assessing risk and informing clinical recommendations. Unlike our proposed VCT, which only incorporates clinical factors, the design and content of clinical tools should aim to capture aspects of the comprehensive patient identity, which appears fundamental to a surgeon's current approach to risk communication and informed consent. Fundamentally, this approach to risk communication and shared decision-making undermines the current emphasis on quantitative risk calculation in everyday shared decision-making. If patient-specific factors, including non-clinical factors, better position the surgeon to provide realistic expectations for the patient and bring the surgeon and patient closer to a shared decision, then future risk calculators and clinical decision aids should incorporate non-clinical factors and broader elements of the patient identity.

While we aim to deliver more personalized approaches to risk communication, shared decision-making, and ultimately informed consent discussions, building evidence-based, procedure-specific databases and associated risk calculators is a clear first step forward. Nearly every surgeon that we interviewed emphasized that procedure and specialty-specific risk calculators would more closely align with their clinical needs. For instance, CeDAR, a procedure-specific risk calculator for open ventral hernia repair, was commended for its clinical utility, added-value in risk communication and impact on patient comprehension of risk—even motivating patients to offset their postoperative morbidity through individual actions such as smoking cessation and weight loss.[5] Developing additional procedure-specific risk calculators should be a priority among surgical specialties and academic organizations. In addition, as discussed in a recent publication by Hu et al., additional resources are needed to help support the documentation of individual goals and care preferences as they relate to clinical decision-making.[24]

4.3. Limitations

Our study had several limitations. First, we interviewed a relatively small cohort of 13 surgeons across two academic medical centers. While efforts were made to obtain a diverse cohort (in terms of both experience, specialty and health system), the findings may not be generalizable to all surgeons and accompanying patient populations. Further research across more health systems and with

a larger cohort is needed to further validate our findings. In addition, the current study evaluated risk assessment and communication across several disciplines. The themes identified revealed important insights regarding the disconnect between commonly used risk calculators and how surgeons assess and communicate risk. Future research is needed within subspecialities to further assess the nuance of risk communication and consent in individual domains. Second, we used a series of urologic cases, and related outcomes, for the prototype demonstration. While these cases represent a range of complexity and associated risk, obtaining feedback across a number of specialties, including the participant's own specialty, may strengthen study findings.

4.4. Conclusion

In this study, we conducted interviews with surgeons to assess their approach to obtaining informed consent and found that there is a significant divergence between current risk calculators and surgeon priorities when evaluating and communicating patient risk. Understanding the implicit heuristic used by surgeons during informed consent has the potential to significantly inform efforts to improve preoperative consent. Tools using risk data to facilitate shared decision-making may benefit from incorporation of non-clinical elements to improve generalizability across patient populations. Because surgeons' communication strategies and priorities are driven by clinical and non-clinical factors, next-generation shared decision-making tools should more directly tailor risk communication to patient attributes.

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None.

Author contributions

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Declaration of competing interest

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Appendix A. Supplementary data

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