A Patient-oriented risk communication tool to improve patient experience, knowledge and outcomes after elective surgery

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Background

Patients consistently report wanting more information about their expected outcomes after surgery; when patients have greater knowledge about surgery they are less anxious and more satisfied. However, most patients report being poorly informed about what to expect after surgery (such as how their risk of complications, or how long they will be in hospital). Our team has reviewed over 240 preoperative consultations for surgery patients at TOH, and in only 19% was there any documentation of a patient's personalized risks. Furthermore, even in cases where documentation was present, patients were provided with qualitative summaries, which are typically meaningless to patients. Following major surgery, 40% of patients experience at least one adverse event, and at TOH, 15% of patients experience a serious complication. Therefore, patients at TOH are undergoing surgery with the hope of experiencing a positive health outcome, but without clear, timely and engaged communication of the risks inherent in having surgery. This lack of communication directly contradicts the values and vision of TOH, and those articulated by the Elizabeth and Matthew Policy on Communication and Access.

More than 15 000 people have surgery at TOH every year, and many suffer complications. However, most patients are not informed of their personalized risks, despite this being a requirement of informed consent. Patients want more information about their risks and expected recovery from surgery, and lack of timely and effective communication of this information is not in keeping with TOH's vision and values. Therefore, our specific objectives are to: (1) develop a patient-oriented, personalized preoperative risk communication tablet application; and (2) to evaluate whether the application improves patient knowledge of their personalized risk profile, and satisfaction with their perioperative care.

Our own research on provision of individualized preoperative risk (documented for less than 1 in 5 patients)[1] is consistent with the existing literature.[2,3] Additionally, a lack of communication of possible risks of surgery is the leading complaint in post-surgery medicolegal cases.[4] Several studies demonstrate that patients feel that the information that they receive before surgery is insufficient, and that this is not adequately addressed by clinicians.[2,3,5] Furthermore, despite discussion of risks being potentially anxiety provoking, better informed patients tend to have less preoperative anxiety and be more satisfied.[6] We have completed a scoping review, which screened over 700 papers using a peer-reviewed, structured search strategy. We identified only 2 processes to communicate personalized risk to patients none that used technology, and none that had undergone evaluation of their effectiveness. Therefore, our proposed process and tablet application represent a novel intervention to address a key gap in perioperative patient-centered care.

We have evidence from our own preoperative clinics that patients can provide their personal health data with a high degree of accuracy (moderate to excellent agreement with physician health histories for all health conditions included in the NSQIP risk calculator).[7] And when applied to our TOH patients, the NSQIP risk calculator shows high levels of predictive accuracy (c-statistic >0.9 for mortality, >0.8 for serious complications and LOS; excellent calibration (Hosmer-Lemeshow $p>0.05$ for all outcomes; overall accuracy Brier score <0.1). Finally, systematic reviews demonstrate that when risk prediction tools and clinical information technology are integrated into care processes in a manner that leverages accurate, local data while engaging and involving patients, the likelihood of successful implementation is increased substantially.[8,9]

Methods

In collaboration with the TOH mHealth team we are developing a tablet-based, patient-oriented, personalized risk communication application. The application leverages features of inclusive design, meaning that it will be useable even by older patients, who represent the largest demographic of surgical patients at TOH. Older individuals are often less tech-familiar, and may have visual and motor challenges that can make mobile technology use difficult. The application features simple and consistent design, large well-lit buttons that tolerate tremor, and simple language. The process will be applied in preoperative clinics at TOH, where patients will be asked to provide their personal health history through a series of questions already used on our TOH preoperative health screener. These values will then populate the NSQIP Universal Risk Calculator, which we have calibrated to TOH data, to generate personalized risks of mortality, serious complications, and hospital length of stay. These risk estimates will be communicated directly to the patient using absolute risk estimates represented pictorially (best practice for risk communication to patients). Risk estimates will also be provided to the patient's clinician. To facilitate shared discussion between patients and physicians, we will also ask the patient to identify up to 3 benefits they hope to achieve from surgery, and patients and clinicians will be provided with 3 evidence-based questions known to support Shared Decision Making (What are my options? What are the pros and cons of each option? How do I get the support to make the right decision for me?).

Study Design

The application will be evaluated using a controlled before-after study design. Patients will be recruited using standardized procedures, and process and outcome measures will be recorded using the same tools and methods in both study phases to decrease the risk of measurement and selection bias. The knowledge questionnaire will be completed prior to the clinic appointment, and repeated after. The primary outcome measure will be the change in knowledge from prior to the clinic appointment to after comparing the pre- and post-implementation groups. The satisfaction (patient experience) questionnaire will be administered after each patient's clinic appointment.

Outcomes

Primary outcome: The primary outcome will be the change in patient knowledge of their risk profile from before their PAU appointment to after. A knowledge questionnaire has been developed using recommended standards.[10] The questionnaire will not test perceived knowledge, but will test factual items specifically related to the patient's personalized risk profile.[11] The pre- and post-appointment knowledge scores will be normalized on a 100 point scale [(questions correct/total questions)*100].

Secondary patient-centered outcomes: Patient experience will be assessed using a likelihood to recommend measurement based on a 10-point Likert scale as recommended by the Institute for Healthcare Improvement's Triple Aim measurement guide.[12] The value of the intervention will be defined using a patient-perceived equation as proposed by Morgan et al.[13] This value framework derives patient-value by dividing patient outcomes measured in natural units by total costs that borne to patients. We will also use a micro-costing technique[14] to estimate the total costs of the eHealth application that covers the costs of iPads, application development and training. Patient anxiety levels

will be measured using the Short Form State-Trait Anxiety Inventory,[15] and acceptability will be measured using a modified version of a validated 5-point Likert scale.[16]

Secondary clinician-centered outcomes: Likelihood to change management will be measured using a 5-point scale, acceptability will be measured using a 5-point Likert scale.[16]

Feasibility outcomes: Proportion of patients for whom a risk score can be calculated, proportion of missing data from patient-entered health questionnaire, proportion of patients with an expected length of stay $\geq 75^{th}$ procedure specific percentile where notification of expected prolonged length of stay is sent to the most responsible physician.

System outcomes: Hospital length of stay in patients with an expected length of stay greater than the 75^{th} procedure specific percentile (captured from linkage to hospital administrative data; the 75^{th} percentile is the most commonly used cut off to define prolonged LOS). [17,18]

Study population: We will recruit all consenting adults aged 18 or older seen in the Pre-Admission Unit prior to elective inpatient surgery at The Ottawa Hospital. Participants will be excluded if they are unable to communicate in English or French, or if they are unable to provide consent on their own due to cognitive impairment. Those scheduled for gastric bypass surgery will also be excluded due to significant differences in their pre-operative risk discussion.

During the post-implementation phase, patients will only be invited to participate in the study if the physician in clinic has provided consent for the study.

Sample Size: Sample sizes of 86 patients before and 86 after achieves 90% power to detect a minimally important difference in the mean improvement in knowledge test of 5 points (i.e., an improvement of 10 points after implementation versus 5 points before implementation) assuming a standard deviation for both groups of 10 and using a two-sided two-sample equal variance t-test at the 5% level of significance. 95 per group will allow for 10% dropout.

Data collection and management: Baseline and outcome data will be measured using various questionnaires (see study flow). Responses will be captured and stored via a RedCap data collection interface on a secure institutional research server. Length of stay data will be obtained by linking our data to our hospital Data Warehouse. All data will be stored in a privacy legislation-compliant manner.

Statistical analysis: Descriptive statistics will be used to compare recruitment rates and characteristics of patients in the pre- and post-implementation phases. Two-sample t-tests or chi-squared tests, as appropriate, will be used to examine statistical significance of differences. All outcomes will be expressed as biweekly means with graphical interpretation as a first step, using biweekly time series plots to detect the presence of any immediate versus gradual effects of intervention, and to examine the presence of trends, cyclical patterns, and outliers.

Primary outcome (change in knowledge from before to after PAU appointment) will be analyzed using a linear segmented regression analysis of the biweekly means. The presence of autocorrelation will be assessed using Durbin-Watson tests, as well as visual inspection of residual plots. If autocorrelation is present, an autocorrelation parameter will be included in the model. The effect of the intervention will be reported as level and trend changes after the intervention, together with 95% confidence intervals. Patient-level linear regression analysis will be additionally conducted to adjust for potential differences

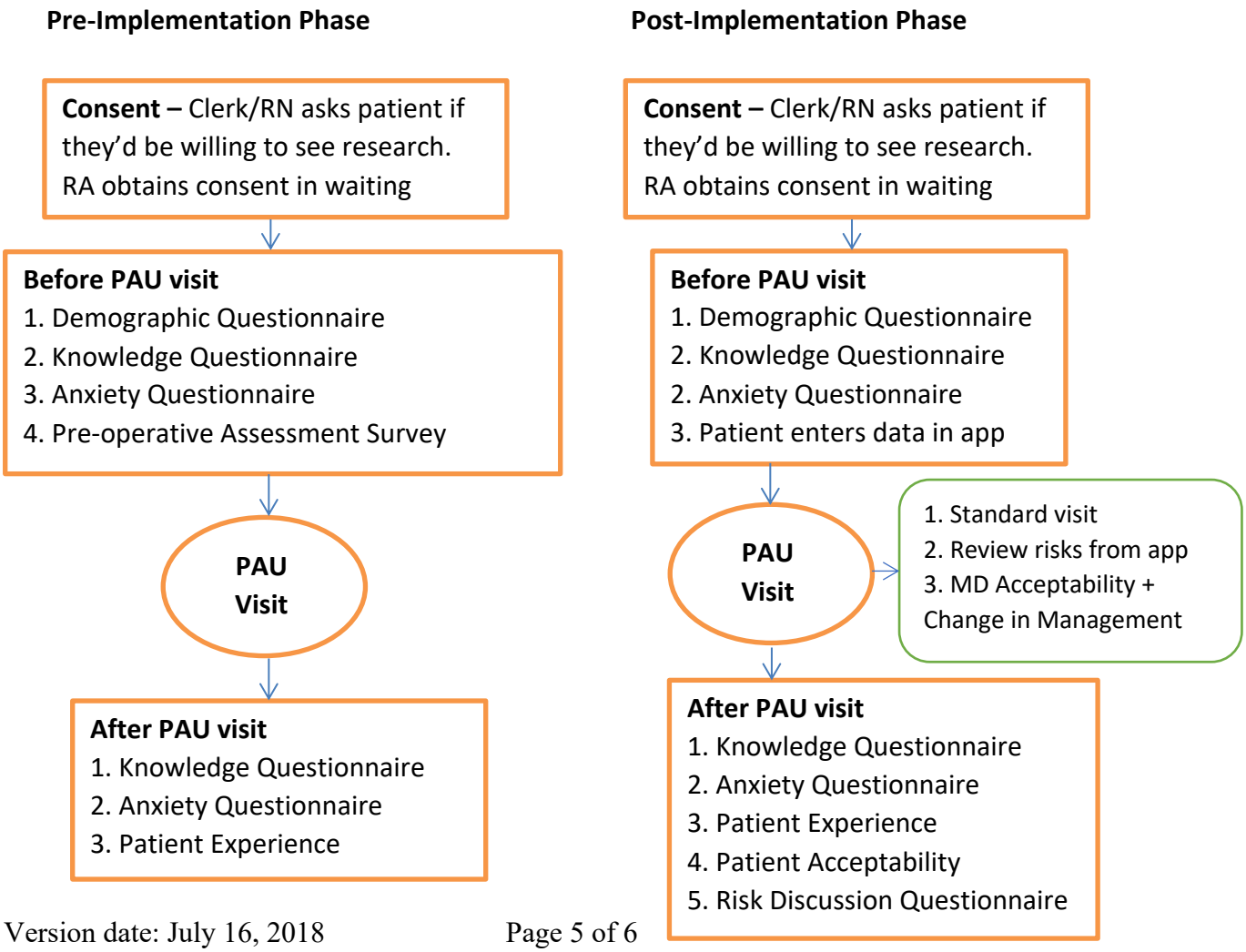
in patient characteristics from pre- to post-implementation and to examine any predictors of outcomes or subgroup effects (e.g., by patient age, sex, multimorbidity status, and procedure). Subgroup analyses will be conducted by including the subgroup variables as well as their interaction with the intervention indicator into the regression models. All analyses will be conducted using SAS v. 9.4 with $\alpha = 0.05$ set for statistical significance.

Secondary patient-centered outcomes (patient experience, value, anxiety, acceptability) will be analyzed as described for the primary outcome. Normalizing transformations will be considered for patient-level analyses in case of substantial skewness, while ordinal logistic regression will be used for outcomes measured using a 5 point Likert scale.

Clinician-centered outcomes (likelihood to change management and acceptability, both measured using a 5-point scale) will be analyzed using biweekly summary measures using segmented autoregression as described for the primary outcome.

Feasibility and system outcomes will be described using frequencies and proportions and tabulated overall, and by implementation phase. Hospital length of stay will be analyzed using segmented linear regression as described for the primary outcome.

Study Flow: Questionnaires



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