Journal of Pediatric Surgery 52 (2017) 859–863

Contents lists available at ScienceDirect

Journal of Pediatric Surgery

journal homepage: www.elsevier.com/locate/jpedsurg

Checklist to improve informed consent process in pediatric surgery: A pilot study

Mohammed Firdouse [a], Amy Wajchendler [b], Martin Koyle [c], Annie Fecteau [c,*]

[a] Faculty of Medicine, University of Toronto, Toronto, ON
[b] York University, Toronto, ON
[c] The Hospital for Sick Children (SickKids), Toronto, ON

ARTICLE INFO

Article history:
Received 27 December 2016
Accepted 23 January 2017

Key words:
Pediatric surgery
Informed consent
Checklist
Communication
Patient satisfaction

ABSTRACT

Purpose: The purpose of this study was to develop and validate a checklist to standardize surgical informed consent process.
Methods: A checklist was created following a literature search. Consent processes were observed from general surgery (GS) and urology (US) in the pre- and post-intervention phases. Competent patients/guardians were asked to complete a satisfaction questionnaire. All trainees and staff surgeons were interviewed on the checklist's utility.
Results: 73 observations (GS = 39, US = 34) and 66 observations (GS = 30, US = 36) were made in the pre- and post-intervention phase, respectively. Our checklist increased the frequency with which surgeons explained alternative treatments (pre-intervention 23.3% vs. post-intervention 81.8%), the role of trainees (15.1% vs. 72.7%), and the potential outcomes of not pursuing surgery (60.3% vs. 87.9%). The patient/guardian average satisfaction score increased between phases within GS (mean[standard deviation] 3.55[0.58] vs. 3.85[0.24]); $p = 0.002$), but not within US (3.53[0.61] vs. 3.52[0.54]); $p = 0.705$) or the overall sample (3.54[0.59] vs. 3.67[0.46]); $p = 0.329$). Interestingly, there was no significant improvement in patient/guardian average anxiety levels in GS ($X^2 = 0.069$, $p = 0.793$), US ($X^2 = 0$, $p = 1$) or the overall sample ($X^2 = 0.143$, $p = 0.706$) following the intervention.
Conclusion: Our checklist aids in standardizing the informed consent process. However, it did not significantly change satisfaction or anxiety levels of patients and guardians.
Type of study: Prognosis study.
Level of evidence: Level III.

1. Background

Informed consent is an ethical and legal requirement to any surgical intervention. Consent is obtained after thorough discussion of the diagnosis, indications for surgery, alternative treatments, associated risks, and the role of different surgical team members. The patient or guardian needs to demonstrate capacity to understand and agree upon the aforementioned topics before the healthcare team can proceed with surgery. Pediatric surgery is a unique niche of medicine in which a significant proportion of patients are too young to make decisions for themselves. Consequently, legally appointed substitute decision makers have the right to make medical decisions for them [1].

There is evidence that the informed consent process is subpar within the field of surgery [2,3]. Studies show that surgeons may overestimate patients' competence and that both guardians as well as pediatric patients may overestimate their comprehension of the information delivered [4–6]. Moreover, Hall et al. demonstrated that many physicians tend to skip vital components of an effective informed consent discussion such as alternative treatment options and benefits of the procedure [7]. Of note, surgeons have their own unique variations in executing the informed consent discussion, which results in a lack of consistent and standardized information being delivered [8,9]. This makes it difficult for patients and substitute decision makers to make an informed decision. Lastly, in the unfortunate event of a poor surgical outcome, inadequate and superficial documentation of informed consent discussions in medical records has been associated with increased risks of surgeons being sued [2,10].

Recent evidences in medicine have demonstrated that checklists like the Keystone ICU patient safety program [11,12] and the WHO surgical safety checklist [13–16], can standardize processes, improve patient safety, and decrease complications. A systematic review of the literature revealed procedure specific checklists for obtaining informed consent, however there were no generic checklists that could be used in any specialty and for any procedure [17]. We propose the innovation and implementation of a generic one-page checklist, incorporating all the essential ethical and legal elements of an informed consent discussion. The aim of our pilot project was to: 1) assess the current quality of surgical informed consents in an outpatient setting at a large tertiary

* Corresponding author at: The Hospital for Sick Children, 555 University Avenue, Toronto, ON, M5S1X8. Tel.: +1 4168137477.
E-mail address: annie.fecteau@sickkids.ca (A. Fecteau).

http://dx.doi.org/10.1016/j.jpedsurg.2017.01.023
0022-3468/

institution in Canada; 2) to suggest ways of improving the consent process; and 3) to evaluate the efficacy and value of our proposed checklist. We hypothesize that the introduction of our checklist will improve the informed consent process by standardizing the information provided to patients and reminding surgeons to document their discussions.

2. Methods

A one-page comprehensive checklist including all the important components of an informed consent checklist was created using the College of Physicians and Surgeons in Ontario (CPSO) guidelines [1]. All residents, fellows and staff surgeons in the departments of general surgery and urology at the Hospital for Sick Children (Toronto, ON) were invited to participate in the study. Considering the low risk nature of this study, a quality improvement project approval was obtained from the Quality and Risk Management Department at The Hospital for Sick Children. The study was divided into three phases:

- Phase I: Discussions of the informed consent process were observed during designated clinic days for two surgical divisions for a total of 4 weeks. They were evaluated for comprehensiveness against our proposed checklist (Appendix A). Competent patients or guardians were asked to answer an anonymous short 4-point Likert scale questionnaire (Appendix B) reviewing their satisfaction with the consent process and suggestions for improvement. A chart review of the documentation of the consent process was conducted.
- Intervention: Our proposed checklist was introduced to the surgeons and fellows of the 2 surgical divisions through a special morning round. The concept of assent, capacity, substitute decision makers and qualities of a good informed consent procedure were presented and discussed. Any questions or concerned were answered. They were then asked to use the checklist for the next 4 weeks as a tool to help in their consent process.
- Phase II: The consent process was observed post intervention and evaluated against the checklist. Patients or guardians were asked to complete the same questionnaire and charts were reviewed for documentation. Audiotaped anonymous interviews were conducted with the surgeons and fellows (specialty and staff versus fellow was noted) after completion of the study to determine their views on the helpfulness of the checklist. A third party who was not involved in the observation of the consent processes asked standardized open-ended questions (Appendix C) for all interviews.

Data were analyzed using descriptive and inferential statistics on Microsoft Excel and SPSS. Chi squared (X^2) test and frequencies were used to compare survey data. Written comments were transcribed and analyzed by themes. Subgroup analysis between general surgery and urology may be performed if numbers permit.

3. Results

3.1. Checklist

A total of 73 (general surgery = 39, urology = 34) and 66 (general surgery = 30, urology = 36) observations of the informed consent process were made in the pre and post-intervention phase. The use of the checklist improved the quality of the informed consent process by increasing the frequency with which surgeons and trainees explained alternative treatments (23.3% vs. 81.8%), explained consequences of not pursuing surgery (60.3% vs. 87.9%), and explained the role of trainees in the surgery (15.1% vs. 72.7%). All participants (100%) in both pre- and post-intervention phase included patient identifiers on the consent form, included an interpreter if needed, explained the diagnosis, risks of the procedures, and answered any questions that the patient or the guardians had. Refer to Fig. 1 and Table 1.

3.2. Patient/Guardian satisfaction

136 survey responses were collected from patients and/or guardians (response rate = 97.8%). The responses to the questions were graded on a 4-point Likert scale where 1 = totally disagree, 2 = disagree, 3 = agree and 4 = totally agree. Patients'/Guardians' average satisfaction score significantly increased between phases within general surgery (mean[standard deviation] 3.55[0.58] vs. 3.85[0.24]); p = 0.002), but not within urology (3.53[0.61] vs. 3.52[0.54]); p = 0.705) or the overall sample (3.54[0.59] vs. 3.67[0.46]); p = 0.329). Interestingly, there was no significant improvement in patients' or guardians' average anxiety levels with the implementation of our checklist (1.79/4 pre vs. 1.94/4 post). Chi squared analysis of the difference in average anxiety levels amongst subgroups in general surgery ($X^2 = 0.069$, p = 0.793), urology ($X^2 = 0$, p = 1) or the overall sample ($X^2 = 0.143$, p = 0.706) were insignificant. Refer to Table 2.

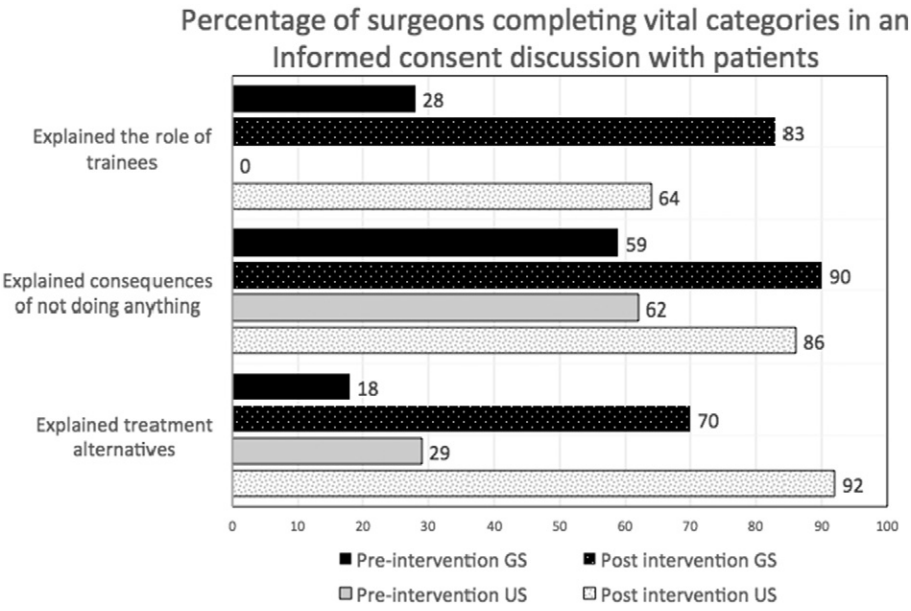

Fig. 1. Difference in percentage of surgeons who completed vital components of an informed consent process with and without using the checklist. P < 0.05 for all categories unless otherwise noted.