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Patient Safety Tip of the Week

November 26, 2024

eConsent: Friend or Foe?

We read with both interest and concerns a recent publication about electronic surgical consent delivery via patient portal. Trang et al. (Trang 2024) recently undertook a study to evaluate the association of eConsent delivery via the patient portal (PP) with operational efficiency and patient engagement.

At UCSF (University of California, San Francisco) procedural consent forms transitioned from paper to digital in February 2023 for all adult patients undergoing procedures in a main operating room at their 3 main hospitals. Their eConsent surgical consent process is as follows: The surgeon discusses informed consent with the patient. After this discussion and submitting the electronic case request via the EHR, the eConsent form can be generated by the surgeon or their designee (resident, fellow, or advanced practice provider). The attending primary surgeon must review and sign the eConsent form. It is then automatically sent to the patient via PP if the patient has an active account and the surgeon selects this option. Patients without PP accounts or who do not sign via PP then sign on a hospital tablet (iPad; Apple Inc) on the day of surgery.

In their study, 8478 surgical eConsents were generated for 7672 unique patients, of which 5318 (62.7%) were signed on hospital tablets and 3160 (37.3%) through the patient portal. Patients who signed eConsents via the PP were younger than those who did not, more commonly White, and more commonly spoke English as a preferred language. Signing the eConsent on a hospital tablet rather than via the PP was more common in those cases with more than 1 primary surgeon or with a higher postoperative level of care, or when the eConsents that were sent to the PP on the same day of surgery rather than before. The median time patients waited to sign an eConsent on the PP was 105 (range 178-528) minutes but once they clicked onto the document it was signed in a median of 2 minutes. Patients had somewhat mixed views of the eConsent process but all participants viewed the informed consent discussion with the surgeon as the most important part of the consent process. Many reported either skimming the paperwork or scrolling to the bottom and signing, relying on the relationship and trust they had with their surgeon and hospital.

Compared with patients who signed an eConsent 1 day or more before surgery, patients who signed on the same day had significantly higher odds of having a delayed first case (OR 1.72). This association remained when the model adjusted for age, sex, race and ethnicity, limited English proficiency, case classification, and surgical service (OR 1.59). The authors noted that surgical case delays are frustrating to staff and patients and are associated with financial costs as well as worse patient outcomes.

They note additional benefits of eConsent via the PP include reduced need for nursing staff to collect signatures and potentially obviated need for a signature witness (due to the authentication and security features of the PP).

Yes, the improved OR efficiency is nice, but the study reaffirms that the discussion and relationship between surgeon and patient remain central to the informed consent process.

In our Patient Safety Tips of the Week for September 10, 2013 "Informed Consent and Wrong-Site Surgery" and September 10, 2024 "Scheduling and Informed Consent Contribute to Wrong-Site Surgery" we discussed the important role informed consent plays in promoting or preventing wrong-site surgery. Having a signed eConsent and the surgical case request form available in the EHR means all parties in the OR should have access to them during the pre-op huddle or surgical timeout. And good electronic case scheduling forms and eConsent forms can help avoid handwriting errors and inappropriate use of abbreviations that contribute to wrong-site surgery.

Reeves et al. (Reeves 2020) made a case that eConsent could actually avoid many of the errors we often see with paper-based consent forms. They note that handwritten, paper-based forms can have error rates as high as 50%, and that those errors can affect patient experience, patient understanding, and clinic and operating room efficiency and can result in litigation. They reported on a pilot study at UCSD (University of California, San Diego). They found an error rate of 1 of 100 (1%) for eConsents and 32 of 100 (32%) for paper-based forms. Incomplete items in paper forms included date/time (18 of 100), signature (8 of 100), discussion of risks (6 of 100), procedure name (2 of 100), and name of the operating surgeon (2 of 100). The illegibility rate was 8 of 100 (8%).

The authors further note that eConsents are environmentally friendly and eliminate the need to fax, scan, copy, or file, allowing support staff to focus on direct patient care. An eConsent is permanently present in the electronic health record and cannot be lost. The documentation of surgical risks was required; however, similar to handwritten forms, documentation appeared to be of variable quality using universal eConsents.

Our main concern about eConsents is that they do not ensure that the most important part of the consent process, the discussion with the surgeon or person performing the procedure, has been adequate. That was echoed by the editorialists (Hwang 2024) who reviewed the Trang study. They point out that the cursory nature of the eConsent review, coupled with feedback from the qualitative interviews, raises concerns that patients may not sufficiently review the eConsent to provide a truly informed consent. We also think

that it may be too easy to simply click on a link that sends the eConsent form to the patient portal without verifying that the truly "informed" part of the discussion has taken place.

Some of our prior columns related to wrong-site surgery:

September 23, 2008 "Checklists and Wrong Site Surgery"
June 5, 2007 "Patient Safety in Ambulatory Surgery"
July 2007 "Pennsylvania PSA: Preventing Wrong-Site Surgery"
March 11, 2008 "Lessons from Ophthalmology"
July 1, 2008 "WHO's New Surgical Safety Checklist"
January 20, 2009 "The WHO Surgical Safety Checklist Delivers the Outcomes"
September 14, 2010 "Wrong-Site Craniotomy: Lessons Learned"
November 25, 2008 "Wrong-Site Neurosurgery"
January 19, 2010 "Timeouts and Safe Surgery"
June 8, 2010 "Surgical Safety Checklist for Cataract Surgery"
December 6, 2010 "More Tips to Prevent Wrong-Site Surgery"
June 6, 2011 "Timeouts Outside the OR"
August 2011 "New Wrong-Site Surgery Resources"
December 2011 "Novel Technique to Prevent Wrong Level Spine Surgery"
October 30, 2012 "Surgical Scheduling Errors"
January 2013 "How Frequent are Surgical Never Events?"
January 1, 2013 "Don't Throw Away Those View Boxes Yet"
August 27, 2013 "Lessons on Wrong-Site Surgery"
September 10, 2013 "Informed Consent and Wrong-Site Surgery"
July 2014 "Wrong-Sided Thoracenteses"
March 15, 2016 "Dental Patient Safety"
May 17, 2016 "Patient Safety Issues in Cataract Surgery"
July 19, 2016 "Infants and Wrong Site Surgery"
September 13, 2016 "Vanderbilt's Electronic Procedural Timeout"
May 2017 "Another Success for the Safe Surgery Checklist"
May 2, 2017 "Anatomy of a Wrong Procedure"
June 2017 "Another Way to Verify Checklist Compliance"
March 26, 2019 "Patient Misidentification"
May 14, 2019 "Wrong-Site Surgery and Difficult-to-Mark Sites"
May 2020 "Poor Timeout Compliance: Ring a Bell?"
September 14, 2021 "Wrong Eye Injections"
October 5, 2021 "Wrong Side Again"
November 9, 2021 "Ensuring Safe Site Surgery"
February 15, 2022 "Wrong-Side Chest Tubes"
May 2022 "PPSA: Updated Wrong-Site Surgery Recommendations"
June 13, 2023 "Preventing Wrong-Site Surgery"
November 2023 "Importance of Timeouts Outside the OR"
January 30, 2024 "Is Your Surgical Safety Checklist Working?"
September 10, 2024 "Scheduling and Informed Consent Contribute to Wrong-Site Surgery"

References:

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