Informed Consent: A Template for Process Improvement

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Our department recently sought to improve and upgrade our informed consent processes. The goal was to develop a system that allows healthcare professionals to easily locate and deploy standardized, electronic informed consent forms containing the information essential to obtaining informed consent from patients undergoing interventional radiology procedures at our institution.

In this review, we share the challenges we faced and the steps we took, with the goal of helping encourage other healthcare facilities facing similar challenges to adopt standardized, digitally based documentation and facilitate more consistent, and potentially more accurate, informed consent processes.

Taking Inventory

The challenges we faced were daunting. Across our entire enterprise, the radiology department had many different paper and electronic informed consent form templates that 1) were either difficult to locate or nonexistent; 2) lacked standard wording; and/or 3) lacked some of the required information regarding the risks, benefits, and alternatives for specific procedures.

As a result, we believed our informed consent process could be impaired, potentially leaving our institution open to medicolegal risks associated with failure to provide patients with sufficient information to give their truly informed consent to undergo a given procedure. Standardized, electronic consent forms have been shown to result in an improved informed consent process with greater consistency and lower error rates.[1]

As every healthcare professional knows, informed consent is a legally mandated, central part of shared decision making between patients and their healthcare professional. The term "informed consent" itself first appeared in a 1957 California Court of Appeals case, Salgo v Leland Stanford Junior University Board of Trustees.

The case involved a patient who had filed suit against his physician for failing to inform the patient beforehand of the risks associated with a procedure that had left the patient permanently paralyzed from the waist down. The Court ruled in the patient's favor, finding that a physician "subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent."[2]

Some components of the informed consent process vary by state, but most require the doctor and/or a qualified member of their team to discuss the risks, benefits, and alternatives of a given procedure with each patient. The conversation must be guided by the informed consent document, a signed copy of which serves as the official record of this important physician-patient interaction.[3]

Consolidating Informed Consent Documentation

We began our quality improvement effort by evaluating the current state of our informed consent processes. We found that hardcopy consent forms were used inconsistently throughout our entire healthcare system; one of our hospitals used hardcopy consent forms for up to 65% of procedures and even added procedure-specific risks by hand in some cases. Almost 90% of templates required some form of alteration, including about one-third of which were missing information; approximately 10% of templates were missing entire sections on risks, benefits, or alternatives.

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We also reviewed all procedures performed in our department during the preceding year. This analysis revealed that certain procedures, such as prostate and pancreatic biopsies, were never performed.

As a result of this comprehensive review, we were able to eliminate some templates and consolidate multiple others into one electronic template that can be customized to generate consent forms with language relating to procedure-specific risks, benefits, and treatment alternatives. Our radiology consent forms now exist as interactive "smart forms" in our electronic health record (EHR) system.

Standardizing Content

The greatest challenge we addressed at this stage related to form content; specifically, whether to include language relating to rare but highly morbid complications on our consent forms, as including such risks may cause undue patient anxiety. In addition, precise mortality risks for some procedures are not available, either because they have not been studied or because they cannot be established. For example, regarding the transjugular intrahepatic portosystemic shunt (TIPS) procedure, it is "impossible … to separate the risk of death due to the condition warranting the TIPS"[3] from the risk of death due to the procedure itself, as the 30-day mortality rate of TIPS is between 3% and 44%.[4]

Owing in part to the difficulty of such determinations in a variety of procedures, we were unable to find a compilation of mortality rates in literature searches and gathered this information from numerous sources.[5]

Confirmative data came from a recent retrospective cohort study which established a consensus that procedures deemed "high risk" carry a 1% or greater risk of death directly attributable to the procedure itself.[6] We chose this as our benchmark in determining whether to include risk

of death on our informed consent forms for procedures.

In addition, a 2019 study involving 184 interventional radiology medicolegal cases litigated between 1963 and 2018 found that 73% of cases pertained to the generally higher-risk vascular procedures, with inferior vena cava (IVC) filters alone comprising 12% of cases.[7] This study also found that a lack of informed consent was relevant in 14% of all cases.

Accordingly, we added risk of death to our templates for lung biopsy, TIPS placement, transarterial chemoembolization (TACE), and IVC filter placement. In addition, owing to the high risks and litigation associated with IVC filter placement, we added language specific to device fracture, embolization, migration, and failure to prevent pulmonary embolism.

As a result of these efforts, our radiologists now overwhelmingly believe the efficiency of our informed consent process has been dramatically improved; hardcopy informed consent forms are now used in only 1% of all cases and procedures.

Some Challenges Remain

Making the changes to our consent templates and forms required the assistance of our radiology information system (RIS) administrators. We had hoped to introduce keywords to facilitate more efficient searching for specific consent forms. However, our RIS only allows searching by the first word of each procedure. Consequently, we renamed some procedures to improve search accuracy. "Fluid/tissue aspiration," for example, became "aspiration of fluid/tissue." We have requested more robust search functionality in future updates to our EHR system.

This undertaking also revealed the value of implementing a periodic, formal review of our informed consent processes, as we believe the lack of a structured program of this type led to many of the issues that prompted our effort to improve our department's informed consent process. We plan to implement periodic reviews in the near future and recommend this to anyone planning a similar improvement project.

Conclusion

As a result of our quality improvement efforts, vetted, more accurate radiology informed consent documents are now available as interactive documents in our EHR system.

Indeed, we believe our experience demonstrates that a thorough review of the literature and developing departmental consensus around procedural benefits, risks, and alternatives while transitioning to RIS-based templates and forms can improve the entire informed consent process for healthcare providers and patients.

References

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