Editorial

Informing the Consent Process

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Because the legal and ethical aspects of informed consent are often foremost in clinicians’ minds, it is easy to forget that the purpose of informed consent is to aid in decision making. Informed consent forms, for example, are often written with legal and institutional priorities in mind, and patients in turn assume that the primary purpose of such forms is to protect physicians and their institutions. Indeed, it is understandable that clinicians may take little intrinsic interest in the informed consent process when seen as an external legal requirement.

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What would happen if the informed consent process were truly seen as an opportunity for optimizing decision making? The traditional attempts at improving informed consent tend to focus only on patient outcomes, typically on whether their factual understanding or satisfaction improves. In this issue of Circulation: Cardiovascular Quality and Outcomes, Arnold and colleagues describe their initial experience using a Web-based individualized risk assessment tool (the Patient Refined Expectations for Deciding Invasive Cardiac Treatments [PREDICT]) as part of the informed consent process for percutaneous coronary intervention (PCI). The results of their study show that, in comparison with historical controls, patients undergoing the customized consent were in general much more involved (and perceived themselves to be so) in the consent process, and, interestingly, the customized consent seems to have affected the choice of stents used. These data suggest that a consent process that successfully engages the clinician and patient affects not only the patient’s perception of informed consent but also the care itself.

Fundamental to the PREDICT program (and informed consent in general) is an accurate estimation of risk. Risk assessment has taken on an increasingly important role in cardiology in response to the Institute of Medicine’s mandate to improve the quality of medical care. Accurately adjusting for patient risk is an essential part of quality assessment because clinical outcomes (such as death) are often used as a proxy of quality. Indeed, mortality models have been developed for acute coronary syndrome and PCI that include patient demographics and concomitant diseases (eg, diabetes, chronic kidney disease). Although death is an attractive outcome to model when assessing quality, other outcomes are important in optimal decision making. In the case of PCI, relevant outcomes of the procedure include not only death but also bleeding and restenosis. To accurately convey these risks to patients whose consent is being sought for PCI, the PREDICT program is based on predictive models for vascular complications and restenosis with either drug-eluting or bare metal stents. This program allows providers to input patient-specific demographic and medical information to generate an estimate of the individual patient’s risk for the relevant outcomes.

Such customized patient-specific data as part of the informed consent process seems to have had an important effect on both the patients and the physicians in the study of Arnold et al. The main patient outcomes from the study indicate improvements in the patients’ sense of engagement—ie, more patients reported having read the form, feeling less anxious, feeling more involved in the decision making, and having been told of the risks (even though they did not recall the complications more accurately). Moreover, the impact of the informed consent process on the type of stent used (if real, rather than a secular trend) likely reflects providers feeling more confident in their recommendations because of the patient-specific risk profile made available to them and to the patients. This resulted in patients at higher risk for restenosis and lower risk for bleeding receiving drug-eluting stents, whereas those at lower risk for restenosis and higher risk for bleeding received bare metal stents.

The study by Arnold et al has limitations. The study is observational, historical controls were used, and there were significant fluctuations in the use of drug-eluting stents during the study period. Therefore, a fundamental question is whether these outcomes are a direct result of the specific program implemented by Arnold and colleagues or if they could be achieved with any informed consent process that fully engages providers and patients. As the authors note, however, their study certainly lays the foundation for a more definitive future work.

Given that the study by Arnold and colleagues underscores the importance of the clinician–patient interaction, what are the next applications of individualized risk assessment? The most logical extrapolation would be to apply these methods to other cardiac procedures for which outcomes have been modeled. However, there are formidable challenges to the widespread application of this strategy. First, there is a dearth of statistical models predicting clinical outcomes from many invasive cardiac procedures. This is especially true for highly specialized procedures, such as percutaneous closure of atrial septal defects or valvuloplasty, or for common procedures in...
which adverse outcomes are rare, such as peripheral arterial intervention. Second, the risk of the outcome can be dependent on how the outcome is defined. For example, studies suggest that the incidence of bleeding during hospitalization for non–ST-segment elevation acute coronary syndrome varies according to the bleeding definition.\textsuperscript{12} In addition, the association between a bleeding event and subsequent death is also dependent on the definition.\textsuperscript{13} Therefore, the outcome must include data elements that are clinically meaningful to the patient and provider. Third, most statistical models of outcomes examine mortality rate rather than other risks associated with these procedures such as bleeding, stroke, and repeat revascularization. As mentioned previously, the risks of these other adverse outcomes are important to convey to patients during the informed consent process. Indeed, an elevated risk of bleeding, for example, may prompt a decision to alter anticoagulant therapy during PCI\textsuperscript{14} or choose alternative vascular access.\textsuperscript{15} Finally, the incidence of adverse outcomes changes over time as procedures become more sophisticated. For example, the incidence of death or myocardial infarction after PCI has declined steadily over time\textsuperscript{16}; therefore, risk models must be revisited and updated periodically to reflect contemporary estimates of adverse outcomes.

The informed consent process has often been taken for granted in modern medicine. In the current era of PCI, in which multiple risk scores exist, this is no longer acceptable. The study by Arnold should serve as a call to action not only for the profession to develop and validate risk models for important clinical outcomes related to common cardiac procedures but also for centers to implement systems of informed consent that more completely engage the clinician and patient. Individualized risk assessment is an essential component of such a system, and the study by Arnold and colleagues serves to remind us of the importance of the clinician–patient interaction. It also provides a template for an improved approach to informed consent. The power of such an approach is that both patient and provider make informed decisions, which leads to improved clinical care.

Disclosures

None.

References


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