Converting the Informed Consent From a Perfunctory Process to an Evidence-Based Foundation for Patient Decision Making

Suzanne V. Arnold, MD, MHA; Carole Decker, RN, PhD; Homaa Ahmad, MD; Olawale Olabiyi, MD; Surya Mundluru, MD; Kimberly J. Reid, MS; Gabriel E. Soto, MD, PhD; Sarah Gansert, BS; John A. Spertus, MD, MPH

Background—Standard consent forms result in highly variable communication between patients and physicians. To enhance the consent process and facilitate shared decision making, we developed a World Wide Web–based program, PREDICT (Patient Refined Expectations for Deciding Invasive Cardiac Treatments), to systematically embed patient-specific estimates of death, bleeding, and restenosis into individualized percutaneous coronary intervention informed consent documents. We then compared patients’ experiences with informed consent before and after implementation of PREDICT.

Methods and Results—Between August 2006 and May 2007, patients undergoing nonemergent cardiac catheterization who received the original consent form (n = 142) were interviewed and compared with those who received the PREDICT consent form (n = 193). Hierarchical modified Poisson regression models were used to adjust for clustering of patients within physicians. Compared with the original consent group, those in the PREDICT group reported higher rates of reading the consent form (72% versus 44%, relative risk [RR] 1.64, 95% confidence interval [CI] 1.24 to 2.16), increased perception of shared decision making (67% versus 45%, RR 1.48, 95% CI 0.99 to 2.22), and decreased anxiety (35% versus 55%, RR 0.70, 95% CI 0.53 to 0.91). Although there were no differences between groups in patients’ ability to name complications of percutaneous coronary intervention, among patients who identified either death or bleeding as a potential complication, more patients in the PREDICT group recalled being informed of their estimated risk of that complication (death: 85% versus 62%, RR 1.37, 95% CI 1.03 to 1.82; bleeding: 92% versus 71%, RR 1.28, 95% CI 1.06 to 1.56).

Conclusions—In this preliminary, single-center experience, individualized consent forms with patient-specific risks were associated with improved participation in the consent process, reduced anxiety, and better risk recall. PREDICT is one potential strategy for improving the current practice of obtaining informed consent for percutaneous coronary intervention. (Circ Cardiovasc Qual Outcomes. 2008;1:21-28.)

Key Words: informed consent ▪ angioplasty ▪ decision making, shared

The Institute of Medicine has challenged the American healthcare system to be more patient centered, evidence based, and transparent, encouraging physicians to include patients in decisions about their care. Patients have also expressed a desire to be fully informed and to play an active part in making decisions about their treatment. The current process of informed consent, a critical opportunity to inform patients of treatment options and risks, falls far short of achieving these goals. Several studies in elective surgery have demonstrated that although patients believe that they are adequately informed during the consent process, they cannot recall the information that was provided. In the few studies that examined the consent process in cardiac catheterization, patients tended to overestimate the benefits of percutaneous coronary intervention (PCI) and to forget the risks of the procedure.

Editorial see p 7
Clinical Perspective see p 28

Given the generic legal informed consent documents often used for PCI, the amount and quality of the education patients receive before the procedure depends primarily on undocumented, qualitative aspects of physician-patient discussions, a process that is highly variable. Moreover, at the time of...
obtaining consent, physicians are charged with the responsibility to inform patients about their risks of complications, which can vary greatly from patient to patient. Because of a lack of viable alternatives, physicians typically provide vague estimations of risk based on their experience and intuition, which have been shown to be poor estimates of patients’ actual risks of complications.

To overcome the communication barriers surrounding education and risk estimation and to facilitate the process of informed consent, we developed and implemented a World Wide Web–based program, PREDICT (Patient Refined Expectations for Deciding Invasive Cardiac Treatments), to systematically embed patient-specific estimates of risk, derived from validated preprocedural multivariable models, into individualized PCI consent documents. We also rewrote the consent form to lower its literacy level (from a 16th-grade level to the 8th-grade level) and to provide visual depictions of hard-to-understand terms, such as angiography and stent implantation. These steps sought to transform a perfunctory phase of clinical care into an educational opportunity to better inform patients about their treatment and to enable them to participate more actively in their care.

The goal of PREDICT is to both enhance and standardize the informed consent process before PCI and to permit both patients and physicians to assess estimated complication risks based on clinical evidence rather than intuition. The goal of the present study was to evaluate the patients’ experiences with the PREDICT consent form compared with the original consent process. As an exploratory analysis, we also investigated the association of PREDICT use with the selection of a drug-eluting stent (DES) or bare-metal stent (BMS). Given that our tool transparently displays the risks of clinical restenosis with each treatment, we anticipated that BMS might be used preferentially in those at low risk for restenosis, for whom the absolute benefits of DES are lower.

Methods
PREDICT Consent Form Development and Implementation
The development and integration of PREDICT into patient care has been described previously. In brief, after design and construction of the technological framework, statistical predictive models were rigorously developed for 4 potential outcomes of PCI (periprocedural bleeding risks, mortality, and clinical restenosis with a BMS or DES). These 4 outcomes were selected on the basis of their value derived estimated risks of complications (Table 1) were compared exact tests for categorical variables, as appropriate. The model-derived estimated risks of complications (Table 1) were compared between groups with t tests on the logit scale because of nonnormality of the raw probabilities. Because the quality of informed consent is dependent on the physician who obtains consent from the patient, we used hierarchical modified Poisson regression models to adjust for the clustering of patients within a specific interventional cardiologist (n=12, median cluster size =29 [interquartile range 10 to 37]) who obtained the informed consent and performed the PCI. Typical analyses use logistic regression to estimate adjusted odds ratios, which are then generally interpreted as relative risks (RRs); however, in the present study, the events being modeled were not rare, such that odds ratios were poor estimates of RRs. To address

Nurses collect and enter 22 patient characteristics (several of which—including age, sex, and laboratory data—are autopopulated from an HL7 [Health Level Seven] interface with other electronic hospital systems) into the Web-based program, which then creates the patient’s individualized, evidence-based informed consent document (see Figure 1 for sample consent document). The document is provided to patients for review before they discuss the procedure with the physician and sign the consent form. In the 4 hospitals in the Saint Luke’s Health System, interventional cardiologists perform all diagnostic catheterizations with the possibility of PCI during the same procedure. Thus, a single consent document is completed for catheterization with possible PCI, and all discussions about risks and benefits of PCI occur before the diagnostic catheterization.

Patient Population
Because PREDICT was integrated into the routine process of care for obtaining informed consent at the time of cardiac catheterization, we evaluated the tool using a prepost design. The pre-PREDICT period included consecutive patients undergoing nonemergent cardiac catheterization with possible PCI during the 6 weeks before the implementation of PREDICT at each of the hospitals, which comprised the group of patients who had received the original consent form. The post-PREDICT group included consecutive patients who had received the patient-specific PREDICT consent forms during the 6 weeks after implementation. Because the informed consent was generated before diagnostic angiography, the population included all patients who underwent nonemergent cardiac catheterization, with or without PCI, during the study period. Patients were excluded if they required emergent cardiac catheterization (including those with ST-elevation myocardial infarctions), used a surrogate for informed consent, or were unable to complete the study interview.

Study Protocol
Patients were interviewed by a nurse or medical student within 48 hours of their procedure in a structured interview (tool available on request). Patients were first asked if they had read the consent form. If they reported having read the form, they were then asked a series of questions, based on a previously validated tool for oncology clinical trials, that were designed to judge the ease of reading, ease of comprehension, and anxiety related to the consent document and process. In early 2007, the tool was modified to additionally determine the patient’s recollection of potential complications from PCI and the estimated risk of those complications occurring. Patients were first asked whether they had had a conversation with the physician about the complications of the procedure. Those patients who reported having had such conversations were asked, in an open-ended question, to list any potential complications of cardiac catheterization. If a patient was able to identify a complication, he or she was then asked what their risk was of that complication occurring. Data on type of stent placed (BMS versus DES) were also collected postprocedurally for all patients who underwent PCI. Institutional Research Board approval was obtained, and a waiver of informed consent was issued.

Statistical Analysis
Clinical and demographic patient characteristics were compared between groups with t tests for continuous variables and χ² or Fisher exact tests for categorical variables, as appropriate. The model-derived estimated risks of complications (Table 1) were compared between groups with t tests on the logit scale because of nonnormality of the raw probabilities. Because the quality of informed consent is dependent on the physician who obtains consent from the patient, we used hierarchical modified Poisson regression models to adjust for the clustering of patients within a specific interventional cardiologist (n=12, median cluster size =29 [interquartile range 10 to 37]) who obtained the informed consent and performed the PCI. Typical analyses use logistic regression to estimate adjusted odds ratios, which are then generally interpreted as relative risks (RRs); however, in the present study, the events being modeled were not rare, such that odds ratios were poor estimates of RRs. To address

Downloaded from http://circoutcomes.ahajournals.org/ by guest on April 20, 2017
Note: This is a fictitious patient record and is intended for demonstration purposes only.

Patient Name: Doe, John
Date of Birth: 01/01/1960
Medical Record Number: 0000404360

Consent for Coronary Angiography ("Heart Dye-Study") and/or an Intervention Procedure ("Opening blood vessels in the heart")

We are asking you to sign this form because it is very important that you be part of the decisions about your care. It is important to understand the procedure, its risks, benefits and alternatives. Your doctor will talk with you about these. Be sure you get your questions answered before you sign this Consent Form. Please initial and date here to show that you understand.

- **Patient's Initials or Authorized Individual**: [Signature]
- **Date**: [Date]

I hereby authorize [Dr.], and any associates/assistants to perform the following procedure(s):

Cardiac catheterization is a medical procedure used to diagnose and treat certain heart conditions. A long, thin, flexible tube called a catheter is put into a blood vessel in the arm, upper thigh (groin), or neck and threaded up into the heart. Through the catheter, doctors can perform diagnostic tests and treatments on the heart.

During the procedure, a special dye is put into the catheter to make the inside of the heart and blood vessels show up on x-rays; this is known as coronary angiography (Figure 1). Angiography can help your doctors determine if the blood vessels that supply your heart have any blockages that may be giving you symptoms or may put you at increased risk for a heart attack.

![Image of catheterization procedure](image1)

Figure 1. If a vessel is blocked, your doctor may decide to treat the blockage with an angioplasty and/or a stent implant. If your doctor decides that surgery is needed instead of a procedure, a coronary artery bypass graft (CABG) may be done at a later time.

Page 3

Sometimes after opening a blocked artery the artery closes again. This procedure may need to be done again. There are 2 types of stents that can be used to keep arteries open: bare metal stents or drug-eluting stents. After either type of stent, patients must take a blood thinner, like Plavix. Patients will be given this medication for a longer time than patients with a bare metal stent. This extra medication can be costly, depending on your insurance. The graphs show your chance for another procedure in the next year if you are treated with a bare metal or a drug-eluting stent.

**Risk of Blood Vessel Closing within a Year**

<table>
<thead>
<tr>
<th>Range of outcomes</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bare Metal</td>
<td>20%</td>
<td>30%</td>
<td>50%</td>
</tr>
<tr>
<td>Drug Eluting</td>
<td>5%</td>
<td>10%</td>
<td>15%</td>
</tr>
</tbody>
</table>

**Percent (%) chance of needing a repeat procedure within a year.**

where **Bare Metal** is the risk of the vessel closing within the next year when a bare metal stent is used.

and **Drug Eluting** is the risk of the vessel closing within the next year when a drug eluting stent is used.

**NOTE:** These graphs use data from many previously treated patients. It is important to know that your results may differ from these prior patients, even though they had similar medical conditions to you. It is impossible to predict what will happen in your case. This information is not a guarantee of your results.

I understand that I may need a blood transfusion during the procedure. I know there are risks with a transfusion. This might be fever, a kidney reaction, hepatitis, Acquired Immune Deficiency Syndrome (AIDS) or other infections.

Possible alternatives to the procedure have been explained to me. This includes not having this procedure at all. Other alternatives might include, but are not limited to:

- If I get a medical device, my Social Security number can be released to the maker of the device. This is because of the Federal Food and Cosmetic Act section 519(e).
- Because this facility is an academic hospital, my medical record may be used for scientific purposes. I understand I may be contacted in the future about my recovery from this procedure.
- I consent to any photographing or video taping of the procedure(s). The pictures or the words describing the pictures will not reveal my identity. I also consent to students or equipment representatives being in the procedure room. This is for medical education or to get important product information.

Page 4

In the event that a health care worker is exposed to my blood, I consent to the drawing of my blood for testing for HIV or hepatitis infection.

**Date**

**Time**

**Patient/Others legally responsible signature**

**Relationship to Patient**

**Why patient is not able to give consent:**

- Minor
- Unconscious
- [Other]

**Certification of Witness**

I hereby certify that I have witnessed or confirmed the patient (authorized individual's signature and have verified the following):

- The patient/authorized individual has read this form or had it read to him/her.
- The patient/authorized individual states that he/she understands this information.
- The patient/authorized individual has no further questions.

**Date**

**Time**

**Signature of Witness**

**Date**

**Time**

**Signature of Witness**

**Certification of Physician**

I hereby certify that I have discussed and explained the nature, purpose, benefits, and risks associated with this and any alternative procedures (as described in this consent form) with the individual granting consent. I have further discussed possible consequences of the procedure, the possible risks involved, and possible complications.

**Date**

**Time**

**Signature of Physician**

Figure 1. Sample copy of the PREDICT consent form.
this issue, we estimated adjusted RR's directly using a modified Poisson regression model. Results of the surveys are thus presented as physician-adjusted RR's of the outcome of interest if given a PREDICT consent form. As an exploratory, descriptive analysis, we sought to determine whether or not presenting the risks for restenosis with BMS and DES to patients and physicians was associated with stent selection. We compared the use of BMS versus DES across the 3 categories of restenosis risk (low [15% risk of restenosis with a BMS in 1 year], moderate [23% risk of restenosis], and high [44% risk of restenosis]) before and after implementation of PREDICT using modified Poisson regression models that adjusted for between-physician variation. Analyses were conducted with SAS software, release 9.1 (SAS Institute, Cary, NC), and statistical significance was inferred from a probability value <0.05.

The authors had full access to the data and take full responsibility for the integrity of the data. All authors have read and agree to the manuscript as written.

Results

Of the 335 patients included in the study, 142 received the original consent form, and 193 received the PREDICT consent form. The mean age was 65 years, and 64% were male. Cardiac comorbidities were common, with 50% having diabetes mellitus, 21% having had a prior coronary artery bypass graft surgery, and 50% having had a prior PCI. The 2 groups were similar in their clinical and demographic characteristics (Table 1), although patients in the PREDICT group were more likely to have had a prior coronary artery bypass graft (26% versus 14%, P=0.006) and reported less preprocedural angina (57% versus 83%, P<0.001). Factors that would be hypothesized to impact comprehension, anxiety, and recall, such as age and prior PCI, were not significantly different between the groups.

The main findings of the study are shown in Tables 2 and 3. After between-physician variation was considered, nearly twice as many patients reported reading the PREDICT consent form than the original consent form (72% versus 44%; RR 1.64, 95% confidence interval [CI] 1.24 to 2.16, P=0.001). A greater percentage of PREDICT patients reported not feeling nervous at all after reading the enhanced consent form than patients given the original consent form (65% versus 45%; RR 1.43, 95% CI 1.10 to 1.87, P=0.008), and more of them thought the form was easy to understand (61% versus 50%; RR 1.21, 95% CI 1.05 to 1.40, P=0.009).

Additionally, there were trends for more patients in the PREDICT group to have felt involved in the decision processes relating to the procedure (67% versus 45%; RR 1.48, 95% CI 0.99 to 2.22, P=0.059) and to be able to report that the descriptions of the complications of PCI were clear (66% versus 53%; RR 1.23 95% CI 1.00 to 1.53, P=0.052; Table 2).

Among the subset of patients assessed for their recall of the risk of complications (n=141), there were no differences between the groups in the percentage of patients who were able to name the potential complications of PCI; however, among patients who were able to identify death or bleeding as a potential complication, a greater proportion of patients in the PREDICT group were able to recall having been told their estimated risk of death (85% versus 62%, RR 1.37, 95% CI 1.03 to 1.82, P=0.029) or bleeding (92% versus 71%, RR 1.28, 95% CI 1.06 to 1.56, P=0.013). There were no differences between the groups for any of the other potential

### Table 1. Baseline and Clinical Characteristics by Consent Type

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Original Consent (n=142)</th>
<th>PREDICT (n=193)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y, mean±SD</td>
<td>64.0±13.2</td>
<td>65.0±11.7</td>
<td>0.45</td>
</tr>
<tr>
<td>Age ≥70 y, %</td>
<td>33.8</td>
<td>38.3</td>
<td>0.39</td>
</tr>
<tr>
<td>Male, %</td>
<td>63.4</td>
<td>63.7</td>
<td>0.95</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>69.7</td>
<td>76.2</td>
<td>0.19</td>
</tr>
<tr>
<td>Diabetes mellitus, %</td>
<td>45.8</td>
<td>53.9</td>
<td>0.14</td>
</tr>
<tr>
<td>Congestive heart failure, %</td>
<td>6.3</td>
<td>7.8</td>
<td>0.62</td>
</tr>
<tr>
<td>Prior coronary artery bypass graft, %</td>
<td>14.1</td>
<td>26.4</td>
<td>0.006</td>
</tr>
<tr>
<td>Prior PCI, %</td>
<td>49.3</td>
<td>49.7</td>
<td>0.94</td>
</tr>
<tr>
<td>Angina pectoris, %</td>
<td>83.3</td>
<td>56.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Extracardiac vascular disease, %</td>
<td>27.7</td>
<td>28.5</td>
<td>0.89</td>
</tr>
<tr>
<td>Creatinine, mg/dL, mean±SD</td>
<td>1.3±1.3</td>
<td>1.2±0.9</td>
<td>0.63</td>
</tr>
<tr>
<td>Anemia, †</td>
<td>23.4</td>
<td>21.2</td>
<td>0.64</td>
</tr>
<tr>
<td>Atrial fibrillation, %</td>
<td>5.6</td>
<td>8.9</td>
<td>0.27</td>
</tr>
<tr>
<td>Risk estimations, %, mean±SD</td>
<td>0.9±1.6</td>
<td>0.6±0.7</td>
<td>0.21</td>
</tr>
<tr>
<td>Periprocedural death</td>
<td>3.5±2.4</td>
<td>3.0±1.8</td>
<td>0.020</td>
</tr>
<tr>
<td>Restenosis at 1 y with BMS</td>
<td>28.2±11.3</td>
<td>25.0±10.3</td>
<td>0.019</td>
</tr>
<tr>
<td>Restenosis at 1 y with DES</td>
<td>7.2±3.7</td>
<td>7.9±3.8</td>
<td>0.030</td>
</tr>
</tbody>
</table>

†Defined as Seattle Angina Questionnaire Angina Frequency score <100.20

### Table 2. Patient Experience With the Consent Form

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Original Consent (n=142)</th>
<th>PREDICT (n=193)</th>
<th>RR* (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Read the consent form, %</td>
<td>44.0</td>
<td>72.0</td>
<td>1.64 (1.24–2.16)</td>
<td>0.001</td>
</tr>
<tr>
<td>Doctor involved me in decision, %</td>
<td>45.1</td>
<td>66.7</td>
<td>1.48 (0.99–2.22)</td>
<td>0.059</td>
</tr>
<tr>
<td>Descriptions of treatment were clear, †%</td>
<td>62.9</td>
<td>65.5</td>
<td>1.04 (0.89–1.22)</td>
<td>0.63</td>
</tr>
<tr>
<td>Descriptions of complications were clear, †%</td>
<td>53.2</td>
<td>65.7</td>
<td>1.23 (1.00–1.53)</td>
<td>0.052</td>
</tr>
<tr>
<td>Form very easy to read, †%</td>
<td>59.7</td>
<td>64.5</td>
<td>1.08 (0.92–1.27)</td>
<td>0.34</td>
</tr>
<tr>
<td>Form very easy to understand, †%</td>
<td>50.0</td>
<td>60.6</td>
<td>1.21 (1.05–1.40)</td>
<td>0.009</td>
</tr>
<tr>
<td>Reading form did not make me nervous, †%</td>
<td>45.2</td>
<td>64.7</td>
<td>1.43 (1.10–1.87)</td>
<td>0.008</td>
</tr>
</tbody>
</table>

*Adjusted for between-physician variation.
†Questions asked only if patient reported having read the form.
complications of PCI, outcomes for which no PREDICT model was generated (Table 3).

In an exploratory analysis of stent selection by risk of restenosis, 188 patients underwent PCI with stent placement during the study period, of whom 157 (84%) received a DES. Eight patients were excluded who did not have sufficient data to determine their restenosis risk category. Of the remaining 180 patients who underwent PCI, 54 (30%) were at low risk for stenosis within the following year if treated with a BMS, 71 (39%) were at moderate risk, and 55 (31%) were at high risk for stenosis. Before the implementation of PREDICT, ≈90% of patients received a DES, regardless of their preprocedural risk of restenosis (Figure 2). After the implementation of PREDICT, patients at low or moderate risk for restenosis were less likely to receive a DES than if they had been given the original consent form (low risk 77% versus 96%, RR 0.80, 95% CI 0.62 to 1.03, \(P=0.08\); moderate risk 61% versus 90%, RR 0.68, 0.53 to 0.88, \(P=0.004\)). In contrast, patients at high risk for restenosis continued to experience very high levels of DES use after implementation of the PREDICT consent form compared with the original consent form (91% versus 91%, RR 1.01, 95% CI 0.86 to 1.19, \(P=0.93\); Figure 2). Variation in the effect of PREDICT by physician was examined by augmentation of the base model with an additional physician-level random treatment effect. This did not result in a significantly improved fit (as measured by log-likelihood and Akaike information criterion statistics), and the PREDICT effect estimates, CIs, and probability values were essentially unchanged, which indicates that the effect of PREDICT was largely consistent across physicians.

**Discussion**

The process of informed consent is intended to provide information to patients in a format they can comprehend so that they can voluntarily elect to proceed with treatment. The results of the present study demonstrate that an individualized consent form, enriched with patient-specific risks for PCI complications and restenosis rates with BMS and DES, was associated with an increased reading of the consent document, an increased perception of shared decision making, reduced anxiety, and an improved recall of having been informed of periprocedural risks. These findings suggest that PREDICT is not only well received by patients but also more effectively facilitates the intent of the informed consent process through a more informed and evidence-based discussion about procedural risks. In addition, these data suggest that presenting patients and physicians with patients’ individualized risks of restenosis may result in a preferential use of DES in patients at high risk for restenosis and a greater use of BMS in those at lower risk.

As previously described, the patient-specific benefits observed in the present study echoed the views of physicians and nurses that the PREDICT informed consent represents an improvement in the processes of care compared with the traditional informed consent documents previously used at our institutions. In fact, based on the provider perspective alone, the project was extended from its initial implementa-

---

**Table 3. Recall of Risks of Complications by Consent Type**

<table>
<thead>
<tr>
<th></th>
<th>Original Consent</th>
<th>PREDICT</th>
<th>RR* (95% CI)</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-identified the following as potential complications (posed as an open-ended question)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death, %</td>
<td>63.0</td>
<td>56.8</td>
<td>0.90 (0.66–1.23)</td>
<td>0.51</td>
</tr>
<tr>
<td>Bleeding, %</td>
<td>60.9</td>
<td>63.2</td>
<td>1.04 (0.75–1.44)</td>
<td>0.82</td>
</tr>
<tr>
<td>Stroke, %</td>
<td>52.2</td>
<td>51.6</td>
<td>0.91 (0.69–1.19)</td>
<td>0.49</td>
</tr>
<tr>
<td>Myocardial infarction, %</td>
<td>54.3</td>
<td>49.5</td>
<td>0.99 (0.78–1.25)</td>
<td>0.92</td>
</tr>
<tr>
<td>Emergency bypass graft surgery, %</td>
<td>54.3</td>
<td>49.5</td>
<td>0.91 (0.62–1.34)</td>
<td>0.63</td>
</tr>
<tr>
<td>Recalled being informed of their estimated risk of the complication occurring†</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death, %</td>
<td>62.1</td>
<td>85.2</td>
<td>1.37 (1.03–1.82)</td>
<td>0.029</td>
</tr>
<tr>
<td>Bleeding, %</td>
<td>71.4</td>
<td>91.7</td>
<td>1.28 (1.06–1.56)</td>
<td>0.013</td>
</tr>
<tr>
<td>Stroke, %</td>
<td>50.0</td>
<td>73.5</td>
<td>1.12 (0.88–1.42)</td>
<td>0.34</td>
</tr>
<tr>
<td>Myocardial infarction, %</td>
<td>76.0</td>
<td>85.1</td>
<td>1.47 (0.92–2.34)</td>
<td>0.10</td>
</tr>
<tr>
<td>Emergency bypass graft surgery, %</td>
<td>64.0</td>
<td>70.2</td>
<td>1.10 (0.77–1.56)</td>
<td>0.60</td>
</tr>
</tbody>
</table>

*Adjusted for between-physician variation.
†Question asked only if patient was able to self-identify as a potential complication.

**Figure 2.** DES use by risk of restenosis. *Adjusted for between-physician variation.
tion at a single site to deployment throughout the healthcare system. Documentation of the improvements in the informed consent process from the patients’ perspectives suggests that such individualized consent processes may represent an important advance in clinical care by replacing a perfunctory informed consent process with an opportunity to educate and involve patients in their clinical care.

The current status of the informed consent process, unfortunately, has repeatedly been found to be inadequate in providing patients with the knowledge and skills necessary to actively participate in decisions about their care. A review of 540 informed consent documents from 157 randomly selected US hospitals concluded that the “forms as designed have limited value: they are constructed to authorize treatment or to document an action pertaining to informed consent, regardless of whether the informed consent process was successfully accomplished or of minimal quality.”2123 In fact, researchers have noted that 69% of patients interviewed after surgery acknowledge not having read the informed consent form.24 Furthermore, truly informed consent requires not only disclosure but also a fundamental understanding of the disclosed information, which has been shown in multiple studies to be severely lacking in current practice. In a study of 100 patients interviewed within days of their surgery, 44 could not provide any details of the procedure, and 27 did not even know which organ had been operated on.25 This suggests that the informed consent process is treated by most providers as simply a legal obligation; however, the opportunity exists to mold the consent process into an important opportunity to educate patients, so that they can become well-informed, responsible, and willing participants in the treatment process.

The results of the present study suggest that PREDICT is a potential strategy for improving the current informed consent process for PCI and can serve as a foundation for better shared decision making. The extent to which individual patients are willing and able to participate in decisions about their care varies greatly26,27; however, prior studies suggest that even in urgent situations, most patients want to understand what is happening to them and what risks are involved in any procedures they are about to undergo.28 PREDICT addresses these needs of the patient in an innovative yet practical manner.

One of the unique advantages of PREDICT is its ability to create individualized consent forms, with the presentation of the risks of the procedure calculated for each individual patient. This method of estimating risks based on validated multivariable models has been shown to be far superior to the estimation of risks based on the intuition of the physicians.29 In so doing, not only do patients have more realistic expectations about the risks going into the procedure, but physicians may also gain access to tools that can guide clinical decisions (eg, if estimated risk of bleeding is high, the physician may elect to use bivalirudin30 or fluoroscopy for vascular puncture). Although many models have been published that can be used to provide estimates of risks of complications, the mathematical complexity of these models has thus far hindered the ability of clinicians to use them in a busy clinical environment. PREDICT provided an avenue for both patients and physicians to readily access the results of such models and to use them in routine care.

Comparison With Other Studies

PREDICT is the first tool of which we are aware that uses computer-generated individualized risks of complications within an actual informed consent document; however, there have been many small studies that have sought to improve the informed consent process through enhancement of the consent document or through the use of multimedia products. Efforts to improve the consent process, including reducing the reading level of the document or providing additional written or verbal information, have been shown to improve satisfaction and decrease anxiety but have not been shown to improve patients’ understanding of the risks and complications of the procedure.19,31 In 2 trials that compared video-assisted informed consent with traditional methods of consent before cardiac catheterization, the addition of video information decreased anxiety levels, but comprehension and retention of information were not assessed.32,33 A recent trial demonstrated that patients scheduled for elective cardiac catheterization were able to answer questions more accurately about the technical aspects of the procedure immediately after a video presentation, although extended retention of this information was not tested.34 Although these are promising strategies, the complexity of arranging for patients to view videos or to meet with educational counselors has precluded their routine use within the frenetic pace of modern cardiac care.

Moreover, although these interventions focused on improving patient comprehension and understanding, this is not sufficient to achieve truly informed consent. For patients to be able to make informed choices, they need to understand the procedure and also know their individualized risks for complications. Risk-prediction models can help patients and healthcare professionals estimate risks and make informed decisions35 but have not yet been leveraged to enhance the infrastructure for more evidence-based personalized discussions between patients and their providers. Recognizing this, we used a multimodal approach to improve the informed consent process, reducing the reading level of the document, providing visual depictions of hard-to-understand terms, and including patient-specific estimated risks of procedural complications. Through these interventions, we believe we were able to create a document that facilitates a meaningful dialogue between the physician and patient and moves the process of informed consent toward one of shared decision making while not disrupting the routine practice of care.

Study Limitations

Several potential limitations should be considered when one interprets the present study. Because our intervention altered several aspects of the consent form, including changes in the reading level of the consent, the inclusion of educational diagrams, and the use of evidence-based, individualized estimates of risk, we cannot specify which aspect of the new consent was most important in attaining the improvements documented in the present study. Furthermore, given the complexity of creating and deploying a tool such
as PREDICT into the practice of obtaining informed consent, we were not able to conduct a randomized clinical trial of the tool within our center. Thus, the present study was designed as “proof of concept” and as a foundation for a larger, multicenter trial that can more fully document the implications of such an approach to informed consent for patients, clinicians, and the healthcare system. The use of a prepost study design could have potentially introduced bias, because assessments of the original consent and PREDICT consent processes were not performed in the same time period. Although the assessment tool was structured to minimize biases, the nurses and medical students who interviewed the patients were aware of the type of consent the patients had received. Moreover, because the nurses and physicians were aware of the changes in the structures and processes of care that accompanied the implementation of PREDICT, they may have altered their attention to the informed consent process. Thus, the observed changes in the present study may not be attributable completely to PREDICT. In addition, the present findings of a more rational use of DES in high-risk patients and a greater use of BMS in lower-risk patients may have been confounded by evolving questions surrounding the safety of DES. However, the fact that we found no change in the high percentage of DES use in patients at high risk for restenosis does suggest that PREDICT was associated with better tailoring of this therapy to those who stand to benefit the most. Because the cost-effectiveness of DES is likely to be increased by focusing its use among patients who stand to benefit the most, a larger study of the use of PREDICT to assist in the allocation of DES is warranted. Regardless of its impact on resource utilization, the present study results do suggest that PREDICT is well received by patients and likely holds a significant positive value for both patients and physicians.

Finally, although the current informed consent document includes estimations of procedural risks, it does not contain risk-adjusted descriptions of benefits or the risks of alternative treatments. Currently, there are few risk-adjustment models of PCI benefits over alternative treatments, and the research community has not embraced a paradigm of sharing the β-coefficients and covariance matrices needed to program PREDICT to execute such models. In addition, although we present risk estimations of complications that we believe hold significant value to patients and physicians, other potential outcomes of PCI may be of interest to patients or physicians, such as less severe bleeding complications or periprocedural myocardial infarction, for which validated risk models have not yet been developed. Thus, opportunities to further improve the current consent document clearly exist. Despite its limitations, we believe that the present study holds significant value because it demonstrates that the translation of risk-prediction models to clinical care can be accomplished in a manner that is useful to patients and clinicians. Further study, however, is needed to understand the full potential of this technology.

Conclusions
In response to well-documented deficiencies in the informed consent process, we have demonstrated that the PREDICT tool can transparently quantify patients’ risk profiles and improve communication between clinicians and patients undergoing PCI. PREDICT thus accelerates the Institute of Medicine’s vision for high-quality healthcare, a vision that encourages patients to be the source of control in selecting treatments most aligned with their individual goals and values. These preliminary data lay the foundation for a clinical trial to better establish the impact of improved informed consent documents on subsequent care, resource utilization, clinician satisfaction, and, ultimately, patient outcomes. This initial experience should stimulate others to create innovative solutions to improve the process of informed consent.

Sources of Funding
The study was funded by Doris Duke Charitable Foundation Innovations in Clinical Research Award No. 20020310. The sponsor had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; or preparation, review, or approval of the manuscript.

Disclosures
Drs Spertus and Soto have a patent pending on the ePRISM technology from which the PREDICT tool was created but have not yet received the patent, nor have they made any money from the sale or licensing of this project. Dr Spertus owns the copyright to the Seattle Angina Questionnaire. The remaining authors report no conflicts.

References
The current informed consent process tends to be a perfunctory legal ritual rather than an opportunity to educate and engage patients in their treatment. To enhance the consent process, we developed a World Wide Web–based program, PREDICT, to systematically embed patient-specific risk estimates of death, bleeding, and restenosis into individualized consent documents for patients undergoing percutaneous coronary intervention. In a pre–post study design, we found that the PREDICT-generated individualized consent forms were associated with higher rates of reading the consent form, improved participation in the consent process, reduced anxiety, and better recall of complication risks. We also noted a more rational application of drug-eluting stents in those at the highest risk of restenosis, who have the most to benefit, and a greater use of bare-metal stents in those at lower restenosis risk. These findings suggest that transparent quantification and sharing of patients’ risk profiles can improve communication and more effectively facilitate the informed consent process. These preliminary data lay the foundation for a clinical trial to better establish the impact of improved informed consent documents on subsequent care, resource utilization, clinician satisfaction, and patient outcomes and should stimulate others to create innovative solutions to improve the informed consent process.
Converting the Informed Consent From a Perfunctory Process to an Evidence-Based Foundation for Patient Decision Making

Suzanne V. Arnold, Carole Decker, Homaa Ahmad, Olawale Olabiyi, Surya Mundluru, Kimberly J. Reid, Gabriel E. Soto, Sarah Gansert and John A. Spertus

doi: 10.1161/CIRCOUTCOMES.108.791863

_Circulation: Cardiovascular Quality and Outcomes_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2008 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-7705. Online ISSN: 1941-7713

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circoutcomes.ahajournals.org/content/1/1/21

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in _Circulation: Cardiovascular Quality and Outcomes_ can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to _Circulation: Cardiovascular Quality and Outcomes_ is online at:
http://circoutcomes.ahajournals.org//subscriptions/