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Improving the Process of Informed Consent for PCI: Patient Outcomes from the ePRISM Study

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Abstract

Background—While the process of informed consent is designed to transfer knowledge of the risks and benefits of treatment and to engage patients in shared medical decision-making, this is poorly done in routine clinical care. We assessed the impact of a novel informed consent form for percutaneous coronary intervention (PCI) that is more simply written, includes images of the procedure and embeds individualized estimates of outcomes on multiple domains of successful informed consent and shared decision-making.

Methods—We interviewed 590 PCI patients receiving traditional consent documents and 527 patients receiving novel ePRISM consents at 9 US centers and compared patients' perceptions, knowledge transfer and *e*ngagement in medical decision-making. Heterogeneity across sites was assessed and adjusted for using hierarchical models.

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Results—Site-adjusted analyses revealed more frequent review (72% for *e*PRISM vs. 45% for original consents) and better understanding of the *e*PRISM consents (odds ratios (ORs)=1.8–3.0, depending upon the outcome) with marked heterogeneity across sites (median relative difference (MRD) in the ORs of *e*PRISM's effect = 2–3.2). Patients receiving *e*PRISM consents better understood the purposes and risks of the procedure (ORs=1.9–3.9, MRDs=1.1–6.2), engaged more in shared decision-making (proportional OR=2.1 [95%CI=1.02–4.4], MRD=2.2) and discussed stent options with their physicians (58% vs. 31%; site-adjusted odds ratio=2.7 [95% CI=1.2, 6.3], MRD=2.6) more often.

Conclusions—A personalized consent document improved the process of informed consent and shared decision-making. Marked heterogeneity across hospitals highlights that consent documents are but one aspect of engaging patients in understanding and participating in treatment.

Innovative strategies are needed to accomplish the Institute of Medicine's goals for safer, more efficient, evidence-based care that respects patients' individual preferences.[1] One opportunity is to improve the process of informed consent, a legally-mandated process prior to treatment.[2] Improved consent forms may not only better educate patients about the risks of treatment, but may also support shared medical decision-making, an ethically-mandated part of treatment decisions.[3] Although distinct,[4] both processes necessitate detailed discussions about the purpose, risks and alternatives for treatment, tailored to a patient's unique clinical situation.

Using evidence to support individualized decision-making is important because there is a heterogeneity of treatment benefits that varies according to patients' characteristics (i.e. while some patients have great potential to benefit from particular treatments, others don't).[5] Despite the availability of numerous risk models to identify patients more (or less) likely to benefit from treatment, they are rarely used in routine clinical care. Integrating such risk models within informed consent documents is an important opportunity to ensure that both shared decision-making and improved informed consent processes are integrated into routine care.

To address the need for improved informed consent documents that also support shared decision-making, we created the Patient Risk Information Services Manager (*e*PRISM).[6] *e*PRISM is a web-based tool that integrates multivariable risk models, using a patient's specific clinical risk factors, within editable documents that can be customized to the consent requirements of individual hospitals. To evaluate *e*PRISM-generated consent forms on patients' experiences with the process of obtaining informed consent for percutaneous coronary intervention (PCI), we examined patients' reviewing and understanding of consents, knowledge transfer (e.g. understanding of their procedure and its risks) and participation in shared medical decision-making in a cohort of patients using traditional consent forms and compared their experiences with a separate cohort of patients treated with the *e*PRISM-generated personalized consent forms.

Methods

Study Design

This study was a survey of patients' perceptions of the informed consent process amongst a group of patients treated with traditional consent forms and a separate cohort of patients in whom the *e*PRISM-generated consents were used. All patients undergoing angiography with the potential of undergoing PCI received the revised consent forms and were eligible for the study. After IRB approval, and before implementation of *e*PRISM, consecutive agreeing patients were asked to participate in a survey eliciting their demographics, education, numeracy[7, 8] and literacy[9], whether they reviewed and understood the consent form, their knowledge about the procedure and its potential complications, their desire for shared decision-making,[10] and their involvement in discussing the use of a bare metal (BMS) or drug eluting stent (DES). This was repeated after introduction of the personalized consent forms. Interviewers approached patients after the procedure, precluding their cardiologists from knowing which patients would be interviewed and without the interventionalist who performed the procedure being present. This study was funded by 2 separate grants (see below), with a goal of enrolling 100 surveys before and after ePRISM at 3 centers (funded by an AHA grant) and 50 at the other 6 (funded by an NHLBI grant). While the *e*PRISM consents were similar across hospitals, the pre-*e*PRISM evaluation used each hospital's original form.

Nine centers, representing diverse geography, patient populations, and academic affiliations, participated in the study. Three (Integris Baptist Health, Oklahoma City OK; Yale-New Haven Hospital, New Haven, CT; and Mayo Clinic, Rochester MN) began participation in 2009 and 6 (Washington University/Barnes-Jewish Hospital, St. Louis MO; The Heart Hospital at Baylor, Plano TX; Kaiser Permanente, San Francisco CA; Baystate Medical Center, Springfield MA; Henry Ford Hospital, Detroit MI; and St. John's Hospital, Springfield IL) in 2010. Site Principal Investigators summarized the processes of informed consent at their institutions, which did not differ after implementation of *e*PRISM. (Appendix 1).

Design and Implementation of ePRISM-generated Informed Consent Documents

Informed consent documents, in general, suffer from being written at too high of an educational level for many patients to understand,[11] omit educational information about the specific procedure and lack patient-specific estimates of risks and benefits. To address this, a template of an informed consent document, written at the 8th grade level and embedded with educational diagrams of angiography and PCI, was provided to each study site for editing (Figure 1).

Within these consent documents, validated risk models from the American College of Cardiology (ACC) National Cardiovascular Data Registry (NCDR) were incorporated, including their peri-procedural mortality model,[12] bleeding risk model[13] and a model predicting target vessel revascularization (TVR) after bare metal (BMS) and drug eluting stents (DES).[14] While mortality is an informational requirement of consent forms,[2] the bleeding model can not only inform patients of their risks, but also assist clinicians in

targeting more aggressive bleeding avoidance therapies in those at higher risk for bleeding.[15] The TVR model represents an opportunity to engage patients in shared decision-making. While DES lower the risk of TVR,[16] DES also require long-term dual anti-platelet therapy for a substantially longer time than BMS when used in the treatment of stable coronary disease.[17, 18] TVR risk was included to enable the interventionalists to quantify the benefits of DES as part of their discussions with patients so that they balance the risks of TVR with the requirements for prolonged dual anti-platelet therapy, which can be costly and increase patients' risks for bleeding.

To implement the *e*PRISM consent forms, each site tailored the consent to their institutional and state requirements. A relay server was then placed in each hospital's network to pre-populate *e*PRISM with demographic and lab information. To generate a personalized consent form, nurses (at 7 of 9 institutions) or physicians (at 2 institutions) entered the 13 variables needed to execute the 4 ACC risk models and to print patients' individualized consent forms. This took, on average, <2 minutes. Patient flow and the timing of acquiring informed consent did not differ at any of the institutions before and after implementation of the *e*PRISM consents. The use of *e*PRISM consent forms was considered a quality improvement initiative by each center and no patient-level consent was required to use the new consent forms. However, interviewing patients' about their perceptions of the consent process was approved by each center's Institutional Review Board and conducted after the patient's PCI.

Statistical Analyses

For the *e*PRISM implementation, we described the proportion of PCIs conducted with an *e*PRISM consent (excluding primary PCI for STEMI, for which a more brief consent is often obtained and there is limited opportunity for shared decision-making). Characteristics of patients receiving original vs. *e*PRISM-generated consents were compared with chi-square and t-tests. Three broad categories of outcomes were assessed; patients' experiences with the consent process, the success of knowledge transfer and their engagement in shared medical decision-making. Patients' experiences were elicited by asking patients whether they had reviewed the consent forms (yes vs. no) and, among those who read the forms, their assessments of the clarity of the information (e.g. its understandability and their nervousness after reading the form) using previously validated instruments.[19, 20] Knowledge transfer was assessed by asking patients' their understanding of the procedure and their recall that death and bleeding were potential complications. Patient engagement in shared decision-making was assessed by using the Deber instrument to quantify patients' desire to participate in treatment decisions and their role in selecting a stent type.[10] Patients were also asked whether or not they discussed stent types with their physicians.

We also examined variability in the impact of *e*PRISM across sites. The independent effect of *e*PRISM was estimated using hierarchical logistic regression models (or proportional odds models for ordinal outcomes), with an overall fixed effect for *e*PRISM and random effects for hospital and for the effect of *e*PRISM within hospital. Patient-level covariates having a standardized difference of >10% between groups, including education, dyslipidemia, smoking status, chronic lung disease, history of depression, procedure type

and clinical status (e.g. stable angina vs. NSTEMI or unstable angina) were included in all adjusted models. All fixed effects were centered within hospital to account for potential confounding by site, yielding within-hospital estimates of effect. This approach accounts for the practice variation present across hospitals and is a more accurate representation of the potential benefits of the personalized consents for "typical" patients at each hospital. The fixed effect of *e*PRISM, reported as an odds ratio, represents the average of the effects across all hospitals. Heterogeneity in the effect of *e*PRISM across hospitals was summarized by the variance of the *e*PRISM random effect, transformed to represent the median relative difference (MRD) in odds ratios between two randomly selected hospitals for patients with identical covariates (e.g., a MRD of 2.0 denotes that the benefits of *e*PRISM in two randomly selected hospitals differ by a factor of 2; an MRD of 1.0 indicates no variation across hospitals).[21] The variability across centers reduced the effective sample size decreased by 30–94%, resulting in significantly lower study power.

Approximately 8% of patients were missing data on one or more of the covariates included in the above models (6% were missing only one; the highest missing rate for any variable was 3%). Missing covariates values were imputed using sequential regression imputation so that all available data could be retained in the analyses.[22] Analyses were conducted in SAS 9.2 (SAS Institute Inc., Cary, NC) and R version 2.13.1.[23] All analyses were 2-tailed and evaluated at a significance level of 0.05.

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Results

Literacy levels were reduced in the *e*PRISM consents and the proportion of patients receiving the *e*PRISM consents varied across centers (Table 1). Characteristics of the 590 patients receiving traditional consents and the 527 patients receiving *e*PRISM consents were generally similar (Table 2), although *e*PRISM cohort included more smokers with a history of lung disease and depression, and who were more often treated for stable angina.

Patients' Perceptions of the Informed Consent Documents

Across all hospitals, substantially more patients reviewed the *e*PRISM consent form than the traditional consents (72% vs. 45%). Moreover, among patients who reviewed the consent forms, those using the *e*PRISM forms were more likely to feel that the treatment (49% vs. 25%) and complications (50% vs. 27%) were completely clear. There was also a significantly greater perception that the forms were more completely understood (52% vs. 31%) and easier to read (48% vs. 24%). Patients reviewing the *e*PRISM consent forms were more likely to report that the forms did not make them nervous at all (77% vs. 62%), even though they contained explicit estimates of risk.

After accounting for the variability across sites, the independent mean effect of the *e*PRISM consent forms, expressed as odds ratios, on patients' review and perceived comprehension

varied from 1.8 – 3.0, with the effects significantly favoring *e*PRISM for all domains except clarity of treatment and patients' nervousness after reviewing the consent (Table 3). Marked heterogeneity in the benefits of the *e*PRISM-generated consents across hospitals was observed, with median relative differences (MRDs) of the benefits varying from 2 to 3.2-fold across centers. A representative figure of the site variability for reviewing the consent forms is shown in Figure 2.

Knowledge Transfer

The *e*PRISM consent forms were more successful at communicating the purpose and risks of PCI. Patients reviewing the *e*PRISM consents were more likely to perceive that they understand the purpose of the procedure (97% vs. 93%) and balloons (87% vs. 79%), but no difference in the purpose of stents was noted (95.1% vs. 94.9%,). While the absolute differences in rates for understanding the procedure itself are small, and unlikely to be of clinical significance, the differences in understanding that there are risks of peri-procedural death and bleeding were large. Patients reviewing the *e*PRISM consent forms were significantly more likely to understand that there were risks for mortality (70% vs. 45%,) and bleeding (70% vs. 40%). After accounting for site variability, there was a 1.9 to 3.9-fold greater odds of effective knowledge transfer, except for the purpose of stents. Again, marked heterogeneity was observed for the impact of *e*PRISM across sites, with MRDs of 4 and 6.2 for patients knowing that there was a risk for mortality or bleeding from the procedure, reducing the statistical significance in patients' improved understanding of the risks of mortality and bleeding (p=0.09 and 0.08, respectively).

Patient Engagement in Shared Decision-making

When asked about their desired role in making decisions about treatment, no differences in patients' desired roles in decision-making were observed (93% using the *e*PRISM form wanted some role vs. 89% using traditional consents). More patients using the *e*PRISM consents discussed stent options with their physician (58% vs. 31%, site-adjusted odds ratio, 2.1 (95%CI=1.2, 6.3)) with an MRD of 2.6. Importantly, when asked who made the decision about whether a DES or BMS should be used, 52% of the *e*PRISM patients felt the doctor alone made the decision, as compared with 72% using traditional consents. The site-adjusted proportional odds of patients being involved in deciding stent type was 2.13 (95%CI=1.02, 4.43), with an MRD of 2.2.

Discussion

We implemented and evaluated a novel consent form that explicitly incorporated patients' individualized risk estimates for complications (i.e. bleeding and mortality) and restenosis after BMS and DES using a more descriptive form with graphical images of the procedure. As compared with traditional consent documents, we found substantial overall improvements in virtually all aspects of informed consent and shared decision-making, including greater patient review, more knowledge transfer and greater participation in stent selection. We also found marked heterogeneity of benefits across sites, with a >4-fold difference in some benefits of *e*PRISM across sites. This variability highlights that an

informed consent document is but one element of a process for informing patients of treatment options and engaging them in shared decision-making.

The personalized consents are congruent with the recent call for improving the process of informed consent,[24] and address well known deficiencies in standard consent documents. In a survey of 157 US hospitals, Bottrell and colleagues concluded that consent "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."[25] Even though we interviewed patients after their procedure, when they may have received additional teaching in the post-procedure setting that could have biased our assessments and minimized differences between groups, we were still able to demonstrate that the novel consent forms could markedly advance the goals of the consent process and better engage patients in shared decision-making. In fact, it is not possible for consents to serve their purpose if patients do not even review them. Finding that less than half of patients read the traditional consents, as compared with almost 3 quarters with the personalized consent forms, further underscores the potential of redesigned forms to improve the processes of care.

A recent study of Medicare patients noted that only 10% of PCI patients were offered alternatives to stenting and only 16% were asked about their treatment preferences.[26] By introducing outcome estimates (i.e. risks of TVR) in the consent form, we were able to engage patients in discussing stent options prior to the use of peri-procedural sedation. It is noteworthy, however, that even with the *e*PRISM consents only 58% of patients recalled discussing stent options with their physician (a 3-fold increased odds of discussing stent types of patients as compared with traditional consents), even though 93.3% wanted to participate in making decisions about their treatment. This underscores the need for further improvements in engaging patients in shared decision-making about stent choices.

Our approach also overcomes some of the challenges of using decision aids, which are often tangential to clinical care and not routinely used.[27] Integrating individualized risk predictions within the legally-mandated informed consent process enables clinicians and patients to use them on a routine basis for shared decision-making. Similar approaches could be considered for other procedures, including orthopedic, bariatric, obstetrical and surgical consents.

Our findings should be interpreted in the context of the following potential imitations. First, we did not randomize patients. Although this study design limits our ability to define causality and exclude confounding, the absolute differences were large and rapid, making it unlikely that secular trends in the process of obtaining consent accounted for our findings. Second, only 9 sites were included in the study, limiting the power of the site-adjusted analyses and generalizability to other institutions. Third, it is possible that participation in the study and the use of new consents may have led to a `Hawthorne Effect'. Importantly, physicians did not know which patients would be interviewed and are unlikely to have been able to `game' the assessment. We are also unable to define which aspect of the process of implementing the personalized consent forms led to the observed improvements (e.g. the forms themselves or the attention given to the consent process during the study). Moreover,

the variability in use of the consent forms substantially limited the power of our analyses and more consistent use within and across sites would have made other outcomes of the consent process more statistically significant. A final concern might be that the risk estimates can become outdated, as new generation stents enter clinical practice. However, once updated models with these new technologies are created, they can be readily implemented in *e*PRISM so that the latest available data are always used.

In summary, we found that the *e*PRISM consent can improve many of the goals of informed consent and shared decision-making in PCI. However, there was substantial heterogeneity in the magnitude of these improvements across the 9 hospitals, underscoring that the consent document is but one aspect of eliciting consent. Nevertheless, redesigning consent forms, potentially including the use of embedded risk models and more educational documents, is a promising strategy for achieving both the ethical mandates of informed consent and encouraging shared decision-making,[3] while also advancing the Institute of Medicine's goals for improving healthcare.[1]

Acknowledgments

Dr. Spertus, but no other authors, discloses a conflict of interest with Health Outcomes Sciences, the commercial entity distributing and supporting *e*PRISM, in which he has an equity stake. After creating the company, both funding agencies were informed of the conflict of interest and a mitigation plan was instituted to include independent review of the study by both UMKC and Saint Luke's hospital, with semi-annual reporting to the American Heart Association. As part of this mitigation plan, independent replication of the analyses from the raw data was performed by, Dr. Theodora Cohen at the Harvard Clinical Research Institute, who takes responsibility for the accuracy of the data analysis. No major concerns were identified in the conduct of the study after thorough review by the oversight committees and funding agencies.

Appendices

Appendix Table 1

Qualitative Description of Consent Process at Each Site

Site	Physician gets consent signed	Nurse gets consent signed	Fellow gets consent signed	Formal educational materials provided to patient	Consent signed in office setting	Consent signed in holding room for outpatient	Consent signed in room for inpatient
1	+++	−	++	++	−	+++	+
2	+	+++	−	++	−	+++	+++
3	++	−	+++	−	+	+++	++
4	++	−	+++	−	−	+++	+++
5	+++	−	++	++	−	++	+++
6	+	+++	−	−	−	+++	+++
7	++	++	−	+++	−	+++	+++
8	+++	−	+++	++	−	−	+++
9	+	−	+++	+	−	+++	++

+++=Predominant mode, ++=Occasional mode, +=Rare mode, −=Notdone

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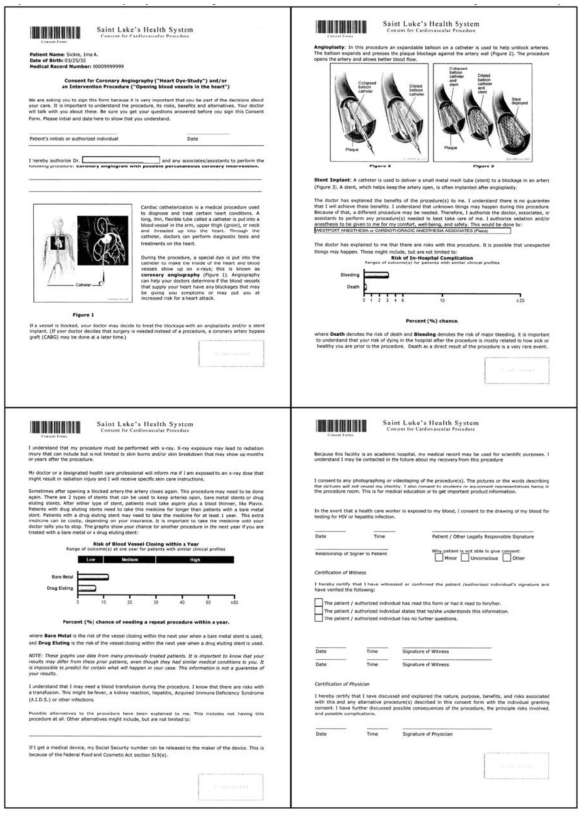

Figure 1.
Template of *e*PRISM-Generated Consent Form

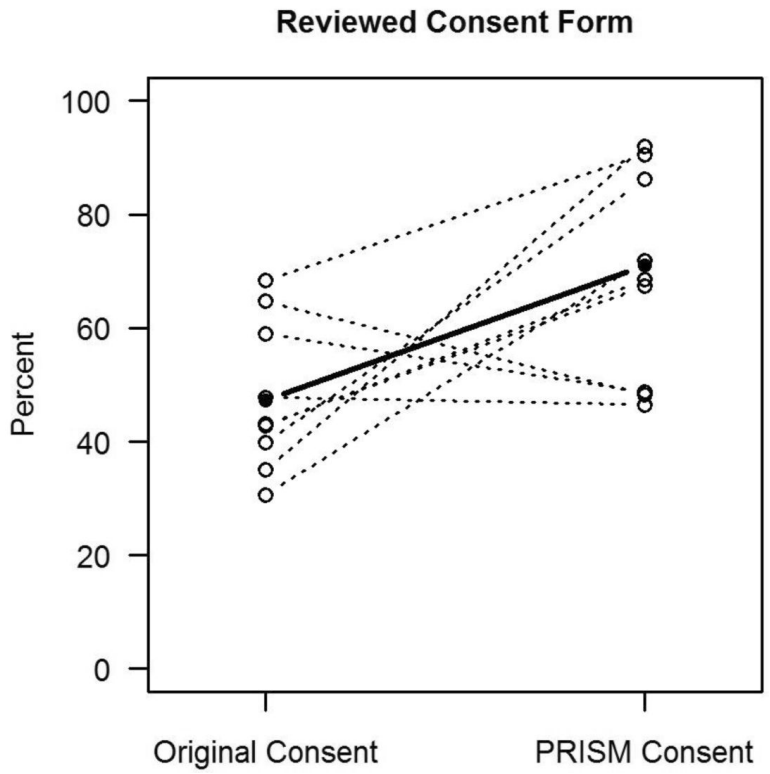

Figure 2.
Site Variability of the proportion of patients reviewing the consent forms across sites.

Table 1

Hospital Characteristics

	Hospital								
	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**
Number of patients surveyed									
Original consent	101	100	65	62	66	68	41	39	48
*e*PRISM consent	101	101	43	65	51	62	21	39	44
Consent form Flesch-Kincaid grade level									
Original consent	15.7	11.0	9.5	12.5	12.7	12.3	9.7	13.7	13.1
*e*PRISM consent	8.6	9.0	9.0	9.1	9.1	9.5	8.0	9.1	9.0
Number of interventionalists	23	19	21	5	52	12	11	15	17
Average monthly PCI-possible caths	137	219	239	360	164	217	152	265	233
Percent of PCI-possible caths using *e*PRISM consent	92%	95%	34%	22%	78%	66%	81%	86%	29%
*e*PRISM consent replaced original form & process	✓	✓				✓	✓	✓	

Table 2

Patient Characteristics

	Original Consent (n=590)	*e*PRISM Consent (n=527)	P-value
Demographics			
Age	64.3 ± 11.4	64.9 ± 10.7	0.41
Female	30.7%	27.1%	0.19
Race			0.31
White/Caucasian	90.0%	92.6%	
Black/African-American	6.2%	4.4%	
Other	3.8%	2.9%	
Education, Literacy and Numeracy			
Education level			0.14
<High School	7.5%	10.7%	
High School	63.5%	57.4%	
College degree	17.5%	18.9%	
Graduate degree	11.4%	12.9%	
REALM-R health literacy score (0–8)	6.8 ± 2.2	6.9 ± 2.2	0.32
Subjective Numeracy Ability score (1–6)	4.3 ± 1.4	4.3 ±1.4	0.47
Subjective Numeracy Preference score (1–6)	4.3 ± 1.3	4.3 ± 1.3	0.58
Clinical History			
Hypertension	82.5%	83.9%	0.53
Dyslipidemia	79.2%	83.7%	0.06
Diabetes	33.5%	33.8%	0.92
Chronic kidney disease	10.5%	9.7%	0.65
Smoking history			0.006
Current	17.2%	14.0%	
Past	32.8%	42.0%	
Never	50.0%	44.0%	
Chronic lung disease	9.6%	14.8%	0.009
History of depression	5.2%	10.2%	0.001
Prior MI	28.2%	29.7%	0.57
Prior PCI			0.70
<6 months	8.6%	6.7%	
6–12 months	4.3%	4.2%	
>1 year	30.2%	31.7%	
Never	56.9%	57.3%	
Prior CABG	19.9%	23.0%	0.22
Chronic heart failure	12.4%	13.3%	0.64
Peripheral arterial disease	8.6%	8.3%	0.86
Prior stroke	5.7%	5.8%	0.93
Cath lab procedure			<0.001
Diagnostic cath only	4.3%	1.0%	

	Original Consent (n=590)	*e*PRISM Consent (n=527)	P-value
PCI	95.7%	99.0%	
Indication for procedure			<0.001
NSTEMI	19.8%	12.4%	
Unstable angina	35.0%	26.0%	
Stable CAD	34.0%	51.3%	
Staged PCI	6.7%	6.6%	
Other	4.5%	4.5%	

Table 3

Study Outcomes

	Original Consent (n=590)	*e*PRISM Consent (n=527)	Hospital-Average Odds Ratio (95% CI)	P-value	Median Relative Difference in OR Across Hospitals
		Reviewing and Understanding			
Reviewed consent form	263 (45.4%)	376 (72.0%)	2.85 (1.05, 7.72)	0.04	3.20
Description of treatments were completely clear*	59 (25.1%)	184 (49.3%)	2.24 (0.88, 5.72)	0.08	2.64
Description of complications were completely clear*	63 (27.2%)	186 (50.3%)	2.19 (1.03, 4.70)	0.04	2.00
Completely understood the information*	72 (30.6%)	194 (52.0%)	2.14 (1.03, 4.46)	0.04	2.01
Consent was easy to read*	55 (23.5%)	167 (47.6%)	2.98 (1.38, 6.45)	0.01	2.04
Reading consent did not make me nervous at all*	148 (62.2%)	292 (77.0%)	1.84 (0.88, 3.88)	0.09	1.99
		Knowledge transfer			
Correctly identified purpose of the procedure	542 (93.4%)	509 (97.0%)	2.17 (1.12, 4.20)	0.02	1.08
Correctly identified purpose of balloon	460 (79.9%)	457 (87.0%)	1.86 (1.03, 3.37)	0.04	1.58
Correctly identified purpose of stent	544 (94.3%)	496 (94.8%)	0.95 (0.35, 2.57)	0.89	1.53
Recalled being told % risk of death	206 (44.5%)	299 (70.4%)	2.79 (0.82, 9.51)	0.09	4.02
Recalled being told % risk of bleeding	177 (39.5%)	284 (70.0%)	3.88 (0.79, 19.00)	0.08	6.19
		Patient Engagement in Shared decision-making			
Who should decide your treatment?			0.86 (0.57, 1.29)	0.43	1.45
Doctor alone	63 (10.8%)	35 (6.7%)			
Mostly the doctor	93 (15.9%)	113 (21.6%)			
Doctor and patient equally	325 (55.7%)	315 (60.1%)			
Mostly the patient	58 (9.9%)	46 (8.8%)			
Patient alone	45 (7.7%)	15 (2.9%)			
Who decided to use drug eluting or bare metal stent?			2.13 (1.02, 4.43)	0.05	2.22
Doctor alone	411 (71.5%)	267 (51.8%)			
Mostly the doctor	82 (14.3%)	123 (23.9%)			
Doctor and patient equally	68 (11.8%)	108 (21.0%)			
Mostly the patient	6 (1.0%)	7 (1.4%)			
Patient alone	8 (1.4%)	10 (1.9%)			
Discussed stent type with doctor before treatment	179 (31.2%)	300 (57.8%)	2.71 (1.18, 6.26)	0.02	2.60

* Denominator restricted to those who reviewed the consent form.