Does Information on Benefits and Risks Help Patients Decide Between Stent Options?

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Abstract

**Background:** Patients undergoing percutaneous coronary intervention (PCI) may receive drug eluting stents (DES) or bare metal stents (BMS). DES reduce the risk of a repeat procedure but necessitate prolonged use of dual anti-platelet therapy (DAPT), which can increase the risk of bleeding, delay elective surgeries, and increase medication costs. Because these trade-offs directly impact patients’ experience and outcomes, patients should be engaged in the decision-making process. However, less than one-third of patients discuss stent choices with their doctors.

**Objectives:** To create and implement a shared decision-making (SDM) tool for stent choice that incorporates individualized estimates of each patient’s likely reduction in repeat procedures from DES and describes the drawbacks of prolonged DAPT, and to study the impact of the SDM tool on patient education, stent preference, participation in SDM, and, secondarily, physicians’ use of DES or BMS.

**Methods:** To create the SDM tool, we interviewed patients and providers to identify the information perceived to be most important in stent selection. We implemented the tool in a nonrandomized, sequential fashion at 2 US hospitals. In the preimplementation phase, we did not use the SDM tool; we interviewed patients to determine their knowledge of stent types, benefits and drawbacks of DES and BMS, and their stent preference. In the 2 sequential postimplementation phases, all patients received the paper SDM tool prior to their procedures, with or without decision coaching from a trained nurse.

**Results:** We assessed experiences with stent selection in 336 patients receiving
“usual care” without the SDM tool, 113 receiving the SDM tool with coaching and 137 receiving the tool without coaching. In fully adjusted analyses, the SDM tool with coaching group, as compared with usual care, resulted in 1.8 (95%CI, 1.5-2.1) out of 6 more correct responses to questions about BMS and DES. For patients receiving the SDM tool with coaching, the rate ratio (RR) for discussing stent options with nurses was 3.7 (95% CI, 2.8-4.7) and for discussing with doctors was 1.5 (95%CI, 1.26-1.79). Patients receiving the tool with coaching were more likely to state a stent preference (RR = 1.9; 95%CI, 1.6-2.3), to report being involved in the decision (RR = 2.87; 95%CI, 1.8-4.5), and to correctly recall the stent that they received (RR = 1.5; 95%CI, 1.1-1.8). No clinically significant differences were observed between use of the SDM tool without coaching and usual care. No differences in physicians’ use of DES and BMS were observed after implementation of the SDM tool, and less than 50% of patients who preferred BMS actually received one.

Conclusions: Implementation of an SDM tool for stent selection, accompanied by decision coaching, was associated with improvements in patient education, participation in SDM, and patient satisfaction, but it resulted in no change in the type of stent used. Use of the SDM tool without decision coaching had no impact on patient education, participation in SDM, or stent selection.

Limitations and Subpopulation Considerations: The intervention was designed to be sustainable in routine clinical care. However, the lack of hospital nursing staff to perform decision coaching, despite available funding, was the most significant limitation. To achieve the benefits of SDM with decision coaching, novel incentives will need to be created to enable hospitals to invest resources necessary to support decision coaching.
B. Background

Percutaneous coronary intervention (PCI) for patients with coronary artery disease (CAD) is performed >600 000 times/year in the United States.\textsuperscript{1} Patients undergoing PCI can be treated with either drug eluting stents (DES) or bare metal stents (BMS). Although DES are associated with a 50% reduction in repeat PCI, by avoiding restenosis of the coronary artery,\textsuperscript{2,3} the magnitude of benefit depends on a patient’s underlying restenosis risk.\textsuperscript{4,5} For example, as few as 6 high-risk patients need to be treated with DES to avoid 1 repeat PCI procedure, while more than 100 low-risk patients may need to be treated with DES to avoid 1 repeat procedure. Importantly, if patients receive DES, they must take a prolonged course (6-12 months) of dual anti-platelet therapy (DAPT), compared with only 1 month if they choose BMS.\textsuperscript{6} This is to minimize the risk of stent thrombosis, a potentially catastrophic complication that can result in heart attack or death. DAPT represents an increased medication burden for patients, can be expensive, can cause increased major and nuisance bleeding,\textsuperscript{7,8} and can complicate future surgeries.\textsuperscript{9} In fact, a recent study demonstrated that nuisance bleeding occurs in 37.5% of patients over the year after a heart attack and is associated with a significantly lower quality of life, and that the use of DAPT doubles the risk of nuisance bleeding.\textsuperscript{7} Despite these trade-offs, DES are currently used in roughly 80% of PCI cases, regardless of risk for restenosis.\textsuperscript{10,11}

In 2010 the American Medical Association advised that when more than one clinically acceptable treatment is available, patients should be engaged in SDM, as it can improve the value of US health care.\textsuperscript{12} The National Academy of Medicine likewise includes patient-centered care as one of its 6 domains of quality.\textsuperscript{13} In the setting of PCI, stent selection should be a preference-sensitive decision because of the offsetting benefits of DES and the drawbacks of prolonged DAPT. Research shows that patients want to be involved in their treatment decisions, with a recent study reporting that only 1 in 10 patients felt that the doctor alone should make the decision. Similarly, in another study that asked patients who made the decision about whether BMS or DES was used, >70% felt that the doctor alone made the decision and only 31% reported discussing stent options with their physician.\textsuperscript{14} These findings were also consistent with a prior study that suggested that only 10% of
patients undergoing PCI were presented with other options, only 19% were presented with a treatment’s drawbacks, and only 16% were asked about their treatment preferences.\textsuperscript{15}

Clinicians may change their behavior in response to personalized risk estimates and this can lead to improved care and outcomes. In a previous 9-center prospective study,\textsuperscript{14} we used the Patient Risk Information Systems Manager (PRISM) to create personalized informed consent documents that included patients’ risks of periprocedural mortality\textsuperscript{16} and bleeding\textsuperscript{17} as well as restenosis requiring a repeat PCI if patients are treated with DES or BMS.\textsuperscript{18} PRISM is a computer program that executes multivariable risk models with a patient’s specific risk factors. Using PRISM, we can take previously validated risk models and the results of comparative effectiveness research and prospectively deploy them in clinical care.

In the aforementioned 9-center prospective study, we demonstrated significant improvements in the informed consent process with PRISM, including more often reading the consent form and better knowledge transfer, suggesting a better patient experience with care.\textsuperscript{14} We also demonstrated that the inclusion of risk estimates for target vessel revascularization (ie, the risk of needing a repeat procedure to treat the same artery) supported greater patient participation in SDM with respect to stent selection, which increased from 31% to 58% of patients discussing stent types with their doctors. Despite this improvement, 42% of patients, even after signing consent forms explaining their target-vessel revascularization (TVR) risk with BMS and DES, did not discuss stent choices with their physicians. To better engage patients undergoing PCI in SDM, the current study sought to create a personalized SDM tool through collaboration with multiple stakeholders, including patients, nurses, and interventional cardiologists. We also trained the medical and nursing staff to serve as decision coaches to support and educate patients. The successful implementation of this technology and documented improvements in knowledge transfer could underscore the feasibility and potential of providing a novel infrastructure and process of care to engage patients undergoing PCI in SDM.

One of the goals of health care is to improve quality while limiting costs. While reducing costs was not a primary goal of this intervention, aligning treatment with patient preference may, indirectly, lower the costs of PCI by using less DES, which are more expensive than BMS. In a prior analysis,\textsuperscript{10} we calculated the cost savings and increased rate
of TVR if the rate of DES use was decreased in patients at low risk for TVR. We found that if the rate of DES use was cut in half (from 74% to 37%) in patients at the lowest risk for restenosis, an estimated $205 000 000/year could be saved in the United States (adding together the cost savings for stents and DAPT and subtracting the costs of repeat procedures). Interestingly, even if DES were entirely withheld from low-risk patients, the absolute increase in TVR would be <1%, with a savings of >$400 000 000/year. Accordingly, we postulated that a higher-quality SDM process might not only improve patient participation in SDM, but that, if patients with less benefit from DES preferred BMS, savings would occur from respecting patient preferences and not from rationing care.

Communicating these concepts to patients, however, can be difficult. Therefore, the goal of this study was to create a SDM tool to enable patients to understand their personal benefits from DES in preventing restenosis, as compared with BMS, and to inform them of the need for prolonged DAPT if DES were used. This would enable patients to choose the stent type that is most aligned with their personal goals and values.

Given that the decision regarding a patient’s optimal stent is likely to involve many considerations, we created our SDM tool based on the critical issues relevant to patients and doctors, as defined by focus groups, in weighing the benefits and risks of DES. It is noteworthy that the investigators had no preferences for which type of stents patients chose, although we were very concerned that, in current practice, the vast majority of patients do not discuss stent options with their physicians. Given the long-term implications of this choice on the need to adhere to DAPT, we believe that patients should be informed and empowered to participate in communicating their personal goals and values. Thus, this novel SDM tool was designed to achieve this goal without directing treatment to one stent or another.

C. Participation of Patients and Other Stakeholders in the Design and Conduct of Research and Dissemination of the Findings

Patients

Local Hospitals and Clinics – We recruited patients from 4 distinct practices to participate in our focus groups (n = 35). First, we recruited patients from Truman Medical
Center (TMC), Kansas City’s Safety Net Hospital and provider for a primarily African American and low-income population. Second, we recruited patients from Saint Luke’s Mid-America Heart Institute (MAHI), which has a more affluent patient population that also includes many rural farmers. We also recruited patients from the Women’s Heart Center at MAHI to ensure that women were well-represented. Finally, we recruited patients from the Cabot Clinic, which serves a primarily Hispanic patient population from which we could recruit an additional segment of patients for focus groups. We used information obtained from these focus groups to design, revise, and finalize the SDM tool for stent selection.

The Society of Participatory Medicine (SPM) – The Society for Participatory Medicine (http://participatorymedicine.org/) is a 501(c)3 public charity devoted to promoting the concept of participatory medicine among patients, caregivers, and their medical teams. SPM advances the ideal of empowered and engaged patients making informed decisions about their care and treatment, and it fosters communication among medical, communication, patient advocacy, and public health subspecialties to exchange a wide range of ideas related to participatory medicine and to support information and research programs in participatory medicine. SPM provided guidance to the research team via Dave deBronkart (e-patient Dave), a nationally recognized patient advocate. He was on the advisory committee that assisted in identifying appropriate comparators and outcomes, helped to coordinate feedback on the SDM tool from additional patients and patient advocates, and assisted in analysis and publication of preimplementation study findings, for which he was credited with authorship.

The Heartland Health Network (HHN) – HHN represents a coalition of community leaders within the Kansas City African American community, including pastors and their churches, community-based organizations, and safety net health care facilities. HHN recently received substantial resources from an infrastructure grant in community-based participatory research (RC4 MD005738). We used HHN to engage the New Bethel Church, an African American Pentecostal Church in Kansas City, Kansas, to recruit patients for the focus groups that addressed the SDM tool for stent selection. A member of New Bethel Church also served on our steering committee.

Steering Committee – We recruited three patients and patient advocates as
members of our steering committee. The committee’s launch, wrap-up, and quarterly meetings informed decision making throughout the study and monitored study conduct and progress. Committee members provided feedback on study design and methodology, creation and implementation of the SDM tool, and analysis and dissemination of study results.

**E-patients.net** – Following the final focus group, we posted the tool to the e-patients.net website ([http://e-patients.net/archives/2014/07/researcher-seeks-patient-input-what-should-a-stent-decision-aid-include.html](http://e-patients.net/archives/2014/07/researcher-seeks-patient-input-what-should-a-stent-decision-aid-include.html)) for 10 days for review and comments before sharing a final version with the steering committee.

**Providers**

We recruited interventional and noninterventional cardiologists from MAHI and TMC (n = 8) to participate in interviews that led to the creation of the SDM tool for stent selection. These cardiovascular practices have extensive experience in the management of CAD/PCI patients among a diverse population of patients. We recruited members from the American College of Cardiology (n = 2), American Heart Association (n = 1), and Society for Cardiovascular Angiography and Interventions (n = 1) to serve on our advisory committee and contribute to the study design and methodology. Further, the steering committee also included 2 interventional cardiologists and 1 noninterventional cardiologist. We are continuing to work with these same organizations to disseminate the study findings.

**Payers**

The chief medical officer for United Healthcare in Kansas City served on the steering committee, helped design this proposal, and contributed to study design and methodology. He is advising us on strategies for disseminating our tool and how it might be appealing to payers.

**D. Methods**

**Phase 1: Developing and Programming an SDM Tool for Stent Choice**

**Study Design**: We developed a paper-based SDM tool with input from the study team, steering committee, 4 patient focus groups, provider interviews, and patients. Three phases of development ensued. First, the study team and steering committee determined
the selection strategy for focus groups, drafted a preliminary SDM tool, and developed the interview guide. The interview guide (Appendix A) articulated preliminary considerations in stent selection and consisted of questions regarding patients’ considerations in stent selection and the framing of risks and outcomes. Multiple presentation formats for the communication of risk were developed and assessed in the patient and physician focus groups as part of phase 2. Examples of each presentation type were used along with appropriate explanatory text. We held a second phase of focus groups to review a revised SDM tool incorporating initial patient input from the first phase. We shared insights from these focus groups with the steering committee before we prepared a final version of the tool to present to a subset of participants in the last, confirmatory phase of tool development.

**Forming the Focus Group Study Cohort:** To elicit the most important aspects of the treatment decisions to include in our SDM tool, we first assembled focus groups with key stakeholders. We conducted focus groups with diverse patients and providers until saturation was attained at MAHI, the Women’s Heart Center at MAHI, TMC, the Cabot Clinic, and New Bethel Church. Participants were compensated for their time. Physician and cath lab staff were interviewed and provided feedback on the tool development.

**Study Setting:** We conducted focus groups on-site, depending on the group.

**Interventions:** We developed interview guides based on an ancestry approach, where potential topics to be explored are tracked from one study to another until redundancy occurs (see Appendix A). We tailored each guide slightly for each cohort, to optimize relevancy for the diverse groups and to carry forward learnings from prior focus groups.

**Follow-up:** None

**Study Outcomes:** Factors of importance in stent selection identified by stakeholders included the risk of repeat procedures, need for additional medication, medication costs, side effects of medication, and the need to delay future procedures or surgeries due to DAPT-related bleeding concerns. For each outcome, the optimal mode of risk presentation was discussed (eg, absolute versus relative risk reduction, positive versus negative framing, expression of risks as frequencies versus percentages). Focus groups collated the most
common questions patients have about the choice of stents, to create an option grid to be used in both the SDM tool and the decision coach training. We also elicited opinions regarding the optimal timing and setting for patients to use the SDM tool.

**Data Collection and Sources:** Following IRB approval, we conducted purposive patient sampling among patients who recently underwent PCI. We developed an interview guide (see Appendix A) to foster discussions on framing and presentation of benefits and risks of DES; discussing the drawbacks to DAPT (ie, medication taking, delaying future surgery, bleeding, bruising); and finally having the participants rank the importance of the 4 main drawbacks to DAPT. Experienced researchers (CD, BG) facilitated the focus groups, with a Spanish facilitator for the Spanish-only group at Cabot Clinic. Each focus group comprised 6-7 subjects/meeting, lasted 40-55 minutes, and was digitally recorded. Similarly, provider interviews were assembled from purposive sampling of the >50 cardiologists, >30 cath lab staff, and >25 nurses working in the cath lab.

**Analytical and Statistical Approaches:** Using qualitative research methods, team members reviewed the transcribed interviews independently and identified patterns and themes.

These data were manually coded according to passages that exemplified key concepts or ideas from each transcript. This iterative 2-phase process captured the meaning behind the transcribed text from the interviews, with the goal of creating an increasingly sophisticated and rich description of participants’ perspectives regarding important outcomes.19-21

After the preliminary codes were identified, team members created a visual display of key nodes and attributes and transformed it into the taxonomy of themes used to assign final coding of the raw narrative data.22 They reviewed conclusions drawn from the qualitative data in the context of the entire data set, with the goal of finding discrepant information and modifying the themes when discrepancies were found. To establish the construct validity of the coding, coders from diverse disciplines were used (ie, nurses, a physician, and an experienced research associate). After separately summarizing and interpreting the findings from patients and clinicians, the research team discussed similarities and differences to reach consensus.
Conduct of the Study: We held focus groups over the course of 2 months, allowing for information gained at one group to refine the materials prior to meeting with the next group. The 4 patient focus groups included 7 patients from MAHI, 7 from TMC, 17 from the New Bethel Church, and 6 from Cabot Clinic. Table 1 shows participants’ demographic characteristics. After each focus group was completed, the transcribed audio recording was reviewed and coded. The tool was then modified and edited to incorporate feedback prior to the next focus group’s meeting. The study timeline is included as Appendix B.

Refining the SDM tool: Each time a “new version” was shared, the original tool was also provided so that member checking (ie, accurate integration of focus group participant feedback into the evolving tool) was ongoing. Following the final focus group, we posted the tool to the e-patients.net website (http://e-patients.net/archives/2014/07/researcher-seeks-patient-input-what-should-a-stent-decision-aid-include.html) for review before sharing a final version with the steering committee.

Phase 2: Implementing and Testing the SDM Tool for Stent Choice

Overview: In the postimplementation phases, patients presenting for PCI or coronary angiography prior to PCI received the SDM tool and decision coaching while in the preparatory area for their procedure (first interventional phase of the study), or the SDM tool alone, without decision coaching (second interventional phase of the study). The patient then underwent the procedure, and following it, once sedation had worn off, the patient was approached to complete a post-procedure interview to assess knowledge transfer, patient assessment of the quality of SDM, and his or her preferences for stent type.
Study Design: Programming: We developed a template of the final SDM tool into which the PRISM system could populate the personalized restenosis risk estimates; those estimates could be delivered on paper to the patients at the time that informed consent for PCI was obtained (see Appendix C). This SDM template included text that describes, in lay terms, the nature of CAD, stents, TVR and DAPT obligations, costs, and risks. All such components were generated from the information obtained from the focus groups.

Implementation: We analyzed the impact of the SDM tool on patient outcomes in a pre-post fashion, by conducting an interview prior to hospital discharge that assessed patients’ knowledge and experience. In addition, we trained nurses to provide decision coaching to patients receiving the SDM tool. We included in the analytic data sets only patients who underwent PCI and compared outcomes for patients who did and did not receive the SDM tool and for patients who did or did not receive decision coaching.

Forming the Study Cohort: We recruited patients for this study at 2 PCI centers: MAHI and TMC. Cardiologists at MAHI and TMC are employed by their respective health systems, with separate administrative organizations that are not affiliated. MAHI has achieved nursing magnet status, but TMC has not. We identified patients based on review of

Table 1: Demographic Characteristics of Patients Participating in Focus Groups

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>n = 35</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>21 (60.0%)</td>
</tr>
<tr>
<td>Male</td>
<td>14 (40.0%)</td>
</tr>
<tr>
<td>Age</td>
<td>60.6 ± 13.8</td>
</tr>
<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>21 (60.0%)</td>
</tr>
<tr>
<td>Other</td>
<td>1 (2.9%)</td>
</tr>
<tr>
<td>White</td>
<td>13 (37.1%)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>6 (17.1%)</td>
</tr>
<tr>
<td>Heart Disease</td>
<td>17 (48.6%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>4-year college degree</td>
<td>3 (9.1%)</td>
</tr>
<tr>
<td>8th Grade or less</td>
<td>1 (3.0%)</td>
</tr>
<tr>
<td>High school diploma or GED</td>
<td>11 (33.3%)</td>
</tr>
<tr>
<td>More than 4 year degree</td>
<td>3 (9.1%)</td>
</tr>
<tr>
<td>Some high school</td>
<td>2 (6.1%)</td>
</tr>
<tr>
<td>Vocational school or some college</td>
<td>13 (39.4%)</td>
</tr>
</tbody>
</table>
the procedure schedule, and patients were approached in the procedural preparatory area prior to coronary angiography to obtain informed consent for participation in the study at TMC. MAHI’s IRB considered the study to be quality Improvement and granted a waiver of written informed consent. There were 1282 patients who underwent PCI during the time period of the study who were not included, mostly due to the lack of a decision coach during the phase in which decision coaching was intended. When a coach was not available, the patient did not receive the SDM tool or coaching and was not enrolled in the study. We do not believe that this affected our study findings, because the availability of a decision coach was a random variable based on the allocation of work days and not associated with patient characteristics.

**Study Setting:** The SDM tool, along with the PRISM-generated informed consent, was provided to patients in the catheterization laboratory preparatory area. Post-procedure interviews were conducted in the patient recovery unit.

**Interventions:** In the postimplementation phase, patients received the paper-based SDM tool (Appendix C) with or without decision coaching. While MAHI already used the PRISM tool for obtaining informed consent in routine clinical care, TMC did not. Therefore, the PRISM platform was implemented at TMC before patients were recruited for the study. Drs. Kathleen Goggin and Delwyn Catley, experts in motivational interviewing, designed a training curriculum for decision coaches to impartially solicit patients’ preferences and empower patients to express them to their physicians. In the postimplementation phases, decision coaches initiated the SDM process by sharing the SDM tool with patients. Coaches also used frequently asked questions (FAQs)/option grids, thus blending supportive training for the coaches with personalized estimates for the patients. Finally, 2 interventional cardiologists (1 at MAHI and 1 at TMC) were trained in motivational interviewing techniques to serve as physician champions and to engage their colleagues at their institutions.

**Follow-up:** Post-procedure interviews were conducted in the patient recovery unit.

**Study Outcomes:** Because the goal of this study was to develop a tool to increase SDM for stent selection in PCI, the primary outcome in this trial was whether patients discussed stent choices with their physicians. We assessed other measures of SDM, including patient preference for a stent type and discussion quality score based on the Health Care
Climate Questionnaire, as secondary end points. Secondary goals of the study were to improve patient education and knowledge retention and to assess the impact of the SDM tool on actual stent selection at time of procedure. Therefore, secondary outcomes included patients’ recall of individual aspects of the stent discussion, stent knowledge score (based on number of correct answers to 6 questions assessing knowledge transfer), concordance of patient stent preference and type of stent received, and alignment of patient values with stent type received.

Data Collection and Sources: A research associate conducted post-PCI patient interviews to collect data. Data collected included answers to questions regarding knowledge transfer surrounding stents and stent types, patients’ value of factors that may play a role in stent selection, preferences for patients’ level of engagement in SDM, and patients’ self-report of their level of engagement in the stent selection decision. Patient demographic, clinical, and procedural characteristics were obtained from the study data collection form (see Appendix D). The data were entered into our electronic data collection system, RedCAP, and regularly audited for completeness.

Analytic and Statistical Approaches: To assess implementation of the SDM tool, we surveyed the sites to understand the barriers and benefits of introducing an SDM tool into clinical practice. To evaluate the effect of the SDM intervention, we compared the study’s outcomes (described above) among patients receiving personalized consents for their PCI procedure only (with no SDM tool), patients receiving the SDM tool along with decision coaching, and patients receiving the SDM tool without decision coaching. We made unadjusted comparisons of continuous variables using 1-way analysis of variance, and comparisons of categorical variables using a chi-square or Fisher exact test. We made adjusted comparisons between groups (usual care, SDM tool with coaching, SDM tool without coaching) using estimates from generalized linear models (normal distribution/identity link for mean differences, binomial or modified Poisson distribution with log link for rate ratios), and adjusting for site and patient characteristics between the 3 phases of the study when the standardized differences of the patients between the 3 groups were >10 (race, diabetes, peripheral arterial disease, prior CABG, prior PCI, admission status, and enrolling site).
Comparisons of patients' correct recollection of the stent type received and of concordance with their stent preference we further adjusted for stent type received. We obtained the data for this cross-sectional study from chart abstraction and patient interviews, without follow-up assessments, resulting in minimal missing data (≤5% for all outcomes). Statistical significance was denoted by 2-sided \( p \) values < 0.05. We performed analyses using SAS version 9.4 (SAS Institute, Cary, NC) and R version 3.3.1 (R Core Team).

**Conduct of the Study:** After IRB approval, we began the patient survey at both centers during the preintervention phase. Study coordinators received training on survey administration and clinical data collection. The survey ran concurrent with the focus groups developing the SDM tool. Following completion of the focus groups, the SDM tool was programmed into PRISM. Study coordinators at both sites then recruited decision coaches for training. At TMC, bedside nurses from the catheterization lab served as decision coaches; at MAHI, a similar plan to use bedside nurses was pursued, but personnel limitations meant that clinical research nurses served as decision coaches. The decision coach curriculum included a didactic portion, with a proposed script highlighting the Ottawa Decision Support framework that addresses decisional needs, decision quality, and decision support. The curriculum also included the use of motivational interviewing techniques and provided opportunities for role playing (see Appendix E). Training was conducted in a 2-hour classroom setting with video examples (https://www.youtube.com/watch?v=8oELU5vGNxw), then modeled by Beth Gialde RN, MSN, in a patient setting. Gialde then supervised initial coaching sessions to ensure consistency. Non-coach research nurses conducted postimplementation surveys. Decision coaching was conducted at MAHI from March 12, 2015, until February 10, 2016, and then attempted by bedside nurses from June 27, 2016, until September 5, 2016. Patient coaching was conducted at TMC from December 8, 2015, until December 16, 2016. The survey portion of the study concluded at both sites on December 16, 2016.

**E. Results**

Specific Aim 1 – Create an SDM tool for stent selection that outlines the potential benefits, risks, and costs of DES versus BMS, under the guidance of a multistakeholder advisory committee and with direct patient and provider input from focus groups.
Findings from the patient focus groups included specific feedback on the visual representation and ranking of the 4 main DAPT drawbacks identified from patient and clinician feedback. We organized all coding according to the 3 main interview guide constructs: framing of the risks and benefits, discussion of the 4 DAPT drawbacks, and ranking of the value of each drawback as to the importance or impact on the individual’s life (Table 2). Additionally, we held a clinician meeting, during which participants viewed the first and final versions of the SDM tool.

Table 2. Representative Statements from Focus Group Participants Grouped by Topic

<table>
<thead>
<tr>
<th>Topic</th>
<th>Quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timing</td>
<td>“I would want the information at the time.” NM15</td>
</tr>
<tr>
<td></td>
<td>“Yes, I would rather have the information prior to the procedure.” NF08</td>
</tr>
<tr>
<td></td>
<td>“I love this. I actually love having this information. I really do.” NF12</td>
</tr>
<tr>
<td></td>
<td>“If I go to the doctor today and they say you have heart problems. Bring this up and let me know what my options are.” NF13</td>
</tr>
<tr>
<td></td>
<td>“Once I’m diagnosed, I want to know what procedure, what I should take.”</td>
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<tr>
<td></td>
<td>“If I was diagnosed with the problem, I would want to know immediately what my options were and what I was going to have to go through and what would be the best procedure for me.” NF14</td>
</tr>
<tr>
<td>Usefulness</td>
<td>“You could have an intelligent conversation with your doctor.” NF12</td>
</tr>
<tr>
<td></td>
<td>“So, I would want this but I would also want my doctor or someone who can sit down with me and go over this with me so that I wouldn’t have to have the focus on this myself.” NM15</td>
</tr>
<tr>
<td></td>
<td>“I’ve got the bare metal simply because tomorrow is another day and there may be something different the next time the procedure, if it’s ever needed. You can always go back and put a drug-eluting stent in backing that one up. So, at that point then you have a choice.” NM20</td>
</tr>
<tr>
<td></td>
<td>“I could see people reading it [education tool] and getting absolutely scared to death. IF THIS WAS SENT TO YOU IN THE MAIL, THIS WOULD BE SCARY? Yes!” HM22</td>
</tr>
<tr>
<td>Topics</td>
<td>“It is the most important thing, the chance of having to come back.” NM09</td>
</tr>
<tr>
<td></td>
<td>“One thing I found when I had my stent put in, they didn’t explain the difference between a regular stent and a medicated stent. ... At the time they did it, I think they could have been better equipped to instruct people on the difference.” NM22</td>
</tr>
<tr>
<td></td>
<td>“I chose the bare metal ... and I guess my main thing is needing other surgery. If you would need some sooner than a year.” NF19</td>
</tr>
<tr>
<td></td>
<td>“I chose the bare metal ... and the main reason was the length of time on the medicine [for DES] of 1 year. The bleeding or bruising I didn’t think was too important one way or the other.” NM20</td>
</tr>
<tr>
<td>Format/</td>
<td>“I like real graphs. I mean I understand graphs.” NF08</td>
</tr>
<tr>
<td>Layout</td>
<td></td>
</tr>
</tbody>
</table>
Following completion of the focus groups and clinician meeting, having met saturation to the point that no new themes were identified during analysis of the final focus group transcript (see Analytical and Statistical Approaches), we posted the tool to the e-patients.net website ([http://e-patients.net/archives/2014/07/researcher-seeks-patient-input-what-should-a-stent-decision-aid-include.html](http://e-patients.net/archives/2014/07/researcher-seeks-patient-input-what-should-a-stent-decision-aid-include.html)) for 10 days of review and comment before sharing a final version with the steering committee. We shared this with the steering committee and patient advisors for their input, with only minor edits being made—except in the case of 1 cardiologist on the steering committee (not an interventional cardiologist) who spent approximately 15 minutes reading and reviewing the tool and who subsequently encouraged additional text at the top of the page to stress that “there is no difference in survival or future heart attacks between the 2 types of stents.” This statement was added in boldface type. Once the tool was finalized (Figure 1), we sent the template to Health Outcomes Sciences for programming into PRISM. It was successfully tested for accuracy, appropriate visual display, and printing capabilities.

Following implementation of the tool and coaching at MAHI, we conducted clinician surveys (n = 30) at MAHI, but not at TMC because the only interventional cardiologist practicing there at the time was a co-investigator. Interventional cardiologists stated they used visual materials in 100% of their discussions with patients, although only 76% included a discussion of the stent type and elicited a patient preference. Most physicians (97%) responded that nearly three-quarters of the patients had no stent preference.

**Specific Aim 2 – Program PRISM and Implement the SDM Tool at 2 PCI Centers**

With the assistance of Health Outcomes Sciences, the entity that supports PRISM, we successfully programmed PRISM by adding the SDM tool template to the existing PRISM-generated, personalized informed consent form and populating the SDM tool with personalized TVR risk estimates with BMS and DES. In the postimplementation phase, at both sites, patients undergoing PCI received a paper-based SDM tool with their personalized consent form.
Coronary Stent Choice

A coronary stent is a device that props open a narrowed artery in the heart. There are 2 types of coronary stents: bare metal and drug-coated. You may prefer one stent over the other based on the information below and a discussion with your doctor.

<table>
<thead>
<tr>
<th>Repeat Heart Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you choose a bare metal stent, 9 out of 100 people like you will need a repeat procedure within a year.</td>
</tr>
<tr>
<td>If you choose a drug-coated stent, 5 out of 100 people like you will need a repeat procedure within a year.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>BARE METAL STENT</th>
<th>DRUG-COATED STENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Required Medicine</strong></td>
<td><strong>Required Medicine</strong></td>
</tr>
<tr>
<td>- Take an extra blood thinner for at least one month</td>
<td></td>
</tr>
<tr>
<td>- Stopping the medicine before one month increases the risk of a heart attack and death.</td>
<td></td>
</tr>
<tr>
<td>- Your total cost for the extra blood thinner for that month would be between $4.00 and $200.00.</td>
<td>- Take an extra blood thinner for at least one year</td>
</tr>
<tr>
<td>- Stopping the medicine before one year increases the risk of a heart attack and death.</td>
<td></td>
</tr>
<tr>
<td>- Your total cost for the extra blood thinner for that year would be between $48.00 and $2500.00.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bruising and Bleeding</th>
<th>Bruising and Bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Most patients bruise and bleed more easily while taking the extra blood thinner.</td>
<td>- Most patients bruise and bleed more easily while taking the extra blood thinner.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Future Procedures or Surgery</th>
<th>Future Procedures or Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Major medical procedures, major dental work, and surgery must wait one month after a bare metal stent.</td>
<td>- Major medical procedures, major dental work, and surgery must wait one year after a drug-coated stent.</td>
</tr>
</tbody>
</table>
Coronary Stent Choice

A coronary stent is a device that props open a narrowed artery. There are 2 types of coronary stents: bare, metal and drug-coated. You are at low risk for your artery narrowing within a year after either type of stent, but you may prefer one over the other based on the information below and a discussion with your doctor.

<table>
<thead>
<tr>
<th>Bare Metal Stent</th>
<th>Drug-Coated Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you choose a bare metal stent, 9 out of 100 people like you will need a repeat procedure within a year.</td>
<td>If you choose a drug-coated stent 5 out of 100 people like you will need a repeat procedure within a year.</td>
</tr>
</tbody>
</table>

**Required Medication**

You will need to take a medicine to prevent a blood clot in the stent. With a bare metal stent, you will need to take the medicine for at least one month after your procedure. Stopping this medicine before one month increases the risk of a heart attack and death. The medicine can cost between $4.00 and $200.00 per month depending upon which medicine is used and your insurance coverage.

**Future Procedures or Surgery**

Major medical procedures, major dental work, and surgery can be done one month after a bare metal stent.

**Bruising & Bleeding**

You may bruise and bleed more easily for the one month you are taking the medicine that prevents a clot in the stent.

Required Medication

You will need to take a medicine to prevent a blood clot in the stent. With a drug-coated stent, you will need to take that medicine for at least one year after your procedure. Stopping this medicine before one year increases the risk of a heart attack and death. The medicine can cost between $48.00 and $2500.00 per year depending upon which medicine is used and your insurance coverage.

**Future Procedures or Surgery**

You will be asked to delay major medical procedures, major dental work, and surgery for one year after a drug-coated stent.

**Bruising & Bleeding**

You may bruise and bleed more easily for the one year you are taking the medicine that prevents a clot in the stent.
A coronary stent is a device that props open a narrowed artery in the heart. There are 2 types of coronary stents: bare metal and drug-coated. The chart below explains the differences between a bare metal stent and a drug-coated stent. Research shows there is no difference in survival or future heart attacks between the two types of stents. You may prefer one stent over the other based on the information below and a discussion with your doctor or nurse.

<table>
<thead>
<tr>
<th></th>
<th>BARE METAL STENT</th>
<th>DRUG COATED STENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Repeat Heart Procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If the stent that you receive today becomes blocked, you will need another heart procedure to place another stent.</td>
<td><img src="chart-bare-metal" alt="Bare Metal Stent" /></td>
<td><img src="chart-drug-coated" alt="Drug Coated Stent" /></td>
</tr>
<tr>
<td>Out of 100 people like you:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>93 will not need a repeat procedure due to stent blockage</td>
<td></td>
<td>96 will not need a repeat procedure due to stent blockage</td>
</tr>
<tr>
<td>7 will need a repeat procedure due to stent blockage</td>
<td></td>
<td>4 will need a repeat procedure due to stent blockage</td>
</tr>
<tr>
<td>Required Medicine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>You will need to take a blood thinner medicine (in addition to aspirin).</td>
<td>At least 1 month†</td>
<td>At least 12 months†</td>
</tr>
<tr>
<td>Stopping the medicine early increases the risk of a heart attack and death.</td>
<td>Before 1 month</td>
<td>Before 12 months</td>
</tr>
<tr>
<td>Cost of medicine varies, depending on insurance coverage.</td>
<td>Total cost: $16 - $300</td>
<td>Total cost: $192 - $3600</td>
</tr>
<tr>
<td>Bleeding and Bruising</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Most patients bruise and bleed more easily while taking the extra blood thinner medicine.</td>
<td>At least 1 month</td>
<td>At least 12 months</td>
</tr>
<tr>
<td>Other Medical Procedures and Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Major medical procedures, major dental work, and surgery must wait.</td>
<td>At least 1 month</td>
<td>At least 12 months</td>
</tr>
</tbody>
</table>

†Duration of medication therapy varies. Do not stop your medicine without talking with your doctor first.

This is not a part of the permanent medical record.
Saint Luke’s Mid America Heart Institute

Patients in our focus groups reached general consensus that they would like information about their procedure as early as possible within the process of care. Therefore, we proposed to cardiology office administrators that the nursing staff should use the SDM tool in the outpatient setting at the time that coronary angiography is ordered.

Alternatively, having identified a gap in knowledge, we postulated that patients could be scheduled for another appointment prior to their procedure, to have an opportunity to speak to a clinician about any questions or concerns. After many discussions regarding possible implementation strategies, it was noted that the most pressing concern was the lack of consistency in the staff who communicated with patients about the need for angiography (often after the results of stress testing were available) and that the pool of nurses was too large to train and deliver the intervention consistently and with adequate fidelity. It was also not possible to add a visit prior to the procedure, which was estimated to add upward of 1000 visits per year, based mostly on the lack of providers and space.

The original intent of the study was to use bedside nurses as decision coaches to help patients better understand their preferences in medical care. After being unsuccessful with implementation in the cardiology office, we pursued training bedside nurses in the cath lab prep/recovery unit. After approval by nursing administration, we trained and certified 5 bedside nurses in decision coaching. These nurses attempted to coach for a period of 8 weeks; however, the unit was experiencing higher-than-usual staff turnover and was reliant on temporary nurse support, which decreased the time available for decision coaches to engage patients in SDM. Lack of support from interventional cardiologists was also reported as a barrier. Ultimately, we deemed these barriers too difficult to overcome, and we elected to have research staff conduct the coaching, with the intention that, if this proved successful, we could reengage hospital administration and nursing staff to implement the tool in routine care.

After concluding that bedside nurses would not be able to provide decision coaching, the study team trained designated research nurses as decision coaches, and 4 nurses became certified. This approach proved to be the most successful; however, it also had limitations and barriers. Because these nurses were not directly caring for the patients, they had to insert
themselves into the process of care and find time with each patient to review the SDM tool and provide decision coaching. This was often difficult because patient care takes priority, and there is often little or no time for additional education/coaching. For example, some patients could not complete decision coaching due to other clinicians needing to speak with them, nursing care being carried out, and patients undergoing other testing (e.g., echos).

Truman Medical Center

At TMC, catheterization laboratory nurses served as decision coaches for the duration of the study.

Specific Aim 3 – Test the Impact of the SDM Tool on Patient Participation in SDM

The consensus of the study team, steering committee, and advisory committee was that a pre-post study design was most appropriate, largely because of concerns that if a randomized study were performed, there would be a “bleeding over” effect of the additional coaching and discussions to nonrandomized patients. Due in part to the barriers outlined above regarding the unavailability of nursing staff to serve as decision coaches, we conducted the study in 3 distinct phases: (1) pre-implementation, in which patients undergoing coronary angiography and possible PCI received a PRISM-generated, personalized consent form with embedded personalized risk estimates for mortality, bleeding, and TVR with BMS and DES, but not the SDM tool; (2) postimplementation with decision coaching, in which patients received the PRISM consent form, the SDM tool for stent selection, and decision coaching from a nurse trained in motivational interviewing; and (3) postimplementation without decision coaching, in which patients received the PRISM-generated consent form and the SDM tool as an additional page of that consent form, with no decision coaching. This provided a unique opportunity to assess whether the coaching was important or if merely presenting a personalized SDM tool with the consent would suffice. We assessed experiences with stent selection in 336 patients not receiving the SDM tool, 113 receiving the SDM tool with decision coaching, and 137 receiving the SDM tool without coaching (Figure 2). Characteristics of patients enrolled in these 3 study phases were generally similar, although we observed statistically significant differences in site of enrollment, race, history of peripheral arterial disease, and admission status (Table 4). The standardized differences denote the difference in means (or proportion) between the 2
groups being compared, divided by their pooled standard deviations (and multiplied by 100 to represent percent of the standard deviation), which rendered a unitless measure of similarity that can be compared across variables with different scales.

Figure 2: Patient Enrollment
Table 4. Patient and Procedural Characteristics of Patients in the Preimplementation and Postimplementation Phases

<table>
<thead>
<tr>
<th></th>
<th>Pre n = 336</th>
<th>Post-No Coach n = 137</th>
<th>Post-Coach n = 113</th>
<th>P-Value</th>
<th>PN vs. Pre</th>
<th>PN vs. PC**</th>
<th>PN vs. Pre</th>
<th>PN vs. PC**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age - years</strong></td>
<td>66.1 ± 11.8</td>
<td>68.6 ± 11.6</td>
<td>67.6 ± 12.9</td>
<td>0.288</td>
<td>21.6</td>
<td>12.3</td>
<td>8.2</td>
<td></td>
</tr>
<tr>
<td><strong>Site</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAHI</td>
<td>191 (56.8%)</td>
<td>132 (96.4%)</td>
<td>86 (76.1%)</td>
<td>&lt; 0.001</td>
<td>105.3</td>
<td>41.6</td>
<td>61.2</td>
<td></td>
</tr>
<tr>
<td>Truman</td>
<td>145 (43.2%)</td>
<td>5 (3.6%)</td>
<td>27 (23.9%)</td>
<td>0.996</td>
<td>0.3</td>
<td>0.9</td>
<td>0.6</td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>166 (64.1%)</td>
<td>88 (64.2%)</td>
<td>71 (64.5%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>93 (35.9%)</td>
<td>49 (35.8%)</td>
<td>39 (35.5%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>77</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White/Caucasian</td>
<td>250 (76.5%)</td>
<td>116 (85.9%)</td>
<td>91 (81.3%)</td>
<td>0.029</td>
<td>25.6</td>
<td>14.7</td>
<td>14.9</td>
<td></td>
</tr>
<tr>
<td>Black/African-American</td>
<td>77 (23.5%)</td>
<td>18 (13.3%)</td>
<td>21 (18.8%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asian</td>
<td>0 (0.0%)</td>
<td>1 (0.7%)</td>
<td>0 (0.0%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>9</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hispanic ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.911</td>
<td>4.0</td>
<td>0.5</td>
<td>3.4</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>45</td>
<td>5</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td>152 (45.4%)</td>
<td>69 (52.7%)</td>
<td>49 (43.4%)</td>
<td>0.269</td>
<td>14.6</td>
<td>4.0</td>
<td>18.6</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td>266 (79.6%)</td>
<td>106 (80.3%)</td>
<td>92 (81.4%)</td>
<td>0.918</td>
<td>1.7</td>
<td>4.5</td>
<td>2.8</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>2</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Peripheral arterial disease</strong></td>
<td>29 (8.8%)</td>
<td>20 (16.5%)</td>
<td>22 (19.5%)</td>
<td>0.004</td>
<td>23.5</td>
<td>31.0</td>
<td>7.6</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>5</td>
<td>16</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prior CABG</strong></td>
<td>53 (15.9%)</td>
<td>28 (22.0%)</td>
<td>20 (17.7%)</td>
<td>0.297</td>
<td>15.8</td>
<td>4.9</td>
<td>10.9</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>2</td>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Prior PCI</strong></td>
<td>137 (41.1%)</td>
<td>66 (49.6%)</td>
<td>50 (44.2%)</td>
<td>0.246</td>
<td>17.1</td>
<td>6.3</td>
<td>10.7</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>3</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Admission status</strong></td>
<td></td>
<td></td>
<td></td>
<td>0.002</td>
<td>30.7</td>
<td>37.1</td>
<td>12.5</td>
<td></td>
</tr>
<tr>
<td>Inpatient</td>
<td>116 (35.6%)</td>
<td>57 (44.2%)</td>
<td>44 (39.6%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatient</td>
<td>189 (58.0%)</td>
<td>71 (55.0%)</td>
<td>67 (60.4%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergent</td>
<td>21 (6.4%)</td>
<td>1 (0.8%)</td>
<td>0 (0.0%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>10</td>
<td>8</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*PN=Post-implementation, No coaching  
**PC=Post-implementation with Coaching  
Continuous variables compared using one-way analysis of variance.  
Categorical variables compared using chi-square or Fisher's exact test.
Preimplementation Data

Complete data for patient preferences about factors related to stent choice were available for 311 patients in the preimplementation phase. Information about the final stent placed was missing in 15 (4.7%) patients and could not be captured due to IRB requirements of working with deidentified data. We found that 14.4% of patients considered avoiding a repeat revascularization procedure as the single most important factor when deciding on a choice of stent, while 20.6% considered avoiding one of the DAPT drawbacks as most important (Figure 3). The remaining 65% of patients considered avoiding at least one of the drawbacks of DAPT as important as avoiding repeat revascularization, underscoring the importance of SDM. These results were recently published.24 Figure 4 shows the percentage of patients who ranked each consideration as one of their top concerns. Table 5 shows the characteristics of patients based on what they most valued.

Although statistically statistical differences in patient preferences were observed according to gender, race, and elapsed time since prior PCI, only a minority of patients in all subgroups valued avoidance of repeat revascularization as the single most important factor in stent selection. Among the 60.6% of patients who subsequently underwent PCI, 85% were treated with DES, and no difference in DES use was observed among patients who most valued avoiding repeat revascularization, who most valued avoiding DAPT drawbacks, or who valued both equally (78.7% versus 86.2% versus 85.6%, respectively, \( p = 0.56 \); Figure 5).
Figure 3: Distribution of the Most Important Considerations to Patients in Selecting a Stent

Patients valued avoiding:

- DAPT drawbacks alone: 20.6%
- Repeat revascularization alone: 14.4%
- Both equally: 63.0%

Figure 4: Distribution of DAPT Drawbacks That Patients Ranked Most Important to Avoid

% patients listing avoiding this factor as top concern³

1. Repeat revascularization: 79.4%
2. Any DAPT drawback: 85.6%
3. Cost: 63%
4. Number of pills/day: 60%
5. Delay future surgery: 48.5%
6. Minor bleeding/bruising: 32%

³Alone as the top concern or with any other factor ranked as a top concern.
Table 5: Factors Most Important in Stent Selection in Patient Subgroups

<table>
<thead>
<tr>
<th></th>
<th>Valued DES benefits N = 45</th>
<th>Valued DAPT drawbacks N = 64</th>
<th>Valued both equally N = 202</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>8 (10.5%)</td>
<td>12 (15.8%)</td>
<td>56 (73.7%)</td>
<td>0.041</td>
</tr>
<tr>
<td>Male</td>
<td>34 (23.0%)</td>
<td>28 (18.9%)</td>
<td>86 (58.1%)</td>
<td></td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>2 (3.5%)</td>
<td>14 (24.6%)</td>
<td>41 (71.9%)</td>
<td>0.032</td>
</tr>
<tr>
<td>Caucasian</td>
<td>37 (16.5%)</td>
<td>46 (20.5%)</td>
<td>141 (62.9%)</td>
<td></td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>15 (11.4%)</td>
<td>36 (27.3%)</td>
<td>81 (61.4%)</td>
<td>0.055</td>
</tr>
<tr>
<td>No</td>
<td>30 (16.7%)</td>
<td>28 (15.7%)</td>
<td>121 (67.6%)</td>
<td></td>
</tr>
<tr>
<td><strong>Hypertension</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>32 (13.7%)</td>
<td>45 (19.3%)</td>
<td>156 (67.0%)</td>
<td>0.193</td>
</tr>
<tr>
<td>No</td>
<td>13 (16.6%)</td>
<td>19 (24.4%)</td>
<td>46 (59.0%)</td>
<td></td>
</tr>
<tr>
<td><strong>PAD</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6 (20.7%)</td>
<td>3 (10.3%)</td>
<td>20 (69.0%)</td>
<td>0.246</td>
</tr>
<tr>
<td>No</td>
<td>39 (13.9%)</td>
<td>61 (21.6%)</td>
<td>182 (64.5%)</td>
<td></td>
</tr>
<tr>
<td><strong>Prior CABG</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>10 (18.5%)</td>
<td>12 (22.2%)</td>
<td>32 (59.3%)</td>
<td>0.483</td>
</tr>
<tr>
<td>No</td>
<td>35 (13.6%)</td>
<td>52 (20.2%)</td>
<td>170 (66.2%)</td>
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<tr>
<td><strong>Prior PCI</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>20 (15.9%)</td>
<td>27 (21.4%)</td>
<td>79 (62.7%)</td>
<td>0.652</td>
</tr>
<tr>
<td>No</td>
<td>25 (13.5%)</td>
<td>37 (20.0%)</td>
<td>123 (66.5%)</td>
<td></td>
</tr>
<tr>
<td><strong>PCI time frame</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 6 months</td>
<td>1 (3.8%)</td>
<td>6 (23.1%)</td>
<td>19 (73.1%)</td>
<td>0.023</td>
</tr>
<tr>
<td>≥ 6 months</td>
<td>17 (18.8%)</td>
<td>18 (20.0%)</td>
<td>55 (61.2%)</td>
<td></td>
</tr>
</tbody>
</table>
Preimplementation and Postimplementation Comparisons

Based on post-procedure interviews, patients who received the SDM tool and decision coaching were more likely to participate in decision making regarding stent selection (60% versus 30%, *p* < 0.001) and to state that they had a stent-type preference (68.8% versus 35.4%, *p* < 0.001), compared with patients in the preimplementation phase (Figures 6 and 7). There was no difference in these parameters between patients in the preimplementation phase and those who received the SDM tool without decision coaching. In fully adjusted analyses (Table 6), patients who received the SDM tool and decision coaching were significantly more likely to participate in decision making regarding stent selection (OR 2.87 [1.84, 4.49]; *p* < 0.001) and to state a stent preference (OR 1.91 [1.57, 2.33]; *p* < 0.001).
**Figure 6: Patients’ Participation in Decision Making Regarding Stent Selection: Answer to the Question, “Who Chose the Type of Stent?”**

- **Doctor alone**
- **Mostly doctor**
- **Doctor and you equally**
- **Mostly you**
- **You alone**

**Figure 7: Patients’ Stated Stent Preference**

- **Pre-implementation**
- **Decision Aid, no Coach**
- **Decision Aid + Coach**

- **DES**
- **BMS**
- **I don’t care**
- **I don’t know**
Specific Aim 4 – Analysis of Study Results on the Secondary Outcomes of Knowledge Transfer, Discussion Quality, and Stent Selection

Preimplementation and PostImplementation Comparisons

Stent knowledge score (0-6) increased from 2.3 ± 1.4 in the preimplementation phase to 4.3 ± 1.5 in patients who received the SDM tool and decision coaching (Table 3; \( p < 0.001 \)). The proportion of patients who answered all 6 questions correctly increased from 1.8% in the preimplementation phase to 24.8% in patients who received the SDM tool with decision coaching (\( p < 0.001 \)). No differences were observed between patients in the preimplementation phase and those who received the SDM tool without decision coaching. In fully adjusted analyses, patients who received the SDM tool and decision coaching demonstrated a higher stent knowledge score (mean difference +1.8 [1.5, 2.1]; \( p < 0.001 \)) and remained more likely to answer all 6 questions correctly (RR 11.7 [4.9, 27.9]; \( p < 0.001 \)). Similarly, patients who received the SDM tool with decision coaching reported higher nurse and physician discussion quality scores than patients who did not receive the SDM tool or those who received the SDM tool without decision coaching (Table 6).

Table 6: Adjusted Analyses of Knowledge Transfer and Shared Decision Making Items Answered Correctly

<table>
<thead>
<tr>
<th></th>
<th>Effect Measure</th>
<th>Post-Coach versus Pre</th>
<th>Post-Coach versus Post-No Coach</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Effect (95% CI)</td>
<td>( P ) value</td>
<td>Effect (95% CI)</td>
</tr>
<tr>
<td><strong>Process of SDM</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discussed stent types with physician(^*)</td>
<td>Risk ratio</td>
<td>1.50 (1.26-1.79)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Physician discussion quality score (0-7)</td>
<td>Mean difference</td>
<td>0.7 (0.3-1.1)</td>
<td>0.002</td>
</tr>
<tr>
<td>Discussed stent types with nurse</td>
<td>Risk ratio</td>
<td>3.7 (2.8-4.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Nurse discussion quality score (0-7)</td>
<td>Mean difference</td>
<td>0.6 (0.2-1.1)</td>
<td>0.006</td>
</tr>
<tr>
<td><strong>Participation in SDM</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stated a stent preference</td>
<td>Risk ratio</td>
<td>1.91 (1.57-2.33)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Shared/kept stent choice decision</td>
<td>Risk ratio</td>
<td>2.87 (1.84-4.49)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Correctly recalled stent type received(\dagger)</td>
<td>Risk ratio</td>
<td>1.45 (1.14-1.83)</td>
<td>0.002</td>
</tr>
<tr>
<td>Stent preference concordant with actual(\dagger)</td>
<td>Risk ratio</td>
<td>0.97 (0.87-1.08)</td>
<td>0.56</td>
</tr>
<tr>
<td><strong>Knowledge transfer</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total correct (out of 6)</td>
<td>Mean difference</td>
<td>1.8 (1.5-2.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>All questions correct</td>
<td>Risk ratio</td>
<td>11.7 (4.9-27.9)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

\(\dagger\)Primary outcome measure.
<table>
<thead>
<tr>
<th>Topic</th>
<th>Quote</th>
<th>Clinician Discipline</th>
</tr>
</thead>
</table>
| Usefulness| “You know, when this tool was used at Truman, I did notice a very quick change in the patient’s engagement. I think this tool is very easy to understand even beyond the already recognized consent process. You know, tabulated in one page, kind of one across the other. You got some quick information out of it without reading paragraphs and stuff. So, I noticed a change in patient engagement out of this tool.”  
“The very rewarding part was to be able to provide the education to the patients and that they went home and I felt like they knew why they needed to take their Plavix and that they would be more compliant. Or there were several cases that because of the decision coaching—‘well, I really need to have this tooth distracted’ or ‘I really need to have my knee replaced or hip replaced’—that they were able to relay that to the physician. And I do feel like it improved patient satisfaction and that it was valuable. So, that was the best part.”  
“And I didn’t value her reason for not having a bare metal stent that much, but I expressed it, that she felt strongly about it. She really didn’t want to take another pill. So, as a clinician, the patient expressing a preference, you believe in your heart of hearts that the other treatment is really better for that and the reason for having a preference really isn’t that important. That’s, of course, from our perspective, not the other perspective.” | Interventional cardiologist            |
| Difficulties| “I think it was difficult because there were some patients that just weren’t engaged. They didn’t care. It didn’t matter to them. And then the patients that were engaged, it wasn’t enough time because this was the first time they were hearing all this information and it would have been nice if they had maybe been exposed to a video or the education at some point at home so that they could hear it again for the second time, have their questions ready, and have more time to process it.”  
“I think the most frustrating part was that the patients wanted to learn. I think they wanted to know. And I didn’t feel like it was the best place to do it and that it could have been better. And then on the back end, if we had a really good discussion, maybe their opinion wasn’t as valued by the physician that was going in after me. And I think that was really frustrated.”  
“And I think the lack of kind of respect towards shared decision-making was the most frustrating from the physician’s standpoint. The buy-in wasn’t good and that was frustrating because I think it’s very valuable.” | Nurse decision coach                  |
| Importance| “Just one thing that I would think be cautious about is that the tool becomes shared decision making. Like, oh, yeah, we just gave the patient the tool so we could share decision making.”  
“But as Delwin said, the shared decision making doesn’t come unless there’s that conversation. So, when you’re developing a decision tool but wanting it to lead to a shared decision-making discussion, those are 2 kind of different | Interventional cardiologist            |
Table 3: Representative Quotes From Providers Regarding the Benefits and Limitations of the SDM Tool

<table>
<thead>
<tr>
<th>Topic</th>
<th>Quote</th>
<th>Clinician Discipline</th>
</tr>
</thead>
</table>
| Value | “I think that the patients really valued having someone go in, sit down, and take time and allowing them ... whether they had a decision or not, at least they had the perception that their decision was valuable. And I think that provided a level of patient satisfaction.”  
“I think that the patients appreciated it. Even if they weren’t really engaged, I think they still enjoyed getting the information and appreciated that someone took the time to come educate them.” | Nurse Decision Coach          |
| Improvements for tool | “I really like the idea that you sort of ask the patient, like if I see something different, is it okay for me to change your recommendation? So, what if you had, at the end of this thing, given this information, they check box under bare metal or drug-eluting. And then if the doctor sees something during the procedure that makes him or her think that the other stent would be better and would go against your preference, then it’s sort of all documented. You’ve got something that really shows the tool was read and used because the patient has checked a couple of boxes. And it gives the doctor a real sense of engagement.” | Interventional cardiologist  |
| Improvements for script | “We’re always asking for their preference. And we use the word preference instead of decision because even when you saw how patients like to make their decisions, it’s only that small percentage that just wants to make the decision with no input from their doctor. But when shared, it’s the preference—physician preference, patient preference and that it’s combined into a decision.” | Interventional cardiologist  |

Figure 8 depicts patients’ stated stent preferences and the concordance between stent preference and stent received. A greater proportion of patients preferred to receive DES as compared with BMS in all 3 phases of the study. DES were used in 86.7% of cases, and Figure 9 shows the concordance between stent preference and stent received stratified by stent preference, which demonstrates that DES use was nearly universal (98%) in patients who preferred DES and very high (85%) in patients who did not have a stent preference.
Conversely, patients who stated a preference for BMS received DES 47% of the time. No differences in the concordance of preference and treatment were observed across phases of the study.

Figure 8: Patients’ Stent Preference, and Concordance Between Stent Preference and Stent Received

![Bar chart showing concordance percentages]

Figure 9: DES Use Stratified by Patients’ Stent Preference

![Bar chart showing DES use by patients]

For figures 8 and 9: DES = drug eluting stents; BMS = bare metal stents
Specific Aim 5 – Conduct a Qualitative Study With Physicians on the Benefits and Limitations of the SDM Tool

Following completion of the implementation study (survey, coaching, and tool), we interviewed several interventional and general cardiologists to get their perspective of the implementation and value of the tool to patient–physician discussion. We also interviewed the decision coach. Table 3 presents representative quotes from the clinicians, grouped by topic.

The clinicians interviewed found both value and frustration with the tool and patient engagement. The nurse decision coach found value, though was she was frustrated with the clinical milieu of apathy for active patient engagement. Two clinicians had suggestions for improvement and enhancement of the tool as well as a comment cautioning that the tool itself should not replace discussion; they emphasized that SDM should occur only when the tool is used in conjunction with a discussion between the clinician and the patient.

Discussion

Decisional Context

In the setting of PCI and because of the offsetting benefits of DES and the drawbacks of prolonged DAPT, stent selection should be a preference-sensitive decision. However, DES are currently used in approximately 80% of PCI cases in the United States, regardless of patient risk for restenosis, and evidence suggests that patients are not typically engaged in SDM with respect to stent selection.

Study Results in Context

While decision aids have been demonstrated to increase patient knowledge and promote shared decision making in patients with coronary artery disease and other conditions, they are inconsistently used and typically do not incorporate personalized risk information. Prior studies have also demonstrated the benefits of decision coaching—both as an alternative to usual care and as a supplement to patient decision aids. This study is the first to elicit and describe patient preferences regarding factors surrounding stent choice, and it provides a unique insight into whether the current use of DES is aligned with patient preferences—or
whether more effort to support SDM is needed. In the preimplementation phase, we found that the majority of patients (65%) valued both the benefits of DES and the drawbacks of prolonged DAPT equally, and only a minority (14.4%) were most concerned about having to return for repeat revascularization. In fact, a similar proportion of patients (20.6%) were most concerned about DAPT drawbacks. Despite this evidence, we found no association between patients’ value of DES benefits and DAPT drawbacks with the actual stent received. Thus, the predominant use of DES in this study suggests that physicians are prioritizing the avoidance of repeat revascularization procedures rather than engaging patients in SDM so that treatment can more closely align with patient preferences. These data underscore the need to more systematically elicit patient preference and engage patients in SDM prior to stent selection during PCI.

By developing and implementing a personalized, evidence-based SDM based on stakeholder feedback, we found significant improvements in patient knowledge, the process of SDM through discussions with doctors and nurses, and participation in and perceived quality of SDM when the tool was supplemented with decision coaching. In both unadjusted and adjusted analyses, patients who received the SDM tool and decision coaching were more likely to participate in decision making regarding stent selection and to state a preference for the stent type they would like to receive, compared with patients who received neither. Of note, no differences in the proportions of patients receiving DES were observed, and concordance between stent preference and stent received remained modest (just over 50%) in patients who preferred to receive BMS.

Among the most important findings from this study is that when the SDM tool was provided without coaching, there were no differences in patients’ participation in SDM or their likelihood to state a stent preference. These data clearly suggest that for a high-quality SDM to occur, a personalized, evidence-based SDM tool needs to be supplemented with decisional coaching. Given the benefits, from patients’ perspectives, this study provides a justification for investing in the infrastructure of health care delivery to support decision coaching.

To align with the stated goals of the American Medical Association and National Academy of Medicine to honor patients’ preferences and for patients to participate in treatment decisions, a transformation in the process of PCI and stent selection is needed. In this
study, through collaboration with patients and patient advocates, providers, and professional societies, we developed a shared decision-making tool for stent selection to better educate patients about the benefits and drawbacks of DES and BMS and to better engage patients in selecting treatment. In addition, we trained nursing staff in motivational interviewing techniques so that they could serve as decision coaches and better engage patients in SDM. We found that patients who received the SDM tool and decision coaching were significantly more likely to participate in SDM with respect to stent selection, to voice a preference for which type of stent they would prefer to receive, and to retain information about stents and stent types. Nevertheless, participation in SDM did not significantly impact physicians’ use of DES and BMS, and what is particularly striking is that while concordance between stent preference and stent received was impressively high (98%) for patients who preferred to receive DES, it was significantly lower (53%) for patients who preferred to receive BMS. These findings suggest that even when patients have participated in SDM and voiced a preference for treatment, physicians are likely to resort to their own preferences when making final treatment decisions.

Implementation of Study Results
Implementation of the SDM tool into the context of clinical care was more difficult than anticipated. The barriers to implementation largely related to limitations in office and hospital personnel, space, and time. Ultimately, the decision to use research nurses as decision coaches at one of the sites allowed us to conduct the study and to analyze the impact of the SDM tool and decision coaching on patient engagement in SDM, knowledge transfer, and stent selection. However, if the results of this study are to be replicated in clinical practice, the same barriers of personnel, space, and time must be addressed. Innovative methods to overcome these barriers could involve telemedicine, videotaped or web-based educational presentations, which could prepare patients for more limited face-to-face discussion of the personalized information provided in the SDM tool, and communication of their preferences. In any scenario, resources to provide nurse and physician training in motivational interviewing should be considered, to educate providers on the benefits of SDM and to train them on methods to best engage patients in SDM.

Despite input from patients, patient advocates, and providers that the SDM tool should be reviewed with patients as far “upstream” of their procedure as possible, to allow patients to
review and ponder the relevant information, we were unable to implement the SDM tool into patient care on an outpatient basis, again due to barriers of personnel, space, and time. Innovative methods to overcome these barriers could involve separating the provision of the SDM tool from decision coaching; for example, the SDM tool could be mailed or e-mailed to the patient or viewed online by the patient ahead of the procedure and reviewed on an outpatient basis, while decision coaching and elicitation of patient preferences could be performed on the day of the procedure, as in this study.

Given that we observed no benefits to providing the SDM tool to patients without decision coaching in this study, we feel that if the SDM tool is to be implemented in clinical practice with the goal of engaging patients in SDM, considerable effort may be needed to convince clinic and hospital administrative bodies to provide the resources necessary to provide decision coaching to patients—and to provide this information to patients upstream from their procedure. This could be accomplished by payers providing a payment to offset the resources required to redesign care, but the payer representative on the steering committee indicated that there would be little interest from payers to do so.

**Generalizability**

The 2 sites of enrollment for this study, Saint Luke’s Mid America Heart Institute and Truman Medical Center, serve different patient populations and were strategically selected so as to encourage recruitment of patients with a broad range of demographic and socioeconomic characteristics. The majority of patients enrolled in this study were Caucasian and male, with a high prevalence of traditional cardiovascular risk factors, as expected. However, the percentage of women enrolled in this study is higher than in most studies, and we enrolled a small but significant proportion of African American patients as well. These findings suggest that the strategy to recruit a diverse group of patients was successful.

Accordingly, it was of interest to evaluate the impact of the SDM tool and decision coaching on primary and secondary outcomes in these diverse patient groups (Table 7). There was little observed impact of enrollment site on knowledge transfer and patient participation in SDM, both of which improved substantially with provision of the SDM tool and decision coaching at MAHI and TMC. The proportion of patients reporting that they discussed stent types with nurses and physicians also improved at both sites, although the proportion of
patients reporting a discussion with the physician was somewhat higher at TMC than at MAHI. The majority of patients who voiced a stent preference preferred DES at MAHI, while the majority of patients at TMC preferred BMS. At both sites, the proportion of patients voicing a stent preference increased significantly following provision of the SDM tool and decision coaching. DES use was higher at MAHI than at TMC, and concordance with patient preference was similarly high at both sites among those preferring DES, with no significant differences observed after provision of the SDM tool and decision coaching. This suggests that the selection of a diverse population to inform development of the SDM tool resulted in a tool that was similarly efficacious across a diverse population of patients, supporting the generalizability of our approach.

Table 7: Site-Specific Comparisons

<table>
<thead>
<tr>
<th></th>
<th>Preimplementation</th>
<th>SDM Tool + Coach</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge transfer: all questions correct (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAHI</td>
<td>2.6</td>
<td>26.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TMC</td>
<td>0.7</td>
<td>18.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discussed with nurse (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAHI</td>
<td>19.6</td>
<td>97.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TMC</td>
<td>33.8</td>
<td>85.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Discussed with physician (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAHI</td>
<td>41.6</td>
<td>63.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TMC</td>
<td>46.2</td>
<td>81.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stent preference DES (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAHI</td>
<td>28.2</td>
<td>46.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TMC</td>
<td>20.3</td>
<td>33.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Stent preference BMS (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAHI</td>
<td>6.6</td>
<td>20.7</td>
<td>&lt;0.001</td>
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<tr>
<td>TMC</td>
<td>15.9</td>
<td>40.7</td>
<td>&lt;0.001</td>
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<tr>
<td>Stent received DES (%)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>MAHI</td>
<td>86.6</td>
<td>88.7</td>
<td>0.095</td>
</tr>
<tr>
<td>TMC</td>
<td>69.7</td>
<td>61.5</td>
<td>0.152</td>
</tr>
<tr>
<td>Concordance with patient preference (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAHI</td>
<td>95.2</td>
<td>94.0</td>
<td>0.120</td>
</tr>
<tr>
<td>TMC</td>
<td>85.0</td>
<td>63.6</td>
<td>0.209</td>
</tr>
<tr>
<td>Participation in decision making (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MAHI</td>
<td>69.9</td>
<td>38.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>TMC</td>
<td>70.2</td>
<td>44.4</td>
<td>0.126</td>
</tr>
</tbody>
</table>
Because decision coaching could not be inserted into existing processes of patient care at MAHI (coaching was performed by a research nurse rather than by clinical staff, in contrast to what was done at TMC), generalizing our findings of the benefits of the SDM tool with coaching requires that a sustainable infrastructure for coaching be developed—ideally in an outpatient consultation with a patient’s provider before a PCI is scheduled.

However, despite our desire to provide the coaching upstream, doing so just prior to treatment is a pragmatic time to elicit patient preferences and is a natural part of the conversation, even if not done well in usual practice. The information contained in the SDM tool was current at the time of the study but should be updated as data change. For example, information regarding the cost of medications should be updated periodically as costs change. Similarly, the recommended duration of DAPT following DES and BMS needs to be updated as guidelines change. Furthermore, the US Federal Drug Administration has approved novel stent platforms such as bioabsorbable vascular scaffolds, and the association of these technologies with TVR should be included, as the data emerges. Finally, if newer risk models for restenosis with DES and BMS or bleeding complications with DAPT are derived in the future, then the SDM tool can be updated to incorporate the most up-to-date information.

Subpopulation Considerations

Further subgroup analysis of the benefits of these interventions may provide additional information on the benefits of the SDM tool and decision coaching as a function of age, gender, race, and socioeconomic status. However, such analyses have not yet been performed.

Study Limitations

The first limitation of this study is that the SDM tool was provided to patients in the catheterization laboratory prep area instead of beforehand. As outlined above, patients and providers in focus groups noted that it would have been preferable to provide this information further upstream from the time of the procedure. On the one hand, had we been able to provide the information sooner, patients may have had more time to reflect on the information and become even more engaged in SDM. On the other hand, it is possible that if the discussion was held too far in advance of the procedure, patients would forget the information over time and knowledge transfer would have been negatively impacted.
The second limitation of this study is that the resources to provide decision coaching to patients in this study were limited, particularly by the frenetic workload of bedside nurses at MAHI, which made it difficult for them to prioritize their opportunity to support the education of patients for SDM. As a result, patients in the postimplementation phase did not receive decision coaching if a nurse was unavailable at that time. While it is possible that relying on coaching to have occurred may have resulted in a selection bias (physicians and nurses more committed to SDM may have better engaged patients in shared decision-making), the need to supplement usual care with a decision coach at MAHI and the lack of any observed benefits of providing the SDM tool without decision coaching minimizes the possibility of such bias.

A final limitation of this study is that providers may not have been fully engaged in the process of SDM with patients in this study. Physician follow-up was not directly obtained, and as a result, we could not directly evaluate factors associated with stent concordance or discordance, such as the presence or length of discussion regarding stent selection. Similarly, the study did not record the length of decision coaching and the length of time that patients spent reviewing the SDM tool.

**Future Research**

While the results of this study appeared largely positive, future research should focus on implementation strategies to overcome the barriers of personnel, location, and time outlined above. Novel implementation strategies might allow for this information to be shared with more patients. Our finding that stent concordance was 98% for patients who preferred to receive DES and only 53% for patients who preferred to receive BMS suggests that physicians are prone to use DES and may be reluctant to change their decisions when patient preferences differ from their own. This finding warrants further investigation to overcome such physician biases and to better deliver treatment that is preferred by patients.
F. Conclusions

Given the growing demand for patient engagement in medical decision making, we described, from the patient perspective, the relative importance of different factors related to stent choice. We found that most patients regarded avoiding the drawbacks of DAPT at least as important as avoiding TVR, and only a minority regarded avoiding TVR as the single most important consideration when selecting a stent. The prominent use of DES, which necessitates a longer duration of DAPT, therefore appears to signal that physicians’ goals of therapy may not always be the same as patients’ and underscores the importance of explicitly eliciting patients’ preferences to better tailor stent choices to the goals and values of individual patients.

To improve the process of stent selection, we developed an SDM tool for BMS versus DES through collaboration with patients, patient advocates, providers, and professional societies, with the goal of better informing patients and engaging them in SDM, and we successfully trained nurses in motivational interviewing techniques so that they could serve as decision coaches. We met substantial barriers in the implementation of the SDM tool, mainly with respect to resources available to provide decision coaching to patients. Nevertheless, we found significant improvements in the processes of—and patients’ engagement in—SDM as well as greater knowledge transfer when the SDM tool was provided to patients along with decision coaching. However, no benefits were observed when the SDM tool was provided to patients without decision coaching. No significant differences in the proportion of DES and BMS were observed in the study, and while patients who preferred to receive DES nearly always received DES, patients who preferred BMS often received DES, suggesting that physician-level barriers to SDM may exist. Resources to educate providers on the benefits of SDM and to train providers on methods to best engage patients in SDM, along with investments by hospitals in supporting decision coaching, are likely necessary to further improve the quality of SDM with respect to stent selection at the time of PCI.
G. References


Appendix
**WELCOME**

Welcome. Thank you for coming today. My name is XXXXXXXX, and I will facilitate today’s discussion. I am a researcher and I work for Saint Luke’s Mid America Heart Institute. We also have XXXXXXXXX, present to take notes for us.

We invited you to take part in this group discussion today because we would like to understand your perspective about how to best convey medical information in a decision-making situation.

**GROUND RULES**

Before we begin, I would like to review a few ground rules for the discussion.

a. I will ask several questions, and I would like to give everyone a chance to give their opinions. We ask that only one person speak at a time.

b. We are interested in your opinions and whatever you have to say is fine with us. We are here to learn from you.

c. Don’t worry about having a different opinion than someone else. But please do respect each other’s responses.

d. If there is a question you don’t want to answer, you don’t have to.

e. We are not going to ask for personal information that could identify you, and we are only going to use first names during the discussion. We also ask that each of you respect the privacy of everyone in the room and not share or repeat what is said here in any way that could identify anyone in this room.

f. We are recording the conversation and taking notes because we don’t want to miss any of your comments.

g. We will not include your names or any other information that could identify you in any reports we write. We will tear up our notes and after we complete our study.

h. Finally, this discussion is scheduled to be 60 minutes long, and we ask that you stay for the entire meeting. At the end of the discussion we will give you a $35 gift card to thank you for participating.

**Does anyone have any questions before we start?**
## Patient Focus Group Discussion Guide

### OPENING (5 minutes)
Today’s discussion will be based on heart stents. I’d like for you to imagine that a loved one has been diagnosed with coronary artery disease (a blocked blood vessel in the heart) and needs to have a procedure— a heart catheterization. I will explain the procedure and your treatment options. Then we will take a short break. After the break, you will be asked to make a decision based on the information I gave you. We will then discuss your decisions as a group. Are there any questions before we get started?

### PCI (25 minutes)
Note: Review PCI education materials.

Now we will take a short break. Please use the time to get refreshments and also think about stent options. Then indicate the choice you would make and rank the four factors for stent selection on the worksheet provided.

### BREAK (10 minutes)

### DECISION-MAKING DISCUSSION (30 minutes)
Note: Remind participants to complete worksheet.

During the first part of the session, we presented a lot of information about angioplasty and stents. Based on that information, please circle your stent choice on the sheet provided. Now, let’s go around the table and state which stent you chose and how you came to that decision.

Thank you for sharing your choices. Today we provided a great deal of complicated information. It may have been difficult to fully understand, so if you were to receive the information in a real-life situation, what would be the best way for us to present it? Why? Who should present that information to you? Why? What is the best format, i.e. paper, electronic, over the phone? Why? Finally, when is the best time to receive the information; would you like to hear it several days in advance or would you be comfortable receiving the information right before the procedure?

### CLOSING
HAND OUT PAYMENTS AND ASK PARTICIPANTS TO SIGN THE PAYMENT RECEIPT FORM.
Appendix B. Study Timeline

10/1/2013
- Contract Award
10/8/2013 - 10/21/2013
- Protocol Development
11/13/2013
- Study Team Meeting
12/17/2013 - 12/31/2013
- Interview Guide Development

1/7/2014
- Steering and Advisory Cmte Mtg
2/3/2014
- Focus Group Recruitment Begins
5/5/2014
- Survey Collection Begins SLH
7/15/2014
- PRISM Implementation Survey Collection Begins TMC
8/15/2014
- 10/20/2014 - 12/15/2014
- DC Training SLH (Research Staff)

1/1/2014
3/1/2014
2/1/2014
- SDM Development
1/1/2015
- 1/30/2015
- Staffing Issues TMC
7/1/2014 - 12/31/2014
3/12/2015
- Implement SDM Tool SLH
- Focus Groups
9/28/2015 - 10/8/2015
- DC Training TMC
12/8/2015
- Implement SDM Tool TMC

1/1/2015
2/1/2015
- 12/31/2016
2/10/2016
- DC Stopped at SLH
5/8/2016
- PI Resigns @TMC
6/27/2016
- Request Extension from PCORI
6/27/2016
- Bedside RN's Trained @SLH
9/5/2016 - 12/30/2016
- PI Received Printed Tool Only @SLH
12/31/2016
- Final Research Completion Date

3/1/2016
2/1/2016
2/1/2017
- 3/1/2017
- 9/30/2017
- 4/24/2017
- Draft Final Research Report Due
5/1/2017
- 4/9/2017 - 8/31/2017
- PCORI Peer Review Process
9/1/2017
- 9/30/2017
- Study Ends

5/1/2017
6/1/2017
7/1/2017
8/1/2017
9/1/2017
1/1/2017
2/24/2017
- Wrap Up Meeting
3/1/2017
4/1/2017
5/1/2017
9/30/2017
- 9/30/2017
- Study Ends
Appendix C. DECIDE decision tool  

**Coronary Stents**

A coronary stent is a device that props open a narrowed artery in the heart. There are 2 types of coronary stents: bare metal and drug-coated. The chart below explains the differences between a bare metal stent and a drug-coated stent. Research shows **there is no difference in survival or future heart attacks between the two types of stents.** You may prefer one stent over the other based on the information below and a discussion with your doctor or nurse.

<table>
<thead>
<tr>
<th>Repeat Heart Procedure</th>
<th>BARE METAL STENT</th>
<th>DRUG COATED STENT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><img src="chart1" alt="Bare Metal Bar Chart" /></td>
<td><img src="chart2" alt="Drug Coated Bar Chart" /></td>
</tr>
<tr>
<td><strong>Out of 100 people like you:</strong></td>
<td><strong>91 will not need a repeat procedure due to stent blockage</strong></td>
<td><strong>95 will not need a repeat procedure due to stent blockage</strong></td>
</tr>
<tr>
<td></td>
<td><strong>9 will need a repeat procedure due to stent blockage</strong></td>
<td><strong>5 will need a repeat procedure due to stent blockage</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Required Medicine</th>
<th>At least 1 month†</th>
<th>At least 12 months†</th>
</tr>
</thead>
<tbody>
<tr>
<td>You will need to take a blood thinner medicine (in addition to aspirin).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stopping the medicine early increases the risk of a heart attack and death.</td>
<td>Before 1 month</td>
<td>Before 12 months</td>
</tr>
<tr>
<td>Cost of medicine varies, depending on insurance coverage.</td>
<td>Total cost: $16 - $200</td>
<td>Total cost: $192 - $2400</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bleeding and Bruising</th>
<th>At least 1 month</th>
<th>At least 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most patients bruise and bleed more easily while taking the extra blood thinner medicine.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Medical Procedures and Surgery</th>
<th>At least 1 month</th>
<th>At least 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major medical procedures, major dental work, and surgery must wait.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

†Duration of medication therapy varies. Do not stop your medicine without talking with your doctor first.
### PATIENT SURVEY

<table>
<thead>
<tr>
<th>Study ID:</th>
<th></th>
<th>Updated 2/24/16</th>
</tr>
</thead>
</table>

#### Name: ________________________________

#### Age: ________________________________

#### Date: ________________________________

**For Internal Use Only**

<table>
<thead>
<tr>
<th>Physician:</th>
<th></th>
<th></th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Stent Type:</th>
<th>□ DES</th>
<th>□ BMS</th>
<th>□ None</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Gender:</th>
<th>□ Male</th>
<th>□ Female</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Race:</th>
<th>□ White/Caucasian</th>
<th>□ Black/African American</th>
<th>□ Asian</th>
<th>□ American Indian/Alaska Native</th>
<th>□ Native Hawaiian/Pacific Islander</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Hispanic ethnicity:</th>
<th>O Yes</th>
<th>O No/UTD</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Diabetes:</th>
<th>O Yes</th>
<th>O No</th>
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</table>

<table>
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<tr>
<th>Hypertension:</th>
<th>O Yes</th>
<th>O No</th>
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<tr>
<th>PAD:</th>
<th>O Yes</th>
<th>O No</th>
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<table>
<thead>
<tr>
<th>Previous CABG:</th>
<th>O Yes</th>
<th>O No</th>
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</table>

<table>
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<tr>
<th>Previous PCI:</th>
<th>O Yes</th>
<th>O No</th>
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</table>

<table>
<thead>
<tr>
<th>&lt; 6 months</th>
<th>O</th>
<th>&gt; 6 months</th>
<th>O</th>
<th>&gt; 1 year</th>
<th>O</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Patient disposition prior to procedure:</th>
<th>O Inpatient</th>
<th>O Outpatient</th>
<th>O Emergent</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Was patient coached?</th>
<th>O Yes</th>
<th>O No</th>
</tr>
</thead>
</table>

---

**I. Have you read the Patient Information about e-PRISM Survey provided to you?**

- O Yes | O No |

**II. Are you willing to participate in the survey?**

- O Yes | O No |

---

1. **What is a stent?**
   - O A metal mesh tube that helps keep the artery open
   - O A type of artificial heart valve
   - O A device that helps the heart rhythm
   - O Other ____________________________ O
   - Don’t know

2. **Which stent has a lower risk of becoming blocked? (Choose one)**
   - O Bare metal stent
   - O Drug coated stent
   - O Neither
   - O Don’t know

3. **How long would you have to take an extra blood thinner if you received a bare metal stent (in addition to aspirin)?**
   - O 1 month
   - O 1-6 months
   - O 6-12 months
   - O Not at all
   - O Don’t know
4. How long would you have to take an extra blood thinner if you received a drug-coated stent (in addition to aspirin)? (Choose one)
   - Longer than if I had a bare metal stent
   - The same amount of time
   - Shorter than if I had a bare metal stent
   - Don’t know

5. Possible side effects of an extra blood thinner are: (Check all that apply)
   - □ Easier bruising
   - □ Easier bleeding after minor cuts
   - □ Increased chance of a major bleed
   - □ Increased chance of recurrent chest pain
   - □ Don’t know

6. If you received a drug-coated stent, would this affect your eligibility for future surgery, medical procedures, and/or major dental work?
   - □ Yes, it would have to be delayed
   - □ No
   - □ Don’t know

On a scale of 1 to 10, with 1 being not at all important and 10 being extremely important, please indicate your feelings about the following issues:

7. Having another heart cath or stent placed within the next year

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<tr>
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<th>9</th>
<th>10</th>
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<tbody>
<tr>
<td></td>
<td>Not at all Important to me</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Extremely important to me</td>
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8. The number of pills/medications you take on a daily basis

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<td>Not at all Important to me</td>
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<td>Extremely important to me</td>
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9. The cost of your medications

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<th>8</th>
<th>9</th>
<th>10</th>
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<tbody>
<tr>
<td></td>
<td>Not at all Important</td>
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<td>Extremely important to</td>
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Study ID: --------------
Updated 2/24/16
10. Having minor bleeding and/or bruising

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<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td></td>
<td></td>
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<td>Extremely important to me</td>
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<td>Important to me</td>
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11. Having to delay future surgeries, medical procedures, and/or major dental work

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<th>5</th>
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<th>8</th>
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<th>10</th>
</tr>
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<tbody>
<tr>
<td>Not at all</td>
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<td></td>
<td>Extremely important to me</td>
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<td>Important to me</td>
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12. For health decisions in general, given the risks and benefits of possible treatments, who should decide how acceptable those risks and benefits are for you?

- Doctor Alone
- Mostly the doctor
- Doctor and You Equally
- Mostly You
- You Alone

13. For health decisions in general, given all the information about risks and benefits of the possible treatments, who should decide what treatment option should be selected?

- Doctor Alone
- Mostly the doctor
- Doctor and You Equally
- Mostly You
- You Alone

14. Who decided what type of stent you got?

- Doctor Alone
- Mostly the doctor
- Doctor and You Equally

15. Do you recall receiving education materials before your procedure?

- Yes
- No (If no, skip to #20)

16. What type of education materials did you receive?

- Pamphlet or packet
- Video

Page 3 of 6

Study ID: ___________________  
Updated 2/24/16
17. If yes, where did you receive the materials?
   - Doctors office
   - In the mail
   - By email
   - In the hospital
   - I looked on the internet
   - Don’t know

18. When did you receive the education materials?
   - Last doctors visit (office)
   - In the last 3 days
   - 3-7 days
   - >a week

19. Were these materials helpful?
   - Yes
   - No

   a. If yes, in what way?
      - Helped me learn more about my heart
      - Helped me learn more about the procedure
      - Helped me understand stent choices
      - Helped me learn about treatments after the procedure

20. Before you had your procedure, do you recall having a discussion with your nurse about types of stents that could be used in your procedure?
   - Yes
   - No (If no, skip to #22)

21. The following questions ask about conversations you have had with your nurse in which your stent selection was discussed. Practitioners have different styles in dealing with patients. Your responses will be kept confidential, so none of the practitioners will know your responses. Please be honest and candid. Choose your answers using the scale below for each question by filling in the blank after each question with a number from 1 to 7.

   1  2  3  4  5  6  7
   Strongly Disagree Neutral Strongly Agree

   a. My nurse provided me with choices and options about my stent selection.

   b. My nurse understood how I see things with respect to my stent selection.

   c. My nurse conveyed confidence in my ability to make decisions regarding my stent selection.

   d. My nurse listened to how I would like to do things regarding my stent selection.

   e. My nurse encouraged me to ask questions about my stent selection.
f. My nurse tried to understand how I see my stent selection before making suggestions. ________

22. Before you had your procedure, do you recall having a discussion with your doctor about types of stents that could be used in your procedure? O Yes O No (If no, skip #24)

23. The following questions ask about conversations you have had with your doctor in which your stent selection was discussed. Practitioners have different styles in dealing with patients. Your responses will be kept confidential, so none of the practitioners will know your responses. Please be honest and candid. Choose your answers using the scale below for each question by filling in the blank after each question with a number from 1 to 7.

1 2 3 4 5 6 7
Strongly Disagree Neutral Strongly Agree

a. My doctor provided me with choices and options about my stent selection. ________

b. My doctor understood how I see things with respect to my stent selection. ________

c. My doctor conveyed confidence in my ability to make decisions regarding my stent selection. ________

d. My doctor listened to how I would like to do things regarding my stent selection. ________

e. My doctor encouraged me to ask questions about my stent selection. ________

f. My doctor tried to understand how I see my stent selection before making suggestions. ________

24. After reviewing the risks and benefits of both types of stents, which type of stent did you want?
   - A drug-coated stent
   - A bare metal stent
   - I didn’t care
   - I don’t know

25. Which type of stent did you receive during your procedure?
   - A drug-coated stent
   - A bare metal stent
   - I did not receive a stent
   - I don’t know
   - The following questions ask about your satisfaction with the consent form for your recent procedure:
The following questions are for the patients who received the Decision Coaching intervention.

26. The following questions ask about your **satisfaction** with the stent preference handout and discussion prior to your procedure:

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Somewhat</th>
<th>Moderately</th>
<th>Very much</th>
<th>Completely</th>
</tr>
</thead>
<tbody>
<tr>
<td>The descriptions of the stents were clear.</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>The descriptions of the risks and benefits were clear.</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>I understood the information.</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>The handout was easy to read.</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>The handout was easy to understand.</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

27. The following questions ask about your **feelings** about the stent preference handout and discussion prior to your procedure:

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Somewhat</th>
<th>Moderately</th>
<th>Very much</th>
<th>Completely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reading the handout and having the discussion made me feel nervous.</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>I felt more nervous after reading the handout and having the discussion than I did before.</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Thoughts about my heart condition made it hard to focus on reading the handout and having the discussion.</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>It makes me nervous to think about the information on the handout and in the discussion.</td>
<td>O</td>
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Thank you for taking the time to help us with this information.
Decision Making Session Guide

I. GREET/INTRODUCE, ASK PERMISSION, AND ELICIT UNDERSTANDING OF PCI:

- Hello my name is _______ and I am ___________. How are you today?

Reflect any feelings of concern or distress

- If it’s ok with you I’d like to spend a few minutes giving you some information about your procedure? What have you heard or been told about your procedure?

Acknowledge patient’s response and provide missing information and/or correct misinformation.

- Yes that’s correct, what you are going to have today is a coronary angiogram where the doctor is going to look at the arteries in your heart. These arteries carry blood to your heart to keep it working. Sometimes the arteries narrow, blocking the blood flow, which can cause chest pain. To treat this, a small, mesh tube called a stent can be inserted into the artery.

Assess the patient’s understanding of the information provided:

- Does that make sense to you?

Clarify any confusion.
II. **USE DECISION SUPPORT TOOL TO DISCUSS STENT DIFFERENCES**

<table>
<thead>
<tr>
<th>STENT TYPES AND INTRO TO SHARED DECISION-MAKING</th>
</tr>
</thead>
<tbody>
<tr>
<td>What I’d like to spend a few minutes talking with you about is the stent you might receive. There are two kinds of stents: a drug coated stent and a bare metal stent. The key difference is that the drug coated stent has a drug coating on it to help it remain open. On this sheet I have some information about the different effects that these two stents can have that I’d like to go over with you. It is important for your doctor to know your preferences. However, during the procedure information may arise that the physician feels one stent is better than the other.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>REPEAT HEART PROCEDURE</th>
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<tbody>
<tr>
<td>Review the comparison between the repeat heart procedure risk and assess patient reaction:</td>
</tr>
</tbody>
</table>

The first comparison I want to show you is the risk that, after your treatment, the artery will close up again requiring a repeat heart procedure to replace the stent. This chart shows you the chance of a repeat procedure for the two types of stents and, as you can see, the chances are quite low for both procedures. For the bare metal stent it is X in 100. However, the medicine on the drug coated stent helps to prevent blood from sticking to it, reducing the chance of the artery closing up again. So the risk for the drug coated stent is Y in 100.

What are your thoughts about that?

Briefly reflect patient reactions to encourage patient thinking/talking and to ensure patient understanding.

<table>
<thead>
<tr>
<th>REQUIRED MEDICINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review the comparison between the required medicines and assess patient reaction:</td>
</tr>
</tbody>
</table>

The second comparison I want to show you is the difference in how long you will have to take a blood thinning medicine after your procedure. As you can see from the chart, with a bare metal stent you will need to take the medicine for at least 1 month, and for the drug coated stent at least 12 months. This is very important because of the risk of a blood clot, heart attack or death if you stop the medicine too soon.

The difference in how long you take the medicine will also affect the cost - although the cost to you will depend on your insurance coverage. It is estimated that the cost of the medicine for the bare metal stent will be between $16-$200 whereas for the drug coated stent it will be between $192-$2400.

What are your thoughts about (1) the difference in how long you have to take the medicine and (2) the difference in cost?
Briefly reflect patient reactions to encourage patient thinking/talking and to ensure patient understanding.

**BRUISING AND BLEEDING**

Review the comparison between the duration of bruising and bleeding effects of the medication:

_The third comparison I want to show you also relates to a side effect of taking the blood thinning medicine and the increased likelihood of bleeding. Examples include easier nose bleeding, gum bleeding, or bleeding from shaving. As you can see from the chart, for the bare metal stent, because you don’t need to take the medicine for as long, you will be affected by the side effect of bruising and bleeding easily for at least a month, whereas for the drug coated stent it will be for at least 12 months._

_What are your thoughts about the difference in time for easy bruising and bleeding?_

Briefly reflect patient reactions to encourage patient thinking/talking and to ensure patient understanding.

**OTHER MEDICAL PROCEDURES AND SURGERY**

Review the comparison between the delay in having other medical procedures and surgery:

_The final comparison I want to show you also relates to the bleeding risk associated with the blood thinning medicine. While you are on the medicine you may not undergo major medical procedures, major dental work, or surgery. As you can see from the chart this means that with the bare metal stent you may need to delay these procedures or surgeries for at least a month, whereas with the drug coated stent you may need to delay it for at least 12 months._

_What are your thoughts about the comparison in how long you have to delay major medical procedures or surgery?_

Briefly reflect patient reactions to encourage patient thinking/talking and to ensure patient understanding.

**PROMPT GLOBAL REFLECTION ON ALL OF THE INFORMATION AND SHARING PREFERENCE WITH DOCTOR**

Review the comparison between the delay in having other medical procedures and surgery:

_So now that we have reviewed all of the pros and cons of the two stent options what are you thoughts?_
Briefly reflect patients overall reactions and preference.

Conclude by encouraging patient to share their preference with their doctor, reminding them that the doctor will make the final decision about what is best for them:

*It sounds like for you what is most important is... [reflect patient concern/preference]. When you speak with your doctor before your procedure you can mention that we talked and that one of your concerns was... [patient concern]. Your doctor will make the decision as to what is best in your case but if there is a choice s/he can take this into account.*

*How does that sound?*

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### III. CONCLUSION

Ensure the patient has all the information they need and conclude.

Do you have any questions? Good! I hope this was helpful and that your procedure goes well.
Patient Screening For Decision Coach Script

DECIDE-PCI

Hello, my name is ___. I’m calling from Saint Luke’s Hospital about your upcoming heart procedure.

I need to get just a little background information from you before you come in. Do you have time for a few questions?

1. First, do you have diabetes?
   - If patient answers “no”: Are you taking any medicine for high blood sugar?
     - Patient may say something like “well my blood sugar was high, but the doctor told me to watch my diet”. If so, mark yes for question #1.

2. Do you have peripheral artery disease? This is sometimes called ‘PAD’; it causes pain in your legs.
   - If patient isn’t sure: Has your doctor ever told you that you have poor circulation in your legs? Or have you had a special test on your legs where they measure the pressure in your arteries, an ankle-brachial index or ‘ABI’?
     - If patient has leg pain due to varicose veins, mark no for question #2
     - If patient has had a stent in his leg, mark yes for question #2

3. Do you have a history of high blood pressure?
   - If patient isn’t sure or answers no: Are you taking any medicine for high blood pressure?
     - Examples include metoprolol,

4. Have you ever had open heart surgery or bypass surgery?

5. Have you ever had a heart cath procedure before? That is the test where they go in through the groin to look at the arteries in your heart. Sometimes it’s called an angiogram, and sometimes you receive heart stents.
   - If patient answers yes: When did you have your last heart cath?

If patient screens positive:
I am going to send you an education sheet about the heart procedure. Do you have e-mail, or would you prefer a mailing? A nurse will call you before your procedure review the education sheet in more detail. When is a good time for her to call?

If patient screens negative:
Thank you for your time. A nurse will call you the night before your procedure.
DECIDE PCI Shared Decision Making Tool Training
What is shared decision-making (SDM)?

• “An approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences”.

• Decision-making task:
  o Clinicians and patients share evidence
  o Support patients to consider options
  o Patients achieve informed preferences
What is shared decision-making?

• When no clearly superior treatment, SDM can ensure care better aligns with patient preferences and values.

• Benefits can include:
  - increased patient knowledge
  - less anxiety over the care process
  - improved health outcomes
  - reductions in unwarranted variation in care and costs
  - greater alignment of care with patients’ values.
What is shared decision-making?

• Assumes that *self-determination* is desirable and that clinicians need to support this

• Some argue that:
  - patients don’t want to be involved (cultural values)
  - lack the capacity or ability (low literacy/numeracy)
  - might make ‘bad’ decisions
  - SDM is not practical
Implementing SDS

- Communication skills
- Patient Decision Aids/Decision Tools
  - written materials, videos, or interactive electronic presentations
  - designed to explain care options, benefits, side effects, costs etc.
- E.g., DECIDE PCI DECISION TOOL
What is PCI and the choice that has to be made?

- Percutaneous coronary intervention (PCI) is a treatment for stenotic (narrowed) coronary arteries.
- Often a small mesh tube or stent is placed at the site of blockage to open the artery.
- Either a drug eluding/drug coated stent or a bare metal stent can be used.
  - The drug-coating helps the drug-eluding stent remain open.
- Pros and cons are associated with each type of stent.
What is the DECIDE PCI Decision Tool?

- Presents factors that could affect patient preferences regarding pros and cons of stent choice.
- Based on the patient’s risk factors.
- Although final choice is based on medical considerations, if both stents are suitable can be helpful to know the patient’s preference.

Purpose:
- Help the patient consider the factors.
- Encourage the patient to communicate any preferences to their cardiologist.
What communication skills are needed to use the tool?

• **Skills should foster the patient’s freedom to choose:**
  - Help patients understand.
  - Help patients process the information.
  - Support patients to make the best choice for themselves.

• **The skills we will be using include:**
  - asking permission
  - open-ended questions
  - reflective listening
  - Summarizing
Asking Permission

- Ask permission anytime we want to:
  - Raise a topic with a patient.
  - Provide information or advice.
Open-ended questions

- What have you heard about open-ended questions?

  - E.g., “How are you feeling about having the procedure?” vs. “Do you have any questions?”
**Reflective listening**

- Saying to the patient what you think they have said.
- Patient *knows* you are listening & understanding.
  - NOT the same as asking more questions, disagreeing, agreeing, praising, reassuring, or interpreting.

**For example:**
- “I really don’t care what they do as long as I don’t have anymore chest pain”

**A reflective statement might be:**
- “You’re not too worried about the details as long as the procedure takes care of the problem”
Reflective listening

- When used correctly reflections serve as/serve to:
  - A statement, not a question
  - Hypothesis testing
    - "If I understand you correctly it sounds like..."
  - Affirm and validate
- Keeps the patient thinking and talking
Reflective listening

- How do you think patients respond to reflective statements?

- Try to follow an open-ended question with reflections until the patient stops elaborating.
Exercise – Group Batting Practice

• One person makes a statement: “Something I’d like to change in my life….”
  o “is to find more time for exercise”

• Everyone tries to come up with reflections:
  o “you are very busy and don’t have enough time to workout”
  o “you want to be healthier”
  o “you wish you were fitter”
Exercise – Group practice role-play

- Groups of 3 (Patient, Decision Coach, Observer)
- Begin with this open question:
  - “What is something in your life that you feel two ways about?”
    - (e.g., things you feel have pros and cons such as exercise, watching TV, raising children, being a nurse).
  - Keep conversation going with reflections to learn how the speaker feels.
- Observer tallies of questions and reflections.
  - When the listener asks two questions in a row the observer should prompt the decision coach to try a reflection instead.
- Switch roles if time permits.
Summarizing

- Brings out the highlights or key points
  - like a long reflection.

- Used at a point of transition:
  - (i.e., to wrap up one topic and move onto a new topic with a new open ended question).
Giving Information using Elicit, Provide, Elicit

- Give information using 3 steps:
  - Elicit what patient already knows/thinks
    - ”What have you heard about the procedure you’re having?”
  - Provide info
    - Give any additional information/correct misinformation
  - Elicit patient reaction/understanding
    - ”Does that make sense?” “What do you think about that?”

DECIDE-PCI Registry Protocol

BACKGROUND

Patients undergoing percutaneous coronary intervention (PCI) face a choice as to whether they receive drug eluting stents (DES) or bare metal stents (BMS). This is an important decision because while DES reduce the risk for restenosis, they necessitate prolonged dual anti-platelet therapy, which can increase the risk of bleeding, delay elective surgeries and increase medication costs compared to BMS. Currently, 80% of patients undergoing PCI receive DES and less than a third of patients report discussing stent choices with their doctors.

To support personalized, evidence-based decision-making during PCI, we developed the PRISM PCI Informed Consent tool (Arnold, 2008), which creates customized personalized consent forms for each patient that includes their individualized risk of restenosis from a validated prediction model. Initial results from a 9-center study demonstrated that the presentation of personalized restenosis risks increased patients’ discussion of stent selection from 31% to 58%, and increased patients’ perception that they had a role in choosing their stent from 28% to 48%.

Despite these improvements, there is a significant opportunity to further improve patient participation in stent selection. To further enhance patients’ engagement in shared decision-making (SDM) regarding stent type, we propose to implement a SDM tool to be administered by a specially trained Decision Coach (registered nurse) to augment the PRISM-generated consent form. We will be guided by a Steering Committee of patients, providers and a payer, with advice from multiple stakeholders who can support the widespread dissemination of the tool. We will then test whether this SDM tool improves patient engagement in SDM over and above our enhanced, personalized consent forms.

STUDY AIMS

Specific Aim 1: Implement a SDM tool for stent selection at two sites: Saint Luke’s Hospital and Truman Medical Center

Procedures & Evaluation:
1. Pre-implementation registry or data retrieval of patient/family satisfaction with information during consent process pre-SDM tool
2. Train hospital staff in motivational interviewing techniques to enhance SDM prior to cardiac catheterization and intervention
3. Implementation of the SDM tool for stent selection
4. Conduct quarterly meetings between research staff and a Steering Committee that includes patients, providers and a payer

Specific Aim 2: Analyze the results of the SDM tool for stent selection

Procedures & Evaluation:
1. Monitor proportion of patients in whom the SDM tool and motivational interviewing is used
2. Post-implementation registry or data retrieval of patient/family satisfaction, knowledge transfer, decisional conflict, and stent selection
3. Interviews of providers (cardiologists and nurses pre- and post-SDM tool) on impact of the decision tool and motivational interviewing on the SDM process.

**STUDY PROCEDURE**

Two cardiac catheterization laboratories will be the units of analysis for this project. A patient population consisting of all patients at both sites undergoing non-emergent coronary angiography and possible PCI in Years 1 and 2 (estimated sample size 1,000 patients). The decision aid will be implemented at both sites in Year 2. Designated cardiac nurses at both sites will be trained in motivational interviewing techniques by study staff (nurse and psychologist). During implementation of the SDM tool, these nurses will act as Decision Coaches for the study population.

Using a novel software platform (ePRISM), we will implement the decision tool. To examine the impact of the tool on SDM from a patient perspective, we will interview consecutive patients undergoing PCI throughout the first 2 years of the study. The primary outcome will be the Decisional Conflict Scale. Other outcomes of interest include knowledge transfer, patient preferences, process of and participation in SDM, physician knowledge of patient preferences, and physicians’ use of DES and BMS. To compare the benefit of the decision tool on the quality of SDM, we will compare the outcomes above between patients unexposed to the decision aid (Year 1) and those who received the tool (Years 2 and 3).

**ANALYSIS**

The success of this project will be determined by:

**Primary Endpoints:** Successful implementation of a SDM tool for stent selection at two sites. Successful implementation is defined as: 1) the activation of ePRISM and generation of the SDM tool for stent selection by ePRISM; and 2) participation of staff in motivational interviewing.

**Secondary Endpoints:** Patient/family satisfaction & knowledge transfer with a SDM tool for stent selection generated by ePRISM. In order to quantify the impact of the SDM process on the patients’ perspectives of the informed consent process, each site will capture patient perspectives of the discussion and informed consent process before and after ePRISM deployment. This will be accomplished through a specially designed questionnaire to quantify patients’ understanding of the procedure and the risks and benefits of DES vs BMS. “Pre-ePRISM” will be done during Year 1 of the study and then for 1 year post-implementation at both sites. Volume of non-emergency coronary angiography patients at both sites should result in a sample size of ~1000 surveys. We developed this questionnaire by leveraging a 14-item survey from a study of oncology clinical trial informed consents (Coyne, et al, 2003) and added items to explicitly quantify 1) patients’ reading of the consent, 2) anxiety, 3) risk recall, and 4) the extent of doctor-patient communication of risks and benefits. We have used this modified “Satisfaction Survey” in subsequent studies (Arnold et al, 2008). The surveys will be administered to consecutive patients undergoing PCI throughout the first 2 years of the study. The characteristics of those receiving the original consent form vs. the ePRISM-generated SDM tool will be compared with chi-square test for categorical variables and t-tests for continuous variables. The independent effect of the SDM tool will be estimated using hierarchical logistic
regression models (or proportional odds models for ordinal outcomes). Patient-level covariates will be included to adjust for patient characteristics that may differ between the original and the SDM tool. Missing covariate values may be imputed using sequential regression imputation so that all available data can be retained for analyses. All analyses will be conducted in SAS 9.2 (SAS Institute Inc., Cary, NC) and R version 2.13.1 (R Foundation for Statistical Computing, Austria).

The goal of enhancing and improving the consent process is consistent with quality improvement practices. Thus this study is presented as a quality improvement project. While there has been controversy about the evaluation of quality improvement projects, a recent article by Miller and Emanuel clearly indicates the ethical foundation by which the DECIDE-PCI Registry should undergo Institutional Review Board (IRB) review, but informed consent should be waived (Miller and Emanuel, 2008). The IRB at Saint Luke’s Hospital in Kansas City, Missouri approved this conceptualization of the project, particularly given that it was not practical to obtain consent for a decision aid, as a routine part of practicing medicine (SLH IRB Protocol # 09-387) in the setting of coronary angiography and percutaneous coronary intervention (PCI). Similarly, waiver of study informed consent is anticipated at both sites.

We believe that by coupling motivational interviewing techniques with individualized, patient-centered estimates of risks and outcomes, that the quality of the current process of care will be elevated. Assuring that information has been provided in a format that is more easily understood (figures and explanatory content, reduced literacy level to improve readability) is likely to improve patient involvement with stent selection. In the absence of any known risks of providing greater education and more information about the treatment, we feel that the benefits markedly outweigh the risks in this study.

In order to determine the impact on staff and clinicians, feedback of their reported value will be assessed qualitatively through one-on-one interviews. We anticipate interviewing 3-5 clinicians from both sites for a total of 6-10 nurses, physicians and other staff involved in the use of the SDM tool for stent selection. If saturation (no new information is being gained from subsequent interviews) has not occurred, then an additional 2-6 clinician interviews will be conducted. An interview guide developed with open-ended questions will be used to capture several constructs: 1) the individual’s experience/use of the SDM tool for stent selection; 2) ease of use; 3) the extent of added value to the process of informed consent for coronary angiography; and 4) the staff/clinician perception of the patient and family’s response to the SDM tool. The main analysis will be performed through the use of field notes and/or recorded and transcribed interviews using descriptive content analysis techniques. The notes will be coded by several members of the research team experienced in qualitative research techniques. Content analysis searches will be performed to identify patterns and themes that occur frequently in a single interview or across multiple interviews; and categorical codes will be generated (Marshall, 1996).
REFERENCES:


DECIDE-PCI Protocol

**Background** Patients undergoing percutaneous coronary intervention (PCI) face a choice as to whether they receive drug eluting stents (DES) or bare metal stents (BMS). This is an important decision because while DES reduce the risk for restenosis, they necessitate prolonged dual anti-platelet therapy, which can increase the risk of bleeding, delay elective surgeries and increase medication costs compared to BMS. Currently, 80% of patients undergoing PCI receive DES and less than a third of patients report discussing stent choices with their doctors.

**Study Goal:** The goal of this study is to gather input from patients who have undergone PCI, their family and/or caregivers, and clinicians to develop a patient decision-aid. The purpose of the decision-aid is to deliver information, including individualized estimates or patients’ restenosis risk, in an understandable format that would be informative and assist in decision-making for patients undergoing PCI.

**Study Plan:** Qualitative research methods (focus groups) will be used to gather the information that would be helpful in decision making as well as review several possible output formats. Several sets of focus groups will be convened, with particular attention to recruitment of a diverse population, including women and underserved minority groups. Using a novel software platform (PRISM), we will implement the decision-aid at Saint Luke’s Hospital and Truman Medical Center, and train hospital staff in motivational interviewing techniques to enhance shared decision-making. We will then evaluate whether the use of the decision-aid improves patient satisfaction with the informed consent process, and test the impact of the decision-aid on physician behavior with respect to BMS and DES use.

**Study Procedure:** We will gather input to create a clinically useful format for presenting the risk estimates for desired outcomes and support clinical decision-making.

*Creating the tool*

**Subjects:** We anticipate 2 or 3 patient focus groups of 6-8 individuals and 2 physician focus groups of 3-5 individuals we be scheduled. Potential patients will be screened for interest and availability for participation in a focus group. The patient, family and/or caregiver will then be contacted by a CV Research Coordinator and invited to attend a scheduled focus group (12-24 patients). Fliers may also be posted to enlist additional patients if necessary. After receiving patient/family/caregiver input, selected clinicians from the SLHS staff, including cardiologists, cardiac nurses and other cardiology staff, will be invited to attend a scheduled focus group. The invitation will be sent via email and followed up with a phone call if necessary (6-10 participants). If a clinician focus group is unable to be scheduled, then individual interviews will be conducted.

**Setting:** Patient focus group sessions will be held at at Saint Luke’s Hospital.

**Meeting Content:** See attached Discussion Guide for the patient/family/caregiver sessions as well as the Physician Discussion Guide. Gift cards will be distributed at the end of the focus group ($35 for patients and $100 for physicians).

*Testing the tool*

**Subjects:** To test the impact of the decision-aid, a patient population consisting of all patients at both sites undergoing non-emergent coronary angiography and possible PCI in Years 1 and 2 (estimated sample size 1,000 patients/year). The decision-aid will be implemented at both sites in Year 2.

**Setting:** Saint Luke’s Hospital and Truman Medical Center

**Methods:** To examine the impact of the tool on shared decision-making (SDM) from a patient perspective, we will interview consecutive patients undergoing PCI throughout the first 2 years of the
study. The primary outcome will be the Decisional Conflict Scale. Other outcomes of interest include knowledge transfer, patient preferences, process of and participation in SDM, physician knowledge of patient preferences, and physicians’ use of DES and BMS. To compare the benefit of the decision-aid on the quality of SDM, we will compare the outcomes above between patients unexposed to the decision-aid (Year 1) and those who received the tool (Years 2 and 3).
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