

## **A Regional Clinical Quality and Value Program in Percutaneous Coronary Intervention**

Executive Summary: As part of a regional strategy to develop a value-based healthcare ecosystem, the Kansas City Area Life Sciences Institute, working with our stakeholders and the broader community, have developed a clinical quality and value program for percutaneous coronary intervention (PCI). We believe this is an ideal program because it has the potential not only to benefit individual institutions by improving quality and outcomes while driving down the costs of PCI, but it also brings value to the greater region. With the majority, if not all, regional hospitals implementing this program, our region can demonstrate leadership in clinical safety, quality and value. This demonstration can put Kansas City in a better position to attract companies to partner with the area's institutions to develop market-viable treatment approaches. This program is a prototype for future collaborative initiatives to drive regional recognition, economic development, and improvement of the health of our citizens.

Background: A regional life science strategy was developed in 2015 in partnership with Deloitte and community leaders, including hospitals and academic institutions. The strategy detailed in the *Path to 2025*<sup>1</sup>, focuses on our regional strengths and includes an emphasis on health IT and clinical outcomes. A working group tasked to this focus area appreciated a significant regional economic development opportunity that could benefit the health and well-being of our citizens.

Project selection: The working group considered many different clinical outcomes projects that could benefit the region, including joint replacement, obesity, diabetes, hypertension, back pain and many others. To guide project selection, the working group developed seven criteria deemed essential for a successful project; including impact, importance, intervention, actionability, feasibility, data availability, and quantitation (Addendum A). Based on these criteria, the project selected most likely to succeed was a program to improve the safety of percutaneous coronary intervention.

Implementation tool: Participation in this program involves implementing a well-studied predictive platform to use at point-of-care. The scientific justification and peer reviewed studies supporting the methodology have been published in many different journals<sup>2-5</sup>. A local company, Health Outcome Sciences (HOS), developed a software tool for interventional cardiologists that integrates with a hospital's existing electronic health record (EHR). The *ePRISM* software (Addendum B) extracts multiple EHR data points from each patient and calculates individualized bleeding risk as low, medium or high and each hospital's risk-specific protocol is provided to optimize safety and minimize variability in care. Additionally, EHR data is used to assess acute kidney injury (AKI) risk and a 'safe contrast limit' is calculated for each patient to minimize the risk. These risks and protocols are readily implemented into the 'Time Out' before PCI and provide an intervention strategy to the cardiologist on the operating room computer monitor boom.

Value proposition: National post-PCI bleeding and AKI rates range up to 12%. With implementation of the *ePRISM* software tool, bleeding and AKI rates can be reduced to <2%. Each bleeding event costs a hospital \$8,658/patient and each AKI event costs a hospital \$10,667/patient (>\$100,000 if dialysis is

required) and aggressive risk management can support same day discharge, which can save hospitals ~\$7,000/case on elective procedures.

Cost: To encourage regional participation, the cost of the *ePRISM* tool is being heavily discounted making it readily recouped from the savings of avoiding even a few adverse events. In this way, institutions can tangibly benefit from the program and improve patient outcomes while collaborating toward a regional economic development strategy.

Next steps: We would like to set up a meeting with your CEO, Quality Officer, Cardiac Administrative Director and Cardiologists to review the proposal and the tool. To estimate the value of the PCI opportunity for your hospital, we ask you to run a report with American College of Cardiology, National Cardiovascular Data Registry (ACC-NCDR) data. This will detail specific bleeding rates, AKI rates and same day discharge to show the potential impact project participation could have for your bottom line and for your patients. Alternatively, we can you send a form allowing approved ACC-NCDR data centers to run the report for you prior to our meeting. Any shared data would be held in strict confidentiality.

Follow-on programs: Following the implementation of the PCI program for the region, the working group hopes to initiate additional programs to help drive value-based healthcare. We hope you will also consider participating in follow-on programs and we welcome your feedback regarding programs that you believe would be of high value for your hospital.

#### References:

- 1) Path to 2025, Kansas City Area Life Sciences Institute, <http://kclifesciences.org/reports/>, September 2015.
- 2) Arnold SV, Decker C, Ahmad H, Olabiyi O, Mundluru S, Reid KJ, Soto GE, Gansert S, Spertus JA. Converting the Informed Consent Form a Perfunctory Process to an Evidence-Based Foundation for Patient Decision Making. *Circ Cardiovasc Qual Outcomes* 2008;1:21-28.
- 3) Rao SC, Chhatriwalla AK, Kennedy KF, Decker CJ, Gialde E, Spertus JA, Marso SP. Pre-procedural estimate of individualized bleeding risk impacts physicians' utilization of bivalirudin during percutaneous coronary intervention. *J Am Coll Cardiol*. 2013;61(18):1847-52.
- 4) Spertus JA, Bach R, Bethea C, Chhatriwalla A, Curtis JP, Gialde E, Guerrero M, Gosch K, Jones PG, Kugelmass A, Leonard BM, McNulty EJ, Shelton M, Ting HH, Decker C: Improving the process of informed consent for percutaneous coronary intervention: Patient Outcomes from the Patient Risk Information Services Manager (ePRISM) study. *Am Heart J*. 2015; 169(2):234-241 e231. PMID: 4315511.
- 5) Spertus JA, Decker C, Gialde E, Jones PG, McNulty EJ, Bach R, Chhatriwalla AK. Precision medicine to improve use of bleeding avoidance strategies and reduce bleeding in patients undergoing percutaneous coronary intervention: prospective cohort study before and after implementation of personalized bleeding risks. *BMJ*. 2015;350:h1302. PMID: 4462518.

### Considerations in Defining a Successful Outcomes Research Project for Kansas City

**Background:** There are a myriad of potential targets for a regional outcomes project, the overarching goal is to have an initial project that is high-impact and provides a quantifiable return to participating providers to inspire them to continue to collaborate with the KCALSI Outcomes Group and lay the foundation for Kansas City to become *the* Outcomes City. After numerous meetings of a small working group, a set of key requirements for this initial project was developed and a proposal created for consideration.

#### ***Key Requirements for a Successful Regional Outcomes Project:***

1. **Impact** – The targeted patient population needs to be costly, prevalent and important to patients, providers, and payers. There should be a documented gap in care.
2. **Importance** – The condition should be deemed by providers to be important to address, ideally with financial benefits accruing for better performance.
3. **Intervention** – For a successful project, there needs to be an intervention that is already proven and capable of effecting change. Ideally, there are already documented variations in care and sub-optimal outcomes that can be improved upon with the intervention.
4. **Actionable** – There needs to be action that results from use of the intervention that can lead to demonstrable improvements in patient outcomes.
5. **Feasible** – The intervention should be readily implementable. As a consequence of this, interventions that are focused within a hospital, so that all patients flow through a common pathway where the intervention can be introduced is far preferable to a broader, outpatient clinic setting where more sites, with variable workflows, need to be engaged for successful implementation.
6. **Data** – There would, ideally, be an already established data collection infrastructure in place so that all participants can be aware of their performance before and after the intervention so that the outcomes can be readily and inexpensively quantified.
7. **Quantifiable** – At the conclusion of the project, there should be a way to convert the observed changes in care into quantifiable clinical and economic outcomes that can be readily communicated to participants, the broader community and the scientific enterprise to demonstrate the value of the KC Regional Outcomes Program.

**Addendum A**

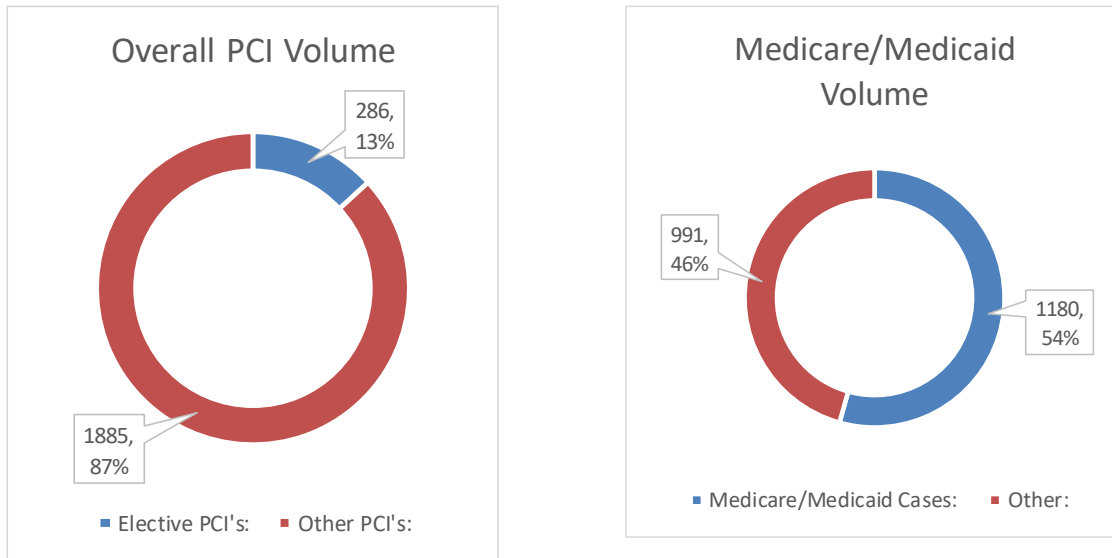
**Proposed Project:** After much deliberation on projects ranging from hypertension, obesity and back pain management to smoking cessation, the working group ultimately settled upon improving the safety and lowering the costs of percutaneous coronary interventions. An outline of how this intervention meets the aforementioned standards is provided below:

<b>Requirement</b>	<b>Rationale</b>
Impact	PCI is the most common cardiac procedure and is one of the most expensive conditions treated by CMS. There is wide variability in the safety of procedures with bleeding or acute kidney injury (AKI) occurring in as many as 12% of cases.
Importance	Medicare is rapidly introducing bundled payments and private insurers are wanting to pursue 'at risk' contracting so that the risks associated with care are shifted to providers. Providers that can deliver better care at lower costs will thrive in such an environment.
Intervention	A well-developed tool, ePRISM, has already been developed, tested and shown to markedly improve the safety of PCI, while lowering costs. It is a decision support tool that accomplishes the triple aim of healthcare by prospectively providing interventional cardiologists with patients' risks for bleeding and AKI so that they can tailor treatment to risk.
Actionable	There are 3 bleeding avoidance strategies that can be used, depending upon patients' risks for bleeding. ePRISM also defines the 'safe contrast' dose for PCI so that the risk of AKI is minimized. Moreover, there is widely demonstrated – and extreme – variability in the way in which different doctors treat patients with similar risks. By prospectively informing interventional cardiologists of the risks of bleeding, applying evidence-based protocols, and supporting feedback and accountability, marked reductions in the variability in care can be achieved – further supporting the safety and lowering the costs of treatment.
Feasible	Most patients undergoing PCI flow through a common 'holding area' and all patients are exposed to a JCAHO-mandated 'time out' during which the risk models can be executed and used as decision-support tools.
Data	Virtually all Kansas City hospitals participate in the American College of Cardiology's National Cardiac Data Registry (ACC NCDR). This insures that all data needed to measure the rates of bleeding and AKI, along with the patient-level clinical risk factors associated with these outcomes, are readily available.
Quantifiable	Using the ACC NCDR, performance before and after implementation can be measured and compared. Moreover, there are clear economic estimates of the costs of bleeding (~\$8,000/patient), AKI (~\$10,000/patient and >\$100,000/dialysis event avoided) and same-day discharge (~\$6,700/patient) that can convert the improvements in safety into economic terms.

**Addendum B**

XXXXX Hospital - Anywhere, USA February 23, 2018

Thank you for the opportunity to analyze the data that XXXXX Hospital submitted to the ACC Cath/PCI Registry. A total of 4 quarters of data between 2015Q2 and 2016Q1 were analyzed. This first section summarizes opportunities for success, both in terms of financial returns as well as improvements in quality, outcomes and patient satisfaction.



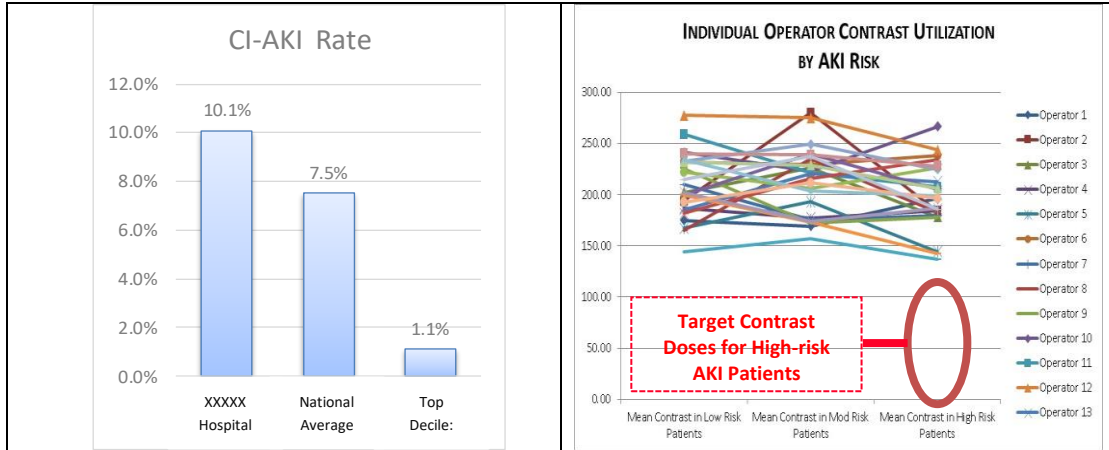
Beyond the summary, we have also provided an in-depth analysis of your performance with detailed explanations of the estimates of potential financial returns from the use of our ePRISM® solution. This Opportunity and Variance Report will analyze 7 major categories of financial and clinical return on investment. Those areas are:

1. Contrast Induced Acute Kidney Injury
2. Reduction of bleeding events and more rational anticoagulant utilization
3. Improving the consistency and reducing inter-operator variation of treatment among physicians
4. Appropriate admission of moderate and high risk patients post-PCI
5. Appropriate documentation of elective PCI cases to support AUC
6. Refined utilization of DES/BMS in low risk TVR patients
7. Improved patient satisfaction through the use of the ePRISM Informed Consent document

### 1. CONTRAST INDUCED ACUTE KIDNEY INJURY BACKGROUND - (Benefit 1)

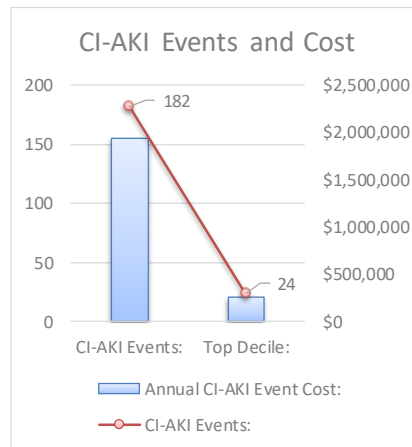
- CI-AKI is a common and morbid complication of PCI and increases patients’ length of stay and mortality risk. The NCDR defines CI-AKI as an increase in the serum creatinine of  $\geq 0.3$  post procedure.
- The prevention of a single CI-AKI event has been shown to reduce length of stay by 7 days and save the hospital over \$10,667 per occurrence.<sup>11</sup>
- The NCDR defines CI-AKI as an increase in the serum creatinine of  $\geq 0.3$  post procedure.
- XXXXX Hospital had 182 CI-AKI events over the past 4 quarters for a rate of 10.1%

#### XXXXX Hospital Performance:



- Substantial variability in average contrast dose/case was observed across operators with little evidence of lower contrast use in the highest risk patients. None of the operators, on average, used less than 100cc/case in the highest risk patients.

#### XXXXX Hospital Opportunity:



- Top decile performance or better would equate to less than 24 CI-AKI events, annually, and would be estimated to save \$1,685,386 or more.

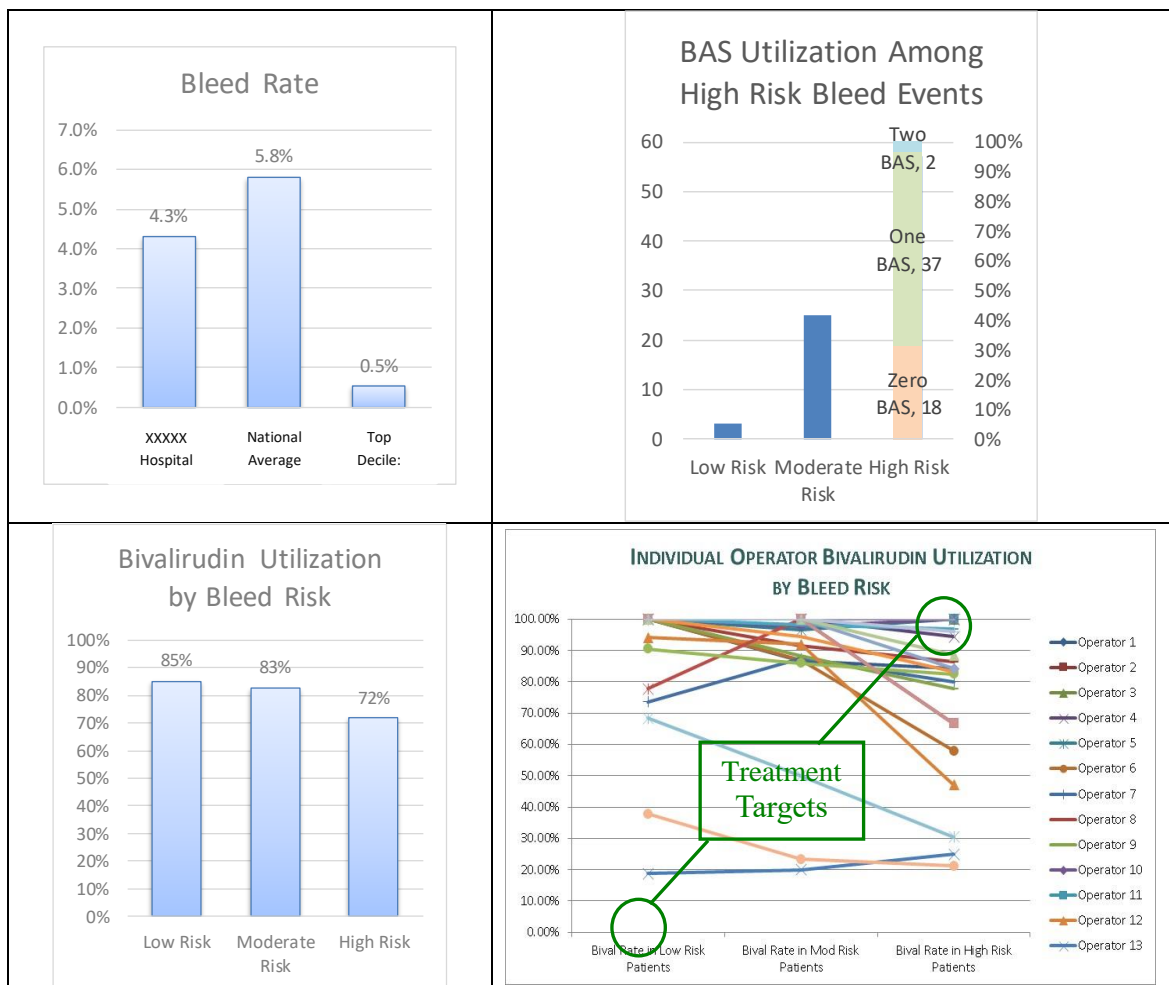
#### HOS Recommendations:

- Adopt the ePRISM CI-AKI model
- Limit operator variability and total contrast delivered to patients at high risk for CI-AKI

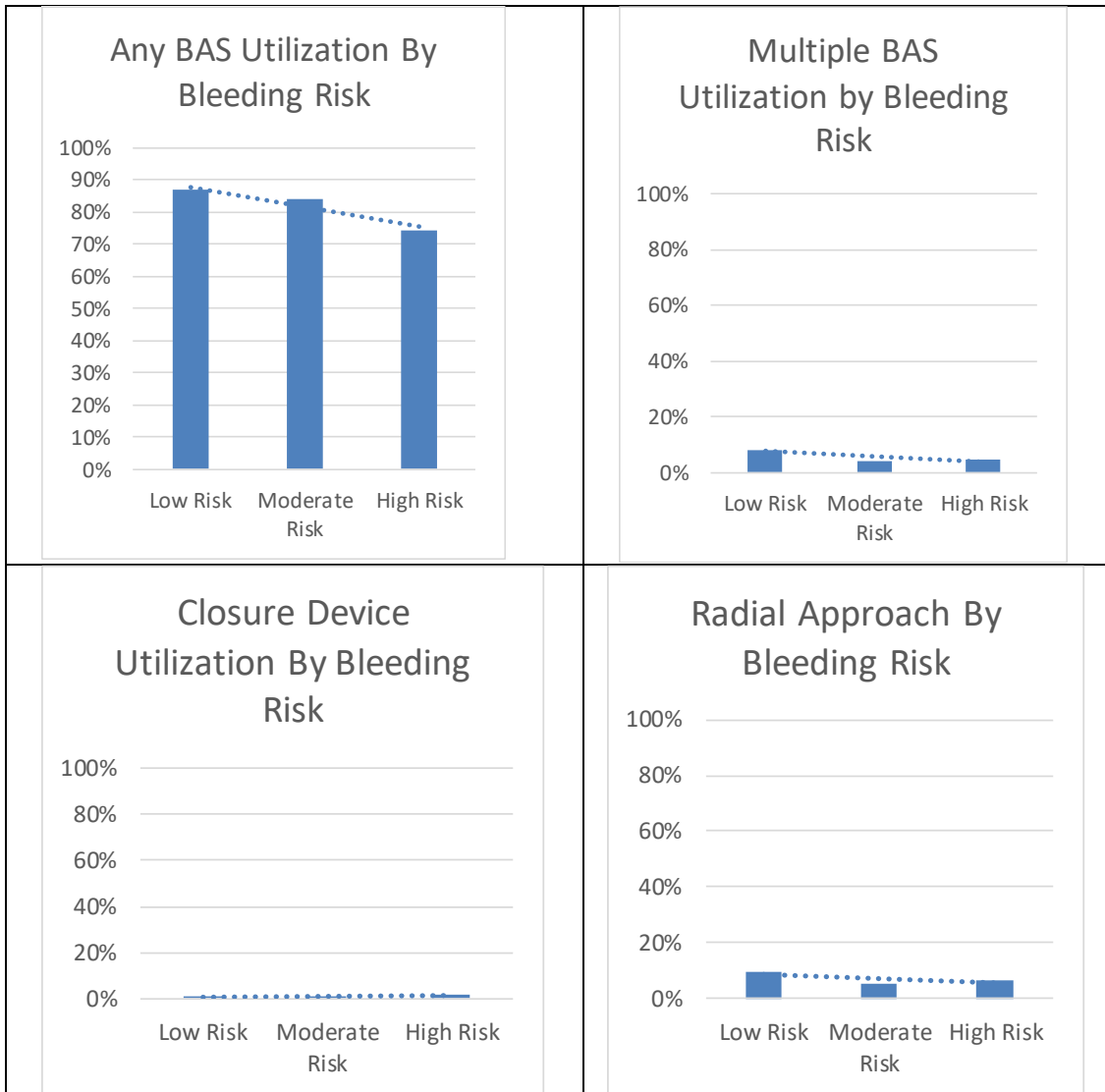
## 2. REDUCTION OF BLEEDING EVENTS AND MORE RATIONAL ANTICOAGULANT UTILIZATION - [\(Benefit 2\)](#)

- Bleeding is the second most common non-cardiac complication of PCI, and is associated with increased morbidity, mortality, length of hospitalization and increased costs.
- Reduction of bleeding events can save between \$2,282 and \$8,658 per event.
- Over the past 4 quarters, XXXXX Hospital has an observed bleeding rate of 4.3% (94 bleeding events). While this is below the national average, it is higher than past performance at XXXXX Hospital and above the top decile performance of 0.5%.

### XXXXX Hospital Performance:



- Moreover, there is substantial variation in the use of bivalirudin across providers and only a minority of patients at high risk for bleeding receive 2 bleeding avoidance strategies.



- Of the patients with post PCI bleeds, 96% would be classified as moderate or high risk for bleeding prior to PCI and would therefore be candidates for bleeding avoidance strategies.
- Bivalirudin was used more often in patients at lower risk for bleeding than in patients at higher risk and marked variability across operators was observed. This highlights an important opportunity to increase the consistency of care with avoidance in low-risk patients and increased use in higher-risk patients.

**XXXXX Hospital Opportunity:**

- Top decile performance is a bleeding rate of 0.5%. If XXXXX Hospital achieved top decile performance or better, it would have less than 11 bleeding events annually and would **save between \$189,406 and \$718,614** (83 bleeding events avoided multiplied by the upper and lower projected cost of bleeding events)

**HOS Recommendations:**

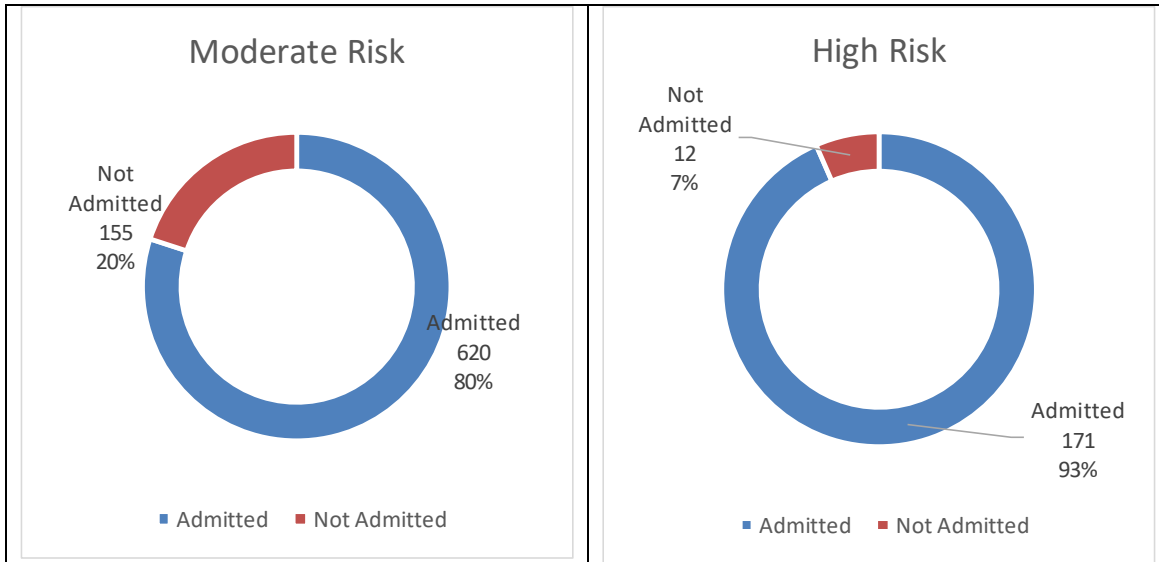
- Review the use of Bivalirudin and other BAS by bleed risk and consider incentivizing appropriate use of BAS



**3. APPROPRIATE ADMISSION OF MODERATE TO HIGH RISK PATIENTS POST PCI – (Benefit 4)**

- The basis of this determination is the difference between hospital payments for an inpatient stay versus outpatient observation post PCI
- The new Two Midnight rule has been modified to favor hospital admission justified by physician judgement and the medical predictability of adverse events

**XXXXX Hospital Performance:**



- 20% of moderate risk patients and 7% of high risk patients are not being admitted to the hospital

**XXXXX Hospital Opportunity:**

- Based on analysis of the data and assuming an **average reimbursement difference of \$7,500** for inpatient vs. outpatient treatment, a decision to admit rather than monitor post PCI would appear to be justified in 155 patients at moderate risk and an additional 12 patients at high risk of bleeding post PCI.
- XXXXX Hospital could see an additional **\$1,252,500** annually by admitting 100% of moderate to high risk PCI patients not treated for STEMI/NSTEMI, although the final protocol adopted by your hospital could alter these potential savings.
- Alternatively, XXXXX Hospital currently does not discharge any elective PCI patients on the same day as their procedure, while other hospitals discharge >80% of their elective cases on the day of the procedure. The estimated savings for same-day discharge is \$6,700/case. Achieving this rate could save XXXXX Hospital **\$1,393,600** annually.

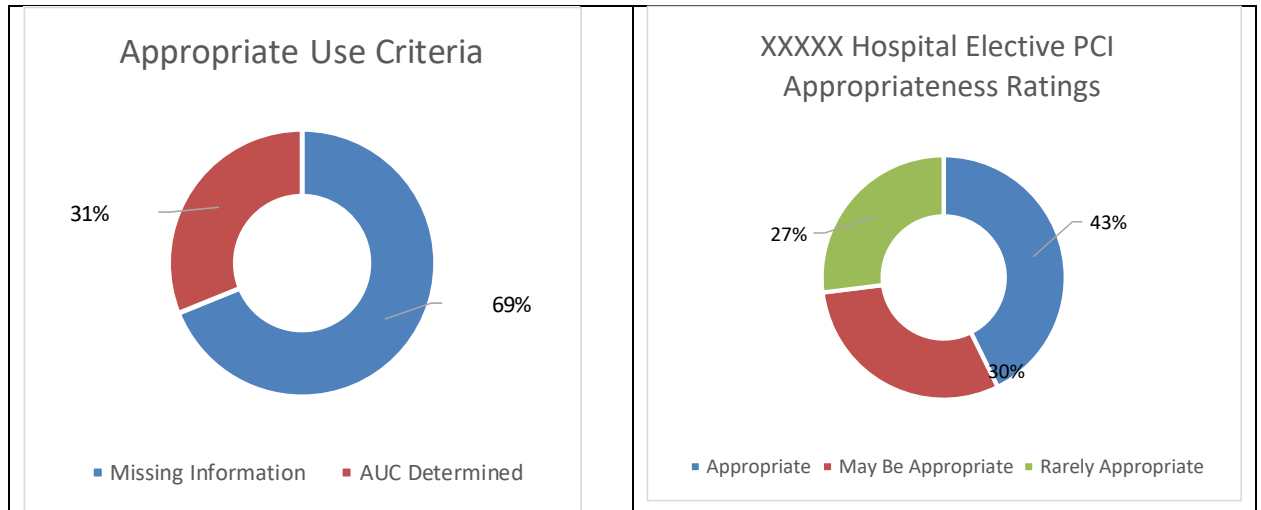
**HOS Recommendations:**

- There would be an additional potential for admitting patients at high risk of contrast induced AKI
- HOS clients have been successful in developing a same day discharge program for low risk patients to further reduce costs.

**4. OPTIMIZE DOCUMENTATION OF CLINICAL CARE USING ACC APPROPRIATE USE – [\(Benefit 5\)](#)**

- Appropriateness of procedures, especially PCI, is being heavily scrutinized
- HOS has the ability to deploy the ACC Appropriate Use Criteria so that clinicians can assess a patient’s appropriateness rating prior to performing the procedure

**XXXXX Hospital Performance:**



- Of the 286 elective PCIs there is a high rate (68.9%, 197 procedures) of PCIs where appropriateness could not be determined because of incomplete/missing documentation
- Analysis of XXXXX Hospital’s elective PCIs shows a high rate (27.0%, 77 procedures) of PCIs performed and characterized as “rarely appropriate care”

**XXXXX Hospital Opportunity:**

- By eliminating the 197 cases missing documentation necessary to calculate AUC, XXXX Hospital can much more readily document the appropriateness of its PCI procedures.
- With prospective assessment of patients’ AUC, other clients have reduced similar rates of rarely appropriate PCIs to the single digits.

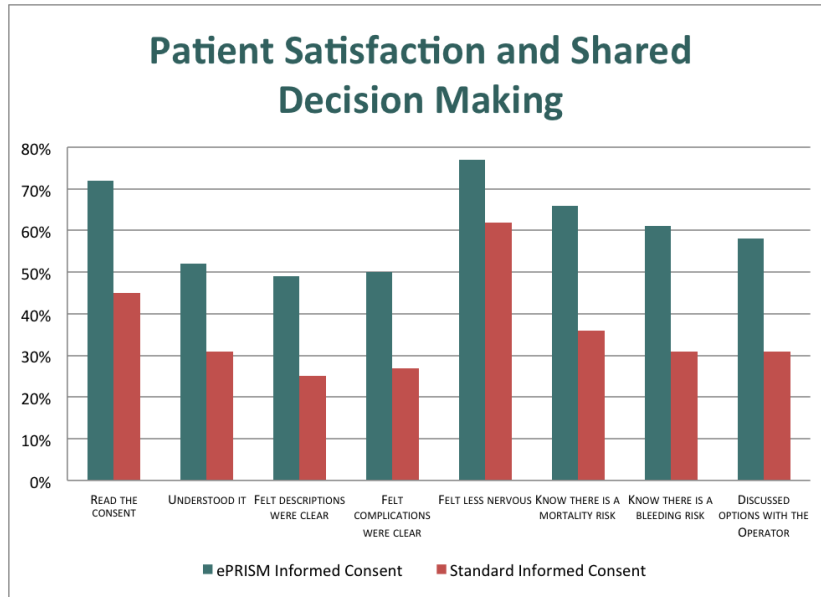
**HOS Recommendations:**

- Implement the ePRISM Appropriate Use Criteria model for Coronary Revascularization
- Reduce or eliminate elective PCI in patients scoring “rarely appropriate” or having incomplete documentation to determine AUC

**5. IMPROVE PATIENT ENGAGEMENT AND SATISFACTION WITH THE CONSENT PROCESS FOR PCI – (Benefit 9)**

- Use of ePRISM seeks to improve all elements of the quadruple aim. Prior studies show significant improvement in patient engagement and satisfaction through the utilization of personalized informed consent documents which leads to shared medical decision-making.

**Results of a 9-Center Study:**



**XXXXXX Hospital Opportunity:**

- XXXXXX Hospital should consider using the ePRISM consent tool in 100% of elective PCI patients

**HOS Recommendations:**

- Fully implement the ePRISM consent tool in elective PCI patients pre-procedure

**Addendum B**



Number of quarters analyzed: 4

Category	Number of Patients:	Savings per Case	Annual Opportunity
Prevention of CI-AKI Events (Top Decile Performance):	158	\$10,667	\$1,685,386
Prevention of Bleeding Events (Top Decile Performance):	83	\$2,282-\$8,658	(\$189,406-\$718,614)
Moderate Risk Bleed Patients Not Admitted:	155	\$5,000-\$10,000	(\$775,000-\$1,550,000)
High Risk Bleed Patients Not Admitted:	12	\$5,000-\$10,000	(\$60,000-\$120,000)
Same-Day Discharge in Elective Cases	208	\$6,700	\$ 1,393,600
AUC Cases Missing Documentation*	197	\$16,000-\$22,000	(\$3,152,000-\$4,334,000)
AUC Cases: "Rarely Appropriate Care"*	77	\$16,000-\$22,000	(\$1,232,000-\$1,694,000)
*Assumes complete CMS clawback of payments for unmappable and rarely appropriate PCIs			(\$7,172,360 - \$10,060,568)

Angiomax Utilization:	Number of Patients:	Current Use (Targeted)	Cost/Savings per Case	Annual Opportunity
Eliminate Use in Low Risk Bleed Patients	430	85.15% (None)	\$705 Cost	\$303,150
Prevent Bleeding in Moderate Risk Bleed Patients	181	82.66% (All)	\$461 Savings	\$83,441
Prevent Bleeding in High Risk Bleed Patients	155	71.72% (All)	\$1,574 Savings	\$243,970
				<b>\$630,561</b>
				Annual Opportunity
				<b>(\$7,802,921-\$10,691,129)</b>

ADDITIONAL OPPORTUNITY

Category:	Number of Patients:	Cost per Case	Annual Opportunity
CMS VBP	Unknown	Unknown	Unknown
Same Day Discharge Program	Unknown	Unknown	Unknown

## Recommendations

### HOS seeks a relationship with XXXXXX Hospital

1. Contrast Induced Acute Kidney Injury:
  - a. Adopt the ePRISM CI-AKI model
  - b. Limit operator variability and total contrast delivered to moderate and high risk for CI-AKI
2. Reduction of bleeding events and more rational anticoagulant utilization:
  - a. Review the use of Bivalirudin and other BAS by bleed risk and consider incentivizing appropriate use of BAS
3. Appropriate admission of moderate to high risk patients post-PCI:
  - a. Review the current admission protocol and consider utilizing bleed risk as a determining factor
  - b. There would be an additional potential for admitting patients at high risk of CI-AKI
  - c. HOS clients have been successful in developing a same day discharge program to further reduce costs. XXXXX Hospital should consider developing/modifying a SDD program
4. Optimize documentation of clinical care using ACC Appropriate Use Criteria:
  - a. Implement the ePRISM ACC Appropriate Use Criteria model for Coronary Revascularization
  - b. Reduce or eliminate elective PCI in patients scoring “rarely appropriate” or having incomplete documentation to determine AUC
5. Review Drug Eluting Stent utilization in Low TVR risk patients:
  - a. Continue to review use of multiple DES in patients at low risk of TVR and identify patients who may benefit from avoiding DES
6. Improve patient engagement and satisfaction with the ePRISM Informed Consent process for PCI:
  - a. Implement the ePRISM consent tool in elective PCI patients pre-procedure
7. XXXXX Hospital should consider implementing other operational models HOS can supply through ePRISM:
  - a. Risk of Diminished Quality of Life or Mortality with TAVR to support patient selection
  - b. Implementation of DAPT Score to support recommendations for long-term DAPT
  - c. Risk of 30-Day Readmission Following Hospitalization for PCI
  - d. Risk of 30-Day Readmission Following Hospitalization for AMI
  - e. Risk of 30-Day Readmission Following Hospitalization for Heart Failure
  - f. Risk of 30-Day Readmission Following Hospitalization for Pneumonia
  - g. Risk of Bleeding and Major Ischemic Event with Clopidogrel vs Prasugrel for ACS Treated with PCI
  - h. Risk of In-Hospital Mortality Following ICD
  - i. Patient-specific benefits in terms of mortality and quality of life from CRT therapy
  - j. Risk of In-Hospital Complication (Including Mortality) Following ICD
  - k. Qualification of ICD or CRT (for Referral Evaluation)
  - l. Risk of Good and Bad Outcome with tPA for Acute Ischemic Stroke
  - m. Risk of Symptomatic Intracranial Hemorrhage within 36 Hours of tPA Administration for Stroke
  - n. Risk of Arteriosclerotic Cardiovascular Disease Over 10 and 30 Years
  - o. Health Status Measurement for Heart Failure (KCCQ)
  - p. Health Status Measurement for Coronary Artery Disease (SAQ)
8. XXXXX Hospital should work with HOS on development of new models judged to be of mutual benefit:
9. XXXXX Hospital should consider opportunities in Value Based Purchasing contracts and the use of risk reduction tools:
10. XXXXX Hospital should consider opportunities in other private payer metrics such as Anthem BCBS-QHIP: