



# Reduce the Risk: PCI Bleed

A Campaign of the  
American College of Cardiology



# Putting your Campaign Tools to Work

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# Webinar Topics

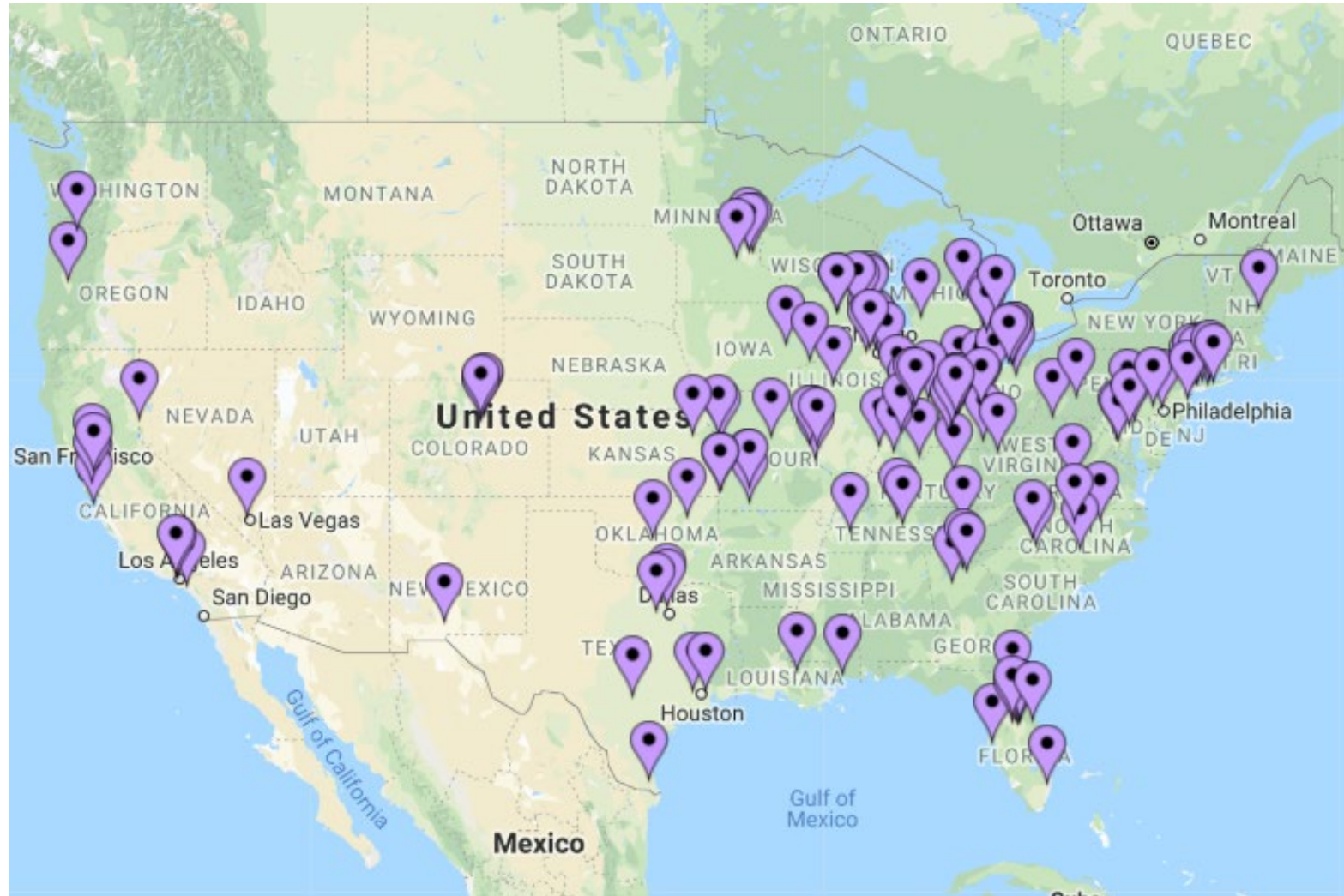
- Program Update
- Tools supporting Risk-Concordant Care
- Toolkit Grand Tour



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## Features

The Reduce the Risk: PCI Bleed Campaign leverages evidence-based best practices to improve the care and outcomes of patient who have undergone a percutaneous cardiovascular intervention (PCI).

### Assessment

Includes benchmarking data and is designed to identify opportunities for improvement.

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### Toolkit

Specific tools and strategies designed to address one general topic area for improvement.

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### Webinars

Listen to webinars that review evidence-based toolkits and lessons learned.

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### Listserv

Collaborate and interact with others



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## ADVERTISEMENT



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## Reduce the Risk: PCI Bleed Toolkit

The table below displays the Reduce the Risk: PCI Bleed Campaign metrics and the tools and strategies to support facilities participating in this Quality Campaign. These tools and strategies are resources available to all participating facilities to assist with meeting the goal of decreasing overall bleeding events.

- Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients.
- Metric 2: Proportion of PCI procedures with transfusion of whole blood or red blood cells.
- Metric 3: Procedures with an observed bleeding event.
- Metric 4: Anticoagulation utilization.
- Metric 5: Access site utilization.
- Metric 6: Method for closure for arterial access site.

Check back for more tools coming soon!

### ▼ Preprocedural (Tools to address Metric #1 and 6)

Metric	Tools
Metric 1: in-hospital risk-standardized rate of bleeding Metric 3: Procedures with an observed bleeding event	<a href="#">CathPCI Bleeding Risk Calculator App</a>
Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients Metric 6: Method for closure for arterial access site	<a href="#">Pre PCI-Procedure Orders</a>
Metric 1: in-hospital risk-standardized rate of bleeding Metric 3: Procedures with an observed bleeding event	<a href="#">The Universal Protocol from the Joint Commission</a>
Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients Metric 4: Anticoagulation utilization	<a href="#">Risk-Concordant Framework for Bleed Avoidance Strategies</a>



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# CathPCI Bleeding Risk Calculator App



Available in the iTunes and  
GooglePlay app stores

Web platform:

[tools.acc.org/CathPCIBleedRisk](https://tools.acc.org/CathPCIBleedRisk)



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# Calculate Risk

## Inputs:

- Age
- Sex
- Race
- Height
- Weight
- Baseline Hgb
- Prior STEMI
- Prior PCI
- Cardiogenic shock w/in 24 hours
- Dialysis

Calculate Risk

Units of Measure: US SI

Reset All

**Patient Demographics**

Age (18-120) Years

Sex: Select

Race: Select

**Patient Pre-Procedural Characteristics** Reset

Procedural Characteristics Reset

Body Mass Index (BMI) kg/m² [Enter the BMI value manually](#)

Height: Feet Inches

Weight: lbs

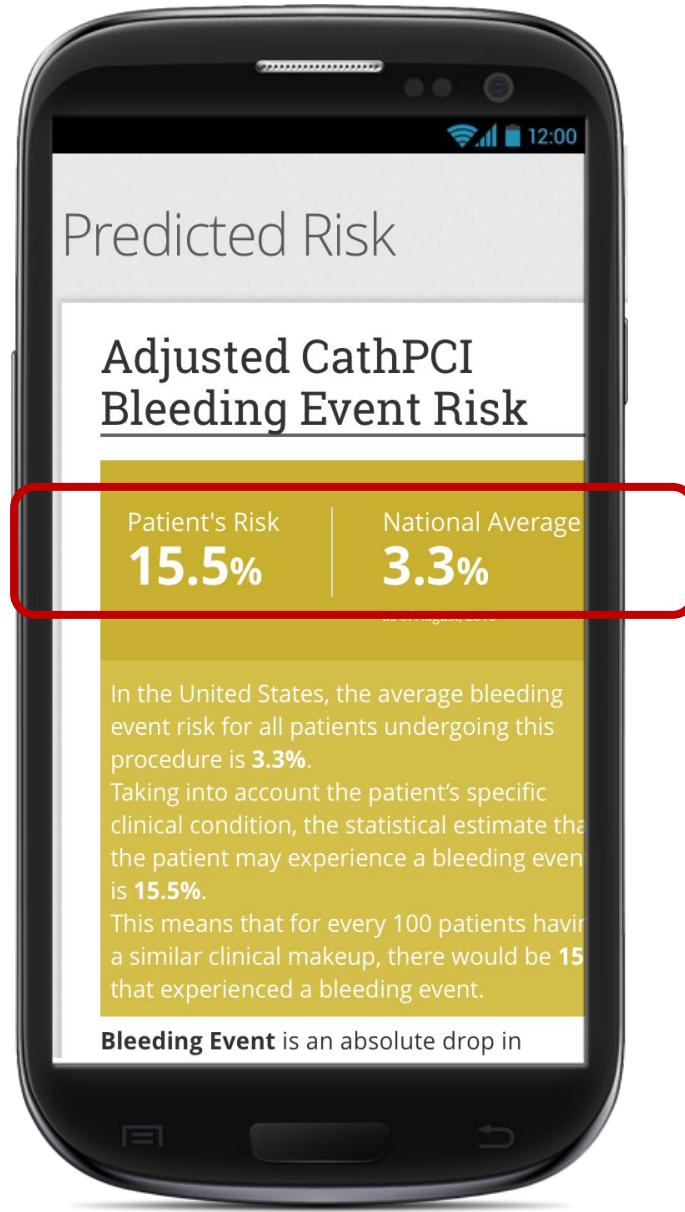
Baseline Hemoglobin g/dL

Prior STEMI: Yes No

Prior PCI: Yes No

# Output: Predicted Risk

Patient  
bleeding event  
risk compared  
to national  
average risk



The smartphone screen displays the 'Patient Demographics' and 'Patient Pre-Procedural Characteristics' sections.

**Patient Demographics**

Age : 55 Years	Sex : Female
Race : Black or African American	

**Patient Pre-Procedural Characteristics**

Body Mass Index (BMI)	31.32 kg/m <sup>2</sup>
Height	5 Feet 7 Inches
Weight	200 lbs
Baseline Hemoglobin	15 g/dL
Prior STEMI	✓ No
Prior Cardiogenic Shock	✓ Yes
Prior PCI	✓ No
Dialysis	✓ Yes
Glomerular Filtration Rate (estimated)	N/A
Serum Creatinine (SCr)	N/A



## Appropriate Use Criteria App



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### PCI Risk Calculator

The predicted risk of mortality is : 24.1%

The risk of blood transfusion (whole blood or packed cells) is : 26.4%

The predicted risk of CIN is : 18.0%


Acknowledgements

Definitions

About SCAI

<http://scaipciriskapp.org/porc>

# App Comparison

	ACC CathPCI Bleeding Risk Calculator App 	SCAI PCI Risk Calculator App
<b>Development</b>	-Based on the 2013 Updated Bleeding Risk Model and NCDR CathPCI Registry	-Based on risk models developed by the NCDR CathPCI Registry and the Massachusetts Data Analysis Center
<b>Scope</b>	-Estimates individual PCI-related bleed risk to the National Average bleed risk -Intended for use as part of pre-procedure assessment	-Estimates in-hospital mortality, acute kidney injury (AKI), and need for a transfusion -Intended for use as part of pre-procedure assessment
<b>Units of Measure</b>	-US or SI	-US
<b>Inputs</b>	-Fewer inputs captured to produce estimated bleed risk	-More inputs are captured to produce three categories of risk.
<b>Bleeding Risk v. Transfusion</b>	-Bleeding event defined as an absolute drop in hemoglobin >4 g/dL, a RBC transfusion and/or a procedural intervention/surgery to reverse/stop bleeding that occurs within 72 hours of the PCI procedure	-Transfusion defined as: reflects any transfusion of either whole blood or packed red blood cells between the start of the PCI procedure and until the next procedure or discharge.
<b>Email function</b>	-Able to email a brief summary of session	-No email function



# Risk-concordant Care: Why & How

## ORIGINAL RESEARCH



### Reversing the “Risk-Treatment Paradox” of Bleeding in Patients Undergoing Percutaneous Coronary Intervention: Risk-Concordant Use of Bleeding Avoidance Strategies Is Associated With Reduced Bleeding and Lower Costs

Amit P. Amin, MD, MSc; Samantha Miller, RN; Brandon Rahn, MHA; Mary Caruso, RN; Andrew Pierce, MHA; Katrine Sorensen, MS; Howard Kurz, MD; Alan Zajarias, MD; Richard Bach, MD; Jasvinder Singh, MD; John M. Lasala, MD, PhD; Hemant Kulkarni, MD; Patricia Crimmins-Reda, RN

**Background**—Bleeding is a common, morbid, and costly complication of percutaneous coronary intervention. While bleeding avoidance strategies (BAS) are effective, they are used paradoxically less in patients at high risk of bleeding. Whether a patient-centered approach to specifically increase the risk-concordant use of BAS and, thus, reverse the risk-treatment paradox is associated with reduced bleeding and costs is unknown.

**Methods and Results**—We implemented an intervention to reverse the bleeding risk-treatment paradox at Barnes-Jewish Hospital, St. Louis, MO, and examined: (1) the temporal trends in BAS use and (2) the association of risk-concordant BAS use with bleeding and hospital costs of percutaneous coronary intervention. Among 3519 percutaneous coronary interventions, there was a significantly increasing trend ( $P=0.002$ ) in risk-concordant use of BAS. The bleeding incidence was 2% in the risk-concordant group versus 9% in the risk-discordant group (absolute risk difference, 7%; number needed to treat, 14). Risk-concordant BAS use was associated with a 67% (95% confidence interval, 52–78%;  $P<0.001$ ) reduction in the risk of bleeding and a \$4738 (95% confidence interval, 3353–6122;  $P<0.001$ ) reduction in per-patient percutaneous coronary intervention hospitalization costs (21.6% cost-savings).

**Conclusions**—In this study, patient-centered care directly aimed to make treatment-related decisions based on predicted risk of bleeding, led to more risk-concordant use of BAS and reversal of the risk-treatment paradox. This, in turn, was associated with a reduction in bleeding and hospitalization costs. Larger multicentered studies are needed to corroborate these results. As clinical medicine moves toward personalization, both patients and hospitals can benefit from a simple practice change that encourages objectivity and mitigates variability in care. (*J Am Heart Assoc.* 2018;7:e008551. DOI: 10.1161/JAHA.118.008551.)

**Key Words:** anticoagulant • bleeding • cost • percutaneous coronary intervention • radial artery catheter

Bleeding is the most common complication of the percutaneous coronary intervention (PCI) procedure.<sup>1–4</sup> Bleeding is life-threatening, morbid, and painful and increases patients' risks of short- and long-term mortality.<sup>2,5,6</sup> Bleeding occurs in 2% to >10% of the more than 600 000 patients who

undergo PCI each year.<sup>2,3,5,6</sup> Bleeding costs \$12 000 per episode; therefore, there are significant health and economic burdens for patients and for society at large.<sup>7–14</sup> Although many hospitals have high rates of bleeding, few hospitals have systematically attempted to reduce bleeding to make PCI safer and more inexpensive.

Bleeding after PCI is predictable and modifiable, and validated risk-prediction models can accurately quantify a patient's risk before bleeding occurs.<sup>4,15,16</sup> If bleeding risk is known, a patient-centered approach that targets patients at risk with effective bleeding avoidance strategies (BAS) can be used, such as bivalirudin,<sup>17,18</sup> radial access,<sup>1,19</sup> and vascular closure devices (VCDs).<sup>3</sup> Frequently, patients at risk of bleeding also have renal disease and calcified vessels and are perceived to have difficulties with BAS use. Therefore, BAS are currently used inconsistently, particularly among patients

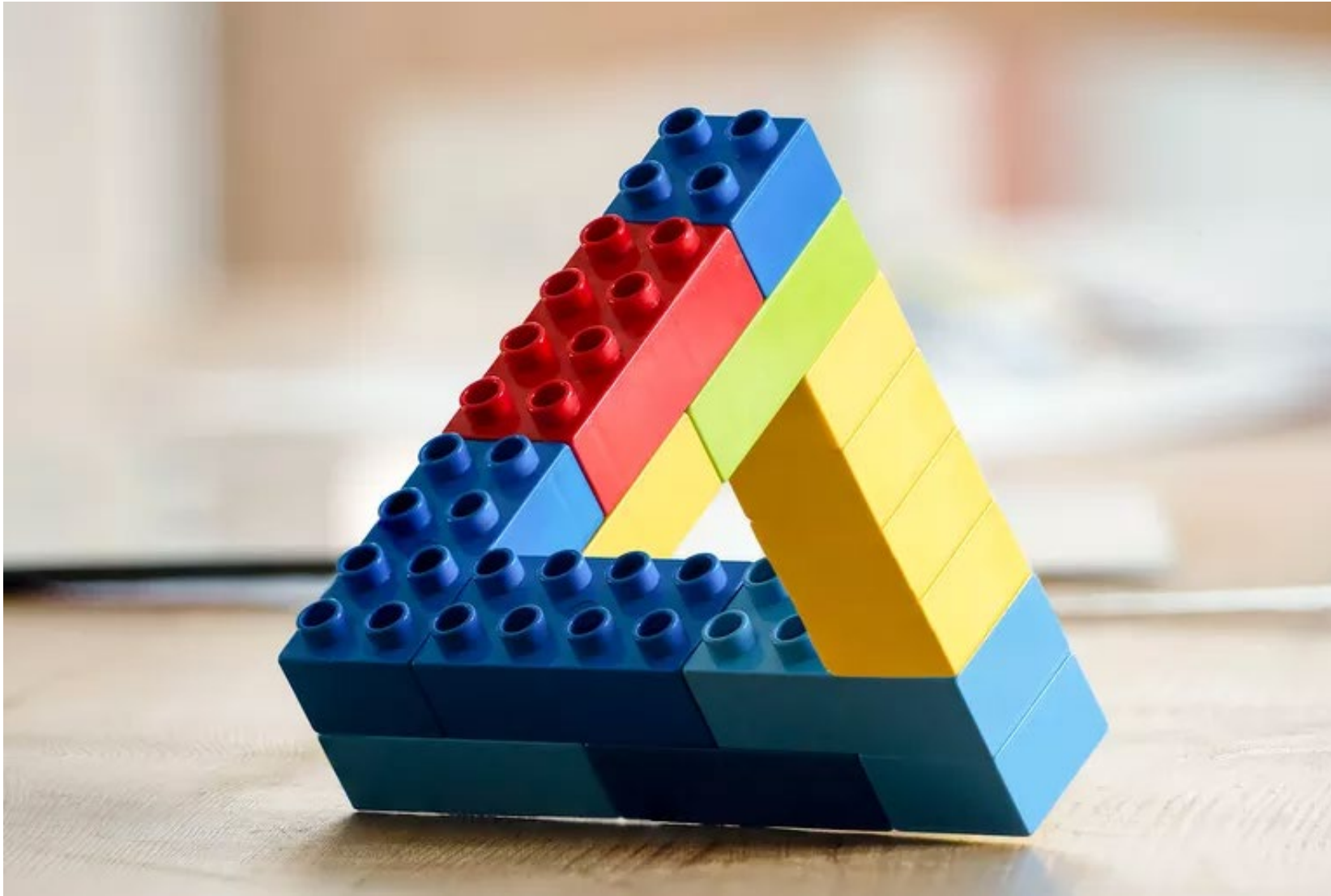
From the Cardiovascular Division (A.P.A., K.S., A.Z., R.B., H. Kurz, J.S., J.M.L.) and Center for Value and Innovation (A.P.A., S.M., B.R., M.C., P.C.-R.), Washington University School of Medicine, St. Louis, MO; Barnes-Jewish Hospital, St. Louis, MO (A.P.A., S.M., B.R., M.C., A.P., A.Z., R.B., H. Kurz, J.S., J.M.L., P.C.-R.); M&H Research, LLC, San Antonio, TX (H. Kulkarni).

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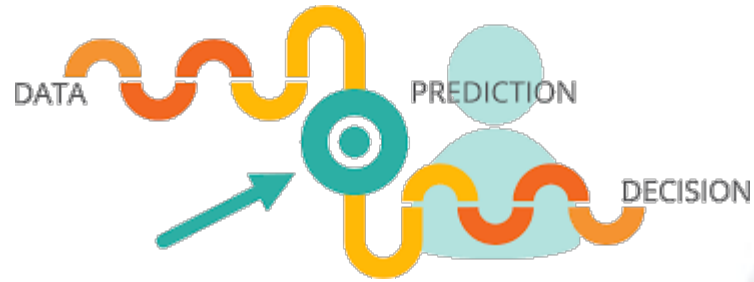
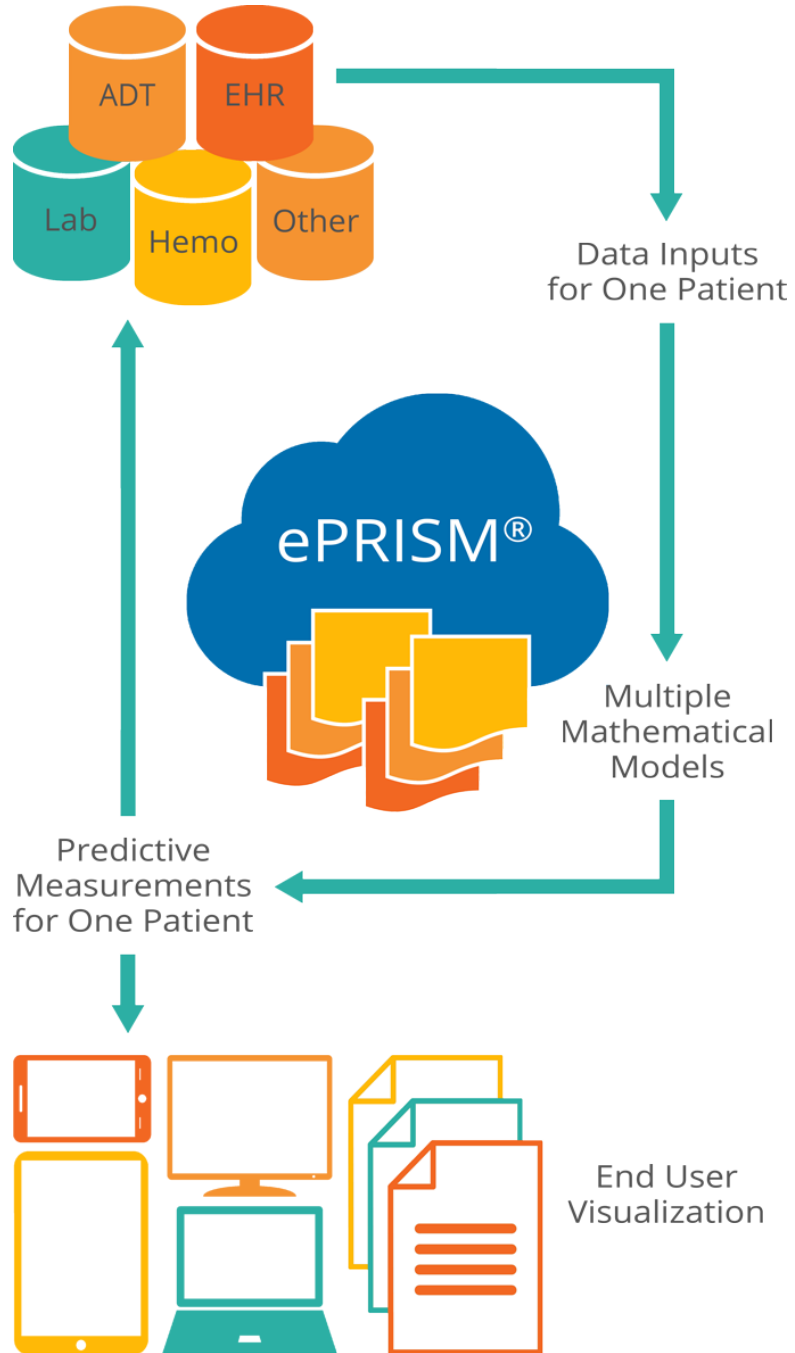
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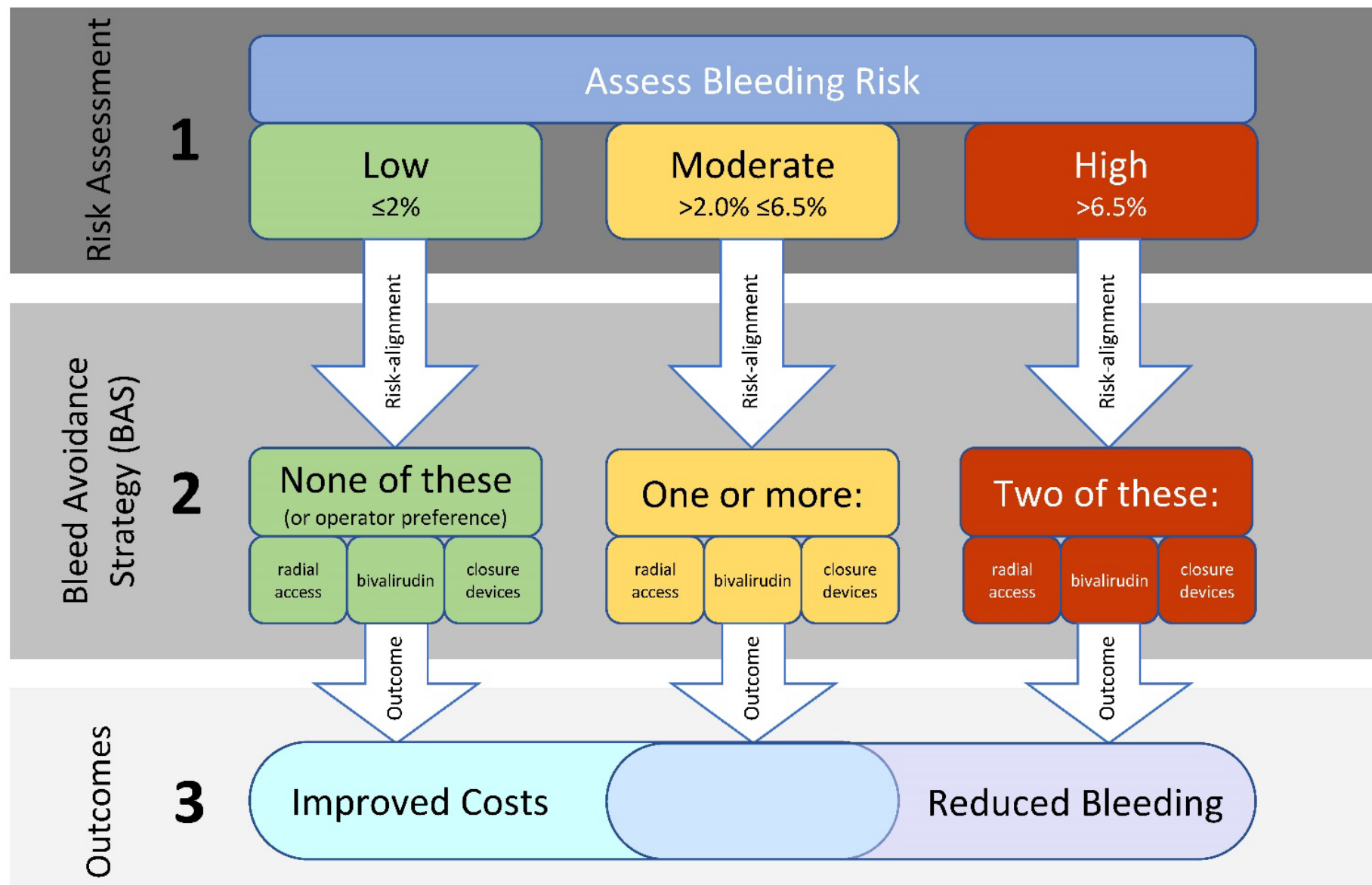
# The “Risk-Treatment Paradox”



# Risk Assessment

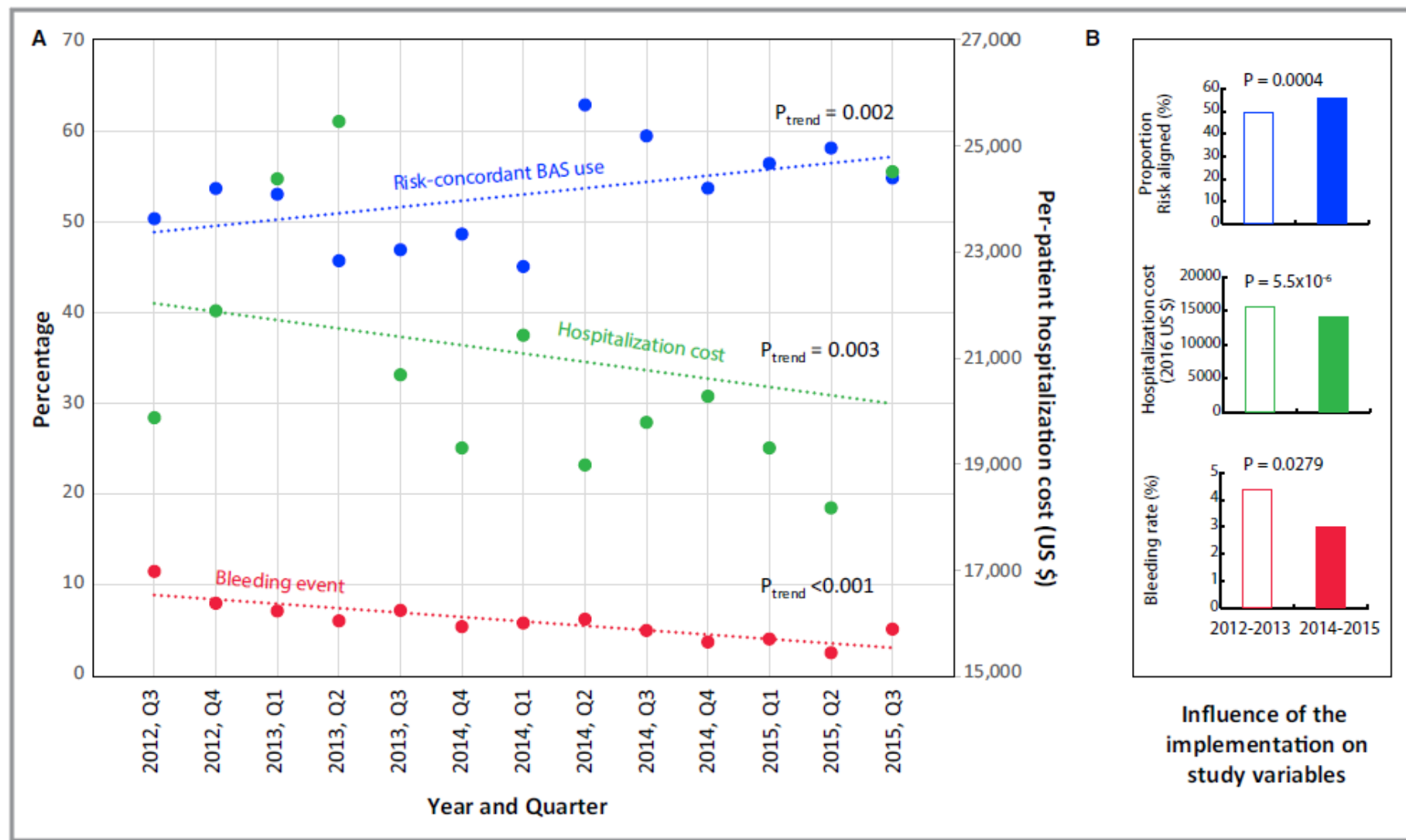


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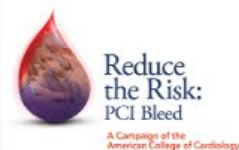


\*The efficacy of bivalirudin with radial PCI is debatable, and the efficacy of closure devices in femoral PCI is debatable, but they may be considered if bleeding risk is moderate to high.





**Figure 2.** Trends in risk-concordant use of bleeding avoidance strategies (BAS), bleeding rates, and hospitalization costs. **A**, Quarterly estimates of risk-concordant BAS use, bleeding rates, and hospitalization costs. Dashed, color-coded lines represent the least squares regression lines. **B**, Comparison of risk-concordant BAS use, bleeding rate, and hospitalization costs before (hollow bars) and after (solid bars) implementation of the patient-centered approach. *P*, significance values estimated using chi-square test for risk-concordant BAS use and bleeding rates and using Mann–Whitney *U* test for hospitalization costs. Costs are shown as inflation-adjusted 2016 US\$. The corresponding regression equations are as follows: logit (proportion risk-concordant) =  $0.0275 \times \text{quarter} - 0.0727$ ; logit (bleeding rate) =  $-0.0698 \times \text{quarter} - 2.8242$ ; hospitalization cost =  $-250.23 \times \text{quarter} + 21\,088.68$ . Q indicates quarter.



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## Reduce the Risk: PCI Bleed Toolkit

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Metric 6: Method for closure for arterial access site.

Check back for more tools coming soon!

### ▶ Preprocedural (Tools to address Metric #1 and 6)

### ▼ Intraprocedural (Tools to address Metric #1, 5, and 6)

Metric	Tools
Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients Metric 5: Access site utilization	<a href="#">Arterial Access Protocol for PCI</a>
Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients Metric 5: Access site utilization Metric 6: Method for closure for arterial access site	<a href="#">Competency Arterial and Venous Sheath Removal</a>
Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients Metric 6: Method for closure for arterial access site	<a href="#">Post PCI Sheath Removal Checklist</a>
Metric 1: in-hospital risk-standardized rate of bleeding events for all PCI patients Metric 6: Method for closure for arterial access site	<a href="#">Post PCI Sheath Removal Protocol</a>

### ▶ Postprocedural (Tools to address Metric #1, 5, and 6)

### ▶ Pharmacotherapy (Tools to address Metric # 1, 2, 3, 4, 5, 6 )



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# These are a few of my favorite things



Clinical Toolkits

## Pre PCI Procedure Orders

Preventing bleeding complications starts with having a well-established pre PCI procedure that includes an order set. The following is an order set that can be used by your institution.

Adapted with permission from the Blue Cross Blue Shield of Michigan Cardiovascular Collaborative (BMC2) Best practice protocols available at (<https://bmc2.org/system/files/private/best-practice-protocols-5-20-14.pdf>)

- ☐ Admit to: Pre-Procedure Holding Area.
  - ☐ Current vital signs include today's weight in kilograms.
  - ☐ IV access 18 g or larger.
  - ☐ Diet: NPO
  - ☐ Confirm or obtain the following lab work within 2 weeks of procedure: CBC, BMP with GFR, PT/INR. PT/INR same day if patient on Coumadin. Notify physician of all abnormal labs.
  - ☐ BHCG on female  $\leq 50$  yo.
  - ☐ EKG
  - ☐ Prep both groins. Palpate and mark pedal pulses bilaterally.
  - ☐ Pre-Op medications **to be given in Pre-procedure area.**
    - o ASA 325 mg
  - ☐ Clopidogrel 75 mg daily
    - o Clopidogrel 600 mg PO x 1
    - o Clopidogrel 150 mg PO x1
    - o Clopidogrel 300 mg PO x 1
  - ☐ DC Heparin
  - ☐ Confirm last dose of Enoxaparin was  $> 12$  hours prior to procedure.
    - o Contrast dye allergy pre-medication
    - o Prednisone – 50 mg PO, 13, 7, and 1 hour prior to the procedure.
    - o Diphenhydramine – 50 mg PO 1 hour prior to the procedure.
- Alternate IV protocol if a patient cannot take oral medications:
- o Hydrocortisone – 200 mg IV, 13, 7, and 1 hour prior to the procedure.
  - o Diphenhydramine – 50 mg IM or IV, 1 hour prior to the procedure.
- ☐ If Diabetic:
  - o Confirm  $\frac{1}{2}$  dose long acting insulin given the night before.
  - o Metformin held pre-procedure and hold for 48 hours post procedure.
  - o Current glucose level.
- ☐ Confirm on Statin, Beta blocker and ACE-I/ARB. If not currently prescribed, flag for post procedure initiation.
- ☐ Obtain consent for procedure.
- ☐ ID those at increased risk for CIN (eGFR  $< 60$ ).
- ☐ 0.9NS (for patients with normal LV function): 1cc/kg for 2 hours prior to the procedure and 3 hours after the procedure
- CAUTION: Patients who are at risk for fluid overload should be given less IV hydration and observed carefully for development of heart failure. Patients who are at risk for bleeding complications should be identified.**
- ☐ Determine contrast threshold at  $3 \times \text{Creatinine Clearance}$  according to the following formula:
  - o Creatinine clearance =  $\frac{(140 - \text{Age in yrs}) \times \text{weight (Kg)}}{(\text{creatinine} \times 72)}$  x 0.85 (if female)
  - o Creatinine clearance x 3 = Contrast Threshold
  - o Contrast Threshold \_\_\_\_\_
- ☐ Nephrology Consult (consider if eGFR  $< 30$ ).
- ☐ Additional orders



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Clinical Toolkits

## Competency: Arterial & Venous Sheath Removal

Name: \_\_\_\_\_ Date: \_\_\_\_\_

Title: \_\_\_\_\_ Employee Number: \_\_\_\_\_ Unit: \_\_\_\_\_

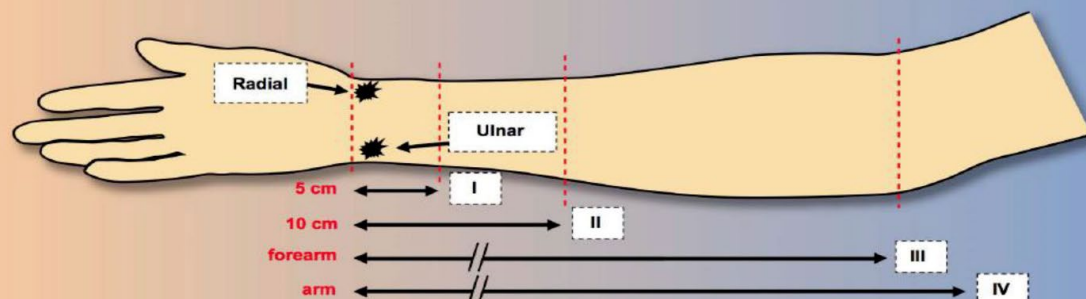
### Skill or Competency Statement:

1. Lists patient information to be collected prior to initiation of procedure.
2. Maintains patient safety
3. Explains sheath removal process to patient and/or family.

Self-Assessment:	Method:	Skill Level Demonstrated:	Reason:
<input type="checkbox"/> Experienced <input type="checkbox"/> Need practice <input type="checkbox"/> Never done <input type="checkbox"/> Not applicable (based on scope of practice)	<input type="checkbox"/> Verbal <input type="checkbox"/> Demonstration/observation <input type="checkbox"/> Practical exercise <input type="checkbox"/> Interactive class	<input type="checkbox"/> Beginner <input type="checkbox"/> Intermediate <input type="checkbox"/> Expert	<input type="checkbox"/> Orientation <input type="checkbox"/> Annual <input type="checkbox"/> New Requirement <input type="checkbox"/>

Performance Criteria:	Successful Completion	Needs Remediation
1. Validates physician order for sheath removal and target ACT/PTT is at goal for Heparin dosing only		
2. Offers explanation to patient		
3. Administers analgesia or other medication as ordered by physician prior to sheath removal.		
4. Obtains necessary equipment and trained personnel.		
5. Provides for privacy.		
6. Performs baseline assessment of circulatory status and access site.		
7. Places patient in a supine position for femoral site sheath removal.		
8. Washes hands and dons gloves.		
9. Removes dressing and sutures as indicated.		
10. Opens supplies.		
11. Dons sterile gloves.		
12. Removes arterial sheath then venous sheath according to procedure.		
13. Assesses and documents the following every 5 minutes during manual arterial compression: <ul style="list-style-type: none"><li>• BP and pulse</li><li>• Monitored rhythm</li><li>• Pulse oximetry</li></ul>		

## EASY Hematoma Classification after Transradial/Ulnar PCI



GRADE	I	II	III	IV	V
INCIDENCE	≤ 5%	< 3%	< 2%	≤ 0.1%	< 0.01%
DEFINITION	Local hematoma, superficial	Hematoma with moderate muscular infiltration	Forearm hematoma and muscular infiltration, below the elbow	Hematoma and muscular infiltration extending above the elbow	Ischemic threat (compartment syndrome)
TREATMENT	Analgesia Additional bracelet Local ice	Analgesia Additional bracelet Local ice	Analgesia Additional bracelet Local ice Inflated BP cuff	Analgesia Additional bracelet, Local ice Inflated BP cuff	Consider surgery
NOTES		Inform physician	Inform physician	Inform physician	STAT call to physician
REMARKS	<ul style="list-style-type: none"><li>- Control blood pressure (BP) (importance of pain management)</li><li>- Consider interruption of any anticoagulation and/or antiplatelet infusion</li><li>- Follow forearm and arm diameters to evaluate requirement for additional bracelet and/or BP cuff inflation</li><li>- Additional bracelet(s) can be placed alongside artery anatomy</li><li>- Ice cubes in a plastic bag or washcloth are placed on the hematoma</li><li>- Finger O<sub>2</sub> saturation can be monitored during inflated blood pressure cuff</li><li>- To inflate blood pressure cuff, select a pressure of 20 mmHg &lt; systolic pressure and deflate every 15 minutes</li><li>- After bracelet removal, use "Velpeau bandage" around forearm/arm for a few hours to maintain mild positive pressure</li></ul>				

Bertrand et al. Circulation 2006;114(24):2646-53

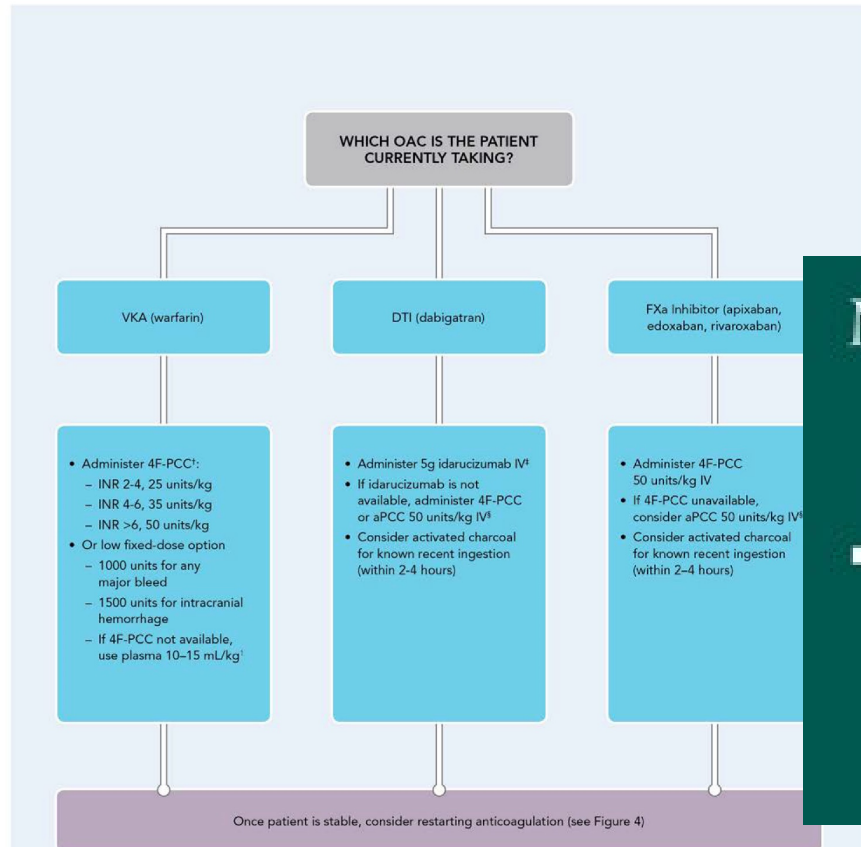
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FIGURE 3.  
Guidance for Administering Reversal Agents\*



4F-PCC = four-factor prothrombin complex concentrate; aPCC = activated prothrombin complex concentrate; DOAC = direct oral anticoagulant; DTI = direct thrombin inhibitor; FXa = Factor Xa; INR = international normalized ratio; IV = intravenous; OAC = oral anticoagulant, including DOACs and VKAs; PCC = prothrombin complex concentrates; VKa = vitamin K; VKa = Vitamin K antagonist.

## Arterial Access Protocol for PCI

PCIs are performed via three access sites - brachial, radial or femoral with the latter two being the most common routes. Vascular complications can affect the well-being of the patient and the effectiveness of the procedure itself. The risk of bleeding complications can be decreased by having a protocol in place for clinicians to follow.

Adapted with permission from the Blue Cross Blue Shield of Michigan Cardiovascular Collaborative (BMC2) Best practice protocols available at (<https://bmc2.org/system/files/private/best-practice-protocols-5-20-14.pdf>)

### Access Site

#### 1. Brachial

- Cut down
  - Performed by Attending Interventionalist or Vascular Surgeon.
- Percutaneous
  - Performed by Attending Interventionalist or Fellow.

#### 2. Radial

- Percutaneous
    - Performed by Attending Interventionalist or Fellow.
  - Set up / Access
    - Confirm no contraindications.
      - Known PAD in upper extremity used for access.
      - Raynaud's
      - Buerger's disease
      - Patient refuses
    - Patient on monitor per standard protocol.
    - Place arm on arm board with wrist gently hyper-extended.
    - Sterile prep and drape.
    - Palpate radial pulse.
    - Administer local anesthetic over radial pulse 1 cm proximal to radial styloid process.
    - Obtain access either with catheter-over-needle system (counter-puncture) or with bare needle.
    - Once sheath placed, administer vasodilators through arterial sheath (vasodilators studied include nitroglycerin 100-400mcg, verapamil 2-5mg, and nicardipine 250 mcg)
    - Administer unfractionated heparin at a dose 50-70 u/kg either intra-arterial or intravenously at some point after access and prior to angiography
- N.B.: Consider using ultrasound guided access routinely or if radial pulse is not palpable
- N.B.: Ulnar artery access may be considered if radial pulse is not palpable

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