ACO 30  Antiplatelet Therapy in Ischemic Vascular Disease

Or
How using aspirin pays in quality and shared-savings

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Accountable Care Organization 2013 Program Analysis

Quality Performance Standards
Narrative Measure Specifications

Prepared for

Quality Measurement & Health Assessment Group
Center for Clinical Standards & Quality
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

google search:
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2013 ACO Narrative Measure Specifications
At-Risk Population Domain

【ACO 30 (GPRO IVD-2) (NQF #0068):】Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic

DESCRIPTION:
Percentage of patients aged 18 years and older with Ischemic Vascular Disease (IVD) with documented use of aspirin or another antithrombotic

DENOMINATOR:
Patients aged 18 years and older with the diagnosis of ischemic vascular disease, or who were discharged alive for acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary interventions (PCI)

NUMERATOR:
Patients who are using aspirin or another antithrombotic therapy

RATIONALE:
Aspirin therapy has been shown to directly reduce 14% of the odds of cardiovascular events among men and 12% of the odds for women. (Berger, 2006) Aspirin use reduced the number of strokes by 20%, myocardial infarction (MI) by 30%, and other vascular events by 30%. (Weisman, 2002) Also, aspirin treatments have been shown to prevent 1 cardiovascular event over an average follow-up of 6.4 years. This means that on average in a 6.4 year time period the use of aspirin therapy results in a benefit of 3 cardiovascular events prevented per 1000 women and 4 events prevented per 1000 men. (Berger, 2006) Even for patients with peripheral arterial disease, aspirin has been shown to reduce coronary heart disease (CHD) in people. (Kikano, 2007)

CLINICAL RECOMMENDATION STATEMENTS:
What CMS wants: the population

Centers for Medicare & Medicaid Services

2013 ACO Narrative Measure Specifications
At-Risk Population Domain

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NUMERATOR:
Patients who are using aspirin or another antithrombotic therapy.

Number using aspirin or other in previous 12mos%

adults
diagnosed with CAD or large artery atherosclerosis
(think carotid and PAD codes also)
Antiplatelet Agents

The class of antiplatelet drugs include:

- Irreversible cyclooxygenase inhibitors
- Aspirin
- Adenosine diphosphate (ADP) receptor inhibitors
  - Clopidogrel (Plavix)
  - Prasugrel (Effient)
  - Ticagrelor (Brilinta)
  - Ticlopidine (Ticlid)
- Phosphodiesterase inhibitors
  - Cilostazol (Pletal)
- Glycoprotein IIb/IIIa inhibitors (intravenous use only)
  - Abciximab (ReoPro)
  - Eptifibatide (Integrilin)
  - Tirofiban (Aggrastat)
- Adenosine reuptake inhibitors
- Dipyridamole (Persantine)
- Thromboxane inhibitors
- Thromboxane synthase inhibitors
  - Thromboxane receptor antagonists
    - Terutroban
But how does Centers for Medicare-Medicaid Services (CMS) know if we are meeting the quality metric??
The National Quality Forum (NQF) Measure Evaluation 4.1 was discussed. The numerator statement is "high % quality + = shared savings," and the denominator statement is "numerator statement."
V58.66 Long-term (current) use of aspirin

V58.63 Long-term (current) use of antiplatelets/antithrombotics

4011F Substance Poisoning
Accident
Therapeutic Use
Suicide Attempt
Assault
Undetermined

NQF Numerator statement
Reimbursement = %

NQF Denominator statement

Table IVD-A: Codes to Identify AMI, PCI and CABG
<table>
<thead>
<tr>
<th>Description</th>
<th>CPT</th>
<th>HCPCS</th>
<th>ICD-9-CM Diagnosis</th>
<th>ICD-9-CM Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMI (inpatient only)</td>
<td>410.x1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CABG (inpatient only)</td>
<td>33510-33514, 33516-33519, 33521-33523, 33533-33536, 32205-52209</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>36.1, 36.2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PCI</td>
<td>92980, 92982, 92995</td>
<td>G0290</td>
<td>00.66, 36.06, 36.07</td>
<td></td>
</tr>
</tbody>
</table>

Table IVD-B: Codes to Identify IVD
<table>
<thead>
<tr>
<th>Description</th>
<th>ICD-9-CM Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVD</td>
<td>411, 413, 414.0, 414.2, 414.8, 414.9, 429.2, 433, 434. 440.1, 440.2, 440.4, 444, 445</td>
</tr>
</tbody>
</table>

- IVD
- Ischemic heart disease
- Angina
- Coronary atherosclerosis
- Coronary artery occlusion
- Cardiovascular disease
- Occlusion or stenosis of precerebral arteries (including basilar, carotid and vertebral arteries)
- Atherosclerosis of renal artery
- Atherosclerosis of native arteries of the extremities
- Chronic total occlusion of artery of the extremities
- Arterial embolism and thrombosis
- Atheroembolism.
Rationale:
Aspirin therapy has been shown to directly reduce 14% of the odds of cardiovascular events among men and 12% of the odds for women. (Berger, 2006) Aspirin use reduced the number of strokes by 20%, myocardial infarction (MI) by 30%, and other vascular events by 30%. (Weisman, 2002) Also, aspirin treatments have been shown to prevent 1 cardiovascular event over an average follow-up of 6.4 years. This means that on average in a 6.4 year time period the use of aspirin therapy results in a benefit of 3 cardiovascular events prevented per 1000 women and 4 events prevented per 1000 men. (Berger, 2006) Even for patients with peripheral arterial disease, aspirin has been shown to reduce coronary heart disease (CHD) in people. (Kikano, 2007)

Meta-analysis 6 trials 1966 - 2005
51,342 women 44,114 men
ACO 30 (GPRO IVD-2) (NQF #0068): Ischemic Vascular Disease (IVD):
Use of Aspirin or Another Antithrombotic

1a.3 Summary of Evidence of High Impact: Coronary Heart Disease (CHD) was an underlying or contributing cause of death for 451,300 people that accounted for 1 of every 5 deaths in the United States in 2004. AMI was as an underlying or contributing cause of death for 156,000 people (AHA, 2008). In addition, the prevalence of CHD for both sexes in 2005 is nearly 16 million people or 7.3% of the American population (AHA, 2008) The cost of cardiovascular diseases and stroke in the United States for 2008 is estimated at $448.5 billion (AHA, 2008)

Modest but real savings 3.5 lives /1000
for 16,000,000 ~56,000 events saved at a savings of several billions of dollars
R. J. HARWELL
BORN 1914
GAVE UP SMOKING 1959
GAVE UP BOOZE 1973
GAVE UP RED MEAT 1983
DIED ANYWAY 1991
Keeping Perspective: Many Risk Factor Modifications Are More Effective

**Established Risk Factors for CHD**

- Blood cholesterol
  - 10% ↓ = 20%-30% ↓ in CHD
- High blood pressure
  - 5-6 mm Hg ↓ = 42% ↓ in Stroke
  - = 16% ↓ in CHD
- Cigarette smoking
  - Cessation = 50%-70% ↓ in CHD
- Body weight
  - BMI < 25 vs BMI > 27 = 35%-55% ↓ in CHD
- Physical activity
  - 20-minute brisk walk daily = 35%-55% ↓ in CHD
"Take an aspirin every day, but before you swallow it, take it out for a five-mile walk."
Framingham Calculator

- Iphone: Safari -> http://sumsearch.org/fram
- Android (tell me)
Clinical recommendation Statements:

1. The U.S. Preventive Services Task Force (USPSTF) strongly recommends that clinicians discuss aspirin chemoprevention with adults who are at increased risk (5-year risk of greater than or equal to 3 percent) for coronary heart disease (CHD). Discussions with patients should address both the potential benefits and harms of aspirin therapy.

The USPSTF found good evidence that aspirin decreases the incidence of coronary heart disease in adults who are at increased risk for heart disease. They also found good evidence that aspirin increases the incidence of gastrointestinal bleeding and fair evidence that aspirin increases the incidence of hemorrhagic strokes. The USPSTF concluded that the balance of benefits and harms is most favorable in patients at high risk of CHD (5-year risk of greater than or equal to 3 percent) but is also influenced by patient preferences.

USPSTF encourages men age 45 to 79 years to use aspirin when the potential benefit of a reduction in myocardial infarctions outweighs the potential harm of an increase in gastrointestinal hemorrhage. They encourage women age 55 to 79 years to use aspirin when the potential benefit of a reduction in ischemic strokes outweighs the potential harm of an increase in gastrointestinal hemorrhage.
Aspirin for the Primary Prevention of Cardiovascular Events in Women and Men
A Sex-Specific Meta-analysis of Randomized Controlled Trials

Jeffrey S. Berger, MD, MS; Maria C. Roncaglioni, MD; Fausto Avanzini, MD; Ierta Pangrazzi, MD; Gianni Tognoni, MD; David L. Brown, MD

Harm of Aspirin Therapy

Aspirin treatment resulted in an approximately 70% increase in the risk of major bleeding events among women and men. Based on the absolute risk increase of 0.25% and 0.33% in women and men, respectively, the number needed to harm over 6.4 years of aspirin treatment by causing 1 major bleeding event was 400 women and 303 men. In other words, aspirin therapy for an average of 6.4 years results in an average absolute increase of approximately 2.5 major bleeding events caused per 1000 women and 3 major bleeding events caused per 1000 men.
ACO 30 (GPRO IVD-2) (NQF #0068): Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic

Clinical recommendation Statements:

2. The American Diabetes Association (ADA) recommends use aspirin therapy (75-162 mg/day) as a primary prevention strategy in those with type 1 or 2 diabetes at increased cardiovascular risk, including those who are 40 years of age or who have additional risk factors (family history of cardiovascular disease (CVD), hypertension, smoking, dyslipidemia, or albuminuria).

Framingham 5 and 10 year risk calculator

5 year risk ≥3% or
10 year risk ≥6%
3. Clinical recommendation Statements:

American Heart Association/American College of Cardiology (AHA/ACC): Start aspirin 75 to 162 mg/day and continue indefinitely in all patients with coronary and other vascular disease unless contraindicated.

- PCI V45.82 Percutaneous transluminal coronary angioplasty status
- CABG V45.81 Aorto coronary bypass status
- MI 410 Acute myocardial infarction
- Carotid PAD

- 411 Other acute and subacute forms of ischemic heart disease
- 413 Angina pectoris
- 414 Other forms of chronic ischemic heart disease
- 414.2 Chronic total occlusion of coronary artery
- 414.8 Other specified forms of chronic ischemic heart disease
  - Chronic coronary insufficiency, myocardial (chronic)
  - Any condition classifiable to 410 specified as chronic, or presenting with symptoms after 8 weeks from date of infarction
- 414.9 Chronic ischemic heart disease, unspecified
  - Ischemic heart disease NOS
- 429.2 Cardiovascular disease, unspecified
  - Arteriosclerotic cardiovascular disease [ASCVD], Cardiovascular arteriosclerosis
- 433 Occlusion and stenosis of precerebral arteries
- 434 Occlusion of cerebral arteries
- 440.1 Of renal artery
- 440.2 Of native arteries of the extremities
- 440.4 Chronic total occlusion of artery of the extremities
- 444 Arterial embolism and thrombosis
  - Includes: infarction, embolic, thrombotic, occlusion
- 445 Atheroembolism
  - Includes: Atherothrombic microembolism, Cholesterol embolism
Institute for Clinical Systems Improvement (ICSI): Aspirin should be prescribed to all patients with stable coronary disease. If a patient is aspirin intolerant, then use clopidogrel.
CURE Trial found 2.1% absolute benefit clopidogrel + ASA vs. ASA alone.

- **EXCLUDED ANY CENTER WITH AN EARLY INVASIVE STRATEGY**

- 6 / 1000 increase in bleeding requiring transfusion.

### Table 2. Incidence of the Main Study Outcomes.

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>CLOPIDOGREL GROUP (N=6259)</th>
<th>PLACEBO GROUP (N=6303)</th>
<th>RELATIVE RISK (95% CI)</th>
<th>P VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>First primary outcome: nonfatal myocardial infarction, stroke, or death from cardiovascular causes</td>
<td>582 (9.3)</td>
<td>719 (11.4)</td>
<td>0.80 (0.72-0.90)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Second primary outcome: first primary outcome or refractory ischemia</td>
<td>1035 (16.5)</td>
<td>1187 (18.8)</td>
<td>0.86 (0.79-0.94)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Death from cardiovascular causes</td>
<td>318 (5.1)</td>
<td>345 (5.5)</td>
<td>0.93 (0.79-1.08)</td>
<td></td>
</tr>
<tr>
<td>Myocardial infarction†</td>
<td>324 (5.2)</td>
<td>419 (6.7)</td>
<td>0.77 (0.67-0.89)</td>
<td></td>
</tr>
<tr>
<td>Q-wave</td>
<td>116 (1.9)</td>
<td>193 (3.1)</td>
<td>0.60 (0.48-0.76)</td>
<td></td>
</tr>
<tr>
<td>Non-Q-wave</td>
<td>216 (3.5)</td>
<td>242 (3.8)</td>
<td>0.89 (0.74-1.07)</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>75 (1.2)</td>
<td>87 (1.4)</td>
<td>0.86 (0.63-1.18)</td>
<td></td>
</tr>
<tr>
<td>Refractory ischemia‡</td>
<td>544 (8.7)</td>
<td>587 (9.3)</td>
<td>0.93 (0.82-1.04)</td>
<td></td>
</tr>
<tr>
<td>During initial hospitalization</td>
<td>85 (1.4)</td>
<td>126 (2.0)</td>
<td>0.68 (0.52-0.90)</td>
<td></td>
</tr>
<tr>
<td>After discharge</td>
<td>450 (7.6)</td>
<td>461 (7.6)</td>
<td>0.99 (0.87-1.13)</td>
<td></td>
</tr>
<tr>
<td>Death from noncardiovascular causes</td>
<td>41 (0.7)</td>
<td>45 (0.7)</td>
<td>0.91 (0.60-1.39)</td>
<td></td>
</tr>
</tbody>
</table>
Dose of Clopidogrel: CURRENT- Oasis7

- Randomized, double-blind, 2x2 factorial trial
- 25,087 ACS patients (70.8% UA/non-STEMI)
- Clopidogrel arm: double dose (600mg then 150mg daily x 7 days then 75mg daily x 22 days) vs standard dose (300mg then 75mg daily x 29 days)
- Aspirin arm: 300-325mg daily vs 75-100mg daily x 30 days.

**Clopidogrel Dose Comparison**

- Overall, for efficacy, double-dose clopidogrel (600 loading dose + 150 for 7 days then 75 mg for 22 days) versus standard dose (300 + 75 for 29 days) produced no significant reduction in the primary composite of major CV events (CV death, MI or stroke).

- The hazard ratio of 0.95 was a weighted average of 0.85 (p=0.03) among the subgroup undergoing PCI and 1.17 (p=0.14) among the subgroup not undergoing PCI.

- Overall, for safety, using the CURRENT definitions, double dose clopidogrel produced significant increases in severe and major bleeds.

*Presented at ESC Congress 2009, Barcelona Spain*
ASA Dose Comparison

ASA 300-325 mg versus ASA 75-100 mg showed no significant differences in efficacy or bleeding.

Presented at ESC Congress 2009, Barcelona Spain
Dual Antiplatelet Therapy after Coronary Stenting

- DES - Clopidogrel 75mg + ASA 81mg for 1 year
- BMS - Clopidogrel 75mg + ASA 81mg for 1 month
Veterans Affairs/Department of Defense (VA/DoD): Ensure that all patients with ischemic heart disease or angina symptoms receive antiplatelet therapy (aspirin 81-325 mg/day). For patients who require warfarin therapy, aspirin may be safely used at a dose of 80 mg/day. If use of aspirin is contraindicated, clopidogrel (75 mg/day) may be used.

caveat emptor
Using warfarin monotherapy as a reference, the hazard ratio (95% confidence interval) for the combined end point was

0.93 (0.88-0.98) for aspirin,
1.06 (0.87-1.29) for clopidogrel,
1.66 (1.34-2.04) for aspirin-clopidogrel
1.83 (1.72-1.96) for warfarin-aspirin
3.08 (2.32-3.91) for warfarin-clopidogrel
3.70 (2.89-4.76) for warfarin-aspirin-clopidogrel
ACO 30 (GPRO IVD-2) (NQF #0068): Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic

Clinical recommendation Statements:

6. American Heart Association/American Stroke Association (AHA/ASA): The use of aspirin is recommended for cardiovascular (including but not specific to stroke) prophylaxis among persons whose risk is sufficiently high for the benefits to outweigh the risks associated with treatment (a 10-year risk of cardiovascular events of 6% to 10%).

Framingham 5 and 10 year risk calculator

Probability of a coronary event is:
- 3.7% in 5 years.
- 8.7% in 10 years

Demographics:
- Age: 45
- Gender: Male ☐ Female ☐

Habits:
- Tobacco: Yes ☐ No ☐

Past medical history:
- Diabetes: Yes ☐ No ☐

Examination:
- Systolic blood pressure: 150

Labs:
- Total cholesterol: 200
- HDL: 45
- EKG LVH: Yes ☐ No ☐

Submit
American College of Chest Physicians (ACCP): For long-term treatment after percutaneous coronary intervention (PCI), the guideline developers recommend aspirin, 75 to 162 mg/day. For long-term treatment after PCI in patients who receive antithrombotic agents such as clopidogrel or warfarin, the guideline developers recommend lower-dose aspirin, 75 to 100 mg/day. For patients with ischemic stroke who are not receiving thrombolysis, the guideline developers recommend early aspirin therapy, 160 to 325 mg/day.

Clinical recommendation Statements:

7. after PCI
   dual antiplatelet therapy
   81mg ASA

after ischemic stroke
   only exception?
   2 x 81mg ASA
Dose-Dependent Side Effects of Aspirin

The 5 Year UK-TIA Trial of about 2400

<table>
<thead>
<tr>
<th>Side Effects</th>
<th>Placebo</th>
<th>300 mg</th>
<th>1200 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI Symptoms</td>
<td>25%</td>
<td>29%</td>
<td>39%</td>
</tr>
<tr>
<td>GI bleeding requiring transfusion</td>
<td>1.6%</td>
<td>2.6%</td>
<td>4.9%</td>
</tr>
</tbody>
</table>

1. For patients with stroke or TIA due to 50% to 99% stenosis of a major intracranial artery, aspirin is recommended in preference to warfarin (Class I; Level of Evidence B). Patients in the WASID trial were treated with aspirin 1300 mg/d, but the optimal dose of aspirin in this population has not been determined. On the basis of the data on general safety and efficacy, aspirin doses of 50 mg to 325 mg of aspirin daily are recommended (Class I; Level of Evidence B). (New recommendation)
Evidence supporting the efficacy of aspirin is substantially weaker than for warfarin. A pooled analysis of data from 3 trials resulted in an estimated relative risk reduction of 21% compared with placebo (95% CI, 0 to 38%). The largest aspirin effect was seen in the Stroke Prevention in Atrial Fibrillation (SPAF 1) Trial, which used aspirin 325 mg/d. However, on the basis of results of studies performed in multiple vascular indications, the best balance of the efficacy and safety of aspirin appears to be approximately 75 mg/d to 100 mg/d.
# Dose Of Aspirin: Indirect Comparisons

<table>
<thead>
<tr>
<th>Regimen</th>
<th>No Trials</th>
<th>% Reduction (SE)</th>
<th>3P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspirin Alone (mg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>500-1500</td>
<td>34</td>
<td>19 (3)</td>
<td>&lt;0.00001</td>
</tr>
<tr>
<td>160-325</td>
<td>19</td>
<td>26 (3)</td>
<td>&lt;0.00001</td>
</tr>
<tr>
<td>75-150</td>
<td>12</td>
<td>32 (6)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>&lt;75</td>
<td>3</td>
<td>13 (8)</td>
<td>NS</td>
</tr>
<tr>
<td>Total</td>
<td>68</td>
<td>23 (2)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

\[X^2_{het} = 8.2, \ P = .04.\]

*AntiThrombotic Trialists Collaboration. Lancet, 2002*
Final thoughts on Aspirin

- Efficacy vs Risk shows 81mg ASA daily can be used as optimal dose FOR ALL indicated CV conditions

- Prior CABG, PCI, MI, and CVA all benefit from lifetime aspirin therapy at time of discharge
Final thoughts on Aspirin

• In all patients without primary event or evidence of athrosclerosis: Use Framingham calculator and document CV risk.

• Discuss risks and benefits with your patient

• By Risk : Benefit analysis ASA can benefit adult patients with 5 year Risk ≥3% and 10 year Risk ≥ 6%
Making Antiplatelet Therapy Pay

• Use aspirin codes to indicate patients using antiplatelet therapy

• Document contraindication to ASA in patients with IVD who you feel risk outweighs benefit

• Increased Quality and Shared Savings = antiplatelet code / IVD 400 athrosclerosis codes
ACO 30 (GPRO IVD-2) (NQF #0068): Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic