NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) **NQF Review #:** 1519 **NQF Project:** Surgery Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Statin Therapy at Discharge after Lower Extremity Bypass (LEB)
De.2 **Brief description of measure:** Percentage of patients aged 18 years and older undergoing infrainguinal lower extremity bypass who are prescribed a statin medication at discharge. This measure is proposed for both hospitals and individual providers.
1.1-2 **Type of Measure:** Process De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** NA
De.4 **National Priority Partners Priority Area:** Population health, Safety De.5 **IOM Quality Domain**: Effectiveness, Patient-centered De.6 **Consumer Care Need:** Getting better

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission A.4 **Measure Steward Agreement attached:** Agreement With Measure Stewards_Agreement Between_National Quality Forum (12-6-2010)-634278516835518374.pdf	**A** Y☐ N☐

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Payment Program	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** Yes, fully developed and tested D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. ***Measures must be judged to be important to measure and report*** *in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**:	
1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, High resource use, Severity of illness, Patient/societal consequences of poor quality **1a.2** **1a.3 Summary of Evidence of High Impact:** Patients who present with lower extremity ischemia bear a large systemic burden of atherosclerotic disease, and therefore face not only the immediate risk of limb loss1 but also an increased risk for cardiovascular events.2-4 The benefits of statin therapy for cardiovascular risk reduction in the PAD population have been demonstrated in several studies, most notably the Heart Protection Study.5, 6 The Heart Protection Study (HPS) is the largest trial to assess the effects of statins on major morbidity and mortality. The investigators enrolled over 20,000 patients deemed to be at high risk for cardiovascular events and randomized them to receive either 40mg of simvastatin or placebo. On survival analysis, they demonstrated that treatment with a statin was significantly associated with a decrease in all-cause mortality (12.9% vs. 14.7%, p=.0003) and that this effect was primarily driven by the reduction in death from vascular causes (7.6% vs. 9.1%, p<.0001). A recently published subgroup analysis6 focusing specifically on patients with documented PAD (n=6748) did not include mortality data. However, the authors demonstrated a significant reduction in the rate of first major vascular event in the simvastatin treatment arm (relative reduction of 22%; p<.0001), when compared to placebo. The PREVENT III trial was a prospective, randomized, double-blinded, multicenter trial designed to examine the efficacy of a novel pharmacologic agent (edifoligide) in preventing autogenous vein graft failure in 1404	**1a** C☐ P☐ M☐ N☐

patients who underwent infrainguinal vein bypass at 83 hospitals exclusively for the treatment of critical limb ischemia.7 This LEB trial, with its high-risk critical limb ischemia (CLI) population, provides another relevant database for examination of the role of statins. The salient finding from this study is that the use of statin drugs was associated with a significant one-year survival benefit in patients undergoing surgical bypass for CLI.8 The Kaplan-Meier analysis also suggested that the benefit continues to increase with time, and might be even greater with longer term follow-up. In these 1404 patients, those not receiving statins experienced a 40% increase in the risk of death at one year. This effect was demonstrated both in the propensity score weighted analysis (HR 1.40, CI 1.02-1.92), and in the Cox proportional hazards model (HR 1.47, CI 1.11-1.96). These findings are consistent with prior observational studies that have examined the effects of statins, albeit, in heterogeneous PAD populations.9-11 The largest of these observational studies, conducted by Feringa and colleagues, enrolled 1374 patients with PAD and followed them for a mean duration of 6.4 years. The authors demonstrated a strong independent association between statin use and all-cause mortality (HR 1.41 for non-users, p<0.0001).9

The DECREASE study randomized 497 patients who had not previously been treated with a statin to receive either 80 mg of extended-release fluvastatin or placebo once daily before undergoing major non-cardiac vascular surgery.12 On evaluation of the primary endpoint, statin therapy conferred a 45% decreased hazard ratio (10.8% versus 19%, p=0.01) for perioperative myocardial infarction. Furthermore, death from cardiovascular causes or myocardial infarction occurred in 4.8% of patients in the fluvastatin group and 10.1% of patients in the placebo group (hazard ratio, 0.47; 95% CI, 0.24 to 0.94; p= 0.03). Fluvastatin therapy was not associated with a significant increase in the rate of adverse events. Several additional studies in patients undergoing LEB have shown similar reductions in perioperative morbidity and mortality associated with statin use.10, 13, 14

Recent studies have also demonstrated a specific benefit in graft patency after LEB in patients on statin therapy.15-17 Abbruzzese et al observed that statin use was associated with improved secondary patency (3-fold increased risk compared to non-users) among 197 patients who had undergone lower extremity bypass using saphenous vein, in a single-center retrospective analysis.16

1a.4 Citations for Evidence of High Impact:

1. Dormandy JA, Rutherford RB. Management of peripheral arterial disease (PAD). TASC Working Group. TransAtlantic Inter-Society Consensus (TASC). J Vasc Surg 2000;31:S1-S296.
2. Criqui MH, Langer RD, Fronek A, Feigelson HS, Klauber MR, McCann TJ, et al. Mortality over a period of 10 years in patients with peripheral arterial disease. N Engl J Med 1992;326:381-6.
3. McKenna M, Wolfson S, Kuller L. The ratio of ankle and arm arterial pressure as an independent predictor of mortality. Atherosclerosis 1991;87:119-28.
4. Howell MA, Colgan MP, Seeger RW, Ramsey DE, Sumner DS. Relationship of severity of lower limb peripheral vascular disease to mortality and morbidity: a six-year follow-up study. J Vasc Surg 1989;9:691-6; discussion 6-7.
5. MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. Lancet 2002;360:7-22.
6. Randomized trial of the effects of cholesterol-lowering with simvastatin on peripheral vascular and other major vascular outcomes in 20,536 people with peripheral arterial disease and other high-risk conditions. J Vasc Surg 2007;45:645-54; discussion 53-4.
7. Conte MS, Bandyk DF, Clowes AW, Moneta GL, Seely L, Lorenz TJ, et al. Results of PREVENT III: a multicenter, randomized trial of edifoligide for the prevention of vein graft failure in lower extremity bypass surgery. J Vasc Surg 2006;43:742-51; discussion 51.
8. Schanzer A, Hevelone N, Owens CD, Beckman JA, Belkin M, Conte MS. Statins are independently associated with reduced mortality in patients undergoing infrainguinal bypass graft surgery for critical limb ischemia. J Vasc Surg 2008;47:774-81.
9. Feringa HH, Karagiannis SE, van Waning VH, Boersma E, Schouten O, Bax JJ, et al. The effect of intensified lipid-lowering therapy on long-term prognosis in patients with peripheral arterial disease. J Vasc Surg 2007;45:936-43.
10. Ward RP, Leeper NJ, Kirkpatrick JN, Lang RM, Sorrentino MJ, Williams KA. The effect of preoperative statin therapy on cardiovascular outcomes in patients undergoing infrainguinal vascular surgery. Int J Cardiol 2005;104:264-8.
11. Kertai MD, Boersma E, Westerhout CM, van Domburg R, Klein J, Bax JJ, et al. Association between long-term statin use and mortality after successful abdominal aortic aneurysm surgery. Am J Med

2004;116:96-103.
12. Schouten O, Boersma E, Hoeks SE, Benner R, van Urk H, van Sambeek MR, et al. Fluvastatin and perioperative events in patients undergoing vascular surgery. N Engl J Med 2009;361:980-9.
13. Poldermans D, Bax JJ, Kertai MD, Krenning B, Westerhout CM, Schinkel AF, et al. Statins are associated with a reduced incidence of perioperative mortality in patients undergoing major noncardiac vascular surgery. Circulation 2003;107:1848-51.
14. O´Neil-Callahan K, Katsimaglis G, Tepper MR, Ryan J, Mosby C, Ioannidis JP, et al. Statins decrease perioperative cardiac complications in patients undergoing noncardiac vascular surgery: the Statins for Risk Reduction in Surgery (StaRRS) study. J Am Coll Cardiol 2005;45:336-42.
15. Christenson J. Preoperative lipid control with simvastatin reduces the risk for graft failure already 1 year after myocardial revascularization. Cardiovasc Surg 2001;9:33-43.
16. Abbruzzese TA, Havens J, Belkin M, Donaldson MC, Whittemore AD, Liao JK, et al. Statin therapy is associated with improved patency of autogenous infrainguinal bypass grafts. J Vasc Surg 2004;39:1178-85.
17. Henke PK, Blackburn S, Proctor MC, Stevens J, Mukherjee D, Rajagopalin S, et al. Patients undergoing infrainguinal bypass to treat atherosclerotic vascular disease are underprescribed cardioprotective medications: effect on graft patency, limb salvage, and mortality. Journal of Vascular Surgery 2004;39:357-65.
18. Hirsch AT, Haskal ZJ, Hertzer NR, Bakal CW, Creager MA, Halperin JL, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. Circulation 2006;113:e463-654.
19. Hirsch AT, Criqui MH, Treat-Jacobson D, Regensteiner JG, Creager MA, Olin JW, et al. Peripheral arterial disease detection, awareness, and treatment in primary care. Jama 2001;286:1317-24.
20. McDermott MM, Mehta S, Ahn H, Greenland P. Atherosclerotic Risk Factors Are Less Intensively Treated in Patients with Peripheral Arterial Disease Than in Patients with Coronary Artery Disease. J Gen Intern Med 1997;12:209-15.
21. Mukherjee D, Lingam P, Chetcuti S, Grossman PM, Moscucci M, Luciano AE, et al. Missed opportunities to treat atherosclerosis in patients undergoing peripheral vascular interventions: insights from the University of Michigan Peripheral Vascular Disease Quality Improvement Initiative (PVD-QI2). Circulation 2002;106:1909-12.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Based on the data summarized in this application, this quality measure will be associated with decreased perioperative morbidity and mortality from major adverse cardiac events including stroke, myocardial infarction, and death. The data also suggest a potential association between perioperative statin use and improved bypass graft patency.

Patients who require LEB have advanced peripheral arterial disease and meet guidelines for secondary prevention with statins. Many of these patients have not received adequate managment of PAD risk factors. The episode of care assoicated with LEB provides an opportunity to initiate statin therapy in these patients in order to improve survival and reduce cardiovascular complications following the procedure.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Current guidelines support the use of statin therapy in all PAD patients with a target LDL level of less than 100 mg/dL (<70 mg/dL for patients deemed at very high risk).18 Because of the pleiotrophic effects of statins, PAD guidelines recommend that all PAD patients be treated, independent of LDL level. However, a significant percentage of patients undergoing lower extremity bypass are not on statin therapy before or after surgery. In the PREVENT III trial referenced above, only 46% of patients were on statin therapy prior to surgery and only 45% of patients were prescribed statin therapy on hospital discharge.8 In the Vascular Study Group of New England (VSGNE), a multicenter quality improvement consortium, data has been collected on 3,693 patients who have undergone LEB. Unpublished analyses of these data demonstrate

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that only 41% of patients were taking statins preoperatively before LEB in 2004. Through quality improvement efforts, this percentage of patients dischared on statins has increased to 79% during the first 6 months of 2010. However, this rate of statin use falls significantly short of the 90% goal set forth by this quality improvement group in 2008. This under-treatment of patients with PAD has been echoed by several other reports in the literature and provides substantial opportunity for improvement.19-21

Patients undergoing infrainguinal LEB in VSGNE were analyzed for this measure submission. There are 2496 patients in the registry who underwent infrainguinal LEB between 2003-2010. Of these, 2% died in hospital. Of those discharged alive, only 2% were intolerant to statins. Across 13 hospitals, the median statin prescribed at discharge rate was 73%, with an interquartile range of 69% to 80%. Across 63 individual providers, the median statin prescribed at discharge rate was 75%, with an interquartile range of 66% to 84%. SVS and VSGNE have set quality targets at 90%. These data demonstrate both significant variation and a significant performance gap.

1b.3 Citations for data on performance gap:

1. Dormandy JA, Rutherford RB. Management of peripheral arterial disease (PAD). TASC Working Group. TransAtlantic Inter-Society Consensus (TASC). J Vasc Surg 2000;31:S1-S296.
2. Criqui MH, Langer RD, Fronek A, Feigelson HS, Klauber MR, McCann TJ, et al. Mortality over a period of 10 years in patients with peripheral arterial disease. N Engl J Med 1992;326:381-6.
3. McKenna M, Wolfson S, Kuller L. The ratio of ankle and arm arterial pressure as an independent predictor of mortality. Atherosclerosis 1991;87:119-28.
4. Howell MA, Colgan MP, Seeger RW, Ramsey DE, Sumner DS. Relationship of severity of lower limb peripheral vascular disease to mortality and morbidity: a six-year follow-up study. J Vasc Surg 1989;9:691-6; discussion 6-7.
5. MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. Lancet 2002;360:7-22.
6. Randomized trial of the effects of cholesterol-lowering with simvastatin on peripheral vascular and other major vascular outcomes in 20,536 people with peripheral arterial disease and other high-risk conditions. J Vasc Surg 2007;45:645-54; discussion 53-4.
7. Conte MS, Bandyk DF, Clowes AW, Moneta GL, Seely L, Lorenz TJ, et al. Results of PREVENT III: a multicenter, randomized trial of edifoligide for the prevention of vein graft failure in lower extremity bypass surgery. J Vasc Surg 2006;43:742-51; discussion 51.
8. Schanzer A, Hevelone N, Owens CD, Beckman JA, Belkin M, Conte MS. Statins are independently associated with reduced mortality in patients undergoing infrainguinal bypass graft surgery for critical limb ischemia. J Vasc Surg 2008;47:774-81.
9. Feringa HH, Karagiannis SE, van Waning VH, Boersma E, Schouten O, Bax JJ, et al. The effect of intensified lipid-lowering therapy on long-term prognosis in patients with peripheral arterial disease. J Vasc Surg 2007;45:936-43.
10. Ward RP, Leeper NJ, Kirkpatrick JN, Lang RM, Sorrentino MJ, Williams KA. The effect of preoperative statin therapy on cardiovascular outcomes in patients undergoing infrainguinal vascular surgery. Int J Cardiol 2005;104:264-8.
11. Kertai MD, Boersma E, Westerhout CM, van Domburg R, Klein J, Bax JJ, et al. Association between long-term statin use and mortality after successful abdominal aortic aneurysm surgery. Am J Med 2004;116:96-103.
12. Schouten O, Boersma E, Hoeks SE, Benner R, van Urk H, van Sambeek MR, et al. Fluvastatin and perioperative events in patients undergoing vascular surgery. N Engl J Med 2009;361:980-9.
13. Poldermans D, Bax JJ, Kertai MD, Krenning B, Westerhout CM, Schinkel AF, et al. Statins are associated with a reduced incidence of perioperative mortality in patients undergoing major noncardiac vascular surgery. Circulation 2003;107:1848-51.
14. O´Neil-Callahan K, Katsimaglis G, Tepper MR, Ryan J, Mosby C, Ioannidis JP, et al. Statins decrease perioperative cardiac complications in patients undergoing noncardiac vascular surgery: the Statins for Risk Reduction in Surgery (StaRRS) study. J Am Coll Cardiol 2005;45:336-42.
15. Christenson J. Preoperative lipid control with simvastatin reduces the risk for graft failure already 1 year after myocardial revascularization. Cardiovasc Surg 2001;9:33-43.
16. Abbruzzese TA, Havens J, Belkin M, Donaldson MC, Whittemore AD, Liao JK, et al. Statin therapy is associated with improved patency of autogenous infrainguinal bypass grafts. J Vasc Surg 2004;39:1178-85.
17. Henke PK, Blackburn S, Proctor MC, Stevens J, Mukherjee D, Rajagopalin S, et al. Patients undergoing infrainguinal bypass to treat atherosclerotic vascular disease are underprescribed

cardioprotective medications: effect on graft patency, limb salvage, and mortality. Journal of Vascular Surgery 2004;39:357-65.
18. Hirsch AT, Haskal ZJ, Hertzer NR, Bakal CW, Creager MA, Halperin JL, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. Circulation 2006;113:e463-654.
19. Hirsch AT, Criqui MH, Treat-Jacobson D, Regensteiner JG, Creager MA, Olin JW, et al. Peripheral arterial disease detection, awareness, and treatment in primary care. Jama 2001;286:1317-24.
20. McDermott MM, Mehta S, Ahn H, Greenland P. Atherosclerotic Risk Factors Are Less Intensively Treated in Patients with Peripheral Arterial Disease Than in Patients with Coronary Artery Disease. J Gen Intern Med 1997;12:209-15.
21. Mukherjee D, Lingam P, Chetcuti S, Grossman PM, Moscucci M, Luciano AE, et al. Missed opportunities to treat atherosclerosis in patients undergoing peripheral vascular interventions: insights from the University of Michigan Peripheral Vascular Disease Quality Improvement Initiative (PVD-QI2). Circulation 2002;106:1909-12.

1b.4 Summary of Data on disparities by population group:
There are not published data regarding disparities in statin usage after infrainguinal bypass in different population groups. Such data will become available if this measure is adopted for reporting and used by more centers with more varied population demographics than found in the New England region.

1b.5 Citations for data on Disparities:
None found

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** As summarized above, this quality measure will be associated with decreased perioperative morbidity and mortality from major adverse cardiac events including stroke, myocardial infarction, and death in patients undergoing lower extremity bypass. The data also suggest a potential association between perioperative statin use and improved bypass graft patency.

1c.2-3. Type of Evidence: Cohort study, Observational study, Evidence-based guideline, Randomized controlled trial, Expert opinion, Meta-analysis

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
Please see the summary of the data presented in 1.a.3.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):**
Level 1.

1c.6 Method for rating evidence: Data obtained from randomized prospective controlled trials.
1. MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. Lancet 2002;360:7-22.
2. Randomized trial of the effects of cholesterol-lowering with simvastatin on peripheral vascular and other major vascular outcomes in 20,536 people with peripheral arterial disease and other high-risk conditions. J Vasc Surg 2007;45:645-54
3. Schouten O, Boersma E, Hoeks SE, Benner R, van Urk H, van Sambeek MR, et al. Fluvastatin and perioperative events in patients undergoing vascular surgery. N Engl J Med 2009;361:980-9.

1c.7 Summary of Controversy/Contradictory Evidence: None

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N☐

1c.8 Citations for Evidence (*other than guidelines*): 1.MRC/BHF Heart Protection Study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: a randomised placebo-controlled trial. Lancet 2002;360:7-22.
2. Randomized trial of the effects of cholesterol-lowering with simvastatin on peripheral vascular and other major vascular outcomes in 20,536 people with peripheral arterial disease and other high-risk conditions. J Vasc Surg 2007;45:645-54; discussion 53-4.
3. Schanzer A, Hevelone N, Owens CD, Beckman JA, Belkin M, Conte MS. Statins are independently associated with reduced mortality in patients undergoing infrainguinal bypass graft surgery for critical limb ischemia. J Vasc Surg 2008;47:774-81.
4. Feringa HH, Karagiannis SE, van Waning VH, Boersma E, Schouten O, Bax JJ, et al. The effect of intensified lipid-lowering therapy on long-term prognosis in patients with peripheral arterial disease. J Vasc Surg 2007;45:936-43.
5. Ward RP, Leeper NJ, Kirkpatrick JN, Lang RM, Sorrentino MJ, Williams KA. The effect of preoperative statin therapy on cardiovascular outcomes in patients undergoing infrainguinal vascular surgery. Int J Cardiol 2005;104:264-8.
6. Kertai MD, Boersma E, Westerhout CM, van Domburg R, Klein J, Bax JJ, et al. Association between long-term statin use and mortality after successful abdominal aortic aneurysm surgery. Am J Med 2004;116:96-103.
7. Schouten O, Boersma E, Hoeks SE, Benner R, van Urk H, van Sambeek MR, et al. Fluvastatin and perioperative events in patients undergoing vascular surgery. N Engl J Med 2009;361:980-9.
8. Poldermans D, Bax JJ, Kertai MD, Krenning B, Westerhout CM, Schinkel AF, et al. Statins are associated with a reduced incidence of perioperative mortality in patients undergoing major noncardiac vascular surgery. Circulation 2003;107:1848-51.
9. O´Neil-Callahan K, Katsimaglis G, Tepper MR, Ryan J, Mosby C, Ioannidis JP, et al. Statins decrease perioperative cardiac complications in patients undergoing noncardiac vascular surgery: the Statins for Risk Reduction in Surgery (StaRRS) study. J Am Coll Cardiol 2005;45:336-42.
10. Christenson J. Preoperative lipid control with simvastatin reduces the risk for graft failure already 1 year after myocardial revascularization. Cardiovasc Surg 2001;9:33-43.
11. Abbruzzese TA, Havens J, Belkin M, Donaldson MC, Whittemore AD, Liao JK, et al. Statin therapy is associated with improved patency of autogenous infrainguinal bypass grafts. J Vasc Surg 2004;39:1178-85.
12. Henke PK, Blackburn S, Proctor MC, Stevens J, Mukherjee D, Rajagopalin S, et al. Patients undergoing infrainguinal bypass to treat atherosclerotic vascular disease are underprescribed cardioprotective medications: effect on graft patency, limb salvage, and mortality. Journal of Vascular Surgery 2004;39:357-65.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number*):
Recommendation #2, Section B1.2.3 (Dormandy et al.)
"In symptomatic PAD patients, statins should be the primary agents to lower LDL cholesterol levels to reduce the risk of cardiovascular events (1)."

Section 2.6.1.1. (Hirsch et al)
"Treatment with a hydroxymethyl glutaryl (HMG)coenzyme-A reductase inhibitor (statin) medication is indicated for all patients with PAD to achieve a target
LDL cholesterol level of less than 100 mg per dL.(Level of Evidence: B)
1. Treatment with an HMG coenzyme-A reductase inhibitor (statin) medication to achieve a target LDL cholesterol level of less than 70 mg per dL is reasonable
for patients with lower extremity PAD at very high risk of ischemic events. (Level of Evidence: B"

1c.10 Clinical Practice Guideline Citation: 1. Dormandy JA, Rutherford RB. Management of peripheral arterial disease (PAD). TASC Working Group. TransAtlantic Inter-Society Consensus (TASC). J Vasc Surg 2000;31:S1-S296.
2. Hirsch AT, Haskal ZJ, Hertzer NR, Bakal CW, Creager MA, Halperin JL, et al. ACC/AHA 2005 Practice Guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral

Arterial Disease): endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation; National Heart, Lung, and Blood Institute; Society for Vascular Nursing; TransAtlantic Inter-Society Consensus; and Vascular Disease Foundation. Circulation 2006;113:e463-654. 1c.11 **National Guideline Clearinghouse or other URL:** NA 1c.12 **Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):** NA 1c.13 **Method for rating strength of recommendation** (*If different from USPSTF system, also describe rating and how it relates to USPSTF)*: NA 1c.14 **Rationale for using this guideline over others:** This quality measure will be associated with decreased perioperative morbidity and mortality from major adverse cardiac events including stroke, myocardial infarction, and death, in patients undergoing lower extremity bypass.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, met? **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
S.1 **Do you have a web page where current detailed measure specifications can be obtained?** S.2 **If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 **Numerator Statement (***Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Patients undergoing infrainguinal lower extremity bypass who are prescribed a statin medication at discharge. 2a.2 **Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** Since hospitals have sufficient annual volume to generate accurate reporting levels, these are proposed for reporting every 12 months for hospital. Since surgeons have lower individual volume, we recommend annual reporting of the last 50 consecutive procedures, which may span more than one year, with suppression if < 10 procedures (ie, reported as too low volume to report). 2a.3 **Numerator Details (***All information required to collect/calculate the numerator, including all codes, logic, and definitions***):** ANY registry that includes anatomic details or CPT procedure codes is required to identify patients for numerator inclusion. The Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) and the Vascular Study Group of New England (VSGNE)are examples of registries capture detailed anatomic information, but the measure is not limited to these registries. Infrainguinal lower extremity bypass is defined as a bypass beginning at or below the external iliac artery and extending into the ipsilateral leg. It includes procedures with CPT codes 35656, 35556, 35583, 35666, 35566, 35585, 35671, 35571, 35587. The numerator is calculated as the number of patients age 18 and over undergoing such a procedure who are prescribed a statin medication at the time of discharge, which is also captured in the above registries.	**2a-specs** **C☐** **P☐** **M☐** **N☐**
2a.4 **Denominator Statement (***Brief, text description of the denominator - target population being*	

measured):
All patients aged 18 years and older undergoing lower extremity bypass as defined above who are discharged alive, excluding those patients who are intolerant to statins.

2a.5 **Target population gender:** Female, Male
2a.6 **Target population age range:** 18 years or older

2a.7 **Denominator Time Window** (*The time period in which cases are eligible for inclusion in the denominator*):
Since hospitals have sufficient annual volume to generate accurate reporting levels, these are proposed for reporting every 12 months for hospital. Since surgeons have lower individual volume, we recommend annual reporting of the last 50 consecutive procedures, which may span more than one year, with suppression if < 10 procedures (ie, reported as too low volume to report).

2a.8 **Denominator Details** (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions*):
ANY registry that includes anatomic details or CPT procedure codes is required to identify patients for denominator inclusion. The Society for Vascular Surgery Vascular Quality Initiative and the Vascular Study Group of New England are examples of registries that capture detailed anatomic information, but the measure is not limited to these registries. Infrainguinal lower extremity bypass is defined as a bypass beginning at or below the external iliac artery and extending into the ipsilateral leg. It includes procedures with CPT codes 35656, 35556, 35583, 35666, 35566, 35585, 35671, 35571, 35587. Only patients who are discharged alive are included in the denominator, and patients who are intolerant to statins are excluded, as described below.

2a.9 **Denominator Exclusions** (*Brief text description of exclusions from the target population*): Chart documentation that patient was not an eligible candidate for statin therapy due to known drug intolerance, or patient died before discharge.

2a.10 **Denominator Exclusion Details** (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions*):
Chart documentation that patient was not an eligible candidate for statin therapy due to known drug intolerance, or patient died before discharge. These data are captured in the SVS VQI and VSGNE registries.

2a.11 **Stratification Details/Variables** (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions*):
Not required

2a.12-13 **Risk Adjustment Type:** No risk adjustment necessary

2a.14 **Risk Adjustment Methodology/Variables** (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method*):
NA

2a.15-17 **Detailed risk model available Web page URL or attachment:**

2a.18-19 **Type of Score:** Rate/proportion
2a.20 **Interpretation of Score:** Better quality = Higher score
2a.21 **Calculation Algorithm** (*Describe the calculation of the measure as a flowchart or series of steps*):
All patients age 18 and older undergoing infrainguinal LEB who were prescribed statin at discharge divided by (all patients over 18 undergoing infrainguinal LEB minus those intolerant to statins minus those who died before discharge).

2a.22 **Describe the method for discriminating performance** *(e.g., significance testing)*:
Standard statistical comparison of rates to provide confidence levels to discriminate meaningful differences from the mean.

2a.23 **Sampling (Survey) Methodology** *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
NA

2a.24 **Data Source** (*Check the source(s) for which the measure is specified and tested)*

Electronic Clinical Data : Registry

2a.25 **Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
The Society for Vascular Surgery Vascular Quality Initiative Registry
The Vascular Study Group of New England Registry

2a.26-28 **Data source/data collection instrument reference web page URL or attachment:** Attachment Infra-Inguinal_Bypass_v1.9.xls

2a.29-31 **Data dictionary/code table web page URL or attachment:** Attachment LEB defs v.01.09.doc

2a.32-35 **Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)*
Clinician : Group/Practice, Clinician : Individual, Facility

2a.36-37 **Care Settings (***Check the setting(s) for which the measure is specified and tested)*
Hospital/Acute Care Facility

2a.38-41 **Clinical Services** (*Healthcare services being measured, check all that apply*)
Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 **Data/sample** *(description of data/sample and size)*: A random sample of 100 patient records representing 5 procedures relevant to the measure from 5 different hospitals based on data collected during the past 2 years. In addition, in-hospital mortality was examined by claims based analysis of 7,205 patients discharged and recorded in the VSGNE registry between 2003 to 2007.

2b.2 **Analytic Method** *(type of reliability & rationale, method for testing)*:
A nurse abstractor completed a form based on medical record review for the variables relevant to this measure. The results of this chart review were then compared with the original registry data. The Kappa statistic was used to judge reliability of the data. For mortality validation, claims data from each of 12 hospitals were matched to patient identified data within the VSGNE registry to compare discharge status (alive vs. dead). Any discrepencies were then further evaluated based on a medical record audit.

2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
The key variables for this measure and testing results were:

1. Correct procedure (infrainguinal lower extremity bypass) performed. Kappa =1.0
2. Statin prescribed at discharge: Kappa=.80 (.11 SE)
3. Hospital mortality: Kappa = .91 (SE .01)

4. Age: 100% agreement, Kappa = 1.0 for age 18 or older categories.
5. Intolerant to statins: Kappa = 1.0

2b
C☐ P☐ M☐ N☐

2c. Validity testing

2c.1 **Data/sample** *(description of data/sample and size)*: See reliability testing

2c.2 **Analytic Method** *(type of validity & rationale, method for testing)*:
The valididty testing of statin prescribed at discharge used the medical record as the gold standard. Discharge medications are routinely and carefully documented in both the discharge summary and discharge orders. The medication list on both the discharge summary and discharge orders were compared to confirm validity.

2c
C☐ P☐ M☐ N☐

Patient age and hospital mortality have face validity. Correctness of operation type compared the operative report as the gold standard with the progress note in the medical record.

Data collected over time in VSGNE have been compared to published literature.

2c.3 Testing Results *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
100% agreement was found between statin prescribed at discharge on the discharge summary and discharge orders. 100% agreement was also found between the procedure type reported in the operative note and that recorded in the daily progress notes.

Discharge statin use has been tracked in VSGNE for these procedures since 2003. Under a quality program, the proportion of patients discharged on statins has gradually improved, providing validity for this measurement.

2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):
The only exclusions are patients who died before discharge, and patients intolerant to statins, as documented in the medical record. Such patients cannot receive statins.

2d.2 Citations for Evidence:
face validity

2d.3 Data/sample *(description of data/sample and size)*: 2496 patients in the registry who underwent infrainguinal LEB between 2003-2010 in VSGNE, all patients in registry for this procedure

2d.4 Analytic Method *(type analysis & rationale)*:
Rate determination

2d.5 Testing Results *(e.g., frequency, variability, sensitivity analyses)*:
2% patients died in hospital
2% were alive but intolerant to statins
Of the remaining, 73% were discharged on statins.
Across 13 hospitals, the median statin prescribed at discharge rate was 73%, with an interquartile range of 69% to 80%. Across 63 individual providers, the median statin prescribed at discharge rate was 75%, with an interquartile range of 66% to 84%.

2d
C☐ P☐ M☐ N☐ NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 Data/sample *(description of data/sample and size)*: Not required for this process measure.

2e.2 Analytic Method *(type of risk adjustment, analysis, & rationale)*:
NA

2e.3 Testing Results *(risk model performance metrics)*:
NA

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: NA

2e
C☐ P☐ M☐ N☐ NA☐

2f. Identification of Meaningful Differences in Performance

2f.1 Data/sample from Testing or Current Use *(description of data/sample and size)*: see section 1.b.3 and above 2,d,5

2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance *(type of analysis & rationale)*:
Standard statistial analysis to determine 95% confidence interval for hospitals and providers to determine practical difference from mean

2f
C☐ P☐ M☐ N☐

2f.3 Provide Measure Scores from Testing or Current Use *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*: see above	
2g. Comparability of Multiple Data Sources/Methods **2g.1 Data/sample** *(description of data/sample and size)*: Other sources not available for testing. **2g.2 Analytic Method** *(type of analysis & rationale)*: NA **2g.3 Testing Results** *(e.g., correlation statistics, comparison of rankings)*: NA	**2g** C☐ P☐ M☐ N☐ NA☐
2h. Disparities in Care **2h.1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: NA **2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:** NA	**2h** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, met? **Rationale:**	***2*** C☐ P☐ M☐ N☐
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Rating
3a. Meaningful, Understandable, and Useful Information **3a.1 Current Use:** In use **3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*): Data from SVS VQI and VSGNE are reported to each hospital and provider in a format that can be transmitted to an appropriate public reporting mechanism. **3a.3 If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** The Vascular Surgery Group of New England (VSGNE) has been tracking periperative statin use in patients undergoing lower extremity bypass. In the VSGNE, a multicenter quality improvement consortium, data has been collected on 3,693 patients who have undergone LEB. Unpublished analyses of these data demonstrate that only 41% of patients were taking statins preoperatively before LEB in 2004. Through quality improvement efforts, percentage of statins prescribed at disccharge has increased to 79% during the first 6 months of 2010. However, this rate of statin use falls significantly short of the 90% goal set forth by this quality improvement group in 2008. www.vsgne.org **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) **3a.4 Data/sample** *(description of data/sample and size)*: VSGNE samples previously described	**3a** C☐ P☐ M☐ N☐

3a.5 Methods *(e.g., focus group, survey, QI project)*: Semi-annual meetings of providers in VSGNE **3a.6 Results** *(qualitative and/or quantitative results and conclusions)*: Benchamrk reports of this process measure have been provided to VSGNE member physician and hospitals since 2003, and discussed at semi-annual meetings. There have been no questions about interpretability.	
3b/3c. Relation to other NQF-endorsed measures **3b.1 NQF # and Title of similar or related measures:** 0118 Antilipid therapy at discharge 0439 Discharged on statin medication	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): **3b.2 Are the measure specifications harmonized? If not, why?** Yes	**3b** C☐ P☐ M☐ N☐ NA☐
3c. Distinctive or Additive Value **3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:** Different patient population **5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:**	**3c** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability?*	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability*, met? **Rationale:**	**3** C☐ P☐ M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	**Eval Rating**
4a. Data Generated as a Byproduct of Care Processes **4a.1-2 How are the data elements that are needed to compute measure scores generated?** Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources **4b.1 Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes **4b.2 If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** C☐ P☐ M☐ N☐
4c. Exclusions	**4c** C☐

4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No **4c.2 If yes, provide justification.**	P☐ M☐ N☐ NA☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences **4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** It is possible to miss or inacurately code statin status. We have overcome this by providing each site with a list of generic and trade names for known statin medications.	4d C☐ P☐ M☐ N☐
4e. Data Collection Strategy/Implementation **4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:** In the VSGNE experience which has been tracking statin usage since 2003, we have not experienced any difficulty with obtaining data related to statin usage. Our percent missing for perioperative statin use has been less than 2%. **4e.2 Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** In the context of the VSGNE and SVS VQI registries, there is no additional cost as all of these data are already collected. **4e.3 Evidence for costs:** NA **4e.4 Business case documentation:**	4e C☐ P☐ M☐ N☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility?*	4
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, met? **Rationale:**	4 C☐ P☐ M☐ N☐
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	Time-limited ☐
Steering Committee: Do you recommend for endorsement? **Comments:**	Y☐ N☐ A☐
CONTACT INFORMATION	
Co.1 Measure Steward (Intellectual Property Owner) **Co.1 Organization** Society for Vascular Surgery, 633 N. Saint Clair St., 22nd Floor, Chicago, Illinois, 60611 **Co.2 Point of Contact** Sarah, Murphy, Staff, smurphy@vascularsociety.org, 312-334-2305-	
Measure Developer If different from Measure Steward	

Co.3 Organization
Society for Vascular Surgery, 633 N. Saint Clair St., 22nd Floor, Chicago, Illinois, 60611

Co.4 Point of Contact
Sarah, Murphy, Staff, smurphy@vascularsociety.org, 312-334-2305-

Co.5 Submitter If different from Measure Steward POC
Sarah, Murphy, Staff, smurphy@vascularsociety.org, 312-334-2305-, Society for Vascular Surgery

Co.6 Additional organizations that sponsored/participated in measure development
The Vascular Study Group of New England

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
N/A

Ad.2 If adapted, provide name of original measure:
Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 Year the measure was first released: 2010
Ad.7 Month and Year of most recent revision: 12, 2010
Ad.8 What is your frequency for review/update of this measure?
Ad.9 When is the next scheduled review/update for this measure?

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment:

Date of Submission (*MM/DD/YY*)**:** 06/13/2011

Vascular Quality Initiative - Infra-Inguinal Bypass

Last Name | First Name | Middle Initial

Date of Birth | Medical Record Number | Social Security Number

General Information

Patient Data

Zip Code

Ethnicity ☐ Not Hispanic or Latino; ☐ Hispanic or Latino

Height ☐ inches or cm

Weight ☐ lbs or kg

Gender ☐ male; ☐ femal

Race ☐ Whit ☐ Black or African American; ☐ Asian; ☐ More than 1 rac ☐ American Indian or Alaskan Native; ☐ Native Hawaiian or other Pacific Islander; ☐ Unknown/other

Admission Data

Visit code (not required)

Admit Date

Surgeon

Discharge Status ☐ home; ☐ rehab unit; ☐ nursing home ☐ deac ☐ other hospital ☐ skilled nursing facility

If dead, date of death

Tranfered from? ☐ no; ☐ hospital; ☐ rehab unit

Discharge Date

Surgery Date

Does the patient have Medicare Part B? ☐ no; ☐ yes

Demographics

Smoking ☐ never; ☐ prior (>1 yr); ☐ current (within yr)

Diabetes ☐ none; ☐ diet; ☐ oral meds ☐ insulin

CAD symptoms ☐ none; ☐ hx MI but no sx; ☐ stable angina; ☐ unstable angina or MI < 6 m

CHF ☐ none; ☐ asymp, hx CHF; ☐ mild ☐ severe

Dialysis ☐ no; ☐ functioning transplant; ☐ on dialysis

Stress Test ☐ normal ☐ (+) ischemia; ☐ (+) MI ☐ (+)both ☐ not done

ASA Class ☐ 1 normal/health ☐ 2 w/mild systemic dx; ☐ 3 w/sever systen ☐ 4 w/severe systemic dx that is a constant threat to life; ☐ 5 moribund, not expectd to survive w/o op

HbA1c ☐ % (most recent value available pre- or post-op)

Hypertension ☐ no; ☐ yes (>=140/90 or histo

Beta blockers ☐ nc ☐ op day only; ☐ pre-op 1-30 days; ☐ chronic >30 days; ☐ no-intolerant

CABG/PTCA ☐ none ☐ <5y ☐ >=5yrs ag

COPD ☐ no ☐ not treated ☐ on me ☐ on home oxygen

Creatinine ☐ mg/dl OR µmol/L

Pre-adm Living ☐ home ☐ nursing ho

Pre-op Hemoglobin ☐ g/dl OR g/L

Previous arterial

Bypass ☐ no; ☐ yes

Aneurysm Repair ☐ no; ☐ yes

Major Amp ☐ no; ☐ yes

CEA ☐ no; ☐ yes

PTA/Stent ☐ no; ☐ yes

Pre-Op Medications

ASA ☐ no; ☐ yes ☐ intolerant

Statin ☐ no; ☐ yes ☐ intolerant

Plavix ☐ no; ☐ yes ☐ intolera

History

	Right	Left
Indication	☐ asymptomatic; ☐ claudication; ☐ rest pain; ☐ tissue loss; ☐ acute ischemia; ☐ not treated	☐ asymptomatic; ☐ claudication; ☐ rest pain; ☐ tissue loss; ☐ acute ischemia; ☐ not treated
Pathology	☐ not treated; ☐ occlusive; ☐ aneurysm	☐ not treated; ☐ occlusive; ☐ aneurysm
Ambulation Pre-Op	☐ amb; ☐ amb w/assistance; ☐ wheelchair; ☐ bedridden	

Previous	Right	Left
Inflow Bypass	☐ no; ☐ yes	☐ no; ☐ yes
Inflow PTA/Stent	☐ no; ☐ yes	☐ no; ☐ yes
Leg Bypass	☐ no; ☐ yes	☐ no; ☐ yes
Leg PTA/Stent	☐ no; ☐ yes	☐ no; ☐ yes
Major Amputation	☐ no; ☐ yes	☐ no; ☐ yes
Minor Amputation	☐ no; ☐ yes	☐ no; ☐ yes

Pre-Op	Right	Left
Pre-Op ABI		
Pre-Op TBI		

Pre-Op Imaging

Duplex ☐ no; ☐ yes

DSA/Arteriorgram ☐ no; ☐ yes

MRA ☐ no; ☐ yes

Vein Mapping ☐ no; ☐ yes

CTA ☐ no; ☐ yes

Vascular Quality Initiative - Infra-Inguinal Bypass

Procedure

Urgency	☐ elective; ☐ urgent; ☐ emergent	Anesthesia	☐ spina ☐ epidural; ☐ general
Side	☐ right ☐ left	Skin Prep	☐ chlorhexadine; ☐ alcohol; ☐ iodine; ☐ chlor+iodine; ☐ chlor+alcohol; ☐ iodine+alcohol ☐ all 3
Graft Origin	☐ ext iliac; ☐ com fe ☐ profunda; ☐ SFA; ☐ AK pop ☐ BK pop; ☐ tibial	Graft Recipient	☐ SFA; ☐ profunda; ☐ AK pop ☐ BK pop; ☐ T-P trunk; ☐ AT; ☐ PT; ☐ peroneal; ☐ DP ankle; ☐ PT ank ☐ tarsal/plantar; ☐ com fem
Graft Vein Type	☐ none; ☐ reversed GSV; ☐ in situ GSV; ☐ non-reversed transposed GSV; ☐ lesser saph; ☐ cephalic; ☐ basilic; ☐ composite vein	# Vein Segments	☐ none; ☐ 1; ☐ 2; ☐ 3 or more
Prosthetic	☐ none; ☐ Dacron; ☐ PTFE; ☐ non-autologous biologic; ☐ composite w/vein	EBL	☐ ml
Groin Incision	☐ none; ☐ vertical; ☐ horizontal	Total Procedure Time	☐ minutes
If a Graft Vein used, complete the following 2 variables:			
Vein Harvest Incision	☐ continuous; ☐ skip; ☐ endoscopic	Vein Graft Location	☐ sub-cutaneous ☐ sub-fascial

Adjuncts

Vein Cuff	☐ no; ☐ yes	Sequential Graft	☐ no; ☐ yes

Heart Rate

On Arrival in OR	☐ bpm	Highest intra-op	☐ bpm

Concomitant Proximal Ipsilateral

PVI	☐ no; ☐ yes (complete a Peripheral Vascular Intervention procedure form)
Bypass	☐ no; ☐ yes (complete a Supra-Inguinal Bypass procedure form)
Endarterectomy	☐ no; ☐ yes

Completion Study

Doppler	☐ no; ☐ yes	Duplex	☐ no; ☐ yes
Arteriogram	☐ no; ☐ yes		

Post-Op Data

Wound Infection	☐ no; ☐ yes	Graft Infection	☐ no; ☐ yes
Transfusion # units PRBC	☐ # units transfused during total hospitalization	Myocardial Infarction	☐ no; ☐ troponin only; ☐ EKG or clinical
Dysrhythmia	☐ no; ☐ yes	CHF	☐ no; ☐ yes
Respiratory	☐ no; ☐ pneumonia; ☐ ventilatc	Change of Renal Function	☐ none; ☐ creat. increase > 0.5 mg/dl (44.2 µmol/L); ☐ temp. dialysis; ☐ permanent dialysis
Stroke	☐ none ☐ mino ☐ major	Ipsilateral Amputation	☐ no; ☐ minor amp; ☐ BK amp; ☐ AK amp
Discharge Patency	☐ primary; ☐ prim. assisted; ☐ secondary; ☐ occluded	Patency Judged by	☐ doppler only; ☐ palpable graft pul ☐ palpable distal pulse; ☐ ABI increase >0.15; ☐ duplex
Return to OR	☐ no; ☐ yes		
for Bleeding	☐ no; ☐ yes	for Thrombosis	☐ no; ☐ yes
for Infection	☐ no; ☐ yes	for Revision	☐ no; ☐ yes

Discharge Medications

ASA	☐ no; ☐ yes ☐ intolerar	Statin	☐ no; ☐ yes ☐ intolerar	Plavix	☐ no; ☐ yes ☐ intolerar
Beta Blocker	☐ no; ☐ yes ☐ intolerar	Coumadin	☐ no; ☐ yes ☐ intolerar		

Discharge	**Right**		**Left**
Post-Op ABI		Post-Op ABI	
Post-Op TBI		Post-Op TBI	

Discharge Ambulation: ☐ amb; ☐ amb w/assistance; ☐ wheelchair; ☐ bedridden

Peri-Op Antibiotic Ordered

Start <1hr Pre-op	☐ no; ☐ yes ☐ no, for medical reason	Stop <24hr Post-op	☐ no; ☐ yes ☐ no, for medical reason
1st-2nd Gen Cephalosporin	☐ no; ☐ yes ☐ no, for medical reason		

Vascular Quality Initiative - Infra-Inguinal Bypass Follow-Up

Last Name:		First Name:		DOB:	
MRN:		SSN:		Zip/Postal Code:	
Visit Code:		Surgeon:		Surgery Date:	
				Side:	

General Information

Date of Contact

Contact By ☐ Office Visit; ☐ Phone; ☐ Refused follow-up visit; ☐ Lost to follow-u

Current Smoking ☐ No; ☐ Yes (within last 6 months)

Current Living Status ☐ Home; ☐ Nursing Home; ☐ Dead

Date of Death

Cause ☐ Operation Related; ☐ Non-Related; ☐ Unsure

Current Medications

ASA ☐ No; ☐ Yes; ☐ Intolerant

Plavix ☐ No; ☐ Yes; ☐ Intolerant

Coumadin ☐ No; ☐ Yes; ☐ Intoleran

Beta Blocker ☐ No; ☐ Yes; ☐ Intolerant

Statin ☐ No; ☐ Yes; ☐ Intolerant

Infra-Inguinal Bypass

Current Ambulation ☐ amb; ☐ amb w/assistance ☐ wheelchair; ☐ bedridden

Ipsilateral Symptoms ☐ asymptomatic; ☐ claudication; ☐ rest pain; ☐ tissue loss

Current Patency ☐ primary; ☐ prim. assisted; ☐ secondary; ☐ occluded

Patency Judged by ☐ doppler only; ☐ palpable graft pulse; ☐ palpable distal pulse; ☐ ABI increase >0.15; ☐ duplex

Ipsilateral ABI

Ipsilateral TBI

Infection ☐ none; ☐ superficial cellulitis; ☐ deep abcess; ☐ infection involving artery or graft

Bypass Revision ☐ n ☐ yes, surgery; ☐ yes, catheter-based; ☐ both

Date

Thrombectomy/lyis - Revision ☐ n ☐ yes, surgery; ☐ yes, catheter-based; ☐ both

Date

Major Amputation ☐ no; ☐ minor amp; ☐ BK amp; ☐ AK amp

Date

LOWER EXTREMITY BYPASS DEFINITIONS– v.01.09

If more than one response applies, select the most severe (highest number) response for each data field.

Pre-op Data

Smoking: Prior = quit ≥ 1 year ago. Current = still smoking within last 12 months. Include cigarettes, pipe, or cigar.

HTN (Hypertension): Defined as ≥ 140/90, either systolic or diastolic, at admission or within last 6 months, or clearly documented in medical record.

Beta-blockers: Peri-operative = started within one month before surgery or during surgery. Chronic = more than one month before surgery.

CAD Symptoms (Coronary artery disease**):** Stable angina = stable pattern or symptoms with or without antianginal medication. Unstable angina = new onset, increasing frequency, lasting > 20 min and/or rest angina.

CABG/PTCA: Coronary artery bypass, angioplasty, or stent.

CHF (Congestive Heart Failure): Documented CHF: Mild = SOB on exertion; Severe = SOB at rest, pulmonary edema, or pitting ankle edema. (Use 2 = mild if severity not documented.)

COPD: Not treated = COPD documented in record but not treated with medication. Medication includes theophylline, aminophylline, inhalers or steroids

Dialysis: Transplant = patient has functioning kidney transplant; Dialysis = currently on hemo- or peritoneal dialysis.

Creatinine: Last available measurement taken before procedure. If multiple measurements, use highest within 30 days of surgery.

Stress Test: Includes stress EKG, stress echo, nuclear stress scans, within 2 years of surgery.

Pre-admin living: Use last living status before any current, acute hospitalization, or rehab unit.

Previous Arterial:

Bypass - Any non-cardiac arterial bypass for occlusive disease
CEA - Carotid endarterectomy
Aneurysm Repair – Any known true arterial aneurysm repair (excluding cerebral or pseudo-aneurysm)
PTA/Stent – Of any non-cardiac artery
Major Amputation – Any amputation above the foot or hand

Pre-Op Medications: Taken within 36 hours of surgery. Statins include any HMG-CoA reductase inhibitor, such as Lipitor, Mevacor, Pravachol, Zocor, Lescol, etc. If Plavix is discontinued prior to surgery it should be coded = 0.

Pre-op Hemoglobin: Most recent pre-op hemoglobin within past 30 days.

Indication: Acute ischemia requires motor-sensory loss, sudden onset, and need for emergent treatment within 24 hours of presentation. Urgent = 12-72 hours. Emergent = <12 hours.

Pathology: If both aneurysm and occlusive disease, select the pathology that was the principal indication for the procedure.

Ambulation Pre-op: Chose best ambulation category experienced within one month of admission (lowest category).

Previous Ipsilateral/Contralateral: Inflow: aorto-iliac-femoral. Leg: intra-inguinal. Amputation: Major = above or below knee (loss of foot); Minor = within foot.

Pre-opABI, TBI: Use highest value from affected leg. TBI = toe-brachial index. Use actual units. Use 2.0 if non-compressible.

DSA/Angiogram: Digital subtraction or conventional arteriogram.

Procedure

Urgency: Urgent = required operation within 72 hours, but >12 hrs of admission. Emergent = required operation within 12 hrs of admission to prevent limb loss.

Recipient: Use most distal site if sequential bypass.

Vein type: Use composite for spliced vein from more than one vein site.

Concomitant Proximal Ipsilateral: Procedure performed proximal to or at origin of leg bypass graft to improve inflow during same operation.

Post-op Data

Wound infection: Culture positive or requiring antibiotic treatment.

Graft infection: Documented in record as exposed graft or graft infection.

Transfusion: Total of all PRBC transfusions pre-op, intra-op, and post-op during this hospitalization.

Myocardial Infarction: Troponin: by local standards for MI. EKG: new Q waves, new ST and T wave changes. Clinical: documentation of MI by clinical criteria or ECHO or other imaging modality.

Dysrhythmia: New rhythm disturbance requiring treatment with medications or cardioversion.

CHF: Pulmonary edema with requirement for monitoring or treatment in ICU.

Respiratory: Pneumonia = Lobar infiltrate on CXR and pure growth of recognized pathogen or 4+ growth of recognized pathogen in presence of mixed growth. Ventilator = required after initially extubated (if applicable).

Change renal function: New increase in creatinine of 0.5mg/dl. New dialysis includes peritoneal dialysis, hemodialysis, and hemo-filtration. (Applies to new dialysis not present pre-op.)

Bleeding; Infection; Thrombosis; Revision: Use 666 if Return to OR = 0.

Discharge patency: Primary = without other intervention; Primary-assisted = after intervention but without thrombosis; Secondary = after intervention for thrombosis.

Patency judged by: Use highest applicable modality. Palpable: clearly palpable pulse (not by Doppler). ABI: increase ABI (or TBI) ≥ 0.15 compared with pre-op.

Post-op ABI, TBI: Use highest value from affected leg. TBI = toe-brachial index. Use actual units. Use 2.0 if non-compressible.

Peri-operative Antibiotics: Use 0=no if antibiotic was not ordered. To use 1=yes, antibiotic must be ordered to be given within 1 hour prior to skin incision and must be ordered to be discontinued within 24 hrs of end of time of operation. To use 2=no for medical reason, a medical reason must be documented in the chart that antibiotic not given. **Acceptable antibiotics include:** Ampicilin/sulbactam, Aztreonam, Cefazolin, Cefmetazole, Cefotetan, Cefuroxime, Ciprofloxacin, Clindamycin, Ertapenem, Erythromycin base, Gatifloxacin, Gentamicin, Levofloxacin, Metronidazole, Moxifloxacin, Neomycin, and Vancomycin.

1st-2nd Generation Cepahalosporin: (Cefazolin or Cefuroxime) Use response 1=yes, if ordered. If documented in medical record that not ordered for medical reason use 2. Otherwise use 0=no.