

Voluntary PVI Procedure and Follow-up Data Dictionaries

Voluntary PVI Registry
Data Collection Definitions

Definitions updated with the changes to the new website 2/1/2023

Table of Contents

PVI Procedure.....	5
Physician	5
Fellow ID/Second Operator	5
Procedure Date & Start Time	5
Procedure Date & End Time.....	5
Status of Procedure	5
Staged Procedure	6
Imaging Studies (w/in past 6 months).....	6
Labs - Pre Procedure	7
Pre Procedure Creatinine.....	7
Pre Procedure Hemoglobin (Hgb).....	7
Labs - Post Procedure	8
Post Procedure Peak Creatinine	8
Post Procedure Nadir Hemoglobin.....	8
Indications.....	8
Indication Type.....	8
Indications for Endovascular Repair of Abdominal Aortic Stenosis.....	9
Indications for Lower Extremity Revascularization	10
Indications for Upper Extremity Revascularization	14
Indications for Mesenteric Revascularization	16
Indications for Renal Revascularization.....	17
Procedure Details	18
Hybrid Procedure	19
Contrast Types.....	19
Total IV Contrast Used.....	20
Heparin Administered.....	20
Peak Intra Procedure Activated Clotting Time (ACT).....	20
End of procedure ACT	20
Locations	21
Vessel Location	21
Lesion Segment Area.....	21
PVI Procedure Performed.....	21
Bypass Graft	22
Graft Type.....	22
Graft Origin	22
Graft Insertion	22
Lesion Length	22
Heavy Calcium.....	22
In-stent Restenosis	23
Thrombus.....	23
Pre Stenosis % (0-100).....	23

Post Stenosis % (0-100)	23
Final Balloon Diameter	23
Stents	24
Vascular Access	24
Vascular Access Site(s)	24
Vascular Access Type	24
Vessel Accessed	25
Access Guidance	25
Access Approach	25
Sheath Size	25
Sheath Removed	25
Vascular Closure Type	26
Sheath Removal Time	26
Outcomes During Procedure	26
Death/Cause (ODP)	26
Dissection (Not Repaired) (ODP)	27
Embolus (ODP)	27
Thrombus (ODP)	27
Stent/Graft Thrombosis (ODP)	27
Vessel Perforation (ODP)	27
TIA/Stroke (ODP)	28
Transfusion (ODP)	28
Vascular Access Complications (ODP)	28
Vascular Surgery Emergent (ODP)	29
Amputation (ODP)	29
Compartment Syndrome (ODP)	30
Outcomes Post Procedure	30
Death/Cause (OPP)	30
Comfort care measures implemented (OPP)	30
Myocardial Injury (OPP)	30
Dysrhythmia (OPP)	32
Congestive Heart Failure (CHF) (OPP)	32
TIA/Stroke (OPP)	32
Infection/Sepsis (OPP)	32
New Requirement for Dialysis (OPP)	33
Transfusion (OPP)	33
Vascular Access Complications (OPP)	33
Compartment Syndrome (OPP)	34
Embolus (OPP)	34
Thrombus (OPP)	34
Stent/Graft Thrombosis (OPP)	35
Vascular Surgery Emergent (OPP)	35

Vascular Surgery Non Emergent (OPP)	35
Amputation (OPP).....	35
PVI Follow-up.....	37
PVI Follow Up Interval.....	37
Contact Date.....	37
Current Living Status.....	37
Smoking.....	37
Antiplatelets	37
Statin	38
Aspirin.....	38
Beta Blocker	38
ACE Inhibitor.....	38
Anticoagulant	38
ARBs (Angiotensin II Receptor Blockers)	39
Other Cholesterol Lowering Agent.....	39
Repeat Procedure.....	39
New Vascular Procedure.....	39
Vascular Access Complication.....	39
Thrombectomy/lysis	40
ABIs	40
TBIs	40
Toe Pressures.....	40
Amputation.....	41
MI	41
TIA/Stroke.....	41
Renal Failure/Dialysis.....	42
Transfusion	42

PVI Procedure

Physician

Data Abstraction Instructions:

Choose the attending physician from the drop down list or create a physician identification if not already listed.

Selections:

- Choose physician

Supporting Definitions:

If physician is not available in the drop down, enter the physician's information to create a physician ID.

Required:

Yes

Fellow ID/Second Operator

Data Abstraction Instructions:

Use the drop down box to choose a physician. If not available in drop down, enter the fellow's or second operator's information to create a physician ID.

Selections:

- Enter Fellow ID/Second Operator

Supporting Definitions:

This is an optional field if your site chooses to track its fellows or second operators.

Required:

No

Procedure Date & Start Time

Data Abstraction Instructions:

Enter the date of the current procedure (mm/dd/yyyy) and enter the time the procedure was initiated. (Military time).

The time the procedure started is defined as the time which local anesthetic was first administered for vascular access, or the time of the first attempt at vascular access for the peripheral intervention (use whichever is earlier). If an arterial sheath is already in place, use the time of the introduction of a catheter or the time the sheath was exchanged.

Selections:

- Enter Date & Time

Required:

Yes

Procedure Date & End Time

Data Abstraction Instructions:

Enter the date and time the procedure ends. (Military time). The time the procedure ended is defined as the time the primary operator leaves the room for peripheral interventions. Should the patient expire in the procedure area, indicate the time the patient was pronounced.

Selections:

- Enter Date & Time

Required:

Yes

Status of Procedure

Data Abstraction Instructions:

Indicate status of the procedure using the following categories.

Elective = The procedure could be deferred without increased risk of compromised vascular outcome. This includes elective or scheduled patients.

Urgent = Required procedure within 72 hours, but > 12 hours of symptoms.

Emergent = Required procedure within 12 hours of symptoms.

Selections:

- Elective
- Urgent
- Emergent

Required:

Yes

Staged Procedure

Data Abstraction Instructions:

Indicate if the intervention is the part of a staged procedure.

Selections:

- Yes
- No

Supporting Definitions:

Interventions planned for subsequent procedures at the time of the initial procedure are considered staged procedure, e.g., initial procedure left superficial femoral angioplasty (SFA) with a plan for right SFA in future. Patients undergoing lysis procedures are considered staged procedures. A plan for a staged procedure can be developed with the patient as an outpatient or an inpatient. Enter a new case for any staged procedure (For the first case, mark No for staged procedure, for the second procedure mark Yes).

The following are NOT staged procedures: a subsequent intervention due to restenosis, a diagnostic angiogram with intervention planned on a separate day, a coronary procedure followed by a peripheral procedure, a return attempt after a failed PVI.

Required:

Yes

Imaging Studies (w/in past 6 months)

Data Abstraction Instructions:

For each of the listed studies, indicate if the study was performed to diagnose PAD, CAD, or as part of a functional assessment within prior 6 months. Also, for each of the listed studies that were performed, indicate if the study was normal or abnormal or include value where applicable. If study was not performed, record the study was not done.

For patients who have multiple procedures during the same hospitalization, do not use the same pre-procedure imaging studies as used prior to the first procedure. Only enter imaging studies performed prior to the specific procedure being entered.

Enter all available data for ABIs, TBIs, and toe pressures that are valid for the present procedure (include both right and left, regardless of the operative side).

For Chest X-Ray enter the documentation of the physical condition of the lungs. For example, if the radiologist documents that an ET tube is in place and there are no structural abnormalities noted in the lungs. Enter Normal.

Selections:

- ABI's Compressible (Compressible \leq 1.4)
 - Yes
 - No
- Right Pre Procedure ABI
 - Yes, enter value
 - No
- Left Pre Procedure ABI
 - Yes, enter value
 - No
- Right Pre Procedure TBI
 - Yes, enter value
 - No
- Left Pre Procedure TBI
 - Yes, enter value
 - No
- Right Pre Procedure Toe Pressure
 - Yes, enter value (mm Hg)
 - No
- Left Pre Procedure Toe Pressure
 - Yes, enter value (mm Hg)
 - No
- Duplex Ultrasound:
 - Yes
 - No
 - If yes, select option
 - Normal
 - Abnormal
- Computerized Tomographic Angiography (CTA):

- Yes
- No
- If yes, select option
 - Normal
 - Abnormal

- Magnetic Resonance Imaging/Magnetic Resonance Angiography (MRI/MRA):

- Yes
- No
- If yes, select option
 - Normal
 - Abnormal

- Contrast Cineangiography:

- Yes
- No
- If yes, select option
 - Normal
 - Abnormal

Required:

Yes

Labs - Pre Procedure**Pre Procedure Creatinine****Data Abstraction Instructions:**

Enter the creatinine value documented within the 30 days before the current procedure. If more than one creatinine value is documented, enter the value that is closest to the procedure start time. If there is no value, enter Not drawn.

Selections:

- Yes
 - Enter value
- Not drawn

Supporting Definitions:

If a patient has multiple procedures within a hospitalization, the pre-procedure labs should be abstracted after the previous procedure. If no labs are drawn from the end of the previous procedure to the start of the current procedure, enter "Not drawn". The range for Pre Procedure Creatinine is 0.1 - 15 mg/dL. Enter 0.1 for a Pre Procedure Creatinine this is <0.1. Enter 15 for a Pre Procedure Creatinine that is >15.

Required:

Yes

Suffix:

mg/dl

Minimum:

0.1

Maximum:

15

Soft Minimum:

0.3

Pre Procedure Hemoglobin (Hgb)**Data Abstraction Instructions:**

Enter the hemoglobin value documented within the 30 days before the current procedure. If more than one hemoglobin value is documented, enter the value that is closest to the procedure start time. If there is no value, mark "Not drawn."

Selections:

- Yes
 - Enter value
- Not drawn

Supporting Definitions:

If a patient has multiple procedures within a hospitalization, the pre-procedure labs should be abstracted after the previous procedure. If no labs are drawn from the end of the previous procedure to the start of the current procedure, enter "Not drawn". The Pre Procedure Hemoglobin range is 2 - 20 g/dL. Enter 2 for a hemoglobin value <2. Enter 20 for a hemoglobin value >20.

Required:

Yes

Suffix:

g/dl

Minimum:

2

Maximum:

Labs - Post Procedure

Post Procedure Peak Creatinine

Data Abstraction Instructions:

Enter the highest creatinine value documented from the end of the procedure to the next procedure or discharge, whichever occurs first.

- If the next procedure is any procedure utilizing contrast or any open surgical procedure, enter the highest creatinine value before the start time of the next procedure.
- If the "next procedure" is a complication of the current procedure, enter the highest creatinine value closest to discharge.
- If there is no value drawn post procedure, mark "Not drawn."
- For extended hospitalizations, greater than 30 days, use the highest creatinine prior to day 30 after the procedure.

Selections:

- Yes
 - Enter value
- Not drawn

Supporting Definitions:

. The range for Post Procedure Peak Creatinine is 0.1 - 15 mg/dL. Enter 0.1 for a creatinine value <0.1. Enter 15 for a creatinine value >15.

Required:

Yes

Suffix:

mg/dl

Minimum:

0.1

Maximum:

15

Post Procedure Nadir Hemoglobin

Data Abstraction Instructions:

Enter the lowest hemoglobin value documented from the end of the procedure to the next procedure or discharge, whichever occurs first.

- If the next procedure is any invasive procedure that could potentially result in significant blood loss, enter the lower hemoglobin value before the start time of the next procedure.
- If the "next procedure" is a complication from the entered procedure, enter the lowest hemoglobin value before discharge.
- If only one value is available post procedure through discharge, that value will be used for the post procedure nadir hemoglobin **and** the discharge hemoglobin.
- If there is no value drawn post procedure, mark "Not drawn."

Selections:

- Yes
 - Enter value
- Not drawn

Supporting Definitions:

The range for Post Procedure Nadir Hemoglobin is between 2 - 20 g/dL. Enter 2 for a hemoglobin <2. Enter 20 for a hemoglobin >20.

Required:

Yes

Suffix:

g/dl

Minimum:

2

Maximum:

20

Indications

Indication Type

Data Abstraction Instructions:

Enter the indication type for the current procedure.

Selections:

- Endovascular Repair of Abdominal Aortic Stenosis
- EVAR/AAA Revascularization
- Lower Extremity Revascularization
- Upper Extremity Revascularization
- Mesenteric Revascularization
- Renal Revascularization

Required:

Yes

Indications for Endovascular Repair of Abdominal Aortic Stenosis

Claudication

Data Abstraction Instructions:

Indicate if the patient has leg pain caused by poor circulation, inhibiting the patient's ability to walk distances as an indication for the procedure. Refers to cramping pains in the legs (usually the calf muscles but may be in the thigh muscles) caused by poor circulation of the blood in the arteries to the leg muscles during exercise. True claudication is relieved with rest from exercise.

Selections:

- Yes
- No

Required:

Yes

Mesenteric Ischemia

Data Abstraction Instructions:

Indicate if the patient has symptoms of bowel ischemia (abdominal pain and discomfort with eating, nausea, weight loss) as an indication for the procedure.

Acute = sudden onset of severe abdominal pain, vomiting, or diarrhea secondary to mesenteric ischemia.

Chronic = more than 1 month of chronic abdominal pain (discomfort, bloating) after eating.

Selections:

- Yes
 - Acute
 - Chronic
- No

Required:

Yes

Renal Insufficiency/Hypertension

Data Abstraction Instructions:

Indicate if the patient has renal insufficiency or hypertension as the indication for the procedure.

Selections:

- Yes
- No

Required:

Yes

Previous Surgery/Stenosis

Data Abstraction Instructions:

Indicate if the patient has had previous aortic surgery resulting in stenosis that is the indication for the procedure.

Selections:

- Yes
- No

Required:

Yes

Acute Limb Ischemia

Data Abstraction Instructions:

Indicate if the procedure is performed for acute limb Ischemia (ALI). ALI is defined as a sudden decrease in limb perfusion that threatens limb viability and represents a major vascular emergency. The clinical presentation is acute if it occurs within 14 days after symptom onset. Symptoms of ALI include pain, pallor (paleness) paralysis (loss of muscle function), pulse deficit, paresthesia (tingling, numbness, burning, prickling sensation) , and poikilothermia (cold or cool extremity when in a warm room).

Reference: ALI: An Update on Diagnosis and Management. Journal of Clinical Medicine. Doi: <https://dx.doi.org/10.3390%2Fjcm8081215>

Critical Limb Ischemia (CLI) is not the same as ALI. CLI is a progressive disease state. It is defined as ischemic rest pain, a nonhealing wound/ulcer, or gangrene for more than two weeks with signs of poor blood flow.

Reference: AHA Outlines Diagnosis, Treatment Options for Underrecognized Critical Limb Ischemia. Tctmd.com. <https://www.tctmd.com/news/aha-outlines-diagnosis-treatment-options-underrecognized-critical-limb-ischemia>

Selections:

- Yes
- No

Required:Yes

Complication from Prior Procedure

Data Abstraction Instructions:

Indicate if the patient had a complication from a prior procedure.

Selections:

- Yes
- No

Supporting Definitions:

The patient had a dissection, perforation or another complication from a prior procedure (such as a cardiac or pulmonary angiogram) that required vascular repair (Percutaneous or Surgical).

Required:Yes

Trauma

Data Abstraction Instructions:

Indicate if the vascular procedure was performed to repair injury that resulted from trauma (motor vehicle accident, fire, fall etc.).

Selections:

- Yes
- No

Required:Yes

Indications for Lower Extremity Revascularization

Claudication

Data Abstraction Instructions:

Indicate if the patient has leg pain caused by poor circulation, inhibiting patient's ability to walk distances.

Selections:

- Yes
- No

Supporting Definitions:

Refers to cramping pains in the legs (usually the calf muscles but may be in the thigh muscles) caused by poor circulation of the blood in the arteries to the leg muscles during exercise. True claudication is relieved with rest from exercise. If the patient has arm claudication from subclavian stenosis, do not include.

Required:Yes

Rest Pain

Data Abstraction Instructions:

Indicate if the patient has severe pain in the foot and toes made worse by elevation of the leg and relieved by sitting or standing. Analgesics do not readily control rest pain.

Selections:

- Yes
- No

Required:Yes

Threatened Bypass Graft

Data Abstraction Instructions:

Indicate if the procedure performed is to maintain patency of a previously placed bypass graft. This may be demonstrated via abnormal duplex scans, abnormal non-invasive imaging, or increased velocities identified during surveillance visits.

Selections:

- Yes
 - Symptomatic
 - Asymptomatic
- No

Required:

Yes

Acute Limb Ischemia**Data Abstraction Instructions:**

Indicate if the procedure is performed for acute limb Ischemia (ALI). ALI is defined as a sudden decrease in limb perfusion that threatens limb viability and represents a major vascular emergency. The clinical presentation is acute if it occurs within 14 days after symptom onset. Symptoms of ALI include pain, pallor (paleness) paralysis (loss of muscle function), pulse deficit, paresthesia (tingling, numbness, burning, prickling sensation) , and poikilothermia (cold or cool extremity when in a warm room).

Reference: ALI: An Update on Diagnosis and Management. Journal of Clinical Medicine. Doi: <https://dx.doi.org/10.3390%2Fjcm8081215>

Critical Limb Ischemia (CLI) is not the same as ALI. CLI is a progressive disease state. It is defined as ischemic rest pain, a nonhealing wound/ulcer, or gangrene for more than two weeks with signs of poor blood flow.

Reference: AHA Outlines Diagnosis, Treatment Options for Underrecognized Critical Limb Ischemia. Tctmd.com. <https://www.tctmd.com/news/aha-outlines-diagnosis-treatment-options-underrecognized-critical-limb-ischemia>

Selections:

- Yes
- No

Required:

Yes

Facilitation of Procedure**Data Abstraction Instructions:**

Indicate if the PVI procedure performed was to facilitate a different endovascular procedure (EVAR, TAVR, etc.). For example, the PVI procedure was necessary to pass a device.

Selections:

- Yes
- No

Required:

Yes

Pre-Procedure Exercise Therapy**Data Abstraction Instructions:**

Indicate if there is documentation that the patient was on or failed some type of pre-procedure exercise program prior to the hospitalization. If so, indicate whether it was informal or structured.

Selections:

- Yes
 - Structured/Supervised
 - Home Based/Informal
- No

Required:

Yes

Impaired Ability to Work**Data Abstraction Instructions:**

Indicate if the procedure is performed due to an inability to work.

Selections:

- Yes
- No

Required:

Yes

Peripheral Aneurysm Repair**Data Abstraction Instructions:**

Indicate if the procedure is being performed for repair of a peripheral aneurysm and whether the patient is experiencing symptoms. Peripheral aneurysms are aneurysms that develop in the upper or lower extremities.

Selections:

- Yes

- Symptomatic
- Asymptomatic

- No

Required:

Yes

Increased Stent Velocity

Data Abstraction Instructions:

Indicate if the procedure performed is due to increased velocities in a pre-existing stent and whether the patient is experiencing symptoms. This may be demonstrated via abnormal duplex scans, abnormal non-invasive imaging, or increased velocities identified during surveillance visits.

Selections:

- Yes
 - Symptomatic
 - Asymptomatic
- No

Required:

Yes

Increased Stent Graft Velocity

Data Abstraction Instructions:

Indicate if the procedure performed is due to increased velocities in a pre-existing stent graft and whether the patient is experiencing symptoms. This may be demonstrated via abnormal duplex scans, abnormal non-invasive imaging, or increased velocities identified during surveillance visits.

Selections:

- Yes
 - Symptomatic
 - Asymptomatic
- No

Required:

Yes

Wound (WIFI)

Data Abstraction Instructions:

Indicate if the patient has a wound present and to what degree.

<i>Grade</i>	<i>Ulcer</i>	<i>Gangrene</i>
0	No ulcer	No gangrene
Clinical description: ischemic rest pain (requires typical symptoms + ischemia grade 3); no wound.		
1	Small, shallow ulcer(s) on distal leg or foot; no exposed bone, unless limited to distal phalanx	No gangrene
Clinical description: minor tissue loss. Salvageable with simple digital amputation (1 or 2 digits) or skin coverage.		
2	Deeper ulcer with exposed bone, joint or tendon; generally not involving the heel; shallow heel ulcer, without calcaneal involvement	Gangrenous changes limited to digits
Clinical description: major tissue loss salvageable with multiple (≥ 3) digital amputations or standard TMA \pm skin coverage.		
3	Extensive, deep ulcer involving forefoot and/or midfoot; deep, full thickness heel ulcer \pm calcaneal involvement	Extensive gangrene involving forefoot and /or midfoot; full thickness heel necrosis \pm calcaneal involvement
Clinical description: extensive tissue loss salvageable only with a complex foot reconstruction or nontraditional TMA (Chopart or Lisfranc); flap coverage or complex wound management needed for large soft tissue defect		

Selections:

- Yes
 - Grade 1
 - Grade 2
 - Grade 3
 - Not Documented
- No

Supporting Definitions:

Grade 1: Minor tissue loss; small shallow ulceration

Grade 2: Major tissue loss; deeper ulceration with exposed bone, joint, or tendon

Grade 3: Extensive ulcer/gangrene;

Required:

Yes

Ischemia (WIFI)

Data Abstraction Instructions:

Indicate the degree of ischemia present.

<i>Grade</i>	<i>ABI</i>	<i>Ankle systolic pressure</i>	<i>TP, TcPO₂</i>
0	≥0.80	>100 mm Hg	≥60 mm Hg
1	0.6-0.79	70-100 mm Hg	40-59 mm Hg
2	0.4-0.59	50-70 mm Hg	30-39 mm Hg
3	≤0.39	<50 mm Hg	<30 mm Hg

ABI, Ankle-brachial index; *PVR*, pulse volume recording; *SPP*, skin perfusion pressure; *TP*, toe pressure; *TcPO₂*, transcutaneous oximetry. Patients with diabetes should have TP measurements. If arterial calcification precludes reliable ABI or TP measurements, ischemia should be documented by TcPO₂, SPP, or PVR. If TP and ABI measurements result in different grades, TP will be the primary determinant of ischemia grade. Flat or minimally pulsatile forefoot PVR = grade 3.

Selections:

- Yes
 - Grade 1
 - Grade 2
 - Grade 3
 - Not Documented
- No

Required:

Yes

Foot Infection (WIFI)

Data Abstraction Instructions:

Indicate if the patient has a foot infection and to what degree.

<u>Grade</u>	<u>Clinical Description</u>	<u>IDSA</u>	<u>IWGDF Class</u>
0	wound without purulence or manifestations of infection	uninfected	1
1	>2 manifestations of infection (erythema or purulence, pain tenderness, warmth or induration) any cellulitis or erythema extends < 2cm around ulcer; infection is limited to skin or subcutaneous tissues; no local complications or systemic illness	mild	2
2	Infection in patient who is systemically and metabolically stable but has ≥1 of the following: cellulitis extending 2cm, lymphangitis; spread beneath fascia; deep tissue abscess; gangrene; muscle, tendon, joint or bone involvement	moderate	3
3	Infection in patient with systemic or metabolic toxicity	severe	4

Selections:

- Yes
 - Grade 1
 - Grade 2
 - Grade 3
 - Not Documented
- No

Supporting Definitions:

Grade 1: >2 manifestations of infection (erythema, purulence, pain, warmth, etc.)
Grade 2: Infection in patient who is systemically stable but has one or more of the following; cellulitis extending 2cm, spread beneath fascia, deep tissue abscess, gangrene, muscle/tendon/bone involvement

Grade 3: Infection in patient with systemic or metabolic toxicity

Required:

Yes

Complication from Prior Procedure

Data Abstraction Instructions:

Indicate if the patient had a complication from a prior procedure.

Selections:

- Yes
- No

Supporting Definitions:

The patient had a dissection, perforation or another complication from a prior procedure (such as a cardiac or pulmonary angiogram) that required vascular repair (Percutaneous or Surgical).

Required:

Yes

Trauma

Data Abstraction Instructions:

Indicate if the vascular procedure was performed to repair injury that resulted from trauma (motor vehicle accident, fire, fall etc.).

Selections:

- Yes
- No

Required:

Yes

Pre-Procedure Smoking Cessation

Data Abstraction Instructions:

Indicate if there is documentation that the patient was counseled on smoking cessation prior to the hospitalization.

Selections:

- Yes
 - Counseling
 - Pharmacologic
 - Other
- No

Supporting Definitions:

Pharmacologic agents may include (but are not limited to) prescription of Chantix or a nicotine patch.

Required:

Yes

Indications for Upper Extremity Revascularization

Ulcer/Gangrene

Data Abstraction Instructions:

Indicate if the patient has an ulcer, gangrene, or if tissue loss is present.

Selections:

- Yes
- No

Required:

Yes

Acute Limb Ischemia

Data Abstraction Instructions:

Indicate if there is any sudden decrease in limb perfusion that causes a potential threat to limb viability.

Indicate if the procedure is performed for acute limb Ischemia (ALI). ALI is defined as a sudden decrease in limb perfusion that threatens limb viability and represents a major vascular emergency. The clinical presentation is acute if it occurs within 14 days after symptom onset. Symptoms of ALI include pain, pallor (paleness) paralysis (loss of muscle function), pulse deficit, paresthesia (tingling, numbness, burning, prickling sensation) , and poikilothermia (cold or cool extremity when in a warm room).

Reference: ALI: An Update on Diagnosis and Management. Journal of Clinical Medicine. Doi: <https://dx.doi.org/10.3390%2Fjcm8081215>

Critical Limb Ischemia (CLI) is not the same as ALI. CLI is a progressive disease state. It is defined as ischemic rest pain, a nonhealing wound/ulcer, or gangrene for more than two weeks with signs of poor blood flow.

Reference: AHA Outlines Diagnosis, Treatment Options for Underrecognized Critical Limb Ischemia. Tctmd.com. <https://www.tctmd.com/news/aha-outlines-diagnosis-treatment-options-underrecognized-critical-limb-ischemia>

Selections:

- Yes
- No

Required:

Yes

Angina/Abnormal Cardiac Stress Test

Data Abstraction Instructions:

Indicate if patient has had episodes of angina, or if patient has had an abnormal cardiac stress test.

Selections:

- Yes
- No

Supporting Definitions:

Indication for revascularization is cardiac ischemia secondary to impaired blood flow to coronary artery bypass graft (e.g., left subclavian stenosis in a patient with an in situ left internal mammary artery bypass graft).

For informational purposes, one of the following criteria are necessary:

- Angina at rest (usually prolonged >20 mins)
- New onset (less than two months) exertional angina of at least Canadian cardiovascular Society Classification (CCSC) class III
- Recent (less than two months) acceleration of angina reflected by an increase in severity of at least one CCSC class to at least CCSC class III. The patient must also NOT have any biochemical evidence of myocardial necrosis.

Required:

Yes

BP discrepancy

Data Abstraction Instructions:

Indicate if the patient has a more than 50 mm difference in systolic BP between L and R arms.

Selections:

- Yes
- No

Supporting Definitions:

This may be seen in subclavian stenosis.

Required:

Yes

Arm Claudication

Data Abstraction Instructions:

Indicate if the patient has arm pain caused by poor circulation.

Selections:

- Yes
- No

Supporting Definitions:

Refers to cramping pains in the arms caused by poor circulation of the blood in the arteries to the arm muscles during exercise. True claudication is relieved with rest from exercise.

Required:

Yes

Peripheral Aneurysm Repair

Data Abstraction Instructions:

Indicate if the procedure is being performed for repair of a peripheral aneurysm and whether the patient is experiencing symptoms.

Selections:

- Yes
 - Symptomatic
 - Asymptomatic
- No

Supporting Definitions:

Peripheral aneurysms are aneurysms that develop in the upper or lower extremities.

Required:

Yes

Complication from Prior Procedure

Data Abstraction Instructions:

Indicate if the patient had a complication from a prior procedure.

Selections:

- Yes
- No

Supporting Definitions:

The patient had a dissection, perforation or another complication from a prior procedure (such as a cardiac or pulmonary angiogram) that required vascular repair (Percutaneous or Surgical).

Required:

Yes

Trauma

Data Abstraction Instructions:

Indicate if the vascular procedure was performed to repair injury that resulted from trauma (motor vehicle accident, fire, fall etc.).

Selections:

- Yes
- No

Required:

Yes

Pre-Procedure Smoking Cessation

Data Abstraction Instructions:

Indicate if there is documentation that the patient was counseled on smoking cessation prior to the hospitalization.

Selections:

- Yes
- No

Required:

Yes

Indications for Mesenteric Revascularization

Mesenteric Ischemia – acute/chronic

Data Abstraction Instructions:

Indicate if the patient has symptoms of bowel ischemia (abdominal pain and discomfort with eating, nausea, weight loss). This includes procedures performed on the celiac artery.

Acute = sudden onset of severe abdominal pain, vomiting or diarrhea secondary to mesenteric ischemia.

Chronic = more than 1 month of chronic abdominal pain (discomfort, bloating) after eating.

Selections:

- Yes
 - Acute
 - Chronic
- No

Required:Yes

Complication from Prior Procedure

Data Abstraction Instructions:

Indicate if the patient had a complication from a prior procedure.

Selections:

- Yes
- No

Supporting Definitions:

The patient had a dissection, perforation or another complication from a prior procedure (such as a cardiac or pulmonary angiogram) that required vascular repair (Percutaneous or Surgical).

Required:Yes

Trauma

Data Abstraction Instructions:

Indicate if the vascular procedure was performed to repair injury that resulted from trauma (motor vehicle accident, fire, fall etc.).

Selections:

- Yes
- No

Required:Yes

Indications for Renal Revascularization

Refractory Hypertension

Data Abstraction Instructions:

Indicate if the patient has refractory hypertension that is resistant to medical treatment.

Selections:

- Yes
- No

Supporting Definitions:

For informational purposes only, having both of the following conditions constitute refractory hypertension:

- BP must be more than 140/90 (if the patient is suffering from diabetes or renal disease, then BP should be more than 130/80)
- Treated with at least 3 drugs (e.g., vasodilator, beta blocker and diuretic therapy).

Required:Yes

Renal Salvage

Data Abstraction Instructions:

Indicate if the patient had an intervention performed to improve renal function or delay the start of dialysis.

Selections:

- Yes
- No

Supporting Definitions:

Emergent/Urgent procedure where patient has extensive renal function loss or in the setting of renal failure.

Required:Yes

Congestive Heart Failure

Data Abstraction Instructions:

Indicate if the patient has documented CHF and it is the indication for the renal intervention.

Selections:

- Yes
- No

Supporting Definitions:

For informational purposes only, CHF can be defined by one of the following criterion:

- Paroxysmal nocturnal dyspnea (PND);
- Dyspnea on exertion (DOE) due to heart failure;
- Chest X-Ray (CXR) showing pulmonary congestion.
- Pedal edema or dyspnea treated with medical therapy for heart failure.
- Elevated serum BNP

Required:

Yes

Transplant Renal Artery Stenosis

Data Abstraction Instructions:

Indicate if the patient has iliac artery stenosis proximal to a transplanted kidney, at the anastomosis of the transplanted renal artery to the external iliac artery, or if the stenosis is within the transplanted renal artery.

Selections:

- Yes
- No

Required:

Yes

Fibromuscular Dysplasia

Data Abstraction Instructions:

Indicate if the procedure is being performed due to FMD (Fibromuscular Dysplasia).

Selections:

- Yes
- No

Required:

Yes

Complication from Prior Procedure

Data Abstraction Instructions:

Indicate if the patient had a complication from a prior procedure

Selections:

- Yes
- No

Supporting Definitions:

The patient had a dissection, perforation or another complication from a prior procedure (such as a cardiac or pulmonary angiogram) that required vascular repair (Percutaneous or Surgical).

Required:

Yes

Trauma

Data Abstraction Instructions:

Indicate if the vascular procedure was performed to repair injury that resulted from trauma (motor vehicle accident, fire, fall etc.).

Selections:

- Yes
- No

Required:

Yes

Procedure Details

Inclusion to the PVI database:

- Endovascular interventions to all arteries on the artery map, except for carotids.
- Endovascular interventions for the indication of:
 - Abdominal aortic stenosis
 - Peripheral aneurysm repair
 - Pseudoaneurysm repair
 - Trauma
- Endovascular interventions for
 - Renal revascularization
 - Mesenteric revascularization
 - FMD diagnosis
- Procedures that resulted from a complication from a prior or current procedure
- All procedures where a sheath was placed, and intervention was attempted, even if the lesion was not able to be crossed with either a wire or device.
- Any endovascular procedure that occurred during a surgical procedure (defined as a hybrid procedure)

Please note: every new lab visit is a new procedure, including procedures that are staged.

Exclusion to the PVI database:

- Any venous procedures
- Carotid artery procedures
- Abdominal Aneurysm repairs at any location, distal, mid, or thoracic
- Lytic infusion as a standalone procedure
- Embolectomy as a standalone procedure
- Fistulas or dialysis grafts
- Thoracic region stenting (pulmonary arteries)
- Patch angioplasty standalone procedures
- Coiling or embolization procedures
- Surgical repairs as standalone procedures
- Endovascular procedures where the sheath was unable to be inserted

Hybrid Procedure

Data Abstraction Instructions:

Indicate if there was a planned combination of angioplasty and surgery. The plan can be developed prior to the procedure or after the initial angiogram. The angiogram or surgical procedure should NOT be a result of a complication of a prior PVI.

Selections:

- Yes
- No

Supporting Definitions:

Hybrid can include a PVI and open surgical procedure within the same setting or can include a PVI procedure and an open surgical procedure within the same hospitalization. An open surgical procedure is one in which significant blood loss is possible.

NOTE: All amputations within the hospitalization are considered hybrid.

Required:

No

Contrast Types

Data Abstraction Instructions:

Enter the type of contrast that was used during the procedure. Select all that apply.

Selections:

- Nonionic, low-osmolar
- Nonionic, Iso-osmolar
- Ionic, hyperosmolar
- Ionic, low-osmolar
- Unknown/Investigational contrast agent
- Gadolinium
- Carbon Dioxide (CO2)
- None

Supporting Definitions:

Commonly used Contrast Agents

- Nonionic low-osmolar
 - Omnipaque, Isovue, Optiray, Ultravist, Oxilam
- Nonionic Iso-osmolar
 - Visipaque
- Ionic, hyperosmolar
 - Hypaque, Conray
- Ionic, low-osmolar
 - Hexabrix
- Unknow/Investigational contrast agent
- Gadolinium
- Carbon Dioxide (CO2)

Required:

Yes

Total IV Contrast Used

Data Abstraction Instructions:

Indicate the volume of contrast (ionic & non-ionic) used in milliliters (ml). The volume recorded should be the total volume for the lab visit. This should be the total between the start of procedure and end of procedure. If half dose contrast was used during the procedure, record only the dose of the contrast given, not the total volume. If CO2 contrast is used, do not include the volume of CO2 used in the total contrast.

Selections:

- Yes
 - Enter value in ml
- Not documented

Supporting Definitions:

If >500 ml of contrast was used, enter 500.

Required:

Yes

Suffix:

ml

Minimum:

0

Maximum:

500

Heparin Administered

Data Abstraction Instructions:

Record if heparin was given, and if yes, the total dose(s)/bolus(es) of unfractionated heparin units that were given during the procedure. If heparin was given and you cannot find documentation of the dose given, enter not documented.

Selections:

Heparin Administered

- Yes
 - Total Heparin Dosage
 - Documented
 - Enter value in units
 - Not documented
- No

Supporting Definitions:

Do not include heparin drip doses in this value. Include only the bolus doses.

Required:

Yes

Suffix:

units

Maximum:

40000

Peak Intra Procedure Activated Clotting Time (ACT)

Data Abstraction Instructions:

Indicate the peak intraoperative ACT in seconds.

Selections:

- Yes
 - Enter value in seconds
- Not documented

Supporting Definitions:

Activated clotting time (ACT) should be measured after the heparin IV bolus is given. In long cases, as clinically indicated, additional heparin boluses may be given, and subsequent ACT measurements may be done. The ACT recorded here must be done during, NOT at the end of the procedure. There must be some part of the intervention procedure performed after the ACT value for it to qualify for peak ACT. Record highest measurement of ACT (peak) in seconds. Enter "Not documented" if peak ACT or clotting measurement was not drawn/document in the patient record.

Required:

Yes

Suffix:

seconds

Maximum:

600

End of procedure ACT

Data Abstraction Instructions:

Record the activated clotting time (ACT) at the conclusion of the procedure while the patient is still in the procedure area.

Selections:

- Yes
 - Enter value in seconds
- Not documented

Required:

Yes

Suffix:

seconds

Minimum:

50

Maximum:

600

Locations

Each procedure type can have one or many locations. In the case of a PVI procedure, there will always be locations.

Vessel Location

Data Abstraction Instructions:

Indicate vessel location of the procedure.

Selections:

Choose Vessel Location from the drop down list

Required:

Yes

Lesion Segment Area

Data Abstraction Instructions:

Identify if the lesion is proximal, mid, distal, or diffuse. If the lesion treated involves more than one segment, check diffuse. E.g., proximal and mid.

Selections:

- Proximal
- Mid
- Distal
- Diffuse
- Not documented

Required:

Yes

PVI Procedure Performed

Data Abstraction Instructions:

Indicate the PVI procedure performed. Select all that apply.

Selections:

- Aspirational Atherectomy (JetStream, Pathways) = Asp-Ather
- Mechanical Thrombectomy (Angiojet) – M-Throm
- Balloon = BA
- Cryoballoon = Cryo-B
- CTO device = CTO
- Cutting Balloon = CB
- Directional Atherectomy (Fox hollow, SilverHawk) = D-Ather
- Distal Protection Device (balloon) = DPD-B
- Distal Protection Device (filter) = DPD-F
- Drug Coated Balloon = DCB
- Flow-wire = FW
- Infusion Catheter (Benephit) = Inf-Cath
- IVUS = IVUS (Intravascular Ultrasound)
- Laser Atherectomy (Excimer laser) = L-Ather
- Lysis (Note: do not record lysis only procedures). Select this box if lytic agents were used during the procedure in addition to any other device. Do not record procedures if only angiojet or fogarty catheter was used.) = LYS
- Not crossed with a device = ND
- Not crossed with a wire = NW
- Other Atherectomy (ClearPath) = Oth-Ather
- Open Endarterectomy
- Open Thrombectomy
- Rotational/Orbital Atherectomy (DiamondBack) = R-Ather
- Re-Entry Catheter (Pioneer, Outback) = Re-Ent-Cath
- Research (whether the procedure was done for research purpose only) = Research

- Scoring Balloon (Angiosculpt) = S-BA
- Stent = STNT
- Thrombus Aspiration (Pronto, Export, Aspire, Diver, Xtract, Fetch, QuickCat) – Throm-Asp
- Vascular Embolectomy = Vasc-E (Fogarty)

Required:

Yes

Bypass Graft

Data Abstraction Instructions:

Indicate if the PVI procedure is performed on an arterial bypass graft.

Selections:

- Yes
- No

Required:

Yes

Graft Type

Data Abstraction Instructions:

Select the type of bypass graft: synthetic or vein.

Selections:

- Synthetic
- Vein
- Not Documented

Required:

Yes

Graft Origin

Data Abstraction Instructions:

Select the bypass graft origin (inflow) using the vessel drop down box.

Selections:

- Select artery name from the drop down list

Required:

Yes

Graft Insertion

Data Abstraction Instructions:

Select the bypass graft insertion (outflow) using the vessel drop down box.

Selections:

- Select artery name from the drop down list

Required:

Yes

Lesion Length

Data Abstraction Instructions:

Visual estimate of the length of the lesion. If not dictated, use balloon/stent length. For tandem lesions, add lengths together. For diffuse disease use the length of the treated segment.

Selections:

- Enter value in mm

Required:

No

Suffix:

mm

Minimum:

0

Maximum:

1000

Heavy Calcium

Data Abstraction Instructions:

Indicate if moderate to heavy calcium is documented as being present in the lesion.

Selections:

- Yes
- No

Required:Yes

In-stent Restenosis

Data Abstraction Instructions:

Indicate if the lesion that is being treated is within a previously place stent.

Selections:

- Yes
- No

Required:Yes

Thrombus

Data Abstraction Instructions:

Indicate if thrombus is present before the PVI intervention. Thrombus is suggested by certain angiographic features: haziness, reduced contrast density or contrast persistence, irregular lesion contours or globular filling defects.

Selections:

- Yes
- No

Required:Yes

Pre Stenosis % (0-100)

Data Abstraction Instructions:

Record the preprocedural percent of stenosis for each segment treated. If a range is given, take the highest value. If unavailable, choose not documented.

Selections:

- Yes
 - Enter value (0 - 100)
- Not documented

Required:

Yes

Suffix:

%

Maximum:100

Post Stenosis % (0-100)

Data Abstraction Instructions:

Record the postprocedural percent of stenosis for each segment treated. If a range is given, take the lowest value. If not recorded, choose not documented.

Selections:

- Yes
 - Enter value (0 - 100)
- Not documented

Required:

Yes

Suffix:

%

Maximum:100

Final Balloon Diameter

Data Abstraction Instructions:

Indicate the diameter, in millimeters, of the final balloon used to treat this lesion. If not recorded, enter not documented.

Selections:

- Yes
 - Enter value in mm

- Not documented

Required:

Yes

Suffix:

millimeters

Minimum:

1.5

Maximum:

30

Stents

Stent Name

Data Abstraction Instructions:

Select the brand name of the stent used in the PVI procedure from the drop down list.

Other = The name of the stent is not in the list.

Selections:

- Choose stent name.

Required:

Yes

Stent Diameter

Data Abstraction Instructions:

Enter the diameter of the stent.

Selections:

- Enter Stent Diameter in mm

Required:

Yes

Suffix:

mm

Minimum:

2

Maximum:

30

Stent Length

Data Abstraction Instructions:

Enter the length of the stent.

Selections:

- Enter Stent Length in mm

Required:

Yes

Suffix:

mm

Minimum:

1

Maximum:

250

Vascular Access

Vascular Access Site(s)

Data Abstraction Instructions:

Indicate location of vascular access.

Selections:

- Select artery from the drop down list

Required:

Yes

Vascular Access Type

Data Abstraction Instructions:

Indicate vascular access type.

Percutaneous = vascular access obtained via skin puncture without direct visualization of artery.

Surgical cutdown = access via skin incision with direct visualization of the underlying structures.

Selections:

- Percutaneous
- Surgical Cutdown

Required:

Yes

Vessel Accessed

Data Abstraction Instructions:

Indicate if the native artery or bypass graft was accessed for the current procedure.

Selections:

- Native Artery
- Bypass Graft

Required:

Yes

Access Guidance

Data Abstraction Instructions:

Indicate if guidance was used for vascular access. If both are utilized, select ultrasound.

Selections:

- Yes
 - Fluoro
 - Ultrasound
- No

Required:

Yes

Access Approach

Data Abstraction Instructions:

Enter the sheath direction at site of insertion. If more than one access was attempted, record the access approach that was used to gain access rather than the failed access approach.

Both = the sheath was utilized in both the retrograde and antegrade direction at the same insertion site.

Selections:

- Antegrade
- Retrograde
- Both

Required:

Yes

Sheath Size

Data Abstraction Instructions:

Indicate the largest size of the sheath placed during the procedure. Include sheaths placed at the end of the procedure.

Selections:

- Enter value (French)

Required:

Yes

Suffix:

French

Minimum:

3

Maximum:

30

Sheath Removed

Data Abstraction Instructions:

Indicate if the sheath was removed by the physician, nurse, technician, or advanced practice professional (NP or PA). In cases of manual removal, indicate the person responsible for holding pressure.

In lysis procedures in which the sheath is left in at the end of the procedure, select yes for "Sheath Removed" and indicate the timeframe/method of eventual removal.

Selections:

- Yes
- No

Supporting Definitions:

Answering "Yes" to this field triggers the 3 following conditional fields: Vascular Closure Type, Failed Closure, and Sheath Removal Time Post Procedure.

Required:

Yes

Vascular Closure Type

Data Abstraction Instructions:

Indicate the arterial closure methods used regardless of whether or not they provided hemostasis. Note: If more than one vascular closure type per access site was used, select all that were used.

Selections:

- Manual: no device or a mechanical type was used, e.g., manual pressure by the personnel pulling the sheath.
- Perclose
- Angioseal
- Mynx
- Starclose
- Surgical
- Exoseal
- Compression Device (i.e.: Femstop, C Clamp, TR Band)
- Boomerang
- Hemostatic Patch
- FISH
- Vascade

Supporting Definitions:

Conditional on "Yes" indicated for Sheath Removed

Required:

Yes

Sheath Removal Time

Data Abstraction Instructions:

Indicate time between end of procedure and sheath removal.

Selections:

- 0-3 hours
- 3-24 hours
- >24 hours

Supporting Definitions:

Conditional on "Yes" indicated for Sheath Removed

Required:

Yes

Outcomes During Procedure

Death/Cause (ODP)

Data Abstraction Instructions:

Indicate if the patient died in association with this procedure while in the lab/OR. If yes, indicate cause of death.

Selections:

- Yes
 - Cardiovascular (includes: AMI, bleed, stroke, cardiogenic shock)
 - Hemorrhage
 - Multisystem Organ Failure (includes acute lung injury and systematic inflammatory response system)
 - Other (include neurologic, renal, liver, GI, cancer)
 - Unknown cause of death
- No

Supporting Definitions:

Select no if the patient was alive throughout the procedure.

Required:

Yes

Dissection (Not Repaired) (ODP)

Data Abstraction Instructions:

Indicate if there was a dissection that was clinically significant (causing a decrease in blood flow) or residual blood flow limiting dissection at the intervention/procedure site.

Selections:

- Yes
- No

Supporting Definitions:

The appearance of contrast material outside the expected luminal dimensions of the target vessel and extending longitudinally beyond the length of the lesion. If the dissection is successfully treated with, e.g., angioplasty or stent, then it should not be considered as a complication. It would be considered a complication if the patient has a dissection identified during a return trip to the lab.

Required:

Yes

Embolus (ODP)

Data Abstraction Instructions:

Indicate if the patient is identified to have an embolus during the procedure. If yes, indicate if it was treated successfully.

Selections:

- Yes
 - Successful
 - Unsuccessful
- No

Supporting Definitions:

An embolus (comprised of atherosclerotic debris and / or blood clot) moves through the blood vessels until it reaches a vessel that is too small to let it pass. When this happens, the blood flow is stopped by the **embolus**.

Required:

Yes

Thrombus (ODP)

Data Abstraction Instructions:

Indicate if a blood clot formed during the procedure, within the treated vessel, which limits distal flow. Do not include any thrombus that was present at the beginning of the procedure.

Selections:

- Yes
- No

Required:

Yes

Stent/Graft Thrombosis (ODP)

Data Abstraction Instructions:

Indicate if a blood clot formed within the stent/graft during the procedure that limits distal blood flow. If yes, indicate if it was treated successfully. If yes, indicate if it was treated successfully.

Selections:

- Yes
 - Successful
 - Unsuccessful
- No

Required:

Yes

Vessel Perforation (ODP)

Data Abstraction Instructions:

Indicate if there was a vessel perforation during the procedure. If yes, indicate if it was treated successfully.

Selections:

- Yes

- o Successful
 - Balloon
 - Covered stent
 - Bare metal stent
 - External compression
 - Reversal of anticoagulation
 - No treatment
- o Unsuccessful
- No

Supporting Definitions:

A perforation occurs when there is angiographic or clinical evidence of a dissection or intimal tear that extends through the full thickness of the arterial wall, distant from the access site caused by device manipulation. Extravasations of contrast beyond vessel wall is usually seen.

Required:

Yes

TIA/Stroke (ODP)**Data Abstraction Instructions:**

Indicate if there was abrupt loss of neurological function with complete return of function within 24 hours or loss of neurological function caused by an ischemic event that is severe enough to leave a persistent deficit for greater than 24 hours. The symptoms should begin while the patient is in the procedure area.

Selections:

- Yes
- No

Required:

Yes

Transfusion (ODP)**Data Abstraction Instructions:**

Indicate if the patient received any transfusion for any reason during the procedure. If yes, select the type of transfusion: PRBC, Whole blood, Platelets, FFP, Other e.g., Cryoprecipitate, Factor VIII infusion. Select all that apply.

Selections:

- Yes
 - Select type of transfusion
 - o PRBC
 - if yes, Enter the number of units for PRBC's (enter # of packed red blood cells 1, 2, 3, etc.)
 - o Platelets
 - o FFP
 - o Other
- No

Supporting Definitions:

NOTE: Return of cell saver product is not captured as a transfusion.

Required:

Yes

Minimum:

1

Maximum:

20

Vascular Access Complications (ODP)**Data Abstraction Instructions:**

Indicate vascular complications at the access site requiring transfusion, prolonged hospital stay, causing a drop in hemoglobin 3.0 gm/dl, or any access site complications requiring surgical repair. Select all that apply.

Retroperitoneal hematoma = bleeding into the anatomical space located behind the abdominal or peritoneal cavity.

Pseudoaneurysm = the occurrence of a disruption and dilation of the arterial wall without identification of the arterial wall layers at the site of the catheter entry demonstrated by arteriography or ultrasound.

Hematoma at access site = blood loss at the site of arterial or venous access due to perforation of a traversed artery or vein that causes at one or more of the following:

- transfusion
- prolonged hospital stay
- drop in hemoglobin > 3.0 gm/dl

Bleeding at access site = Blood loss associated with decreased Hgb (greater than or equal to 3.0 gm/dl) and/or causes an increased length of hospital stay. Without other obvious source (GI, GU, operative, or hemolysis) that is attributable to intraprocedural blood loss (e.g., during equipment changes) should be considered bleeding at the access site even if no hematoma is palpable or documented on imaging studies.

AV fistula = A connection between the access artery and the accompanying vein that is demonstrated by arteriography or ultrasound and most often characterized by a continuous bruit.

Acute thrombosis = Total obstruction of the artery by thrombus most commonly at the site of access.

Surgical repair of the vascular access site = such as surgical closures, exploration of the arteriotomy site, balloon angioplasty or covered stent (JOMED GraftMaster) placement to deal the arterial tear.

Other = a vascular access complication that is not in this list.

Selections:

- Yes
 - Retroperitoneal hematoma
 - Pseudo-aneurysm
 - Hematoma at access site
 - Bleeding at access site
 - AV fistula
 - Acute thrombosis
 - Surgical repair of the vascular access site
 - Other
- No

Required:

Yes

Vascular Surgery Emergent (ODP)

Data Abstraction Instructions:

Indicate if the patient needed to go to the operating room immediately from intervention room or conversion to an unplanned open procedure.

Selections:

- Yes
 - Artery Rupture
 - Access Site Complication
 - Bleeding
 - Bowel Ischemia
 - Limb Ischemia
 - Thrombosis/Embolus
 - Conversion to Open Procedure
 - Other
- No

Supporting Definitions:

The procedure may include any of the following:

- dissection of artery requiring surgical repair
- embolus or thrombosis not manageable by percutaneous devices
- ischemic leg in lab requiring surgery, device removal, or repair of vascular access complications.

Emergent surgery must be performed to prevent loss of major organ, tissue/limb or life. Do not include staged procedures.

Required:

Yes

Amputation (ODP)

Data Abstraction Instructions:

Indicate if an amputation is performed at any time during the procedure.

Selections:

Selections:

- Yes
 - Select type of amputation
 - Left hip disarticulation
 - Left AKA
 - Left BKA
 - Left foot
 - Left metatarsal
 - Left digit
 - Right hip disarticulation
 - Right AKA
 - Right BKA
 - Right foot
 - Right metatarsal
 - Right digit
- No

Required:
Yes

Compartment Syndrome (ODP)

Data Abstraction Instructions:

Indicate if the patient was determined to have compartment syndrome at any time during the procedure. This is defined as compression of nerves and blood vessels within an enclosed space which leads to muscle and nerve damage and problems with blood flow.

Selections:

- Yes
- No

Supporting Definitions:

Required:
Yes

Outcomes Post Procedure

All outcomes from the end of the procedure through discharge are captured here. In discharges with multiple procedures, outcomes should be included on the procedure they follow so the record reads like a book.

Death/Cause (OPP)

Data Abstraction Instructions:

Indicate if the patient died in association with this hospitalization. If yes, indicate cause of death.

Selections:

- Yes
 - Cardiovascular (includes: AMI, bleed, stroke, cardiogenic shock)
 - Hemorrhage
 - Multi System Organ Failure (includes acute lung injury, and systemic inflammatory response system)
 - Other (include neurologic, renal, liver, GI, cancer)
 - Unknown cause of death
- No

Supporting Definitions:

Select no if the patient was alive throughout the hospitalization.

Required:
Yes

Comfort care measures implemented (OPP)

Data Abstraction Instructions:

Indicate if care was withdrawn or comfort care measures were implemented prior to death. If so, indicate the date.

Selections:

- Yes
 - Enter date
- No

Required:
Yes

Myocardial Injury (OPP)

Data Abstraction Instructions:

Indicate if the patient suffered any type of myocardial injury post procedure, including an Acute Myocardial Injury, Type 2 myocardial infarction, Type 1 NSTEMI or STEMI. If Yes is entered, indicate the date of the first elevated troponin value and the peak troponin value. **The peak troponin value should be obtained within 30 days of the procedure.**

Selections:

- Yes
 - Enter date of first occurrence post procedure _____
 - Enter type of injury:
 - Acute Myocardial Injury
 - Type 2 Myocardial Infarction
 - Type 1 NSTEMI
 - STEMI
 - Not documented
- No

Supporting Definitions:

Myocardial ischemia = The patient has one or more of the following:

- Chest pain
- Nausea
- Shortness of breath
- new ischemic EKG changes (S-T elevations, S-T depression, pathological Q waves)
- An Echo/MRI/Stress test that is positive for ischemia
- Thrombus seen on angiogram or autopsy

Acute Myocardial Injury = Elevated cardiac troponin value(s) greater than the 99th percentile URL (upper reference limit) with a rise and/or fall in troponin **without** myocardial ischemia. Some causes of an Acute Myocardial Injury are hypertension, acute heart failure, or myocarditis.

Type 2 Myocardial Infarction = Elevated cardiac troponin value(s) greater than the 99th percentile URL (upper reference limit) with a rise and/or fall in troponin **with** myocardial ischemia. With Type 2 Myocardial Infarction, a supply and demand imbalance is causing a stressor to the heart. Some causes of Type 2 Myocardial Infarction are severe hypertension, sustained tachyarrhythmias, hemorrhagic shock/anemia, sepsis, pulmonary embolism, hypoxia, respiratory failure, or heart failure.

Type 1 NSTEMI (Non-ST Elevation Myocardial Infarction) = Elevated cardiac troponin value(s) greater than the 99th percentile URL with a rise and/or fall in troponin **with** myocardial ischemia related to atherosclerotic plaque disruption, which causes a complete or partial blockage in the coronary artery. The EKG during an NSTEMI will not show ST elevations.

STEMI (ST Elevation Myocardial Infarction) = Elevated cardiac troponin value(s) greater than the 99th percentile URL with a rise and/or fall in troponin **with** myocardial ischemia related to atherosclerotic plaque disruption, which causes a complete or partial blockage in the coronary artery. The patient having a STEMI will develop new ST-segment elevations in 2 contiguous leads or new bundle branch blocks with ischemic repolarization patterns.

Not documented = The type of injury is not documented, or there is not sufficient information recorded to determine what type of injury the patient suffered.

No =

- A single abnormal troponin value was found without other criteria for myocardial injury.
- Troponins are elevated but stable (no rise and/or fall).
- The patient did not suffer a myocardial injury post procedure.

Reference: Thygesen, K., Alpert, J. S., Jaffe, A. S., Chaitman, B. R., Bax, J. J., Morrow, D. A., White, H. D., & The Executive Group on behalf of the Joint European Society of Cardiology (ESC)/American College of Cardiology (ACC)/American Heart Association (AHA)/World Heart Federation (WHF) Task Force for the Universal Definition of Myocardial Infarction. (2018, November 13). *Fourth Universal Definition of Myocardial Infarction (2018)*. Fourth universal definition of myocardial infarction (2018). Retrieved August 22, 2022, from <https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000000617>

Required:

Yes

Peak post-operative troponin value**Data Abstraction Instructions:**

Indicate the peak value and type of troponin drawn within 30 days post procedure.

Selections:

Peak post-operative troponin

- Yes
 - troponin I
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No
 - troponin T
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No

- o troponin I HS
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No
- o troponin T HS
 - Yes
 - Enter lab value _____
 - Pick unit of lab value from list
 - ng/dL
 - ng/mL
 - ng/L
 - pg/mL
 - No

- Not Drawn

Required:

Yes

Dysrhythmia (OPP)**Data Abstraction Instructions:**

Indicate if there was a new rhythm disturbance post procedure, requiring treatment with medications or cardioversion.

Selections:

- Yes
- No

Required:

Yes

Congestive Heart Failure (CHF) (OPP)**Data Abstraction Instructions:**

Indicate if it was documented that the patient had new onset or exacerbation of CHF post procedure.

Selections:

- Yes
- No

Supporting Definitions:

Heart failure is defined as physician documentation or report of any of the following clinical symptoms of heart failure described as unusual dyspnea on light exertion, recurrent dyspnea occurring in the supine position, fluid retention, or the description of rales, jugular venous distension, pulmonary edema on physical exam, or pulmonary edema on chest x-ray. A low ejection fraction alone, without clinical evidence of heart failure, does not qualify as heart failure.

Required:

Yes

TIA/Stroke (OPP)**Data Abstraction Instructions:**

Indicate if there was abrupt loss of neurological function with complete return of function within 24 hours or loss of neurological function caused by an ischemic event that is severe enough to leave a persistent deficit for greater than 24 hours.

Selections:

- Yes
- No

Required:

Yes

Infection/Sepsis (OPP)**Data Abstraction Instructions:**

Positive cultures requiring treatment with antibiotics. Do not include patients that are placed on antibiotics during a hospitalization with no positive cultures.

Pneumonia may be indicated when evidenced on CXR (lobar infiltrate on CXR and/or pure growth of recognized pathogen or 4+ growth of recognized pathogen in presence of mixed growth) and treatment with antibiotics, even without positive culture.

If yes, select all that apply.

Selections:

- Yes
 - o Access site

- o Central Line/IV
- o Blood
- o Graft infection
- o Pulmonary
- o UTI
- o Wound site
- o Unknown
 - Enter date of first occurrence post procedure (date of first positive culture)

- No

Required:

Yes

New Requirement for Dialysis (OPP)

Data Abstraction Instructions:

Indicate if the patient had acute or worsening renal failure, post procedure, which led to dialysis during the hospitalization.

Selections:

- Yes
- No

Required:

Yes

Transfusion (OPP)

Data Abstraction Instructions:

Indicate if the patient received any transfusion for any reason post procedure. If yes, select the type of transfusion: PRBC, Whole blood, Platelets, FFP, Other e.g., Cryoprecipitate, Factor VIII infusion. Select all that apply.

Selections:

- Yes
 - Select type of transfusion
 - o PRBC, if yes, # units for PRBC's (enter # of packed red blood cells 1, 2, 3, etc.)
 - o Platelets
 - o FFP
 - o Other
 - Enter date of first occurrence post procedure
- No

Required:

Yes

Minimum:

1

Maximum:

20

Hemoglobin prior to Transfusion (OPP)

Data Abstraction Instructions:

Enter the hemoglobin value drawn prior to the first Transfusion of PRBC's post procedure. This is the value on which they made the decision to transfuse.

Selections:

- Yes
- No
- Not Documented

Required:

Yes

Suffix:

mg/dL

Soft Minimum:

2

Soft Maximum:

20

Vascular Access Complications (OPP)

Data Abstraction Instructions:

Indicate vascular complications at the access site requiring transfusion, prolonged hospital stay, causing a drop in hemoglobin 3.0 gm/dl, or any access site complications requiring surgical repair. Select all that apply.

Retroperitoneal hematoma = bleeding into the anatomical space located behind the abdominal or peritoneal cavity.

Pseudoaneurysm = the occurrence of a disruption and dilation of the arterial wall without identification of the arterial wall layers at the site of the catheter entry demonstrated by arteriography or ultrasound.

Hematoma at access site = blood loss at the site of arterial or venous access due to perforation of a traversed artery or vein that causes at one or more of the following:

- transfusion
- prolonged hospital stay
- drop in hemoglobin > 3.0 gm/dl

Bleeding at access site = Blood loss associated with decreased Hgb (greater than or equal to 3.0 gm/dl) and/or causes an increased length of hospital stay. Without other obvious source (GI, GU, operative, or hemolysis) that is attributable to intraprocedural blood loss (e.g., during equipment changes) should be considered bleeding at the access site even if no hematoma is palpable or documented on imaging studies.

AV fistula = A connection between the access artery and the accompanying vein that is demonstrated by arteriography or ultrasound and most often characterized by a continuous bruit.

Acute thrombosis = Total obstruction of the artery by thrombus most commonly at the site of access.

Surgical repair of the vascular access site = such as surgical closures, exploration of the arteriotomy site, balloon angioplasty or covered stent (JOMED GraftMaster) placement to deal the arterial tear.

Other = a vascular access complication that is not in this list.

Selections:

- Yes
 - Retroperitoneal hematoma
 - Pseudo-aneurysm
 - Hematoma at access site
 - Bleeding at access site
 - AV fistula
 - Acute thrombosis
 - Surgical repair of the vascular access site
 - Other
- No

Required:

Yes

Compartment Syndrome (OPP)

Data Abstraction Instructions:

Indicate if the patient was determined to have compartment syndrome at any time post procedure.

Selections:

- Yes
- No

Supporting Definitions:

Compartment syndrome is defined as compression of nerves and blood vessels within an enclosed space which leads to muscle and nerve damage and problems with blood flow.

Required:

Yes

Embolus (OPP)

Data Abstraction Instructions:

Indicate if the patient is identified to have an embolus post procedure. If yes, indicate if it was treated successfully.

Selections:

- Yes
 - Successful
 - Unsuccessful
- No

Supporting Definitions:

An embolus (comprised of atherosclerotic debris and / or blood clot) moves through the blood vessels until it reaches a vessel that is too small to let it pass. When this happens, the blood flow is stopped by the embolus. This occurs after exiting the procedure area.

Required:

Yes

Thrombus (OPP)

Data Abstraction Instructions:

Indicate if a blood clot formed, post procedure, within the treated vessel, which limits distal flow.

Selections:

- Yes
- No

Supporting Definitions:

Do not include any thrombus that was present at the beginning of the procedure. If the thrombus formed within a stent of graft, select the outcome "Stent/graft thrombosis" and do not select thrombus.

Required:

Yes

Stent/Graft Thrombosis (OPP)

Data Abstraction Instructions:

Indicate if a blood clot formed within the stent/graft that limits distal blood flow. If yes, indicate if it was treated successfully.

Selections:

- Yes
 - Successful
 - Unsuccessful
- No

Required:

Yes

Vascular Surgery Emergent (OPP)

Data Abstraction Instructions:

Indicate if the patient needed to go to the operating room post procedure through 12 hours post procedure for an unplanned open procedure. If yes, select reason for surgery.

Selections:

- Yes
 - Artery rupture
 - Access Site Complication
 - Bleeding
 - Bowel Ischemia
 - Limb Ischemia
 - Thrombosis/Embolus
 - Conversion to Open Procedure
 - Other
- No

Supporting Definitions:

This procedure may include any of the following:

- dissection of artery requiring surgical repair, embolus or thrombosis not manageable by percutaneous devices
- ischemic leg in procedure area requiring surgery
- device removal, and repair of vascular access complications.

Emergent surgery must be performed to prevent loss of major organ, tissue/limb, or life. Do not include staged procedures.

Required:

Yes

Vascular Surgery Non Emergent (OPP)

Data Abstraction Instructions:

Indicate if the patient had any elective vascular surgery procedure that occurs any time from 12 hours post PVI intervention to discharge or death. Include hybrid procedures or vascular surgery performed for revascularization after failed percutaneous interventions.

If an amputation is performed post procedure, enter No for Vascular Surgery Non Emergent.

Selections:

- Yes
- No

Required:

Yes

Amputation (OPP)

Data Abstraction Instructions:

Indicate if an amputation is performed at any time post procedure. If an amputation is performed post procedure, enter No for Vascular Surgery Non Emergent.

Selections:

- Yes
 - Select type of amputation
 - Left hip disarticulation
 - Left AKA
 - Left BKA
 - Left foot

- o Left metatarsal
- o Left digit
- o Right hip disarticulation
- o Right AKA
- o Right BKA
- o Right foot
- o Right metatarsal
- o Right digit
 - Enter date of first occurrence post procedure

- No

Required:
Yes

PVI Follow-up

PVI Follow Up Interval

Data Abstraction Instructions:

Choose the time frame for the Follow Up.

Selections:

- 30 Day
- 6 Month

Required:

Yes

Contact Date

Data Abstraction Instructions:

Enter the date of contact for follow up information. The contact date is when the patient was contacted, came to the clinic, or had a phone call to determine their status

Selections:

- Enter date into the text box.

Required:

Yes

Current Living Status

Data Abstraction Instructions:

Indicate the living status of the patient at the time of follow up. Current Living Status can be obtained through the medical record or a phone call to the patient.

Selections:

- Home
- Nursing Home/Extended Care
- Assisted Living
- In Hospital
- Dead
 - Enter date of death
 - Select cause of death
 - Cardiovascular
 - Procedure related
 - Unknown/other
- Not documented

Required:

Yes

Smoking

Data Abstraction Instructions:

Indicate if the patient is smoking cigars, cigarettes (including electronic cigarettes), chew (tobacco), pipe (tobacco), or marijuana at the time of follow-up. Smoking can be obtained through the medical record or a phone call to the patient.

Selections:

- Yes
- No
- Not documented

Required:

Yes

Antiplatelets

Data Abstraction Instructions:

Indicate if the patient is taking antiplatelets (other than ASA) at the time of the follow up and if there is a contraindication to antiplatelets. Current medications may be obtained from a phone call if the patient is asked to gather their medication bottles and read them.

Selections:

- Yes
- No
 - Contraindicated
 - Yes

- No
- Not documented

Required:Yes

Statin

Data Abstraction Instructions:

Indicate if the patient is taking a statin at the time of the follow up and if there is a contraindication to a statin. Current medications may be obtained from a phone call if the patient is asked to gather their medication bottles and read them.

Selections:

- Yes
- No
 - Contraindicated
 - Yes
 - No
- Not documented

Required:Yes

Aspirin

Data Abstraction Instructions:

Indicate if the patient is taking aspirin at the time of follow up and if there is a contraindication to aspirin. Current medications may be obtained from a phone call if the patient is asked to gather their medication bottles and read them.

Selections:

- Yes
- No
 - Contraindicated
 - Yes
 - No
- Not documented

Required:Yes

Beta Blocker

Data Abstraction Instructions:

Indicate if the patient is taking a beta blocker at the time of follow up and if there is a contraindication to a beta blocker. Current medications may be obtained from a phone call if the patient is asked to gather their medication bottles and read them.

Selections:

- Yes
- No
 - Contraindicated
 - Yes
 - No
- Not documented

Required:Yes

ACE Inhibitor

Data Abstraction Instructions:

Indicate if the patient is taking an ACE Inhibitor at the time of follow up and if there is a contraindication to an ACE Inhibitor. Current medications may be obtained from a phone call if the patient is asked to gather their medication bottles and read them.

Selections:

- Yes
- No
 - Contraindicated
 - Yes
 - No
- Not documented

Required:Yes

Anticoagulant

Data Abstraction Instructions:

Indicate if the patient is taking an Anticoagulant (Coumadin, Pradaxa, etc.) at the time of follow up. Current medications may be obtained from a phone call if the patient is asked to gather their medication bottles and read them.

Selections:

- Yes
- No
- Not documented

Required:

Yes

ARBs (Angiotensin II Receptor Blockers)**Data Abstraction Instructions:**

Indicate if the patient is taking ARBs at the time of follow up. Current medications may be obtained from a phone call if the patient is asked to gather their medication bottles and read them.

Selections:

- Yes
- No
- Not documented

Required:

Yes

Other Cholesterol Lowering Agent**Data Abstraction Instructions:**

Indicate if the patient is taking any other cholesterol lowering agent at the time of follow up, other than statins. Current medications may be obtained from a phone call if the patient is asked to gather their medication bottles and read them.

Selections:

- Yes
- No
- Not documented

Required:

Yes

Repeat Procedure**Data Abstraction Instructions:**

Indicate if the patient was readmitted to the hospital for a repeat procedure. A repeat procedure is defined as an intervention on the same site of the corresponding discharge record. This information should be gathered from a patient's medical record and not from interviewing the patient.

Selections:

- Yes
 - Enter date of occurrence post discharge
- No
- Not documented

Required:

Yes

New Vascular Procedure**Data Abstraction Instructions:**

Indicate if the patient was admitted to the hospital from time of discharge or last follow up to the time of current follow up for a new vascular procedure on a different site than the corresponding discharge record. This information should be gathered from a patient's medical record and not from interviewing the patient.

Selections:

- Yes
 - Surgical
 - Percutaneous
 - Enter date of occurrence post discharge
- No
- Not documented

Required:

Yes

Vascular Access Complication

Data Abstraction Instructions:

Indicate if the patient was readmitted to the hospital for an vascular access site complication. If yes, indicate if an intervention was performed. This information should be gathered from a patient's medical record and not from interviewing the patient.

Selections:

- Yes
 - Intervention
 - No Intervention
 - Enter date of occurrence post discharge
- No
- Not documented

Required:Yes

Thrombectomy/lysis

Data Abstraction Instructions:

Indicate if the patient was readmitted to the hospital for a thrombectomy or thrombolysis. This information should be gathered from a patient's medical record and not from interviewing the patient.

Selections:

- Yes
 - Enter date of occurrence post discharge
- No
- Not documented

Required:Yes

ABIs

Data Abstraction Instructions:

Indicate if the patient has had ABIs measured after discharge, and if so, enter the value. This information should be gathered from a patient's medical record and not from interviewing the patient.

Selections:

- Yes
 - Enter Value for ABIs Right
 - Enter Value for ABIs Left
- No
- Not documented

Required:

Yes

Minimum:

0

Maximum:1.39

TBIs

Data Abstraction Instructions:

Indicate if the patient has had TBIs measured after discharge, and if so, enter the value. This information should be gathered from a patient's medical record and not from interviewing the patient.

Selections:

- Yes
 - Enter Value for TBIs Right
 - Enter Value for TBIs Left
- No
- Not documented

Required:

Yes

Minimum:

0

Maximum:1.39

Toe Pressures

Data Abstraction Instructions:

Indicate if the patient has had toe pressures measured after discharge, and if so, enter the value. This information should be gathered from a patient's medical record and not from interviewing the patient.

Selections:

- Yes
 - Enter Value for Toe Pressure Right
 - Enter Value for Toe Pressure Left
- No
- Not Documented

Required:

Yes

Suffix:

mmHg

Amputation

Data Abstraction Instructions:

Indicate if the patient has had an amputation post hospitalization. If yes, indicate the level of amputation, and the date of first occurrence. Amputation may be obtained through a phone call with the patient.

Selections:

- Yes
 - Left hip disarticulation
 - Left AKA
 - Left BKA
 - Left foot
 - Left metatarsal
 - Left digit
 - Right hip disarticulation
 - Right AKA
 - Right BKA
 - Right foot
 - Right metatarsal
 - Right digit
 - Enter date of occurrence post discharge
- No
- Not documented

Required:

Yes

MI

Data Abstraction Instructions:

Indicate if the patient was readmitted to the hospital for a myocardial infarction post procedure. This information should be gathered from a patient's medical record, not from interviewing the patient.

Enter MI if the patient is diagnosed with Type 2 Myocardial Infarction, Type 1 NSTEMI, or STEMI. If no diagnosis is documented, enter MI if the patient has an elevated cardiac troponin value(s) greater than the 99th percentile URL (upper reference limit) with a rise and/or fall in troponin and at least one of the following:

- Chest pain
- Nausea
- Shortness of breath
- New ischemic EKG changes (S-T elevations, S-T depression, pathological Q waves)
- An Echo/MRI/Stress test that is positive for ischemia
- Thrombus seen on angiogram or autopsy

Reference: Thygesen, K., Alpert, J. S., Jaffe, A. S., Chaitman, B. R., Bax, J. J., Morrow, D. A., White, H. D., & The Executive Group on behalf of the Joint European Society of Cardiology (ESC)/American College of Cardiology (ACC)/American Heart Association (AHA)/World Heart Federation (WHF) Task Force for the Universal Definition of Myocardial Infarction. (2018, November 13). *Fourth Universal Definition of Myocardial Infarction (2018)*. Fourth universal definition of myocardial infarction (2018). Retrieved August 22, 2022, from <https://www.ahajournals.org/doi/epub/10.1161/CIR.0000000000000617>

Selections:

- Yes
 - Enter date of occurrence post discharge
- No
- Not documented

Required:

Yes

TIA/Stroke

Data Abstraction Instructions:

Indicate if the patient was readmitted to the hospital for a TIA or stroke post procedure. This information should be gathered from the patient's medical record and not from interviewing the patient.

Selections:

- Yes
 - Enter date of occurrence post discharge
- No
- Not documented

Required:Yes

Renal Failure/Dialysis

Data Abstraction Instructions:

Indicate if the patient had to be readmitted for renal failure or new dialysis post procedure. This information should be gathered from a patient's medical record and not from interviewing the patient.

Selections:

- Yes
 - Enter date of occurrence post discharge
- No
- Not documented

Required:Yes

Transfusion

Data Abstraction Instructions:

Indicate if the patient has been readmitted and received a transfusion of PRBCs post discharge. This information should be gathered from a patient's medical record and not from interviewing the patient.

Selections:

- Yes
 - Enter date of occurrence post discharge
- No
- Not documented

Required:Yes
