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STANDARDS AND GUIDELINES

SCAI Expert Consensus Statement on Percutaneous Coronary Intervention Without On-Site Surgical Backup

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Although once considered high risk and below the standard of care, percutaneous coronary intervention (PCI) without on-site surgical backup has been performed with acceptable outcomes since the 1980s.[1] An initial consensus document on PCI without surgery on site (SOS) was published by the Society for Cardiovascular Angiography and Interventions (SCAI) in 2007 and updated in 2014.[2,3] The 2014 document summarized new research, reviewed existing guidelines and other publications related to PCI without SOS, and recommended best practices and requirements for facilities performing PCI without SOS. At the time, the research and practice of PCI without SOS were still limited, and as a result, the recommendations for case selection and practice were conservative.

Since the publication of the 2014 consensus statement, same-day discharge after elective PCI has increased to 28.6% of all PCIs and 39.7% of radial PCIs in the United States in 2017.[4] Elective PCI in non-SOS settings has increased in volume and complexity. Concurrently, interventional cardiologists have been performing PCI in office-based laboratories (OBLs) and ambulatory surgery centers (ASCs). Although constituting a small percentage of annual PCI procedures, this setting has garnered increased attention, notably with the 2020 expansion of coverage by the Centers for Medicare and Medicaid Services (CMS) to include PCI in the ASC setting.[5] PCI at ASCs may improve access and patient satisfaction and reduce costs. Several new studies in the United States and abroad have demonstrated that PCIs performed at

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ABBREVIATIONS AND ACRONYMS

ASC = ambulatory surgery center

CABG = coronary artery bypass graft

CMS = Centers for Medicare and Medicaid Services

CPT = Current Procedural Terminology

CTO = chronic total occlusion

MACCE = major adverse cardiovascular and cerebrovascular event(s)

MACE = major adverse cardiovascular event(s)

MI = myocardial infarction

OBL = office-based laboratory

PCI = percutaneous coronary intervention

SCAI = Society for Cardiovascular Angiography and Interventions

SOS = surgery on site

non-SOS centers have very low rates of complications and similar outcomes to PCIs performed with SOS. Moreover, recent consolidation of surgical services within health systems have resulted in some well-established, experienced, and high-quality PCI centers' being restricted from performing complex PCI because of the perceived need for on-site surgery.

Thus, the writing committee has revised the 2014 document to 1) update the available data; 2) reconsider the types of cases that could be undertaken without on-site surgical backup; 3) review data regarding which patients are at higher risk; and 4) recommend patient selection criteria on the basis of patient risk, operator experience, and facility capabilities. Importantly, as PCI without SOS is often the predominant mode of delivery globally, we expanded the document to include international experience, perspectives, and outcomes.

METHODS

This statement has been developed according to SCAI Publications Committee policies for writing group composition, disclosure, management of relationships with industry, internal and external review, and organizational approval.

The writing group was organized to ensure diversity of perspectives and demographics, multistakeholder representation, and appropriate balance of relationships with industry. Relevant author disclosures are included in the Supplemental Appendix. Before appointment, members of the writing group were asked to disclose financial and intellectual relationships from the 12 months prior to their nomination. A majority of the writing group disclosed no relevant, significant financial relationships. Disclosures were periodically reviewed during document development and updated as needed. SCAI policy requires that writing group members with current, relevant financial interests be recused from participating in related discussions or voting on recommendations. The work of the writing committee was supported exclusively by SCAI, a nonprofit medical specialty society, without commercial support. Writing group members contributed to this effort on a volunteer basis and did not receive payment from SCAI.

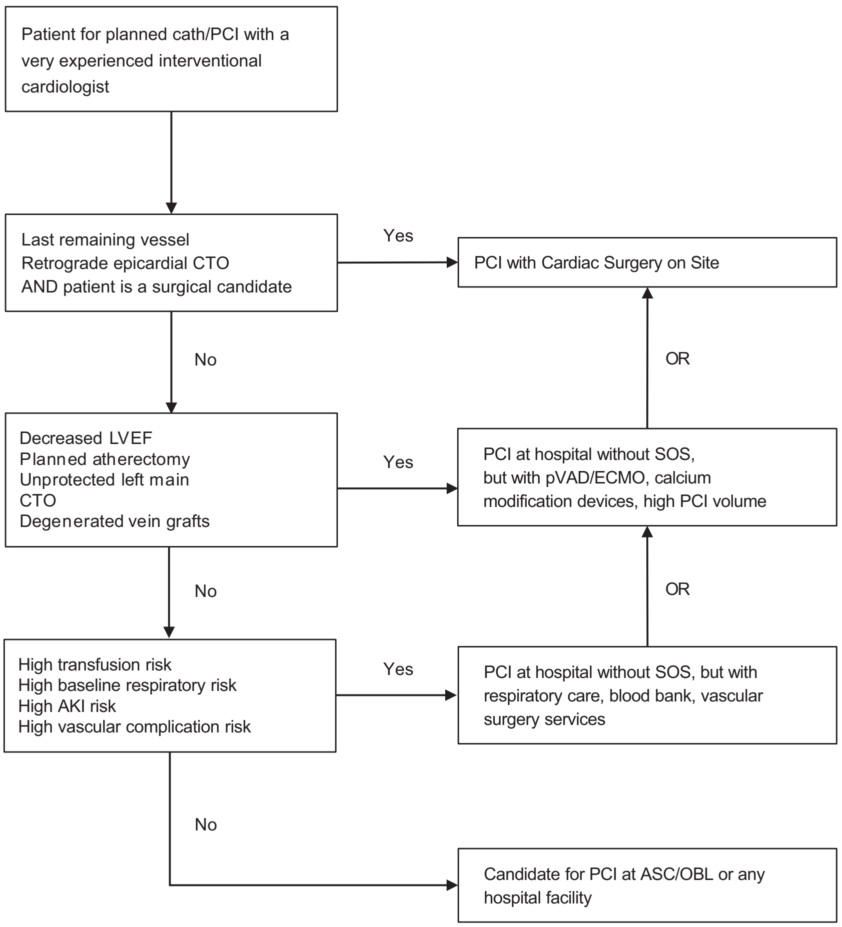
Searches were performed by group members designated to lead each section, and initial section drafts were authored primarily by the section leads in collaboration with other members of the writing group. Recommendations were discussed by the full writing group until a majority of group members agreed on the text and qualifying remarks. All recommendations are supported by a short summary of the evidence or specific rationale.

The draft manuscript was posted for public comment in May 2022, and the document was revised to address

KEY POINTS

- Elective PCI in settings without SOS has increased in volume and complexity (extending beyond the simple lesion recommendations in the 2014 document). In addition, PCI is now being performed outside the hospital setting, in OBLs and ASCs.
- Several new studies in the United States and abroad have demonstrated that PCIs performed at non-SOS centers have very low rates of complications and similar outcomes to PCIs performed at surgical centers.
- Despite increases in age, comorbidities, and lesion complexity, the rate of periprocedural complications has remained constant, or declined, with rates of emergency surgery as low as 0.1% in many series.
- Complex PCI, including unprotected left main, is being performed at some non-SOS centers, with no increase in MACE or emergency CABG surgery compared with PCI at surgical centers. There have been no comparative studies in other complex PCI subgroups, such as CTO and atherectomy, but observational studies demonstrate reasonable outcomes and suggest feasibility with experienced interventional cardiologists.
- The authors propose a new PCI treatment algorithm (**Figure 1**) that expands the type of cases that can be performed without SOS compared with the 2014 document, with consideration of patients' clinical and lesion risk, operator experience (both recent and accumulated), and the experience and rescue capabilities of the site.
- In the United States, there are considerable financial savings (to insurers and Medicare) for PCI to be performed at ASCs and OBLs, so outmigration of procedures from hospitals should be anticipated.

FIGURE 1 Simplified Algorithm for Case Selection for Elective PCI at Different Facilities, Assuming an Experienced Interventional Cardiologist



AKI = acute kidney injury; ASC = ambulatory surgery center; cath = catheterization; CTO = chronic total occlusion; ECMO = extracorporeal membrane oxygenation; LVEF = left ventricular ejection fraction; OBL = office-based laboratory; PCI = percutaneous coronary intervention; pVAD = percutaneous ventricular assist device; SOS = surgery on site.

pertinent comments. The writing group unanimously approved the final version of the document. The SCAI Publications Committee and Executive Committee endorsed the document as official society guidance in November 2022.

SCAI statements are intended primarily to help clinicians make decisions about treatment alternatives. Clinicians also must consider the clinical presentation, setting, and preferences of individual patients to make judgments about the optimal approach.

IMPROVEMENTS IN PCI SAFETY OVER TIME

Advances in procedural techniques, equipment, and pharmacologic treatments have enhanced the safety of PCI over the past decade, despite increasing patient age and comorbidities.[6,7] Coronary anatomical complexity has similarly increased over time as providers embark on revascularization of patients with complex multivessel coronary artery disease according to newer comparative data, surgical ineligibility, or patient preference.[8,9] Despite this increase in complexity, the rate of periprocedural complications has remained constant or declined over the past decade. The National Cardiovascular Data Registry describes static rates of coronary perforations (0.4%) and serious vascular access complications (1.4%) in the most recent years analyzed.[10,11] In the U.S. Department of Veterans Affairs health care system, complication rates continue to decline and remain lower than 1%.[7] The development of multidisciplinary conferences[12] and national peer-review systems[13] may also serve to ensure better case selection and management of complications. Increased use of radial access,[7,11] changes in procedural methods, and improvements in PCI equipment, including physiological assessment and intravascular imaging, may all be associated with this reduction in periprocedural complications. Finally, evolution in the equipment to rescue complications, such as more deliverable covered stents and more widely available mechanical support options, may reduce the need for emergent bypass. Collectively, these advances suggest that percutaneous revascularization can be performed safely with a very low complication rate in the contemporary era.

EMERGENCY CARDIAC SURGERY

Surgical intervention may be required after complications such as coronary perforation with tamponade, aortic root dissection, recurrent acute vessel closure, or retained devices that cannot be managed with percutaneous approaches. The National Cardiovascular Data Registry defines emergency surgery as operative intervention required without delay for patients with ongoing, refractory cardiac compromise unresponsive to therapy other than cardiac surgery.[14]

The rates of emergent bypass performed for a periprocedural complication after PCI have remained extremely low. After randomizing patients to undergo PCI at facilities with or without on-site cardiac surgery, the MASS COMM (Percutaneous Coronary Intervention Outcomes in Community Versus Tertiary Settings) trial demonstrated no difference in the need for emergency surgery, with an incidence of 0.3% vs 0.1%, respectively.[15] Data from the British Cardiovascular Intervention Society between 2006 and 2012 revealed that emergency surgery was required for 0.04% of patients at centers without SOS, compared with 0.1% at centers with SOS.[16] A propensity-matched comparison of nonprimary PCI showed that surgery was performed in 0.5% at centers with surgery and 0.3% at centers without.[17] Furthermore, a meta-analysis encompassing several clinical trials and registries demonstrated a rate of emergent bypass surgery of 0.5%,[18] with more contemporary data from Michigan[17] and the Veterans Affairs health care system[19] suggesting rates <0.1%.

Predictors of Need for Emergency Surgery

Patients presenting acutely, with impaired left ventricular function and cardiogenic shock, are at higher risk for emergency surgery,[20-22] as are female patients and patients with chronic total occlusions (CTOs) and proximal lesions.[23] Other anatomical factors, such as vessel tortuosity and severe calcification, also contribute to risk. Interventions on CTOs, bifurcation lesions, and complex right coronary arteries have been recognized as being higher risk for root dissection, perforation, and need for emergency surgery.[20] From an analysis of the National Inpatient Sample database, risk factors for emergency surgery included complex anatomy, peripheral vascular disease, heart failure, stroke, hypertension, hemodialysis, connective tissue disease, lung disease, and obesity.[21] Scores have been developed to predict the need for emergent surgical support, but even the highest tertile of patients in these scoring systems required emergent surgery in only 0.6% of cases.[21]

Outcomes After Emergency Surgery

Emergency coronary artery bypass graft (CABG) surgery after PCI is associated with high mortality rates, ranging between 7.4% and 21%.[21,22,24,25] U.K. registry data reported in-hospital major adverse cardiovascular and cerebrovascular events (MACCE) of 14%, with a prolonged in-hospital stay of 9 days longer in those surviving surgery.[26] Despite the high perioperative risk for mortality, it appears that survivors have a good long-term prognosis.[22]

Not surprisingly, a longer time to surgery occurred in patients transferred from centers without SOS (306 minutes) compared with those at centers with surgical capability (160 minutes). Paradoxically, despite more rapid emergency CABG at surgical hospitals, the in-hospital mortality rate was 12-fold higher.[22] The explanation for this finding is not clear, but along with patient- and procedure-related factors, it is possible that patients transferred in extremis from non-SOS centers may have died before getting to surgery or that they underwent successful bailout PCI, which may not have been attempted had the surgical option been more readily available. These times to surgery are important considerations as even with SOS, patients with complications must be stabilized sufficiently in the catheterization laboratory with mechanical support to survive the 2 to 3 hours before surgery can be performed.

UPDATED PUBLICATIONS COMPARING PCI AT NON-SOS VS SURGICAL CENTERS

The outcomes of PCI performed at non-SOS centers have been studied in only 2 randomized controlled studies, both of which excluded patients requiring primary PCI or high-risk features such as poor left ventricular function. The CPORT-E trial showed noninferiority of PCI at hospitals without SOS compared with surgical centers at 6 weeks and 9 months.[27] As described previously, the MASS COMM trial showed no significant differences in the rates of death, myocardial infarction (MI), repeat revascularization, and stroke between the 2 hospital settings.[15]

A meta-analysis of 23 studies comparing PCI outcomes at centers with and without on-site surgical backup including 1,101,123 patients was published in 2015.[18]

TABLE 1 Studies of Nonprimary PCI at Centers Without SOS Published Since 2014

	Study Type	Number of Patients	Mortality	EmCABG	Comments
Lee et al (2015)[18]	Meta-analysis: 4 RCTs, 19 registries	Non-SOS = 58,670 SOS = 908,879	1.6% 2.1%	0.5% 0.8%	No difference in death (OR: 1.15; 95% CI: 0.94-1.41), EmCABG (OR: 1.14; 95% CI: 0.62-2.13), CVA, reMI, or tamponade
Garg et al (2015)[16]	UK registry, 2006-2012 (79% SA or NSTEMI)	Non-SOS = 119,096 SOS = 264,917	0.3% SA, 1.6% NSTEMI 0.4% SA, 1.7% NSTEMI	0.04% 0.1%	Lower rates of EmCABG at non-SOS centers ($P < 0.001$); no difference in death; 3-fold increase in non-SOS cases
Akasaka et al (2017)[32]	3,241 patients with ACS from the Kumamoto Intervention Conference Study (Japan)	Non-SOS = 477 SOS = 2,764	2.9% 3.7%	0% 0.1%	No difference in in-hospital mortality, cardiac death, nonfatal MI, or stroke; greater re-PCI at SOS centers for culprit vessels (12.9% vs 8.4%) and nonculprit vessels (7.1% vs 4.6%) compared with non-SOS centers
Goel et al (2017)[30]	National Inpatient Sample database, 2003-2012	Non-SOS = 396,471 SOS = 6,515,491	0.5% elective, 0.9% NSTEMI, 4.2% STEMI 0.4% elective, 0.9% NSTEMI, 4.6% STEMI	NA NA	No difference in TIA, CVA, or transfusion; less vascular injury with PCI at non-SOS centers (0.9% vs 1.1%; $P < 0.001$); 7-fold increase in non-SOS cases
Afana et al (2018)[28]	PPCI at 47 hospitals in Michigan from January 2010 to December 2015	Non-SOS = 4,091 (propensity score–matched population) SOS = 4,091	5.8% 5.4%	1.9% 2.9%	No difference in primary endpoint of all-cause, in-hospital mortality, contrast-induced nephropathy, NCDR-defined bleeding, major bleeding, and stroke; significant difference in EmCABG (2.9% vs 1.9%; $P = 0.0008$)
Dziewierz et al (2018)[36]	66,707 patients presenting with STEMI undergoing PPCI from 154 centers in Poland	Non-SOS = 51,667 SOS = 15,040	Whole cohort, 1.6%; matched cohort, 1.67% Whole cohort, 1.09%; matched cohort, 1.04%		Lower mortality, no reflow, and coronary perforation in matched cohort at SOS centers
Hannan et al (2019)[29]	New York PCI registry, 2013-2015	Non-SOS = 10,962 SOS = 65,735	0.7% NSTEMI, 2.8% STEMI 0.7% NSTEMI, 2.6% STEMI	NA NA	Adjusted mortality similar in all subgroups (STEMI, NSTEMI, and elective PCI); no difference in CVA or transfusion but less vascular injury at non-SOS centers (0.9% vs 1.1%; OR: 1.31; 95% CI: 1.26-1.35)
Afana et al (2020)[17]	Michigan BCBS PCI registry, nonprimary PCI, 2016-2018	Non-SOS = 4,721 SOS = 46,096	0.5% 0.6%	0.3% 0.5%	No difference in any clinical outcome in propensity-matched population; 3-fold increase in volume at non-SOS sites
Waldo et al (2021)[19]	VA CART registry	Non-SOS = 21,856 SOS = 53,708		Overall rate 0.05%	No difference in death, CVA, or EmCABG; no difference in high-risk lesions (31% vs 36%; $P = 0.126$); decrease in non-SOS volume attributed to SCAI document in 2014
Li et al (2021)[46]	Claims database, outpatient PCI, 2007-2016, propensity matched	ASC PCI = 849 Hospital OP PCI = 95,492	NA NA	NA NA	No difference in MI or hospitalization; ASC PCI increased risk for bleeding (location and severity of bleeding not noted)
Hanson et al (2022)[37]	Victorian Cardiac Outcomes Registry data (Australia), unprotected LMS PCI	Non-SOS = 136 SOS = 594	30-d mortality 24% 30-d mortality 12%	1.5% 2.2%	On-site cardiac surgery was not associated with in-hospital mortality (OR: 0.68; 95% CI: 0.32-1.43; $P = 0.31$) or 30-d mortality (OR: 0.70; 95% CI: 0.33-1.48; $P = 0.35$)
Rashid et al (2022)[38]	British Cardiovascular Interventional Society registry, LMS PCI, 2006-2020	Non-SOS = 13,922 SOS = 26,822	In-hospital mortality 5.7% In-hospital mortality 7.0%	0.2% 0.1%	Absence of SOS was not associated with in-hospital mortality (OR: 0.92; 95% CI: 0.69-1.22), in-hospital MACCE (OR: 1.00; 95% CI: 0.79-1.25), or EmCABG (OR: 1.00; 95% CI: 0.95-1.06); non-SOS sites had fewer BARC type 3-5 bleeding complications (OR: 0.53; 95% CI: 0.34-0.82)

ACS = acute coronary syndrome; ASC = ambulatory surgery center; BARC = Bleeding Academic Research Consortium; CART = Clinical Assessment Reporting and Tracking; CVA = cerebrovascular accident; EmCABG = emergency coronary artery bypass graft; LMS = left main stem; MACCE = major adverse cardiovascular and cerebrovascular events; MI = myocardial infarction; NA = not applicable; NCDR = National Cardiovascular Data Registry; NSTEMI = non-ST-segment elevation myocardial infarction; OP = outpatient; PCI = percutaneous coronary intervention; PPCI = primary percutaneous coronary intervention; RCT = randomized controlled trial; reMI = recurrent myocardial infarction; SA = stable angina; SCAI = Society for Cardiovascular Angiography and Interventions; SOS = surgery on site; STEMI = ST-segment elevation myocardial infarction; TIA = transient ischemic attack.

For primary PCI (133,574 patients), all-cause mortality (OR: 0.99; 95% CI: 0.91-1.07; $P = 0.729$) and emergency CABG (OR: 0.76; 95% CI: 0.56-1.01; $P = 0.062$) did not differ by the presence of SOS. Similarly, for nonprimary PCI (967,549 patients), all-cause mortality (OR: 1.15; 95% CI: 0.94-1.41; $P = 0.172$) and emergency CABG (OR: 1.14; 95% CI: 0.62-2.13; $P = 0.669$) were not significantly different. Importantly, the pooled effect size for all-cause mortality after primary PCI did not shift over time, despite the differences in practice patterns or patient populations from 1995 to 2014.

Much of the more recent data for PCI procedures undertaken at non-SOS centers have been derived from observational studies (Table 1). Analysis of Blue Cross Blue Shield of Michigan Cardiovascular Consortium data including all nonprimary PCI cases performed at 47 hospitals (14 without and 33 with surgery) between 2016 and 2018 revealed that 4,721 of 50,817 PCI procedures (9.3%) were undertaken at non-SOS centers, with an increase over time.[17] Patients undergoing PCI at non-SOS sites were younger, with fewer comorbidities, and were more likely to present with non-ST-segment elevation MI

(34.7% vs 28.4%; $P < 0.001$). In contrast, PCI of the left main (4.0% vs 1.0%; $P < 0.001$), bypass grafts (6.4% vs 3.5%; $P < 0.001$), and CTOs (4.8% vs 1.9%; $P < 0.001$) was more likely to be undertaken at surgical centers, in keeping with the prior SCAI recommendations. Major adverse cardiovascular events (MACE) (2.6% vs 2.8%; $P = 0.443$), and all-cause in-hospital mortality (0.6% vs 0.5%; $P = 0.465$) were similar, as were major bleeding, transfusion, other vascular complications, subacute stent thrombosis, target lesion revascularization, dialysis, urgent or emergent CABG, contrast nephropathy, and length of stay. Rates of stroke and heart failure were lower at non-SOS centers, although absolute differences were small and likely reflect a lower risk population. In a smaller subgroup of Medicare fee-for-service patients whose postdischarge outcomes could be tracked, 90-day readmission rates (18.8% vs 20.0%; $P = 0.400$) and costs ($26,457.25 vs $26,279.80; $P = 0.902$) were similar at sites with and without cardiac surgery. A separate analysis from the same registry reported similar outcomes in patients undergoing primary PCI, with mortality (5.4% vs 5.8%; $P = 0.442$) as well as composite and individual outcomes of in-hospital mortality, contrast-induced nephropathy, bleeding, and stroke between surgical and nonsurgical centers.[28]

The New York PCI registry reported no significant difference in mortality or 2-year repeat target lesion PCI between non-SOS and surgical centers, with similar findings reported in the ST-segment elevation MI subgroup, except for 2-year repeat target lesion PCI, which was lower at surgical centers.[29] Similarly, an analysis from the National Inpatient Sample reported no significant difference in the rate of in-hospital mortality between non-SOS and surgical centers (OR: 1.01; 95% CI: 0.98-1.03) for acute coronary syndrome and elective PCI, with similar odds of in-hospital transient ischemic attack or stroke.[30] In contrast, the incidence of vascular injury was higher at centers with SOS (1.1% vs 0.9%; adjusted OR: 1.31; 95% CI: 1.26-1.35), although there was no difference in the incidence of blood transfusion (0.7% vs 0.8%; adjusted OR: 1.02; 95% CI: 0.98-1.06).

Overall clinical complexity, as assessed by the National Cardiovascular Data Registry CathPCI score, was greater for patients treated with PCI at Veterans Affairs surgical facilities (18.4) compared with those at sites without (17.9; $P < 0.001$). However, over time, anatomical complexity increased more in patients treated at non-SOS sites, such that by the end of the study, Veterans Affairs SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) scores were similar between the 2 groups. Complications and mortality rates were similar across the subgroups at sites with and without cardiothoracic surgery.[19] In summary, the most recent data fail to demonstrate any clinically significant differences in outcomes of PCI at PCI centers with vs without SOS.

INTERNATIONAL DATA

Much of the data derived from the United States are from health care systems in which non-SOS centers represent the minority of PCI cases undertaken. In contrast, there are no formal criteria regarding which patients cannot be treated at non-SOS centers in the United Kingdom, and PCI at these centers is the norm and in fact represents the majority of PCI activity (74 of the 118 centers [63%] in 2020).[16] Unlike in the United States, patients undergoing PCI at non-SOS sites were older, had a higher prevalence of previous PCI or CABG, and were more likely to undergo PCI for stable angina. Up to 40% of left main cases and 27% of cases using circulatory support (predominantly with intra-aortic balloon pumps) were undertaken at non-SOS centers. No significant differences in mortality were observed between surgical and nonsurgical centers following adjustments for differences in baseline covariates in the overall cohort, as well as in patients undergoing PCI for stable angina, non-ST-segment elevation MI, or ST-segment elevation MI.[16]

Dutch studies have shown that primary PCI undertaken at non-SOS centers (14 of the 30 total PCI centers) is safe and associated with shorter door-to-balloon times, with similar MACE rates to surgical centers (7.9% and 8.1%, respectively).[31] Further data from Japan suggest no significant difference in clinical outcomes following PCI for acute coronary syndrome between hospitals with and those without on-site cardiac surgical backup.[32] Furthermore, in a recent report from Australia of 1,179 patients with cardiogenic shock, there was no difference in in-hospital MACCE and mortality if treated at a non-SOS hospital compared with a surgical center.[33]

A national report from Canada (excluding Quebec) using medical administrative databases between 2016 and 2018 also confirmed the short-term safety of performing PCI without SOS.[34] However, a study from Ontario among patients who were diagnosed with severe multivessel disease and were subsequently revascularized within 90 days revealed a potential adverse association if diagnostic angiography was performed at non-SOS centers (HR: 1.09 [95% CI: 1.02-1.18] for death; HR: 1.10 [95% CI: 1.03-1.17] for MI).[35] The mechanism of this poor outcome is uncertain, because institutional capability was not predictive of referral for PCI vs CABG.

The Polish National Registry reported 66,707 patients undergoing primary PCI from 154 centers, of whom 22.6% were treated at surgical centers.[36] On-site surgical backup was associated with a higher PCI annual volume (1,098.7 $\pm$ 483.5 vs 662.4 $\pm$ 301.8; $P < 0.001$) but a lower operator PCI volume (207.8 ± 96.6 vs 226.7 ± 126.0; $P < 0.001$). Periprocedural mortality was lower in patients undergoing primary PCI at surgical centers, and surgical backup (OR: 0.62; 95% CI: 0.52-0.74; $P < 0.001$) was independently associated with reduced periprocedural death.

PCI OF COMPLEX LESIONS AT NON-SOS CENTERS

Although previous analyses have focused on outcomes associated with overall PCI, there have been more limited data regarding high-risk lesion subsets. An analysis of 32 centers (17 surgical centers, 15 nonsurgical centers) that contribute to the Victorian Cardiac Outcomes Registry in Australia reported that 19% of unprotected left main procedures (136 of 730) were undertaken at non-SOS centers.[37] Patients treated at non-SOS sites had a higher prevalence of left ventricular dysfunction, ST-segment elevation MI, and/or cardiogenic shock or required intubation and had higher mortality and MACE rates. Importantly, however, on-site cardiac surgery was not independently associated with in-hospital mortality (OR: 0.68; 95% CI: 0.32-1.43; $P = 0.31$) or 30-day mortality (OR: 0.70; 95% CI: 0.33-1.48; $P = 0.35$). A large series of 40,744 left main PCIs from the United Kingdom reported that these procedures were commonly performed at non-SOS centers (36.7% of all left main PCIs in 2020).[38] There was no association between surgical backup status and risk for death, MACCE, or emergency CABG, and interestingly, bleeding complications were lower at non-SOS centers. Other single-center registries have shown the feasibility of PCI for unprotected left main at non-SOS sites but have lacked comparative data from surgical centers, making interpretation of outcomes challenging.

There have been no comparative studies in other complex PCI subgroups such as CTO and atherectomy; however, several observational studies have been reported. A retrospective analysis of 221 cases using orbital atherectomy at non-SOS sites reported an in-hospital MACE rate of 0.5% (1 MI) and a 30-day MACE rate of 1.4%.[39] In-hospital coronary perforation and no reflow were reported at 0.5%, and procedural success was 97.3%. A retrospective analysis of 531 patients undergoing rotational atherectomy at 3 non-SOS centers in Australia noted 11 (2.1%) procedure-related deaths (of which 5 were directly attributable to rotational atherectomy) within 30 days. Complications directly attributable to rotational atherectomy included coronary dissection (1%), perforation (0.5%), tamponade (0.4%), and burr entrapment (1.3%). Only 2 patients (0.4%) were referred to off-site cardiac surgery for bailout.[40] These complication rates are comparable with those seen in other case series with atherectomy, suggesting that atherectomy procedures can be safely performed at non-SOS centers.

One series of 20 antegrade CTO cases (mean J-CTO [Multicenter CTO Registry in Japan] score 1.65 ± 1.2) reported an 85% success rate, with 3 minor procedural complications.[41] Only 2 patients had post-PCI MI, and there were no in-hospital or 30-day deaths. A U.K. retrospective analysis of 276 CTO cases undertaken over a 5-year period from a single non-SOS center[42] demonstrated that antegrade wire escalation was used in 82.2% (n = 227), retrograde wire escalation in 2.2% (n = 6), antegrade dissection re-entry in 8.7% (n = 24), and retrograde dissection re-entry in 6.9% (n = 19) of CTO cases. The success rate was 76% at first attempt by all operators. Complications included side branch occlusion in 3.5%, perforation in 4%, and cardiac tamponade in 1%. Death occurred in 1.4%, MI in 1.1%, target lesion revascularization in 1.8%, and cerebrovascular accident in 1.1%. Although such outcome data are undoubtedly difficult to interpret in the absence of a comparator group, they suggest that CTO procedures are feasible in centers with experienced operators but with higher complication rates than with other anatomical subsets.

PCI STANDARDS AT HOSPITALS WITHOUT SOS, ASCS, AND OBLS

Potential Non-SOS Settings

In the United States, there are several settings in which non-SOS PCI may take place. Similar to Europe, there are non-SOS acute care hospitals performing PCI on an outpatient basis with same-day discharge. These hospitals provide the safety net of conversion to an inpatient stay if necessary as well as additional support services including an intensive care unit, anesthesia support, medical imaging (computed tomography, magnetic resonance imaging, and ultrasound), transfusions, renal replacement therapy, and emergency vascular surgery.

Unique to the United States, non-SOS PCI may also take place at a freestanding facility completely detached and geographically separate from a hospital. Staffing is often streamlined, consisting of an interventional cardiologist, nurses, technologists, and support staff members. Two types of facilities exist: ASCs and OBLs. They are distinguished primarily by the level of regulatory requirements and oversight. ASCs must meet requirements set forth by Medicare at the federal level as well as specific state requirements. Consistent with the name, OBLs are legally indistinct from medical offices and may exist within physicians' medical office buildings or at freestanding separate sites. Compared with ASCs, OBLs have lower regulatory standards that are governed by state-specific policies.

Equipment and Supplies

High-quality image acquisition and digital archive systems should be present in all catheterization laboratories regardless of setting. Fixed, mounted fluoroscopic systems should be the standard rather than mobile C-arm fluoroscopic machines. Portable ultrasound machines should be available with trained staff members or physicians to obtain and interpret images, to facilitate vascular access, and for emergency assessment of ventricular dysfunction and to exclude pericardial tamponade. General resuscitation equipment, including emergency airway kits, cardiac arrest and vasoactive medications, and defibrillators, is mandatory.

Equipment for intravascular imaging and physiological assessment is required for hospital facilities and strongly recommended for ASCs given the benefit for guiding PCI and reducing complications. Current Medicare reimbursement policy makes the use of these valuable adjunctive technologies in the ASC environment economically challenging but is scheduled to be corrected in 2023.

Catheterization laboratories should have an appropriate inventory of interventional and rescue equipment, including guide catheters, guide extension catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices (if treating vein grafts); covered stents; temporary pacemakers; and pericardiocentesis trays. At minimum, an intra-aortic balloon pump should be available for mechanical support and facilities that perform more complex PCI procedures should also have a percutaneous left ventricular assist device available.

Transfer Agreements

Facilities without SOS should have transfer arrangements and protocols in place with cardiac surgery facilities to provide emergency surgery and ongoing care when necessary. A transfer protocol should outline communications between the ambulatory facility, emergency medical services, and the receiving facility (see the Supplemental Appendix for an example transfer agreement). Patients undergoing emergency or salvage cardiac surgery are high risk and may be financially unprofitable for the receiving institution, potentially causing delays in transfers in the absence of well-established transfer agreements (despite legal and ethical requirements to accept patients to a higher level of care). Collaborating institutions may be financially or organizationally tied, contractually obligated, or linked by memoranda of understanding.

Rapid transfer of critically ill patients requires appropriate ground or air transportation with appropriate support. Ambulances should be large enough to accommodate a balloon pump or ventricular assist device, with an optimal goal to arrive at the non-SOS center within 30 minutes. Some facilities may choose to invest in their own transportation on site, should ambulance services fail to meet these requirements. If intensive care is necessary in transit, this may require members of the referring team to assist or travel with the patient. Transport protocols should be tested a minimum of 2 times per year, involving both the referring and receiving facility.

Quality Assurance

There is clearly the need for a standardized mechanism by which both ASC and OBL facilities—and those who provide patient care in such facilities—can be evaluated and credentialed.

Comparison with national benchmarks is critical to identify program deficiencies and opportunities for improvement. Quality and outcomes including procedural indications and complications must be reviewed regularly and entered into a national registry such as the National Cardiovascular Data Registry and/or state-specific registries. The Outpatient Endovascular and Interventional Society is developing a registry specific to the ambulatory setting that should be available soon. In the future, registries may provide a pathway for the safe expansion of practice within the ambulatory setting and for assisting in the credentialing of interventional cardiologists.

A robust quality program is essential. Ideally, internal peer review should occur regularly, with access to external review available. In programs with a single interventional cardiologist, a process for external peer review should be defined. There should be ongoing audits for MACE with predefined correction plans. Mock codes and bailout drills are strongly recommended to prepare staff members for the possibility of serious, but infrequent, complications. An ideal practice is to conduct next-day and 30-day follow-up calls to identify late-presenting complications.

Informed Consent

Respect for patient autonomy demands that patients receive full informed consent for their procedures. A need for emergency surgery, although rare in the modern era (0.2%), remains a potential complication. Patients must be informed that should emergency surgery be required during their PCI procedure, a transfer would be necessary. Documentation of this detail may be protective should legal action arise after an emergency transfer.

Operator Requirements

Interventional cardiologists in non-SOS hospitals should be experienced and fully trained in resuscitation and the treatment of complications including vascular damage with bleeding, arrhythmias, acute vessel closure, cardio-respiratory arrest, pericardial tamponade, and shock.

TABLE 2 Case Selection

	ASC/OBL	Level 1 Non-SOS Hospital	Level 2 Non-SOS Hospital	Cardiac Surgery Facility
Typical characteristics	No ICU, code team, blood bank	Low-volume (<200 PCIs) catheterization lab	Experienced interventional cardiologists Well-staffed team (4/room) Well-resourced Often multiple catheterization labs and ORs 24/7 ICU/anesthesia/radiology/OR support	Experienced interventional cardiologists High-volume catheterization laboratory Structural heart procedures Well-staffed, resourced, on-call catheterization laboratory team Multiple operating rooms On-call cardiac surgeon and perfusionist Shock team
Rescue/support capabilities	IABP	IABP	IABP pVAD or ECMO Vascular/thoracic surgery	IABP pVAD cardiopulmonary bypass ±ECMO ±RVAD ±LVAD ±Transplantation
Plaque modification devices	Often cutting balloon or IVL	Often cutting balloon or IVL	Rotational atherectomy Orbital atherectomy IVL	Rotational atherectomy Orbital atherectomy IVL
Cases that may be higher risk to avoid	High transfusion risk Calcified lesions Atherectomy Low EF CTO Unprotected left main Degenerated vein grafts	Calcified lesion atherectomy Low EF CTO Unprotected left main Degenerated vein grafts	Epicardial retrograde CTO Last remaining vessel/conduit	

CTO = chronic total occlusion; ECMO = extracorporeal membrane oxygenation; EF = ejection fraction; IABP = intra-aortic balloon pump; ICU = intensive care unit; IVL = intravascular lithotripsy; LVAD = left ventricular assist device; OBL = office-based laboratory; OR = operating room; pVAD = percutaneous ventricular assist device; RVAD = right ventricular assist device; other abbreviations as in Table 1.

Advanced cardiovascular life support resuscitation certification and significant experience with mechanical circulatory support device insertion is required. New interventional cardiologists require mentorship and oversight and should generally avoid ASCs and complex procedures at non-SOS facilities. Operators should be board certified in interventional cardiology and, unless experienced or very experienced, should average at least 50 PCI procedures annually. Individual operator volume is only one of several factors that should be considered in assessing operator competence, which include lifetime experience, experience with other cardiovascular interventions, quality assessment of ongoing performance, and institutional volume.

Staffing Requirements

Facility administrative leadership support is necessary to maintain minimum staffing requirements in the cardiac catheterization laboratory. Required roles include administration of sedation and airway monitoring, recorder, and circulator. Nurses and technicians should have appropriate training and certification to work in a critical care catheterization laboratory environment, including advanced cardiovascular life support training, electrocardiogram recognition, airway management, hemodynamic monitoring, and management of temporary pacemakers, balloon pumps, and ventricular assist devices. All staff members should be fully trained in algorithms for cardiopulmonary resuscitation and patient emergency evacuation and transfer protocols. As with interventional cardiologists, novice staff members should not be placed in high-risk situations until they have received adequate mentorship and experience.

Surgical Consultation

Patients often undergo ad hoc elective PCI without consultation with a cardiac surgeon, at both SOS and non-SOS facilities. Although there are limited direct data supporting the heart team approach, clinical guidelines strongly endorse the practice to ensure the best care of patients. Prior documents[3] attempted to formalize the role of the cardiac surgeon by recommending that the surgeon have privileges at the referring facility and regular meetings with the referring interventional cardiologists. In the current era, formal staff privileges for off-site cardiac surgeons are rarely extended or necessary. However, the principles of the heart team approach should be operationalized through regular communication of referrals, reviews of cases performed, and comparison with guideline recommendations and appropriate use criteria. Ad hoc elective PCI should be performed primarily in patients for whom the guidelines and good judgment are clearly in favor of PCI, whereas in borderline cases, especially including patients with intermediate or high SYNTAX scores, we strongly recommend that a heart team approach, and at a minimum a surgical consultation, should follow the diagnostic angiogram.

TABLE 3 Operator Experience

New Interventional Cardiologist	Experienced Interventional Cardiologist	Very Experienced Interventional Cardiologist
<3 y experience	3-10 y experience	>10 y experience
Limited exposure to atherectomy devices	Competent to use atherectomy devices	Extensive complex PCI experience
Limited STEMI/shock experience	Intermediate experience in STEMI/shock	Significant STEMI/shock experience
Limited prior experience and judgment, familiar with guidelines only	Prior practice in cardiac surgery facility, is familiar with surgical perspective	
Should avoid ASCs and independent atherectomy cases and have case selection reviewed by colleague and scrub in on higher risk cases	Should be able to independently practice all IC in any setting with standard facility oversight	

IC = interventional cardiology; other abbreviations as in Table 1.

Case Selection and Management

Notably, the United Kingdom and Canada have no formal criteria restricting the type of PCI or patient subgroup that can be treated with PCI without SOS. By contrast, prior U.S. statements recommended avoidance of long, calcified, or angulated lesions, nonculprit lesions, and unprotected left main cases, and explicitly precluded the performance of CTO PCI without cardiac surgical backup.[3,5] However, despite the goal of protecting patients, these recommendations may have restricted practice, limited patient choice, and exposed interventional cardiologists to legal risk. Such prohibitions have become outdated as the skill of interventional cardiologists and technological advances have expanded treatment options, outcomes data show no harm with PCI without SOS, and government policies actively encourage moving care to lower cost areas. In particular, the prohibition of rotational and other atherectomy devices can paradoxically result in increased risk to the patient when balloon angioplasty is attempted in a calcified vessel. Similarly, CTO PCI tools and techniques have advanced significantly, and the risk of antegrade wire escalation, antegrade dissection and re-entry, and retrograde septal approaches may be acceptable at selected, experienced non-SOS facilities, although operator experience and available rescue equipment must factor into decision making.

We propose a new algorithm that takes into account not only patients' clinical risk and lesion risk but also the rescue capabilities of the site (Table 2). Equally important is the experience (both recent and accumulated) of the interventional cardiologists on site, as such experience is essential for accurate risk assessment, complication identification and management, and knowledge of rescue options (Table 3).

PCI IN FREESTANDING AMBULATORY LOCATIONS

The United States has been leading the migration of PCI outside the hospital setting, driven by market forces and reimbursement policies. PCI outside the hospital setting may be performed at a freestanding ASC or OBL. For simplification of discussion, PCI at both settings is referred to here as ambulatory PCI. ASCs and OBLs can provide more convenient and timely care, are more local for patients, and reduce costs. ASCs must meet criteria outlined by Medicare at the federal level, as well as any additional state requirements.[43,44] Many states also have certificate-of-need laws that must be met prior to beginning a PCI program. ASCs and OBLs should meet the same facility, equipment, supplies, and other common requirements for catheterization laboratories as noted earlier.

At present, only 0.9% of 2021 Medicare claims for coronary stenting Current Procedural Terminology (CPT) code 92928 occurred at ASCs, with the remaining 99% split evenly between inpatient and outpatient hospital procedures.[45] In a commercial insurance claims database, 0.9% of ambulatory PCIs from 2007 to 2016 were done at ASCs and 99.1% were done in hospital outpatient departments.[46] However, Bain & Company estimated that up to 33% of all cardiac procedures will move to the ambulatory setting in the coming years.[47]

As noted previously, judicious case selection is paramount for the safe performance of ambulatory PCI. Most patients with acute coronary syndromes are admitted to hospitals and therefore are not considered for procedures in ASCs or OBLs. Patient comorbidities, particularly those that might require ancillary support, would favor the hospital setting: 1) decompensated heart failure or severe left ventricular dysfunction; 2) respiratory compromise (hypoxia at rest); 3) high risk for blood transfusion; 4) risk for acute kidney injury; 5) history of severe contrast allergy; 6) critical valvular heart disease; and 7) any condition likely to require overnight observation.

Other scenarios not listed here may also favor the hospital setting; the guiding principle for the physician should be to avoid cases with a significant possibility of requiring support beyond what can be readily provided in the ambulatory setting.

TABLE 4 CMS Designations of Place of Service and Applicable Reimbursement[43,44]

Place of Service	CMS Designation for Place of Service	Commercial Payers	CMS Covers	Facility CMS Reimbursement	Provider CMS Reimbursement
Inpatient hospital care	Place of service 21	All PCI	All PCI	DRG	CPT
Outpatient hospital procedures	Place of service 22	All PCI (excluding CTO, STEMI)	All PCI (excluding CTO, STEMI)	APC	CPT
ASC	Place of service 24	Similar to CMS coverage with some contractual exceptions	Ambulatory PCI excluding CTO, bypass grafts, atherectomy	ASC	CPT
Physician office-based laboratory	Place of service 11	PCI in many states	Diagnostic heart catheterization only	CPT global payment	

APC = ambulatory payment classification; CMS = Centers for Medicare and Medicaid Services; CPT = Current Procedural Terminology; DRG = diagnosis-related group; STEMI = ST-segment elevation myocardial infarction; other abbreviations as in Tables 1 and 2.

Some lesion subsets carry higher risk and therefore should be approached with caution for ambulatory PCI. Unprotected left main lesions, heavily calcified lesions, CTOs, and vein grafts should generally be considered for transfer to a setting with greater support. Yet even these lesions can be, and have been, treated in ASC and OBL environments. It is incumbent on physicians to exercise good judgment and practice within the limits of both their own skill sets and those of their teams. Although ad hoc ambulatory PCI is common practice, interventional cardiologists should strongly consider staged PCI for lesions with an increased risk for complications.[48]

The same standards for credentialing should apply across all places of service. This applies to both interventional cardiologists and staff members. Early-career interventional cardiologists and inexperienced staff members should avoid the ambulatory PCI environment. Independent practice within the ambulatory environment should be reserved for experienced interventional cardiologists with established records of acceptable outcomes.

Currently, there are few published data on outcomes of ambulatory PCI. Using a commercial insurance database from 2007 to 2016, 0.9% of PCIs (n = 849) performed at ASCs were less likely to undergo physiological assessment and more likely to have bleeding complications compared with hospital outpatient procedures.[46] Additional unpublished data are available from National Cardiovascular Partners, which manages 20 catheterization laboratories and ASCs in 6 states with 135 interventional cardiologists performing PCI. Three-day and 30-day PCI outcomes have been collected on 10,581 patients from 2013 through 2021. The combined urgent and emergent transfer rate from the centers following PCI was 0.87% (n = 92), the hospitalization rate within 72 hours after discharge home from the facility was 0.04% (n = 4), and the cardiovascular death rate was 0.04% (n = 4) at 30 days from 2013 to 2021 (internal unpublished data, personal communication courtesy of Kelly Bemis). A critical need in this space will be the publication of such data, reporting of registry results, and ultimately conducting prospective collaborative studies.

REIMBURSEMENT AND ECONOMIC CONSIDERATIONS

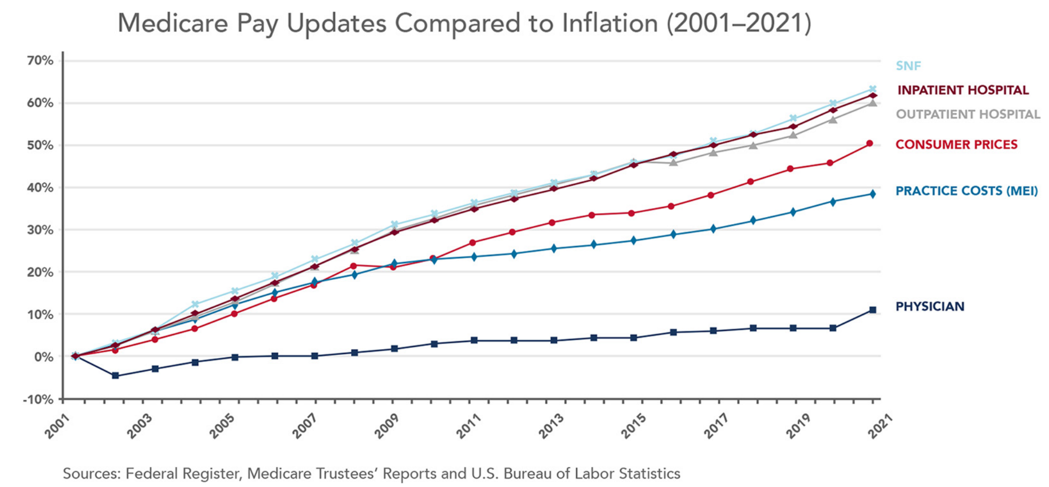
The economics of insurance reimbursement in the United States strongly favor the outpatient migration of PCI. Most coronary interventions at non-SOS facilities involve hospital inpatients or outpatients, but increasingly, coronary interventions are performed in ASCs, although the number remains small. Although physicians are often oblivious to financial considerations regarding the hospital, physicians who have a financial interest in an ambulatory place of service as investors, owners, or practitioners are significantly affected by costs and reimbursement.

Reimbursement for PCI services serves 2 purposes. The first is payment for the professional work performed by the physician. The second is reimbursement for the facility cost of providing PCI services. Physician work is generally described using CPT codes. CMS assigns relative value units to each CPT code. CMS payments to providers are based on the physician work relative value unit of a service multiplied by the conversion factor, which is set annually by CMS ($33.59 for 2022), with small modifications for local factors.[49,50] Most private payers recognize CPT codes and reimburse for services on the basis of a service's relative value unit value multiplied by the payer's conversion factor. Payment for physician effort often constitutes a small proportion of the total cost of a procedure (often <10%) and is generally agnostic to the practice setting (with the exception of a global fee for OBLs).

CMS reimbursement for the cost of providing PCI services is based on the facility expense, which varies according to the place of service. CMS recognizes 50 different places of service[51]; Table 4 lists those relevant to this discussion.

Facility reimbursement varies widely from one place of service to another, with reimbursements higher for hospital inpatients compared with hospital outpatients, which in turn is higher than ASCs and OBLs. For example, the CMS payment for CPT code 92928 (coronary stenting) for 2022 is $5,618 in the ASC setting compared with

FIGURE 2 Medicare Pay Updates Compared With Inflation, 2001 to 2021



According to data from the Centers for Medicare and Medicaid Services (CMS), Medicare physician pay has increased just 11% over the past 2 decades, or 0.5% per year on average, compared with 60% for hospital fee updates and a 39% increase in practice expenses over the same period. MEI = Medicare Economic Index; SNF = skilled nursing facility. Source: American Medical Association.[56]

$10,258 in the hospital outpatient setting.[49] Hospital costs are higher and reimbursed accordingly because of higher facility overhead costs, management costs, and compliance costs, along with cross-subsidizing of less profitable service lines and uncompensated care. Another major reason for higher costs on the basis of site of service is that although physician reimbursement has increased by only 7% from 2001 to 2021 (0.35% annually), facility fees have increased 60% (2.4% annually), outpacing inflation.[52] Figure 2 and Table 5 demonstrate some examples of the resulting differences in total payments for a procedure on the basis of location and type of insurance.[53,54]

The foregoing examples illustrate the large savings to payers that can accrue from a transition to ambulatory PCI, and why. The responsible migration of PCI from the hospital outpatient setting to an ASC or OBL can provide value-based care and reduced costs for overburdened health care systems without incurring unnecessary risk.

Policy risks in the transition to ambulatory PCI include inadvertently incentivizing higher cost or lower quality care. For instance, for hospital-based outpatient procedures, the patient copayment under Medicare is subject to a cap. Such cap does not apply to ASC-based procedures, thus making the patient copay potentially exceed that in the hospital outpatient department, even when such procedures are significantly less expensive to Medicare in the ASC. Deeply discounted reimbursement of PCI services at ASCs may force ASCs to affiliate with large systems and stifle competition. Lower profit margins for procedures in ASCs can potentially encourage unnecessary use, although this has not been demonstrated to date. The current absence of additional reimbursement for intracoronary imaging and hemodynamic assessment discourages the availability and use of these proven technologies, but this policy error is scheduled to be rectified according to the CMS proposed rule for 2023.

TABLE 5 Example Reimbursement Differences Based on Place of Service and Type of Insurance

Place of Service	Diagnostic Catheterization Facility Fee	PCI Facility Fee, Single-Vessel DES	Physician Professional Fee
Hospital outpatient: commercial insurance[a]	$8,100	$29,426	Contractual rates
Hospital outpatient: Medicare[b]	$2,962	$10,259	$137-$436 for catheterization; $628 for one-vessel DES
ASC: Medicare[b]	$1,321	$6,111	$253-$650 depending on procedure
ASC commercial	Contractual rates	Contractual rates	Contractual rates
OBL Medicare[b]	$891-$1,418	Not covered	Global payment
OBL commercial	Contractual rates	Contractual rates in certain states	Global payment

[a]Contractual average estimate based on Shields et al,[9] showing that the average commercial rate was 293% of the Medicare rate. [b]Based on Medicare rates for 2022 published on CMS.gov.

DES = drug-eluting stent; other abbreviations as in Tables 1 and 2.

ASCs can be very profitable when performing procedures for patients with private insurance. For example, in 2020, the average profit margin for ASCs in Pennsylvania was 23.4%.[55] Economically and clinically successful ASCs have low overhead costs, low costs of compliance with quality programs, careful selection of patients, and efficiencies because of the close involvement of physicians. Headwinds that may be faced by ASCs providing cardiac procedures are the costs of new CMS-mandated programs, the cost of maintaining equipment for emergencies (eg, balloon pumps, covered stents), and migration of increasingly complex (and therefore expensive) cardiac procedures to the ASC setting.

SUMMARY

PCI without SOS is as safe as PCI at centers with SOS across randomized controlled trials, observational studies, and international experiences. Adequate operator experience, appropriate clinical judgment and case selection, and facility preparation are essential to a safe and successful PCI program without SOS. The economic benefits of PCI without SOS have driven and will continue to drive payers toward the migration of PCI to the ambulatory setting. This expert consensus statement summarizes the evidence supporting PCI without SOS and provides the community with the guidance necessary for this transition.

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KEY WORDS ambulatory surgery, cardiac surgery, complications, health policy, percutaneous coronary intervention

APPENDIX For the writing group disclosure summary and an example facility transfer agreement, please see the online version of this paper.