Technology Assessment

Technology Assessment Program

Cardiac Catheterization in Freestanding Clinics

A Review

Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, Maryland 20850

September 7, 2005

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A Review

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EXECUTIVE SUMMARY

The Centers for Medicare & Medicaid Services (CMS) requested that AHRQ commission an evidence report to assist in updating the CMS policy regarding cardiac catheterization in freestanding clinics. Accordingly, on February 9th 2005, AHRQ issued a Statement of Work (SOW) contracting ECRI to prepare an evidence report on this topic. The SOW specified that ECRI undertake the following tasks in assembling this report:

1. Systematically search, review, and analyze the relevant scientific evidence for each question. Search MEDLINE and other suitable databases containing primary literature relevant to the questions to be addressed. Identify other sources of relevant literature, such as meeting abstracts, clinical trials currently in progress and clinical practice guidelines.
2. Retrieve and review full articles on eligible studies, assessing quality and extracting key data from each eligible study.
3. Prepare abbreviated evidence tables and summary of important findings.
4. Synthesis of data.

In commissioning this report, AHRQ, in consultation with CMS and ECRI, developed five Key Questions to be addressed. The findings of our assessment as they pertain to the five Key Questions are presented below.

Key Question 1: **Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for diagnostic catheterization procedures?**

After searching the literature, retrieving articles, and applying the inclusion/exclusion criteria, we identified 23 publications that reported complication rates of diagnostic catheterization procedures in a freestanding or hospital outpatient setting. None of these studies directly compared complication rates in freestanding and hospital settings.

Thus, the quality of the evidence is low. The studies' generalizability to the Medicare population was fair[1].

Five separate studies reported complications in a freestanding laboratory (two of these studies were reported only in a systematic review but have not been otherwise published). The mortality rates ranged from 0 to 0.16%, as did the rate of MI, while the rate of stroke/transient ischemic attack (TIA) ranged from 0 to 0.03%. Vascular complications ranged from 0 to 2.0%.

Nineteen studies reported complication rates in a mobile or fixed hospital outpatient setting. No deaths occurred in any of the three mobile laboratory studies, while the mortality rate ranged from 0 to 0.3% among the 16 fixed hospital outpatient studies. Rates of MI ranged from 0 to 0.1% in mobile labs and 0 to 0.7% in fixed outpatient settings, while rates of stroke/transient ischemic attack (TIA) ranged from 0 to 0.3% in mobile labs and 0 to 0.4% in fixed outpatient clinics. Rates of vascular complications ranged from 0 to 0.1% in mobile labs and 0 to 2.0% in fixed outpatient settings.

The available evidence did not reveal substantial differences in complication rates of diagnostic catheterization procedures among freestanding clinics and hospital outpatient settings. However, this indirect and informal comparison of low quality studies could not be risk-adjusted to compensate for differences in patient characteristics among the studies. Also, none of the freestanding clinic studies reported the length of followup; if it was shorter than the average followup in the hospital outpatient studies, this would create bias in the comparison. Furthermore, we cannot determine whether the relatively low complication rates reported in freestanding studies are generalizable to all freestanding centers, as this evidence base was susceptible to potential publication bias. Since all freestanding clinic studies and most hospital outpatient studies were published in the 1980s, the degree of relevance of the findings to current

[1] High = Characteristics of all enrolled patients typical of Medicare population; Fair = Characteristics of some enrolled patients typical of Medicare population; Poor = Characteristics of only a few enrolled patients typical of Medicare population or enrolled patients represent a subgroup of Medicare population.

clinical practice is also unknown. These weaknesses in the evidence base mean that we cannot completely rule out the possibility of differences in complication rates between these settings.

Key Question 2: **Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for interventional catheterization procedures?**

Our literature searches identified no studies that addressed this question. No evidence-based conclusion was possible regarding interventional catheterization procedures in freestanding centers. An American College of Cardiology (ACC)/Society for Cardiac Angiography and Interventions (SCAI) consensus document recommended that such procedures not be performed in freestanding settings, and we found no information to suggest that percutaneous coronary intervention (PCI) procedures are currently being performed in this setting.

Key Question 3: **Do hospitals without cardiac surgical support and hospitals with cardiac surgical support have comparable complication rates for diagnostic and interventional catheterization procedures? This question will only be addressed if the literature is insufficient for questions 1 and/or 2 for freestanding clinics.**

Because no evidence was available to address Key Question 2, we evaluated outcomes of PCI procedures at hospitals with and without surgical support. However, hospitals without cardiac surgical support are an imperfect surrogate for freestanding clinics, because even hospitals without cardiac surgical support have support services and resources beyond what is typically found in freestanding settings. Thus, one cannot be certain to what extent, if any, the findings for interventional procedures in a hospital setting can be extrapolated to a freestanding setting.

We identified seven retrospective controlled studies (five articles and two meeting abstracts) that compared complication rates of non-primary or primary PCI in hospitals with or without cardiac surgical support. These studies ranged from low to fair in quality based on U.S. Preventive Services Task Force (USPSTF) ratings. All were vulnerable to potential selection bias from lack of randomization and lack of followup of patients

transferred to other hospitals. Generalizability to the Medicare population was fair except for one study where it was high.

Three studies of non-primary PCI (PCI for reasons other than emergent acute MI) reported conflicting results. One of these studies exclusively evaluated elective PCI procedures and found no statistically significant differences in complication rates between care settings. The remaining two studies evaluated all non-primary PCI procedures (including some emergent procedures). The only study that exclusively evaluated Medicare patients showed a significantly higher mortality rate in hospitals without cardiac surgical support, while the remaining study showed no significant difference between care settings. However, the latter study was low quality because no adjustments were made to account for baseline differences in the characteristics of patients who were seen at the differing hospital settings. Because these studies were vulnerable to selection bias and differed from each other in several characteristics, the conflicting results cannot be explained with certainty.

Six studies of primary PCI showed consistent findings of no statistically significant difference in rates of mortality or serious morbidity between hospitals with and without cardiac surgical backup. Three of the studies adjusted for differences in patient risk. However, all of these studies were vulnerable to selection bias to a greater or lesser degree, and some may have lacked adequate statistical power to detect a meaningful difference in rates. These flaws in the evidence base mean that failure to demonstrate a difference does not eliminate the possibility that a difference may exist.

Key Question 4: **What are the characteristics of patients who have had catheterization procedures in freestanding cardiac catheterization clinics vs. hospitals?**

We found no studies that directly addressed this question, but 17 of 23 studies from Key Question 1 indirectly addressed the question through their patient inclusion/exclusion criteria. The quality of these studies was low, and their generalizability to the Medicare population was fair.

Two studies of freestanding facilities reported detailed inclusion/exclusion criteria,and these criteria were very similar to those reported in hospital outpatient studies. Both freestanding and hospital outpatient studies included clinically stable patients and excluded one or more subgroups of higher risk patients (with recent MI, Class IV cardiac disease, refractory unstable angina, and severe congestive heart failure, among others). Minor variability appeared in the specific subgroups of patients excluded among the different studies.

An ACC/SCAI expert consensus document recommended similar but slightly more stringent exclusion criteria for freestanding settings than for hospitals without cardiac surgical support. A published multivariable model for predicting complication risks during cardiac catheterization procedures is consistent with some of these recommendations.

Key Question 5: **What are the current state regulations, Certificate of Need (CON) requirements, and oversight procedures for freestanding cardiac catheterization clinics? Include a table summarizing regulations from all 50 states. Include also a review of international regulations and guidelines; at a minimum include information from the U.K. and Canada.**

Currently, 37 states (plus Washington, D.C.) do not prohibit diagnostic cardiac catheterization procedures in a freestanding setting. In these states, regulation usually occurs through certificate of need (CON) programs (16 states plus D.C.). Sixteen states without CON programs have no regulations or licensure requirements for such clinics. Sources in 13 states (plus D.C.) that do not prohibit freestanding catheterization services reported that there were no such facilities (or at least they were not aware of any) currently operating in these states.

Thirteen states have regulations prohibiting cardiac catheterization in freestanding clinics. In three of these states, pilot programs or regulatory loopholes have allowed at least one freestanding facility to perform cardiac catheterization procedures.

Any facility performing cardiac catheterization procedures can voluntarily seek Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation. The facility must meet several functional standards to gain accreditation.

Our survey of two other countries revealed that the United Kingdom does not allow any cardiac catheterization procedures to be performed outside of a hospital setting. Canada has no specific regulatory prohibitions on the national level, and four provinces did not report specific prohibitions, but all four provinces reported that no freestanding facilities were performing cardiac catheterization procedures. We cannot confirm whether any freestanding facilities perform these procedures in the remaining nine Canadian provinces and territories.

SCOPE OF REPORT

The Centers for Medicare & Medicaid Services (CMS) requested that AHRQ commission an evidence report to assist in updating the CMS policy regarding cardiac catheterization in freestanding clinics. Accordingly, on February 9th 2005, AHRQ issued a Statement of Work (SOW) contracting ECRI to prepare an evidence report on this topic. In commissioning this report, AHRQ, in consultation with CMS and ECRI, developed five Key Questions to be addressed. These questions are as follows:

1. Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for diagnostic catheterization procedures?
2. Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for interventional catheterization procedures?
3. Do hospitals without cardiac surgical support and hospitals with cardiac surgical support have comparable complication rates for diagnostic and interventional catheterization procedures? This question will only be addressed if the literature is insufficient for questions 1 and/or 2 for freestanding clinics.
4. What are the characteristics of patients who have had catheterization procedures in freestanding cardiac catheterization clinics vs. hospitals?
5. What are the current state regulations, Certificate of Need (CON) requirements, and oversight procedures for freestanding cardiac catheterization clinics? Include a table summarizing regulations from all 50 states. Include also a review of international regulations and guidelines; at a minimum include information from the U.K. and Canada.

The issues and procedures addressed in this report are similar to those addressed in the American College of Cardiology (ACC)/Society for Cardiac Angiography and Interventions Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards.(1) Although catheterization labs have evolved over the years, the core diagnostic procedures remain cardiac catheterization and coronary angiography, which are the most widely performed diagnostic procedures in cardiac

catheterization facilities (including freestanding clinics). For catheterization laboratories that perform interventional procedures, the major interventional procedures are percutaneous coronary interventions (PCI), including percutaneous transluminal coronary angioplasty (PTCA) and coronary stenting.

Other procedures, such as electrophysiologic studies (EPS), are beyond the scope of this report. EPS are catheter-based procedures that map induced or spontaneous tachyarrhythmias to investigate electrical activities in the heart. Although these procedures are performed in some catheterization facilities, they are performed in a separate EPS lab at many institutions. EPS represent a different area of clinical specialization, requiring a different skill set than that required for performance of core catheterization procedures. Diagnostic cardiac catheterization, coronary angiography, and PCI procedures are generally performed by invasive or interventional cardiologists, while EPS (and associated interventional procedures such as radiofrequency ablation) are generally performed by electrophysiologists.

Another limit in the scope of this report concerns the patient population. Pediatric patients were beyond the scope of this report for two reasons. First, cardiac catheterization procedures are not performed on pediatric patients in any setting except a hospital with pediatric cardiac surgery services. Second, this report is intended to be most relevant to the Medicare population.

BACKGROUND

Cardiac Catheterization

Cardiac catheterization is the current standard of care for many patients for the diagnosis and treatment of coronary artery disease (CAD). It is a minimally invasive procedure in which a catheter is guided through blood vessels in the arm or leg into the left or right side of the heart. Once in place, the catheter is used to perform hemodynamic assessments which include measuring pressures within the heart, heart muscle function (cardiac output) and oxygen saturation.(2) The majority of diagnostic catheterizations are performed in the left heart. Right heart catheterization is a diagnostic procedure usually targeted toward patients with heart failure, valvular disease, or congenital heart disease. Some patients undergo combined left and right heart catheterization.

Catheters are also used to inject x-ray contrast dye, which enables identification of arterial blockages via coronary angiography (also referred to as coronary arteriography). Angiography is considered the standard for defining the site, severity, and morphology of lesions. This technology can also aid the qualitative assessment of coronary blood flow and the identification of collateral vessels. Combined analysis of coronary angiograms and left ventriculograms (angiographic studies of the left ventricle) can identify potentially salvageable myocardial tissue that may benefit from an interventional revascularization procedure.(2)

Two additional catheter-based diagnostic procedures are worth noting. Intravascular ultrasound (IVUS) is a catheter-based vascular imaging procedure that has become a valuable adjunct to angiography in recent years.(3) A related procedure that is not widely used is intracardiac echocardiography (ICE). Whereas IVUS is generally used in smaller blood vessels (such as the coronary arteries), ICE is used for imaging cardiac chambers and major blood vessels (such as the aorta).(4)

Diagnostic catheterization is routinely performed on patients in acute care facilities across the U.S. In some states, diagnostic catheterization procedures are also performed in freestanding clinics.

Recent advances in non-invasive imaging technologies, such as multislice CT angiography may decrease demand for minimally invasive diagnostic catheterizations. Conversely, these non-invasive technologies may lead to increases in the number of patients screened, which, in turn, could increase the number of patients receiving interventional catheterization procedures.(5)

Approximately 30% of patients who undergo diagnostic catheterization in an outpatient setting must subsequently undergo interventional catheter-based procedures or surgery (e.g., coronary artery bypass grafting). The most common interventional catheterization procedures are percutaneous coronary interventions (PCI), specifically, percutaneous transluminal coronary angioplasty (PTCA) with or without stents. Drug-eluting stents are currently used in >90% of PCI procedures in the U.S.(6) These procedures are used to open blocked or constricted coronary arteries. Valvuloplasty is a procedure similar to angioplasty but uses a balloon to expand a constricted heart valve rather than a constricted artery.

In recent years, diagnostic catheterization procedures have increasingly been combined with PCI procedures during the same hospital visit if the diagnostic catheterization indicates a need for intervention. Combining the procedures may lower the overall cost associated with these procedures. The alternative is a staged approach where the PCI is scheduled for a later visit. Patients who go to freestanding clinics or diagnostic-only hospitals do not have the option of a combined procedure, because the PCI must be performed at a different institution. However, not all patients are considered good candidates for a combined procedure. Although combined procedures may be less costly, they may place certain patients at higher risk of complications.(7,8)

Although many states restrict PCI to hospitals with cardiac surgery backup, some states have made an exception for emergency primary angioplasty as an alternative to thrombolytic drug therapy for acute ST-elevation myocardial infarction patients. Whether

PCI procedures can successfully be performed in facilities lacking on-site surgical backup may affect the future treatment of CAD patients.(9)

Freestanding Cardiac Catheterization Clinics

According to an expert consensus document issued jointly by the American College of Cardiology (ACC) and the Society for Cardiac Angiography and Interventions (SCAI) in 2001, a freestanding catheterization laboratory is not physically attached to a hospital, and quick transportation of a patient to a hospital by gurney is not possible.(1) Although some hospitals build catheterization laboratories adjacent to their primary facility, many such laboratories are privately owned.

The ACC/SCAI document further mentions recommended requirements for freestanding laboratories. The committee states that “it is the responsibility of each freestanding laboratory to have a formal relationship with at least 1 tertiary referral hospital so that a written established plan for the emergency transfer of patients is in place. Furthermore, freestanding facilities must have the necessary equipment for intubation and ventilatory support. Physicians using these facilities must be capable of performing endotracheal intubation and inserting an intra-aortic balloon pump. Appropriate quality assurance (QA) and ongoing quality improvement (QI) programs must be established in writing and documented. Oversight has traditionally been provided by a tertiary referral hospital, but alternatives that comply with the maintenance of the highest concern for patient care may be used if acceptable by local standards and if a well-defined QA program is operative.”(1)

The most recent SCAI survey of cardiac catheterization laboratories (published in 1999) identified 58 non-hospital-based laboratories in the U.S., up from 16 in the 1993 survey.(10) This number might be higher if freestanding catheterization laboratories were allowed in all 50 states (see Findings of Included Studies, Key Question 5, for a list of states that allow freestanding catheterization clinics).

The demand for diagnostic catheterization in freestanding settings has arisen in part from long waiting times in certain hospitals that perform diagnostic and interventional catheterization procedures. Because urgent or emergent patients who require PCI must take precedence, low-risk patients scheduled for diagnostic procedures sometimes have to wait all day or even be rescheduled for another day. By providing a setting exclusively for low-risk diagnostic procedures, freestanding clinics can eliminate the long waiting periods that sometimes occur in a hospital setting.(11) Cost-savings and stricter credentialing of physicians have also been reported as advantages of freestanding facilities.(12)

Reported concerns about freestanding catheterization clinics include the ability to maintain an adequate case load to ensure experienced operators, the potential for lapses in quality control mechanisms, and the time required to transfer patients to hospitals in the event of emergency.(12,13) Some experts have also expressed concerns that the development of some freestanding labs has been driven not by actual patient need but “almost exclusively by a desire to capture market share.”(14) Because such facilities are often physician-owned, the potential exists for financial incentives to inappropriately influence the development of freestanding catheterization clinics. Such incentives might conflict with the publication of procedural outcomes, contributing to potential publication bias (through suppression of negative results) in the body of literature concerning this topic.(6)

Mobile cardiac catheterization laboratories (that can move between facilities) can be based at hospitals with or without surgical backup or in freestanding settings. Mobile labs based in the latter environment may be classified as freestanding labs.(1)

Procedures Performed in Freestanding Catheterization Clinics

The primary procedure performed at these freestanding clinics is coronary arteriography, which requires arterial access and is performed by advancing catheters to the coronary artery. Cardiac catheterization for evaluation of hemodynamics is also performed in these settings. Although the majority of diagnostic catheterizations are performed in the left heart (including left ventriculography), some patients have

undergone right heart, or combined left and right heart catheterization, in a freestanding setting. These are considered to be lower-risk procedures than coronary arteriography. Whether other diagnostic catheterization procedures (such as IVUS, ICE, or EPS) have been performed in a freestanding center is not clear, as no published literature has yet addressed this issue. However, IVUS and ICE are generally used in specialized circumstances in facilities that perform interventional procedures, so they are less likely to be used in a freestanding clinic. Because EPS only requires monitoring and the risk of surgery is negligible, it is perhaps more likely to be used in freestanding settings now or in the future.(6)

An interventional procedure that may possibly be used in some freestanding labs is peripheral artery angioplasty/stenting, which is considered to have a lower complication risk than coronary angioplasty/stenting. However, this has not been reported in the published literature. We have found no information suggesting that coronary interventional procedures are currently performed in freestanding clinics.

Current CMS Policy Regarding Cardiac Catheterization in Freestanding Clinics

Current CMS policy appears in the *NCD for Cardiac Catheterization Performed in Other than a Hospital Setting* (20.25). The benefit category is listed as Diagnostic Tests. The indications and limitations of coverage section states that “cardiac catheterization performed in a hospital setting for either inpatients or outpatients is a covered service. The procedure may also be covered when performed in a freestanding clinic when the carrier, in consultation with the appropriate Quality Improvement Organization (QIO), determines that the procedure can be performed safely in all respects in the particular facility. Prior to approving Medicare payment for cardiac catheterizations performed in freestanding clinics, carriers must request QIO review of the clinic.”(15)

However, according to the *NCA Tracking Sheet for Cardiac Catheterization Performed in Other than a Hospital Setting*, “(QIOs) ceased doing reviews of core freestanding, cardiac catheterization facilities in the early 1990s. Since the implementation of

Coverage Issues Manual (CIM) 35-45, we are unaware of any emerging evidence that there is a greater risk of adverse events at these freestanding clinics. Therefore, CMS is opening this policy to review the evidence and correct the discrepancy."(16)

Training and Credentialing of Personnel in Freestanding Cardiac Catheterization Clinics

We found no documents specifically pertaining to training/credentialing of personnel in freestanding catheterization clinics. Personnel in these clinics most likely follow the same training/credentialing protocols as personnel in hospital environments.

According to an ACC Task Force document on training in cardiac catheterization, "Level 2" training is required for independent diagnostic catheterization and angiography. This requires all the components of "Level 1" training, which covers "formal training in radiation physics, radiation safety, fluoroscopy and radiologic anatomy, as well as clinical cardiovascular physiology." Level 1 also requires some experience with pulmonary artery catheterization, left and right heart catheterization, temporary right ventricular pacemaker insertion, and pericardiocentesis. Level 2 requires further training in percutaneous arterial entry and arterial incision and repair, additional education in radiation physics and safety, and a working knowledge of catheterization laboratory equipment. Knowledge of the principles of cardiac output determination, shunt detection, and pressure waveform recording and analysis is mandatory. Additional training in endomyocardial biopsy techniques and intraaortic balloon counterpulsation insertion and management is required. Finally, specialized training (including one month in a pediatric catheterization laboratory) is required for catheterization of patients with complex congenital heart disease.(17)

Clinical Practice Guidelines

An ACC/SCAI expert consensus document issued jointly in 2001 is the only document published in the last five years to make recommendations about the procedures that can safely be performed in a cardiac catheterization laboratory in all potential care

settings (freestanding, hospital without cardiac surgical support, or hospital with cardiac surgical support). The recommendations are based predominantly on expert consensus (the committee believed that the evidence base was not sufficiently well-developed to be evaluated by the formal ACC/American Heart Association (AHA) Practice Guidelines process).

This consensus document states that diagnostic catheterization procedures can be performed in any of the three care settings listed above, although the recommended patient selection criteria vary among different settings. Hospitals with cardiac surgical support have no recommended patient exclusion criteria, while freestanding facilities have the highest number of recommended patient exclusion criteria (see Findings of Included Studies, Key Question 4, for further information on patient selection criteria).

The consensus document also makes recommendations about interventional procedures. It states that “interventional procedures of any kind should not be performed in a freestanding facility.” Also, elective interventional procedures are generally not recommended in hospitals without cardiac surgical support. Primary PCI (for MI) is acceptable in hospitals without cardiac surgical support if there is a proven plan for rapid access (within one hour) to a nearby facility with cardiac surgery support and appropriate hemodynamic support capability for transfer. The document further recommends that primary PCI be performed by experienced practitioners (those performing ≥75 PCIs/year) at facilities performing a minimum of 36 primary PCIs/year. The committee did not reach consensus regarding a minimum necessary caseload for diagnostic catheterization.(1)

A 2001 clinical guideline issued by the ACC/AHA makes recommendations regarding the appropriate care setting for PCI. The document “recommends that primary PCI for acute MI performed at hospitals without established elective PCI programs should be restricted to those institutions with a proven plan for rapid and effective PCI as well as rapid access to cardiac surgery in a nearby facility.” The committee further recommends “that elective PCI should not be performed in facilities without on-site cardiac surgery.”(18)

Ongoing Trials

Our searches (Appendix A) did not identify any ongoing trials involving freestanding cardiac catheterization clinics. We identified one ongoing nationwide multicenter study (40 hospitals) comparing the use of elective PTCA among 13,000 patients in hospitals with and without cardiac surgical backup. The lead investigator is Dr. Thomas Aversano at Johns Hopkins University School of Medicine.(19)

METHODS

Key Questions Addressed

In order to meet the objectives of this report, we address the following Key Questions:

1. Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for diagnostic catheterization procedures?
2. Do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for interventional catheterization procedures?
3. Do hospitals without cardiac surgical support and hospitals with cardiac surgical support have comparable complication rates for diagnostic and interventional catheterization procedures? This question will only be addressed if the literature is insufficient for Questions 1 and/or 2 for freestanding clinics.
4. What are the characteristics of patients who have had catheterization procedures in freestanding cardiac catheterization clinics vs. hospitals?
5. What are the current state regulations, Certificate of Need (CON) requirements, and oversight procedures for freestanding cardiac catheterization clinics?

In assessing safety, we consider all reported complications that may be related to the catheterization procedure.

Literature Searches

Details of our literature searches, which included searches of 12 electronic databases, hand searches of the bibliographies of all retrieved articles, and searches of the gray literature, are presented in Appendix A.

Inclusion/Exclusion Criteria

We used the following general criteria to determine which studies would be included in our analysis for Key Questions 1 through 4:

1. Studies must have been published in English.
2. Studies must have addressed one of the Key Questions.
3. Studies must have included at least 100 patients per arm. This is to ensure that adverse events that occur in at least 1% of patients are detectable (Questions 1-3) and to ensure a representative sampling of patients (Questions 1-4). Although event rates below 1% may also be of interest, we chose a less conservative criterion to allow inclusion of more studies.
4. Full published studies and relevant meeting abstracts will be included.
5. If the same study is reported in multiple publications, only the most recent publication will be included. This serves to avoid duplication of data.

Additional criteria specific to individual questions are presented in the Results section under each Key Question.

Data Extraction

Information extracted from the included studies is presented in Evidence Tables in Appendix E. These tables describe study results, design details (prospective, blinding status, etc.), information on enrolled patients (demographics, underlying etiology, etc.), and information on the setting of the study (freestanding or hospital, hospital with or without surgical support).

We have only extracted outcome data relevant to the Key Questions in this report. If relevant data were reported in figures but not in text, we estimated them from the figures. When study authors did not report dichotomous data as percentages, we computed percentages.

Evaluation of the Quality of the Evidence Base

We rated evidence strength and internal validity using standard criteria as proposed by the U.S. Preventive Services Task Force (USPSTF). The first step in this process involves identifying the study design and labeling it according to the hierarchy shown in Table 1.(20)

Table 1. Hierarchy of Research Design (USPSTF)

Level	Definition
I	Evidence obtained from at least one properly randomized controlled trial.
II-1	Evidence obtained from well-designed controlled trials without randomization.
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
II-3	Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (e.g., penicillin) also qualify.
III	Opinions of respected authorities, based on clinical experience, descriptive studies and case reports, or reports of expert committees.

In recent years USPSTF has recognized that this hierarchy by itself gives inadequate consideration of internal validity (how well a study was conducted). For example, a well-designed cohort study may be of higher quality than a poorly-conducted randomized controlled trial. Therefore, they adopted an additional system for ranking internal validity ("good", "fair", or "poor"). A "good" rating means that a study meets all criteria for that particular study design, a "fair" study does not meet all criteria but is judged to have no fatal flaw that invalidates its results, and a "poor" study contains a fatal flaw.(20) We have added an additional category called "low", which describes a study that is borderline acceptable (not quite "fair", but not necessarily fatally flawed). For more information on the criteria used to rate studies, see the Quality of Included Studies section under each Key Question in the Evidence Synthesis section of the report.

We estimated the generalizability of each study to the U.S. Medicare population using study enrollment criteria and the reported characteristics of the patients who were actually enrolled in the study.

EVIDENCE SYNTHESIS

Because each Key Question had a different evidence base, we describe each evidence base separately under the relevant Key Question.

Key Question 1: Do Freestanding Cardiac Catheterization Clinics and Hospitals Have Comparable Complication Rates for Diagnostic Catheterization Procedures?

Question-Specific Inclusion/Exclusion Criteria

In addition to the general inclusion/exclusion criteria listed under Methods, the following additional criteria were used to select studies for this question:

1. Studies must be controlled studies that compare data from freestanding clinics to parallel or historical control groups in outpatient hospital settings. If no controlled studies are available, outpatient case series will be included for indirect comparison of freestanding clinics and hospitals.
2. Studies must include data related to the Key Outcomes.
3. Studies must provide a quantitative description of findings (e.g., numbers or percentages).

Evidence Base

Our searches found no controlled trials that addressed this question, so we searched for lower level evidence (uncontrolled case series from freestanding clinic or hospital outpatient settings). We identified 27 articles that potentially met our *a priori* inclusion criteria and were therefore retrieved. On retrieval, four of the 27 articles were found not to meet our inclusion criteria. The reasons for exclusion were either that inpatient and outpatient data were not reported separately (two articles) or that no quantitative statement (number or percentage) of complications was reported. These articles and the reason for their exclusion are listed in Table B-1 of Appendix B.

Having excluded the four articles above, 23 studies remained. These studies, which are listed in Table 2, consist of one randomized controlled trial (RCT) and 22 case series. The RCT randomized patients to receive diagnostic catheterization on an inpatient or outpatient basis in a hospital setting. For the purposes of this question, only the outpatient group in the RCT was relevant, so only the outpatient data were included (effectively making it equivalent to the other case series). Details of these studies are presented in Table C-1 to C-3, Appendix C.

Table 2. Evidence Base for Key Question 1

Study Design	References
Randomized Controlled Trials	Block et al.(21)
Case series	Akdemir et al.(22); Peterson and Peterson(23); Bersin et al.(24); Elliott et al.(25); Clark and Dolce(26); Clements and Gatlin(27); Kern et al.(28); Jackson(27); Murray and Rothman(29); Oldroyd et al.(30); Pink et al.(31); Murdock et al.(32); Mahrer et al.(33); Fighali et al.(34); Klinke et al.(35); Fierens(36); Diethrich et al.(37); Mahrer and Eshoo(38); Gavin et al.(39); Oehlert(40); Perrigo et al.(41); Baird(42)

Quality of Included Studies

None of the included studies compared the complication rates of diagnostic catheterization in freestanding clinics and hospitals, so no direct comparisons are possible in this technology assessment. The only published data on complications in freestanding clinics appear in case series. For the purpose of informal indirect comparison, we have also included case series reporting complication rates of diagnostic catheterization in hospital outpatient settings.

We have not included case series that reported complication rates among hospital inpatients or in a mixed series of inpatients and outpatients, because sicker patients are included among the inpatients. Thus, inpatients will be more likely to experience procedure-related complications, which would bias any comparison with a group of lower-risk patients diagnosed in a freestanding setting. By contrast, outpatient series will include mostly low-risk patients who are more comparable to the low-risk patients who would be diagnosed in freestanding clinics. However, even this comparison is imperfect, because risk levels may differ somewhat even among different outpatient settings. For example, some evidence suggests that community hospitals are more likely to receive somewhat higher risk patients among their outpatient population than physician-owned specialty hospitals. Similarly, hospital outpatient departments in general may be more likely to receive higher risk patients than ambulatory surgical centers or physician offices for the same outpatient procedures.(43)

Despite our attempts to select the most comparable studies, indirect comparisons are inherently problematic. Patient populations in case series performed at different institutions will never be completely identical, and these studies may contain additional differences that undermine cross-study comparisons. Although differences in patient characteristics can be adjusted for statistically in some circumstances, this was not possible in the current evidence base due to the lack of individual patient data. Thus, if differences in adverse event rates appear when comparing freestanding and hospital outpatient series, one can never be certain that the differences can be explained solely

by the difference in setting. Nevertheless, this is the best comparison possible given the available literature.

A related issue of some concern is the possibility that this evidence base could be affected by publication bias. If some freestanding clinics have not published data because of substandard outcomes, then the published results of freestanding clinics will appear to be better than they would have appeared had results from all clinics been published. The low number of freestanding clinic studies (only five were identified) precludes determination of whether or to what extent this literature may have been affected by publication bias. However, the potential for bias exists and must be considered when interpreting the results.

Finally, differences in follow-up time might lead to differences in complication rates among studies. All of the studies in freestanding clinics and some of the hospital outpatient studies did not report the length of followup. Most complications of diagnostic catheterization occur within the first 24 hours, and most studies probably reported data from within this time period at least. However, a few hospital outpatient studies reported complications for up to one week or even four weeks, and what percentage of additional complications may occur during this extended period is unknown, as the studies did not report the time at which complications occurred.

According to USPSTF criteria, all studies in this evidence base are Level III studies, which are generally considered to be of low quality (because only one arm of the RCT by Block et al. could be used, this study had to be evaluated as a case series for this question). Because none of the studies contains a direct, within-study comparison of complications in freestanding settings and hospital outpatient facilities, the quality of all of the individual studies (and hence the evidence base) is low.

Details of Study Enrollees and Study Generalizability

None of the study populations were completely generalizable to the Medicare population. All of the studies that reported age had some overlap with the Medicare population, but the age ranges were generally large, ranging from adolescent or young

adult to elderly. Furthermore, females tended to be underrepresented in these studies relative to the Medicare population. Finally, not all studies reported age or gender information. Therefore, the generalizability of the studies to the Medicare population is "Fair."[2] Details of the patients enrolled in these studies are presented in Table C-2 and Table C-3 of Appendix C.

Another noteworthy issue is that the majority of studies in the evidence base were published in the 1980s. Therefore, they may only have limited relevance to current clinical practice in the indicated settings. However, complication rates generally tend to decrease over time due to increasing practitioner experience and improvements in technology.

Findings of Included studies

Studies in Freestanding Laboratories

Five separate studies with a total of 18,082 patients reported data concerning complication rates of diagnostic catheterization in freestanding settings. All were published in the 1980s. Two consisted of data from registries that were reported as part of a systematic review of the topic, but not otherwise published.(12) The remaining three were single-laboratory case series, one of which was published as a meeting abstract.

The mortality rates in these studies ranged from 0 to 0.16%, as did the rate of MI, while the rate of stroke/transient ischemic attack (TIA) ranged from 0 to 0.03%. Vascular complications ranged from 0 to 2.0%. Other complications were inconsistently reported across studies (see Table C-4, Appendix C for specific complication rates for each study).

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[2] High = Characteristics of all enrolled patients typical of Medicare population; Fair = Characteristics of some enrolled patients typical of Medicare population; Poor = Characteristics of only a few enrolled patients typical of Medicare population or enrolled patients represent a subgroup of Medicare population.

Studies in Hospital Outpatient Laboratories (Mobile or Fixed)

Nineteen studies reported complication rates of diagnostic catheterization in this setting. Twelve of these were published in the 1980s, with the remaining seven published more recently.

Three of the most recent studies reported complications in mobile laboratories which serviced hospitals that lacked catheterization labs. There were no reported deaths out of a total of 4,261 patients in these three studies. Rates of MI ranged from 0 to 0.3%, rates of stroke/TIA ranged from 0 to 0.1%, and rates of vascular complications ranged from 0 to 0.1%.

The remaining 16 studies reported complication rates for a total of 20,129 patients in fixed hospital outpatient laboratories. Mortality rates ranged from 0 to 0.3%, MI rates ranged from 0 to 0.7%, rates of stroke/TIA ranged from 0 to 0.4%, and vascular complications ranged from 0 to 2.0%. Among the less serious complications, the most frequent was bleeding/hematoma, with rates ranging from 0 to 7% (see Table C-4, Appendix C for specific complication rates for each study).

These complication rates do not differ substantially from the rates reported in the largest study of diagnostic catheterization complications, a multicenter registry study of 222,553 patients who received coronary arteriography between 1984 and 1987.(44) This study did not meet our inclusion criteria because it did not report findings separately for inpatients and outpatients. However, we note that the average rates reported by this study for mortality (0.1%), MI (0.06%), stroke/TIA (0.07%), and vascular complications (0.46%) all fall within the ranges reported by the studies that met our inclusion criteria.

Subsection Summary

After searching the literature, retrieving references, and applying our inclusion/exclusion criteria, we identified 23 publications that reported complication rates of diagnostic catheterization procedures in a freestanding or hospital outpatient setting. None of

these studies directly compared complication rates in freestanding and hospital settings. Thus, the quality of the evidence is low. The studies' generalizability to the Medicare population was fair.

Five studies reported complications in a freestanding laboratory (two of these studies were reported only in a systematic review). The mortality rate ranged from 0 to 0.16% and equal or lower rates were found for MI and stroke. No deaths occurred in any of the three mobile laboratory studies, while the mortality rate ranged from 0 to 0.3% among the 16 fixed hospital outpatient studies. Rates of MI, stroke/TIA, and vascular complications were similar or slightly higher than those reported in freestanding settings (see Table 3).

Table 3. Range in Complication Rates in Different Care Settings

Care setting	Number of studies	Mortality rate (range)	MI rate (range)	Stroke rate (range)	Vascular complications (range)
Freestanding clinic	5	0 to 0.16%	0 to 0.16%	0 to 0.03%	0 to 2.0%
Hospital outpatient (mobile)	3	0 to 0%	0 to 0.1%	0 to 0.3%	0 to 0.1%
Hospital outpatient (fixed)	16	0 to 0.3%	0 to 0.7%	0 to 0.4%	0 to 2.0%

The available evidence did not reveal substantial differences in complication rates of diagnostic catheterization procedures among freestanding and hospital outpatient settings. However, this indirect and informal comparison of low quality studies could not be risk-adjusted to compensate for differences in patient characteristics among the studies. Also, none of the freestanding studies reported the length of followup; if it was shorter than the average followup in the hospital outpatient studies, this would create bias in the comparison. Furthermore, we cannot determine whether the relatively low complication rates reported in freestanding studies are generalizable to all freestanding centers, as this evidence base was susceptible to potential publication bias. These

flaws in the evidence base mean that we cannot completely rule out the possibility of differences in complication rates between these settings.

Key Question 2: Do Freestanding Cardiac Catheterization Clinics and Hospitals Have Comparable Complication Rates for Interventional Catheterization Procedures?

Question-Specific Inclusion/Exclusion Criteria

In addition to the general inclusion/exclusion criteria listed under Methods, the following additional criteria were used to select studies for this question:

1. Studies must be controlled studies that compare data from freestanding clinics to parallel or historical control groups in outpatient hospital settings. If no controlled studies are available, outpatient case series will be included for indirect comparison of freestanding clinics and hospitals.
2. Studies must include data related to the Key Outcomes.
3. Studies must provide a quantitative description of findings.

Evidence Base

Our searches identified no articles or meeting abstracts that potentially met our *a priori* inclusion criteria. Thus, no evidence-based conclusion is possible for this question. An ACC/SCAI consensus document recommended that such procedures not be performed in freestanding settings, and we found no information to suggest that PCI procedures are currently being performed in this setting.

Key Question 3: Do Hospitals without Cardiac Surgical Support and Hospitals with Cardiac Surgical Support have Comparable Complication Rates for Interventional Catheterization Procedures?

We address this question because Key Question 2 could not be answered in an evidence-based fashion. However, hospitals without cardiac surgical support are an imperfect surrogate for freestanding clinics, because even hospitals without cardiac surgical support have support services and resources beyond what is typically found in freestanding settings. Therefore, one cannot be certain to what extent, if any, the findings for interventional procedures in a hospital setting can be extrapolated to a freestanding setting.

Question-Specific Inclusion/Exclusion Criteria

In addition to the general inclusion/exclusion criteria listed under Methods, the following additional criteria were used to select studies for this question:

1. Studies must be controlled studies that compare data from hospitals with and without cardiac surgical support. If no controlled studies are available, case series will be included for indirect comparison of hospitals with and without cardiac surgical support.
2. Studies must include data related to the Key Outcomes.
3. Studies must provide a quantitative description of findings.

Evidence Base

Our searches identified 14 articles or meeting abstracts that potentially met our *a priori* inclusion criteria and were therefore retrieved. Because controlled trials were available, we did not retrieve case series. On retrieval, seven of the 14 articles were found not to meet our inclusion criteria. The primary reasons for exclusion (four articles) were that the studies combined data from several procedures (PCI, CABG, thrombolytic therapy) and did not separately report the data for patients who received PCI. The remaining

three articles were excluded for a variety of other reasons. These latter articles and the reason for their exclusion are listed in Table B-1 of Appendix B.

Having excluded the seven articles above, five articles and two meeting abstracts remained. These studies, which are listed in Table 4 are all non-randomized retrospective cohort studies. Details of these studies are presented in Table D-1 to D-6, Appendix D.

Table 4. Evidence Base for Key Question 3

Study Design	References
Non-Randomized Retrospective Controlled Studies	Kutcher et al.(45); Sanborn et al.(46,47); Singh et al.(48); Wennberg et al.(49); Wharton et al.(50); Weaver et al.(51); Garratt et al.(52)

Quality of Included Studies

Seven studies that enrolled a total of 933,477 individuals compared PCI-related complication rates in hospitals with and without cardiac surgical support.(46,48-52) The results of our analysis of the quality of these studies are summarized in Table 5. We based the quality ratings for each study (shown in Table 3) on the criteria and information presented in Table D-1 of Appendix D. The difference between a judgment of "fair" or "low" generally depended upon whether the study authors performed any type of risk-adjustment in their comparisons of different patient groups.

Table 5. Quality of Studies Comparing Interventional Catheterization Procedures in Hospitals With and Without Cardiac Surgical Support

Reference	Year	Study Design	USPSTF Quality Rating[a]
Sanborn et al.(46,47)	2004	Non-Randomized Retrospective Controlled Study	Level II-3-Low
Singh et al.(48)	2004	Non-Randomized Retrospective Matched Controlled Study	Level-II-3-Fair
Wennberg et al.(49)	2004	Non-Randomized Retrospective Controlled Study	Level II-3-Fair
Wharton et al.(50)	1999	Non-Randomized Retrospective Controlled Study	Level II-3-Low
Weaver et al.(51)	1995	Non-Randomized Retrospective Controlled Study	Level II-3-Fair
Kutcher et al.(45) (abstract)	2004	Non-Randomized Retrospective Controlled Study	Level II-3-Low
Garratt et al.(52) (abstract)	2002	Non-Randomized Retrospective Controlled Study	Level II-3-Fair

[a] See criteria proposed by the U.S. Preventive Services Task Force.(20)

Details of Study Enrollees and Study Generalizability

Details about the patients enrolled in these studies are presented in Table D-3 to D-6 of Appendix D. Only the study by Wennberg et al., which focused exclusively on Medicare enrollees, was found to be highly generalizable to the elderly Medicare population.(49) The remaining six studies included some adults under age 65, and women tended to be underrepresented (they were 21% to 35% of the population in each study) relative to the Medicare population. Therefore, the generalizability of these latter studies was considered to be "Fair."[3]

Findings of Included Studies

We present separate findings based on two categories of PCI reported in the literature: non-primary and primary PCI. Our definition of these terms is based on the definitions provided in the study by Wennberg et al.(49) Accordingly, in this document, non-primary PCI refers to all PCI procedures performed for reasons other than an emergency admission for acute MI. Conversely, primary PCI refers to all PCI procedures performed for emergency admission for acute MI. We recognize the fact that the terminology is somewhat inconsistent in the literature. We do not include all cases of rescue PCI (PCI used after failed thrombolysis) in the category of non-primary PCI, as rescue PCI may be performed in patients with or without emergent acute MI. The only study that reported cases of rescue PCI (Wennberg et al.) divided these cases into the separate groups of non-primary and primary PCI.(49)

Non-Primary PCI

Three included studies compared complication rates among patients receiving non-primary PCI in hospitals with and without surgical support (results appear in Table D-7, Appendix D). Although none of these patients had emergent acute MI, non-primary PCI

[3] High = Characteristics of all enrolled patients typical of Medicare population; Fair = Characteristics of some enrolled patients typical of Medicare population; Poor = Characteristics of only a few enrolled patients typical of Medicare population or enrolled patients represent a subgroup of Medicare population.

may still include patients who had an emergency admission for other reasons (e.g., unstable angina). Because none of the studies were randomized, all were vulnerable to selection bias that could have confounded the comparisons. Another potential weakness in these studies is that, with one exception, they did not state whether they accounted for patients who arrived at the study hospitals but were transferred to another facility for treatment. Sanborn et al. was the only study that mentioned this problem, and they acknowledged that they did not track the mortality status of transfer patients.(46) Not accounting for such patients could have biased the comparison.

Garratt et al. conducted the only controlled study that exclusively evaluated patients who received elective PCI procedures.(52) Because freestanding clinics generally perform elective diagnostic procedures, the patient population receiving treatment in the Garratt et al. study may be the most relevant to a freestanding setting. This study found similar death rates for elective PCI at two hospitals, one with cardiac surgical support (0.72%) and one without (0.49%).(52) However, this study was not large enough to detect small differences in mortality rates.

The remaining two studies compared all non-primary PCI procedures at hospitals with and without surgical support. Wennberg et al. conducted a large retrospective study of Medicare enrollees who had received PCI. Of patients who received non-primary PCI, most were at hospitals with cardiac surgery support (583,149 vs. 6,373 at hospitals without surgical support). Some patients in this group received rescue PCI for causes other than emergent acute MI. They found a significantly higher mortality rate at hospitals without cardiac surgery support (4.6% vs. 2.8%, $p < 0.001$). The adjusted odds ratio (adjusted for age, sex, race, year, comorbidity score, primary diagnosis, acuity, multivessel PCI, and stent use) was also statistically significant (1.38, 95% CI 1.14 to 1.67, $p = 0.001$).(49) The authors performed a number of further subgroup analyses that suggested that the excess mortality at hospitals without cardiac surgical backup was higher among emergent patients and at low volume institutions. Because hospitals without surgical backup received more emergent patients and were much more likely to be low volume institutions than hospitals with surgical backup, the difference in mortality

rates could be potentially accounted for by a combination of these factors rather than the lack of surgical backup. However, subgroup analyses are potentially misleading, as the findings of such analyses may occur by chance. At best, they can only generate hypotheses that may be further tested in future studies.

Kutcher et al. made a similar comparison of PCI procedures reported in the ACC-NCDR database. Again, the majority of patients received PCI at hospitals with cardiac surgical support (198,555 vs. 1,668 at hospitals without surgical support). Despite the large number of patients, this study did not find a statistically significant difference in death rates between the two settings (0.54% without support vs. 0.46% with support, p = 0.79).(45) Because this study made no risk adjustments to account for between-group patient differences, it was more vulnerable to bias than the other two studies.

Primary PCI

Six of the seven included studies compared complication rates in patients with acute MI receiving primary PCI in hospitals with and without cardiac surgical support (see Table D-8, Appendix D). All of these patients had suffered an acute MI. As stated earlier, patients with acute MI are likely to be sent to a hospital's emergency department, so this subgroup of patients may be different than patients who would undergo non-emergency procedures in a freestanding setting.

Using data from the National Registry of Myocardial Infarction (NRMI), Sanborn et al. compared patients in three different hospital settings (diagnostic catheterization only, PCI only, and PCI with surgical support) and found no significant difference in rates of mortality (3.2%, 4.2%, 4.8%, p = 0.07), stroke (0.6%, 0.4%, 0.7%, p = 0.44), or recurrent AMI (0.6%, 1.5%, 1.2%, p = 0.19).(46) However, they did not attempt to adjust for differences in patient characteristics, and they acknowledged that they did not track the mortality status of patients transferred out of hospitals without cardiac surgical support. These factors could have confounded the comparisons.

Singh et al. compared patients receiving PCI after AMI in two hospitals, one without and one with cardiac surgery backup. Patients were matched according to age,

procedure date, ST-segment elevation MI, anterior site of infarction, presentation with congestive heart failure, and a propensity score based on numerous risk factors. No statistically significant between-hospital difference was observed for mortality (1.9% vs 1.3%, p = 0.56), need for CABG (0.6% vs 0.6%), or reinfarction rates (0.6% vs 0%, p = 0.32).(48)

Wennberg et al.'s study of Medicare enrollees also compared patients who received PCI following emergent admission for MI at hospitals without or with surgical backup. Some of these patients received rescue PCI for failed thrombolysis. They found no statistically significant between-setting differences in mortality rates (11.3% vs 12.2%, p = 0.24)) or need for CABG (4.6% vs 5.1%, p = 0.29), even after risk-adjustment (for age, sex, race, year, comorbidity score, primary diagnosis of acute MI, acuity, multivessel PCI, and stent use).(49)

Wharton et al. conducted a study of primary angioplasty at two hospitals that did not offer surgical support.(50) Although this was technically an uncontrolled study, they compared a subgroup of patients (all patients with ST-segment elevation MI) to a similar group of patients described in the Primary Angioplasty Registry (a registry of hospitals with cardiac surgical backup).(53) They found no statistically significant between-group differences in mortality (3.9% vs 4.0%, p = 0.82), stroke (0.4% vs 1.0%, p = 1.0), or reinfarction rates (3% vs 3%). The authors did not make risk adjustments to account for potential differences between the two populations.

Weaver et al. compared post-PCI outcomes after MI at several hospitals with and without cardiac surgical backup that participated in the Myocardial Infarction Triage and Intervention (MITI) registry. They found no statistically significant between-setting difference in rates of mortality (7% for each) or need for CABG by discharge (8.5% vs 12%, p = 0.07). However, patients at hospitals with cardiac surgical support had a significantly greater chance of undergoing CABG within six hours (p <0.01) or 24 hours (p <0.03) of admission. The authors also performed a multivariable analysis of 30 day mortality, adjusting for baseline differences, and found no significant difference between hospital settings.(51)

Finally, Kutcher et al. compared PCI results in settings with or without surgical support separately for patients with Non-ST MI and ST elevation MI. In both cases they found no statistically significant difference between settings for mortality or need for emergency surgery.(45) However, they did not adjust for baseline differences among patients in different care settings.

Subsection Summary

After searching the literature, retrieving articles, and applying the inclusion/exclusion criteria, we identified seven retrospective controlled studies (five articles and two meeting abstracts) that compared complication rates of non-primary or primary PCI in hospitals with or without cardiac surgical support. These studies ranged from low to fair in quality based on USPSTF ratings. All were vulnerable to potential selection bias from lack of randomization and lack of followup of patients transferred to other hospitals. Generalizability to the Medicare population was fair except for one study where it was high.

Three studies of non-primary PCI (PCI for reasons other than emergent acute MI) reported conflicting results. One of these studies exclusively evaluated elective PCI procedures and found no statistically significant differences in complication rates between care settings. The remaining two studies evaluated all non-primary PCI procedures (including some emergent procedures). The only study that exclusively evaluated Medicare patients showed a significantly higher mortality rate in hospitals without cardiac surgical support, while the remaining study showed no significant difference between care settings. However, the latter study was of low quality because no adjustments were made to account for baseline between-group differences in patient characteristics. Because these studies were vulnerable to selection bias and differed from each other in several characteristics, the conflicting results cannot be explained with certainty.

Three of the six available studies of primary PCI adjusted for differences in patient risk and three did not. None of them found a statistically significant difference in rates of

mortality or serious morbidity between hospitals with and without cardiac surgical backup. However, the low to fair quality of these studies means that failure to demonstrate a difference does not eliminate the possibility that a difference may exist.

Key Question 4: What Are the Characteristics of Patients Who Have Had Catheterization Procedures in Freestanding Cardiac Catheterization Clinics vs. Hospitals?

Question-Specific Inclusion/Exclusion Criteria

In addition to the general inclusion/exclusion criteria listed under Methods, the following additional criteria were used to select studies for this question:

1. Studies of any design that met the general criteria were acceptable, provided that they contained information on prognostic factors that determined patient care setting (freestanding clinic, hospital with or without cardiac surgical support).

Evidence Base

Our searches did not identify any published studies that directly addressed this question. Since patients at freestanding catheterization centers have typically received only diagnostic procedures, we evaluated only studies of diagnostic procedures for this question. Although there are several relevant studies, none has clearly identified prognostic factors that influenced the physician's decision to treat patients in a given care setting. We therefore looked for studies that indirectly addressed the question.

In this indirect approach, we examined the patient inclusion/exclusion criteria of published studies. Thus, we re-examined all 23 studies that met our criteria for Key Question 1. Studies that reported no information on inclusion/exclusion criteria were excluded from further consideration. Seventeen of the 23 studies reported sufficient information to be included for this question. These studies are listed in Table 6. The excluded studies appear in Table B-1 (Appendix B) along with the reason for exclusion.

Table 6. Evidence Base for Key Question 4

Study Design	References
Randomized Controlled Trials	Block et al.(21)
Case series	Peterson and Peterson(23); Bersin et al.(24); Elliott et al.(25); Clements and Gatlin(27); Kern et al.(28); Murray and Rothman(29); Oldroyd et al.(30); Pink et al.(31); Murdock et al.(32); Mahrer et al.(33); Fighali et al.(34); Klinke et al.(35); Diethrich et al.(37); Gavin et al.(39); Mahrer and Eshoo(38); Baird(42)

Quality of Included Studies

None of the included studies directly studied prognostic factors related to patient referral to a particular care setting. Thus, the quality of all of these studies is low.

Details of Study Enrollees and Study Generalizability

None of the study populations were found to be completely generalizable to the Medicare population. All of the studies that reported age had some overlap with the Medicare population, but the age ranges were generally large, ranging from adolescent or young adult to elderly. Furthermore, females tended to be underrepresented in these studies relative to the Medicare population. Therefore, the generalizability of the studies to the Medicare population was "Fair."[4] Details of the patients enrolled in these studies are presented in Table C-2 and Table C-3 of Appendix C.

Findings of Included Studies

The two studies of freestanding catheterization clinics and the fifteen studies of hospital outpatient catheterization laboratories (see Table E-1, Appendix E) generally included patients who were clinically stable, and excluded one or more subgroups of those considered at high risk (Class IV cardiac disease, refractory unstable angina,

[4] High = Characteristics of all enrolled patients typical of Medicare population; Fair = Characteristics of some enrolled patients typical of Medicare population; Poor = Characteristics of only a few enrolled patients typical of Medicare population or enrolled patients represent a subgroup of Medicare population.

severe congestive heart failure, and recent MI were the most common reasons for exclusion). The majority of studies excluded at least some proportion of higher risk patients, although there was minor variability in the subgroups of patients excluded.

The ACC/SCAI Clinical Expert Consensus Document on Cardiac Catheterization Laboratory Standards recommends slightly different exclusion criteria for diagnostic catheterization in hospital and freestanding settings. Patients thought to be at an increased risk for complications are recommended to be sent to hospitals with cardiac surgical support. Thus, in hospitals without cardiac surgical support, the document recommends the following exclusion criteria for adult patients:

- age >75 years
- NYHA Class III or IV heart failure
- acute, intermediate or high risk ischemic syndromes
- Recent MI with post-infarction ischemia
- Pulmonary edema thought to be caused by ischemia
- Markedly abnormal noninvasive test indicating a high likelihood of left main or severe multivessel coronary disease
- Known left main coronary artery disease
- Severe valvular dysfunction, especially in the setting of depressed left ventricular performance
- Patients at increased risk for vascular complications
- Complex adult congenital heart disease

For freestanding laboratories, the document recommends using all of the above exclusion criteria with the additional exclusion of patients at high risk due to the presence of comorbid conditions, including the need for anticoagulation therapy, poorly controlled hypertension or diabetes, contrast allergy, or renal insufficiency.(1)

These recommendations were published in 2001, which is more recent than most of the published studies evaluating diagnostic catheterization.

Although these recommendations were based on expert consensus, evidence from a published multivariable model for predicting complication risk during diagnostic cardiac catheterization is consistent with some of the above-listed criteria. Based on an analysis of the 1990 SCAI database of diagnostic cardiac catheterization procedures, this study found that unstable angina, congestive heart failure, cardiomyopathy, aortic valve disease, shock, acute MI <24 hrs, multivessel disease, hypertension, and NYHA Class IV were significant independent predictors of an increased complication risk during these procedures (inpatient and moribund status were also independent predictors, but these cases are unlikely to be seen at freestanding clinics).(54)

Subsection Summary

We found no studies that directly addressed this question, but the patient inclusion criteria in 17 of 23 studies from Key Question 1 indirectly provide relevant information. The quality of these studies was low, and their generalizability to the Medicare population was fair.

Both freestanding and hospital outpatient studies included clinically stable patients and excluded one or more subgroups of higher risk patients (with recent MI, Class IV cardiac disease, refractory unstable angina, and severe congestive heart failure, among others). Minor variability appeared in the specific subgroups of patients excluded among the different studies.

An ACC/SCAI expert consensus document recommended similar but slightly more stringent exclusion criteria for freestanding settings than for hospitals without cardiac surgical support. A published multivariable model for predicting complication risks during cardiac catheterization procedures is consistent with some of these recommendations.

Key Question 5. What Are the Current State Regulations, Certificate of Need (CON) Requirements, and Oversight Procedures for Freestanding Cardiac Catheterization Clinics?

This question consists of a review summarizing regulations concerning freestanding cardiac catheterization clinics from all 50 states. Also included is a review of relevant regulations and guidelines from the United Kingdom and Canada.

Question-Specific Inclusion/Exclusion Criteria

To address this question, we considered any type of information related to state regulations, Certificate of Need requirements (CON), and oversight procedures for freestanding catheterization clinics in the U.S. Regulatory information from the U.K. and Canada was also included.

Evidence Base

Our searches identified web documents describing state regulations for freestanding cardiac catheterization clinics. Some documents had no specific language regarding cardiac catheterization or freestanding clinics, but were still relevant (e.g., in certain cases they indicated that the procedures or procedural settings were unregulated). The searches also identified documents describing similar regulations in the U.K. and Canada.

Quality of Included Studies

Because this question involves only reporting existing regulations, assessment of study quality is not relevant.

State Regulations

States that Do Not Prohibit Freestanding Cardiac Catheterization Facilities

The following states currently do not prohibit cardiac catheterization services in freestanding settings: Alabama, Alaska, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maine, Maryland, Minnesota, Missouri, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, Wisconsin, and Wyoming. The District of Columbia also does not prohibit cardiac catheterization services in a freestanding setting. Table F-1 in Appendix F contains regulatory information relevant to freestanding cardiac catheterization services in each of these states.

Although these states have no regulations prohibiting such facilities, sources in 13 (Alabama, Alaska, Connecticut, Hawaii, Maine, Minnesota, Montana, Nebraska, Nevada, North Dakota, Oregon, Rhode Island, West Virginia, plus D.C.) reported that they were unaware of any freestanding diagnostic catheterization clinics currently operating in those states.

States with Regulations Prohibiting Freestanding Cardiac Catheterization Facilities

The following states have regulations that prohibit the performance of cardiac catheterization procedures in a freestanding setting: Colorado, Delaware, Iowa, Massachusetts, Michigan, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, and Vermont. Table F-2 in Appendix contains specific information concerning the regulations prohibiting freestanding cardiac catheterization services in each of these states.

Two states with regulations prohibiting freestanding catheterization facilities have made exceptions to allow diagnostic catheterization procedures in at least one freestanding

facility. The Pennsylvania Department of Health has made an exception for one freestanding center in Philadelphia as part of a demonstration project.(11) If the performance is satisfactory over the trial period, permits may be issued for other such facilities. New Jersey does not currently allow freestanding catheterization facilities, but one freestanding facility is currently operating because it was established as a “private practice of medicine” prior to a statutory change in 1991. Since it was established as a private practice, it is not subject to licensure or any other regulation by New Jersey’s Department of Health and Senior Services.(55)

Although Colorado generally prohibits cardiac catheterization procedures in freestanding settings, this is not true if an ambulatory surgical center is hospital-owned. If so, it does not require a separate license from the state, even if it is not on the same campus as the owner hospital. In this case, the center is free to perform cardiac catheterization procedures. According to a source at the ACC-NCDR database, at least one freestanding facility is currently performing these procedures in Colorado.(56)

Certificate of Need (CON) Laws

If hospitals or medical practices wish to expand or initiate certain healthcare services within a given community, CON laws require them to prove that a need for such services exist within that community. Currently, 36 states plus Washington, D.C. have CON laws, with variations in each state regarding what services are regulated and the minimum economic thresholds that require state review of projects.(57)

Of the 36 states (plus the District of Columbia) with CON laws, 25 (plus D.C.) have CON laws specifically pertaining to cardiac catheterization services. Of these 25 states, 16 (Alabama, Alaska, Connecticut, Georgia, Hawaii, Illinois, Kentucky, Maine, Maryland, Missouri, Rhode Island, South Carolina, Tennessee, Virginia, Washington, and West Virginia) currently do not prohibit freestanding cardiac catheterization facilities and regulate them through CON (see Table F-1 for regulatory information). The remaining nine (Delaware, Iowa, Michigan, Mississippi, New Hampshire, New Jersey, New York,

North Carolina, and Vermont) have regulations prohibiting cardiac catheterization in freestanding settings (see Table F-2 for regulatory information).

Further details regarding state CON laws can be found in the 2005 edition of the National Directory of Health Planning, Policy, and Regulatory Agencies.(58)

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standards

JCAHO is an independent, not-for-profit organization that conducts surveys of healthcare organizations to determine whether they meet certain functional standards related to safety and quality of care. Healthcare organizations that meet the standards after an on-site survey by a team of Joint Commission healthcare professionals receive accreditation. To maintain accreditation, an organization must be surveyed at least once every three years (except for laboratories, which must be surveyed every two years).(59) JCAHO standards are not enforceable by law; they are intended to provide a benchmark of performance that healthcare organizations should attain.

JCAHO functional standards are grouped into nine "chapters": 1) Ethics, rights, and responsibilities, 2) Provision of care, treatment, and services, 3) Medication management, 4) Surveillance, prevention, and control of infection, 5) Improving organization performance, 6) Leadership, 7) Management of the environment of care, 8) Management of human resources, and 9) Management of information. The standards that apply to cardiac catheterization laboratories appear in Table F-3, Appendix F. Further details on standards, including elements of performance used to assess an organization's compliance with standards, can be found in the 2005-2006 Comprehensive Accreditation Manual for Ambulatory Care.(60)

Regulations in Canada and the U.K.

Currently, Health Canada guidelines do not directly specify that cardiac catheterization laboratories must be located in hospitals.(61) Since Canada does not have a national policy on cardiac catheterization services, regulation occurs at the level of the provincial

governments. Of the 13 Canadian provinces and territories, only four responded to our requests for information. These provinces (Alberta, Manitoba, Nova Scotia, and Saskatchewan) all reported that cardiac catheterization services are only performed in hospital settings (although a source in Manitoba stated that no specific regulation prohibited these services in freestanding settings).(62-65) A source in Saskatchewan stated that all insured health services are provided only in hospitals, and cardiac catheterization is an insured service.(65)

The United Kingdom does not allow any cardiac catheterization procedures to be performed outside of a hospital setting.(66)

Subsection Summary

Currently, 37 states (plus D.C.) do not prohibit diagnostic cardiac catheterization procedures in a freestanding setting. In these states, regulation usually occurs through CON programs (16 states plus D.C.). However, 16 states without CON programs have no regulations or licensure requirements for such clinics. Sources in 13 states (plus D.C.) that do not prohibit freestanding catheterization services reported that there were no such facilities (or at least they were not aware of any) currently operating in these states.

Thirteen states have regulations prohibiting cardiac catheterization in freestanding clinics. In three of these states, pilot programs or regulatory loopholes have allowed at least one freestanding facility to perform cardiac catheterization procedures.

Any facility performing cardiac catheterization procedures can voluntarily seek JCAHO accreditation. The facility must meet several functional standards to gain accreditation.

The United Kingdom does not allow any cardiac catheterization procedures to be performed outside of a hospital setting. Canada has no specific regulatory prohibitions on the national level, and four provinces did not report specific prohibitions, but all four reported that no freestanding facilities were performing cardiac catheterization

procedures. We cannot confirm whether any freestanding facilities perform these procedures in the remaining nine Canadian provinces and territories.

Conclusions

The available evidence (consisting of 24 case series) did not reveal substantial differences in complication rates of diagnostic catheterization procedures among freestanding clinics (five studies) and hospital outpatient settings (19 studies). However, this indirect and informal comparison of low quality studies could not be risk-adjusted to compensate for differences in patient characteristics among the studies. Also, none of the freestanding clinic studies reported the length of followup; if it was shorter than the average followup in the hospital outpatient studies, this would create bias in the comparison. Furthermore, we cannot determine whether the relatively low complication rates reported in freestanding studies are generalizable to all freestanding centers, as this evidence base was susceptible to potential publication bias. Since all freestanding clinic studies and most hospital outpatient studies were published in the 1980s, the degree of relevance of the findings to current clinical practice is also unknown. These weaknesses in the evidence base mean that we cannot completely rule out the possibility of differences in complication rates between these settings.

No evidence-based conclusion was possible regarding interventional coronary procedures in freestanding centers. An ACC/SCAI expert consensus document recommended that such procedures not be performed in freestanding settings, and we found no information to suggest that PCI procedures are currently being performed in this setting. Thus, patients who may be potential candidates for combined diagnostic and PCI procedures during a single visit do not have that option in a freestanding clinic. The PCI procedure must be scheduled for another time at a hospital that performs interventional procedures.

This report also evaluated outcomes of PCI procedures at hospitals with and without surgical support. However, hospitals without cardiac surgical support are an imperfect surrogate for freestanding clinics, because even hospitals without cardiac surgical

support have support services and resources beyond what is typically found in freestanding settings. Thus, one cannot be certain to what extent, if any, the findings for interventional procedures in a hospital setting can be extrapolated to a freestanding setting.

Three non-randomized controlled studies of non-primary PCI procedures in hospitals with and without cardiac surgical backup reported conflicting results. Two studies showed no difference in complication rates while the remaining study (the only study that exclusively evaluated Medicare patients) showed significantly higher mortality at hospitals without cardiac surgical support. Because these studies were vulnerable to selection bias and differed from each other in several characteristics, the conflicting results cannot be explained with certainty.

Six non-randomized controlled studies of primary PCI showed consistent findings of no statistically significant difference in rates of mortality or serious morbidity between hospitals with and without cardiac surgical backup. Three of these studies adjusted for differences in patient risk. However, all of these studies were vulnerable to selection bias to a greater or lesser degree, and some may have lacked adequate statistical power to detect a meaningful difference in rates. These flaws in the evidence base mean that failure to demonstrate a difference does not eliminate the possibility that a difference may exist.

Characteristics of patients undergoing cardiac catheterization procedures in freestanding settings and hospital outpatient settings could only be addressed indirectly by examining inclusion/exclusion criteria of freestanding and hospital outpatient case series. Two freestanding clinic studies and 15 hospital outpatient studies included clinically stable patients and excluded one or more categories of higher risk patients (with recent MI, Class IV cardiac disease, refractory unstable angina, and severe congestive heart failure, among others). Minor variability appeared in the specific subgroups of patients excluded among the different studies.

An ACC/SCAI expert consensus document recommended similar but slightly more stringent exclusion criteria for freestanding settings than for hospitals without cardiac

surgical support. A published multivariable model for predicting complication risks during cardiac catheterization procedures is consistent with some of these recommendations.

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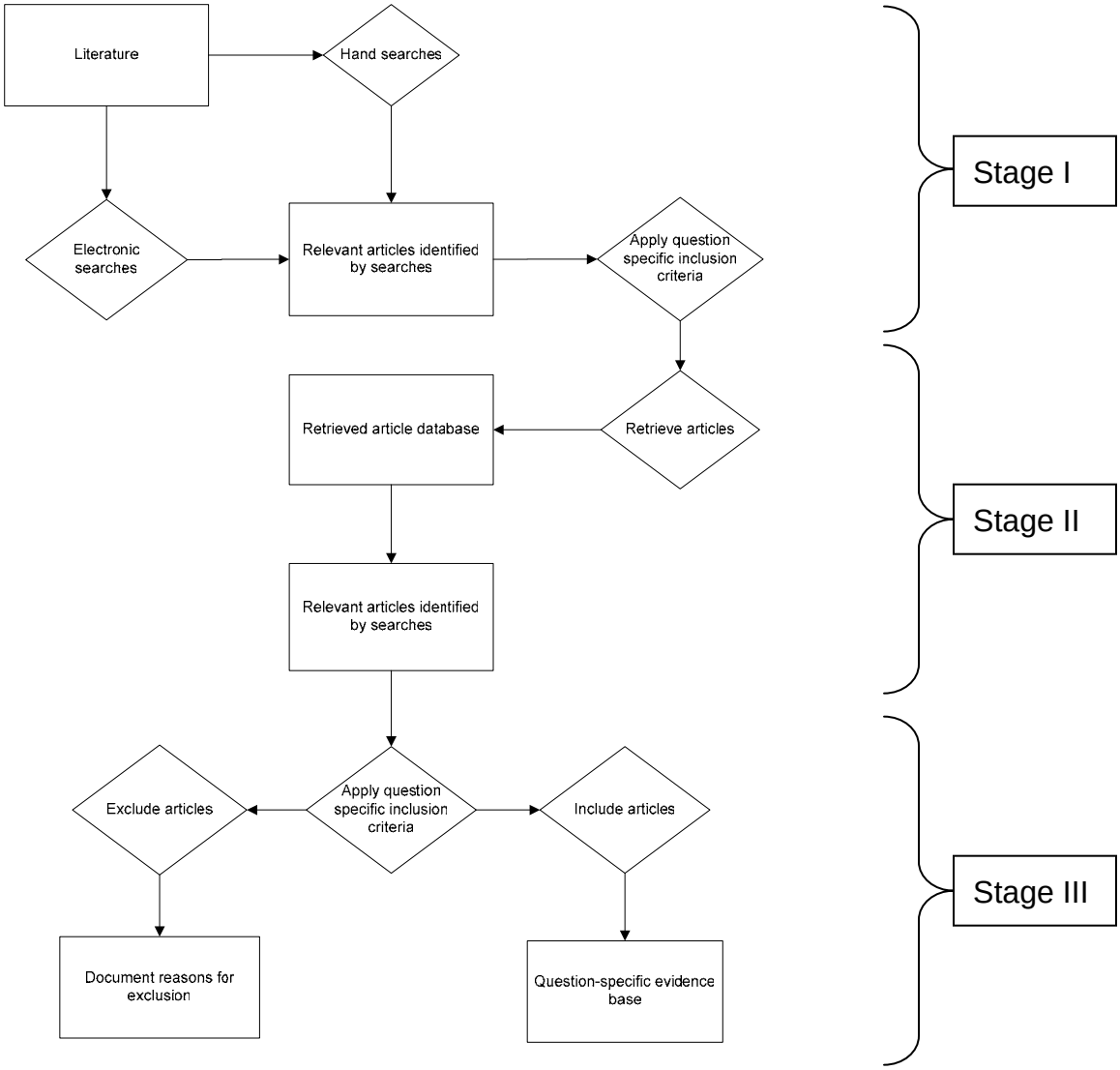
APPENDICES: SUPPORTING DOCUMENTATION AND EVIDENCE TABLES

Appendix A. Literature Searches

The clinical studies included in this report were identified using the algorithm shown in Figure A-1. The first stage of this multi-staged study selection process consisted of a comprehensive literature search. The second stage of the process consisted of the retrieval of all articles that met a set of *a priori* retrieval criteria. The final stage of the study selection algorithm consisted of the selection of the actual studies that form the evidence base for this report using a set of *a priori* inclusion criteria.

Figure A-1. Study Selection Algorithm



Electronic Database Searches

To obtain information for this report, we searched the following databases for relevant information:

PubMed

Several searches were conducted in PubMed to answer the different questions posed by CMS. Searches were not limited by year; retrieval was restricted to English language; fields are “all fields” unless otherwise noted.

Search 1: Questions 1 & 2 : do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for diagnostic/interventional procedures?

1. heart catheterization OR cardiac catheterization
2. heart diseases/su[mh] OR heart diseases/th[mh] OR percutaneous transluminal coronary angioplasty OR ptca OR coronary angioplasty OR cardiac angioplasty OR coronary atherectomy OR intracoronary thrombectomy OR angioplasty, transluminal, percutaneous coronary[mh] OR atherectomy, coronary[mh]
3. heart diseases/di[mh] OR coronary angiography
4. adverse events[sh] OR complications OR safety OR quality of health care OR treatment outcome
5. laboratories OR freestanding OR outpatient clinics, hospital[mh] OR ambulatory care facilities OR outpatient clinic* OR mobile health units
6. #1 OR #2 OR #3
7. #6 AND #4 AND #5
8. hospital units[mh] OR hospitals[mh] OR hospitalization[mh] OR operating room* OR surgical back-up
9. #7 AND #8
10. #1 AND #5 AND comparative study

11. (cardiac catheterization laborator* AND #4) NOT case reports[pt]
12. (#7 OR #11) AND (quality of health care OR treatment outcome)
13. (#1 OR #2) AND #4 AND (evidence-based medicine[mh] OR follow-up studies[mh] OR cross-sectional studies[mh]) AND (#8 OR #5)

Search 2: Question 3: Can interventional catheterization procedures be performed with comparable complication rates at hospitals with and without surgical back-up?

1. c-port OR atlantic cardiovascular patient outcomes research team OR pami-no sos
2. percutaneous coronary intervention* OR pci OR cardiac angioplast* OR coronary angioplast* OR heart angioplast* OR rotational atherectom* OR directional coronary atherectom* OR ptca
3. extraction atherectom* OR laser angioplast* OR intracoronary stent*
4. angio, transluminal, percutaneous coronary[mh] OR coronary artery bypass[mh] OR atherectomy, coronary[mh] OR angioplasty, laser[mh] OR coronary arteriosclerosis/th[mh] OR coronary arteriosclerosis/su[mh]
5. #2 OR #3 OR #4
6. surgery OR surgical
7. backup OR back-up OR onsite OR on-site OR stand-by OR standby
8. #5 AND #6 AND #7
9. #8 NOT (editorial[pt] OR letter[pt] OR case reports[pt]
10. cardiology service, hospital[mh] AND #7 AND #6
11. Prague-2 AND clinical trial*
12. (#2 OR myocardial infarction) AND (transport* OR patient transfer)

Search 3: Question 4: patient characteristics.

1. heart diseases/su[mh] OR heart diseases/th[mh] OR percutaneous transluminal coronary angioplasty OR ptca OR coronary angioplasty OR

cardiac angioplasty OR heart angioplasty OR angioplasty, transluminal, percutaneous coronary[mh]

2. coronary atherectomy OR cardiac atherectomy OR heart atherectomy OR intracoronary thrombectomy OR atherectomy, coronary[mh]
3. cardiac electrophysiology OR coronary angiography OR heart angiography OR cardiac angiography OR echocardiography
4. patient selection[mh] OR outcome assessment (health care)[mh] OR prognostic factors OR survival analysis[mh] OR patient characteristics
5. laboratories OR freestanding OR outpatient clinics, hospital[mh] OR ambulatory care facilities OR outpatient clinic* OR mobile health units OR stand-alone OR cardiac catheterization laborator* OR cath lab*
6. heart catheterization OR cardiac catheterization
7. #1 OR #2 OR #3 OR #6
8. #4 AND #7 AND #5
9. #8 NOT (letter[pt] OR editorial[pt] OR case reports[pt])
10. #7 AND (#5 OR cardiology service, hospital[mh]) AND (patient selection[mh] OR health services accessibility[mh])
11. #5 OR cardiology service, hospital[mh] OR cardiac care facilities
12. #11 AND #7 AND #4
13. #12 AND (comparative study OR health services accessibility[mh])
14. #7 AND utilization[sh]
15. #14 AND #11
16. #7 AND #11 AND comparative study
17. #16 NOT (letter[pt] OR editorial[pt] OR case reports[pt])
18. #7 AND (cath lab*[tw] OR catheterization lab*[tw])
19. #18 AND comparative study

20. #18 AND #4

Search 4: Guidelines and standards for cardiac catheterization procedures.

1. consensus development conferences[mh] OR consensus development conference[pt] OR consensus development conference, nih[pt]
2. #1 OR standards[sh] OR guideline[pt] OR practice guideline[pt] OR guidelines[mh]
3. heart catheterization OR cardiac catheterization
4. #3 AND #2
5. heart diseases/su[mh] OR heart diseases/th[mh] OR percutaneous transluminal coronary angioplasty OR ptca OR coronary angioplasty OR cardiac angioplasty OR angioplasty, transluminal, percutaneous coronary[mh] OR coronary atherectomy OR intracoronary thrombectomy OR atherectomy, coronary[mh] cardiac electrophysiolog* OR intracardiac echocardiography
6. #5 AND #2
7. (#5 OR #3) AND (guideline* OR standard* OR consensus OR “position paper”) AND (in process[sb] OR publisher[sb])
8. cath lab* OR (#3 AND laborator* OR freestanding OR ourpatient clinics, hospital[mh] OR ambulatory care facilities OR outpatient clinic* OR mobile health units)
9. #8 AND (guideline* OR standarad* OR consensus OR “position paper”)
10. #9 AND (united states OR Canada OR great Britain)
11. #8 AND facility regulation and control[mh]

Cath Lab Digest (serial not indexed in PubMed) Searched publication Web site using the following terms:

1. surgical back-up
2. surgical support

3. clinical trials AND back-up
4. c-port
5. freestanding
6. mobile
7. cardiac surgery
8. regulations

National Institute for Clinical Excellence (NICE)

Catheterization [Web site search]

Catheterization [interventional procedures search]

Any[disease] AND cardiology[speciality] AND any[status] [interventional procedures search]

Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Catheterization

National Guideline Clearinghouse (NGC)

Catheterization AND diagnostic tool

Catheterization AND therapeutic tool

Freestanding AND “cardiac catheterization”

Freestanding AND “heart catheterization”

Cath lab*

“cardiac catheterization”[kw] AND diagnosis[category] AND cardiology[clinical speciality]

“cardiac catheterization”[kw] AND treatment[category] AND cardiology[clinical speciality]

Healthcare Standards Directory online (ECRI)

Cardiac catheterization laboratories[kw]

“cardiac catheterization” AND (clinic* OR free*)

“heart catheterization” AND (clinic* OR free*)

percutaneous transluminal coronary angioplasty[kw]

atherectomy AND “coronary artery disease”

cardiac catheterization[kw]

cardiac catheters[kw]

cardiac diagnostic facilities[kw]

electrophysiology AND (cardiac OR coronary OR heart OR coronary)

coronary angiography[kw]

echocardiography[kw]

“vascular stents” AND (coronary OR cardiac OR heart OR “peripheral artery” OR cardiology)

angioplasty AND (coronary OR intracoronary OR cardiac OR heart OR cardiology)

catheter ablative procedures[kw]

Joint Commission for Accreditation of Healthcare Organizations (JCAHO)

Catheterization (JCAHO standards are in the *Comprehensive Accreditation Manual for Ambulatory Care*)

Medscape

Content type – conference coverage.

“onsite surgical” OR “surgical standby” OR “surgical support” OR “surgical backup” OR “onsite surgery” OR surgery standby OR surgery support OR surgery backup

(cardiac OR heart) AND (surgery or surgical) AND (onsite OR on-site OR standby OR stand-by OR backup OR back-up)

(ptca OR coronary angioplasty OR coronary interventions OR pci) AND (onsite OR on-site OR standby OR stand-by OR backup OR back-up)

c-port

pami no-sos

Prague-2

Cochrane

1. Heart catheterization OR cardiac catheterization
2. Freestanding OR stand-alone OR mobile OR ambulatory OR outpatient
3. #1 AND #2
4. angioplasty OR pci OR percutaneous coronary intervention*
5. (on-site OR onsite OR standby OR stand-by OR backup OR back-up) AND (surgery OR surgical)
6. #4 AND #5
7. c-port OR Prague-2 OR pami no-sos

Google

Cardiac catheterization meeting

Heart catheterization meeting

Cath lab meeting

Cardiac catheterization surgical back-up

Heart catheterization surgical back-up

Cath lab surgical back-up

c-port catheterization

pami no-sos

Prague-2 catheterization

LEXIS

State Administrative Codes, combined

(Cardiac catheterization OR heart catheterization) w/5 (freestanding OR ambulatory OR mobile OR outpatient OR stand-alone)

(cardiac catheterization OR heart catheterization) AND freestanding

(heart OR cardiac) catheterization w/p (laborator! OR clinic!) w/p (mobile or freestanding OR ambulatory OR outpatient)

(heart OR cardiac) catheterization w/5 (freestanding OR ambulatory OR mobile) AND [heading] certificate of need

(laborator! OR clinic!) w/10 freestanding AND cardiac

cath lab AND (freestanding OR mobile)

State codes, constitutions, court rules, combined

(cardiac OR heart) catheterization AND (freestanding OR stand-alone OR mobile OR ambulatory OR outpatient)

cath lab! AND (freestanding OR mobile OR stand-alone OR ambulatory OR outpatient)

The following states were searched individually in Lexis because there was no retrieval in the combined search:

Idaho, Connecticut, Colorado, Indiana, Wyoming, Wisconsin, West Virginia, Washington, Utah, Texas, South Dakota, Oregon, Oklahoma, North Dakota, New York, New Mexico, New Hampshire, Nevada, Nebraska, Montana, Missouri, Michigan, Louisiana, Kansas.

Search strategy:

(cardiac catheterization OR heart catheterization OR cath lab!) AND (freestanding OR mobile OR ambulatory OR outpatient) in administrative codes and statutes

The following states were searched more broadly to retrieve additional information:

Alabama, Arkansas, Colorado, Florida, Georgia, Hawaii, Illinois, Kentucky, Maine, Minnesota, Missouri, New York, North Carolina, Rhode Island, South Carolina, Tennessee, West Virginia.

Search strategy:

(heart OR cardiac) w/5 catheter! In Admininstrative codes and Statutes.

Because nothing was found in Lexis search for Colorado and Kentucky, these states were also searched in FindLaw.

EMBASE

The Medline search strategy was translated into Dialog search strategy so that duplicate citations could be removed. All searches were limited to English, human and 1980:2005.

Search 1: Questions 1 & 2 : do freestanding cardiac catheterization clinics and hospitals have comparable complication rates for diagnostic/interventional procedures?

1. Heart()catheterization OR cardiac()catheterization OR intracoronary()thrombectomy OR transluminal coronary angioplasty/de OR (coronary OR heart OR cardiac)(2n)atherectomy OR angiocardiography/de OR heart electrophysiology/de OR echocardiography/de OR percutaneous coronary intervention/de OR intracoronary()stent? OR coronary()stent! OR coronary artery bypass graft/de OR angioplasty/de
2. Adverse()event? OR complication/de OR safety/de OR treatment outcome/de
3. (freestanding or outpatient or mobile or ambulatory)(3N)(clinic OR clinics OR facilit? OR laborat? OR center? OR unit?)
4. Dc=n1.10.400.400 OR operating()room? OR cardiology()service? OR (cardiac()care(3n)(facilit? OR unit?))
5. (1 AND 2) AND (3 OR 4)

Search 2: Question 3. Can PCIs be performed with comparable complication rates at hospitals with and without surgical back-up?

8. (surgery OR surgical)(3n)(backup OR back-up OR onsite OR on-site OR stand-by OR standby) OR patient(3n)(transfer or transport?)
9. 1 AND 8

Search 3: Question 4: patient characteristics

6. Patient()selection/de OR outcome()assessment OR prognostic()factors OR patient()characteristics

7. 1 AND 3 AND 6

Search 4: Guidelines and standards for cardiac catheterization procedures

10. Consensus development/de or practice guideline/maj OR practice()guideline/ti OR position()paper/ti
11. 1 AND 10

Dept. of Health, United Kingdom

Used all of the following strategies:

(heart OR cardiac) AND catheter

“cardiac catheter laboratories”

Cardiac catherisation AND “policy guidance”

Cath labs AND “policy guidance”

Hand Searches of Journal and Nonjournal Literature

Journals and supplements maintained in ECRI’s collections were routinely reviewed. Nonjournal publications and conference proceedings from professional organizations, private agencies, and government agencies were also screened. Other mechanisms used to retrieve additional relevant information included review of bibliographies/reference lists from peer-reviewed and gray literature. (Gray literature

consists of reports, studies, articles, and monographs produced by federal and local government agencies, private organizations, educational facilities, consulting firms, and corporations. These documents do not appear in the peer-reviewed journal literature).

Appendix B. Excluded Studies

Table B-1. Excluded Studies

Reference	Year	Reason for exclusion
Key Question 1		
Chandrasekar et al.(67)	2001	Inpatient and outpatient complications not reported separately
Lee et al.(68)	1990	Inpatient and outpatient complications not reported separately
Johnson et al.(44)	1989	Inpatient and outpatient complications not reported separately
Beauchamp(69)	1981	No quantitative statement (number or rate of complications not reported)
Schneider(70)	1977	No quantitative statement (number or rate of complications not reported)
Key Question 3		
Alter et al.(71)	2003	Combined results for all treatments (PCI, CABG and thrombolysis)
Blondheim et al.(72)	2001	Combined results for all treatments (PCI, CABG and thrombolysis)
Rogers et al.(73)	2000	Combined results for all treatments (PCI, CABG and thrombolysis)
Every et al.(74)	1997	Combined results for all treatments (PCI, CABG and thrombolysis)
Bonzel et al.(75) (abstract)	1994	No quantitative statement regarding complications
Weaver et al.(76)	1993	Earlier results of included study(51)
Meier et al.(77)	1992	Patients were allocated to surgical standby or no surgical standby at a hospital with a cardiac surgery department. Since patients were selected for surgical standby based on specific characteristics that other patients (in the no surgical standby group) lacked, the comparison has a high potential for bias that could confound the comparison.
Key Question 4[a]		
Akdemir et al.(22)	2004	Insufficient information on patient inclusion/exclusion criteria
Clark and Dolce(26)	1993	Insufficient information on patient inclusion/exclusion criteria
Jackson(12)[b]	1989	Insufficient information on patient inclusion/exclusion criteria
Jackson(12)[c]	1989	Insufficient information on patient inclusion/exclusion criteria
Oldroyd et al.(30)	1989	Insufficient information on patient inclusion/exclusion criteria
Fierens(36)	1984	Insufficient information on patient inclusion/exclusion criteria
Perrigo et al.(41) (abstract)	1981	Insufficient information on patient inclusion/exclusion criteria

[a] All studies excluded for Key Question 1 were also excluded for Key Question 4. To avoid redundancy, we have not listed them twice.
[b] Two separate series of patients in freestanding settings were reported in this article. This series was retrospective.
[c] Two separate series of patients in freestanding settings were reported in this article. This series was prospective.

Appendix C. Evidence Tables for Key Question 1

Table C-1. Patient Enrollment Criteria for Studies Addressing Key Question 1

Reference	Year	Inclusion Criteria	Exclusion Criteria
Jackson(12)[a]	1989	NR	NR
Jackson(12)[b]	1989	NR	NR
Diethrich et al.(37)	1981	All patients who received cardiac catheterization in the laboratory over a 20-month period. Patients were selected for catheterization based on their stability and the severity of symptoms.	Patients deemed at high risk (functional Class IV cardiac disease while receiving beta-blockers, highly unstable angina, poorly compensated congestive heart failure, or uncontrolled arrhythmia) were referred to a hospital for invasive study.
Baird(42)	1980	All patients who received cardiac catheterization in the laboratory over 4.5 years. Included patients were clinically stable, ambulatory adults with arteriosclerotic, valvular, or congenital heart disease.	Patients were excluded from the clinic if they had recent MI, arrhythmias, severe congestive heart failure, or were hospitalized with unstable angina complicated by hemodynamic impairment or other serious complications requiring intensive care.
Perrigo et al.(41) (abstract)	1981	NR	NR
Akdemir et al.(22)	2004	NR	NR
Peterson and Peterson(23)	2004	All patients undergoing diagnostic catheterization in the mobile lab over a 7-year period. Only stable patients were accepted.	Patients with refractory unstable angina or MI in evolution were transferred to a tertiary center.
Bersin et al.(24)	1994	All patients undergoing mobile cardiac catheterization at 8 hospitals in 2 mobile labs over a 20-month period. Patients were selected using criteria described in AHA/ACC guideline for outpatient catheterization.	Criteria described in AHA/ACC guideline for outpatient catheterization. Patients with one or more exclusions were recommended for catheterization at a tertiary facility.
Elliott et al.(25)	1994	Patients who did not meet mobile catheterization criteria but were clinically stable enough to enable prescheduling with a planned hospital stay of ≤24 hr.	Patients too unstable to have cardiac catheterization delayed to a prescheduled date.

Table C-1. Patient Enrollment Criteria for Studies Addressing Key Question 1 (continued)

Reference	Year	Inclusion Criteria	Exclusion Criteria
Clark and Dolce(26)	1993	NR	NR
Clements Jr. and Gatlin(27)	1991	All patients who received cardiac catheterization in the outpatient laboratory over a 3-year period. Patients were selected for outpatient catheterization if they were ambulatory and symptoms were not unstable.	Recent MI, congestive heart failure, and advanced age were considered general contraindications.
Kern et al.(28)	1990	All patients undergoing diagnostic left heart catheterization and selective coronary arteriography who were discharged in ≤23 hr after admission in 5 medical centers over a 7-month period.	Patients were excluded if they required continued heparin and arterial sheath placement before either angioplasty or coronary artery bypass surgery, or if they required use of 7F or 8F catheters because of unusually difficult 5F catheter placement or suboptimal angiograms, or both.
Murray and Rothman(29)	1989	All patients planned as day cases over an 11-month period. Patients were considered suitable as day cases if their medical condition was stable, if there was no prolonged period of assessment or treatment planned as an inpatient and if there was no problem in travelling to and from the hospital the same day.	If any of the inclusion criteria were not fulfilled or if a femoral approach to catheterization was planned.
Oldroyd et al.(30)	1989	All patients who received outpatient catheterization performed by the modified Judkins technique over a 3-year period.	None stated
Pink et al.(31)	1989	All patients who received outpatient catheterization over a 41-month period. Patients of any age were accepted if they were clinically stable and free from serious non-cardiac disease.	Patients with unstable coronary syndrome, uncompensated congestive heart failure, serious ventricular arrhythmia, or any other indication of hemodynamic or electrical instability were excluded from the outpatient lab.
Block et al.(21)	1988	Patients scheduled for routine cardiac catheterization with the clinical diagnosis of coronary artery disease, valvular disease, or congenital heart disease.	Patients were excluded if they were over age 70 (women) or age 75 (men), or if they had any of the following conditions: unstable angina pectoris, valvular heart disease with congestive heart failure, bleeding diasthesis, renal insufficiency with a blood urea nitrogen level of >10.7 mmol per liter (30 mg/dl) or a creatinine concentration of >176.8 μmol/l (2 mg/dl), or uncontrolled systolic hypertension (systolic blood pressure >180 mm Hg). Patients were also excluded if they lived >25 miles from the hospital unless they could stay overnight in nearby lodging.

Table C-1. Patient Enrollment Criteria for Studies Addressing Key Question 1 (continued)

Reference	Year	Inclusion Criteria	Exclusion Criteria
Murdock et al.(32)	1988	All patients admitted for outpatient coronary angiography over a 22-month period.	Patients with NYHA functional grade 3 or 4, those with a high probability of proceeding to angioplasty at the same procedure and those who were already inpatients.
Mahrer et al.(33)	1987	All patients seen as elective outpatients over a 31-month period. Elective outpatients were those with stable coronary problems.	Not stated
Fighali et al.(34)	1985	All patients who received outpatient catheterization at the same institution over a 33-month period. Specific criteria for selecting outpatients was not stated.	Patients who were in NYHA functional class 4 in spite of optimal medical management and patients who preferred to be hospitalized for the catheterization procedure.
Klinke et al.(35)	1985	All outpatient cardiac catheterizations performed at the same institution over a 66-month period. Specific criteria for selecting outpatients was not stated, although the authors stated that criteria was up to the individual cardiologist.	Patients already hospitalized because of cardiovascular disease-related complications such as unstable angina, MI or congestive heart failure.
Fierens(36)	1984	NR	NR
Gavin et al.(39)	1981	Consecutive outpatients. Requirements for outpatient catheterization were not stated.	Patients with an identified surgical lesion were selected for inpatient catheterization.
Mahrer and Eshoo(38)	1981	All consecutive outpatients. Patients were considered for outpatient study if they did not meet any of the specific exclusion criteria.	Patients with unstable symptoms, history of recent congestive heart failure, history of life-threatening arrhythmias, severe valvular disease, or associated illnesses such as insulin-dependent diabetes, severe chronic obstructive pulmonary disease (COPD), or steroid dependency were excluded from outpatient study.
Oehlert(40)	1981	Consecutive outpatients. All were required to be clinically stable	Not stated

[a] Two separate series of patients in freestanding settings were reported in this article. This series was retrospective.
[b] Two separate series of patients in freestanding settings were reported in this article. This series was prospective.

NR – Not reported

Table C-2. Characteristics of Patients Receiving Diagnostic Cardiac Catheterization

Author/ year	Care setting	N	Age (mean ±SD)	% female	% prior catheterization	% prior PTCA	% prior CABG	% prior MI	% diabetes	% peripheral vascular disease	% hypertension	% COPD	% current smokers	% CHF	% angina	% history of cholesterol ≥240 mg/dl
Jackson 1989(12)[a]	Freestanding clinic	12472	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Jackson 1989(12)[b]	Freestanding clinic	4512	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Diethrich et al. 1981(37)	Freestanding clinic	254	60 (range 29 to 79)	17.7	27	NR	NR	42.5	11.4	NR	35	NR	24	4.3	NR	NR
Baird 1980(42)	Freestanding clinic	620	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Perrigo et al. 1981(41)	Freestanding clinic	224	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Akdemir et al. 2004(22)	Hospital outpatient (mobile)	1485	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table C-2. Characteristics of Patients Receiving Diagnostic Cardiac Catheterization (continued)

Author/ year	Care setting	N	Age (mean ±SD)	% female	% prior catheterization	% prior PTCA	% prior CABG	% prior MI	% diabetes	% peripheral vascular disease	% hypertension	% COPD	% current smokers	% CHF	% angina	% history of cholesterol ≥240 mg/dl
Peterson and Peterson 2004(23)	Hospital outpatient (mobile)	1775	58.5 (range 27 to 90)	39.5	NR	11 (PTCA or CABG)	See PTCA	NR	NR	NR	NR	NR	NR	NR	NR	NR
Bersin et al. 1994(24)	Hospital outpatient (mobile)	1001	Range 22 to 84	43.6	NR	NR	NR	NR	NR	NR	NR	NR	NR	7.1	46.4	NR
Elliott et al. 1994(25)	Hospital outpatient	277	61 (range 29 to 88)	33.6	NR	NR	NR	NR	NR	NR	NR	NR	NR	13.4	NR	NR
Clark and Dolce 1993(26)	Hospital outpatient	847	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Clements Jr. and Gatlin 1991(27)	Hospital outpatient[c]	3000	NR	NR	NR	NR	13	NR	NR	NR	NR	NR	NR	NR	NR	NR
Kern et al. 1990(28)	Hospital outpatient	287	58 (range 25 to 91)	42	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table C-2. Characteristics of Patients Receiving Diagnostic Cardiac Catheterization (continued)

Author/ year	Care setting	N	Age (mean ±SD)	% female	% prior catheterization	% prior PTCA	% prior CABG	% prior MI	% diabetes	% peripheral vascular disease	% hypertension	% COPD	% current smokers	% CHF	% angina	% history of cholesterol ≥240 mg/dl
Murray and Rothman 1989(29)	Hospital outpatient	855	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Oldroyd et al. 1989(30)	Hospital outpatient	900	54 (range 18 to 76)	20	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Pink et al. 1989(31)	Hospital outpatient	1000	Range 23 to 84	21.5	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Block et al. 1988(21)	Hospital outpatient	192	55.7	18.2	NR	NR	10.9	35.9	2.6	NR	34.4	NR	NR	NR	62	NR
Murdock et al. 1988(32)	Hospital outpatient	1398	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Mahrer et al. 1987(33)	Hospital outpatient	2011	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Fighali et al. 1985(34)	Hospital outpatient	676	59 (range 16 to 76)	32	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table C-2. Characteristics of Patients Receiving Diagnostic Cardiac Catheterization (continued)

Author/ year	Care setting	N	Age (mean ±SD)	% female	% prior catheterization	% prior PTCA	% prior CABG	% prior MI	% diabetes	% peripheral vascular disease	% hypertension	% COPD	% current smokers	% CHF	% angina	% history of cholesterol ≥240 mg/dl
Klinke et al. 1985(35)	Hospital outpatient	3071	NR	26	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Fierens 1984(36)	Hospital outpatient	5107	Range 14 to 86	30	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Gavin et al. 1981(39)	Hospital outpatient	>100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Mahrer and Eshoo 1981(38)	Hospital outpatient	308	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Oehlert 1981(40)	Hospital outpatient	100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

[a] Two separate series of patients in freestanding settings were reported in this article. This series was retrospective.

[b] Two separate series of patients in freestanding settings were reported in this article. This series was prospective.

[c] Outpatient diagnostic cardiac catheterizations are performed in a building across the street from the hospital. However, the building is connected to the hospital by an underground tunnel, so it does not fit the ACC/AHA definition of a freestanding catheterization facility (which is not physically connected to a hospital).

NR – Not reported

Table C-3. Additional Characteristics of Patients Receiving Diagnostic Cardiac Catheterization

Author/ year	Care setting	N	Age (mean ±SD)	% female	% >50% left main stenosis	% three-vessel disease	% two-vessel disease	% single-vessel disease	% mild CAD (lesions ≤50%)	% normal angiogram	% valvular disease	% cardiomyopathy	% left ventricular hypertrophy	% congenital disease
Jackson 1989(12)[a]	Freestanding clinic	12472	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Jackson 1989(12)[b]	Freestanding clinic	4512	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Diethrich et al. 1981(37)	Freestanding clinic	254	60 (range 29 to 79)	17.7	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Baird 1980(42)	Freestanding clinic	620	NR	NR	Ischemic heart disease 59% (not broken down into subcategories)					28.9	9.5	1.3	NR	0.6
Perrigo et al. 1981(41)	Freestanding clinic	224	NR	NR	Significant coronary artery disease 53% (not broken down into subcategories)				NR	NR	14	4	NR	4
Akdemir et al. 2004(22)	Hospital outpatient (mobile)	1485	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Peterson and Peterson 2004(23)	Hospital outpatient (mobile)	1775	58.5 (range 27 to 90)	39.5	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table C-3. Additional Characteristics of Patients Receiving Diagnostic Cardiac Catheterization (continued)

Author/ year	Care setting	N	Age (mean ±SD)	% female	% >50% left main stenosis	% three-vessel disease	% two-vessel disease	% single-vessel disease	% mild CAD (lesions ≤50%)	% normal angiogram	% valvular disease	% cardiomyopathy	% left ventricular hypertrophy	% congenital disease
Bersin et al. 1994(24)	Hospital outpatient (mobile)	1001	Range 22 to 84	43.6	4.7	18	16	19.7	13.6	22.8	4.3	13.3 (cardio-myopathy or LVH)	See cardio-myopathy	NR
Elliott et al. 1994(25)	Hospital outpatient	277	61 (range 29 to 88)	33.6	6.9	22	17.7	26	9.7	12.4	10.1	NR	4	NR
Clark and Dolce 1993(26)	Hospital outpatient	847	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Clements Jr. and Gatlin 1991(27)	Hospital outpatient[c]	3000	NR	NR	2.2	10.8	16	23.5	8.6	23.5	2	NR	NR	NR
Kern et al. 1990(28)	Hospital outpatient	287	58 (range 25 to 91)	42	NR	20	22	24	NR	33	NR	11	NR	NR
Murray and Rothman 1989(29)	Hospital outpatient	855	NR	NR	NR	NR	NR	NR	NR	9	9	NR	NR	NR

Table C-3. Additional Characteristics of Patients Receiving Diagnostic Cardiac Catheterization (continued)

Author/ year	Care setting	N	Age (mean ±SD)	% female	% >50% left main stenosis	% three-vessel disease	% two-vessel disease	% single-vessel disease	% mild CAD (lesions ≤50%)	% normal angiogram	% valvular disease	% cardiomyopathy	% left ventricular hypertrophy	% congenital disease
Oldroyd et al. 1989(30)	Hospital outpatient	900	54 (range 18 to 76)	20	6.2	37.9	22	16.1	NR	17.8	17	5	NR	0.8
Pink et al. 1989(31)	Hospital outpatient	1000	Range 23 to 84	21.5	6.8	33	22.5	33	NR	11.5	2	0.7	NR	0
Block et al. 1988(21)	Hospital outpatient	192	55.7	18.2	5.2	34.4	25.5	21.9	NR	NR	3.7	NR	NR	NR
Murdock et al. 1988(32)	Hospital outpatient	1398	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Mahrer et al. 1987(33)	Hospital outpatient	2011	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Fighali et al. 1985(34)	Hospital outpatient	676	59 (range 16 to 76)	32	5	30	16	14	NR	12	15	4	NR	2
Klinke et al. 1985(35)	Hospital outpatient	3071	NR	26	5	27	32	36	NR	13.6	12.5	3.5 (cardio-myopathy or congenital)	NR	See cardio-myopathy

Table C-3. Additional Characteristics of Patients Receiving Diagnostic Cardiac Catheterization (continued)

Author/ year	Care setting	N	Age (mean ±SD)	% female	% >50% left main stenosis	% three-vessel disease	% two-vessel disease	% single-vessel disease	% mild CAD (lesions ≤50%)	% normal angiogram	% valvular disease	% cardiomyopathy	% left ventricular hypertrophy	% congenital disease
Fierens 1984(36)	Hospital outpatient	5107	Range 14 to 86	30	Coronary artery disease 61% (not broken down into subcategories)					16.5	NR	2.8	NR	NR
Gavin et al. 1981(39)	Hospital outpatient	>100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Mahrer and Eshoo 1981(38)	Hospital outpatient	308	NR	NR	14.6	27.6	22	9.7	NR	16.3	2.6	NR	NR	6.8
Oehlert 1981(40)	Hospital outpatient	100	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

[a] Two separate series of patients in freestanding settings were reported in this article. This series was retrospective.
[b] Two separate series of patients in freestanding settings were reported in this article. This series was prospective.
[c] Outpatient diagnostic cardiac catheterizations are performed in a building across the street from the hospital. However, the building is connected to the hospital by an underground tunnel, so it does not fit the ACC/AHA definition of a freestanding catheterization facility (which is not physically connected to a hospital).

NR – Not reported

Table C-4. Adverse Events Related to Diagnostic Catheterization (Freestanding Clinic and Hospital Outpatient)

Author/ year	Care setting	Length of followup	N	% death	% MI	% stroke/TIA	% pulmonary edema	% coronary dissection	% embolism	% accelerated angina	% ventricular fibrillation	% ventricular tachycardia	% bradycardia/hypotension/ vasovagal reaction	% allergic reaction	% bleeding/hematoma	% arterial thrombosis/ loss of radial pulse	% pseudoaneurysm	% other complications
Jackson 1989(12)[a]	Freestanding clinic	NR	12472	0.03	0.05	0.03	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Jackson 1989(12)[b]	Freestanding clinic	NR	4512	0	0	0.02	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Diethrich et al. 1981(37)	Freestanding clinic	NR	254	0	0	0	0	0	0	0.4	0.4	NR	0.4	0.4	3.1	0	0	Numbness 1.2 Nausea 0.8 Pain 2.0
Baird 1980(42)	Freestanding clinic	NR	620	0.16	0.16	0	0	0.16	0.16	NR	NR	0.16	NR	NR	NR	2.0	NR	Knotted catheter 0.16
Perrigo et al. 1981(41) (abstract)	Freestanding clinic	NR	224	0	0	0	0	0	0	NR	1.8 (arrhythmias)		NR	NR	NR	0.9	NR	NR
Akdemir et al. 2004(22)	Hospital outpatient (mobile)	NR	1485	0	0	0.1	0	0	0	NR	NR	NR	NR	0	NR	NR	0.1	NR

Table C-4. Adverse Events Related to Diagnostic Catheterization (Freestanding Clinic and Hospital Outpatient) (continued)

Author/ year	Care setting	Length of followup	N	% death	% MI	% stroke/TIA	% pulmonary edema	% coronary dissection	% embolism	% accelerated angina	% ventricular fibrillation	% ventricular tachycardia	% bradycardia/hypotension/ vasovagal reaction	% allergic reaction	% bleeding/hematoma	% arterial thrombosis/ loss of radial pulse	% pseudoaneurysm	% other complications
Peterson and Peterson 2004(23)	Hospital outpatient (mobile)	NR	1775	0	0.06	0.06	0	0	0	0.2	0	0.06	0.06	0.2	0.2	NR	NR	Decreased peripheral pulse 0.06 Catheter problem 0.06 Other 0.1
Bersin et al. 1994(24)	Hospital outpatient (mobile)	1 day	1001	0	0.3	0.1	0	0	0	0	0	0.1	0.1	0.2	0.3	0	0.1	0
Elliott et al. 1994(25)	Hospital outpatient	1 day	277	0	0.36	0	0	0	0	0.72	0	0	0	0.36	0	0	0	0
Clark and Dolce 1993(26)	Hospital outpatient	NR	847	0	0	0.1	0	0	0	NR	NR	0.2	0.1	NR	0.2	0.1	NR	NR
Clements Jr. and Gatlin 1991(27)	Hospital outpatient[c]	1 day	3000	0	0	0.07	0.07	0	0	0	0.2	0	0	0.07	0.1	0	0.1	Emergency PTCA 0.3 Peripheral nerve injury 0.3 Infection 0.3

Table C-4. Adverse Events Related to Diagnostic Catheterization (Freestanding Clinic and Hospital Outpatient) (continued)

Author/ year	Care setting	Length of followup	N	% death	% MI	% stroke/TIA	% pulmonary edema	% coronary dissection	% embolism	% accelerated angina	% ventricular fibrillation	% ventricular tachycardia	% bradycardia/hypotension/ vasovagal reaction	% allergic reaction	% bleeding/hematoma	% arterial thrombosis/ loss of radial pulse	% pseudoaneurysm	% other complications
Kern et al. 1990(28)	Hospital outpatient	1 to 3 days	287	0	0	0.3	0	0	0	0	0	0.7	0	0	7.0	0	0	0
Murray and Rothman 1989(29)	Hospital outpatient	NR	855	0	0	NR	NR	NR	NR	1.0	0	0	0.2	NR	0.4	0.2	NR	NR
Oldroyd et al. 1989(30)	Hospital outpatient	NR	900	0.2	0.7	0.1	0.3	0.7	0.1	1.1	0.1	0	0.3	0.2	0.6	0	0.1	0
Pink et al. 1989(31)	Hospital outpatient	1 day	1000	0	0.2	0.4	0	0.1	0	0.9 (un-stable)	0.4 (VF or VT)		0.1	0.3	1.5	0.1	0.1	Congestive heart failure 0.1
Block et al. 1988(21)	Hospital outpatient	7 days	192	0	1.6	0	0	0	0	1.6	NR	NR	0.5	0.5	12	0.5	0	Numbness/ weakness of extremity 0.5 Cold or blue extremity 1.6

Table C-4. Adverse Events Related to Diagnostic Catheterization (Freestanding Clinic and Hospital Outpatient) (continued)

Author/ year	Care setting	Length of followup	N	% death	% MI	% stroke/TIA	% pulmonary edema	% coronary dissection	% embolism	% accelerated angina	% ventricular fibrillation	% ventricular tachycardia	% bradycardia/hypotension/ vasovagal reaction	% allergic reaction	% bleeding/hematoma	% arterial thrombosis/ loss of radial pulse	% pseudoaneurysm	% other complications
Murdock et al. 1988(32)	Hospital outpatient	Up to 1 day	1398	0	0	0.3	0	0	0	0.9 (developed before procedure)	0.14	0	NR	NR	2.9	0.3	0	Ruptured pulmonary artery during Swan-Ganz catheterization 0.07
Mahrer et al. 1987(33)	Hospital outpatient	7 to 14 days	2011	0.05	0.05	0.05	NR	NR	NR	NR	0.6	NR	NR	NR	0	Vascular complications 0.15		Other (unspecified) 0.05
Fighali et al. 1985(34)	Hospital outpatient	1 day	676	0	0	0	0	0	0	0.4	0	0	0	0.1	0	0.4	0	0
Klinke et al. 1985(35)	Hospital outpatient	Up to 30 days	3071	0.13	0.07	0.14	0	0	0.03	NR	0.26 (VF or VT)		0.16	NR	NR	Vascular complications 0.35		NR
Fierens 1984(36)	Hospital outpatient	NR	5107	0	0	0.02	0	0	0	NR	0.14	NR	NR	0.02	NR	2.0	NR	NR
Gavin et al. 1981(39)	Hospital outpatient	NR	>100	0	0	0	0	0	0	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table C-4. Adverse Events Related to Diagnostic Catheterization (Freestanding Clinic and Hospital Outpatient) (continued)

Author/ year	Care setting	Length of followup	N	% death	% MI	% stroke/TIA	% pulmonary edema	% coronary dissection	% embolism	% accelerated angina	% ventricular fibrillation	% ventricular tachycardia	% bradycardia/hypotension/ vasovagal reaction	% allergic reaction	% bleeding/hematoma	% arterial thrombosis/ loss of radial pulse	% pseudoaneurysm	% other complications
Mahrer and Eshoo 1981(38)	Hospital outpatient	7 to 14 days	308	0.3	0.6	0	0	0	0.3	NR	NR	NR	NR	NR	0.6	NR	NR	NR
Oehlert 1981(40)	Hospital outpatient	NR	100	0	0	0	0	0	0	NR	1.0	NR	NR	NR	NR	NR	NR	NR

[a] Two separate series of patients in freestanding settings were reported in this article. This series was retrospective.

[b] Two separate series of patients in freestanding settings were reported in this article. This series was prospective.

[c] Outpatient diagnostic cardiac catheterizations are performed in a building across the street from the hospital. However, the building is connected to the hospital by an underground tunnel, so it does not fit the ACC/AHA definition of a freestanding catheterization facility (which is not physically connected to a hospital).

NR – Not reported

Appendix D. Evidence Tables for Key Question 3

Table D-1. Study Design Characteristics Pertaining to Internal Validity

Reference	Year	Clear definition of interventions?	Prospective?	Sampling method	All baseline patient characteristics comparable?	Blinding?	Overall Attrition: % (n =)	Differential Attrition: % (n =)	Adjustment for potential confounders?	Power of study[a]	USPSTF Quality Rating
Full articles											
Sanborn et al.(46,47)	2004	Yes	No	Cons	No	No	NR	NR	No	NR	Level II-3-Low
Singh et al.(48)	2004	Yes	No	Cons	No	No	NR	NR	Partial	NR	Level-II-3-Fair
Wennberg et al.(49)	2004	Yes	No	Cons	No	No	NR	NR	Yes	Sufficient for all outcomes	Level II-3-Fair
Wharton et al.(50)	1999	Yes	No	Cons	No	No	NR	NR	No	NR	Level II-3-Low
Weaver et al.(51)	1995	Yes	No	Cons	No	No	NR	NR	Yes	NR	Level II-3-Fair
Meeting abstracts											
Kutcher et al.(45)	2004	Yes	No	Cons	No	No	NR	NR	No	Sufficient for all outcomes	Level II-3-Low
Garratt et al.(52)	2002	Yes	No	Cons	No	No	NR	NR	Partial	NR	Level II-3-Fair

Cons – consecutive patients
NA – Not applicable
NR – Not reported

Table D-2. Patient Enrollment Criteria for Studies Addressing Key Question 3

Reference	Year	Inclusion Criteria	Exclusion Criteria
Sanborn et al.(46)	2004	Patients with ST-segment elevation admitted between April 1998 and October 2001 and eligible (ST-segment elevation and/or left bundle branch block at presentation <12 hours after onset of pain) for reperfusion (thrombolytics/PCI) were evaluated.	Patients transferred from another hospital and patients transferred out at <48 hours were excluded from the analysis of primary PCI results.
Singh et al.(48)	2004	Patients with a diagnosis of acute MI in whom PCI was performed at a single institution over a 14-month period. Comparable patients from the same time period at a tertiary center with cardiac surgical backup were included.	Patients with cardiogenic shock or incessant ventricular tachyarrhythmia and those who had received thrombolytic therapy were excluded. Also excluded were patients who were treated at both institutions.
Wennberg et al.(49)	2004	All fee-for-service Medicare enrollees who were aged at least 65 years and who underwent PCIs at acute care facilities between January 1, 1999 and December 31, 2001. Only first procedures were included.	Patients with unknown procedure dates were excluded, as were patients who had CABG surgery during hospitalization but prior to PCI. Patients with PCIs occurring after December 1, 2001 were also excluded to allow 30 days of followup, as were patients who had PCIs in hospitals that opened or closed CABG surgery programs during the study period.

Table D-2. Patient Enrollment Criteria for Studies Addressing Key Question 3 (continued)

Reference	Year	Inclusion Criteria	Exclusion Criteria
Wharton et al.(50)	1999	Consecutive patients with AMI who received PCI at two institutions over a 6-year period. The study population included patients with a clinical impression of AMI: over 30 min of ischemic pain not controlled by conventional medications or an ECG demonstrating ≥2 mV of ST segment elevation in 2 or more contiguous leads. There was no time cutoff if the clinical impression suggested myocardial necrosis. Patients with cardiogenic shock surviving the emergency department were included. Also included were all patients with out-of-hospital ventricular fibrillation who had successful cardioversion in the field, regardless of acute mental status on arrival.	Patients who presented more than 12 h after onset of pain were not included if they were symptom-free on emergency department arrival. Also not included were patients with ventricular septal rupture or papillary muscle rupture, who were taken to the catheterization laboratory for stabilization and IABP before emergent transfer. Angioplasty was not performed if there was Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow in the infarct-related artery (IRA) in hemodynamically stable asymptomatic patients, or if there was significant (≥60%) stenosis of an unprotected left main coronary artery upstream from an acute occlusion in the left coronary system that might be disrupted by the angioplasty catheter. Angioplasty was also avoided in extremely long or angulated infarct-related lesions with TIMI grade 3 flow, infarct-related lesions of small or secondary vessels and lesions in other than the IRA (unless they appeared to be flow-limiting in patients with hemodynamic instability or ongoing symptoms).
Weaver et al.(51)	1995	All patients with AMI admitted over a 6-year period at 10 hospitals who were treated using primary coronary angioplasty within 6 hours of admission and who did not receive intravenous thrombolytic therapy.	Patients with MI as a consequence of other illnesses or those with MI after admission for unstable angina were not included. Patients who had cardiac arrest prior to hospital admission and patients who were initially treated by thrombolysis and then underwent angioplasty (rescue angioplasty) were also excluded.
Kutcher et al.(45) (abstract)	2004	NR	NR
Garratt et al.(52) (abstract)	2002	All patients who received elective PCI at two institutions over a 2-year period. Specific criteria for selection of patients for elective PCI were not reported.	NR

NR – Not reported

Table D-3. Characteristics of Patients Receiving Non-Primary Percutaneous Coronary Intervention

Author/ year	Type of hospital	n	Age (mean ±SD)	% female	% prior revascularization	% prior PTCA	% prior CABG	% prior MI	% diabetes	% peripheral vascular disease	% hypertension	% multivessel disease	% COPD	% current smokers	% history of CHF	% history of angina	% hypercholesterolemia
Wennberg et al. 2004(49)	Without surgical support	6373	NR	45.5	NR	NR	NR	6.8	25.6	9.4	NR	NR	14.4	NR	NR	NR	NR
	With surgical support	583149	NR	43.2	NR	NR	NR	10.5	24.8	9.4	NR	NR	13.3	NR	NR	NR	NR
Kutcher et al. 2004(45) (abstract)[a]	Without surgical support	2537	NR	NR	NR	26	13	24	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	275568 (total – non-primary plus primary)	NR	NR	NR	35 p <0.0001	19 p <0.0001	29 p <0.0001	NR	NR	NR	NR	NR	NR	NR	NR	NR
Garratt et al. 2002(52) (abstract) elective PCI	Without surgical support	206	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	690	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

[a] For this study, patient characteristic data only reported for the entire patient group (not divided into primary and non-primary PCI).

NR – Not reported

Table D-4. Additional Characteristics of Patients Receiving Non-Primary Percutaneous Coronary Intervention

Author/ year	Type of hospital	N	Age (mean ±SD)	% female	% >50% left main stenosis	% three-vessel disease	% two-vessel disease	% single-vessel disease	% mild CAD (lesions ≤50%)	% normal angiogram	% valvular disease	% cardiomyopathy	% left ventricular hypertrophy	% congenital disease
Wennberg et al. 2004(49)	Without surgical support	6373	NR	45.5	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	583149	NR	43.2	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Kutcher et al. 2004(45) (abstract)[a]	Without surgical support	2537	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	275568 (total – non-primary plus primary)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Garratt et al. 2002(52)	Without surgical support	206	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
(abstract) elective PCI	With surgical support	690	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table D-5. Characteristics of Patients Receiving Primary Percutaneous Coronary Intervention

Author/ year	Type of hospital	n	Age (mean ±SD)	% female	% prior revascularization	% prior PTCA	% prior CABG	% prior MI	% diabetes	% peripheral vascular disease	% hypertension	% multivessel disease	% COPD	% current smokers	% history of CHF	% history of angina	% hypercholesterolemia
Sanborn et al. 2004(46)	Diagnostic cath without surgical support	817	61.1 (12.7)	30.5	NR	9.6	3.3	15.1	16.4	NR	46.8	NR	NR	41.3	4.4	7.2	33.8
	Elective PCI without surgical support	1057	61.4 (13.1)	26.7	NR	13.2	5.7	17.7	17.3	NR	46.6	NR	NR	41.6	3.7	4.9	35.5
	With surgical support	24890	62.0 (13.1)	28.8	NR	14.6 p = 0.0001	6.2 p = 0.002	16.9	18.4	NR	47.9	NR	NR	37.2 p = 0.001	3.3	8.5 p = 0.0001	36.7
Singh et al. 2004(48)	Without surgical support	160	64 (13)	24	13	11	4	NR	16	9	56	54	NR	29	4	NR	33
	With surgical support	160	64 (13)	35 p = 0.04	21 p = 0.04	17	7	NR	19	5	63	49	NR	33	5	NR	58 p <0.001

Table D-5. Characteristics of Patients Receiving Primary Percutaneous Coronary Intervention (continued)

Author/ year	Type of hospital	n	Age (mean ±SD)	% female	% prior revascularization	% prior PTCA	% prior CABG	% prior MI	% diabetes	% peripheral vascular disease	% hypertension	% multivessel disease	% COPD	% current smokers	% history of CHF	% history of angina	% hypercholesterolemia
Wennberg et al. 2004(49)	Without surgical support	1795	Means NR. See other	42.7	NR	NR	NR	4.6	18.2	5.3	NR	NR	13.9	NR	NR	NR	NR
	With surgical support	34537		44.2	NR	NR	NR	4.5	19.7	5.7	NR	NR	13.7	NR	NR	NR	NR
Wharton et al. 1999(50)	Without surgical support	231	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	245	58 (median)	25	NR	13	7	21	14	7	50	NR	NR	42	2	NR	NR
Weaver et al. 1995(51)	Without surgical support	470	59 (50 to 67)	21	NR	7	7	13	11	NR	NR	NR	NR	NR	2	23	NR
	With surgical support	592	61 (53 to 70)	27 p = 0.01	NR	10	9	16	11	NR	NR	NR	NR	NR	4	25	NR

Table D-5. Characteristics of Patients Receiving Primary Percutaneous Coronary Intervention (continued)

Author/ year	Type of hospital	n	Age (mean ±SD)	% female	% prior revascularization	% prior PTCA	% prior CABG	% prior MI	% diabetes	% peripheral vascular disease	% hypertension	% multivessel disease	% COPD	% current smokers	% history of CHF	% history of angina	% hypercholesterolemia
Kutcher et al. 2004(45) (abstract)[a]	Without surgical support	2537	NR	NR	NR	26	13	24	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	275568 (total – non-primary plus primary)	NR	NR	NR	35 p <0.0001	19 p <0.0001	29 p <0.0001	NR	NR	NR	NR	NR	NR	NR	NR	NR

[a] For this study, patient characteristic data only reported for the entire patient group (not divided into primary and non-primary PCI).

NR – Not reported

Table D-6. Additional Characteristics of Patients Receiving Primary Percutaneous Coronary Intervention

Author/ year	Type of hospital	N	Age (mean ±SD)	% female	% >50% left main stenosis	% three-vessel disease	% two-vessel disease	% single-vessel disease	% mild CAD (lesions ≤50%)	% normal angiogram	% valvular disease	% cardiomyopathy	% left ventricular hypertrophy	% congenital disease
Sanborn et al. 2004(46)	Diagnostic cath without surgical support	817	61.1 (12.7)	30.5	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Elective PCI without surgical support	1057	61.4 (13.1)	26.7	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	24890	62.0 (13.1)	28.8	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Singh et al. 2004(48)	Without surgical support	160	64 (13)	24	NR	54		NR	NR	NR	NR	NR	NR	NR
	With surgical support	160	64 (13)	35 p = 0.04	NR	49 (multivessel disease)		NR	NR	NR	NR	NR	NR	NR
Wennberg et al. 2004(49)	Without surgical support	1795	Means NR. See other	42.7	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	34537		44.2	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table D-6. Additional Characteristics of Patients Receiving Primary Percutaneous Coronary Intervention (continued)

Author/ year	Type of hospital	N	Age (mean ±SD)	% female	% >50% left main stenosis	% three-vessel disease	% two-vessel disease	% single-vessel disease	% mild CAD (lesions ≤50%)	% normal angiogram	% valvular disease	% cardiomyopathy	% left ventricular hypertrophy	% congenital disease
Wharton et al. 1999(50)	Without surgical support	231	NR	NR	NR	NR	NR	NR			NR	NR	NR	NR
	With surgical support	245	58 (median)	25	NR	18	35	47 (0 to 1 vessel disease)			NR	NR	NR	NR
Weaver et al. 1995(51)	Without surgical support	470	59 (50 to 67)	21	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	592	61 (53 to 70)	27 p = 0.01	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Kutcher et al. 2004(45) (abstract)[a]	Without surgical support	2537	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	275568 (total – non-primary plus primary)	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table D-7. Adverse Events Related to Non-Primary Percutaneous Coronary Intervention (Hospitals With and Without Surgical Support)

Author/ year	Type of hospital	n	Length of followup	% death	% CABG	% reinfarction	% stroke/TIA	% pulmonary edema	% coronary dissection	% embolism	% accelerated angina	% ventricular fibrillation	% ventricular tachycardia	% bradycardia/hypotension/ vasovagal reaction	% allergic reaction	% bleeding/hematoma	% arterial thrombosis/ loss of radial pulse	% pseudoaneurysm	% other complications
Wennberg et al. 2004(49)	Without surgical support	6373	30 days	4.6	1.2	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	583149		2.8 p = 0.001	1.1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Kutcher et al. 2004(45) (abstract)	Without surgical support	1668	NR	0.54	0.24	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	198555		0.46	0.62	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Garratt et al. 2002(52)	Without surgical support	206	NR	0.49	0.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
(abstract) elective PCI	With surgical support	690		0.72	0.43	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

NR – Not reported

Table D-8. Adverse Events Related to Primary Percutaneous Coronary Intervention (Hospitals With and Without Surgical Support)

Author/ year	Type of hospital	n	Length of followup	% death	% CABG	% reinfarction	% stroke/TIA	% pulmonary edema	% coronary dissection	% embolism	% accelerated angina	% ventricular fibrillation	% ventricular tachycardia	% bradycardia/hypotension/ vasovagal reaction	% allergic reaction	% bleeding/hematoma	% arterial thrombosis/ loss of radial pulse	% pseudoaneurysm	% other complications
Sanborn et al. 2004(46)	Diagnostic cath without surgical support	817	IH	3.2	0	0.6	0.6	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Elective PCI without surgical support	1057		4.2	0	1.5	0.4	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	24890		4.8	4.9	1.2	0.7	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Singh et al. 2004(48)	Without surgical support	160	IH	1.9	0.6	0.6	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	160		1.3	0.6	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Wennberg et al. 2004(49)	Without surgical support	1795	30 days	11.3	4.6	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	34537		12.2	5.1	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

Table D-8. Adverse Events Related to Primary Percutaneous Coronary Intervention (Hospitals With and Without Surgical Support) (continued)

Author/ year	Type of hospital	n	Length of followup	% death	% CABG	% reinfarction	% stroke/TIA	% pulmonary edema	% coronary dissection	% embolism	% accelerated angina	% ventricular fibrillation	% ventricular tachycardia	% bradycardia/hypotension/ vasovagal reaction	% allergic reaction	% bleeding/hematoma	% arterial thrombosis/ loss of radial pulse	% pseudoaneurysm	% other complications
Wharton et al. 1999(50)	Without surgical support	231	IH	3.9	NR	3.0	0.4	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	245		4.0	NR	3.0	1.0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Weaver et al. 1995(51)	Without surgical support	470	IH	7	8.5	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	592		7	12	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Kutcher et al. 2004(45) (abstract)	*ST elev MI*		NR																
	Without surgical support	491		4.89	1.22	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	38939		4.89	1.19	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	Non-ST elev MI		NR																
	Without surgical support	378		2.65	0	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
	With surgical support	38005		2.23	0.83	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

IH – In-hospital. Duration of hospital stay varied among patients; average duration was not reported.
NR – Not reported

Appendix E. Evidence Tables for Key Question 4

Table E-1. Patient Enrollment Criteria for Studies Addressing Key Question 4

Reference	Year	Inclusion Criteria	Exclusion Criteria
Diethrich et al.(37)	1981	All patients who received cardiac catheterization in the laboratory over a 20-month period. Patients were selected for catheterization based on their stability and the severity of symptoms.	Patients deemed at high risk (functional Class IV cardiac disease while receiving beta-blockers, highly unstable angina, poorly compensated congestive heart failure, or uncontrolled arrhythmia) were referred to a hospital for invasive study.
Baird(42)	1980	All patients who received cardiac catheterization in the laboratory over 4.5 years. Included patients were clinically stable, ambulatory adults with arteriosclerotic, valvular, or congenital heart disease.	Patients were excluded from the clinic if they had recent MI, arrhythmias, severe congestive heart failure, or were hospitalized with unstable angina complicated by hemodynamic impairment or other serious complications requiring intensive care.
Peterson and Peterson(23)	2004	All patients undergoing diagnostic catheterization in the mobile lab over a 7-year period. Only stable patients were accepted.	Patients with refractory unstable angina or MI in evolution were transferred to a tertiary center.
Bersin et al.(24)	1994	All patients undergoing mobile cardiac catheterization at 8 hospitals in 2 mobile labs over a 20-month period. Patients were selected using criteria described in AHA/ACC guideline for outpatient catheterization.	Criteria described in AHA/ACC guideline for outpatient catheterization. Patients with one or more exclusions were recommended for catheterization at a tertiary facility.
Elliott et al.(25)	1994	Patients who did not meet mobile catheterization criteria but were clinically stable enough to enable prescheduling with a planned hospital stay of $\leq$24 hr.	Patients too unstable to have cardiac catheterization delayed to a prescheduled date.
Clements Jr. and Gatlin(27)	1991	All patients who received cardiac catheterization in the outpatient laboratory over a 3-year period. Patients were selected for outpatient catheterization if they were ambulatory and symptoms were not unstable.	Recent MI, congestive heart failure, and advanced age were considered general contraindications.

Table E-1. Patient Enrollment Criteria for Studies Addressing Key Question 4 (continued)

Reference	Year	Inclusion Criteria	Exclusion Criteria
Kern et al.(28)	1990	All patients undergoing diagnostic left heart catheterization and selective coronary arteriography who were discharged in ≤23 hr after admission in 5 medical centers over a 7-month period.	Patients were excluded if they required continued heparin and arterial sheath placement before either angioplasty or coronary artery bypass surgery, or if they required use of 7F or 8F catheters because of unusually difficult 5F catheter placement or suboptimal angiograms, or both.
Murray and Rothman(29)	1989	All patients planned as day cases over an 11-month period. Patients were considered suitable as day cases if their medical condition was stable, if there was no prolonged period of assessment or treatment planned as an inpatient and if there was no problem in travelling to and from the hospital the same day.	If any of the inclusion criteria were not fulfilled or if a femoral approach to catheterization was planned.
Pink et al.(31)	1989	All patients who received outpatient catheterization over a 41-month period. Patients of any age were accepted if they were clinically stable and free from serious non-cardiac disease.	Patients with unstable coronary syndrome, uncompensated congestive heart failure, serious ventricular arrhythmia, or any other indication of hemodynamic or electrical instability were excluded from the outpatient lab.
Block et al.(21)	1988	Patients scheduled for routine cardiac catheterization with the clinical diagnosis of coronary artery disease, valvular disease, or congenital heart disease.	Patients were excluded if they were over age 70 (women) or age 75 (men), or if they had any of the following conditions: unstable angina pectoris, valvular heart disease with congestive heart failure, bleeding diasthesis, renal insufficiency with a blood urea nitrogen level of >10.7 mmol per liter (30 mg/dl) or a creatinine concentration of >176.8 μmol/l (2 mg/dl), or uncontrolled systolic hypertension (systolic blood pressure >180 mm Hg). Patients were also excluded if they lived >25 miles from the hospital unless they could stay overnight in nearby lodging.
Murdock et al.(32)	1988	All patients admitted for outpatient coronary angiography over a 22-month period.	Patients with NYHA functional grade 3 or 4, those with a high probability of proceeding to angioplasty at the same procedure and those who were already inpatients.
Mahrer et al.(33)	1987	All patients seen as elective outpatients over a 31-month period. Elective outpatients were those with stable coronary problems.	Not stated

Table E-1. Patient Enrollment Criteria for Studies Addressing Key Question 4 (continued)

Reference	Year	Inclusion Criteria	Exclusion Criteria
Fighali et al.(34)	1985	All patients who received outpatient catheterization at the same institution over a 33-month period. Specific criteria for selecting outpatients were not stated.	Patients who were in NYHA functional class 4 in spite of optimal medical management and patients who preferred to be hospitalized for the catheterization procedure.
Klinke et al.(35)	1985	All outpatient cardiac catheterizations performed at the same institution over a 66-month period. Specific criteria for selecting outpatients were not stated, although the authors stated that criteria were up to the individual cardiologist.	Patients already hospitalized because of cardiovascular disease-related complications such as unstable angina, MI or congestive heart failure.
Gavin et al.(39)	1981	Consecutive outpatients. Requirements for outpatient catheterization were not stated.	Patients with an identified surgical lesion were selected for inpatient catheterization.
Mahrer and Eshoo(38)	1981	All consecutive outpatients. Patients were considered for outpatient study if they did not meet any of the specific exclusion criteria.	Patients with unstable symptoms, history of recent congestive heart failure, history of life-threatening arrhythmias, severe valvular disease, or associated illnesses such as insulin-dependent diabetes, severe chronic obstructive pulmonary disease (COPD), or steroid dependency were excluded from outpatient study.
Oehlert(40)	1981	Consecutive outpatients. All were required to be clinically stable	Not stated

NR – Not reported

Appendix F. Regulations and Standards (Key Question 5)

Table F-1. Regulations in States that Do Not Prohibit Cardiac Catheterization in Freestanding Settings

State	Regulation	Regulating body
Alabama	No law or regulation prohibits cardiac catheterization in a freestanding setting. Currently, no such services are offered in a freestanding setting; initiation of such a clinic would require a CON application.(78,79)	State Health Planning and Development Agency
Alaska	No law or regulation prohibits cardiac catheterization in a freestanding setting. Currently, no such services are offered in a freestanding setting; initiation of such a clinic would require a CON application, unless built by a physicians group (and not defined as a health care facility) or if the cost was below the state's CON threshold of $1 million.. Interventional catheterization procedures are limited to hospitals with cardiac surgical support.(80)	Department of Health and Social Services
Arizona	Freestanding cardiac catheterization facilities are allowed and licensed under the category "outpatient treatment centers". This category prohibits any procedures that would require an overnight stay.(81,82)	Arizona Department of Health Services
Arkansas	As long as the procedures performed do not include (a) surgical procedures; nor (b) the use of general or intravenous anesthetics; and, (c) in the opinion(s) of the attending physicians, hospitalization is not necessary, a clinic or office does not fall within the Arkansas definition of an Ambulatory or Outpatient Surgical Center ("ASC"), nor of a Hospital.(83) Arkansas currently has no regulations that require licensure under the above-described conditions, and a freestanding cardiac catheterization facility could meet all of these conditions.	None
California	According to the California Health and Safety Code, Section 100921-100922, "a freestanding cardiac catheterization laboratory that as of December 31, 1993, was in active status in the Health Care Pilot Project…..may be licensed by the State Department of Health Services as a freestanding cardiac catheterization laboratory." These laboratories are "subject to the Department's regulations that govern cardiac catheterization laboratories operating in hospitals without facilities for cardiac surgery," as well as other general regulations. The laboratories must also have a system for the ongoing evaluation of their operations and the services they provide, including a written plan for evaluating the efficiency and effectiveness of the health care services provided.(84)	California Department of Health Services

Table F-1. Regulations in States that Do Not Prohibit Cardiac Catheterization in Freestanding Settings (continued)

State	Regulation	Regulating body
Connecticut	According to a source at the Office of Health Care Access, No law or regulation prohibits cardiac catheterization in a freestanding setting. Currently, no such services are offered in a freestanding setting; initiation of such a clinic would require a CON application.(85)	Office of Health Care Access
District of Columbia	No law or regulation prohibits cardiac catheterization in a freestanding setting. Currently, no such services are offered in a freestanding setting; initiation of such a clinic would require a CON application.(86)	State Health Planning and Development Agency
Florida	There are no state licensure requirements for freestanding cardiac catheterization facilities.(87) Inpatient cardiac catheterization facilities are regulated through the CON program.(88)	None (for freestanding facilities)
Georgia	Freestanding cardiac catheterization facilities are allowed and regulated through the CON program. According to Rules and Regulations of the State of Georgia 272-2-.09 (Standards and Criteria, amended), "for CON purposes, Adult Cardiac Catheterization Services is classified as a new institutional health service which must be delivered in a permanently fixed location in either an acute care hospital or in a diagnostic, treatment, or rehabilitation center (DTRC). A CON will be required prior to the establishment of a new or expanded adult cardiac catheterization service." Interventional catheterization procedures must be performed in acute care hospitals with open heart surgery services or in a hospital that has a Department-approved written agreement for open heart surgery backup with an adjacent acute care hospital.(89)	Division of Health Planning, Department of Community Health
Hawaii	No law or regulation prohibits cardiac catheterization in a freestanding setting. Currently, no such services are offered in a freestanding setting; initiation of such a clinic would require a CON application.(90)	State Health Planning and Development Agency
Idaho	No law or regulation prohibits cardiac catheterization in a freestanding setting.(91) However, any procedure requiring an overnight stay must be performed in a hospital setting.	None
Illinois	Freestanding cardiac catheterization facilities are allowed and regulated through the CON program. The Illinois Administrative Code 205.135 (Diagnostic Catheterization Procedures) contains further details of the requirements that must be met for diagnostic catheterization procedures to be performed in this setting.(92)	Department of Public Health
Indiana	Freestanding cardiac catheterization facilities are licensed as "ambulatory surgical centers" under the Indiana Administrative Code 410 IAC 15-2.(93)	Indiana State Department of Health
Kansas	No law or regulation prohibits cardiac catheterization in a freestanding setting.(94,95)	None

Table F-1. Regulations in States that Do Not Prohibit Cardiac Catheterization in Freestanding Settings (continued)

State	Regulation	Regulating body
Kentucky	Freestanding cardiac catheterization facilities are allowed and regulated through the CON program. Currently, only one is operating in the state.(96)	Office of Certificate of Need
Louisiana	No law or regulation prohibits cardiac catheterization in a freestanding setting, and there are no licensing requirements for such facilities.(97)	None
Maine	No law or regulation prohibits cardiac catheterization in a freestanding setting. Currently, no such services are offered in a freestanding setting; initiation of such a clinic would require a CON application.(98)	Bureau of Elder and Adult Services, Department of Health and Human Services
Maryland	Freestanding cardiac catheterization facilities are allowed and regulated under the licensure category "freestanding ambulatory care facility/major medical equipment facility." Licensure requires a CON or an exemption from CON. (Code of Maryland Regulations 10.05.03, Freestanding Major Medical Equipment Facilities).(99)	Department of Health and Mental Hygiene
Minnesota	No law or regulation prohibits cardiac catheterization in a freestanding setting. The Department is not aware of any freestanding clinics currently offering these services in the state.	None
Missouri	Freestanding cardiac catheterization facilities are allowed and regulated through the CON program.(100)	Department of Health and Senior Services
Montana	No law or regulation prohibits cardiac catheterization in a freestanding setting, as long as patients do not require an overnight stay (this would require that the procedure take place in a hospital). (Montana Code Annotated 50-5-101). A source at the Licensure Bureau was unaware of any freestanding cardiac catheterization clinics operating at present in Montana.(101)	None
Nebraska	No law or regulation prohibits cardiac catheterization in a freestanding setting, except if a patient requires a stay >24 hours, in which case the site would require licensing as a hospital. Sources at the Department of Health and Human Services were unaware of any freestanding cardiac catheterization facilities currently operating within the state.(102,103)	None

Table F-1. Regulations in States that Do Not Prohibit Cardiac Catheterization in Freestanding Settings (continued)

State	Regulation	Regulating body
Nevada	No law or regulation prohibits cardiac catheterization in a freestanding setting, except if a patient requires a stay >24 hours, in which case the site would require licensing as a hospital. A source at the State Health Division was unaware of any freestanding cardiac catheterization facilities currently operating within the state.(104)	None
New Mexico	Freestanding cardiac catheterization facilities are allowed under the category "ambulatory surgical center," which can only provide services that do not require an overnight stay (New Mexico Administrative Code, Title 7, Chapter 11, part 2, Requirements for facilities providing outpatient medical services and infirmaries). These centers are licensed by the Department of Health.(105)	New Mexico Department of Health, Division of Health Improvement, Health Facility License and Certification
North Dakota	No law or regulation prohibits cardiac catheterization in a freestanding setting. A source at the Office of Community Assistance was unaware of any freestanding catheterization clinics currently operating in the state.(106)	None
Oklahoma	No law or regulation prohibits cardiac catheterization in a freestanding setting.(107)	None
Oregon	No requirement that cardiac catheterization facilities be licensed. Freestanding facilities are unregulated. A source at the Office of Public Health Systems was unaware of any freestanding facilities currently performing cardiac catheterization procedures in the state.(108)	None
Rhode Island	No law or regulation prohibits cardiac catheterization in a freestanding setting. Currently, no such services are offered in a freestanding setting; initiation of such a clinic would require a CON application.(109)	Rhode Island Department of Health
South Carolina	Freestanding cardiac catheterization facilities are allowed and regulated through the CON program. Currently, only one is operating in the state.(110)	DHEC, Division of Planning and CON
South Dakota	No requirement that cardiac catheterization facilities be licensed. Freestanding facilities are unregulated.	None
Tennessee	Freestanding cardiac catheterization facilities are allowed and regulated through the CON program. Currently, 11 have been approved in the state.(111)	Tennessee Health Services and Development Agency
Texas	No law or regulation prohibits cardiac catheterization in a freestanding setting. According to a source at the Texas Department of State Health Services, the procedure can be performed in a licensed ambulatory surgery center.(112)	None

Table F-1. Regulations in States that Do Not Prohibit Cardiac Catheterization in Freestanding Settings (continued)

State	Regulation	Regulating body
Utah	No law or regulation prohibits cardiac catheterization in a freestanding setting, except if a patient requires an overnight stay, in which case the procedure can only be performed in a hospital.(113)	Utah Department of Health
Virginia	Freestanding cardiac catheterization facilities are allowed and regulated through the CON program. However, the Virginia Administrative Code 5-260-40 (Criteria and Standards for Cardiac Catheterization Services) specifies that "proposals for the use of freestanding or mobile cardiac catheterization services should only be approved if such services will be provided at a site located on the campus of a general/community hospital."(114)	Virginia Department of Health
Washington	No law or regulation concerns the environment of care in which diagnostic catheterizations are performed. However, interventional catheterizations can only be performed in a hospital setting with an approved CON for heart surgery.(115)	Department of Health
West Virginia	No law or regulation prohibits cardiac catheterization in a freestanding setting. According to a source at the Health Care Authority, no freestanding cardiac catheterization clinics are currently in operation in the state. Initiation of such a clinic would require a CON application.(116)	West Virginia Health Care Authority
Wisconsin	No law or regulation prohibits cardiac catheterization in a freestanding setting.(117)	None
Wyoming	According to a source at the Wyoming Department of Health, the Department "does not require a license for freestanding clinics or any specific procedures in those clinics."(118)	None

CON – Certificate of Need

Table F-2. Regulations in States that Prohibit Cardiac Catheterization in Freestanding Settings

State	Regulation	Regulating body
Colorado	According to State Board of Health Regulation 6 CCR 1011-1, Chapter XX (Ambulatory Surgical Center), "surgical procedures shall be limited to the following: 1. those that do not exceed 23 hours combined operating and recovery and/or convalescent time, and; 2. those that do not generally result in extensive blood loss, *require major or prolonged invasion of body cavities*, directly involve major blood vessels, or constitute an emergency or life threatening procedure."(119) According to a source at the agency, cardiac catheterization is prohibited in ambulatory surgical centers because it directly involves major blood vessels. However, there is a loophole; if an ambulatory surgical center is hospital-owned, it does not require a separate license from the state, and is free of the above restrictions.(120) According to a source at the ACC-NCDR database, at least 1 freestanding facility is performing cardiac catheterization procedures in Colorado.(56)	Department of Public Health and Environment
Delaware	According to a source at the Department of Health and Social Services, "Delaware does not permit such procedures in a freestanding setting. The length of the procedure (plus recovery) is too long to meet the timeframe definition of procedures that may be performed in a freestanding surgical center." (Procedures cannot exceed 90 minutes and the recovery time cannot exceed 4 hours). "Additionally, a freestanding setting does not provide the emergency/support services that may be necessary when a procedure such as this is performed." (This position is not codified in writing, but is based on the 1991 American College of Cardiology/ American Heart Association Guidelines for Cardiac Catheterization. This document stated that further development of cardiac catheterization services operating without on-site cardiac surgery facilities "cannot be endorsed at this time" due to a lack of appropriately controlled safety and need data.)(121)	Department of Health and Social Services
Iowa	According to the Iowa Administrative Code, Chapter 203 (Standards for CON Review), "there should be no new cardiac catheterization unit open in any facility not performing open heart surgery."(122)	Iowa Department of Public Health
Massachusetts	According to the Code of Massachusetts Regulations, Chapter 130.000 (Hospital Licensure), "Cardiac catheterization procedures shall not be performed in a satellite facility or a freestanding clinic."(123)	Massachusetts Department of Public Health
Michigan	According to a source at the Department of Community Health, "the Michigan CON standards for Cardiac Catheterization do not allow for any cardiac catheterization services to be offered outside of a hospital setting."(124)	Michigan Department of Community Health

Table F-2. Regulations in States that Prohibit Cardiac Catheterization in Freestanding Settings (continued)

State	Regulation	Regulating body
Mississippi	According to a policy statement in the State Health Plan, all cardiac catheterizations and open-heart surgery services must be located in acute care hospitals. No CON will be approved for these services in freestanding facilities or in freestanding ambulatory surgery facilities.(125)	Mississippi Department of Health
New Hampshire	According to the New Hampshire Code of Administrative Rules, He-Hea 1102.01 (Location of Adult Diagnostic Cardiac Catheterization Services), "Adult diagnostic cardiac catheterization services shall only be provided on the campus of an acute care facility."(126)	New Hampshire Department of Health and Human Services
New Jersey	The New Jersey Administrative Code 8:33E-1.3b states that "all cardiac catheterization procedures, regardless of the category, shall be performed in a hospital-based facility where inpatient services are available on site."(127) However, one freestanding catheterization facility was established as a private practice of medicine prior to a statutory change in 1991. It is not subject to licensure or regulation by the Department of Health and Senior Services.(55)	New Jersey Department of Health and Senior Services
New York	According to a source at the Department of Health, "New York State does not allow for cardiac cath labs in freestanding clinics. All cardiac cath labs must be within the walls of a hospital."(128,129)	New York State Department of Health
North Carolina	According to the North Carolina Administrative Code, Section 1600 (Criteria and standards for cardiac catheterization equipment and cardiac angioplasty equipment), applicants for such equipment must provide "documentation that the cardiac catheterization equipment and cardiac angioplasty equipment and the procedures for operation of the equipment are designed and developed based on the American College of Cardiology/ American Heart Association Guidelines for Cardiac Catheterization (1991)." This document stated that further development of cardiac catheterization services operating without on-site cardiac surgery facilities "cannot be endorsed at this time" due to a lack of appropriately controlled safety and need data.(130)	Department of Health and Human Services
Ohio	According to the Ohio Administrative Code, 3701-84-30 (Adult cardiac catheterization service standards), "a cardiac catheterization service shall only be provided in a fully permanent setting within the permanent frame of the building of a registered hospital that is classified as a general hospital or a special hospital-cardia that primarily furnishes limited services to patients with cardiac conditions."(131)	Ohio Department of Health

Table F-2. Regulations in States that Prohibit Cardiac Catheterization in Freestanding Settings (continued)

State	Regulation	Regulating body
Pennsylvania	According to the Pennsylvania Administrative Code, 138.14 (Programs and services), "to perform cardiac catheterization a hospital shall be an acute care facility."(132) However, the Pennsylvania Department of Health has made an exception for one freestanding center in Philadelphia as part of a demonstration project.(11)	Pennsylvania Department of Health
Vermont	According to the Vermont CON guidelines, Appendix A (Cardiac Catheterization Work Group Recommendations), cardiac catheterization facilities must "be hospital-based, meaning that they are physically located within a hospital or that they be one of (three) types of mobile labs." These mobile labs cannot operate in a freestanding setting.(133)	Vermont Department of Banking, Insurance, Securities, and Health Care Administration

CON – Certificate of Need

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities

Standard functional chapter	Standard
Ethics, Rights, and Responsibilities (RI)	*Organization Ethics* RI.1.10 – the organization follows ethical behavior in its care, treatment, and services and business practices. RI.1.10 – the organization addresses conflicts of interest. RI.1.30 – the integrity of decisions is based on identified care, treatment, and service needs of the patients. RI.1.40 – when care, treatment, and services are subject to internal or external review that results in the denial of care, treatment, services, or payment, the organization makes decisions regarding the provision of ongoing care, treatment, and services, or discharge based on the assessed needs of the patients.

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities (continued)

Standard functional chapter	Standard
	Individual Rights RI.2.10 – the organization respects the rights of patients. RI.2.20 – patients receive information about their rights. RI.2.30 – patients are involved in decisions about care, treatment, and services provided. RI.2.40 – informed consent is obtained RI.2.50 – consent is obtained for recording or filming made for purposes other than the identification, diagnosis or treatment of patients. RI.2.60 – patients receive adequate information about the person(s) responsible for the delivery of their care, treatment, and services. RI.2.70 – patients have the right to refuse care, treatment, and services in accordance with law and regulation. RI.2.80 – the organization addresses the wishes of the patient relating to end-of-life decisions. RI.2.90 – patients and, when appropriate, their families are informed about the outcomes of care, treatment, and services that have been provided, including unanticipated outcomes. RI.2.100 – the organization respects the patient's right to and need for effective communication. RI.2.110 – not applicable RI.2.120 – the organization addresses the resolution of complaints from patients and their families. RI.2.130 – the organization respects the needs of patients for confidentiality, privacy, and security. RI.2.140 – not applicable RI.2.150 – patients have the right to be free from mental, physical, sexual, and verbal abuse, neglect, and exploitation. RI.2.160 – patients have the right to pain management. RI.2.170 – not applicable RI.2.180 – the organization protects research subjects and respects their rights during research, investigation, and clinical trials involving human subjects.
	Individual Responsibilities RI.3.10 – patients are given information about their responsibilities while receiving care, treatment, and services.

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities (continued)

Standard functional chapter	Standard
Provision of Care, Treatment, and Services (PC)	*Entry to Care, Treatment, and Services* PC.1.10 – the organization accepts for care, treatment, and services only those patients whose identified care, treatment, and service needs it can meet.
	Assessment PC.2.10 – not applicable PC.2.20 – the organization defines in writing the data and information gathered during assessment and reassessment. PC.2.30 through PC.2.110 – not applicable PC.2.120 – the organization defines in writing the time frame(s) for conduction the initial assessment(s). PC.2.130 – initial assessments are performed as defined by the organization. PC.2.140 – not applicable PC.2.150 – patients are reassessed as needed.
	Additional Standards for Victims of Abuse PC.3.10 – patients who may be victims of abuse or neglect are assessed PC.3.20 through PC.3.220 – not applicable
	Diagnostic Services PC.3.230 – diagnostic testing necessary for determining the patient's health care needs is perfomed.
	Planning Care, Treatment, and Services PC.5.10 – the organization provides care, treatment, and services for each patients according to the plan of care, treatment, and services. PC.5.20 through 5.40 – not applicable PC.5.50 – care, treatment, and services are provided in an interdisciplinary, collaborative manner. PC.5.60 – the organization coordinates the care, treatment, and services provided to a patient as part of the plan for care, treatment, and services and consistent with the organization's scope of care, treatment, and services.

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities (continued)

Standard functional chapter	Standard
	Education PC.6.10 – the patient receives education and training specific to the patient's needs and as appropriate to the care, treatment, and services provided. P.C.6.20 – not applicable P.C.6.30 – the patient receives education and training specific to the patient's abilities as appropriate to the care, treatment, and services provided.
	Nutritional Care PC.7.10 – the organization has a process for preparing and/or distributing food and nutrition products as appropriate to the care, treatment, and services provided.
	Pain PC.8.10 – pain is assessed in all patients.
	Administering Blood and Blood Components PC.9.10 – blood and blood components are administered safely, as appropriate to the setting.
	Responding to Life-Threatening Emergencies PC.9.20 – the organization responds to life-threatening emergencies according to organization's policy and procedure.
	Restraint and Seclusion PC.11.10 through PC.11.60 – not applicable PC.11.70 – patients in restraint are monitored. PC.11.80 and 11.90 – not applicable PC.11.100 – each episode of restraint use is documented in the patient's medical record, consistent with organization policies and procedures.
	Operative or Other High-Risk Procedures and/or the Administration of Moderate or Deep Sedation or Anesthesia PC.13.10 – licensed independent practitioners define the scope of assessment for operative or other procedures and/or the administration of moderate or deep sedation or anesthesia are planned. PC.13.30 – patients are monitored during the procedure and/or administration of moderate or deep sedation or anesthesia. PC.13.40 – patients are monitored immediately after the procedure and/or administration of moderate or deep sedation or anesthesia.

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities (continued)

Standard functional chapter	Standard
	Discharge or Transfer from the Organization PC.15.10 – a process addresses the needs for continuing care, treatment, and services after discharge or transfer. PC.15.20 – not applicable PC.15.30 – when patients are transferred or discharged, appropriate information related to the care, treatment, and services provided is exchanged with other service providers.
	Waived Testing PC.16.10 through 16.60 – not applicable
Medication Management (MM)	*Patient-Specific Information* MM.1.10 – patient-specific information is readily accessible to those involved in the medication management system.
	Selection and Procurement MM.2.10 – medications available for dispensing or administration are selected, listed, and procured based on criteria.
	Storage MM.2.20 – medications are properly and safely stored throughout the organization. MM.2.30 – emergency medications and/or supplies, if any, are consistently available, controlled, and secure in the organization's patient care areas. MM.2.40 – a process is established to safely manage medications brought into the organization by patients or their families.
	Ordering and Transcribing MM.3.10 – not applicable MM.3.20 – medication orders are written clearly and transcribed accurately.

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities (continued)

Standard functional chapter	Standard
	Preparing and Dispensing MM.4.10 – all prescriptions or medication orders are reviewed for appropriateness. MM.4.20 – medications are prepared safely. MM.4.30 – medications are appropriately labeled. MM.4.40 – medications are dispensed safely. MM.4.50 – the organization has a system for safely providing medications to meet patient needs when the pharmacy is closed. MM.4.60 – if the organization does not operate a pharmacy but routinely administers medications, the organization has a process for obtaining medications from a pharmacy. MM.4.70 – medications dispensed by the organization are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration for safety reasons. MM.4.80 – medications returned to the pharmacy are appropriately managed.
	Administering MM.5.10 – medications are safely and accurately administered.
	Monitoring MM.6.10 – the effects of medication(s) on patients are monitored. MM.6.20 – the organization responds appropriately to actual or potential adverse drug events and medication errors.
	High-Risk Medications MM.7.10 – the organization develops processes for managing high-risk or high-alert medications. MM.7.20 and 7.30 – not applicable MM.7.40 – investigational medications are safely controlled and administered.
	Evaluation MM.8.10 – the organization evaluates its medication management system.

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities (continued)

Standard functional chapter	Standard
Surveillance, Prevention, and Control of Infection (IC)	*The IC Program and Its Components* IC.1.10 – the risk of development of a health care-associated infection is minimized through an organizationwide infection control program. IC.2.10 – the infection control program identifies risks for the acquisition and transmission of infectious agents on an ongoing basis. IC.3.10 – based on risks, the organization establishes priorities and sets goals for preventing the development of health care-associated infections within the organization. IC.4.10 – once the organization has prioritized its goals, strategies must be implemented to achieve those goals. IC.5.10 – the infection control program evaluates the effectiveness of the infection control interventions and, as necessary, redesigns the infection control interventions. IC.6.10 – as part of emergency management activities, the organization prepares to respond to an influx, or the risk of an influx, of infectious patients.
	Structure and Resources for the IC Program IC.7.10 – the infection control program is managed effectively. IC.8.10 – representatives from relevant components/functions within the organization collaborate to implement the infection control program. IC.9.10 – organization leaders allocate adequate resources for the infection control program.
Improving Organizational Performance (PI)	PI.1.10 – the organization collects data to monitor its performance. PI.2.10 – data are systematically aggregated and analyzed. PI.2.20 – undesirable patterns or trends in performance are analyzed. PI.2.30 – processes for identifying and managing sentinel events are defined and implemented. PI.3.10 – information from data analysis is used to make changes that improve performance and patient safety and reduce the risk of sentinel events. PI.3.20 – an ongoing, proactive program for identifying and reducing unanticipated adverse events and safety risks to patients is defined and implemented.

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities (continued)

Standard functional chapter	Standard
Leadership (LD)	LD.1.10 – the organization identifies how it is governed. LD.1.20 – governance responsibilities are defined in writing, as applicable. LD.1.30 – the organization complies with applicable law and regulation. LD.2.10 – an individual(s) or designee(s) is responsible for operating the organization according to the authority conferred by governance. LD.2.20 – each organizational program, service, site, or department has effective leadership. LD 2.30 and 2.40 – not applicable LD.2.50 – the leaders develop and monitor an annual operating budget and, as appropriate, a long-term capital expenditure plan. LD.3.10 – the leaders engage in both short-term and long-term planning. LD.3.15 – not applicable LD.3.20 – patients with comparable needs receive the same standard of care, treatment, and services throughout the organization. LD.3.30 and 3.40 – not applicable LD.3.50 – services provided by consultation, contractual arrangements, or other agreements are provided safely and effectively. LD.3.60 – communication is effective throughout the organization. LD.3.70 – the leaders define the required qualifications and competence of those staff who provide care, treatment, and services, and recommend a sufficient number of qualified and competent staff to provide care, treatment, and services. LD.3.80 – the leaders provide for adequate space, equipment, and other resources. LD.3.90 – the leaders develop and implement policies and procedures for care, treatment, and services. LD.3.100 and 3.11 – not applicable LD.3.120 – the leaders plan for and support the provision and coordination of patient education activities. LD.3.130 through 3.150 – not applicable LD.4.10 – the leaders set expectations, plan, and manage processes to measure, assess, and improve the organization's governance, management, clinical, and support activities.

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities (continued)

Standard functional chapter	Standard
	LD.4.20 – new or modified services or processes are designed well. LD.4.30 – not applicable LD.4.40 – the leaders ensure that an integrated patient safety program is implemented throughout the organization. LD.4.50 – the leaders set performance improvement priorities and identify how the organization adjusts priorities in response to unusual or urgent events. LD.4.60 – the leaders allocate adequate resources for measuring, assessing, and improving the organization's performance and improving patient safety. LD.4.70 – the leaders measure and assess the effectiveness of the performance improvement and safety improvement activities. LD.5.10 through 5.40 – not applicable LD.5.50 – clinical practice guidelines are used in designing or improving processes that evaluate and treat specific diagnoses, conditions, and/or symptoms. LD.5.60 – the leaders identify criteria for selecting and implementing clinical practice guidelines. LD.5.70 – appropriate leaders, practitioners, and health care professionals in the organization review and approve clinical practice guidelines selected for implementation. LD.5.80 – the leaders evaluate the outcomes related to clinical practice guidelines and refine the guidelines to improve processes.

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities (continued)

Standard functional chapter	Standard
Management of the Environment of Care (EC)	Planning and Implementation Activities EC.1.10 – the organization manages safety risks. EC.1.20 – the organization maintains a safe environment. EC.1.25 and 1.27 – not applicable EC.1.30 – the organization develops and implements a policy to prohibit smoking except in specified circumstances. EC.2.10 – the organization identifies and manages its security risks. EC.3.10 – the organization manages its hazardous materials and waste risks. EC.4.10 – the organization addresses emergency management. EC.4.20 – the organization conducts drills regularly to test emergency management. EC.5.10 – the organization manages fire safety risks. EC.5.20 – newly constructed and existing environments are designed and maintained to comply with the Life Safety Code®. EC.5.30 – the organization conducts fire drills regularly. EC.5.40 – the organization maintains fire-safety equipment and building features. EC.5.50 – the organization develops and implements activities to protect occupants during periods when a building does not meet the applicable provisions of the Life Safety Code®. EC.6.10 – the organization manages medical equipment risks. EC.6.20 – medical equipment is maintained, tested, and inspected. EC.7.10 – the organization manages its utility risks. EC.7.20 – the organization provides an emergency electrical power source. EC.7.30 – the organization maintains, tests, and inspects its utility systems. EC.7.40 – the organization maintains, test, and inspects its emergency power systems. EC.7.50 – the organization maintains, tests, and inspectis its medical gas and vacuum systems. EC.8.10 – the organization establishes and maintains an appropriate environment. EC.8.20 – not applicable EC.8.30 – the organization manages the design and building of the environment when it is renovated, altered, or newly created.

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities (continued)

Standard functional chapter	Standard
	Measuring and Improving Activities EC.9.10 – the organization monitors conditions in the environment. EC.9.20 – the organization analyzes identified environment issues and develops recommendations for resolving them. EC.9.30 – the organization improves the environment.
Management of Human Resources (HR)	Planning HR.1.10 – the organization provides an adequate number and mix of staff and licensed independent practitioners that are consistent with the organization's staffing plan. HR.1.20 – the organization has a process to ensure that a person's qualifications are consistent with his or her job responsibilities.
	Orientation, Training, and Education HR.2.10 – orientation provides initial job training and information. HR.2.20 – staff members, licensed independent practitioners, students, and volunteers, as appropriate, can describe or demonstrate their roles and responsibilities, based on specific job duties or responsibilities, relative to safety. HR.2.30 – ongoing education, including in-services, training, and other activities, maintains and improves competence.
	Assessing Competence HR.3.10 – competence to perform job responsibilities is assessed, demonstrated, and maintained. HR.3.20 – the organization periodically conducts performance evaluations.
	Credentialing and Assignment of Clinical Responsibilities of Licensed Independent Practitioners HR.4.10 – there is a process for ensuring the competence of all practitioners permitted by law and the organization to practice independently. HR.4.20 – individuals permitted by law and the organization to practice independently are granted clinical privileges. HR.4.30 – the organization has a process for granting temporary clinical privileges, when appropriate. HR.4.40 – there are mechanisms, including a fair hearing and appeal process, for addressing adverse decisions regarding reappointment, denial, reduction, suspension, or revocation of clinical privileges that may relate to quality of care, treatment, and service issues. HR.4.50 – clinical privileges and appointments/reappointments are reviewed and revised at least every two years.

Table F-3. JCAHO Standards Applicable to Cardiac Catheterization Facilities (continued)

Standard functional chapter	Standard
Management of Information (IM)	Information Management Planning IM.1.10 – the organization plans and designs information management processes to meet internal and external information needs.
	Confidentiality and Security IM.2.10 – information privacy and confidentiality are maintained. IM.2.20 – information security, including data integrity, is maintained. IM.2.30 – the organization has a process for maintaining continuity of information.
	Information Management Processes IM.3.10 – the organization has processes in place to effectively manage information, including the capturing, reporting, processing, storing, retrieving, dissemination, and displaying of clinical/service and nonclinical data and information.
	Information-Based Decision Making IM.4.10 – the information management system provides information for use in decision making.
	Knowledge-Based Information IM.5.10 – Knowledge-based information resources are readily available, current, and authoritative.
	Patient-Specific Information IM.6.10 – the organization has a complete and accurate medical record for every individual assessed, cared for, treated, or served. IM.6.20 – records contain patient-specific information, as appropriate to the care, treatment, and services provided. IM.6.30 – the medical record thoroughly documents operative or other high-risk procedures and the use of moderate or deep sedation or anesthesia. IM.6.40 – for patients receiving continuing ambulatory care services, the medical record contains a summary list of all significant diagnoses, procedures, drug allergies, and medications. IM.6.50 – designated qualified personnel accept and transcribe verbal orders from authorized individuals. IM.6.60 – the organization can provide access to all relevant information from a patient's record when needed for use in patient care, treatment, and services.