Inclusion Criteria
- All patients undergoing cardiac ablation and/or pacemaker/internal cardiac defibrillator (ICD) device implantation at Texas Children's Hospital.

Exclusion Criteria
- None

Background
Over the past 20 to 30 years, pediatric cardiac catheterization has evolved from solely diagnostic procedures to therapeutic procedures. Technological advancements have significantly progressed management of cardiovascular disease in children and adolescents with congenital heart disease (CHD). Catheter ablation and the insertion of pacemaker/internal cardiac defibrillator (ICD) devices are therapeutic modalities proven safe and effective for the pediatric population but are associated with some risk because of their invasive nature. An effective, evidence-based, post-procedure, management strategy is essential for achieving optimal outcomes. The aim of this evidence summary is to provide acceptable standards of practice for post procedure care of patients undergoing cardiac catheter ablation or pacemaker/ICD device implantation, thereby improving patient outcomes. The recommendations within this evidence summary address the areas of hospitalization, aspirin therapy and post-operative antibiotics for cardiac ablation and pacemaker/ICD implantation procedures.

Critically Analyze the Evidence

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. The table below defines how the quality of evidence is rated and how a strong versus a weak recommendation is established.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Type of Evidence</th>
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<tr>
<td>STRONG</td>
<td>Desirable effects clearly outweigh undesirable effects or vice versa</td>
</tr>
<tr>
<td>WEAK</td>
<td>Desirable effects closely balanced with undesirable effects</td>
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Quality: Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies
Moderate: Evidence from RCTs with important limitations (e.g., inconsistent results, methodological flaws, indirect evidence, or imprecise results) or unusually strong evidence from unbiased observational studies
Low: Evidence for at least 1 critical outcome from observational studies, from RCTs with serious flaws or indirect evidence
Very Low: Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence

PICO Question 1: For patients undergoing left-sided ablations, is overnight hospitalization/observation necessary to minimize morbidity associated with potential strokes?

Recommendation(s): Strong (consensus) recommendation with low quality evidence to admit patients undergoing left-sided ablations for 23-hour observation. (7-13)

The reported incidence of thromboembolic complications in adults after ablation procedures is ~1 %. (11) The incidence in children appears to be lower, but data is limited. (15) A prospective study of 2761 pediatric ablations found no cerebrovascular accidents (CVA) and suggested a very low incidence. (13) Retrospective evaluation of patients with congenital heart disease found 1 CVA in 105 ablations; however, this was in a 47 year old with severe Ebstein's anomaly of the heart. (8)

PICO Question 2: For patients undergoing left-sided ablations, does aspirin therapy minimize the risk of stroke?

Recommendation(s): Weak (consensus) recommendation with very low quality evidence to administer aspirin prophylactically for 6 weeks after left-sided ablations. (14-16)

A review of the literature revealed no studies specifically evaluating the utility of aspirin therapy after left-sided ablations in children. A single multi-center study in adults found no relationship between thromboembolism and anticoagulation protocol. (15) Rare case reports in children do document the occurrence of cerebrovascular accidents (CVA) after left-sided ablation procedures as late as 7 hours after...
the procedure and recommend overnight observation to facilitate early recognition and treatment. (17) These reports also recommend continued use of anticoagulation and aspirin although it is recognized that there is limited data to support this.

**PICO Question 3:** For patients undergoing pacemaker/ICD implantation, do postoperative antibiotics decrease the risk of infectious complications?

**Recommendation(s):** Strong recommendation with moderate quality evidence to administer routine antibiotic prophylaxis for 48 hours after pacemaker and defibrillator implantation to limit the incidence of infective complications. (18-22)

A review of literature revealed 1 meta-analysis, 1 randomized controlled trial and 3 observational studies. The meta-analysis reviewed 60 studies and determined that lack of antibiotic prophylaxis was one of the predictors for cardiovascular implantable electronic device (CIED) infection. (18) None of the studies were performed in the pediatric population. In a prospective randomized, double-blinded, placebo-controlled trial of 649 adult patients, it was determined that the use of prophylactic antibiotics significantly reduced infectious complications. (19) Chiang (2013), an observational study of adult patients, determined that the efficacy of 1-day course of prophylactic antibiotics was similar to the efficacy of a 3 day course. (20) The study concluded that a longer duration of antibiotic treatment should be considered for patients who develop pocket hematomas; otherwise, the one-day course of antibiotics was effective enough to prevent device related infections and reduce hospital length of stay.

**Critical Points of Evidence**

**Evidence Supports**
- Administration of routine antibiotic prophylaxis for 48 hours after pacemaker and defibrillator implantation to limit the incidence of infective complications. (18-22) – Strong recommendation, moderate quality evidence

**Evidence Lacking/Inconclusive**
- Overnight hospitalization and observation after left-sided ablation procedures is reasonable given the potential of morbidity of thromboembolic complications and the possibility of early detection and intervention. However, there is no data to support or refute its benefit and universal application. (7-13) – Strong (consensus) recommendation, low quality evidence
- Prophylactic aspirin administration for 6 weeks after left-sided ablations is also reasonable given case reports of late embolic complications and potential associated morbidity; however, data to support this is again limited. (14-16) – Weak (consensus) recommendation, very low quality evidence

*NOTE: The references cited represent the entire body of evidence reviewed to make each recommendation.*
References


Clinical Standards Preparation
This clinical standard was prepared by the Evidence-Based Outcomes Center (EBOC) team in collaboration with content experts at Texas Children’s Hospital. Development of this clinical standard supports the TCH Quality and Patient Safety Program initiative to promote clinical standards and outcomes that build a culture of quality and safety within the organization.

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No relevant financial or intellectual conflicts to report.

Development Process
This clinical standard was developed using the process outlined in the EBOC Manual. The literature appraisal documents the following steps:

1. Review Preparation
   - PICO questions established
   - Evidence search confirmed with content experts

2. Review of Existing External Guidelines
   - Consensus Document on Antithrombotic Therapy in the Setting of Electrophysiological Procedures; PACES/HRS Expert Consensus Statement on the Use of Catheter Ablation in Children and Patients with Congenital Heart Disease; Guidelines for the Diagnosis, Prevention and Management of Implantable Cardiac Electronic Device Infection; Clinical Practice Guidelines for Antimicrobial Prophylaxis in Surgery; Update on Cardiovascular Implantable Electronic Device Infections and Their Management

3. Literature Review of Relevant Evidence

4. Critically Analyze the Evidence
   - 2 systematic reviews/meta-analyses, 1 randomized controlled trial, and 12 observational studies

5. Summarize the Evidence
   - Materials used in the development of the clinical standard, literature appraisal, and any order sets are maintained in a Post Ablation and Pacemaker Implant Management evidence-based review manual within EBOC.

Evaluating the Quality of the Evidence
Published clinical guidelines were evaluated for this review using the AGREE II criteria. The summary of these guidelines are included in the literature appraisal. AGREE II criteria evaluate Guideline Scope and Purpose, Stakeholder Involvement, Rigor of Development, Clarity and Presentation, Applicability, and Editorial Independence using a 4-point Likert scale. The higher the score, the more comprehensive the guideline.

This clinical standard specifically summarizes the evidence in support of or against specific interventions and identifies where evidence is lacking/inconclusive. The following categories describe how research findings provide support for treatment interventions. “Evidence Supports” provides evidence to support an intervention. “Evidence Against” provides evidence against an intervention. “Evidence Lacking/Inconclusive” indicates there is insufficient evidence to support or refute an intervention and no conclusion can be drawn from the evidence.

The GRADE criteria were utilized to evaluate the body of evidence used to make practice recommendations. The table below defines how the quality of the evidence is rated and how a strong versus weak recommendation is established. The literature appraisal reflects the critical points of evidence.

<table>
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Recommendations
Practice recommendations were directed by the existing evidence and consensus amongst the content experts. Patient and family preferences were included when possible. The Content Expert Team and EBOC team remain aware of the controversies in the post ablation and pacemaker implant management in children. When evidence is lacking, options in care are provided in the clinical standard and the accompanying order sets (if applicable).

Approval Process
Clinical standards are reviewed and approved by hospital committees as deemed appropriate for its intended use. Clinical standards are reviewed as necessary within EBOC at Texas Children’s Hospital. Content Expert Teams are involved with every review and update.

Disclaimer
Practice recommendations are based upon the evidence available at the time the clinical standard was developed. Clinical standards (guidelines, summaries, or pathways) do not set out the standard of care and are not intended to be used to dictate a course of care. Each physician/practitioner must use his or her independent judgment in the management of any specific patient and is responsible, in consultation with the patient and/or the patient’s family, to make the ultimate judgment regarding care.

Version History
Date       | Comments
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Jan 2018   | Updated
Oct 2009   | Originally completed