



LVAD INFECTION PREVENTION **TOOLKIT**

Infection Prevention Following Durable LVAD Implantation

A Toolkit

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[Goals of the Toolkit](#)

A quick guide for LVAD teams to the contents of the toolkit, including an eight-step process of how to implement the toolkit at your center.



[Identify Areas for Infection Prevention](#)

A guide for LVAD teams to assess your team's strengths and weaknesses and identify them.



[Prioritize Recommendations](#)

A guide for LVAD teams to prioritize candidate infection prevention recommendations.



[Team Roles & Responsibilities: LVADS](#)

A guide for LVAD teams for identifying and assigning the necessary roles and responsibilities to advance the implementation for each recommendation.



[Appendix A: Detailed List of Recommendations](#)

A detailed list of recommendations, divided into 4 buckets (patient and caregiver directed, clinician directed, leadership directed, and program directed) and relevant STS Intermacs fields.



[Appendix B: Data Collection Worksheets](#)

Worksheets to evaluate your team's infection prevention practices and outcomes



[Appendix C: Recommendation Prioritization Worksheets](#)

Worksheets to prioritize candidate infection prevention recommendations.



[Appendix D: Team Roles and Responsibilities Worksheets](#)

Project management worksheets to advance the implementation of infection prevention recommendations.



[Appendix E: Study Information - How Recommendations Were Derived](#)

Background information about the development of the infection prevention recommendations.



[Appendix F: Fact Sheet Infections after Durable LVADs](#)

Fact sheets about infections (e.g., rate, subtype, associated clinical and financial impact) and variability in occurrence across centers.

Section A

Goals of the Toolkit



Goals of this Toolkit

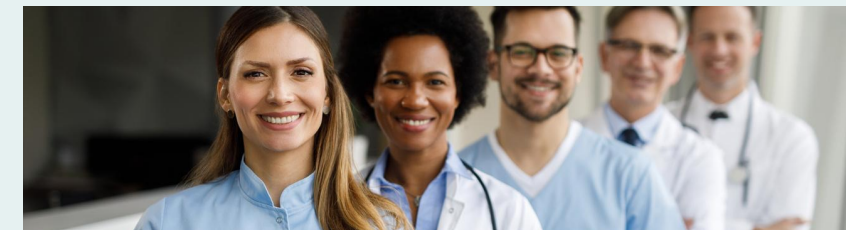
This toolkit provides the necessary foundational support for centers to advance infection prevention activities in the setting of durable left ventricular assist device (LVAD) implantation.

This toolkit includes infection prevention recommendations and accompanying implementation materials (e.g., guides, data collection worksheets).

This toolkit groups recommendations into the following four categories based on their foci and unique set of resource documents and implementation strategies:



LVAD PROGRAM



CLINICIANS



**PATIENTS &
CAREGIVERS**



LVAD LEADERSHIP

How to Use this Toolkit

The toolkit includes an eight-step process for advancing infection prevention activities at your center. We anticipate centers will initiate a number of these cycles over the course of their work to advance infection prevention activities.



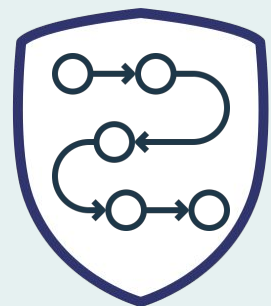
STEPS 1-3

focus on reviewing your team's strengths and weaknesses regarding infection prevention, identifying potential recommendations to implement, and prioritizing recommendations for initial areas of focus.



STEPS 4-6

focus on developing the necessary infrastructure to prepare your team to successfully implement the recommendations you have chosen.



STEPS 7-8

focus on undertaking your action plan and assessing its associated impact.

Monitor and report back outcomes



Set the action plan in motion



Collect additional data

elements outside of STS Intermacs as needed (e.g. sterile driveline dressing change techniques).



Develop an action plan

and desired outcomes with LVAD team.



LVAD INFECTION PREVENTION TOOLKIT

Identify areas

to prevent post-implant infections (e.g., improve patient/caregiver education)



Identify candidate

recommendations for areas of focus (using the recommendation lookup guide)



Prioritize recommendations

Use recommendation prioritization table.



Identify team member roles

to implement recommendations.
Use LVADS ASsignment List



Section B

Identify Areas for

Infection

Prevention



Step 1: Identify areas to prevent infections post-implant.

See [Appendix B](#) for data collection worksheets to guide your assessment of your team's strengths and weaknesses.



Use your existing LVAD multidisciplinary team meetings to review your team's strengths and weaknesses regarding infection prevention



Your team's strengths and weaknesses can be assessed by reviewing your STS Intermacs reports, existing protocols (e.g., patient/caregiver education, management of driveline infections). Sources can be documented in the Data Collection Worksheet.



Your team will use these data and a summary of your discussions to review the recommendation lookup guide (see next slide).



Step 2: Identify candidate recommendations.

The Recommendation Lookup Guide is designed to help your team identify recommendations relative to your infection prevention strengths and weaknesses

- This interactive online guide ([click here](#)), which can be filtered by your team, contains:
 - Numerical sequencing of each recommendation
 - Groupings of each recommendation into the four categories (LVAD Program, Clinicians, Patients and caregivers, LVAD leadership)
 - List of recommendations
 - Areas of focus (e.g., technology, patient/caregiver education, care bundles)





Screenshot of Recommendation Lookup Guide

☐	Reco... ▾	Recommendation ▾	Audience ▾	Tags ▾
1	1	Infection Prevention Data Access Up-to-date unit and service line level infection prevention data should be provided to members of the VAD team, including consulting services, to advance evidence-based care and outcomes.	Program Directed	Team Communication Protocol Updates Outcome Assessment and Improve...
2	2	Patient Image-Sharing Platform Consistent usage of a HIPAA-compliant patient portal can support post-discharge HAI surveillance (e.g., transmission of driveline exit site images to the patient's care team).	Program Directed	Technology Protocol Updates Outcome Assessment and Improve...
3	3	Advancing Supply Availability Adherence to evidence-based HAI prevention bundles may be advanced by ensuring patients have equitable access to infection prevention items (e.g., driveline dressing kits).	Program Directed	Protocol Updates Care Bundles Outcome Assessment and Improve...
4	4	Standardized Provider Education Efforts to enhance clinician onboarding and continuing education may benefit from standardized curricula.	Program Directed	Staffing Provider Education

Section C

Prioritize

Recommendations



Step 3: Prioritize recommendations.

This toolkit supports your team in prioritizing infection prevention recommendations (See Appendix A)

The toolkit includes a Recommendation Prioritization Table to guide institutional decision-making regarding:

- The choice of recommendation(s) to focus on
- The type of support needed to advance the chosen set of recommendations
- The anticipated timeline for implementing infection prevention recommendations

See [Appendix A](#) for more in-depth examples and worksheets.



Considerations for Applying Recommendations

This toolkit and the recommendations contained therein are not comprehensive, and thus may not include all necessary actions to improve healthcare delivery and outcomes at your center.

Please consult with your center's multidisciplinary working group and other collaborators to determine your implementation plan (see [Section D](#)).



LVAD INFECTION PREVENTION TOOLKIT

The recommendations:

- Were developed in part based on the analysis of qualitative interviews conducted across low and high-performing centers, and
- May be contextualized for a center's resources, staffing, location, academic affiliation status, and external factors (see Appendix E for study information).

Chandanabhumma PP, Feters MD, Pagani FD, Malani PN, Hollingsworth JM, Funk RJ, Aaronson KD, Zhang M, Kormos RL, Chenoweth CE, Shore S, Watt TMF, Cabrera L, Likosky DS

Understanding and Addressing Variation in Health Care—Associated Infections After Durable Ventricular Assist Device Therapy: Protocol for a Mixed Methods Study

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JMIR RESEARCH PROTOCOLS

Chandanabhumma et al

Protocol

Understanding and Addressing Variation in Health Care—Associated Infections After Durable Ventricular Assist Device Therapy: Protocol for a Mixed Methods Study

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This is a corrected version. See correction statement in: <https://www.researchprotocols.org/2022/6/e39663>

Section D

Team Roles and

Responsibilities:

LVADS



Step 4: Identify team member roles to implement recommendations.

Your team has now prioritized the infection prevention recommendations that you will implement.

We have developed the acronym L-V-A-D-S to help your team identify the necessary roles and responsibilities to implement each recommendation.

The next slide describes each of these roles in more detail.

See [Appendix D](#) for more in-depth examples and worksheets.

L-V-A-D-S

Team Member Role and Responsibilities in Implementing and Evaluating Infection Prevention Recommendations



Leader

Someone assigning strategic direction. The Leader works closely with the Delegator. The Leader sets the team member roles (**Step 4**)



Validator

Someone who helps provide external review and/or data support. (**Steps 1, 6, and 8**)



Actor

Someone who performs a task (do-er, taking action in the real-world). (**Step 8**)



Delegator

Someone who facilitates and helps delegate tasks (often called a Project Manager). The Delegator will develop the action plan (**Step 5**) and monitoring/feedback (Steps 7-8) in coordination with the Leader.



Supporter

Someone who provides data support to the team. The Supporter will be relied on for **Step 6**.



Step 5: Develop an action plan and desired outcomes with LVAD team.

- Your team has now assigned roles and responsibilities to advance your prioritized infection prevention recommendations.
- Many teams will use a Plan-Do-Study-Act (PDSA) approach to guide their approach for Steps 5-8.
- The first part of the PDSA cycle is to plan your intervention and identify how you will assess whether your intervention worked.
- The following AHRQ website provides more information about the PDSA approach.

<https://www.ahrq.gov/evidencenow/tools/pdsa-form.html>





Step 6: Collect additional data elements outside of STS Intermacs as needed.

- The next step is to identify any data elements your team might need to collect to successfully undertake your intervention.
- [Appendix B](#) includes sample data collection worksheets that your team might consider. We envision some interventions may require primary data collection, while others may solely require STS Intermacs, institutional nursing and/or infection surveillance data.
- For each data element, please specify a definition, primary/secondary data sources and validated ranges (in the case of continuous variables).



Step 7: Set the action plan in motion.

- Your team has now assigned roles and responsibilities to advance your prioritized infection prevention recommendations, as well as identified the data elements needed to move forward with your study.
- We encourage you to start with small tests of change, and incrementally move forward thereafter.



Step 8: Monitor and report back outcomes.

- Your team has now begun the task of monitoring progress on your intervention.
- Successful teams often have a project-specific dashboard that includes process measures and outcomes. These teams share updated dashboards with their team members on a frequent basis.
- During this step, your team will likely identify barriers that impede your progress (e.g., challenges with data collection, finding time to meet as a team).
- Anticipate several PDSA change cycles as your team advances its workflow and engagement with frontline clinical staff.

Appendix A

Detailed List of

Recommendations



Program Directed Recommendations

Program Directed Recommendations (1 of 6)

Infection Data Access

Up-to-date unit and service-line level infection data (e.g., rates, prevention practices) should be provided to members of the LVAD team, including consulting services, to advance evidence-based care and outcomes.

Standardized Provider Education

Efforts to enhance clinician onboarding and continuing education may benefit from standardized curricula.

Program Directed Recommendations (2 of 6)

Real-Time Provider Communication

Longitudinal infection surveillance may be advanced through HIPAA-compliant electronic communication between patients and their clinical team members. The patient's electronic medical record should be updated to reflect the content of any correspondence.

Standardizing Infection Prevention Practices

Efforts should be made to raise awareness of and disseminate evidence-based infection prevention practices across clinicians in varied care settings.

Program Directed Recommendations (3 of 6)

Advancing Supply Availability

Adherence to evidence-based infection prevention bundles may be advanced by ensuring patients have equitable access to infection prevention items (e.g., driveline dressing kits).

Tailoring Ongoing Caregiver Education

Tailored (e.g., assessing patient and caregiver surveys), evidence-based infection prevention practices should be designed in conjunction with LVAD team members (e.g., HF cardiologists, surgeons, LVAD Coordinators, nurse educators).

Program Directed Recommendations (4 of 6)

Patient Image-Sharing Platform

Consistent usage of a HIPAA-compliant patient portal can support post-discharge infection surveillance (e.g., transmission of driveline exit site images to the patient's care team).

Clinical Practice Guideline Changes

Infection prevention strategies should be routinely reassessed per institutional protocol (e.g., yearly) in addition to more frequently as needed (e.g., as new data emerge).

Program Directed Recommendations (5 of 6)

Access to Customizable Care Bundles

Efforts to enhance adherence to evidence-based infection prevention practices may benefit from: (1) standardization through order sets and (2) availability of LVAD-specific supplies (e.g., driveline dressing kits) for clinicians and patients.

Engaging Physical and Occupational Therapy in Care Delivery

Patient and caregiver level care capacities may be effectively addressed during the pre- and post-implant settings by physical and occupational therapists.

Program Directed Recommendations (6 of 6)

Offering a Reference for Standards of Care

Efforts to implement standards of care may benefit from an accessible, up-to-date repository of HAI-prevention resources, policies, and procedures (e.g., hand hygiene program, line replacement protocol, patient and caregiver education tips).



Patient and Caregiver Directed Recommendations

Patient and Caregiver Directed Recommendations (1 of 3)

Multiple committed caregivers

Adherence to evidence-based infection prevention practices is advanced through a pool of long-term, engaged patient caregivers.

Personalized education program

A patient and caregiver-centered education program (e.g., customized to their health literacy level and preferred language, addressing caregiver concerns) and support (e.g., interpreters available during office visits, discussing options for transportation to implanting hospital with patient & caregiver with social work) can advance their long-term commitment to evidence-based infection prevention practices.

Patient and Caregiver Directed Recommendations (2 of 3)

Lifestyle change expectation education

Adherence to infection prevention practices may be advanced through achieving longitudinal patient and caregiver commitment (e.g., Lifestyle Contract).

Engaging patient advisors in patient education

Patient advisors (e.g., patients on long-term durable LVADs) may be used to inform the design and implementation of effective tailored patient education curricula and as peer mentors for patients who are newly implanted or being evaluated for durable LVAD implantation.

Patient and Caregiver Directed Recommendations (3 of 3)

Documentation of health behavior counseling

Documented counseling for patients/caregivers to promote health behavior changes (e.g., quitting smoking, changing diet, self-limiting exertion) to minimize the risk of post-implantation infection.



Clinician Directed Recommendations

Clinician Directed Recommendations (1 of 6)

Well-rounded provider education

Teaching of evidence-based HAI-prevention practices should balance device-related concerns with patient quality of life, such as their ability to participate safely in pre-implant hobbies and to engage in functional activities pre- and post-implant.

Multidisciplinary protocol development

Multidisciplinary data-driven discussions support the advancement and implementation of evidence-based LVAD practices and protocols.

Clinician Directed Recommendations (2 of 6)

Regular line replacement

Early removal of invasive devices (e.g., urinary catheter, central line) may support the prevention of infection.

Outpatient infection education reinforcement

Post-discharge outpatient visits, including through telehealth modalities, may be used to advance patient and caregiver education and adherence to evidence-based infection prevention practices (e.g., video visit to reinforce optimal driveline dressing changes).

Clinician Directed Recommendations (3 of 6)

Anchor and binder usage

Use of safety devices to secure the percutaneous driveline (e.g., anchors) may prevent inadvertent trauma to the interface between the driveline and subcutaneous tissue and increase the risk of subsequent infections.

Care bundle adherence

Adherence to evidence-based nursing care bundles may reduce post-implant infections.

Clinician Directed Recommendations (4 of 6)

Health equity considerations

In order to effectively advance the delivery of patient and caregiver education, clinicians should be aware of potential barriers (e.g., educational, socioeconomic, resource limitations) and other disparities experienced by their patients.

Communicating positive patient outcomes

Team member well-being may be enhanced through the development and dissemination of positive patient outcomes (e.g., including stories of patient successes in an LVAD newsletter).

Clinician Directed Recommendations (5 of 6)

Patient centered framing during meetings

Patient and caregiver confidence in executing HAI-prevention practices may be enhanced through patient-centered communication practices during their appointments with LVAD team members.

Suture color selection

High contrast suture colors may advance early post-implant infection identification among diverse patient populations.

Clinician Directed Recommendations (6 of 6)

Standardizing LVAD Care in Ancillary Departments

The utilization of evidence-based infection prevention and management practices may be enhanced through specific LVAD management protocol for clinical staff working across diverse settings (e.g., emergency department nurses, emergency medical technicians, rehabilitation facilities).

Early extubation plan

Developing an early extubation plan, including effective postoperative pain control, pulmonary hygiene, repeated ventilator wean assessments, and appropriate sedation, may minimize infection risk.



Leadership Directed Recommendations

Leadership Directed Recommendations (1 of 6)

Engaging Infection Control/Prevention and Antimicrobial Stewardship

In-hospital infection prevention and management may be advanced through a multidisciplinary team rounding approach (e.g., heart failure cardiology, surgery, nursing, anesthesia, pharmacy) that addresses antimicrobial stewardship and infection prevention.

Peer-to-Peer Accountability Measures

Consistent nurse-physician dyads, which increase accountability and team familiarity, advance evidence-based HAI-prevention practices.

Leadership Directed Recommendations (2 of 6)

Multipronged Infection Prevention Approach

Efforts aimed at reducing in-hospital infection rates should leverage both existing inpatient infection prevention initiatives (e.g., invasive line management, ERAS, hand hygiene) as well as institutional resources (e.g., Environmental Services, Facilities, Maintenance).

Documenting Impacts of Protocol Changes

Extensive documentation of successful interventions (e.g., hand hygiene program, "scrub the hub") and the effect of protocol changes are key to maintaining low infection rates.

Leadership Directed Recommendations (3 of 6)

Surveillance and Performance Data

Ensuring accurate and reliable surveillance and performance data via auditing are foundational for advancing evidence-based HAI-prevention strategies.

Real-Time OR Infection Tracking

A longitudinal, robust and up-to-date infection tracking system including OR surveillance may be used to support an LVAD program's infection prevention strategy.

Leadership Directed Recommendations (4 of 6)

Unit and Service Level Data Reporting

Infection surveillance data should be reported at the unit and service level to support local quality improvement efforts.

Patient-Reported Outcomes and Care Practices•Developing a reporting system for post-implant patient-reported outcomes can promote improved post-implant patient care and inform interventions that mitigate inconsistent execution of protocol.

Leadership Directed Recommendations (5 of 6)

Operating Room (OR) Optimization

OR size and layout should be optimized for complex cardiac surgery to advance efficiency and mitigate infection risk, including evaluating if there is adequate and well-coordinated use of space.

Dedicated LVAD/SOT Data Analysts

Institutional quality assurance and improvement initiatives may be advanced through dedicated team members (e.g., database programmer, biostatistical analyst, quality improvement coordinator).

Leadership Directed Recommendations (6 of 6)

LVAD Quality Champions

Encourage engagement with infection prevention initiatives from physicians, nurses, and/or LVAD Coordinators by nominating quality champions.

Expand Real-Time Comparison via INTERMACS Dashboard

Advocate for the expansion of available functions of the INTERMACS dashboard to advance real-time comparisons with aggregate INTERMACs data. These comparisons may improve: (1) the evaluation of an intervention's efficacy and (2) tracking of institutional data more effectively.

Appendix B

Data Collection

Worksheets

Data Collection Worksheet

- Each of our institutions collect a variety of data concerning infections (e.g., nursing care bundles, unit-level infection rates), although these data are often not widely shared.
- Some pertinent data (e.g., patient and/or caregiver adherence to driveline dressing change protocols) are often not collected in a systematic fashion.
- These realities make the evaluation of your LVAD program's strengths and weaknesses more challenging
- We have developed the following data collection guide to support your team's evaluation process. Some data may be readily available, while others may require primary data collection.

How to Complete the Data Collection Worksheet (example)

Data Type	Specifics	Data Source(s)	Data Custodian(s)
Infection Rates	Type of infection and date of occurrence	STS Intermacs	LVAD Coordinator
Infection Rates	Unit-level C. DIFF rate	Nursing documentation and laboratory	Infection Prevention
Adherence to driveline dressing recommendations	Bundle adherence rate	Chart review	LVAD Coordinator

How to Complete the Data Collection Worksheet (example)

Data Type	Specifics	Data Source(s)	Data Custodian(s)

Appendix C

Recommendation

Prioritization

Tables



How to Complete the Recommendation Prioritization Tables

- There are a number of potential infection prevention recommendations for your team to consider.
- When completing the recommendation prioritization tables, we suggest that your team consider each recommendation focal area as a whole and prioritize the individual recommendations within each area by rating the “Anticipated Patient Impact” and “Anticipated Center Impact” (high to low) as well as the “Ease of Implementation” (high to low).
- Next, we suggest that your team complete the “Actions Needed” column that will be used to document the individual(s) who will lead specific actions, as well as steps and resources needed to implement the recommendation.
- This appendix provides a set of tables that your team may use to prioritize which recommendations to focus on as a team.



How To Complete The Table (Example)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
1	10		5	Efforts should be made to raise awareness of and disseminate evidence-based infection prevention practices across clinicians in varied care settings.	Charlie Johnson: - Create workgroup - Research protocols at other sites	Sep - Oct 2023
2	10		1	Developing an early extubation plan, including effective postoperative pain control, pulmonary hygiene, repeated ventilator wean assessments, and appropriate sedation, may minimize infection risk.	Dr. Brown: • Create an early extubation protocol • Develop a training and dissemination plan for all LVAD providers involved	Sep 2023 – May 2024

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)

Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Program Directed Recommendations (1/6)

Rank	Anticipat ed Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Up-to-date unit and service line level infection prevention data should be provided to members of the VAD team, including consulting services, to advance evidence-based care and outcomes.		
				Efforts to enhance clinician onboarding and continuing education may benefit from standardized curricula.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Program Directed Recommendations (2/6)

Rank	Anticipate d Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Tailored (e.g., assessing patient and caregiver surveys), evidence-based HAI prevention practices should be designed in conjunction with VAD team members (e.g., HF cardiologists, surgeons, VAD Coordinators, nurse educators).		
				Efforts should be made to raise awareness of and disseminate evidence-based HAI prevention practices across clinicians in varied care settings.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Program Directed Recommendations (3/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Adherence to evidence-based HAI prevention bundles may be advanced by ensuring patients have equitable access to infection prevention items (e.g., driveline dressing kits).		
				Tailored (e.g., assessing patient and caregiver surveys), evidence-based HAI prevention practices should be designed in conjunction with VAD team members (e.g., HF cardiologists, surgeons, VAD Coordinators, nurse educators).		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Program Directed Recommendations (4/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Consistent usage of a HIPAA-compliant patient portal can support post-discharge HAI surveillance (e.g., transmission of driveline exit site images to the patient's care team).		
				HAI prevention strategies should be routinely reassessed per institutional protocol (e.g., yearly) in addition to more frequently as needed (e.g., as new data emerge).		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Program Directed Recommendations (5/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Efforts to enhance adherence to evidence-based HAI prevention practices may benefit from (1) standardization through order sets and (2) availability of VAD-specific supplies (e.g., driveline dressing kits) for clinicians and patients.		
				Patient and caregiver-level care capacities may be effectively addressed during the pre-and post-implant settings by physical and occupational therapists.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Program Directed Recommendations (6/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Efforts to implement standards of care may benefit from an accessible, up-to-date repository of HAI-prevention resources, policies, and procedures (e.g., hand hygiene program, line replacement protocol, patient and caregiver education tips).		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Patient and Caregiver Directed Recommendations (1/3)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Adherence to evidence-based HAI prevention practices is advanced through a pool of long-term, engaged patient caregivers.		
				A patient and caregiver-centered education program (e.g., customized to their health literacy level and preferred language, addressing caregiver concerns) and support (e.g., interpreters available during office visits, discussing options for transportation to implanting hospital with patient & caregiver with social work) can advance their long-term commitment to evidence-based HAI prevention practices.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Patient and Caregiver Directed Recommendations (2/3)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Adherence to infection prevention practices may be advanced through achieving longitudinal patient and caregiver commitment (e.g., Lifestyle Contract).		
				Patient advisors (e.g., patients on long-term durable LVADs) may be used to inform the design and implementation of effective tailored patient education curricula and as peer mentors for patients who are newly implanted or being evaluated for durable LVAD implantation.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Patient and Caregiver Directed Recommendations (3/3)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Documented counseling for patients/caregivers to promote health behavior changes (e.g., quitting smoking, changing diet, self-limiting exertion) to minimize the risk of post-implantation infection.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Clinician Directed Recommendations (1/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Teaching of evidence-based HAI-prevention practices should balance device-related concerns with patient quality of life, such as their ability to participate safely in pre-implant hobbies and to engage in functional activities pre- and post-implant.		
				Multidisciplinary data-driven discussions support the advancement and implementation of evidence-based LVAD practices and protocols.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Clinician Directed Recommendations (2/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Early removal of invasive devices (e.g., urinary catheter, central line) may support the prevention of HAI.		
				Post-discharge outpatient visits, including through telehealth modalities, may be used to advance patient and caregiver education and adherence to evidence-based HAI prevention practices (e.g., video visits to reinforce optimal driveline dressing changes).		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Clinician Directed Recommendations (3/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Use of safety devices to secure the percutaneous driveline (e.g., anchors) may prevent inadvertent trauma to the interface between the driveline and subcutaneous tissue and increase the risk of subsequent HAIs.		
				Adherence to evidence-based nursing care bundles may reduce post-implant HAIs.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Clinician Directed Recommendations (4/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				In order to effectively advance the delivery of patient and caregiver education, clinicians should be aware of potential barriers (e.g., educational, socioeconomic, resource limitations) and other disparities experienced by their patients.		
				Team member well-being may be enhanced through the development and dissemination of positive patient outcomes (e.g., including stories of patient successes in a VAD newsletter).		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Clinician Directed Recommendations (5/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Patient and caregiver confidence in executing HAI-prevention practices may be enhanced through patient-centered communication practices during their appointments with VAD team members.		
				High contrast suture colors may advance early post-implant HAI identification among diverse patient populations.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Clinician Directed Recommendations (6/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				The utilization of evidence-based HAI prevention and management practices may be enhanced through specific VAD management protocol for clinical staff working across diverse settings (e.g., emergency department nurses, emergency medical technicians, and rehabilitation facilities).		
				Developing an early extubation plan, including effective postoperative pain control, pulmonary hygiene, repeated ventilator wean assessments, and appropriate sedation, may minimize HAI risk.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Leadership Directed Recommendations (1/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				In-hospital infection prevention and management may be advanced through a multidisciplinary team rounding approach (e.g., heart failure cardiology, surgery, nursing, anesthesia, pharmacy) that addresses antimicrobial stewardship and infection prevention.		
				Consistent nurse-physician dyads, which increase accountability and team familiarity, advance evidence-based HAI-prevention practices.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Leadership Directed Recommendations (2/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Efforts aimed at reducing in-hospital HAI rates should leverage both existing inpatient HAI prevention initiatives (e.g., invasive line management, ERAS, hand hygiene) as well as institutional resources (e.g., Environmental Services, Facilities, Maintenance).		
				Extensive documentation of successful interventions (e.g., hand hygiene program, "scrub the hub") and the effect of protocol changes are key to maintaining low HAI rates.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Leadership Directed Recommendations (3/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Ensuring accurate and reliable surveillance and performance data via auditing are foundational for advancing evidence-based HAI-prevention strategies.		
				A longitudinal, robust, and up-to-date HAI tracking system including OR surveillance may be used to support an LVAD program's HAI prevention strategy.		
				Infection surveillance data should be reported at the unit and service level to support local quality improvement efforts.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Leadership Directed Recommendations (4/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Developing a reporting system for post-implant patient-reported outcomes can promote improved post-implant patient care and inform interventions that mitigate inconsistent execution of protocol.		
				OR size and layout should be optimized for complex cardiac surgery to advance efficiency and mitigate infection risk, including evaluating if there is adequate and well-coordinated use of space.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Leadership Directed Recommendations (5/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Institutional quality assurance and improvement initiatives may be advanced through dedicated team members (e.g., database programmer, biostatistical analyst, quality improvement coordinator).		
				Encourage engagement with infection prevention initiatives from physicians, nurses, and/or LVAD Coordinators by nominating quality champions.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)



Leadership Directed Recommendations (6/6)

Rank	Anticipated Patient Impact	Anticipated Center Impact	Ease of Implementation	Recommendation	Actions Needed	Timeline
				Advocate for the expansion of available functions of the INTERMACS dashboard to advance real-time comparisons with aggregate INTERMACs data. These comparisons may improve (1) the evaluation of an intervention’s efficacy and (2) tracking of institutional data more effectively.		

Scoring Guide

Anticipated Impact: Low (1) ---- Medium (5) ---- High (10)
Ease of Implementation: Difficult (1) ---- Medium (5) ---- Easy (10)

Appendix D

Team Roles and Responsibilities: LVADS



Implementation Analysis

How to Complete the L-V-A-D-S Assignment of Tasks Matrix

Guidance: For each of the recommendation groups, please assign members from your institution’s LVAD multidisciplinary working group to each the above roles. Please specify the assigned names for each role, as well as any specific needs they might have to successfully execute the implementation of the infection prevention recommendations. The above table may serve as an example. Worksheets for each of the recommendation groups are provided in the accompanying slides.

Role	Name	Needs Assessment (e.g., administrative support, institutional buy-in)
L: Leader	Jane Desai	Administrative support, financial resources to fund
V: Validator	James Garcia	Further training on how to navigate large data sets
A: Actor	John Smith	Educational materials and access to training
D: Delegator	Noah Chen	Implicit and explicit authority to delegate tasks to team members
S: Supporter	River Jones	Resources necessary to gather required data (e.g., programming time, institutional authority) with LVAD team

Implementation Analysis

Program Directed

Role	Name	Needs Assessment (e.g., administrative support, institutional buy-in)
L: Leader		
V: Validator		
A: Actor		
D: Delegator		
S: Supporter		

Implementation Analysis

Patient and Caregiver Directed

Role	Name	Needs Assessment (e.g., administrative support, institutional buy-in)
L: Leader		
V: Validator		
A: Actor		
D: Delegator		
S: Supporter		

Implementation Analysis

Clinician Directed

Role	Name	Needs Assessment (e.g., administrative support, institutional buy-in)
L: Leader		
V: Validator		
A: Actor		
D: Delegator		
S: Supporter		

Implementation Analysis

Leadership Directed

Role	Name	Needs Assessment (e.g., administrative support, institutional buy-in)
L: Leader		
V: Validator		
A: Actor		
D: Delegator		
S: Supporter		

Appendix E

Study Information:

How

Recommendations

were Derived

Impact of Healthcare-Associated Infections After Durable Left Ventricular Assist Device (LVAD) Implantation



- Healthcare-associated infections (HAIs):
 - Among most common & debilitating sequelae of LVAD implantation¹
 - Vary in rate across hospitals²
- HAI prevention initiatives typically one-size—fits all approaches that lack customization.
- The structure, content and delivery of an evidence-based, customizable HAI prevention toolkit should be informed by key LVAD stakeholders.

Integration of Quantitative & Qualitative Findings



- Identify low- and high- performance outliers based on national evaluation of of 90-day HAIs for patients undergoing durable LVAD.^{2, 3-9}
- Conduct 72 semi-structured interviews with clinical and operational team members at each of 3 low and 5 high performance centers.^{3, 10}
- Conduct thematic analysis of de-identified interview transcripts

Development of a Customizable and Deployable HAI Prevention Toolkit



- Structure of toolkit designed based on prior AHRQ-led toolkits¹¹
- Content informed by mixed methods analyses and input from focus groups involving external experts
- Toolkit designed to facilitate
 - Self-assessment of existing performance
 - Ranking of priorities
 - Tracking of toolkit adoption

Citations:

- Rates and Types of Infections in Left Ventricular Assist Device Recipients: A Scoping Review. doi: 10.1016/j.xjon.2021.08.005
- Interhospital variability in health care-associated infections and payments after durable ventricular assist device implant among Medicare beneficiaries. doi: 10.1016/j.jtcvs.2021.04.074
- Understanding and Addressing Variation in Health Care-Associated Infections After Durable Ventricular Assist Device Therapy: Protocol for a Mixed Methods Study. doi: 10.2196/14701
- Mortality following durable left ventricular assist device implantation by timing and type of first infection. doi: 10.1016/j.jtcvs.2021.10.056
- Non-patient factors associated with infections in LVAD recipients: A scoping review. doi: 10.1016/j.healun.2021.10.006
- Patient factors associated with left ventricular assist device infections: A scoping review. doi:10.1016/j.healun.2022.01.011
- Mortality following Durable Left Ventricular Assist Device Implant by Timing and Type of First Infection. doi: 10.1016/j.jtcvs.2021.10.056
- Association Between Care Fragmentation and Total Spending After Durable Left Ventricular Device Implant: A Mediation Analysis of Health Care-Associated Infections Within a National Medicare-Society of Thoracic Surgeons Intermacs Linked Dataset. doi: 10.1161/CIRCOUTCOMES.121.008592
- Care fragmentation predicts 90-day durable ventricular assist device outcomes. doi: 10.37765/ajmc.2022.89280
- Expanding Our Methodological Toolbox to Improve Quality: The Role of Mixed-Methods Evaluations. doi: 10.1161/CIRCOUTCOMES.122.009629
- Agency for Healthcare Research and Quality. <https://qualityindicators.ahrq.gov/resources/toolkits>. Accessed May 23, 2022.

Study Methodology

Complex mixed methods (integrating quantitative & qualitative findings) study design to develop a customizable and deployable infection prevention toolkit of expert guided recommendations

Key study phases:

- Quantitatively analyze associated impact of infections after durable LVAD implantation
 - Analyze national Medicare claims merged with InterMACs (FDA-approved devices)
 - Identify patient, clinician, and hospital-level determinants of interhospital variability in infections (based on national data analyses and scoping reviews of published articles)
 - Findings inform low and high-performing centers for the qualitative phase
- Qualitatively explore contexts and perspectives on infections after durable LVAD implantation
 - Conduct 72 semi-structured interviews with clinicians and operational team members at 3 low and 5 high-performing centers (based on 90-day infection rates)
 - Interviews focused on individuals' perceived practices, barriers and facilitators contributing to infections
 - Analyses of the interview transcripts, field notes, and interview debriefs informed content and structure of an infection prevention toolkit
- Integrate quantitative and qualitative findings by comparing two data sources and synthesizing recommendations through team discussions and team input
- External advisory team of content experts (database coordinators, cardiac surgeons/heart failure cardiologists, infectious disease/nursing/intensive care) provided quantitative and qualitative feedback on draft toolkit's content and implementation
- Iteratively enhance toolkit content and structure based on advisory team feedback

Data Coordinating Center Team



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Jeffrey McCullough, Ph.D.

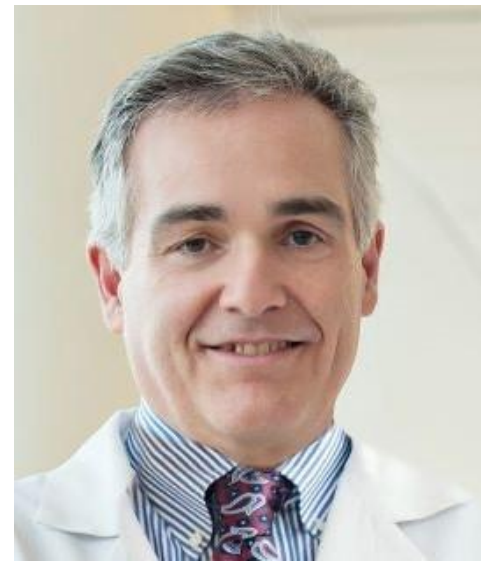
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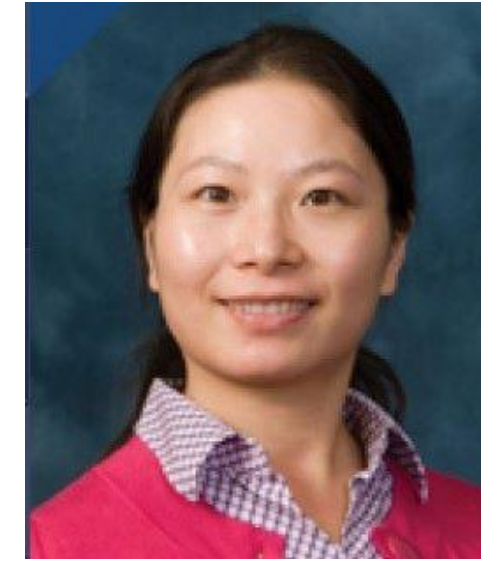
Tessa Watt, M.D.



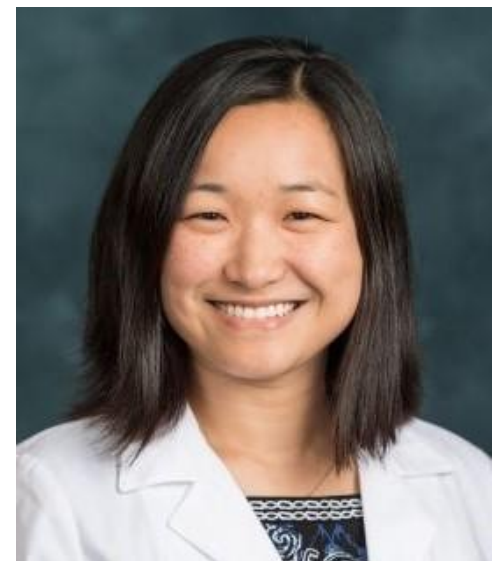
Guangyu Yang, Ph.D.



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Appendix F

Fact Sheet: Infections after Durable LVADs

Fact Sheet about Infections after Durable LVAD Implantation

Overall and interhospital rate of short- and long-term infections

Reference	DOI Number	Design	Sample Size	Methods	Main findings
Likosky et al.	10.1016/j.jtcvs.2021.04.074	Cohort study	8,688	Secondary analyses of 2 data sources: (1) Medicare claims, and (2) Intermacs data	• There were 3982 infections identified among 27.8% (2417/8688) of patients developing an infection. The median (25th, 75th percentile) adjusted incidence of infections (per 100 patient-months) across hospitals was 14.3 (9.3, 19.5) and varied according to hospital (range, 0.0-35.6). • Total Medicare payments from implantation to 90 days were 9.0% (absolute difference: \$13,652) greater in high versus low infection tercile hospitals ($P<.0001$). • The period between implantation to discharge accounted for 73.1% of the difference in payments during the implantation to 90-day period across terciles.

Associated Impact of Infections on Provider Networks, Spending and Health-Related Quality of Life

Reference	DOI Number	Design	Sample Size	Methods	Main findings
Zhou et al.	10.1016/j.healun.2023.05.006	Cohort Study	11,618 patients	Secondary analyses of 2 data sources: (1) Medicare claims, and (2) Intermacs data	4,768 (41.0%) patients developed an infection during the one-year post-implantation follow-up period; with 2,282 (19.6%) patients having> 1 infection. Adjusting for covariates, each additional infection was significantly associated with a 22% increased odds of the primary composite adverse outcome (i.e., not thriving or death). This significant effect was observed across all infection types. Among patients surviving to 1-year, the occurrence of any infection was associated with more impairment in HRQOL dimensions compared to patients without infection.
Funk et al.	10.37765/ajmc.2022.89280	Cohort Study	5,159 patients	Secondary analyses of 2 data sources: (1) Medicare claims, and (2) Intermacs data	11.2% patients died and 27.6% experiencing an infection within 90 days after implant. After adjustment, a 1-unit increase in network fragmentation was associated with an increase of 0.179 in the probability of in-hospital infection and an increase of 0.183 in the probability of 90-day infection (both P < .05). Similar results were observed in models of the numbers of in-hospital and 90-day infections. Network fragmentation was predictive of the probability of 90-day mortality, although this relationship was not significant after adjustment.
Kim et al.	10.1161/CIRCOUTCOMES.121.008592	Cohorts Study	4,897 patients	Secondary analysis of (1) Medicare claims and (2) STS Intermacs data	The patient cohort was 81% male, 73% white, 11% Intermacs Profile 1 with mean (SD) age of 63.1 years (11.1). The mean (SD) level of care fragmentation in provider networks was 1.7 (0.2) and mean (SD) payment from admission to 180 days post-discharge was \$246,905 (\$109,872). Mean (SD) total payments at the lower, middle, and upper terciles of care fragmentation were \$250,135 (\$111,924), \$243,288 (\$109,376), and \$247,290 (\$108,241), respectively. In mediation analysis, the indirect effect of care fragmentation on total payments, through infections, was positive and statistically significant (β =16032.5, p=0.008).
Yang et al.	10.1016/j.healun.2022.07.001	Cohort Study	14,063 patients	Secondary analyses of 2 data sources: (1) Medicare claims, and (2) Intermacs data	HRQOL incompleteness at high-rate hospitals was more often due to administrative reasons (risk difference, EQ-5D: 10.1%; KCCQ-12: 11.6%) and less likely due to patient reasons (risk difference, EQ-5D: -8.9%; KCCQ-12: -11.4%). A 10% increase in the adjusted pre-implant EQ-5D incompleteness rate was significantly associated with higher risk of infection-related mortality (HR: 1.09), infection (HR: 1.05), and renal dysfunction (HR: 1.03). A 10% increase in the adjusted pre-implant KCCQ-12 incompleteness rate was significantly associated with higher risk of infection (HR: 1.04).

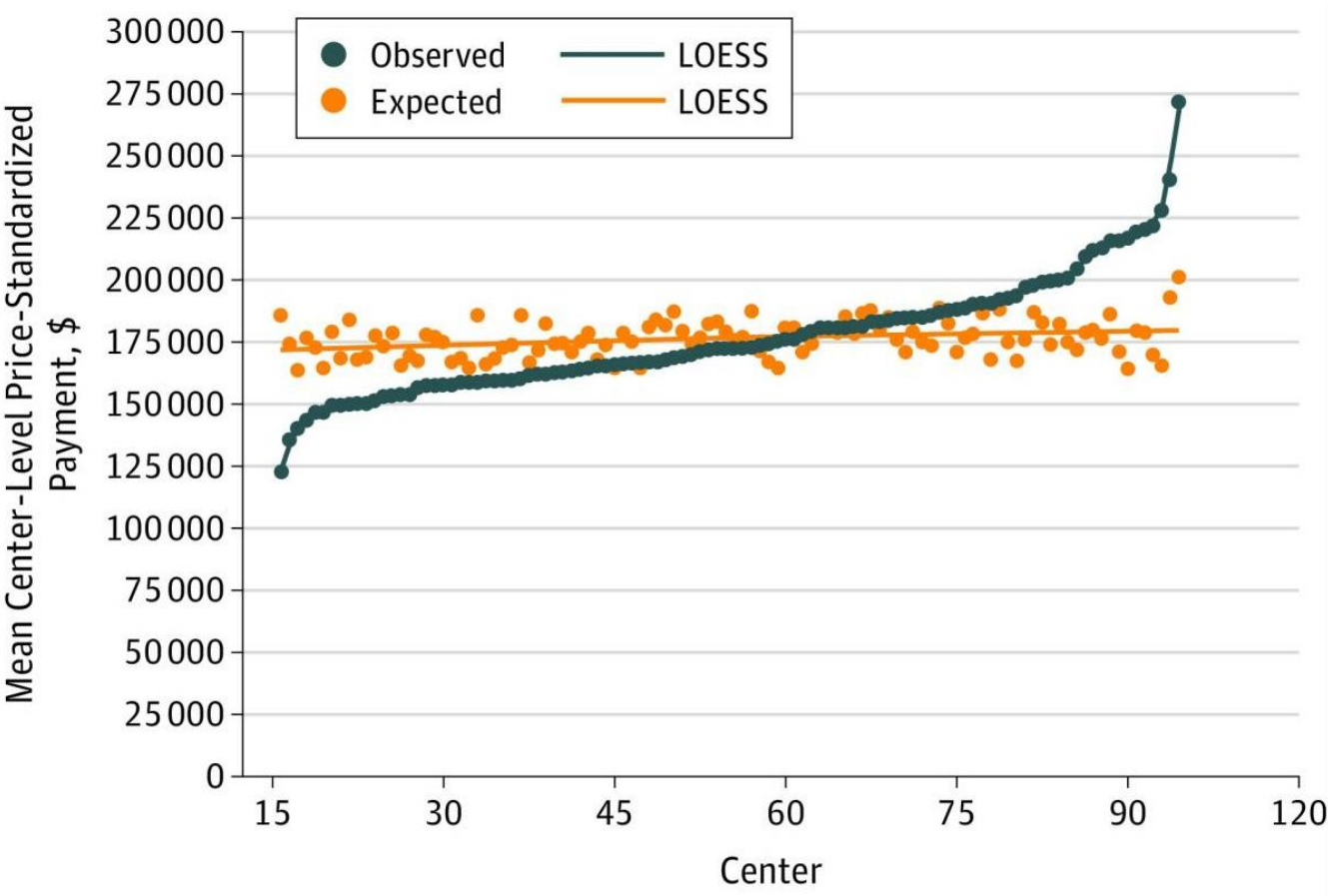


Determinants of Infections (overall and by subtype)

Reference	DOI number	Design	Sample Size	Methods	Main findings
Pienta et al.		Scoping review	132 studies	Synthesis of published evidence related to rates of different types of infections in LVAD recipients.	Most studies of infections in LVAD recipients did not utilize standardized infection definitions and did not complete information on infection locations and types.
Shore et al.	10.1016/j.healun.2021.10.006	Scoping review	43 studies	Synthesis of non-patient factors associated with infections among durable LVAD recipients	Only two non-patient related factors were consistently associated with lower infection risk in LVAD recipients: increasing center experience and establishing a silicone-skin interface at driveline exit site. The large variability in reporting across multiple studied interventions limited the ability to discern their effectiveness.
Pienta et al.	10.1016/j.healun.2022.01.011	Scoping review	31 studies	Systematically summarize all existing studies examining patient-related factors associated with infections after LVAD implantation.	Studies were frequently single-center with heterogeneity in definition of infectious outcomes as well as exposure variables. Patient race and sex did not correlate with infection risk. There was no consistent association noted between obesity, diabetes, or psychosocial/socio-economic factors and infections in LVAD recipients. Two studies reported a significant association between malnutrition and hypoalbuminemia and post implant infections.

Center Variation in Medicare Spending for Durable Left Ventricular Assist Device Implant Hospitalizations

Rank-Ordered Center-Level Mean Observed Price-Standardized Payments for Durable Left Ventricular Assist Device (LVAD) Implant Hospitalizations and Expected Payments Accounting for Patient Case Mix



Variation in Observed, Price-Standardized, and Price-Standardized and Risk-Standardized Payments for Durable Left Ventricular Assist Device Hospitalizations

Payments	Payment Quartile, Mean (SD), \$		Difference Between First and Fourth Quartile			Attributed to Payment Category, %
	First (Lowest)	Fourth (Highest)	Absolute (95% CI)	Relative, %	P Value	
Observed	153 266 (110 913)	260 086 (138 183)	106 820 (96 053-117 586)	70	<.001	100
DRG	129 591 (88 854)	218 481 (114 410)	88 890 (80 247-97 534)	69	<.001	83
Outlier	16 898 (38 601)	30 349 (56 143)	13 451 (9108-17 794)	80	<.001	13
Physician services	6777 (7054)	11 256 (9088)	4479 (3734-5223)	66	<.001	4
Price standardized	152 714 (36 465)	208 160 (77 920)	55 446 (50 250-60 641)	36	<.001	100
DRG	137 703 (25 435)	144 632 (18 228)	6929 (4917-8940)	5	<.001	13
Outlier	8209 (24 477)	50 951 (68 452)	42 742 (38 354-47 132)	521	<.001	77
Physician services	6803 (6354)	12 577 (10 993)	5774 (4995-6553)	85	<.001	10
Price and risk standardized	154 110 (7025)	207 331 (12 417)	53 221 (52 653-53 789)	35	<.001	100
DRG	139 516 (4703)	143 939 (3333)	4423 (3996-4850)	3	<.001	8
Outlier	6515 (21 714)	51 479 (38 437)	44 964 (42 460-47 468)	690	<.001	84
Physician services	8079 (2383)	11 913 (3125)	3834 (3633-4035)	47	<.001	7

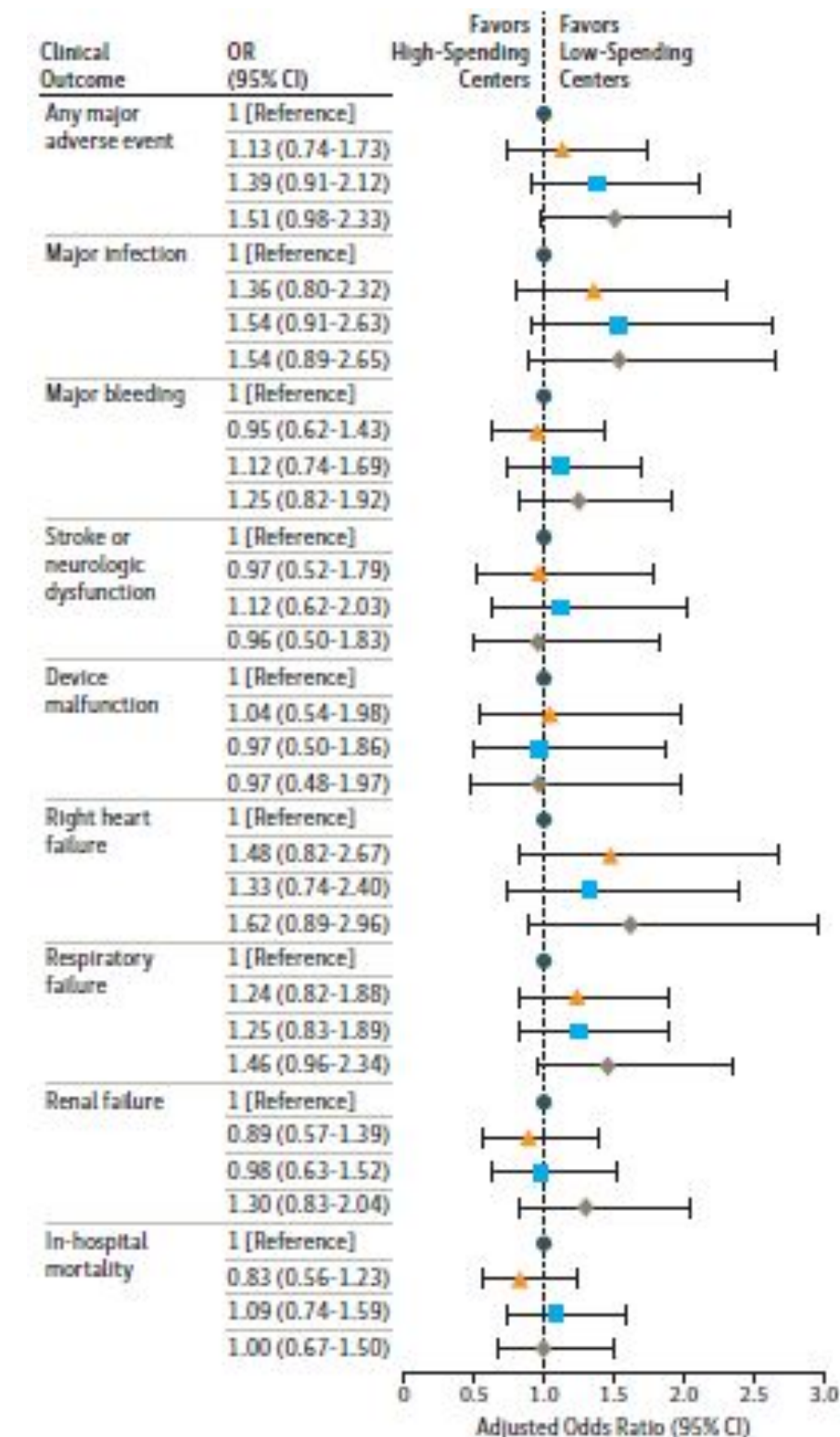
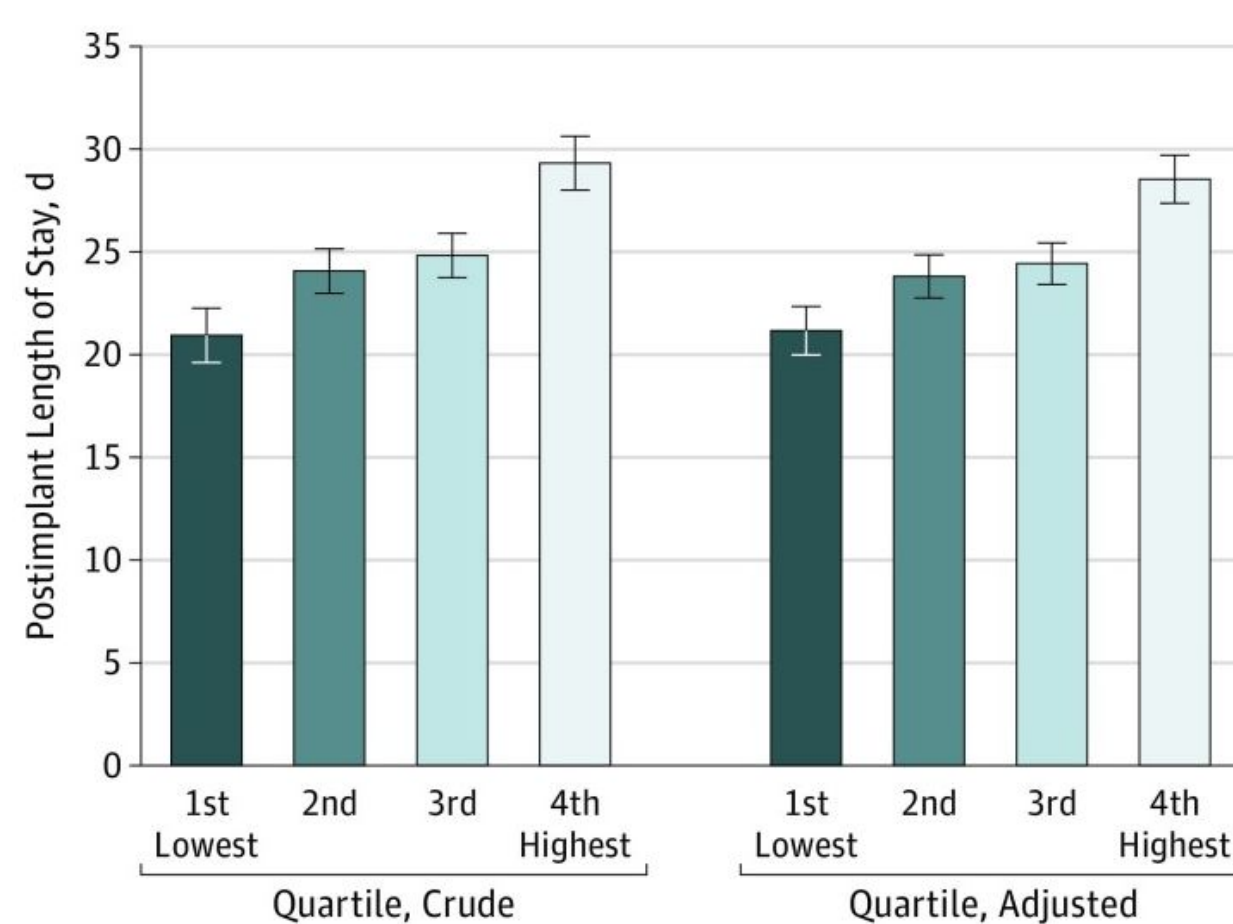
Abbreviation: DRG, diagnosis-related group.



Center Variation in Medicare Spending for Durable Left Ventricular Assist Device Implant Hospitalizations

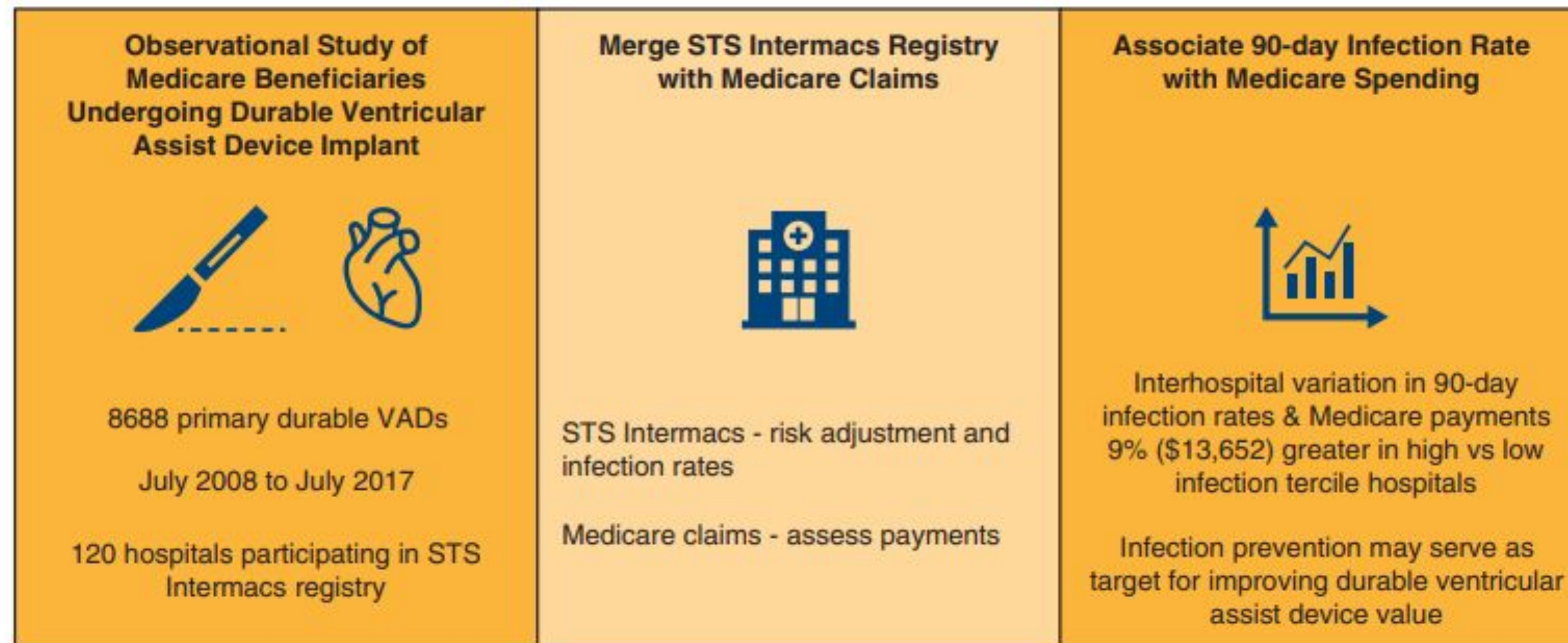
Risk-Adjusted Adverse Events for Durable Left Ventricular Assist Device (LVAD) Implant Hospitalizations by Price-Standardized Payment Quartile (Compared With Lowest Spending Quartile)

Crude and Adjusted Mean Postimplant Length of Stay (and 95%CI) by Price-Standardized Payment Quartile





Interhospital variability in healthcare-associated infections and payments after durable ventricular assist device implant among Medicare beneficiaries





Additional Resources

- Society of Thoracic Surgeons Intermacs Registry (STS Intermacs)
 - o National, longitudinal registry of FDA-approved LVADs
 - o Website - <https://www.sts.org/sts-national-database>
- International Society for Heart and Lung Transplantation
 - o Multidisciplinary community representing individuals caring and treating patients with mechanical circulatory support devices and/or heart transplantation.
 - o Has a professional community focusing on infectious disease
 - o Website: <https://www.isHLT.org/>