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## Left Ventricular Assist Device (LVAD) Driveline Infection Rates Between Two Different Dressing Methods

Gretchen Compton

University of Missouri-St. Louis, gwww8@umsystem.edu

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**Left Ventricular Assist Device (LVAD) Driveline Infection Rates Between Two  
Different Dressing Methods**

Gretchen L. Compton

B.S. Nursing, University of Missouri Saint Louis, 2017

A Dissertation Submitted to The Graduate School at the University of Missouri-St. Louis  
in partial fulfillment of the requirements for the degree  
Doctor of Nursing Practice  
with an emphasis in Family Nurse Practitioner

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Advisory Committee

Diane Saleska, DNP, RN, CHSE  
Chairperson

Cathy Koetting, PhD, DNP, APRN, CPNP, PMHS, FNP-C

Dana Bush, PhD, RN, CNE, CEN

### Abstract

*Problem:* Heart failure has a growing impact on Americans, and this contributes to an increased number of patients requiring treatment for advanced heart failure. Typical treatment options may include cardiac transplant or the implantation of a left ventricular assist device (LVAD). The use of an LVAD requires sterile management of an external driveline site. Driveline infections are a common complication in this patient population and can lead to chronic complications. There are no published guidelines on the management of the driveline site. This project aimed to provide evidence that can be used in the establishment of standardized guidelines for driveline site care. *Methods:* This QI initiative compared driveline infections between two different dressing change protocols at a single midwestern hospital. Data was compared from the years 2017-2021 with the change in dressing protocol occurring in 2019. A retrospective medical record review was conducted, and the data was analyzed using independent sample t-tests to measure significance. A confidence interval of 95% was used. *Results:* A bi-weekly dressing change protocol using a pre-packaged kit, clear occlusive dressing, silver-impregnated ring, and driveline stabilization device resulted in a reduction of LVAD driveline infections (with significance p-value <0.001) when compared to the retired method. Further research could be conducted on how patient compliance impacts driveline infections. *Implications for Practice:* The results of this QI initiative may be useful in the creation of standardized published guidelines for LVAD driveline site care.

*Keywords:* left ventricular assist device (LVAD) care, driveline site infections, LVAD driveline site infections

## **Driveline Infection Rates Between Two Different Dressing Methods**

### **Introduction**

#### **Background and Significance**

Heart failure is a common chronic condition in the United States and a leading cause of hospital readmission with up to 50% of patients readmitted within six months or discharge (O'Connor, 2017). There are many treatment options for heart failure, and some patients require a cardiac transplant for their condition. As the population ages, there is a large number of patients diagnosed with heart failure that no longer qualify for transplant due to age and/or the number of co-morbidities. Projections estimate that by 2030, there will be two million Americans with heart failure over the age of eighty (DeFilippis et al., 2019). An alternative therapy to transplant for these patients who may not qualify is the implantation of a left ventricular assist device (LVAD). This device helps improve quality of life and reduce symptoms associated with heart failure. As the population with heart failure gets older, the use of the LVAD may become more prevalent.

A ventricular assist device consists of an implanted pump connected via a driveline to an external power source and controller. The pump is inserted into the apex of the heart during open-heart surgery. The pump takes blood from the ventricle of the heart and moves it through a tube to the aorta to continuously pump it through the body. A driveline runs from the pump, exiting through the abdominal wall, to an external controller connected to a power source. The goal of the implantation is either destination therapy to help control heart failure symptoms and prolong life or as a bridge to transplant. Using an LVAD can improve a patient's one-year survival rate from 25% to

50% compared to guideline medical therapy (Hove et al., 2020). Guideline-directed medical therapy consists of a complex medication regime including beta-blockers, angiotensin-converting enzyme inhibitors, angiotensin II receptor blockers, and diuretics. It requires strong adherence and close follow-up to manage treatment. The four-year survival rate for patients who receive an LVAD is similar to that of a cardiac transplant (Hove et al., 2020).

There is sufficient evidence to support using a ventricular assist device to manage heart failure, but it is not without risk. The internal pump connects to a driveline that exits through the body to an external power source. This exit site requires specific care and attention to prevent infection. Unfortunately, a driveline-site infection is the most common adverse occurrence in this patient population and can pose long-term complications (Juraszek et al., 2021). Within the first year of implant, 18.1% of patients with an LVAD will experience a driveline infection, and 11.9% of LVAD patients will experience a driveline infection beyond the first year (Hove et al., 2020). Driveline infections can pose a chronic issue and place the patient at a higher risk for stroke. As many as 13% of patients in a study of LVAD patients with driveline infections experienced a stroke within six weeks of their infection and suffered reduced cumulative survival as a result (Cho et al., 2019). The high incidence of driveline infections emphasizes the importance of an effective care management protocol of the driveline site.

### **Purpose**

Currently, there are no published standardized guidelines on exit site dressing care protocol for an LVAD driveline. Therefore, the purpose of this quality improvement (QI) project was to retrospectively compare LVAD driveline infection rates between two

different dressing change protocols to determine which method results in fewer infections in the first year following LVAD placement. This project aim was to provide evidence to assist in the development of specific dressing change guidelines for the management of an LVAD driveline.

This QI initiative sought to answer the following question: “In adults ages 55 years or older that have a ventricular assist device, what is the effect of using a driveline dressing kit and bi-weekly dressing change compared to the previous method with daily dressing change, on driveline infection rates over the first year of implantation?” The outcomes that were measured include the driveline infection rates of each dressing change protocol, the type of LVAD, and when the infection occurred.

The previous method of dressing changes for LVAD patients at a Midwest urban acute facility consisted of a daily dressing change using sterile technique. The old dressing is removed, and the driveline insertion site is cleansed initially with chlorhexidine and sterile water-soaked gauze, followed by gauze only soaked in sterile water. The site is dried with sterile gauze and re-dressed with split gauze, 4x4 gauze, and covered with Hypafix® (water-resistant hypoallergenic adhesive) tape. The driveline site covered with gauze is not visible between dressing changes. The driveline is anchored to the skin using the Centurion® urinary catheter holder. This dressing change protocol will be referred to in this QI project as the “retired protocol.”

The new method of driveline care was initiated in Fall 2019 and consists of a pre-packaged kit that includes all necessary dressing and cleaning supplies. The kit contains hand sanitizer packages for glove changes, two sets of clean gloves, adhesive remover, two sets of sterile gloves, two chlorhexidine swab sticks, a skin barrier applicator, a

silver-impregnated dressing ring, a transparent Tegaderm™ dressing, and a new Centurion® urinary catheter anchor device. The old dressing is removed using clean gloves and adhesive remover. Hand hygiene is performed, and sterile gloves are donned. The skin surrounding the driveline site is cleansed with the first chlorhexidine swab. The driveline itself is cleaned using the second chlorhexidine swab. The silver-impregnated ring is then placed around the driveline exit site, and skin barrier is applied. Finally, the transparent dressing is applied and provides visibility of the driveline site. These dressing changes are completed twice a week. This method will be referred to as the “current protocol.”

### **Literature Review**

A literature search was conducted using the following databases: PubMed, Cumulative Index of Nursing and Allied Health Literature (CINAHL) and SUMMON. Search terms included “LVAD AND driveline infections,” “LVAD driveline care,” and “LVAD dressing AND infection.” The trajectory and criteria used for article identification and selection for this review can be found in Appendix A. Fourteen articles underwent critical review for this QI project and include one practice guideline, three systematic reviews, four correlational studies, three mixed-methods studies, two descriptive/non-experimental studies, and one quasi-experimental study.

A significant gap in the available literature is the lack of established standardized guidelines for the dressing care and management of LVAD driveline sites. The lack of standardized guidelines leaves the decision on dressing care to the providers’ clinical expertise, available evidence on wound management, and facility provided supplies. In addition, reference can be made to other sterile line management guidelines.

Through analysis of the available literature, five emerging themes or aspects of driveline care impacting the incidence of infection were identified. These include the type of cleaning agent, type of dressing material, presence of an anchor device to secure the driveline, frequency of dressing change, and use of a pre-packaged dressing kit.

### **Cleaning Agent**

Cleaning agents identified for the driveline site care include chlorhexidine, hydrogen peroxide, iodine, Octanisept® (solution of octenide hydrochloride and alcohol), and a polymyxin-trimethoprim solution (Juraszek et al., 2021). Studies using chlorhexidine solution reported lower driveline infection rates, as low as 5.4% (Koken et al., 2021). The Octanisept® solution had infection rates of 11%, while the polymyxin-trimethoprim had infection rates of 13.8% (Koken et al., 2021). Iodine solutions also had higher infection rates and was often cited as the alternative agent to chlorhexidine for patients with an allergy to that agent. While three articles used chlorhexidine, there were discrepancies in how the agent was used. Many articles did not mention how these agents were used to clean, while one mentioned soaking gauze in Octanisept® and letting it sit on the skin (Juraszek et al., 2021).

### **Dressing**

The type of dressings applied to driveline insertion sites were not often specified, but usually included occlusive dressing materials including Tegaderm™, Hypafix®, or a silver-based dressing (Yoshi et al., 2018). In addition, one study included dressing types that were impregnated with polyhexamethylene biguanide, an antiseptic. A silver-based dressing was the most often used antiseptic dressing in LVAD patients (Juraszek et al.,

2021). There were no studies that referenced how the type of dressing influenced infection rates.

### **Anchoring Device**

The next aspect identified affecting driveline infection rates was the type of fixation device used. Trauma to the driveline site is a significant risk for infection. Using a stabilization device helps prevent movement of the driveline (Bejko et al., 2018). The two most often mentioned methods for stabilization include the Centurion® urinary catheter holder and an abdominal binder. One study mentioned that driveline fixation has the most considerable impact on infection risk and utilized surgical immobilization via sutures for thirty days after implant (Bernhardt et al., 2020). The retired and current protocols at the study facility used the Centurion® urinary catheter holder to anchor the driveline. This device works by adhering to the abdomen and securing the driveline in place to prevent tension on the exit site. Both protocols changed the anchor device on an as-needed basis. The use of an abdominal binder was associated with a higher infection rate (Koken et al., 2021).

### **Dressing Change Frequency**

Although dressing change frequency was not found to have a direct impact on driveline infection rates, it may influence patient adherence to dressing care. In one study, dressing changes could be completed daily and then every two or three days after the site had time to heal (Schlöghofer et al., 2020). Variation in dressing change frequency ranges from every three days or daily if there was drainage from the site. Another study used daily dressing changes from the time of implant through the duration of the LVAD (Imamura et al., 2017).

### **Pre-Packaged Kit**

Another common theme between articles was the use of a dressing kit. The dressing kit contains all necessary supplies, including sterile gloves, the cleaning agent, and dressings. The kits were easy to use and resulted in fewer driveline infections (DeFilippis et al., 2019). Although two articles mentioned using a kit in managing the driveline site, details were not provided on what was included in the kit or how the care was managed prior to using the kit.

An additional factor identified in the literature that may contribute to driveline infection is the position of the driveline. The internal portion of the driveline has a velour interface section designed for better adherence internally. If patients experience trauma to the site, this velour section may become external. Patients with the velour completely implanted have a 50% less chance of developing a driveline infection (Zinoviev et al., 2020).

A few articles discussed additional strategies to mitigate driveline infections and the associated complications. One suggestion to lower infection risk is to use a specialized nurse to provide education and training to patients (Rahal et al., 2019). This education would include daily care instructions as well as recognizing alarms and troubleshooting. Some LVAD providers mention using long-term antimicrobial suppression to lower the risk of complications from driveline infections. The decision for suppression therapy is often left to clinical expertise, but it has been shown to positively affect those who experience driveline infections frequently (Radcliffe et al., 2020).

Because there is little published evidence on the management of LVAD driveline sites, a review of the American Society of Anesthesiologists (2020) published guidelines

on central line access was included for comparison. These guidelines recommend chlorhexidine as the cleaning agent, using a transparent bio-occlusive dressing, and securing the line with an anchoring device (American Society of Anesthesiologists, 2020). It was mentioned that an adhesive fixation device should be used when applicable, and a dressing impregnated with chlorhexidine should be used if tolerated by the patient (American Society of Anesthesiologists, 2020). Although a central line is different from a driveline, it is helpful to review the management of central access lines for comparison.

### **Analysis of Evidence**

The articles selected provide valuable information on the dressing care of driveline sites. Strengths of the evidence include strong follow-up with and minor loss or participants in each study. Although studies included had small sample sizes of less than 75 people, they appear to be a good representation of the LVAD population for the site studied. Most, if not every, patient with an LVAD were included in the studies. In addition, articles provided new evidence on a topic and patient population that has been lacking in the literature. Many articles discussed care and management of the same type of LVADs, reducing an additional variable and making it easier to gather cumulative data.

It was difficult to compare studies due to lack of consistency in driveline site care from study to study. Better descriptions of how each cleaning agent was used would have been useful. All articles selected were retrospective studies. A prospective study about driveline infections would allow for the generation of more robust evidence.

### **Gaps in the Literature**

No studies identified compared different dressing protocols within the same patient group or facility and resulting driveline infection rate. No two articles were found that use the same dressing method, with each driveline management protocol differing in some way. The literature reviewed all discussed the importance of cleaning, covering, and stabilizing the driveline, but with significant variation in methods and infection outcomes. Further studies are needed which include a description of how cleaning agents are applied. Due to the lack of standardization, there is a need to determine which dressing protocols result in lower infection rates.

Additional gaps include information on patient adherence and compliance. Patient adherence to dressing change protocols could potentially be a factor affecting driveline infection rates.

It is worth exploring whether using antimicrobial dressings impact infection rates when controlling all other factors. A few articles used a transparent adhesive dressing, while others used an antimicrobial one, and it would be helpful to know if the antimicrobial dressing reduces infection rates.

Finally, although the use of pre-packaged kits was discussed, the studies reviewed do not identify specific kit contents. Additional studies comparing kit contents and impact on infection and patient compliance would provide more clarity when developing a standardized LVAD dressing change protocol.

### **Theoretical Framework for Change**

The Iowa Model is a valuable framework in guiding nurse-led change in the clinical setting and was selected for the QI initiative. This model provides a clear path for implementing change triggered by a clinician's question of current practice standards

(Melnyk & Fineout-Overholt, 2019). The Iowa Model provides an easily applied framework for developing an evidence-based practice standard. Clinical questions can be addressed using the evidence-based practice process and provide feedback loops to continue progress. The first step in applying this model is identifying the problem and stating the purpose (Melnyk & Fineout-Overholt, 2019). Once the purpose is established, the researcher puts together a team. Evidence is identified and synthesized in order to create a practice change design (Melnyk & Fineout-Overholt, 2019). The design change is piloted and evaluated to see if it is appropriate to adopt it into practice (Melnyk & Fineout-Overholt, 2019). The final step of this framework is to disseminate the results with other professionals. Evidence sharing can be through presentations or publications, and it helps promote the use of evidence-based practice in the clinical setting.

## **Method**

### **Design**

This QI initiative evaluated the use of evidence-based practice in the care of LVAD patients to reduce driveline infection rates by improving dressing management. This initiative was a comparative descriptive study with no experimental variable introduced. The study was correlational as it described the relationship between the dressing protocols and the incidence of driveline infections in the LVAD population. The data was collected via a retrospective medical record review to measure the incidence of driveline infections.

### **Setting**

This quality improvement initiative took place in an urban hospital located in a medium-sized metropolitan area located in the Midwest. The hospital belongs to a system

consisting of four metropolitan hospitals, multiple community hospitals, a rehabilitation facility, and a hospice house. This hospital has over 600 physicians that span more than 60 medical specialties, and it is nationally ranked in cardiac care.

### **Sample**

Due to the specific qualities needed for this initiative, purposeful sampling was used to select patients to be included. The potential participants included patients with a HeartMate II, HeartMate III, or HeartWare ventricular assist device implanted. The inclusion criteria were patients with an LVAD, patients 55 or older, and patients who had a driveline infection between 2017-2021 and were within their first year of implant. The exclusion criteria included patients younger than 55 years old and patients who do not have an LVAD.

### **Approval Processes**

The approval processes included approval by an appointed doctoral committee and two Institutional Review Boards (IRB). IRB training was completed. IRB approval was obtained from the hospital site where data was collected, and from the DNP candidate's (primary investigator) educational facility. There were no identified risks for the patient samples as their identity was kept anonymous. De-identified data collected was stored on the investigator's private laptop which was kept at the investigator's home.

### **Data Collection/Analysis**

The data that was collected included the patient's age, type of LVAD implanted, and the incidence of a driveline infection, including when the driveline infection occurred. More specifically, infection rates were collected on LVAD patients who had an infection between the years 2017-2021 and were within the first year of implant. There

was a total of 42 patients included in the retired protocol sample and a total of 54 patients included in the current protocol sample. This information was gathered through a retrospective review of medical records. Data analysis was conducted via independent t-tests to compare the effect of the different dressing protocols on infection rates.

### **Procedures**

In order to gather information on the incidence of driveline infection, a retrospective review of the medical records for all LVAD patients was conducted. Patients who had their LVAD driveline infection between 2017-2021 were excluded based on stated exclusion criteria, and those that met the inclusion criteria were included in the study. At this point, the medical record was reviewed to assess whether the driveline infection occurred during the retired protocol or with the current protocol for driveline care. The rates of infection were compared using Excel spreadsheets to organize the information.

### **Results**

Upon completion of the retrospective medical record review, a total of 16 driveline infections had occurred in the specified time and qualifications. Table 1 provides a breakdown of the number of infections occurring in each year. The average age of the patients affected was seventy-two years old, and the most common organism identified as methicillin susceptible staphylococcus aureus (MSSA). Patient demographics are identified in Appendix B. The majority of patients were treated with a course of intravenous antibiotics although some required surgical treatment in addition to intravenous medication. Of the 15 patients who experienced a driveline infection under the retired protocol, seven of the patients had the Heartmate II LVAD, seven had the

HeartWare LVAD, and one had the Heartmate III. The patient who had a driveline infection under the new protocol had a Heartmate III LVAD. While there was a much lower incidence of infection in the Heartmate III, it also was not used clinically until 2019, which was the same year that the dressing protocol was changed. The average time after implant for the onset of infection was seven months but ranged from three months to eleven months.

**Table 1**

*Breakdown of Infection Totals per Year*

<b>Protocol</b>	<b>Infection Total (2017-2021)</b>	<b>Total LVAD Patients</b>	<b>Infection Ratio</b>
Retired	15	42	36%
Current	1	54	2%

In order to test for significance in the protocol change, an independent t-test was completed using Statistical Package for the Social Sciences (SPSS) software. A 95% confidence interval was used with a p-value of .05 to measure significance. After completing the independent t-test, a p-value of <0.001 was resulted. This data can be found in Figure 1.

**Figure 1**

*SPSS Data Output*

	Independent Samples	T-test for Equality of	95% Confidence
	Test	Means	Interval of the
			Difference

	t	df	Sig. (2- tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Equal Variance Assumed	4.607	107	<.001	.28946	.06283	.16491	.41400
Equal Variance Not Assumed	4.221	54.042	<.001	.28946	.06858	.15197	.42695

The result reflects a significant difference in infection rates between the retired and current dressing protocols. The analysis results of the quality improvement project support that the current protocol reduced infection rates in the LVAD population when compared with the retired protocol.

### **Discussion**

The implementation of a bi-weekly dressing change using a pre-packaged dressing change kit reduced driveline infections in LVAD patients when compared with a daily dressing change and no pre-packaged kit. Patients who were within their first year of implant experienced significantly fewer driveline infections when using the current protocol for driveline site dressing change. The use of an antimicrobial dressing (silver impregnated ring) may have aided in the prevention of microbial infection at the sterile driveline site. In addition, decreasing the number of times the sterile site is exposed to

open air may help to prevent potential additional exposure to bacteria. The changes in dressing care also help reduce the impact of human error. A daily dressing change put more reliance on the person changing the dressing to maintain sterility at all times. After the frequency was decreased to twice weekly, the chance for human error and contamination during a dressing change appear to be decreased.

In addition to decreasing the frequency of dressing changes, the use of a pre-packaged kit appears to enhance compliance and reduce human error. The pre-packaged dressing change kit provides for a step-by-step process, making it easier to complete. In addition, the kits provide hand sanitizer which may help remind the person completing the dressing change to complete hand hygiene to reduce contamination. The dressing kit clearly separates the clean portion from the sterile portion of the dressing change. This kit helps to ensure that the person completes all of the necessary steps required prior to donning sterile gloves.

The evidence supporting the use of a pre-packaged dressing kit combined with bi-weekly dressing changes can improve outcomes and reduce driveline site infections. This data supports the continuation of the current protocol for dressing change. In addition, thorough patient education prior to implantation is warranted. The practice change made in the dressing care for LVAD patients may reduce human error that can contribute to infection. Ensuring a thorough education on the care of the LVAD and the driveline site may help to further reduce infections. This data may be useful in establishing standardized and published guidelines for LVAD driveline site care. Standardizing driveline site care for all LVAD patients can improve patient outcomes by lowering infection rates.

One limitation to this project is that there was no control for the driveline material. For patients who experience pulling on their driveline, they risk exposing a velour material meant to stay internal for adherence. The exposure of the velour material increases the risk for a driveline infection (Imamura et al., 2017). In addition, patient compliance is another variable that could not be controlled for this project. Future studies to determine the impact of patient compliance with site dressing changes on driveline infection rates is recommended. In addition, it is recommended to study how the frequency of dressing changes impact patient compliance.

This quality improvement (QI) practice change should be implemented on a permanent basis. In addition, continued surveillance of infection rates is recommended. In addition, expanding this study to other hospitals that implant LVADs would help to aggregate more data that would indicate the results of this study are generalizable and can support a standardized approach to driveline site care.

### **Conclusion**

A patient who requires an LVAD has already been impacted by serious health issues and failing medical treatments. Implantation of LVADs helps to improve quality of life in heart failure patients and can also prolong their lives. The driveline site is a common place for infection which can pose major complications for the patient. These pumps require specific management to prevent infection at the driveline site. The protocols for management of driveline sites have not been standardized; however, two different dressing change methods were compared in a single Midwest facility. The retrospective medical record review revealed that using a pre-packaged dressing kit with bi-weekly dressing changes significantly decreased driveline infection rates when

compared to a daily dressing change without a pre-packaged kit. Data provided in this study may help to contribute to the development of published guidelines for driveline sites in LVAD patients to improve overall outcomes and reduce driveline infection rates.

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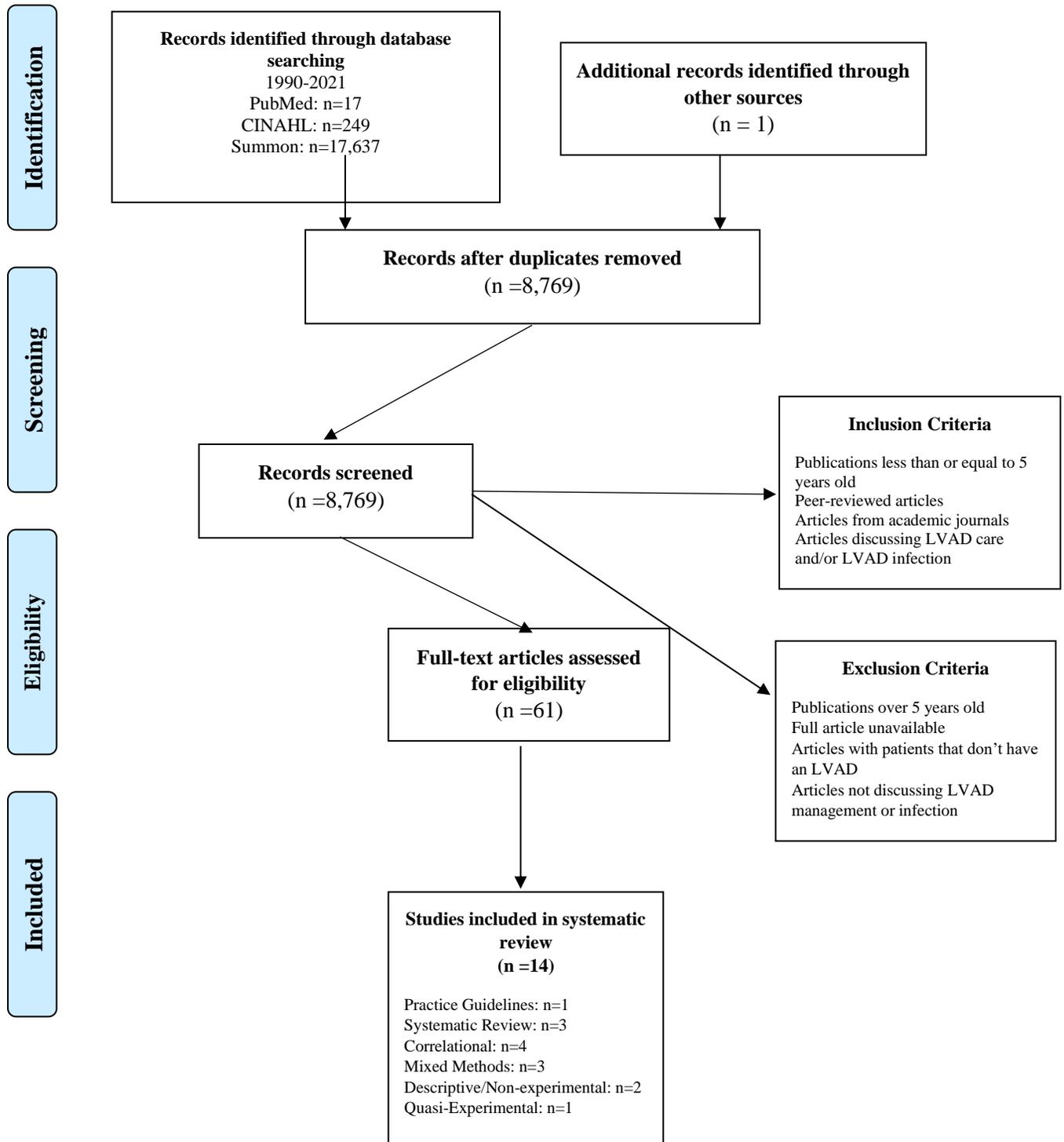
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Appendix A

Prisma Diagram of Literature Review



PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

## Appendix B

## Data Collection Excel Spreadsheet

Patient Identifier	LVAD Type	Year Implanted	Year of Infection	LVAD age at Infection	Dressing Method	Type of Bacteria
A81674	Heartmate II	2016	2017	3 months	Retired	MRSA
A47167	Heartmate II	2016	2017	3 months	Retired	MRSA
A82166	Heartmate II	2016	2017	8 months	Retired	MSSA
A10516	Heartmate II	2016	2017	11 months	Retired	Unknown
A61771	Heartmate II	2017	2018	7 months	Retired	MSSA
A11178	HeartWare	2017	2018	2 months	Retired	Unknown
A31175	HeartWare	2017	2018	3 months	Retired	MSSA
A74177	HeartWare	2017	2018	5 months	Retired	S.Epi
A85177	Heartmate II	2017	2018	9 months	Retired	MSSA
A10617	Heartmate II	2017	2018	11 months	Retired	Unknown
A14518	HeartWare	2018	2018	10 months	Retired	MSSA
A91884	HeartWare	2018	2019	11 months	Retired	MSSA
A39187	HeartWare	2018	2019	8 months	Retired	Proteus
A44186	Heartmate III	2018	2019	6 months	Retired	Unknown
A63187	HeartWare	2018	2019	10 months	Retired	Pseudomonas
A57216	Heartmate III	2021	2021	3 months	Current	Unknown