

# An International Study on Ventricular Assist Device Program Models

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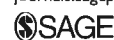
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## Abstract

**Background:** Advanced technology and improved outcomes have led to rapid growth of ventricular assist devices (VADs) throughout the world, but little exists regarding their structure. We sought to study trends in VAD programs on a global level.

**Methods:** We distributed a 26-question online survey to 321 individuals who work within those programs. Four categories of questions were formed: patient management, coordinator role, multidisciplinary support, and leadership. **Results:** Fifty-eight surveys (47 United States, 11 international) were analyzed. The majority of programs cared for 26 to 100 device-assisted patients (62%), 26% cared for  $\leq 25$  patients, and 12% cared for  $\geq 100$  patients. Advanced practice providers (APPs) were used in 69% of programs as a device coordinator. In-hospital rounding was performed equally among the APPs and registered nurses. Most programs used a social worker (90%), nutritionist (74%), pharmacist (72%), palliative care (66%), and finance coordinator (64%). Less than half (43%) included a case manager and only 33% used a pharmacist. The program leader was identified as a cardiologist (31%) or surgeon (26%) or both equally (43%). **Conclusion:** This study demonstrates differences and similarities between VAD program structures. Additional research is warranted to evaluate the effect of program structure on outcomes, job satisfaction, and retention regions.

## Keywords

ventricular assist device, program models, VAD coordinator, VAD teams

## Introduction

Approximately 6.5 million people older than 20 years are living with heart failure (HF) in the United States, with 10% of those patients diagnosed with the end-stage form of this deadly disease.<sup>1,2</sup> Although heart transplantation remains the gold-standard treatment for end-stage HF, a shortage of donors creates the need for alternative therapies.<sup>3</sup> Various types of mechanical circulatory devices have been increasingly used among patients with advanced HF.<sup>4</sup> One class of devices includes durable ventricular assist devices (VADs), used as a bridge to transplant or destination therapy.<sup>5</sup> Patient selection criteria for VAD implantation are outlined by the INTERMACS classification.<sup>6</sup> Based on the most recent INTERMACS Annual Report, the 1-year survival for a continuous flow VAD was 82%, with a 5-year survival of 46%.<sup>7</sup> To assure positive patient outcomes, the delivery of care to these complex patients is driven by an interdisciplinary team that unifies the capabilities of the particular center and what is formed as a program model.

The initial concept of a program model was conceptualized by Dr Norman Shumway, one of the pioneers of cardiac transplantation. Dr Shumway of the Stanford University performed the first heart transplant in the United States in 1968 with the

help of a transplant team. However, at that time, it was the widely held belief that the key component of advanced HF care was the surgeon, rather than a team. It was Shumway who initially voiced the need to utilize and credit a team concept, as opposed to taking full credit for his achievement.<sup>8</sup> Citing the example set by Dr Shumway and other physicians in cardiac transplantation, a well-structured, specialized VAD program model was determined to be crucial for clinical care of this complex patient population.

Components of a VAD program encompass foci including patient education, psychosocial support, research, finance, and equipment maintenance, in addition to direct patient care responsibilities.<sup>9</sup> To maintain a program, financial support, adequate staffing, long-term goals, and supportive administrative leadership are key in not only the business realm but also the humanistic domain.<sup>10</sup> With nearly 175 US centers and over

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350 non-US centers delivering care to VAD patients, there is still insufficient data to examine the composition and how the structure of these global programs are related to each other, if at all. An international survey study from 2011 explored staffing patterns for HF and transplant clinics. The study showed that HF programs had a fixed ratio of staffing roles and that more professionals were hired in equal numbers to support increases in patient activity. The study showed that the HF programs comprised an average of 2.65 physician full-time equivalents (FTEs), 2.21 nonphysician practitioner FTEs, and 2.61 nurses or nurse coordinator FTEs annually. With calls to develop staffing guidelines and establish common standards, this study aligns with our goals of exploring the current VAD program structure.<sup>11</sup> The aim of this study is to examine the patient management, VAD coordinator role, multidisciplinary support, and program leadership of international VAD programs. In doing this, we hope this study prompts further research regarding ideal VAD team compositions to improve patient outcomes.

## Methods

### Design

To accomplish our study aim, we employed an exploratory descriptive research design, approved for publishing by the University of Chicago Medical Center institutional review board (IRB) under IRB 17-0413. The individual surveys were identified as completely voluntary in nature in an effort to provide additional knowledge to the VAD community related to VAD program structure.

### Study Population

The target population of this study would include every hospital program implanting durable VADs globally. The accessible population included available respondents willing to complete the survey who represented VAD programs from the United States as well as non-US programs. The program name was disclosed, but specific data of the respondent including gender, educational background, and length of employment were not relevant to the study as the program structure, not the individual respondent, was the focus.

### Sample

Our research team invited 321 global VAD team members with the inclusion of VAD coordinators to complete our survey. Inclusion criteria encompassed programs that provided destination therapy and/or bridge-to-transplant patient care to adults implanted with durable VADs. Respondents who were excluded were from programs that only provided temporary VAD therapy or if the durable VAD was only provided to the pediatric population.

### Data Collection and Analysis

From October 31 to December 1, 2018, an email list was created by combining professional contacts and International Consortium of Circulatory Assist Clinicians email distribution lists. Separate emails were sent to 321 members of various VAD programs internationally. Participants were provided with a link to complete the 26 question survey. Following removal of duplicate and incomplete surveys, 58 surveys were retained and subsequently analyzed through Qualtrics® data analysis software. Descriptive statistics (mean, standard deviation, and frequency distribution) were applied to characterize our sample (N = 58).

### Procedure

Our research team developed and launched an online survey instrument through Qualtrics®. The content of the survey focused on 4 concepts: (1) patient management, (2) VAD coordinator role, (3) multidisciplinary support, and (4) leadership. Face validity of this survey was established by 2 VAD coordinators from a large program and then evaluated by a nurse scientist with extensive VAD experience from a second large volume VAD program. These individuals each have over 10 years of field expertise. The survey was comprised of 26 items, including 25 multiple-choice questions and 1 question to identify the name of the institution. The survey took approximately 5 minutes to complete. Answers from all surveys were kept confidential.

### Results

A total of 58 surveys were deemed to fit our inclusion criteria, with the majority (84%, N = 49) completed by programs in the United States. Programs were classified as small when they reported managing less than 25 durable VAD patients (n = 15, 26%), medium if the program cared for 26 to 100 VAD patients (n = 28, 48%), or large if the program managed ≥100 patients (n = 15, 26%). The majority of the programs (n = 34, 58%) implanted 26 to 150 devices annually, followed by less than 25 VADs (n = 23, 40%), and 151 to 200 VADs (n = 1, 2%). Most programs used 2 surgeons (n = 31, 53%) and 3 to 4 cardiologists (n = 19, 33%). Nine (15%) programs identified themselves as serving only destination therapy patients, with the remaining 49 also using VAD for bridge to transplant.

Within the VAD coordinator role, we defined advanced practice providers (APPs) as physician assistants or advanced practice nurses. They were used in 69% (n = 40) of the programs while registered nurses (RNs) were used in the majority (n = 52, 90%) of programs. Two US respondents reported engineers existed in the VAD coordinator role. In-hospital rounding was performed equally among APPs and RNs in 55% (n = 32) of programs. In the outpatient clinic, APP VAD coordinators were used less frequently (62%, n = 36) than RN VAD coordinators (69%, n = 40). Identifying the person immediately accessible by phone or pager, identified as the

**Table 1.** Differences in Ventricular Assist Device Program Composition by Percentage (%) Between US and International Teams.

	The United States, N = 47		International, N = 11	
		%		%
Program leader				
Cardiologist	11	23	3	27
Surgeon	15	32	4	36
Shared equally	21	45	4	36
Equipment management				
VAD coordinator	27	57	7	64
Perfusionist	2	4	3	27
Engineer	13	28	1	9
Outpatient clinic				
Cardiologist	43	91	10	91
Surgeon	6	5	5	45
Advanced practice provider VAD coordinator	32	68	4	36
RN VAD coordinator	32	68	8	73
Inpatient rounding				
Cardiologist	47	100	9	82
Surgeon	35	74	7	64
Advanced practice provider VAD coordinator	27	57	5	45
RN VAD coordinator	29	62	3	27

Abbreviation: VAD, ventricular assist device.

person "on call," was covered by RNs in 75% (n = 43) of VAD programs. Of note, VAD coordinators were involved with research in 79% of VAD programs and were deemed the primary person (58%) to manage outpatient equipment. Engineers were used for equipment maintenance in 13 VAD centers.

Multidisciplinary support, though essential, is varied between programs. Most respondents stated that a social worker (n = 52, 90%), nutritionist (n = 43, 74%), pharmacist (n = 42, 72%), palliative care (n = 38, 66%), and finance coordinator (n = 37, 64%) are part of their multidisciplinary team. Less than half (n = 25, 43%) of programs stated a case manager was assigned to their program. The program leader was identified as a cardiologist (n = 18, 31%) or surgeon (n = 15, 26%) or both equally (n = 25, 43%). In the non-US teams, leadership is shared equally between surgeons and cardiologists (45%) as compared to the US programs (36%), thus showing a more multidisciplinary, cohesive team infrastructure. However, what is most noteworthy is that the non-US teams used RN VAD coordinator inpatient rounding (27%) significantly less than US teams (62%; see Table 1).

## Discussion

This study explored the composition of global VAD program models with respect to 4 categories: patient management, VAD coordinator role, multidisciplinary support, and program leadership.

## Patient Management

Inpatient quality metrics, such as readmissions, adverse event rates, and mortality data, are strong indicators for the success of a VAD program. The underlying reason for differences in patient management between inpatient and outpatient settings within our study results was unclear. Questions addressing patient management were inserted in the survey to obtain information regarding adverse events, readmission, survival, and inpatient and outpatient settings to name a few. Results show that although both surgeons and HF cardiologists rounded with VAD coordinators in the inpatient setting, the majority of outpatient VAD care was managed by VAD coordinators and HF cardiologists. We did not compare the number of patients supported by a program and the number of cardiologists/cardiac surgeons required to sufficiently manage this complex patient population; however, these data are important to examine in the future in order to determine optimal patient-to-provider ratio. Additionally, it remains unclear if the number of physicians required to manage care was different in a hospital system using relative value units.

## Ventricular Assist Device Coordinator Role

The VAD coordinators have a unique role as the hub of the wheel of patient care, in addition to working as educators, technicians, and researchers. We addressed these multifaceted responsibilities in our survey, with questions addressing (1) professions used in this role, (2) inpatient rounding, (3) outpatient clinic duties, (4) call coverage, and (5) ancillary duties. The responding VAD coordinators were comprised of APPs, RNs, and engineers. Our research team questions the absence of APPs in this area since their scope would be better aligned with this duty. Accordingly, the American Nurses Association Standards of Professional Nursing Practice states the role of the APP is to influence the plan of care, including to motivate the team and incorporate effective change, while the role of the RN is to implement and coordinate the plan.<sup>12</sup> If an APP is identified as on call, there may be a difference in autonomy and ability to conduct orders due to a larger scope of practice compared to that of an RN. The American Association of Nurse Practitioners reports that in the United States, all 50 states use nurse practitioners. Despite this, various states in the United States vary from full practice (primarily northwest), reduced practice (central states), or restricted practice (southeast).<sup>13</sup> The APP role may not be used as frequently in non-US programs. The RN can appropriately cover call, but there was generally less scope as compared to the APP in a potentially high-acuity situation that may require rapid assessment and care changes. Standard protocols may be used with the RN while taking call to aid in clinical decision making to ensure they practice at the top of their license. This is certainly an area that needs further exploration to determine whether patient care is influenced by the role assuming call coverage.

In addition to their clinical role, VAD coordinators can be looked upon to facilitate research for their programs.

Ventricular assist device coordinators devote a large amount of time to other duties, including equipment management. Despite their clinical knowledge, it is unclear why such a high number of VAD coordinators assume this responsibility when it would be justifiable for unlicensed, nonclinical individuals to handle this task. Many of the time-consuming, nonclinical tasks coordinators performed may be a result of institutional resistance to change as VAD care began with a much smaller patient volume and a VAD coordinator completed any and all VAD-related tasks.

The growth of a program, anticipated or unanticipated, requires evolution of the VAD coordinator role and the addition of nonclinical personnel to assume additional tasks. In addition, the nonclinical realm included meticulous data entry to maintain the INTERMACS database. Our data indicate that some programs continue to use RNs and/or advanced practice nurses to enter these data or similar data in other registries such as EUROMACS. Because VAD coordinators maintain advanced clinical knowledge of VAD care and ideas regarding how to evolve such care, it seems that VAD coordinators are under used for independent research projects.

### **Multidisciplinary Support**

In assessing multidisciplinary support, we asked survey questions that addressed the roles of social workers, case managers, pharmacists, finance coordinators, and palliative care specialists. Multidisciplinary support is crucial during the continuum of care of VAD patients, and its importance in patient care cannot be overstated. A significant amount of time and expertise is required to effectively manage adverse events. For example, determining appropriate antibiotic therapy to treat acute and ongoing VAD-associated infections often requires pharmacy recommendations and additional time. Jennings et al<sup>14</sup> reported that VAD pharmacists assist with medication reconciliation, medication nonadherence, as well as providing medication education, which can decrease the daily workload of the VAD coordinator.

Our study team noted that palliative care was used in only 66% ( $n = 38$ ) of the programs that responded. Over the past years, emphasis has been placed on the crucial need for greater palliative care involvement in critically ill patients. The International Society of Heart and Lung Transplantation Guidelines for Mechanical Circulatory Support includes a recommendation to consult palliative care specialists during the evaluation for VAD implant.<sup>15</sup> Though there are variations in the role of palliative care within the VAD team, involving this role is crucial for the patient's goals, preferences, and values to be incorporated into the plan of care.<sup>16</sup> In the postimplantation setting, continuing psychosocial needs exist, as do the risks of common adverse clinical events associated with implantation. In caring for these needs, the palliative care clinician collaborates with a multitude services in order to aid in the patient's wishes. Thus, with these results, the authors suggest extensive research into the appropriate use of palliative care clinicians.

### **Program Leadership**

Leadership styles can shape a program and may vary depending on if the leader is a cardiologist as compared to a cardiac surgeon, or if the leaders have VAD experience or not. A competent leader is crucial, as it is necessary to periodically analyze operating metrics and outcomes, including, but not limited to, patient care outcomes, financial margins, staffing needs, and technological resources.<sup>9</sup> A leader needs to be able to relate to the team. A clear understanding of the roles filled by a VAD coordinator is a necessity of all leadership within a VAD program, especially for those responsible for performance evaluations and decisions directly related to patient care. Differences between US and non-US team composition are particularly intriguing and leave vast gaps of research.

A systemic review of medical leadership with physician and nonphysician chief executive officers (CEOs) in a study analyzing hospital performance reported a positive link between physician CEOs and hospital performance ( $P < .001$ ), although causes were not determined.<sup>17</sup> Kisa and Ersoy<sup>18</sup> found that medical managers have poor skills regarding time management. Additionally, these leaders have no formal leadership training. We did not pursue whether the respondents felt medical leaders were effective and support further studies regarding this topic.

### **Study Limitations**

The authors acknowledge several limitations to this study. Though the sample size is adequate, more program participation could make the statistical analysis more powerful. Programs from within the United States were heavily represented within this sample; thus, ensuring greater global participation is suggested to increase generalizability. However, international surveys may only be appropriate to answer certain questions due to differences in national health care systems. Additionally, the use of electronic surveys rather than face-to-face interviews inhibited the ability to expand on responses and elicit rationales for answers. Surveys were sent to participants through email links and resulted in various time frames to complete the survey before the study window ended and varied between 15 and 60 days.

### **Conclusions**

This study demonstrated that differences and similarities exist within global VAD programs with respect to their structure. Due to the lack of data published on VAD program models and formal definitions for the VAD coordinator role, this study should facilitate further research on how program structures impact patient outcomes, job satisfaction, and retention of the specialized professionals needed to deliver this complex care.

### **Declaration of Conflicting Interests**


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