Administrative Aspects of the Ventricular Assist Device Program

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Development

First and foremost, identifying the need for a VAD program is essential. Many variables are evaluated to determine if a VAD program is necessary and is an appropriate business strategy for an institution. One of the first steps is to undergo a market analysis and estimate the number of prospective LVAD implants that may take place annually within the institutional catchment area. The financial and business leadership of the institution should be able to guide this determination by assessing the center's heart failure referral data, readmission rates and length of stay for patients with advanced heart failure. Some organizations welcome the input of VAD manufacturer partner representatives who can assist with accessing regional data.

Upfront Costs

It is important to anticipate that initially a VAD program may not be cost effective due to the amount of capital expenditures needed to establish the infrastructure. Conversely, not only will the VAD program provide direct revenue for the institution, it will also produce an increase in returns for the medical center via the

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downstream revenue associated when evaluating a patient for candidacy. During the evaluation phase for a VAD, the candidate may undergo many procedures, surgeries, electrophysiology procedures, and tests, which are all associated with revenue for the institution. Many of the potential candidates will not meet the criteria for advanced therapies but the clinical evaluation for candidacy will be profitable for the health system. This is an important factor to present clearly to hospital leadership to garner full support of this expensive endeavor [1, p. 932].

Leadership and Team Structure

To ensure a successful program having capable, motivated, and effective VAD program, leadership is vital [2]. The core VAD program leadership should include the following:

- Qualified cardiothoracic surgeon with training and experience in mechanical circulatory support (MCS) implantation and management.
- Qualified advanced heart failure cardiologist.
- Either or both surgeon and cardiologist mentioned above will serve as Medical or Surgical Director with responsibility to oversee the program clinical practices, assess, and manage patient selection, quality outcomes, regulatory compliance, and financial contributions to the organization.
- VAD Coordinator will assist with creating and evaluating policies, initial and ongoing MCS education, and periodic competency assessments. Clinical responsibilities include troubleshooting device malfunctions, monitoring during procedures, facilitate treatment of complications, outpatient clinic management, as well as manage data management systems, i.e., INTERMACS registry. Physician Assistant, Nurse Practitioner, Registered Nurse, Biomedical Engineer, and Perfusionist are the common roles to fulfill this position. It is common in Europe for a surgeon or engineer to fill this role. It is critical to protect the scope of practice within the law.

  Additional team personnel to identify include:

- Additional VAD Coordinators: Establish triggers to recruit and hire additional staff members when programmatic growth begins to rise.
- Data personnel: Programs may choose to partner with an existing quality department in the initial stages of development. It is important to have a dedicated team member that is specific to the VAD program to evaluate metrics.
- MCS Educators: Typically these responsibilities are yielded to the VAD Coordinator initially however as the program grows, leadership should consider partnering with unit educators or establishing a dedicated role within the VAD program.
- Equipment management personnel: Typically new programs designate the VAD Coordinator for this role and identifies alternate non-licensed personnel later as the program increases in size.

- Social worker: In the United States, it is a regulatory requirement to have a social worker as a member of the core team who is knowledgeable in the unique needs of the VAD patient and caregiver.
- Palliative care services: In the United States, it is a regulatory requirement to have access to palliative care as needed and there be representation within the core team. Palliative care is specifically addressed in chapter "Psychosocial and Palliative Aspects of VAD Care."
- Psychologist: Should be knowledgeable of the unique needs of the VAD patient and caregiver. Many programs consider clearance from psychiatry vital to ensure the patient and family can handle the device and the mental health strains that accompany VAD therapy.
- Physical therapist and occupational therapists: It is crucial for patients recovery to ensure increased physical activity. This is addressed in detail in chapter "Exercise and Physical Therapy with Ventricular Assist Devices."
- Nutritionist/dietician: Nutrition before and after LVAD implantation are vital to successful outcomes for wound healing and ensuring appropriate caloric intake. This is described in further detail in chapter "Exercise and Physical Therapy with Ventricular Assist Devices."
- Financial team representatives: As discussed in chapter "Reimbursement in Ventricular Assist Device Implant and Care," ensuring appropriate and accurate billing and coding is crucial to ensuring financial integrity. This is also a key factor in discussing with the facility administration when increased resources are needed.
- Anesthesiologist: It is important to collaborate with the provider team for safe anesthesia during the implant operation and subsequent procedures requiring anesthesia.
- Specialty service partners: Gastroenterology, Infectious Diseases, Nephrology, Neurology, and Neurosurgery should preemptively be included.

Cost Analysis

Once the core team is established and in agreement, a presentation to the hospital leadership should be developed with the intention of securing their support. A great deal of attention will be centered around the costs and revenue associated with the program. Prepare a thorough financial analysis which includes community need, patient benefits, marketing strategies, program infrastructure, in addition to capital and operating expenditures. This should encompass items such as salaries and benefits, hospital owned equipment, single use equipment items, and operating items, such as office supplies. It will be vital to demonstrate all anticipated revenue; this includes not only the surgical implant but the evaluation period as well as the longer term revenue for the length the patient is on support. Items to consider discussed here include echocardiograms and right heart catheterizations.

When presenting to hospital, leadership create a clear and large scale vision that will be encouraging while including the possible short-term positives. Successful programs need to be built on evidence-based practice and expert recommendations

to gain administrative support. An essential factor to ensure support is aligning the initiatives with national priorities, especially those that are avant-garde and specific to the institution. Once funded by the institution, it is important to provide frequent program updates to help transition from being helpful to a becoming fully committed in the support of the successes of the LVAD program [1, p. 933]. Remember that this is not a one-time venture. It is crucial to keep the administration on board for long-term support.

Preparing for Implantation

Once the core team is established, an educational roll out is needed for the team and facility. Education is critical, and it is important to start with a structured competency model. An education model to consider is one that has tiers that range from VAD awareness to VAD expert. Staff resistance to this change should be anticipated. It is important to recognize that culture change is fundamental to program success [3, p. 509]. Having unit-specific VAD Champions is a helpful way to decrease the staff resistance. Education will be a big endeavor for the VAD Coordinator in the beginning of the program and ensuring early success is key. Utilization of the unit champions and staff educators can assist with the long-term education that will be needed periodically. Various units such as the operating room (OR), emergency room (ED), interventional radiology (IR), gastroenterology lab (GI) have different educational needs and it will be easier on the VAD team if staff in these departments are empowered to do the ongoing education that is required within their own department.

If this is a destination therapy (DT) program, identifying a nearby heart transplant program is essential. Having a good rapport with the personnel at this transplant center is important, especially for patients who have LVADs as a bridge to decision or who later become bridge to transplant (BTT) [1, p. 934]. Having this relationship will help build the infrastructure for the new program and it would be helpful to align some of your policies regarding patient selection and long-term care of the patient.

Programmatic Guidelines

In the early years of the program, it is advantageous to develop guidelines as opposed to hospital policies so that changes can be made easily and quickly. Changes to administrative policies can take time to get on agendas for review. As the program grows and the “kinks” are worked out, then these guidelines can be converted to hospital policy as appropriate. Keep in mind policies are hard and fast rules for the organization, whereas guidelines are evidence-based practices established to reduce variation but may be modified in practice based on individual patient needs. Consider meeting with your department with oversight responsibilities for organizational policies to provide guidance within your hospital structure. Bear in mind, programs should not reinvent the wheel and should rely on team member exposure and prior

experience when starting the program. Networking with other established programs and utilizing guidelines shared from others will direct the program initially, then fine-tune them over time as your institution culture and practices are better defined.

Once these guidelines/policies are in place and staff is educated, the program is now ready to implant the first case. Multiple aspects happen simultaneously and while this is certainly very exciting, it is also an extremely busy time. Recognize this will become easier as the program becomes more comfortable, especially if there is a solid foundation within the team and education plan.

Certification

Hospital administration will need to determine which certifying agency should be evaluating the program; the Joint Commission (TJC) and Det Norske Veritas (DNV) are two US regulatory bodies that certify VAD programs. Depending on which certificating agency the hospital selects the VAD program will need to participate in a nationally audited implant registry. At the time of this writing, STS/INTERMACS is the only one of this sort. The VAD program will need to apply for participation in order to enter this first implant in a timely manner.

In the United States, the Centers for Medicare and Medicaid services (CMS) has determined certification is required for reimbursement of VAD medical care. CMS has granted DNV or TJC the privilege of being a certifying agency on their behalf. It will be necessary to implant one VAD into a patient prior to being eligible for certification, and thus reimbursement by CMS.

Generally, hospital administration will choose to cover all costs instead of delaying the start of the program [1, p. 934]. Further details on these certifying agencies can be found in chapter "Regulatory Agencies Impacting Mechanical Circulatory Support Programs."

Equipment

Equipment that supports the VAD patient should be considered within the administrative and organizational aspects of the program. Peripheral equipment requires tracking, long-term follow-up and replacing when appropriate. This is labor-intensive and should be considered from a financial mindset not solely for the equipment but also the personnel that are responsible for the maintenance. Having a relationship with a durable medical equipment DME company can be beneficial to take on this management. It may be financially advantageous to bill, track, dispense, and re-order equipment solely within the organization structure as discussed in chapter "Reimbursement in Ventricular Assist Device Implant and Care." Should this be the decision, advocate for an equipment manager or establish processes that limit the equipment management time requirements for the VAD Coordinator as this task can become very time consuming with a large number of patients. This activity is critical to revenue integrity, Food and Drug Administration (FDA) requirements, CMS

compliance regulations, and designated certifying agency standards. Mistakes can be costly for the organization and should not be taken lightly. As the program population grows, the equipment management tasks increase seemingly and exponentially.

Growth and Evolution

Long-term success of the program occurs with continued growth and good outcomes. These are both achieved when the team continues to work together. Long-term goals need to be established collectively as well as how to grow the program and when to add new team members. The program can grow quickly and if triggers for adding personnel are not set at the beginning, the program may suffer from VAD Coordinator burn out due to increased responsibilities. Reminding the administration that it takes at least 6 months to develop a VAD Coordinator to the competent level may be beneficial.

Continued Coverage

Often forgotten about for VAD program development is on call coverage during off hours. Programs must set up a system whereby the VAD patients can be in contact with a team member 24/7 in emergency settings. As this device is considered life supporting and mechanical, it does not always fall into the 9–5 timeframe when typical medical offices are open for patient care. The other area for administrator education is the variation from traditional cardiothoracic surgery patients. VAD patients are longitudinally, clinically managed by the VAD team unlike a patient with a CABG or a valve intervention which are transitioned back to their primary teams after a short time. The program population continues to grow which is a positive as the only loss of the patient is due to transplantation or eventual mortality.

Outreach

Outreach is critical in the beginning of a program. Educating the community and colleagues in health care about the new services provided by the VAD program is vital for growth. Referrals typically come from the cardiologist or primary care physician in the community setting and teaching them about VADs is part of the program's responsibility. Helping providers know when to refer a patient is vital to continuing successful referrals. Maintaining open lines of communication whether the patient is accepted as a VAD recipient or not helps gain more knowledge, and by extension, helps the program. Communicating program outcomes to the referring providers will maintain the relationship so they continue to refer patients. When a patient that is referred receives an LVAD, it is a good practice to request the patient to visit the referring provider. It is a great way to reinforce the timely referral: that the therapy is effective and the patient can do very well post-operatively. The patient will also be able to share their experience and thus market the program.

Lastly, developing a plan to align and prepare community resources to care for LVAD patients is critical to successful living away from the VAD center. Resources such as local first responders, often affiliated with fire departments and police stations but may include ambulance companies, need to be trained in emergency responses for a patient with a VAD. In urban areas with multiple VAD centers, it is possible these first responders have already been educated and simply notifying them of the program's initiating VAD services may be all that is needed. Collaborating with those other centers to share the burden of emergency management systems (EMS) training may be prudent. However, if the program is rural or isolated, the burden is solely on the implanting facility to prepare the EMS for responding to and transporting the VAD patient to the nearest appropriate resource. Additional community resources to consider are subacute and acute rehabilitation facilities, dialysis treatment centers, and cardiac rehabilitation programs. Each will need to be trained in caring for a VAD patient. Though this can be time consuming, this can be a great way to connect with the community and teach them about VAD therapy, taking the mystery out of the machine. Asking a VAD patient from that specific community is very useful to demonstrate the equipment but to also show the stability of a VAD patient. When possible, consider asking the specific VAD patient being referred to the treatment center to attend the training as a means of introduction.

Conclusion

In conclusion, excellent outcomes are the essence for success of a VAD program. The financial stability of the program, new or continued referral patterns, and support of hospital administrators are dependent on positive results. Sharing the program successes via media releases, leadership forums, and professional conferences or publications will inform all stakeholders of the value of the therapy. Furthermore, implementing a systematic interdisciplinary patient management approach from the point of patient selection to long-term care improves outcomes for LVAD recipients, and thus lends to the continued success of the program [3, p. 515].

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