Allina Health

ABBOTT
NORTHWESTERN
HOSPITAL

Ventricular Assist Device Therapy
Review of Information and Expectations

Abbott Northwestern Hospital offers Ventricular Assist Device (VAD) Therapy to people with end-stage heart failure. Your doctors feel you may need such a device either as you await eligibility for heart transplant, while listed for a transplant, or for destination (life-long) therapy. The process is often lengthy and makes many demands on patients, families and caregivers. Most importantly, successful living with a Ventricular Assist Device (VAD) depends on a good working relationship between patients, their caregivers, and the Advanced Heart Failure/VAD/Transplant Team.

The following information is provided in order to help you learn about Ventricular Assist Devices (VADs). Therapy includes the preoperative evaluation process, surgery, potential risks, potential benefits, postoperative plans, expectations and lifestyle changes. This information has been, or will be, discussed with you by the VAD team during your evaluation. During this time, it is important you actively participate in your health care plans. If you have questions about tests or procedures you are asked to participate in, please discuss these with your medical team.

Why am I Being Asked to Consider Ventricular Assist Device Therapy?

Your doctors feel you have advanced heart failure. Heart failure is a condition in which your heart is unable to pump enough blood to support the basic needs of your body. Heart Failure can make you feel weak and tired; have swollen feet, and be short of breath. Although medications and lifestyle changes can improve heart function initially, for most people heart failure gets worse over time. As heart failure becomes more severe, symptoms increase and other organs may begin to fail (often the liver and kidneys).

You are being asked to consider the possibility of having a ventricular assist device (a **heart pump**) surgically implanted in your body. Your doctors feel without a VAD your chance of dying from heart failure in the coming months is very high. Before you undergo this surgery, it is important you and your family understand the options including: potential benefits, risks, and expectations associated with having a VAD (heart pump). It is important for you and your caregiver(s) to understand and to agree with the treatment plan and that you are willing to participate in the guidelines outlined in the following pages.

What is a Ventricular Assist Device (VAD) and what Devices are Available?

A VAD is a pump that assists a weakened heart to improve blood flow to the rest of your body. This most often involves assisting the heart with the placement of a **left ventricular assist device (LVAD**). There are several different types of artificial heart pump devices designed to meet the needs of individual patients:

- **Left Ventricular Assist Device (LVAD)** helps the left side of the heart pump blood to a large blood vessel called the aorta and to the rest of the body.
- **Right Ventricular Assist Device (RVAD)** helps the right side of the heart pump blood to the lungs.

Ventricular Assist Device Therapy
Review of Information and Expectations

- **Bi-Ventricular Assist Device (BiVAD)** helps both sides of the heart pump, essentially by using both an LVAD and RVAD.
- **Total Artificial Heart (TAH)** replaces the heart and pumps blood both to the body and to the lungs. TAH is the only device that requires the removal of your own heart and replaces it with an artificial one. A LVAD or RVAD are sewn into your own heart to pull blood out of your weakened heart and pump blood forward into the rest of your body.

VADs can be used as short and/or long-term therapies. Short-term devices are used when patients are unstable and need help to pump blood for a few days or weeks. Short-term devices are easier to put in and take out. This can be important for very sick patients who may not survive a more difficult surgery. Long-term devices are used for patients that need assistance for months or years. Long-term devices require a longer and more complicated surgery, but the device is more securely placed, so patients are able to leave the hospital and go on living life. Some patients may receive a short-term device before getting a long-term device.

VADs have four main parts: the implantable heart pump, a tube with electrical wires which passes through the skin of your abdomen (driveline), a controller (small computer) outside of the body that controls the pump, and an external power source (batteries or power device).

When is a Ventricular Assist Device (VAD) used?
VADs are used to increase blood flow when your heart failure has become severe and is not responding well to medications and other treatments.

Is this Temporary Or Permanent?
VADs can be used as temporary support to stabilize patients until a different therapy can be offered or as a permanent support for patients.

- **Bridge-To-Transplant (BTT)** therapy is a treatment option for patients who get a VAD in the advanced stages of heart failure who are currently awaiting heart transplantation.
- **Destination Therapy (DT)** is a permanent treatment option for patients who get a VAD in the advanced stages of heart failure that are not eligible for heart transplantation. Some of these patients may become eligible for heart transplantation in the future.

Allina Health

ABBOTT
NORTHWESTERN
HOSPITAL

Ventricular Assist Device Therapy
Review of Information and Expectations

Your doctors will tell you the option for which you are being evaluated. The evaluation itself may help decide which option is right for you.

Even if you are being considered for bridge to heart transplantation, this is subject to change pending the results from your evaluation and the transplant team's decisions. This information pertains only to VAD support. Transplant staff will provide you with specific information regarding listing and donor heart allocation as well as transplantation procedures and risks at a different time if you are also being considered for heart transplantation. It is possible that you will not be a transplant candidate after you receive a VAD as a bridge to transplant should there be complications and/or your medical condition changes.

What does the Evaluation Involve?
The evaluation process is designed to help decide if a VAD is the best choice for you. You will undergo (or may have undergone) a number of blood draws, tests, and consultations. Some of the people that may help evaluate you include Cardiologists, Heart Surgeons, Social Workers, Chaplain, members from the Palliative Care Team, and VAD Coordinators. This evaluation includes assessing your personal support system, your previous medical compliance as well as providing you information about the financial and long-term self-care requirements.

The entire team will assess your readiness, willingness and ability for activities that are required as part of the follow-up after the VAD surgery. Your social support and willingness to participate in your care is essential to living successfully with the VAD and will be looked at during your treatment and evaluation for VAD therapy.

Other medical concerns that are found during the evaluation may need to be addressed before a VAD can be implanted. The intent is to evaluate any medical concerns and potential issues to VAD implantation in order to make sure the therapy is right for you.

After the evaluation, the Advanced Heart Failure/VAD/Transplant Team will decide if you meet the criteria to have a heart pump implanted. **If it is a medically reasonable option, <u>you</u> will also need to decide if it is the right personal choice for you.** If you choose that this is not the best option for you, you may choose to be re-evaluated at a later time. In the future, if your condition worsens, you may need to repeat tests to determine if you are eligible for treatment.

What are my Other Options?
If you are <u>not</u> found to be a candidate for a VAD, or if you decide that a VAD is not the best option for you, you will continue to receive standard medical care. You should be aware the reason you are being evaluated for a VAD is because the current therapies you are

receiving are not adequately treating your heart failure. Without a VAD your doctors feel it is likely your condition will worsen and there is a high chance of death in the coming weeks to months. Patients with advanced heart failure who do not proceed with VAD surgery often use palliative care and hospice to help them with end of life care.

Why would I NOT be a Candidate for a Ventricular Assist Device?
VAD’s improve blood flow. These devices can only fix health problems that will improve with better blood flow. Implantation of a VAD requires a major surgery which you must be able to survive. There will also be ongoing issues with the VAD which you must be able to manage. Some of the reasons a VAD may not be a good option include the following:

- Medical issues that would make surgery too difficult or dangerous. For example, if the chances of surviving VAD surgery is felt to be too small. Other examples include; high lung artery pressures and right heart failure, problems with the existing heart valves, a small left ventricle, a damaged aorta, blood clotting disorders, poor food intake, current pregnancy, or high risk of infection.
- Other non-heart diseases that would increase the risk of VAD therapy include; cancer, permanent kidney disease, liver disease, severe emphysema of the lung, blockages of the arteries to the legs or the brain, uncontrolled diabetes, and frailty.
- Factors that would likely limit the ability of the patient to properly care for the VAD long term. Examples include; impaired thinking (dementia or significant psychiatric disorder), use of illicit drugs or alcohol, a history of not following medical recommendations or self-destructive behavior, inadequate social support (patients **must** identify a primary “caregiver”), or financial hardship.

What Benefits can I Expect?
The overall goal is improved health and quality of life. In most cases, blood flow improves and you can expect to have more energy and an improvement in heart failure symptoms (decreased shortness of breath and fatigue). The VAD may not make all your symptoms go away. You will **always** have heart failure. Since successful VAD surgery helps deliver more oxygen rich blood, you may feel well enough to resume many of the activities and hobbies you enjoy. The improved blood flow may also prolong life. This is supported by research studies that have shown, on average, LVAD patients live longer than similar patients with advanced heart failure who are treated with medications alone.

What are the Risks and Potential Downsides?
As with any surgery or procedure, there are risks and the possibility of complications. These include risks related to the surgery, risks of undergoing anesthesia, and risks related to the VAD itself. Properly selected patients ***on average*** **feel better and live longer with the VAD (heart pump)**. On the other hand, **some individual patients have complications and may feel worse or die sooner** after the VAD. The Cardiac Surgeon who will perform your surgery will discuss the risks in detail with you. Below is a list of possible risks:

Allina Health

ABBOTT
NORTHWESTERN
HOSPITAL

Ventricular Assist Device Therapy
Review of Information and Expectations

***Short-Term Risks** around the Time of Surgery:* There are many risks with this major surgery, including but not limited to:

Likely, Can Be Serious:

- Discomfort after surgery similar to any major heart surgery
- Bleeding
- Right-sided heart failure and/or failure to increase blood flow, resulting in ongoing symptoms of heart failure

Less Likely, Usually Serious:

- Need for re-operation (surgery)
- Kidney failure, potentially with need to start dialysis
- Lung failure, possible need to remain on a mechanical breathing machine (ventilator)
- Blood clots that can travel to other parts of the body; this could result in stroke or loss of a limb or organs
- Liver failure
- Infection
- Irregular heart beat

***Longer-Term Risks** after the Surgery:* Include but not limited to:

- Bleeding: Nose bleeds, which can be severe enough to require medical help. Stomach or intestinal bleeds. Bleeding is very common because
    1) Patients with VADs require some form of blood-thinning medication to reduce the risk of clots forming in the pump
    2) Many VAD's affect the body's natural ability to prevent bleeding
- Blood clots: Clots in the device make it malfunction, leading to other problems and may require major surgery to replace the device.
- Stroke
- Infection
- Disturbances in thinking or emotions, behavioral changes
- Ongoing pain, particularly discomfort around the area that the driveline (power cord) exits your body
- Device malfunction and need for re-operation (surgery)
- Decrease in quality of life, either from possible complications or from the natural limitations and ongoing care required of the VAD
- Caregivers (spouse, family, friends) may experience increased stress and caregiving responsibilities

Ventricular Assist Device Therapy
Review of Information and Expectations

In particular, **bleeding, stroke, and infection of the VAD are common and can be life-threatening**. If you would like to discuss this in detail, please ask your cardiologist and surgeon. It is important for you to understand that failure to care for your VAD or follow medical advice may result in pump (VAD) failure, infection or a decline in your health. Any or all of these things may lead to serious complications or risk of death and require being admitted to Abbott Northwestern Hospital.

Surgery: What will the Surgery be like?
The surgery to implant the VAD will be open-heart surgery and can take between 6-12 hours. The surgeon will make an incision (cut) down the front of your chest to reach your heart. You will have a breathing tube and be under general anesthesia. In some cases, you will be on a heart/lung machine during the surgery. The VAD is placed below the heart and the surgeon will connect the pump to your heart and secure it in place. Once the pump is in place, the VAD and your heart will together pump blood through your body. After the surgery is completed, you will return to the intensive care unit (CV ICU - H4100/H4200).

Post-Operative Care: What can I expect in the hours to days after Surgery?
Upon arrival to the ICU, you will receive close monitoring and support. You will have a breathing tube, drainage tubes (chest tubes) and a catheter in your bladder. You will receive medications for sedation and for pain control. You will also be on intravenous (IV) medications until your blood pressure is stable. Your length of stay in the ICU will depend on how fast you recover. Once you are breathing on your own and more stable, you will be transferred to a general care unit (telemetry – H4000) where you can expect to stay for another 1-3 weeks. On average, patients spend about three weeks in the hospital after the VAD surgery, but this can vary depending on how sick you were before the surgery and if there are any complications after the surgery. Most patients are able to return home after VAD surgery, but this cannot be guaranteed. You may need additional rehabilitation and recovery at an inpatient rehabilitation facility.

Education: What do I need to Learn before going home with a VAD?
During the time in the hospital after surgery, it is expected that you and your family will learn how to take care of the VAD and how to take care of yourself at home. You and your caregiver(s) will be trained by a VAD coordinator to take care of your VAD. Other staff, such as your bedside nurse, the Occupational and Physical Therapists, and Cardiac Rehabilitation Therapists will also provide training. You and your caregiver(s) must be able to manage the VAD, understand how it works, troubleshoot problems, and care for your driveline exit site. *It is expected* that a caregiver(s) will be present and available while you are in the hospital to learn how to take care of you and your VAD before leaving the hospital. The education will be ongoing while you are in the hospital. A VAD coordinator will also provide training to your local fire department, emergency medical services (EMS), and

any other relevant community members as needed. Your home must have consistent electricity and phone services, so it is vital that you pay your utility and phone bills on time.

Discharge Process: What will happen when I leave the Hospital and go Home?
Daily you will be followed by a team of people involved in your care, including your surgeon, your cardiologist, VAD coordinators, nurses, nurse practitioners, physician assistants, pharmacists, physical/occupational therapists, and social workers. They will monitor your recovery and help you adjust to life with your VAD. Soon after your surgery, it will be very important to begin preparing to go home. You will have to be both physically strong and able to care for your VAD to be discharged from the hospital. Most patients return home, but some patients choose to live with a caregiver or need a rehabilitation facility for a short period of time before returning home. If necessary, a home health nurse may come to your home for a few hours a week to help with your care.

Follow up care: How often do I see my Doctors after I go Home?
After you are discharged, you will follow up in the clinic with your Advanced Heart Failure/VAD/Transplant Team. They will work together to care for you and make decisions about your treatment. Typically, your first visit will be within one (1) week after discharge. As your health improves, visits may be further apart. Once you are considered stable, your doctors *may* decide that you can follow-up every 2-3 months. Along with seeing a Heart Failure Cardiologist, you will have testing done on a regular basis in order to monitor and maintain your health. The types of testing that you may need will be decided by your doctors but the most common tests include: blood tests, electrocardiograms (EKGs), echocardiograms, and implantable cardioverter defibrillator (ICD) checks. If you have received an investigational VAD, you may have other testing that will be required for the research study.

Patients who have a VAD need to take anticoagulation medications (blood thinners such as warfarin/Coumadin) which require regular monitoring with blood tests. You will also be in frequent contact with a VAD coordinator who will make phone calls to see how you are doing at home and assist you with any problems. A VAD coordinator is available 24 hours a day for any questions or emergencies. On average, about 8-12 weeks after surgery you can expect to be able to do most activities, with the permission of your doctors.

What Do I Need To Know About the Device And Equipment?
Along with the VAD (heart pump) that is implanted inside your body, you will have a number of other external pieces of equipment that will require care and maintenance. You will have a driveline that exits your body through your abdomen which is attached to a controller (computer) that runs the heart pump. The controller will alarm if there are any problems with the pump or the controller itself. In order to power the VAD and the controller, you will have batteries, a battery charger, and an electric (AC) power device. The batteries allow you to

move around freely without being attached to outlet power. The battery charger allows you to re-charge your batteries when needed. And the AC power device allows you to be connected to electric (wall) power for long periods of time such as when you are sleeping. The equipment will be specific to your type of VAD and can be found on an included separate page.

Your driveline will require special care. You and/or your caregiver will be taught the process for sterile dressing changes while in the hospital. Sterile dressing changes to the VAD exit site will be a *lifetime* requirement. The supplies needed to maintain your driveline will be mailed to your home by a durable medical equipment provider (medical supply company). <u>There will be payments/copayments associated with these supplies that insurance may not cover.</u>

What Lifestyle Changes can I expect living with a VAD?
You will have some limitations. Certain activities are hazardous or even fatal with a VAD.

- *Water*: Persons with implantable VADs must not allow their controller/computer and electrical equipment to submerge in water. Showering is possible with proper protective equipment. You may only resume showering once your driveline has healed and your physician gives permission. **Swimming and baths are not allowed.**
- *Activity*: Contact sports or repetitive jumping are examples of activities that may cause trauma to the pump attachments and must be avoided.
- *Travel*: One of the goals of this therapy is to improve the quality of your life; we encourage you to travel if this something you enjoy doing. If you travel out of the area, please let the team know so we can assist you with an emergency plan and provide other information you may need for airline travel.
- *MRI*: You may **NOT** have a magnetic resonance imaging (MRI) test because of the magnetic fields.
- *Driveline and Device Care*: Driveline exit site dressings must be performed as directed by the VAD team. Maintenance care of the equipment, batteries, and driveline is necessary to prevent pump failure, infections, or other serious complications.
- *Medical care after implant includes:* Lifetime follow-up to monitor device function and health status. VAD therapy requires significant self-care responsibility and a willingness to participate with your VAD team. You must keep the team informed regarding your contact information and address.
- *Health Maintenance:* If alcohol, tobacco or other substance abuse has been identified as an issue, you must commit to stopping these activities. You may be screened for drug, alcohol or nicotine use.

Ventricular Assist Device Therapy
Review of Information and Expectations

- *Pregnancy*: If you are of childbearing years, it is recommended you have effective birth control in place. Blood thinner and heart failure medications can pose a high risk to both fetus and mother.
- *Driving:* In general, you won't be allowed to drive until your chest bone (Sternum) has healed, which normally takes about 8 weeks, and you have physically recovered from the implant surgery. Other medical issues may prohibit driving but in most cases, patients with a VAD will be able to continue driving.

Although there are limitations, the majority of patients who undergo VAD placement eventually feel better than they did before the surgery and resume many of the activities they previously enjoyed.

How Will a VAD Affect My Emotional Wellbeing?
The potential emotional risks after VAD include but are not limited to: depression, post-traumatic stress disorder, and generalized anxiety. Depression is very common in patients who have been diagnosed with heart disease. It is also very common to experience feelings of depression after surgery and once you are home from the hospital.

Symptoms of Depression:
- feeling "blah" or "down in the dumps", unable to identify how you are feeling
- loss of interest or pleasure in activities you used to enjoy
- being irritable
- unable to sit still, pacing, pulling or rubbing on skin, clothes or other objects
- increase or decrease in appetite
- increase or decrease in amount of sleep
- fatigue, decreased level of energy
- feelings of worthlessness or guilt, difficulty thinking, concentrating, making a decision or remembering things
- thoughts of death or self-harm

The responsibility of having a VAD, taking new medication and adjusting to life with a VAD can be overwhelming and you may find yourself feeling anxious about these changes.
Symptoms of Anxiety:
- restlessness or feeling on edge
- being tired easy
- difficulty concentrating or mind going blank
- being irritable
- sleep disturbances (difficulty falling or staying asleep, restlessness)
- racing thoughts
- excessive worry

Allina Health
ABBOTT
NORTHWESTERN
HOSPITAL

Ventricular Assist Device Therapy
Review of Information and Expectations

Surgery and hospitalization can be a traumatic event and can sometimes bring up feelings or reactions from past traumatic events (for example illness, loss of a loved one, natural disaster, car accident, child event, etc.).
Symptoms of Post-Traumatic Stress Disorder:

- intense feeling of fear
- feeling helpless
- agitated behaviors (angry outbursts)
- avoiding things that remind you of the traumatic event
- feeling “numb”
- being overly attentive to your surroundings, easily startled
- nightmares or “flashbacks” related to the traumatic event
- being irritable
- difficulty concentrating or completing tasks

These emotions may be the result of not knowing what to expect, not being able to do simple tasks without becoming overly tired or from feeling the need to depend on others. Temporary feelings of sadness are normal and should gradually go away within a few weeks as you get back to your normal routine and activities. If your doctors feel that you would benefit, you may be placed on antidepressant therapy to control these symptoms. If you experience any of the above symptoms and feel they are interfering with your ability to live as normal as possible, please contact the VAD office for further assessment and help.

End of Life with a VAD
Our goal is to support VAD patients from admission through recovery so they may return to a state of good health and return home. However, if despite all efforts, a patient who has no reasonable chance of surviving may eventually be faced with deciding whether VAD support is no longer serving the original purpose. Patients have the right to turn the device off (which usually results in death within minutes to hours) if they decide the VAD is no longer helping or working properly. You also have the right to not have the device replaced if it malfunctions. Decisions to turn the VAD off will be made by you, your family and health care team. If the VAD is stopped, all comfort measures will be available and provided to you at that time.

It is the recommendation of the Advanced Heart Failure/VAD/Transplant team that before surgery, you complete an advanced health care directive. This documents your health care wishes so doctors can honor your decisions if you are unable to speak for yourself at any time during the rest of your life. We have these forms available for you. The social worker or member of the palliative care team is available to help if you request.

AllinaHealth

ABBOTT
NORTHWESTERN
HOSPITAL

Ventricular Assist Device Therapy
Review of Information and Expectations

What about Clinical Trials?
The Advanced Heart Failure/VAD/Transplant Team will review your records to see if you are eligible for any VAD clinical trial(s). If you are determined to be eligible, the Research Nurse will give you more information regarding the specific trial so you can determine if you wish to participate. Clinical trials will have a separate consent form to participate. The Research Nurse will provide consents, answer questions, and review device specific information. Participation in any clinical trial is voluntary. You will not be enrolled into a clinical trial without your consent.

What Else?
This document was designed to provide you with a basic overview of Ventricular Assist Device support. It is intended to start the conversation, not end it. You should have additional questions. We want you to speak openly and honestly with the VAD team now and in the coming days. You should also speak with your family and loved ones. Some people find it helpful to speak to patients who have undergone VAD placement, and if that is of interest to you the team can help make that happen. Let the people around you help you in this difficult time.

By signing below, I acknowledge that I received information about the process of receiving a Ventricular Assist Device. I understand that a member of the Advanced Heart Failure/VAD/Transplant team is available at any time to answer questions. The VAD Coordinator on-call can be reached by calling the Transplant Office at Abbott Northwestern Hospital 612-863-5638. This document is NOT consent for treatment. It is only intended to be informational.

☐ By checking this box, I give my permission for the Advanced Heart Failure Team to communicate my VAD implant with my electric company and local EMS providers.

Patient and or Family Signature and Date Please Print Name

Signature of VAD Staff and Date