The Heart Transplant Journey - What You Should Know

Date: June 15, 2022
Time: 6:00-7:15 PM ET

Thank you for joining the webinar!

All participant microphones are on mute upon joining.
If you have any questions please use the Q&A feature.

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Our mission is to provide **HOPE** and support to patients and families with Dilated Cardiomyopathy through research, advocacy, and education.

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Please Submit Your Questions

- An open Q&A session will follow the presentation.
- **If you have a question, please enter it into the Q&A feature of Zoom at any time during the presentation.**

DISCLAIMER

The information presented in today's webinar is not intended to be a substitute for professional **medical** advice, diagnosis, or treatment. Always seek the advice of your physician or other qualified **health** provider with any questions you may have regarding a **medical** condition.

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Poll #1

Who is attending tonight's webinar?

- DCM Patient
- Family Member / Friend
- Medical Professional
- Industry Professional

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A Word from Greg Ruf

DCM Foundation Executive Director & Board President

Heart Transplant Recipient - July 2021

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Tonight's Presenter

Mary Beth Maydosz, ANP-BC, CCT

Nurse Practitioner / Certified Heart Transplant Coordinator

Inova Heart Transplant

Mary Beth received her BSN in 1982 and began working at Lenox Hill Hospital in NYC on the combined CVICU and stepdown unit.

She then became Assistant Nurse Manager of the Cardiac Step-down unit at Inova Fairfax Hospital only 5 months after they had done their 1st Heart transplant. Fascinated by Heart transplant, she then received her Certification for Clinical Transplant Coordinator and has has worked over the last 34 years in the Heart Transplant Program at Inova Fairfax Hospital.

During these 34 years, she helped start the Inova Lung transplant program, received her Master's Degree in the Nurse Practitioner program at George Mason university in 1999, was the Quality Coordinator for all organ Transplants, and became the first Nurse Practitioner to work in transplant at Inova where she continues to work as an independent Provider for the Heart Transplant program.

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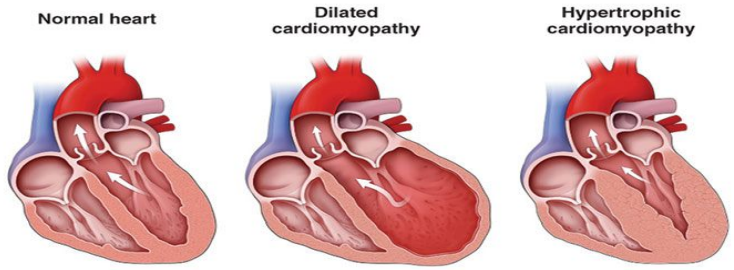
Indications for Heart Transplant

- Heart transplantation is recommended for patients with a severely damaged or weakened heart muscle (cardiomyopathy).

- Cardiomyopathy can be caused by a heart attack, viral illness, long-term high blood pressure, congenital abnormality, genetics, or may occur without an obvious cause (idiopathic).

- When the heart muscle is enlarged, the heart muscle does not pump as efficiently, and you experience

  symptoms of heart failure including shortness of breath, swelling, and fatigue.



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Indications for Heart Transplant

- Patients who may be candidates for a heart transplant continue to have symptoms and a weakened heart despite being on good medical therapy.
- They are very limited by their disease, and they have no other treatment choices that are as effective as a heart transplant.
- Heart failure is a chronic and progressive disease.
- Patients with a cardiomyopathy have a shortened life span.

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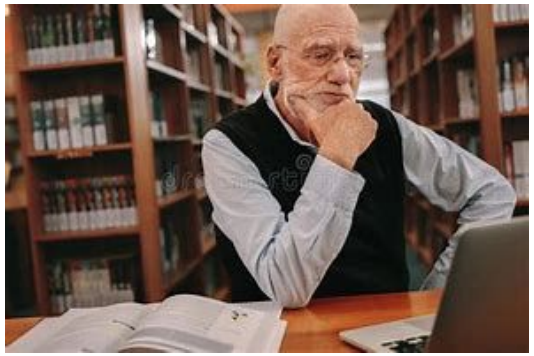
Benefits of Heart Transplant

The benefit of a successful heart transplant is a longer life and a chance to do the things you enjoy.



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Alternatives to Heart Transplant

- All patients have the right to refuse a transplant at any time during the process of evaluation and to select an alternative treatment.

- Possible alternative treatments include:
  - Medical management
  - Implantable devices
    - Such as Ventricular Assist Devices (VAD)
  - Palliative or Hospice care

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Risks of Heart Transplant

Medical risks:

- Rejection of the new heart
- Failure of the transplanted heart and a need for re-transplantation
- Infections, such as wound infections and pneumonia
- Heart rhythm disturbances including heart stoppage
- Blood clot formation and blood vessel blockages in the new heart
- Failure of other vital organs
- Death

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Risks of Heart Transplant

Psychosocial risks:

- Depression
- Post-traumatic stress disorder (PTSD)
- General feelings of anxiety and guilt
- Issues of dependence
- Concerns regarding finances and insurance

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Evaluation:

Do I need a transplant and am I a candidate?

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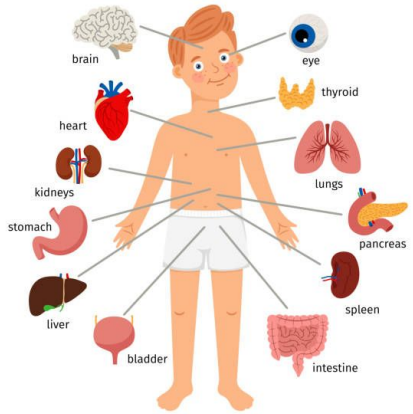
Transplant Evaluation is a Head-to-Toe Assessment

- Every patient undergoing an evaluation gets the similar testing, consults, and education.

- Some people need additional testing and consults depending on their medical history or condition found during a standard evaluation.



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Heart Transplant Evaluation Tests

- Cardiopulmonary Stress Test
- Pulmonary Function Test
- Laboratory Tests
  - To evaluate other organ function
  - Check for previous/current infections including HIV and hepatitis
- EKG
- CTs of the Chest, Abdomen, Pelvis
- Echocardiogram
- Abdominal Ultrasound
- Carotid Ultrasound (arteries leading to the brain)
- Leg Artery Ultrasound
- Right and Left Heart Catheterization

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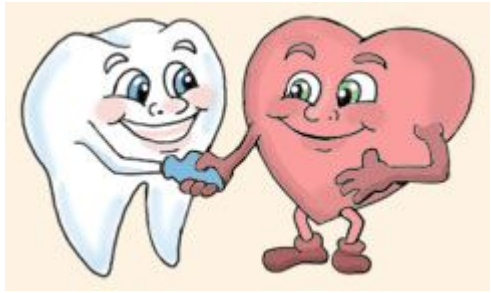
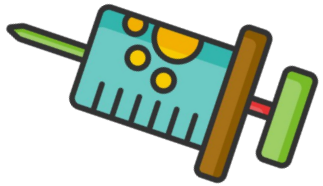
Screenings and Vaccinations

(Many tests may need to be completed <u>prior</u> to transplant)

- Dental Clearance
- Colonoscopy / Cologuard
- Mammogram / PAP smear
- Hepatitis B Vaccine series
- Covid 19 vaccines
    - Strongly recommend caregiver(s) and other eligible household members complete primary vaccination series.
- Annual Influenza Vaccine
- Pneumonia Vaccines
- As indicated: Shingles (Shringrix) and Varicella Vaccines





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Possible Contraindications to Transplant

- Advanced age
- Obesity
- Non-adherence
- Psychosocial instability
- Alcohol or drug use including tobacco
- Inadequate insurance
- HIV
- Untreated hepatitis
- Pulmonary hypertension
- Recent blood clot in lungs
- Diabetes
- Peripheral vascular/ carotid disease
- Kidney or Liver disease
- Cancer
- Active Infection
- Peptic ulcer disease

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Committee Presentation

- Once the evaluation is completed, usually your transplant team cardiologist will present your case to the multidisciplinary team.

- Every candidate is evaluated on an individual basis. They are evaluated and considered even if they have relative contraindications.

Transplant Team Members (consults)

- Transplant Cardiologist
- Transplant Surgeon
- Social Worker
- Transplant Coordinators
- Dietitian
- Financial Coordinator
- Research Coordinator
- Pharmacist
- Specialists as needed

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The Committee Decision

Accepted for transplant

- Candidate is appropriate for transplant and will be added to waitlist.

Declined for transplant

- The team determines there is a strong contraindication to transplant, and the patient would not benefit from a heart transplant.
  - Centers can facilitate a referral to another center. Transplant centers have different acceptance criteria. Patients declined at one center may still be eligible at another center.
- If you are declined for transplant for a contraindication that can be modified or improved, you may be eligible for reconsideration.
  - Examples of this include current or recent smoking or substance abuse, obesity, poorly controlled diabetes, or current, uncontrolled infection.

Deferred

- More information needs to be gathered about the patient's transplant candidacy before a decision can be made.
- The center will coordinate the additional testing and consults.
- You will be notified of the expected timeframe for a decision.

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Poll #2

What is your listing status (or that of your family member)?

- Currently listed - Status 1-4
- Currently listed - Status 5-7
- Not listed but approaching being listed
- Not listed or planning on it soon
- Already received a heart transplant

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What is Listing for Transplant?

“Listing”: Your name is added to the UNOS National Database

United Network for Organ Sharing (UNOS)

- Organization contracted by the government to maintain the wait list and fairly allocate donated organs based on policy.

Your Regional Transplant Community

- Local group tasked with following policies and standards set by UNOS. Responsible for working with the donor, the donor’s family, and for coordinating organ recovery.

Listing

- Your insurance company will approve your listing prior to your information being added to the UNOS database.
- You will be notified when you are listed and when there are any changes to your status including removal.
- Being placed on the waitlist does not guarantee you will receive a transplant.

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Listing and Multiple listing

Reasons for removal from the waitlist

- Becoming too sick.
- Loss of insurance coverage.
- Inadequate social support.
- Non-compliance with medical plan including medications & follow-up care.
- The Patient's choice.

Multiple Listing

- You have the option to be on more than one transplant center's UNOS waitlist.
  - The centers must be in different areas, but still within hours of each other so that you may get there when organ is found.
  - Patient must be evaluated & accepted by the additional transplant centers.
  - Check with insurance company.
  - Multiple listing may shorten wait time.

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Criteria for Medical Urgency on the Waitlist (Status)

Status 1

- VA ECMO (veno-arterial extra corporeal membrane oxygenation)
- Non-dischargeable, surgically implanted, non-endovascular biventricular support device
- MCSD (mechanical circulatory support device) with life-threatening ventricular arrhythmia

Status 2

- Non-dischargeable, surgically implanted, non-endovascular LVAD
- IABP (intra-aortic balloon pump)
- V-tach / V-fib, mechanical support not required
- MCSD with device malfunction/mechanical failure
- TAH (total artificial heart), BiVAD, RVAD, or VAD for single ventricle patients
- Percutaneous endovascular MCSD

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Criteria for Medical Urgency Status

Status 3

- Dischargeable LVAD for discretionary 30 days
- Multiple inotropes or single high-dose inotrope with continuous hemodynamic monitoring
- VA ECMO after 7 days; percutaneous endovascular circulatory support device or IABP after 14 days
- Non-dischargeable, surgically implanted, non-endovascular LVAD after 14 days
- MCSD with one of the following:
    - device infection
    - right heart failure
    - hemolysis
    - pump thrombosis
    - mucosal bleeding
    - aortic insufficiency

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Criteria for Medical Urgency Status

Status 4

- Dischargeable LVAD without discretionary 30 days
- Inotropes without hemodynamic monitoring
- Retransplant
- Diagnosis of one of the following:
  - congenital heart disease (CHD)
  - ischemic heart disease with intractable angina
  - hypertrophic cardiomyopathy
  - restrictive cardiomyopathy
  - amyloidosis

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Criteria for Medical Urgency Status

Status 5

- On the waitlist for at least one other organ at the same hospital.

Status 6

- All remaining active candidates.

Status 7

- Inactive. Not currently receiving heart offers.

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Waiting on the List

Aside from your medical urgency status, these factors influence your time on the waitlist

- Body size
  - Body surface area
- Blood type
  - **O** is the universal donor. They wait the longest on the list.
  - **AB** is the universal recipient. They wait the shortest on the list.
- Being highly sensitized
- Donor availability

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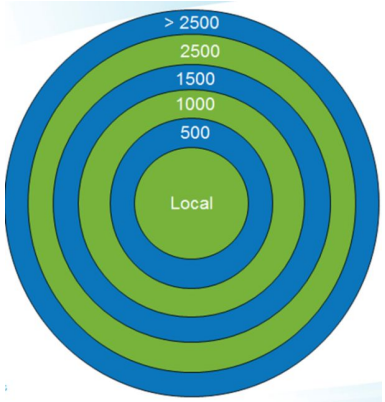
Geographic Distribution

- When a donor has been identified, if there are no matching local patients, the next level of matching is for patients at hospitals within 500 nautical miles of the donor hospital (a nautical mile = 1 minute of longitude when traveling 1.1508 land-measured miles).
- If no one accepts the organ offer at that level, it then goes to anyone within 1,000 miles, and so on.
- Most donated hearts, if they're not used locally, will go to a recipient within 1,000 miles.



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Outcomes

- Every six months the transplant center is required to communicate the most current outcomes of **1-year** patient survival and **1- year** graft survival.

- **SRTR <u>Heart Transplant</u> Data is Released every 6 months**

- **<u>Patients transplanted 07/01/2018 – 03/12/2020 (US Transplant Centers)</u>**
  - Graft Survival: 1 year 91.24%
  - Patient Survival: 1 year 91.65%

Additional information about both national and any transplant center's outcomes can be found on the <u>Scientific Registry of Transplant Recipients</u> website: srtr.org

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Waiting for Transplant:
Being healthy and informed

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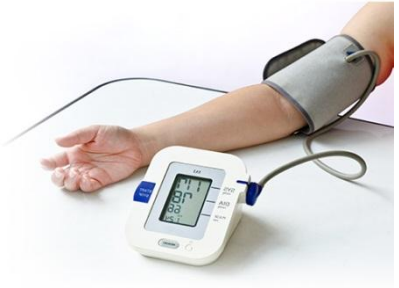
Waiting for a Transplant: What do I do NOW?

- During the waiting period, the transplant team will follow you routinely. <u>But remember, you are an important part of your own health team</u>.

- Learn self monitoring skills: You should take your pulse, blood pressure and weight daily.



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What do I do NOW (cont'd)

- Be as active as you can be.
  - Cardiac rehab
  - Walking
- Eat healthy
- Learn coping skills
- Educate yourself about life after transplant.
- Take your medications as directed
- Monitor your health:
  Weight, Blood pressure etc.
- Let your medical team know if you are having problems and ask for help.

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When a Donor Organ is Offered to You

- You are expected to be available by phone 24/7.
- You may be called any time day or night.
- Don’t leave town without letting your team know.
  - You must be within the accepted ***traveling time to your transplant center*** while on the list. If you go outside the accepted traveling time you must notify your team.

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Organ Donor

Where does the heart come from?

- Donated hearts are most likely to function if they are transplanted within 4 to 6 hours of being recovered from the donor. Your transplant center will want to keep preservation time as short as possible.

- The Donor is a person who has been declared “brain dead”.
  - Extensive, irreversible damage to the brain.
  - Family of the donor consents to organ donation.
  - Donation is a **gift** of life.

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Organ Evaluation

The organ is evaluated before being offered to your team.

- Donor age, medical history, psychosocial and behavioral history, including a history of high-risk behaviors, are considered.
- To assess organ function, tests are completed such as:
  - Echocardiogram
  - Right/ left heart catheterization
  - Other imaging including chest CT
- Blood work including viral serologies are completed.
  - Hepatitis B, hepatitis C, HIV
- The coordinator, cardiologist, and surgeon review the donor testing results.

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Decision to Transplant

- Transplant physicians and surgeons will determine if an organ is appropriate for transplant.
- They will consider how sick you are, the quality and function of the donor heart, and the donor's age and history.
- If the organ donor meets the PHS (Public Health Service) risk criteria, you will be notified.
- You have the right to refuse an organ for any reason and continue to be listed on the waitlist instead.

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Donor Organ Risk Criteria

Some Donor Organs may have One or More Risk Criteria

- Donors whose medical/social history has been determined by the CDC (Centers for Disease Control) to have risk factor(s) for infection but have negative tests.

- Organs from donors who meet risk criteria have a small chance of transmitting hepatitis B, hepatitis C, and HIV.
  - As with every test, there can be a small chance that the test is negative even if the virus is present. A negative test may occur if the donor had a very recent infection.
  - Risk of HIV, HBV, or HCV transmission from a NAT (nucleic acid test) negative donor organ is low, but not zero (approximately 1 in 10,000 to 1 in a million).

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https://optn.transplant.hrsa.gov/media/4351/1004_align2020phsguideline_dec2020_policynotice.pdf

Donor Organ Meeting One or More Risk Criteria

- Donors meeting one or more risk criteria are evaluated fully with blood tests and an assessment of their social history. Your team will weigh the risk of disease transmission versus your risk of not receiving the organ (continuing to wait for transplant) and make a recommendation.

- You have the right to refuse a donor organ meeting one or more risk criteria and continue to wait. You should also consider that your chance of dying while waiting for another organ offer may be greater than the risk of infection.

- After transplant, ALL patients will receive routine testing as dictated by the CDC to monitor for development of infections from donation. Should transmission occur, effective therapies are available.

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https://optn.transplant.hrsa.gov/media/4351/1004_align2020phsguideline_dec2020_policynotice.pdf

Hepatitis C Positive Donors

- Some programs are now accepting hepatitis C donors because the donors are often young and otherwise healthy, and the hepatitis C drugs are excellent. Teams are confident they will be able to treat the hepatitis.
- Multiple centers throughout the country and certainly the larger centers are using donors with hepatitis C.
- There are long wait times for people on organ transplant waitlists.
- Up to 50% of patients may die waiting for a transplant.

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Donor Information

- It is important for the recipient to understand that donor information is confidential and cannot be shared.

- Organ families donate under the condition that the donor's identity is kept confidential. The transplant team will share if your donor meets PHS risk criteria. Please respect your donor's privacy and do not expect additional information will be shared.

- If the recipient would like to express their gratitude for the donation, a team member can help in this process.

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Being Called in for a Heart

- Keep a small bag packed and ready to go by the door.
  - LVAD patients should bring their **shower bag and other safety equipment such as batteries.**
- Stop eating and drinking as soon as you are called by a coordinator.
- The coordinator will tell you where to report.
- What is a “dry run”?
- Durable Power of Attorney
- Living Will
- Medical Advanced Directives

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Surgical Experience

- Before you go into the operating room, members of your team will talk with you.
- Some testing will be repeated including labs.
- The surgery requires general anesthesia. You will need to be on a breathing machine for the surgery and during the immediate post-operative phase.
- The surgeon will perform a sternotomy in order to do the transplant.
- Tubes are placed to drain fluid from the operative area.
- IVs are placed in your arms and neck to monitor your vital signs and for medication administration.

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Immediate Post-operative Period

- The length of hospital stays varies, but expect to stay in the ICU for a couple of days to about a week. Then you may be transferred to a Cardiovascular Step-Down Unit until discharge.

- During your stay you will learn about life as a transplant recipient and how to care for yourself.
    - Learn as much as you can before transplant, and it will be that much easier to take it all in.

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Preventing Rejection

- FOR THE REST OF YOUR LIFE, you and your transplant team will need to modulate your immune system so that it does not recognize the new heart as foreign.

- During the surgery, you will start receiving medications to suppress your immune system.

- You will need to take immunosuppressant medications for the rest of your life.

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How is Rejection Monitored?

- **Endomyocardial Biopsies** are performed on all heart transplant recipients routinely to monitor for rejection.
- Protocol schedules vary by Transplant Center
- There is also a blood test that can be used to evaluate for risk of rejection (HeartCare).

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Before Discharge - Know How to Care for Yourself

- Medications, names, dose, purpose
- Infection control measures
- Diet: Low Fat, Low Sodium, No Grapefruit
- Exercise plan (Denervated Heart)
- Follow-up schedule for biopsies and clinic
- Emergency contacts
- Have all your prescriptions
- Post-transplant teaching with transplant team

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Long-Term Follow-up

- Initially you will be seen in your heart transplant center frequently per their protocol (even when you are not scheduled for a biopsy) and routinely for the rest of your life.

- You will also need to see your PCP and Dermatologist at least annually for routine physicals and skin checks.

- No over-the-counter Herbs or Medications without discussing with the transplant team as they may interact with your other medications.

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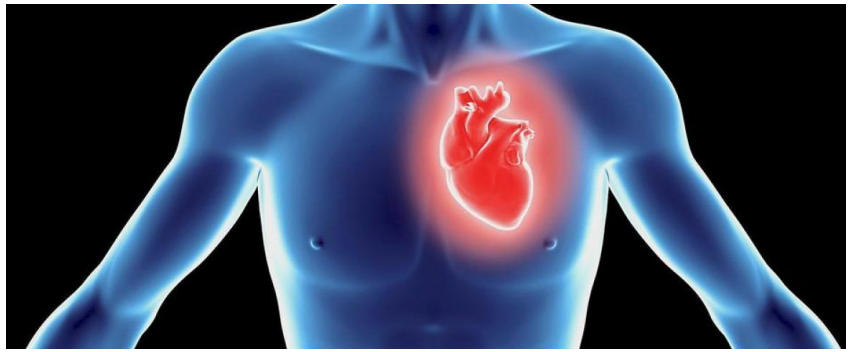
Keys to Success

- Go to your transplant appointments as scheduled
- Take medications as directed
- Maintain insurance policies that have transplant coverage
- Notify the team when problems first occur, **DON'T WAIT** for small problems to become emergencies
- Take care of your whole body



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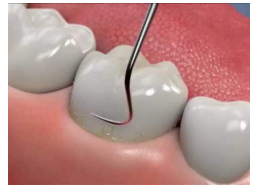
Waiting for Transplant: Keep Up to Date on Routine Care

- ❑ Immunizations:
  - ❑ Covid vaccines
  - ❑ Yearly influenza vaccine
  - ❑ Pneumonia vaccines
  - ❑ Hepatitis B vaccine (as indicated)
- ❑ Dental care
- ❑ Colonoscopy/Cologuard (as indicated)
- ❑ Mammogram/Pap smears



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Transplant Resources

- www.ustransplant.org
- www.transplantliving.org
- www.optn.org
- www.inova.org
- www.cdc.gov
- www.ISHLT.org
- Your center's support group

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Questions?

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Hold the Date for our Next Webinar

Wednesday, July 20, 2022

6:00 PM ET

“DCM Gene Therapy Advancement at Tenaya Therapeutics”

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