

A DECISION AID FOR IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDs) (Primary Prevention)



* The information provided in this decision aid is designed to help you make a decision with your health care provider(s). It is not meant to replace their advice.

This decision aid is for you if:



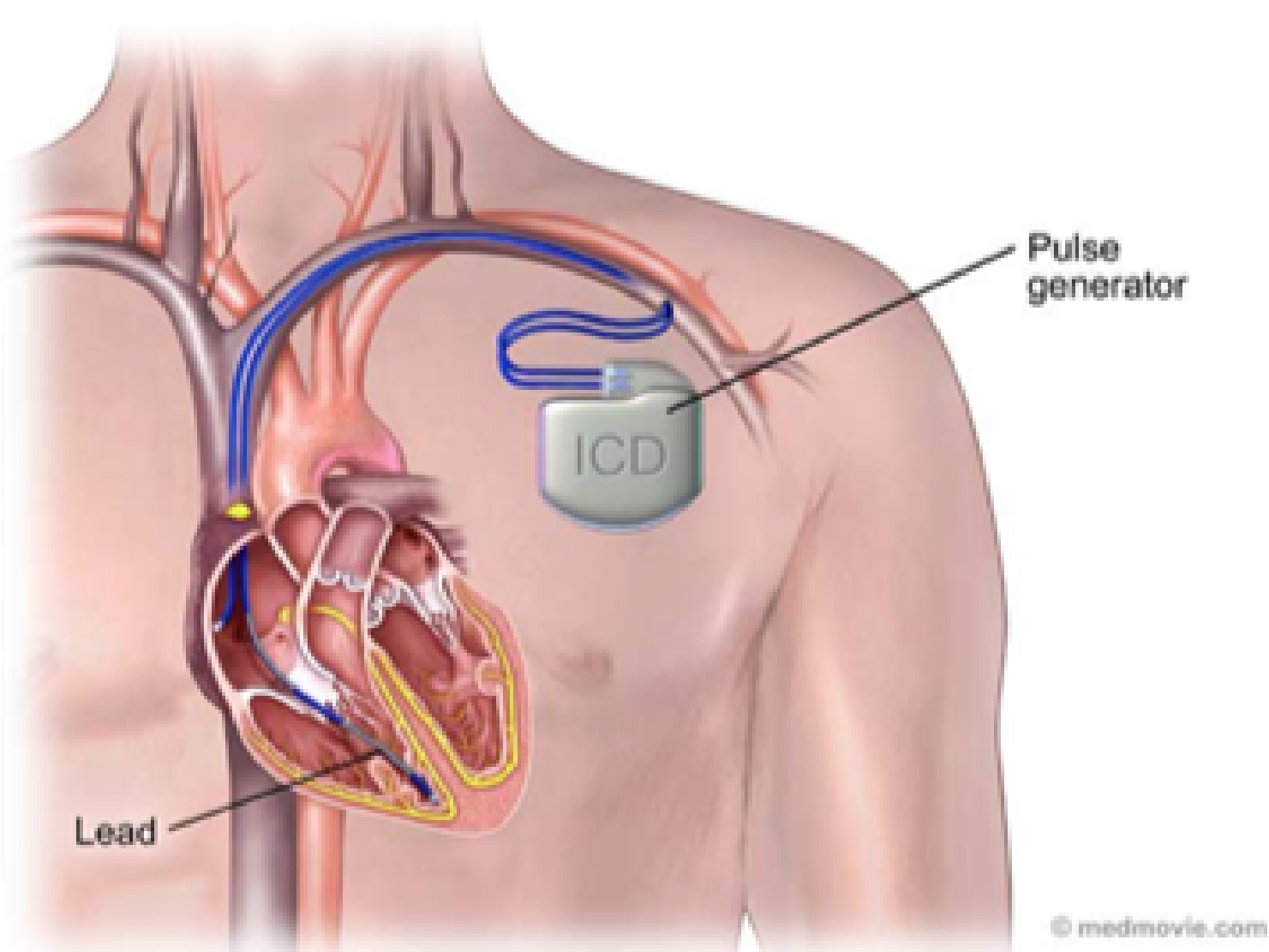
- You are thinking about an ICD because your health care provider believes you could be at risk for a fast dangerous heart rhythm—but you have never had one.
- Primary prevention ICDs are for people who have cardiomyopathy. Cardiomyopathy refers to conditions that affect your heart muscle. It means your heart cannot pump blood very well to the rest of your body because your left ventricle, your heart's main pumping chamber, is enlarged and weak. You may have one of two types:
 - In **ischemic cardiomyopathy (ICM)**, the weak pumping chamber is caused by ischemia, a lack of blood supply to the heart muscle caused by heart attacks and coronary artery disease (narrowed arteries).
 - In **non-ischemic cardiomyopathy (NICM)**, often an exact cause is not known.
- You want to prepare for a visit with a health care provider about an ICD.
- You want to think about the benefits and risks of your treatment options and what matters most to you and your family.
- You currently do not have an ICD.

This decision aid is **NOT** for you if:

- You are thinking about a subcutaneous ICD (S-ICD). This is different than a traditional ICD because the wires (leads) that connect the device to your heart are implanted under the skin rather than through the veins.
- You are thinking about an ICD with an "extra" wire that can improve the way your heart beats (called a cardiac re-synchronization therapy (CRT-ICD) device).
- You are thinking about a pacemaker.

What is an ICD?

- An ICD is a small battery-operated device that can detect and deliver therapy to correct fast dangerous heart rhythms. The ICD keeps track of your heart rate and rhythm.
- An ICD monitors heart rhythm, detects dangerous fast rhythms, and delivers an electric shock to restore a normal heart rhythm.
- Treating fast dangerous heart rhythms in persons who are known to be *at-risk* can prevent a sudden cardiac arrest. This type of ICD therapy is called an *appropriate* shock (or therapy).



The ICD sits below the skin in your chest so you cannot see it - but you can see the scar and feel a small bump.

What does ICD therapy feel like?



- If the ICD senses a fast dangerous heart rhythm, it can deliver ICD therapy two ways: 1) a shock, or 2) lower energy therapy. ICD therapy may occur with or without signs or symptoms. Some people feel well. Other people feel light-headed and dizzy. Others may lose consciousness.
- Shocks have been described as feeling like a strong punch to the chest (it hurts). You may not feel anything if the ICD delivers the lower energy therapy.
- You could receive ICD therapy when you should not (called an *inappropriate* shock).

What can't an ICD do?

- An ICD will not prevent fast dangerous heart rhythms from starting.
- A standard ICD cannot correct other heart related symptoms like trouble breathing, feeling tired, or chest pain.
- A standard ICD does not change your underlying heart disease or heart condition causing the dangerous heart rhythm.
- The ICD does not prevent you from all causes of death.
- The ICD does not correct irregular heart rhythms like atrial fibrillation.

As you go through this information, think about:

- How you want to live the rest of your life.
- What you hope for?
- What you fear?
- What questions you may have for your health care provider(s)?





KNOW YOUR OPTIONS



The decision to have an ICD implanted is not a simple one. The answer will depend on what feels right for you and what you think will fit best in your life. Your health care providers want to help you make the best decision for you.

You have 2 options:



OR



Implant ICD and continue with medical management

Continue with medical management

Get an ICD and continue with medical management

- What?** Have an ICD implanted.
- How?** An incision is made to open the skin to place the ICD. You are awake during the surgery. The doctor will inject freezing into the area and will give you medicine to relax you. The surgery lasts about 45 minutes.
- Who?** People who have either ischemic (narrowing of the arteries) or non-ischemic heart disease (heart disease from other factors).
- Length of Hospital Stay?** On average, 2 to 4 hours. You will return home the same day.
- Recovery Time?** On average, 5 to 7 days.
- Follow Up?** Every 3 to 6 months. After 5 to 10 years, the ICD will need to be replaced.

Do not get an ICD and continue with medical management

- What?** Continue with your usual medications.
- How?** You will meet regularly with your cardiologist and other health care providers to monitor medications.
- Who?** People who work as welders and need to be near magnetic fields would not be able to have an ICD. You would be managed with medications.
- Length of Hospital Stay?** None.
- Recovery Time?** None.
- Follow Up?** Regularly, as suggested by your cardiologist/health care team.

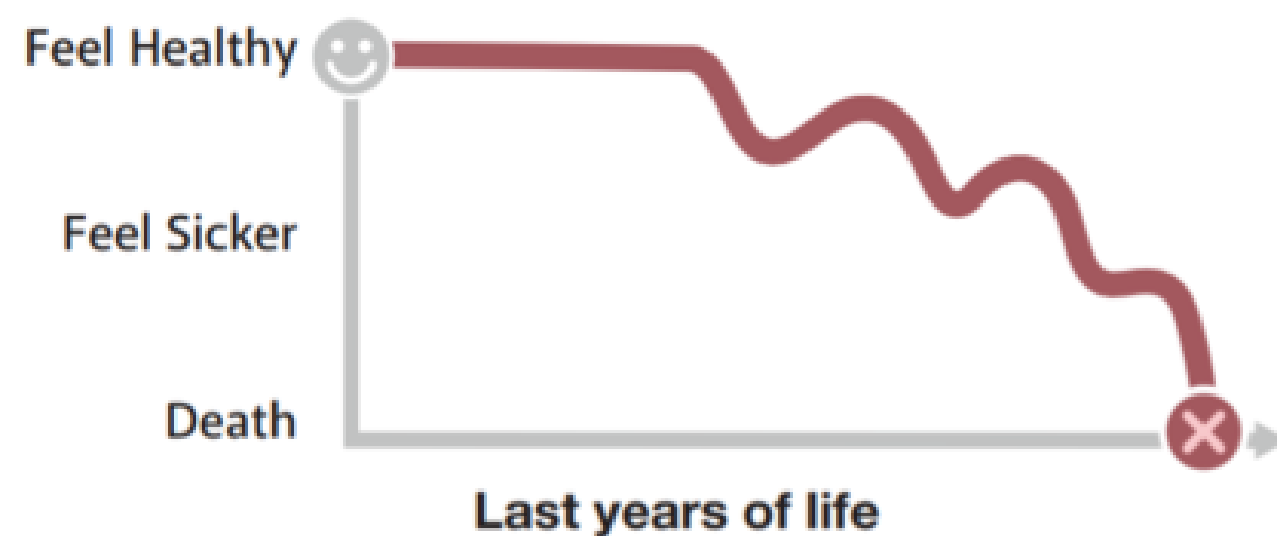
Understand the benefits and risks of your decision.



Consider two possible paths:

Path 1

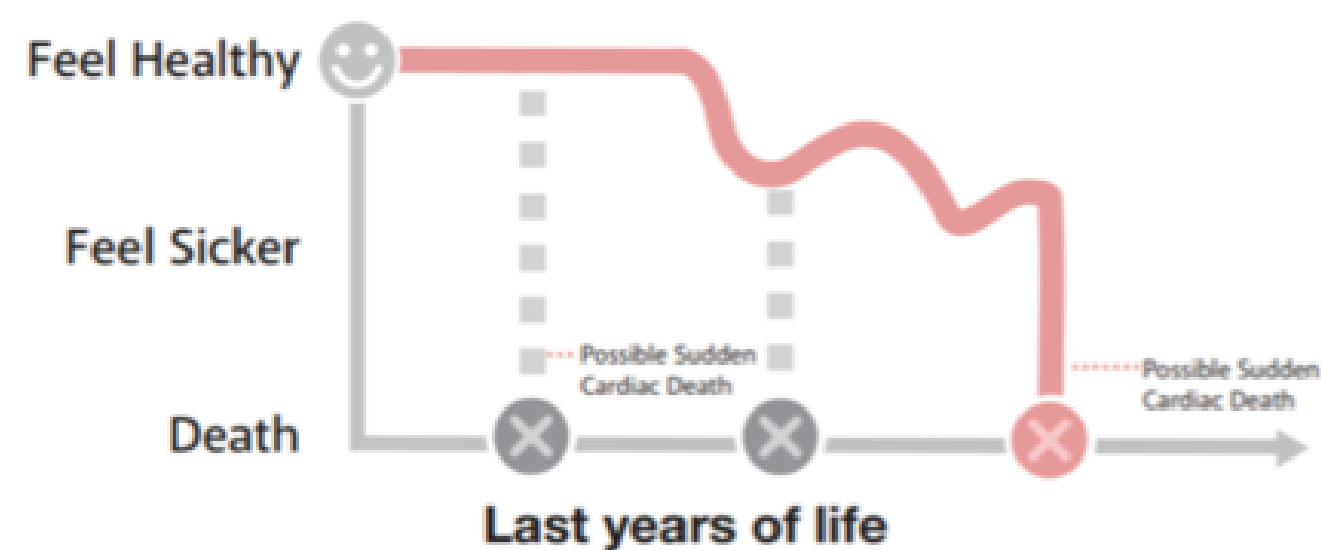
You may choose to get an ICD. You may be feeling like you usually do, then a dangerous heart rhythm could happen. The ICD may help you live longer by treating a dangerous heart rhythm. You will continue to live with heart failure that may get worse over time.



"I'm not ready to die. I have so much I'm trying to stay alive for. Even if it means getting shocked, I'm willing to do anything that can help me live longer."

Path 2

You may choose to NOT get an ICD. You may be feeling like you usually do, and then a dangerous heart rhythm could happen. You may die quickly from the dangerous heart rhythm. This can happen at any time.



"I've lived a good life. The idea of dying quickly sounds like a painless way to go. I've always said I hope to die in my sleep. Going through surgery and getting shocked is not the kind of thing I want."

Reprinted with permission: Matlock, D. University of Colorado, 2017.

What are some of the benefits of an ICD?

The ICD may lower your risk of a sudden cardiac death from a fast dangerous heart rhythm.

The ICD may give you peace of mind that if you have a fast dangerous heart rhythm it could be corrected.

The ICD is proven to successfully treat fast dangerous heart rhythms.

Over 4 years, 21 out of 100 people with ICM will receive appropriate shocks/ICD therapy.¹ Over 6 years, 16 out of 100 people with NICM will receive appropriate shock/ICD.²

In Canada, there is no cost for patients to receive an ICD.

What are the risks of an ICD?

Risks of ICD surgery:

There is a chance of infection from the ICD surgery: 5% of those with ICM,³ and 4% of those with NICM.⁴

There could be bleeding at the time of the ICD surgery.

A lung could collapse at the time of the ICD surgery.

Risks over the long term:

Over 4 years, 10 out of 100 people with ICM will receive inappropriate shocks/ICD therapy.⁵ Over 6 years, 8 out of 100 people with NICM will receive inappropriate shocks/ICD therapy.⁶

There may be problems with the wires (leads) over the short or long term.

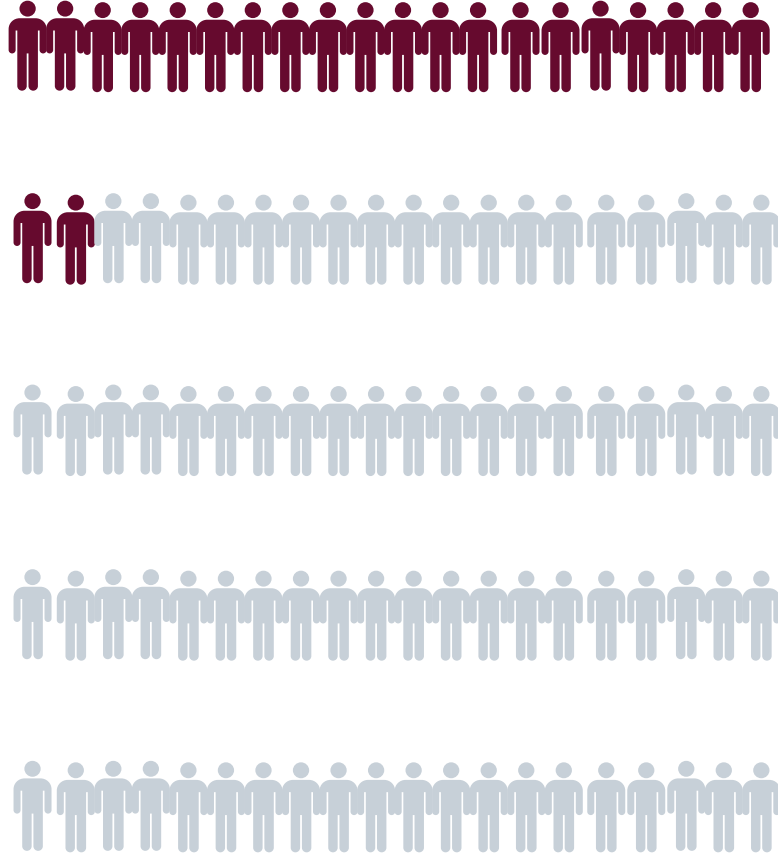
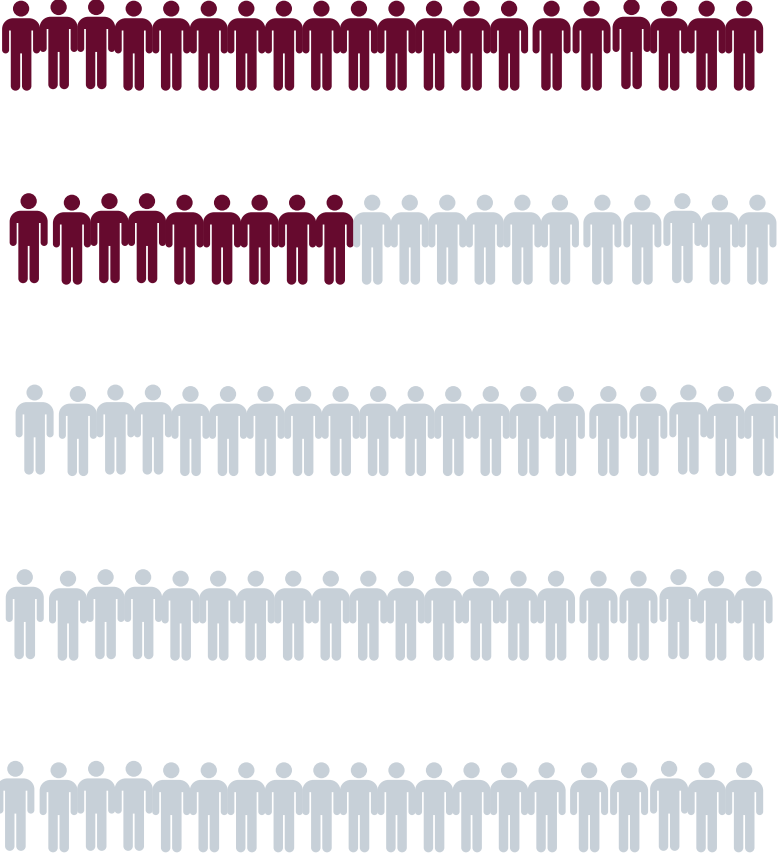
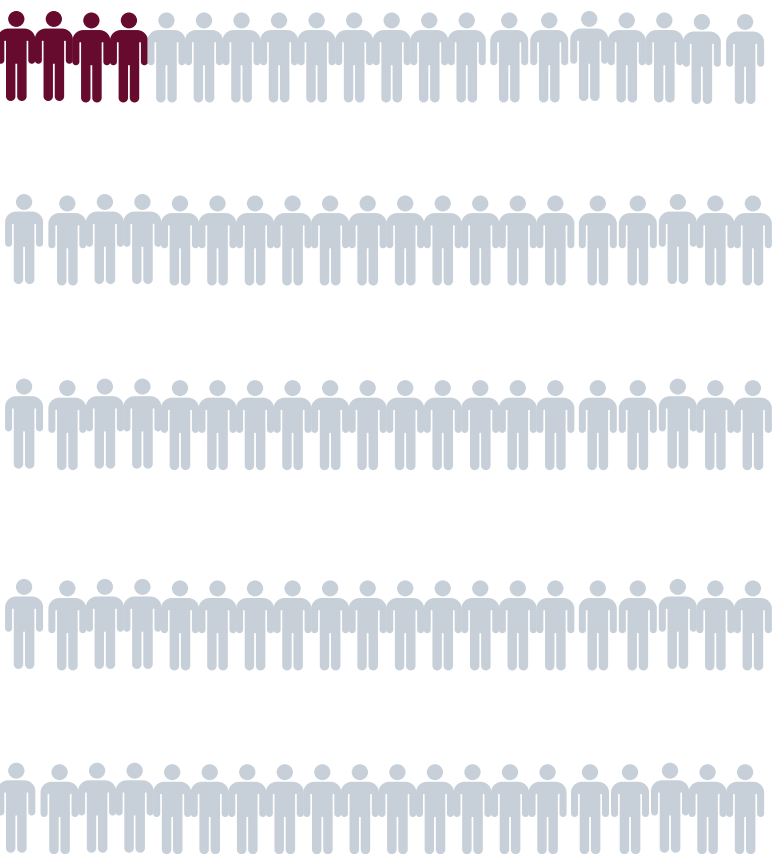
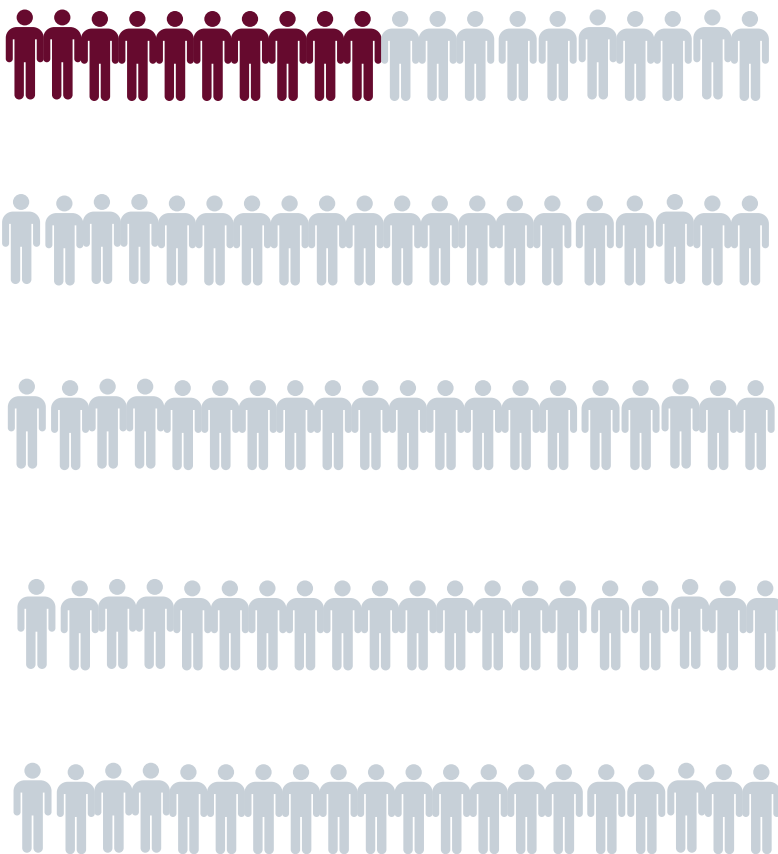
You may face short term driving restrictions if the ICD delivers *appropriate* shocks/therapy to treat a fast dangerous heart rhythm.

If you receive shocks from the ICD, you may worry about future shocks.

UNDERSTAND THE BENEFITS AND RISKS OF YOUR DECISION




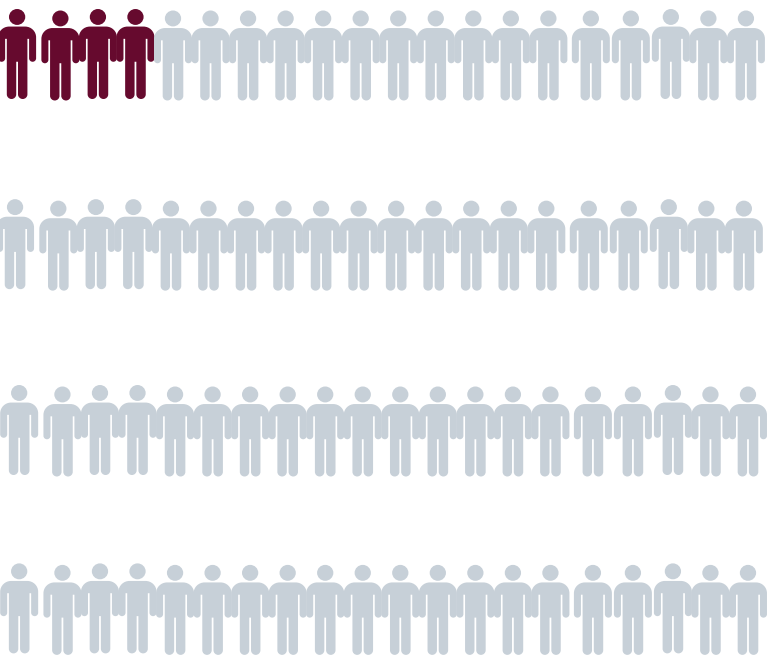




Implanting an ICD can also impact death, and these numbers will vary depending on whether you have **ischemic (ICM) or non-ischemic (NICM) cardiomyopathy**. These 100 figures (👤) show a best estimate of what happens to **100** people if they choose an ICD or continue with medication with regards to death and complications. Each figure (👤) stands for one person. The red figures (👤) show the number of people affected. These estimates of risk will vary based on your personal risk profile, sex, age, or other health problems (e.g. kidney disease, lung disease, prior stroke, diabetes). Talk to your doctor about your individual risks.

For patients with ischemic cardiomyopathy (ICM):

Ischemic (ICM)	ICD	No ICD
<p>Fewer patients who got an ICD died from all-causes.⁷</p> <p>☆☆☆</p>	 <p>22 out of 100 patients who got an ICD died over 4 years.</p>	 <p>29 out of 100 patients without an ICD died over 4 years.</p>
<p>Fewer patients who got an ICD died from sudden cardiac causes i.e. arrhythmias.⁸</p> <p>☆☆☆</p>	 <p>4 out of 100 patients who got an ICD died over 4 years.</p>	 <p>10 out of 100 patients without an ICD died over 4 years.</p>

☆☆☆ Represents higher level of evidence

For patients with non-ischemic cardiomyopathy (NICM):

Non-ischemic (NICM)	ICD	No ICD
<p>Fewer patients who got an ICD died from all-causes.⁹</p> <p>☆☆☆</p>	  <p>20 out of 100 patients who got an ICD died over 6 years.</p>	  <p>24 out of 100 patients without an ICD died over 6 years.</p>
<p>Fewer patients who got an ICD died from sudden cardiac causes i.e. arrhythmias.¹⁰</p> <p>☆☆☆</p>	  <p>3 out of 100 patients who got an ICD died over 6 years.</p>	  <p>7 out of 100 patients without an ICD died over 6 years.</p>

☆☆☆ Represents higher level of evidence

Consider what matters most to you

To understand your options, it is important to discuss how an ICD can impact your life.

Daily life	<ul style="list-style-type: none"> You can exercise, travel, have sexual relations and use your cell phone.
Driving	<ul style="list-style-type: none"> You can still drive, but if you have a shock you need to stop for 6 months.
Medical procedures	<ul style="list-style-type: none"> Special care may be required before some medical procedures. For example, in the case of magnetic resonance imaging (MRI). Before any medical procedure, it is advised to talk to your health care team about your ICD.
Non Replacement	<ul style="list-style-type: none"> At some point, you and your doctor may decide that you no longer want therapy from an ICD. You can choose to not replace the battery.
Quality of life	<ul style="list-style-type: none"> Some people with an ICD worry about when, where, and during what activity they could receive a shock.
Deactivation	<ul style="list-style-type: none"> You can choose to have the ICD therapies turned off. This can be done at the device clinic. Letting your family know your preferences through advanced healthcare directives is important.

CONSIDER WHAT MATTERS MOST TO YOU

On a scale of 1 to 10...

How important is it to you to lower your chances of a sudden cardiac death?



1

2

3

4

5

6

7

8

9

10



Not Important

Live whatever time I have left without an ICD. This means I may die quickly (e.g. dying suddenly in my sleep).

Very Important

I wish to live as long as possible, even if that means receiving shocks from an ICD, facing risks associated with the ICD, or living with an illness that might get worse over time.

What else do you need to make a choice?

Do you know the benefits and risks of each option? Yes No

Are you clear about which benefits and risks matter most to you? Yes No

Do you have enough support and advice to make a choice? Yes No

Do you feel sure about the best choice for you? Yes No

The SURE Test ©2008 O'Connor & Légaré

Is there anything else making your decision difficult?

List questions or concerns you want to talk about with your health care provider(s).

Additional info

Canadian website with ICD information for patients and families:

<https://www.ottawaheart.ca/document/icds-implantable-cardioverter-defibrillators>

Copyright © 2022.

Primary Content Editor: Sandra L. Carroll RN PhD, McMaster University.

This patient decision aid was developed by a team of researchers including patients, family members, and clinicians with expertise in shared decision-making and ICDs. For more information please contact S. Carroll directly at carroll@mcmaster.ca.

Original Version funded by Canadian Institutes of Health Research.

Current Version funded in part by Canadian Cardiovascular Society and CANet.

None of the authors stand to gain or lose from the choices patients make after using this decision aid. No conflict of interest to declare.

Sources

¹ Based on data from 1 RCT (SCD-HeFT, 2005) with a total sample size of 431 for ICD group.

² Based on data from 3 RCT's (CAT, 2002; DANISH, 2016; SCD-HeFT, 2005) with a total sample size of 1,004 for ICD group.

³ Based on data from 3 RCT's (CABG-PATCH, 1996; MADIT I, 1996; MADIT II, 2002) with a total sample size of 1,283 for ICD group.

⁴ Based on data from 3 RCT's (CAT, 2002; DANISH, 2016; DEFINITE, 2004) with a total sample size of 835 for ICD group.

⁵ Based on data from 1 RCT (SCD-HeFT, 2005) with a total sample size of 431 for ICD group.

⁶ Based on data from 2 RCT's (DANISH, 2016; SCD-HeFT, 2005) with a total sample size of 954 for ICD group.

⁷ Based on data from 6 RCT's (CABG-PATCH, 1996; DINAMIT, 2004; IRIS, 2009; MADIT I, 1996, MADIT II, 2002; SCD-HeFT, 2005) with a total sample size of 2,491 for ICD group and 2,719 for non-ICD standard medical therapy group.

⁸ Based on data from 5 RCT's (CABG-PATCH, 1996; DINAMIT, 2004; IRIS, 2009; MADIT I, 1996, MADIT II, 2002) with a total sample size of 2,060 for ICD group and 1,840 for non-ICD standard medical therapy group.

⁹ Based on data from 5 RCT's (AMIOVIRT, 2003; CAT, 2002; DANISH, 2016; DEFINITE, 2004; SCD-HeFT, 2005) with a total sample size of 1,284 for ICD group and 1,708 for non-ICD standard medical therapy group.

¹⁰ Based on data from 3 RCT's (AMIOVIRT, 2003; DANISH, 2016; DEFINITE, 2004) with a total sample size of 836 for ICD group and 841 for non-ICD standard medical therapy group.

