Understanding the ICD Medicare Coverage and the Shared Decision Making Requirement

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Presenters

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Recent Coverage History

- CMS initiated the coverage reconsideration process May 2017
- Societies commented together in June and December
- Collaboration facilitated success in making changes
- Members can rely on recent guideline and related tools for success, including this webinar

Updated NCD Issued on February 15, 2018

Updated Clinical Indications

Exceptions to Waiting Periods

End of Registry Requirement

Shared Decision Making

Decision Memo for Implantable Cardioverter Defibrillators (CAG-00157R4)

www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R29NCD.pdf

Or

www.hrsonline.org/Policy-Payment/Updated-ICD-Coverage-Policy-2018

Shared Decision Making & Improving Patient Care

- Shared decision making (SDM) should be an integral part of heart rhythm care.
- 2017 Guidelines: “clinicians should adopt a shared decision-making approach in which treatment decisions are based not only on the best available evidence but also on the patients’ health goals, preferences, and values”
- SDM interaction must occur prior to ICD implantation, and be documented in the medical records.
- The effectiveness of SDM tools for ICDs is under evaluation in a multicenter randomized clinical trial.

Shared Decision Making Requirement

“A formal shared decision making encounter must occur between the patient and a physician or qualified non-physician practitioner (physician assistant, nurse practitioner, or clinical nurse specialist) using an evidence-based decision tool on ICDs prior to initial implantation. The shared decision making encounter may occur at a separate visit.”

Covered Indications Requiring SDM Tool B2-B3.

2. Patients with a prior myocardial infarction and a measured left ventricular ejection fraction (LVEF) ≤ 0.30. Patients must not have:
   - New York Heart Association (NYHA) classification IV heart failure;
   - Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
   - Had a myocardial infarction within the past 40 days; or
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

3. Patients who have severe ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%. Additionally, patients must not have:
   - Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
   - Had a myocardial infarction within the past 40 days; or
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

Covered Indications Requiring SDM Tool B4-B5.

4. Patients who have severe non-ischemic dilated cardiomyopathy but no personal history of sustained ventricular tachyarrhythmia or cardiac arrest due to ventricular fibrillation, and have New York Heart Association (NYHA) Class II or III heart failure, left ventricular ejection fraction (LVEF) ≤ 35%, been on optimal medical therapy (OMT) for at least 3 months. Additionally, patients must not have:
   - Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or
   - Had a myocardial infarction within the past 40 days; or
   - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

5. Patients with documented familial, or genetic disorders with a high risk of life-threatening tachyarrhytmias (sustained ventricular tachycardia or ventricular fibrillation), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.

Case Study of the Colorado SDM Tool

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Colorado Program for Patient Centered Decisions

Multidisciplinary team led by Dan Matlock, MD MPH

- Decision Scientists/Implementation Scientists
- Generalists, Cardiologists, and Electrophysiologists
- Literacy Experts
- Medical Graphic Artists
- Photographers/Video Producers/Web Designers
- Patients

Decision tools for CIEDs (Developed with NIH and PCORI funding)

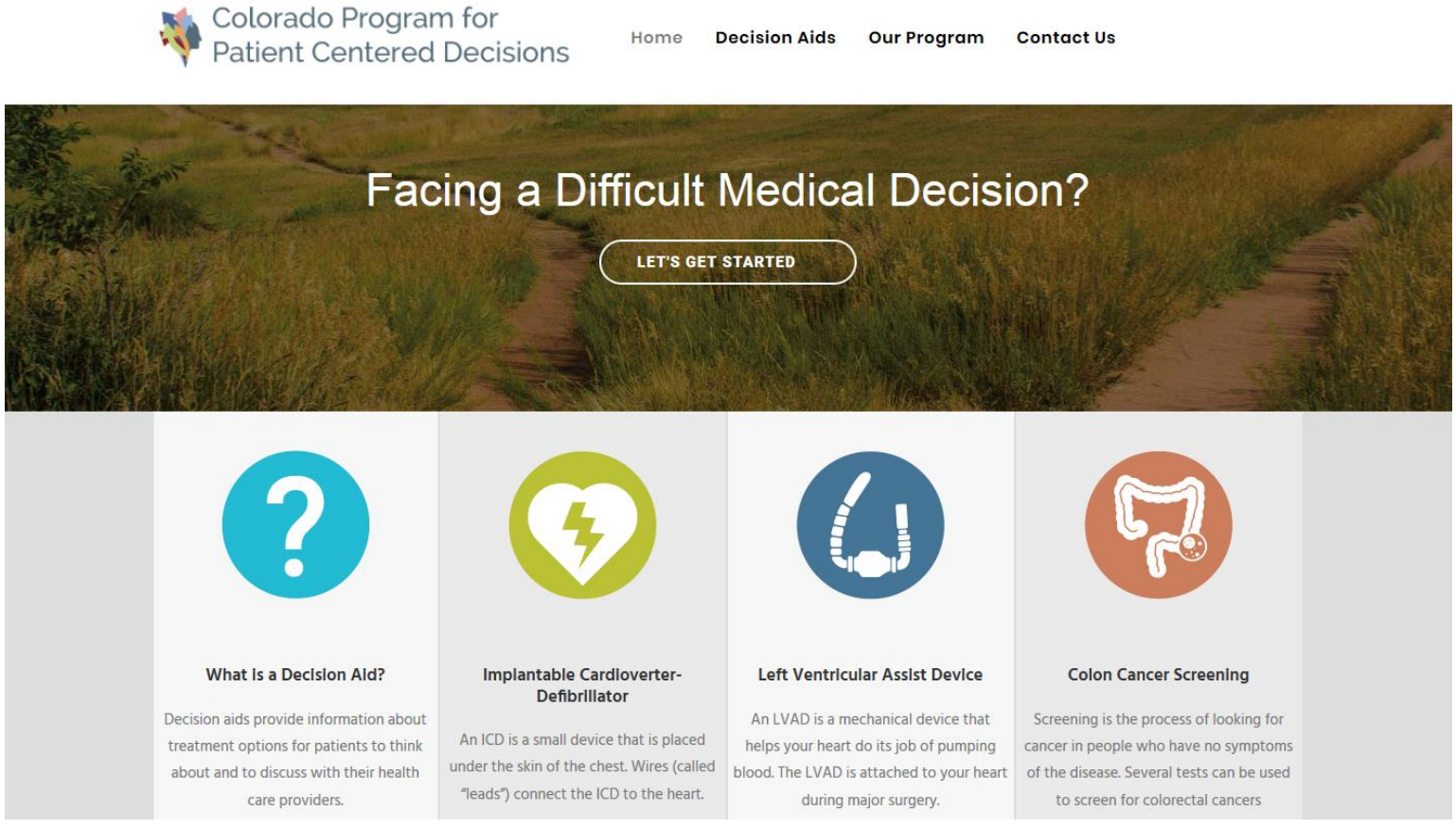
- Primary Prevention ICD
- ICD generator replacement
- CRT

Formal study – DECIDE-ICD

- NIH R01 Multicenter Randomized Controlled Trial (ongoing) – Matlock, PI

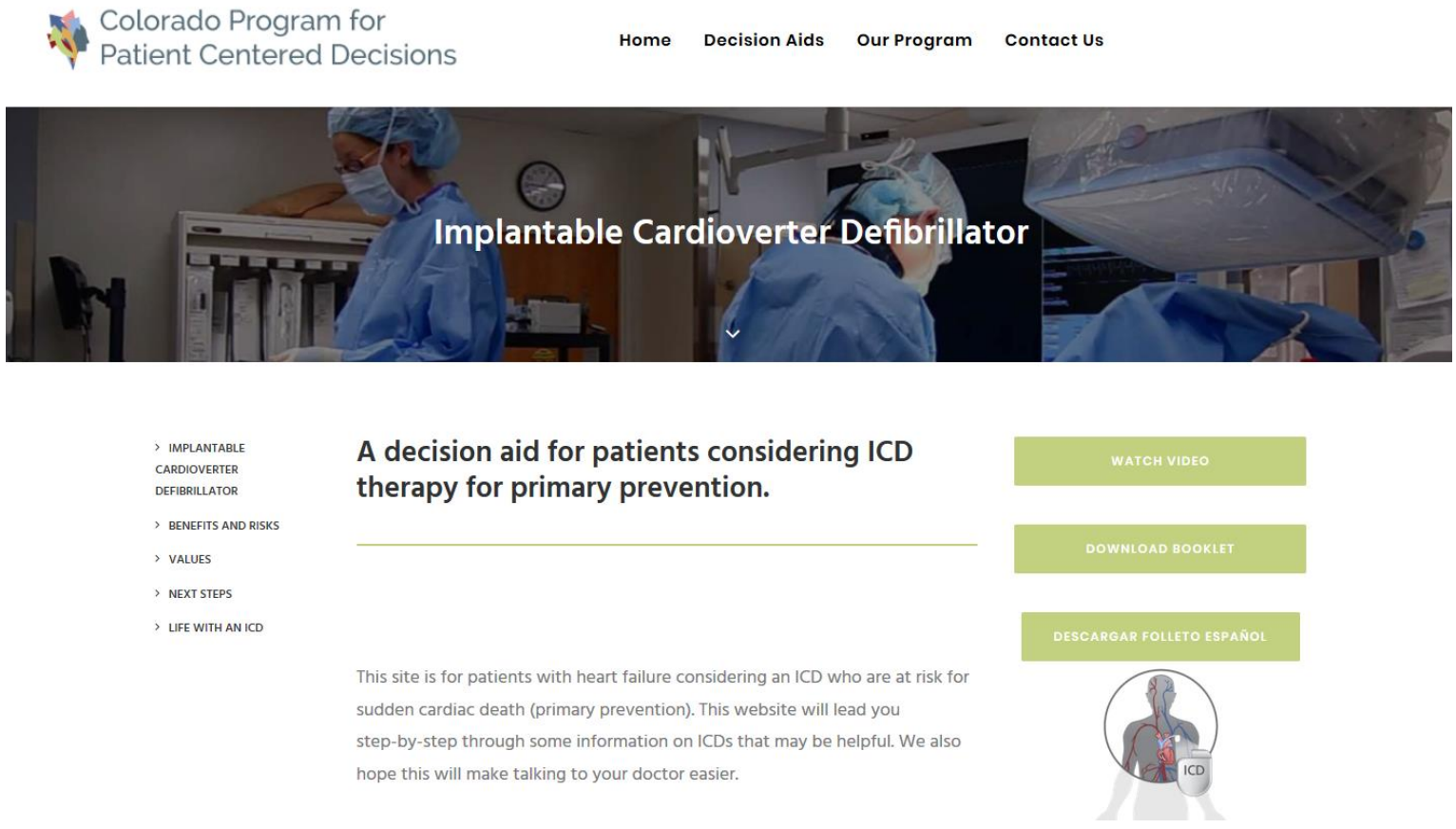
https://patientdecisionaid.org

https://patientdecisionaid.org



Interactive Website

Interactive Website



Infographic (PDF)

(Available for Download)

Infographic (PDF)

(Available for Download)

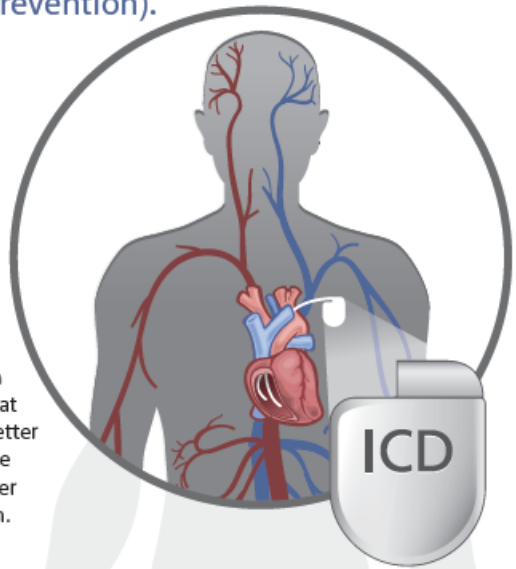
A decision aid for

Implantable Cardioverter-Defibrillators (ICD)

For patients with heart failure considering an ICD who are at risk for sudden cardiac death (primary prevention).

What is an ICD?

An ICD is a small device that is placed under the skin of the chest. Wires (called "leads") connect the ICD to the heart. An ICD is designed to prevent an at-risk person from dying suddenly from a dangerous heart rhythm. When it senses a dangerous heart rhythm, an ICD gives the heart an electrical shock. It does this in order to get the heart to beat normally.



See the back page for real-life sizes of the device

Is an ICD right for me?

Your doctor has suggested that you might benefit from having an ICD. This is a big decision. Understanding what to expect after getting an ICD might help you to feel better about your decision. The ICD may not be right for some people. Although this may be hard to think about, other patients like you have wanted to know this information.

While the future is always unpredictable, there is an important trade-off to consider when deciding whether to get an ICD. Consider two possible paths:

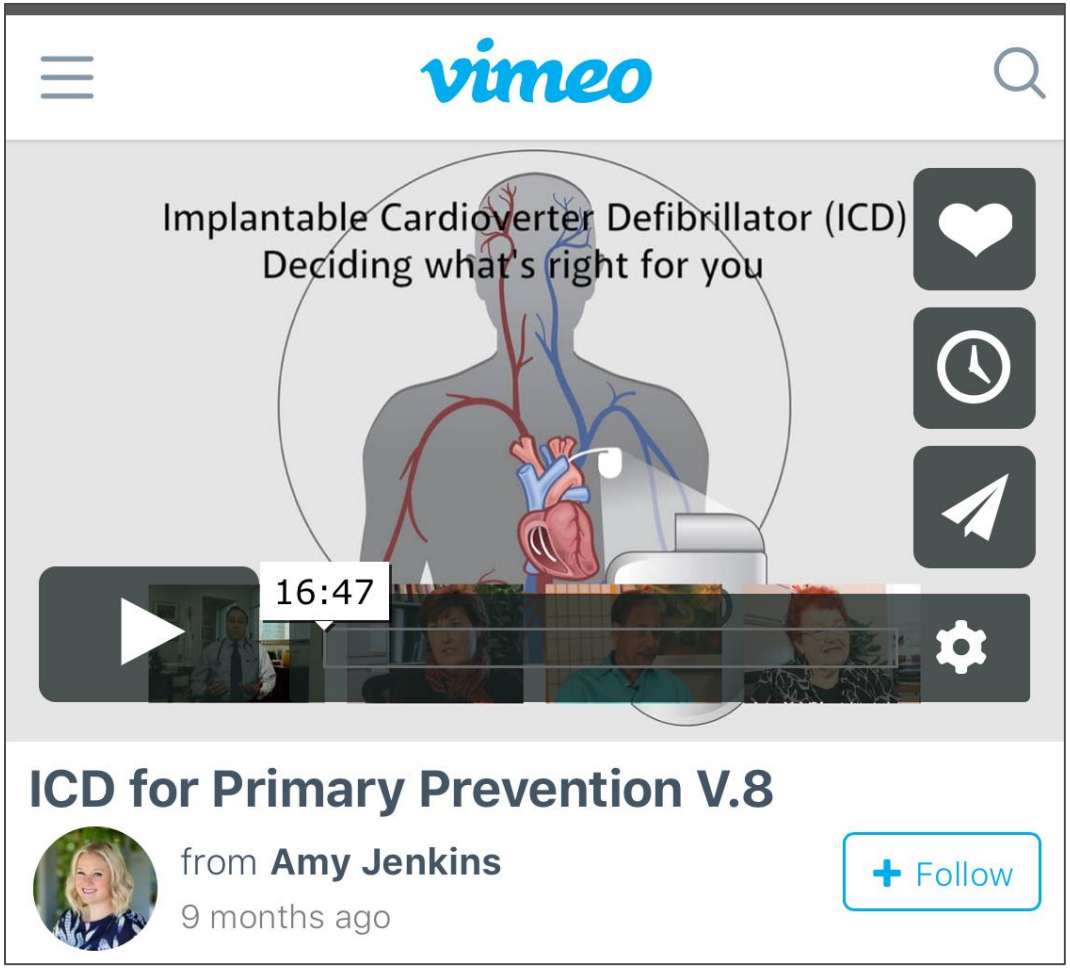
Path 1

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

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

Video


vimeo
Implantable Cardioverter Defibrillator (ICD)
Deciding what's right for you
16:47
ICD for Primary Prevention V.8
from Amy Jenkins
9 months ago
+ Follow

Video

Our Practice – How we use these tools

Our practice is a tertiary referral program spanning much of the Rocky Mountain Region from southern Colorado to northern Montana

- Referral generally starts with an electronic consult request
- Patients come from large distances, we often begin with a phone conversation
- Given the distances, we don't necessarily bring every patient for a clinic visit prior to the procedure

The website and tools give the patients valuable information before they even come to Denver

- Information is balanced and evidence-based
- The format of all the tools is really ideal for patients – easy to understand language, visually appealing
- The case vignettes are highly relatable to patients

Relatively few patients decline ICDs after receiving information via the tools

Patients are better equipped to make decisions, and they feel better about the decisions they make

A Few Thoughts on our Experiences Using SDM

Using decision tools supports, but definitely does not replace our conversations with patients

- SDM goes beyond informed consent in eliciting patient goals/values formally

My visits with patients are even more rewarding

- I have more time to talk about the big picture, and I understand patients' goals/values better
- Patients feel better about their decisions

SDM does not at all prevent making a recommendation to patients

- Sometimes patients make different decisions than I would, and that's OK

A Few More Thoughts

With regard to SDM, we are better off leading than waiting for others to tell us what to do

- Payors and patient groups are increasingly asking for SDM

Tools like these are most useful in the hands of the people who are best able to talk about the procedure – the EP team

- It is a huge win for us and for our patients that HRS and ACC leadership convinced CMS to remove the requirement that the SDM interaction be conducted by an “independent” physician

We need more SDM tools developed by others!

Wrap Up and Summary

Changes to the CMS ICD Coverage Policy

- Updated clinical indications
- Exceptions to the waiting periods
- End of ICD registry requirement
- Shared decision making

Shared Decision Making is now required,
but it is entirely feasible and may help your practice