Implantable Cardioverter-Defibrillators (ICDs): Too Many?

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22-October-2011

INDIANA UNIVERSITY
SCHOOL OF MEDICINE

Presenter Disclosure Information

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Title:

ICDs: Too Many?

Financial Disclosure:

Grants / Research Support: Muscular Dystrophy Association
Speaker's Bureau, Consulting: None

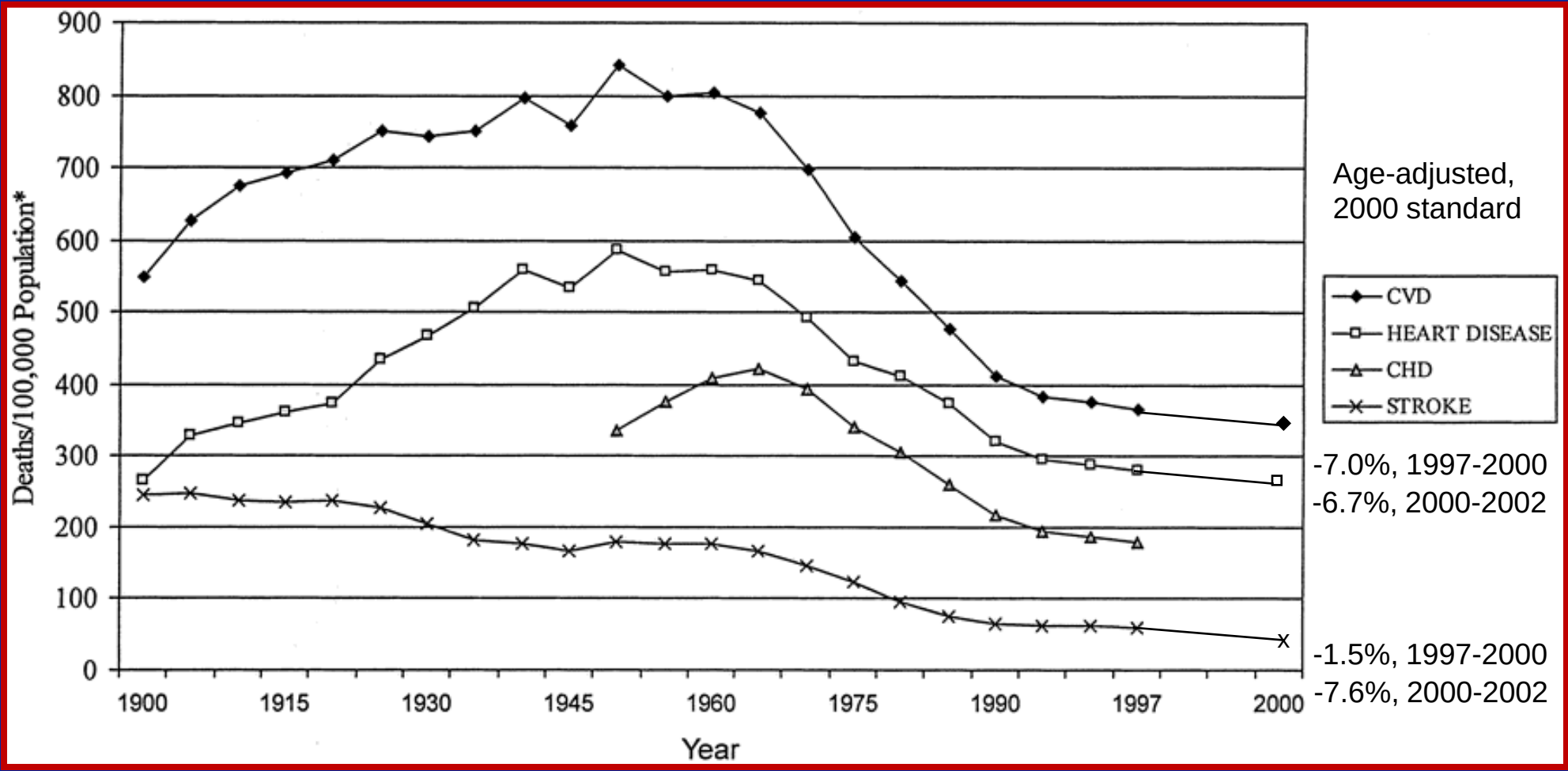
Unlabeled / Unapproved Use Disclosure:

The talk does not contain any unlabeled / unapproved use discussion except to point out others unlabeled uses

Learning Objectives: Too many ICDs?

1. Current status of ICD use. Where are we and how did we get here?
2. Limitations in the prediction of sudden death risk. The problems with “NNT”.
3. Do doctors follow rules? Appropriate use criteria, guideline creep, and ICDs.
4. Super committees, deficits, Medicare / Medicaid: Can we afford primary prevention ICDs?

Current status of ICD use: Where are we and how did we get here?



Circulation 2000;102:3137

Current status of ICD use: Where are we and how did we get here?

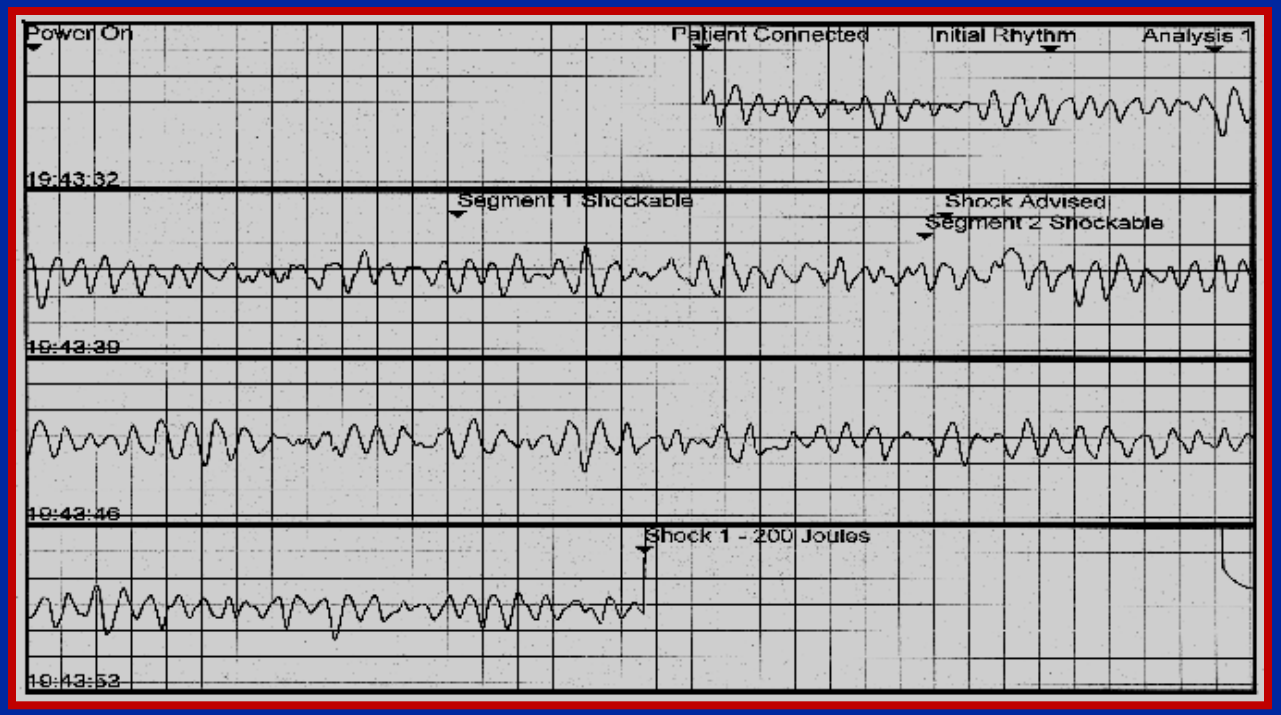
Sudden Cardiac Death (SCD):

Death due to a cardiac cause that occurs within one hour of the onset of symptoms in an individual without a prior condition that would appear fatal (cardiac arrest)

- Up to one-half of all cardiac deaths
- Aborted SCD: interrupted by a therapy
- Out-of-hospital cardiac arrest (OHCA)

Current status of ICD use: Where are we and how did we get here?

Sudden Cardiac Death (SCD):



Ventricular tachycardia (VT) / ventricular fibrillation (VF)

Current status of ICD use: Where are we and how did we get here?

Prevention: ***an action that stops something from happening***

Sudden Death due to ventricular fibrillation in high risk patients:

- **Stop VF from ever occurring (antiarrhythmia drugs)**
- **Treat VF once it occurs thereby preventing death**
  - **Implantable cardioverter-defibrillator (ICD)**
  - **Emergency response network including early defibrillation (AEDs)**

Current status of ICD use: Where are we and how did we get here?

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⬇

Sudden Death due to ventricular fibrillation in high risk patients:

- **Stop VF from ever occurring (antiarrhythmia drugs)** **X**
- **Treat VF once it occurs thereby preventing death**
  - **Implantable cardioverter-defibrillator (ICD)** **+++**
  - **Emergency response network including early defibrillation (AEDs)** **++**

Current status of ICD use: Where are we and how did we get here?

Emergency response network including early defibrillation (AEDs)

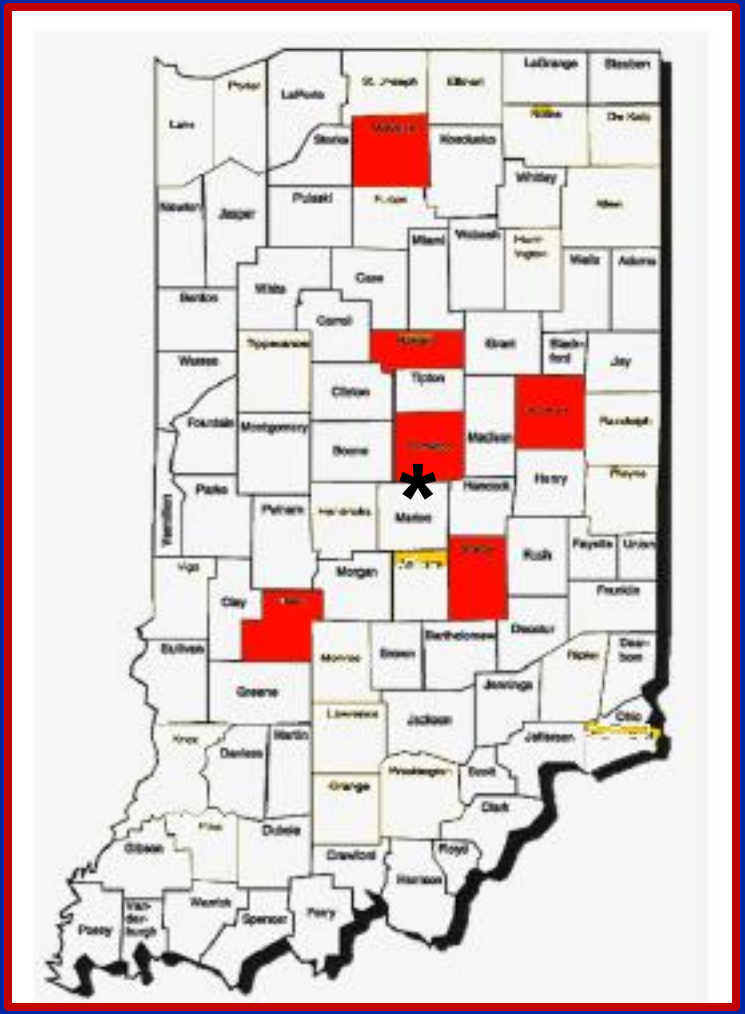
Early access (witnessed)

Early CPR

Early defib

Early advanced care

Current status of ICD use: Where are we and how did we get here?



Parade Study

County	Pop.	Pop. Density (sq. mi.)
Hamilton	154,785	389
Shelby	43,151	105
Delaware	117,625	299
Marshall	45,337	102
Howard	83,586	285
Owen	20,257	53
Total	**464,741**	**200**

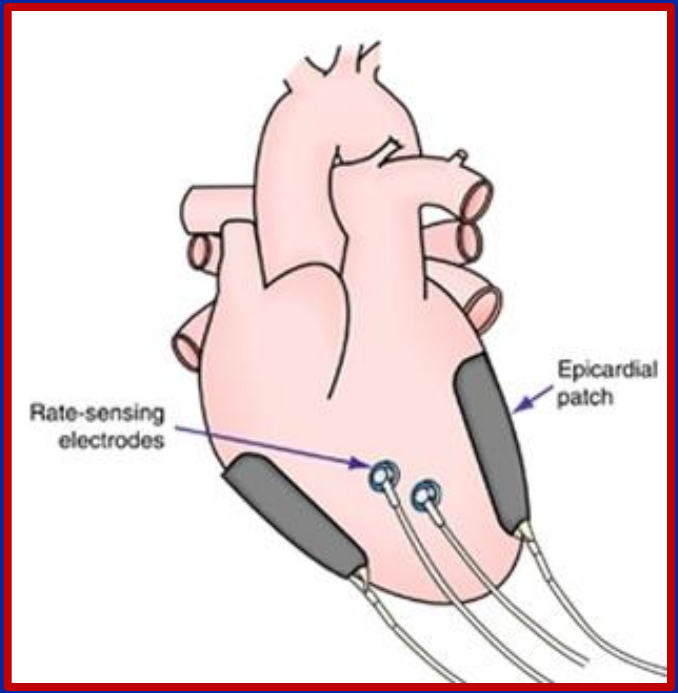
Acad Emerg Med 2001;8:324

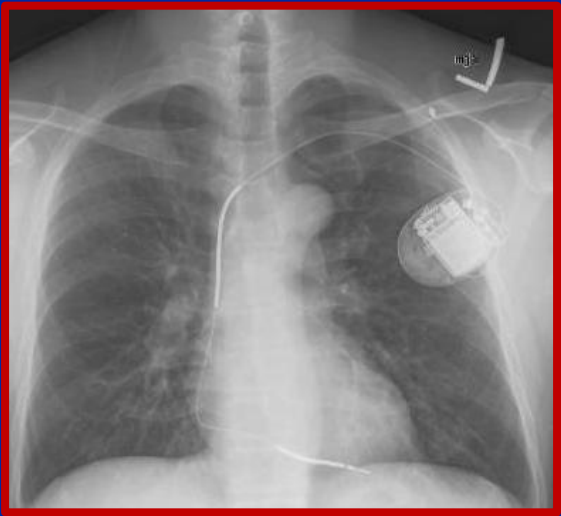
Current status of ICD use: Where are we and how did we get here?

Characteristics- OHCA (resuscitation attempted)	USA-rural (Indiana)
Annual Incidence / 100,000 pop.	42
Male	66 %
Age - years	66
Location - home	75 %
Witnessed	53 %
Bystander CPR	52 %
Initial rhythm – VF	46 %
Survival to hospital discharge VF / (all)	11 % (5 %)

Acad Emerg Med 2001;8:324

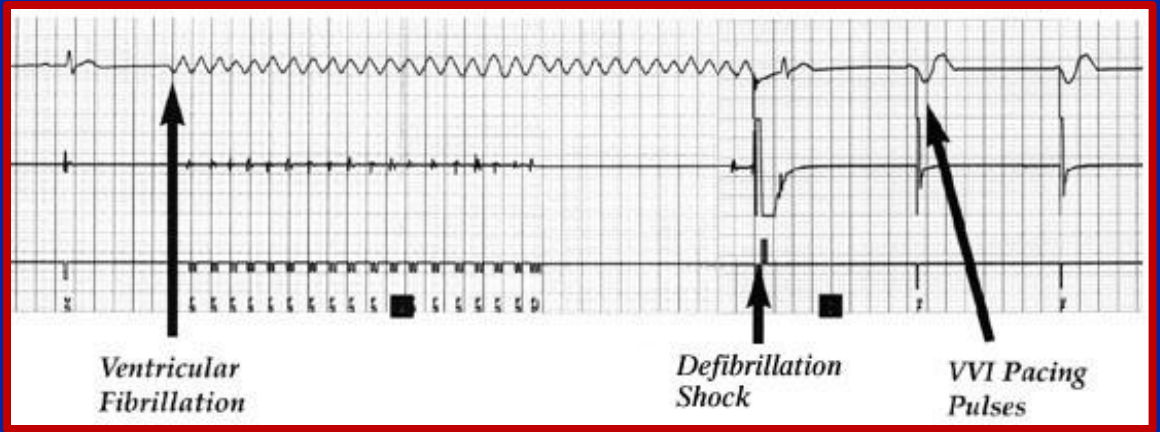
Current status of ICD use: Where are we and how did we get here?





TERMINATION OF MALIGNANT VENTRICULAR ARRHYTHMIAS WITH AN IMPLANTED AUTOMATIC DEFIBRILLATOR IN HUMAN BEINGS

M. Mirowski, M.D., Philip R. Reid, M.D.,



N Engl J Med 1980;303:322

Limitations in the prediction of sudden death risk. The problems with "NNT".

Modern use of ICDs:

- Secondary Prevention – prevent future events in a patient with life- threatening ventricular arrhythmias

- Primary Prevention – prevent future events in a patient with cardiac disease but no life- threatening ventricular arrhythmias

Limitations in the prediction of sudden death risk. The problems with "NNT".

Modern use of ICDs:

20 - 25%

- **Secondary Prevention – prevent future events in a patient with life- threatening ventricular arrhythmias**

75 - 80%

- **Primary Prevention – prevent future events in a patient with cardiac disease but no life- threatening ventricular arrhythmias**

Limitations in the prediction of sudden death risk. The problems with "NNT".

(n)	Entry Criteria (CHD xSCD-Heft)	Follow-up	Mortality-Conventional	Mortality-ICD	NNT
MADIT (196)	EF≤ 0.35, NSVT, Inducible, NS EPS	**27 M**	**38.6%**	**15.8%**	**4.3**
CABG-Patch (900)	EF < 0.36, +SA-ECG, CABG	**32 M**	**20.9%**	**22.6%**	**-**
MUSST (704)	EF≤ 0.40, NSVT, Inducible at EPS	**39 M**	**55% (5 yrs)**	**24% (5 yrs)**	**3.2**
MADIT-II (1232)	EF≤ 0.30	**20 M**	**19.8%**	**14.2%**	**17.9**
COMPANION (1520, 1:2:2)	NYHA Class III, IV CHF, QRS≥ 0.12s	**15 M**	**25.0%**	**16.0%**	**11.1**
SCD-HeFT (2521)	NYHA Class II, III CHF, EF≤ 0.35	**46 M**	**28.8%**	**22.0%**	**14.6**

N Engl J Med 1996;335:1933
N Engl J Med 1997;337:1569
N Engl J Med 1999;341:1882
N Engl J Med 2002;346:877
J Am Coll Cardiol 2003;41:1707
N Engl J Med 2005;352:225

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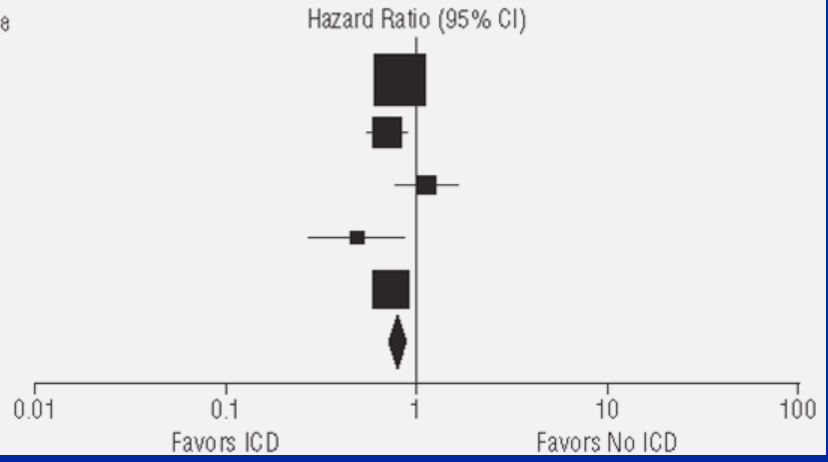
Limitations in the prediction of sudden death risk. The problems with "NNT".

1. NNT = 1 / absolute mortality benefit
2. A limitation of "imperfect" risk factors and therapy
3. Up to 18 ICDs to save 1 life – over a benefit period that may last as short as 20 months – Too many?
4. Exposes those not "needing" the ICD to all the risks without any potential benefit
5. Marked increase in overall cost to Medicare / Medicaid, private insurers, individuals
6. Solution – continue to evaluate risk factors, therapy, and populations for improved predictive power

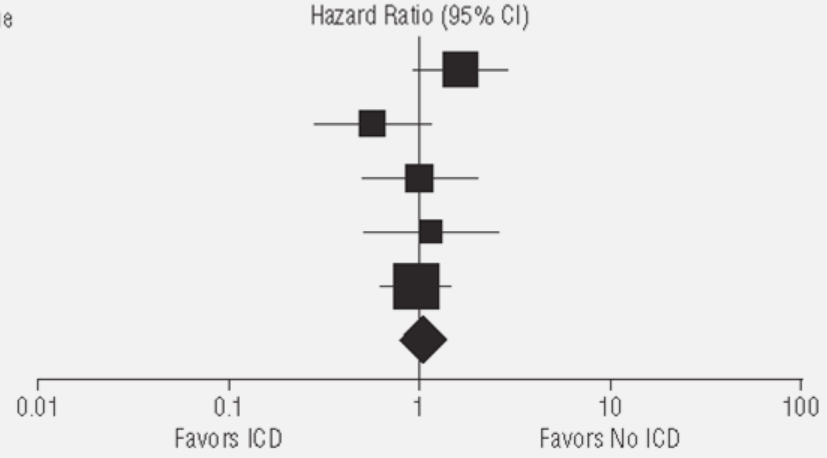
Limitations in the prediction of sudden death risk. The problems with "NNT".

Study Name	Hazard Ratio	(95% CI)	No. of Men	*P* Value
MUSTT	0.83	(0.71-0.97)	636	.02
MADIT II	0.66	(0.48-0.91)	1040	.008
DINAMIT	1.14	(0.77-1.69)	514	.51
DEFINITE	0.49	(0.27-0.89)	326	.02
SCD-HeFT	0.71	(0.57-0.88)	1294	.004
Combined	**0.78**	**(0.70-0.87)**	**3810**	**<.001**



Men

Study Name	Hazard Ratio	(95% CI)	No. of Women	*P* Value
MUSTT	1.64	(0.92-2.92)	68	.09
MADIT II	0.57	(0.28-1.18)	192	.12
DINAMIT	1.00	(0.49-2.04)	160	>.99
DEFINITE	1.14	(0.50-2.64)	132	.76
SCD-HeFT	0.90	(0.56-1.43)	382	.66
Combined	**1.01**	**(0.76-1.33)**	**934**	**.95**



Women

Arch Intern Med 2009;169:1500

Do doctors follow rules? Appropriate use criteria, guideline creep, and ICDs.

Medical Guidelines (clinical practice guidelines)

- A document with an aim to guide decisions regarding diagnosis and management of health care problems
- Increasingly evidence-based rather than consensus-based
- Define care for the “average” patient and not for all patients
- Uses
  - standardize care (evaluative role)
  - raise the level of care
  - reduce risk at all levels
  - payment / coverage decisions (civil investigations?)

Do doctors follow rules? Appropriate use criteria, guideline creep, and ICDs.

January 4, 2011

Many Defibrillators Implanted Unnecessarily, Study Says

By DENISE GRADY

Doctors are implanting high-tech heart devices in thousands of people who probably do not need them, a new study finds. The procedures cost more than $35,000, involve surgery and anesthesia, and may unnecessarily harm some patients.

Do doctors follow rules? Appropriate use criteria, guideline creep, and ICDs.

Non–Evidence-Based ICD Implantations in the United States

All patients included in this analysis had a prior MI and left ventricular ejection fraction of 30% or lower, or prior congestive heart failure and left ventricular ejection fraction of 35% or lower. Patients were classified as receiving a non–evidence-based ICD implant if they met any of the following criteria: (1) had an MI within 40 days before ICD implantation; (2) had CABG surgery within 3 months before ICD implantation; (3) had NYHA class IV symptoms; or (4) had newly diagnosed heart failure at the time of ICD implantation (a patient could meet >1 criterion). Patients were classified as receiving an evidence-based ICD implant if they met none of these criteria.

Non–Evidence-Based (n = 25 145)	Evidence-Based (n = 86 562)

No. (%) of Patients Who Received Non–Evidence-Based ICD[a]			
MI Within 40 d (n = 9257)	CABG Within 3 mo (n = 814)	NYHA Class IV Symptoms (n = 3022)	Newly Diagnosed Heart Failure (n = 15 604)

ICD Implant, No. (%) [95% CI]	
Non–Evidence-Based (n = 25 145)	Evidence-Based (n = 86 562)
813 (3.23) [3.01-3.45]	2085 (2.41) [2.31-2.51]

J Am Med Assoc 2011;305:43

Do doctors follow rules? Appropriate use criteria, guideline creep, and ICDs.

Heart Rhythm Society℠

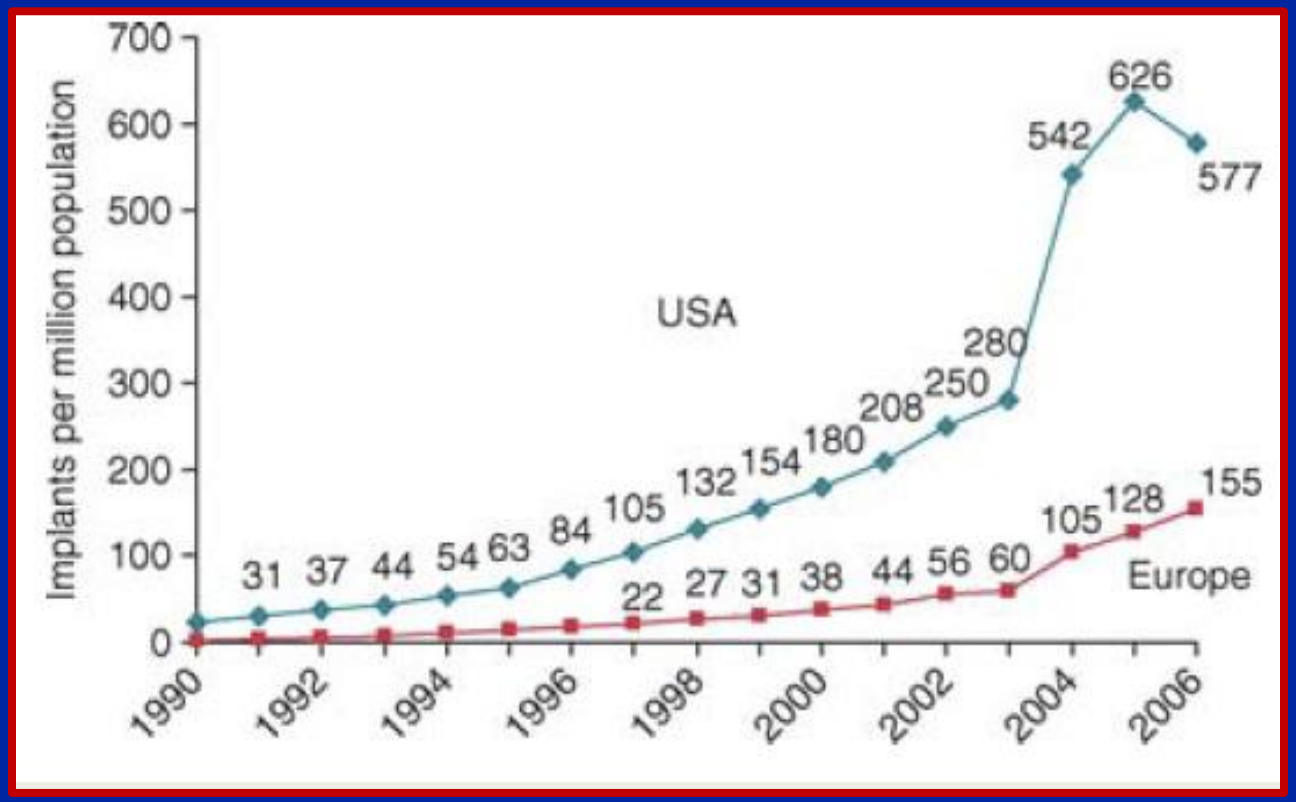
MEMBER ADVISORY

RECOVERY AUDIT CONTRACTOR (RAC) PROGRAM

"The RAC"

I confess, I confess –
The MI was only 39 days
before the defibrillator!

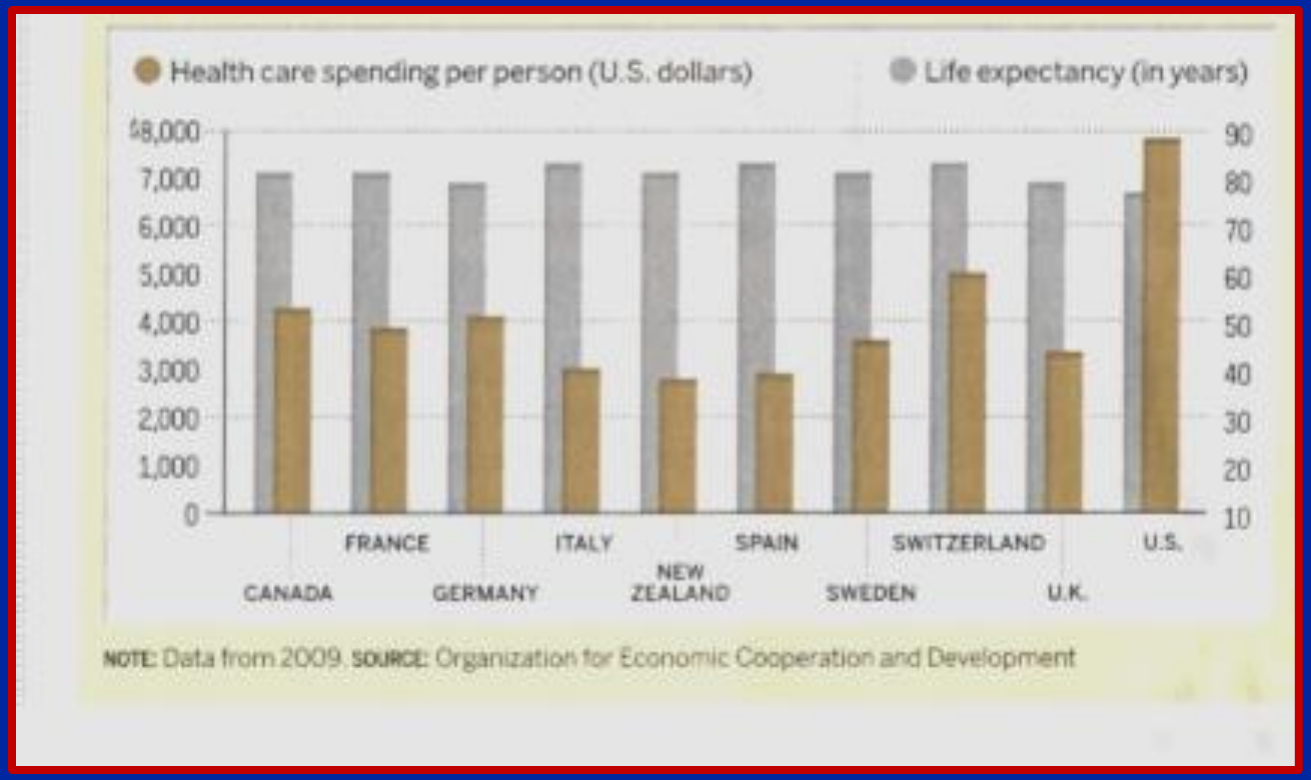
Super committees, deficits, Medicare / Medicaid: Can we afford primary prevention ICDs?



Europace 2010;12:1063

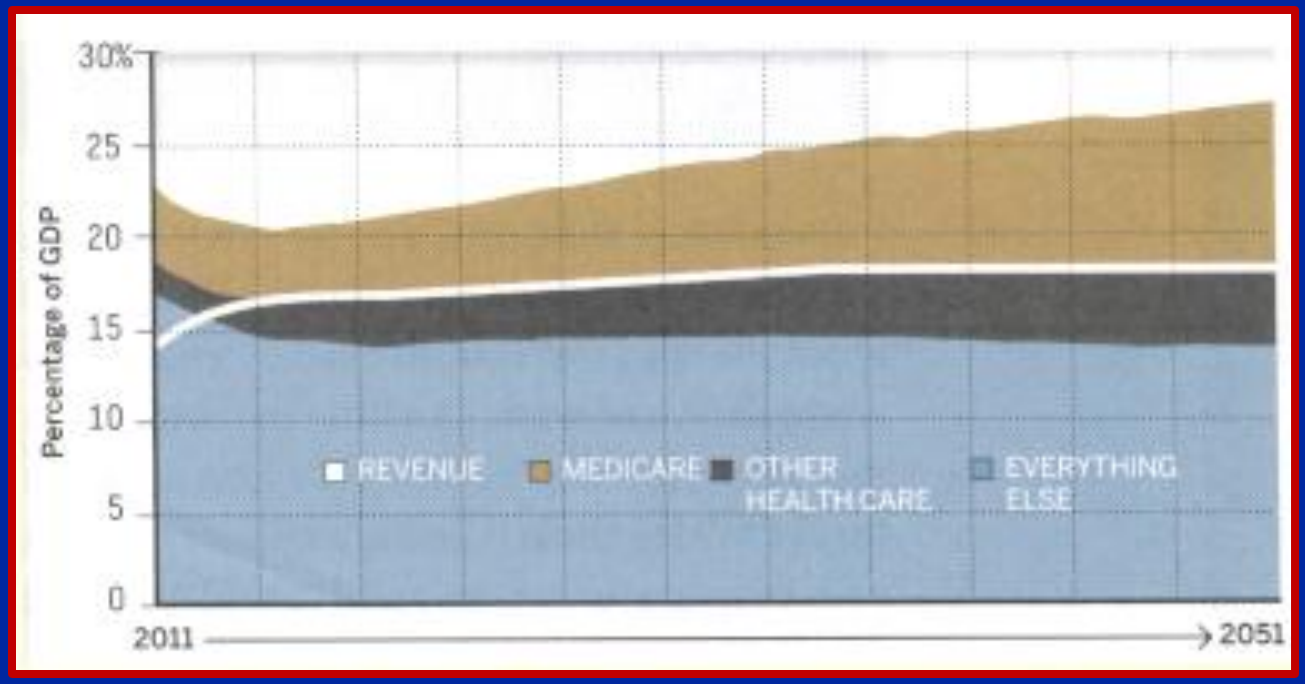
Indiana University Health

Super committees, deficits, Medicare / Medicaid: Can we afford primary prevention ICDs?



Organization for Economic Cooperation and Development

Super committees, deficits, Medicare / Medicaid: Can we afford primary prevention ICDs?



Organization for Economic Cooperation and Development

ICDs: Too Many?

Conclusions

1. ICDs are effective therapy for preventing sudden cardiac death due to arrhythmias.
2. Using current primary prevention criteria, up to 17 ICDs need to be implanted to save 1 life.
3. Some large populations (women) have limited clinical evidence for benefit from primary prevention ICDs.
4. There is data that up to 22% of primary prevention ICDs are not being implanted under appropriate use criteria.
5. Economic realities in the U.S. will make continued use of “cost-effective” but costly therapies such as ICDs open to increasing scrutiny.

ICDs: Too Many?

Questions / Comments