Shared Decision Making for PFO Closure: How to Make the FDA Requirements Work (and, are they requirements?)

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Grant/Research Support	None
Consulting Fees/Honoraria	Boston Scientific, Edwards Lifesciences
Major Stock Shareholder/Equity	None
Royalty Income	None
Ownership/Founder	None
Intellectual Property Rights	None
Other Financial Benefit	None

Agenda

- FDA mandates age, neurology and cardiology assessment of stroke etiology, and device
- Recommendation for shared decision making in IFU
- Controversial: is PFO closure in cryptogenic stroke a preference-sensitive decision?

Re: P120021
Trade/Device Name: AMPLATZER PFO Occluder
Filed: November 30, 2012
Amended: August 12, 2013, September 9, 2013, February 26, 2014, April 28, 2014, July 1, 2014, February 27, 2015, September 17, 2015, October 8, 2015
Product Code: MLV

Dear Rashmi Bhushan:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the AMPLATZER PFO Occluder. This device is indicated for percutaneous transcatheter closure of a patent foramen ovale (PFO) to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

AMPLATZER™

PFO Occluder

Instructions for Use

Device Description

The AMPLATZER™ PFO Occluder (Figure 1) is a self-expandable, double-disc device made from a Niti
discs are linked together by a short connecting waist. In order to increase its closing ability, the discs c
fabric. The polyester fabric is securely sewn to each disc by a polyester thread.

The device has radiopaque marker bands on the distal and proximal ends of the device. The device cont
the proximal end to facilitate delivery and deployment. The device is sterilized with ethylene oxide.

Amplatzer PFO Occluder IFU

Patient Selection for Treatment

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decision-makin
AMPLATZER™
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l the safety and
A shared
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..recommended **that the medical team (neurologist and cardiologist) and the patient engage in a shared decision-making process…taking into account the patient's values and preferences**

It is recommende
process where th
taking into accour
in the Clinical Studies section of the Instructions for Use.

ecision-making
discussed while
Patient Guide and

FDA requirements for PFO closure

- Ages 18-60 years
- *Cryptogenic stroke* determined by neurologist and cardiologist
- Amplatzer PFO Occluder device

Shared decision making in PFO closure

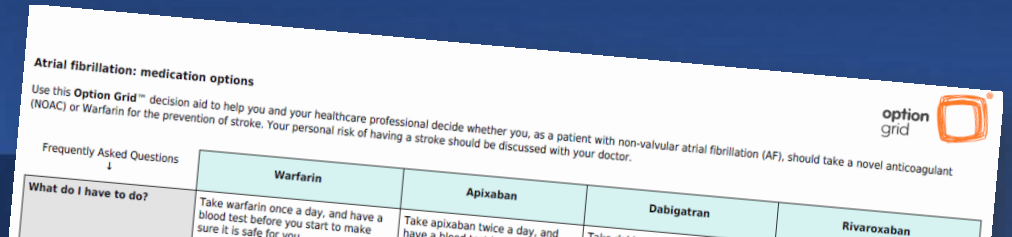
- "(I)t is essential that we engage in shared decision making with neurologists…"
- "Team-based, multidisciplinary, Bayesian clinical judgment on an individual basis still remains the core of decision-making."
- "(T)he medical team and the patient (discuss) risks and benefits…while taking into account the patient's values and preferences."

Poulin and Kavinsky. *Cardiac Interventions Today.* May/June 2017;
Pristipino et al. *Catheterization and Cardiovascular Interventions* 2013;
Instructions for Use, Amplatzer PFO Occluder

Common myths

- The decision is shared between the two subspecialists- and a recommendation is made
- Impossible- patients always ask me what I would do
- We already do it perfectly (or, at least, our patients are happy)
- It's easy! Just give the patient a pamphlet to review

Legare, Thompson-Leduc. Patient Educ Couns 2014



Atrial fibrillation: medication options

Use this **Option Grid**™ decision aid to help you and your healthcare professional decide whether you, as a patient with non-valvular atrial fibrillation (AF), should take a novel anticoagulant (NOAC) or Warfarin for the prevention of stroke. Your personal risk of having a stroke should be discussed with your doctor.

option grid

Frequently Asked Questions ↓	Warfarin	Apixaban	Dabigatran	Rivaroxaban
What do I have to do?	Take warfarin once a day, and have a blood test before you start to make sure it is safe for you	Take apixaban twice a day, and		

Patient materials- 8 pages

Patent Foramen Ovale Closure with the AMPLATZER™ PFO Occluder

Information Guide for Patients and Caregivers

This guide is for patients who have previously suffered a stroke that was from an unknown cause (also called “cryptogenic stroke”) and also have an opening between the two upper chambers of the heart that never fully closed after birth. The medical term for this opening in the heart is a patent foramen ovale (PFO). The information in this patient guide will help you learn more about cryptogenic stroke, PFO, and treatments to reduce the chance of having another stroke. Be sure to ask your physician to explain all of your treatment options and risks and benefits of each.

Review

Knowledge is *not* power for patients: A systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making

Natalie Joseph-Williams [a,*], Glyn Elwyn [b], Adrian Edwards [a]

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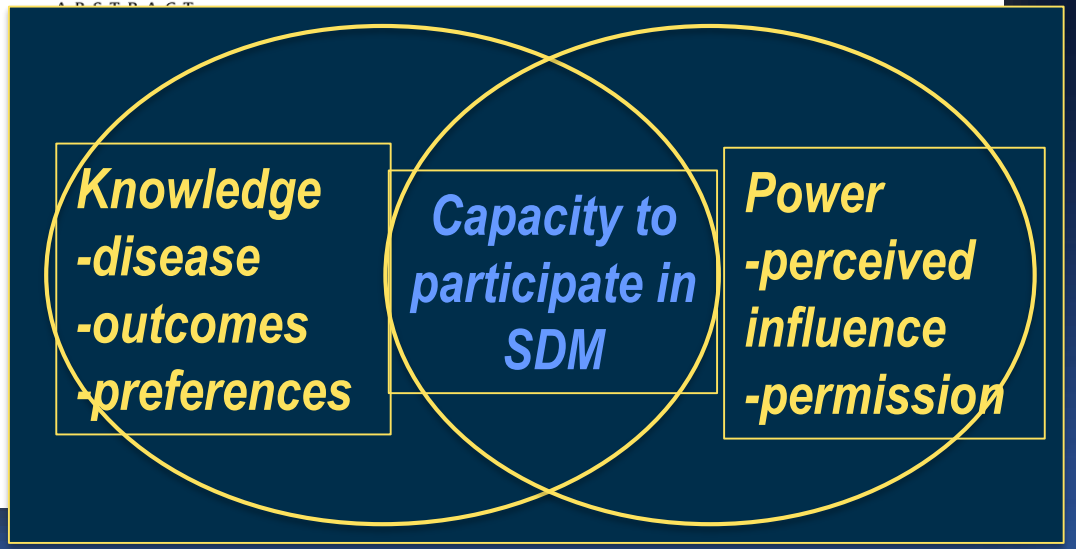
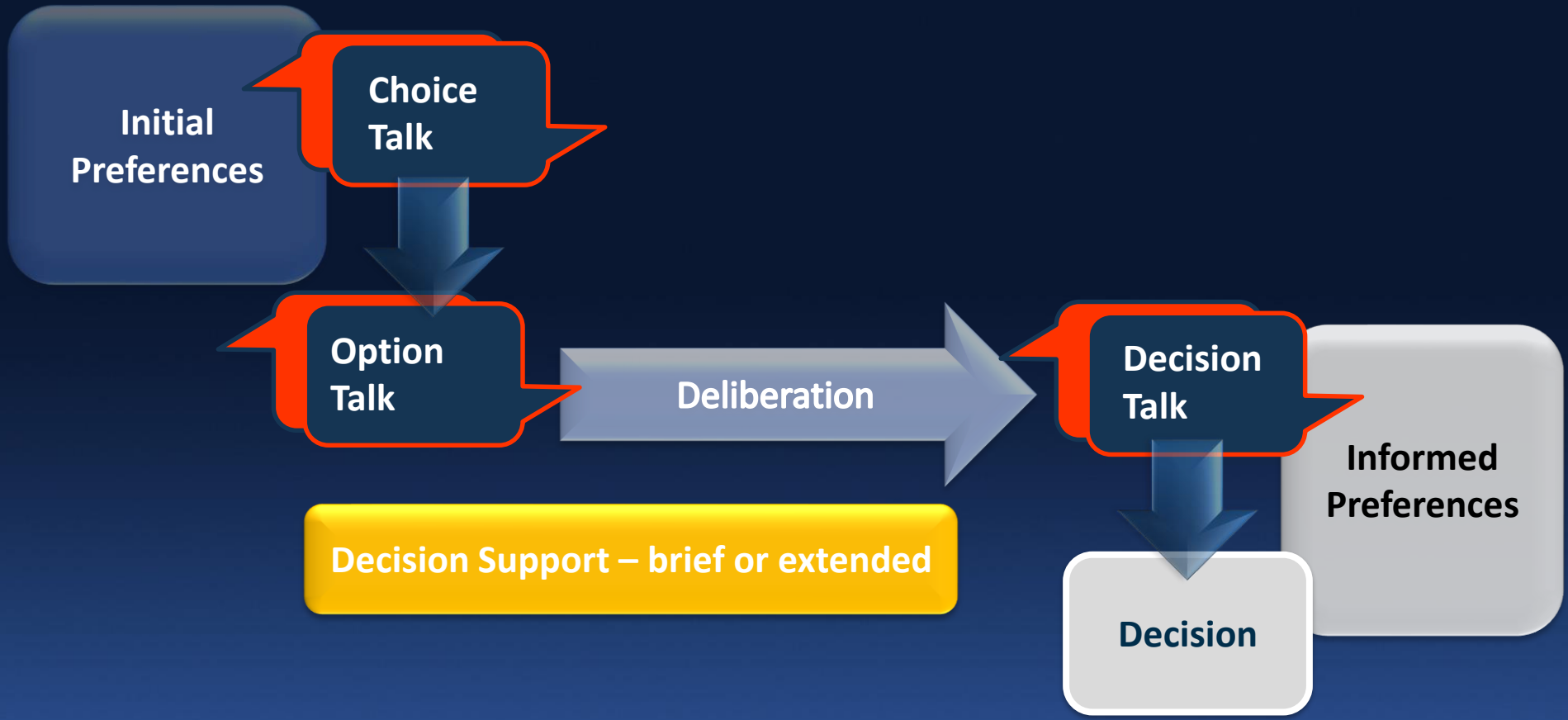
ARTICLE INFO

Article history:
Received 8 August 2013
Received in revised form 16 October 2013
Accepted 30 October 2013

Keywords:
Shared decision making
Implementation
Patient-reported barriers/facilitators
Patient-centered healthcare



“At one year from now, what are the things that are most important?”



Adapted from Joseph-Williams et al. BMJ 2017;357:bmj.j1744

Who mandates a shared decision making approach?

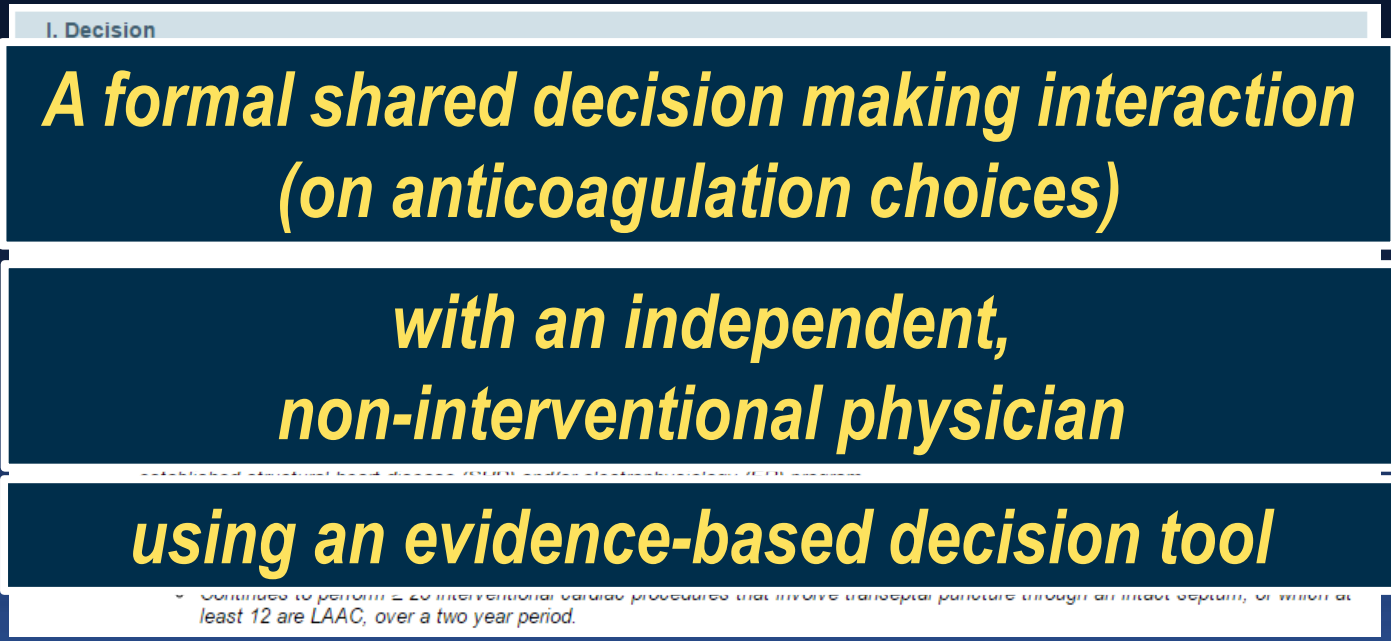
Preference-sensitive decisions

- More than one reasonable option exists
- Uncertainty exists in evidence
- Patient preferences vary (i.e. geographically) or are distinct from healthcare professional preferences

CMS defines preference-sensitive conditions

- **"(A) medical condition in which the clinical evidence *does not clearly* support one treatment option, and the appropriate course of treatment depends on the values or preferences of the beneficiary regarding… the scientific evidence for each treatment option."**

Medicare National Coverage Decision for left atrial appendage closure

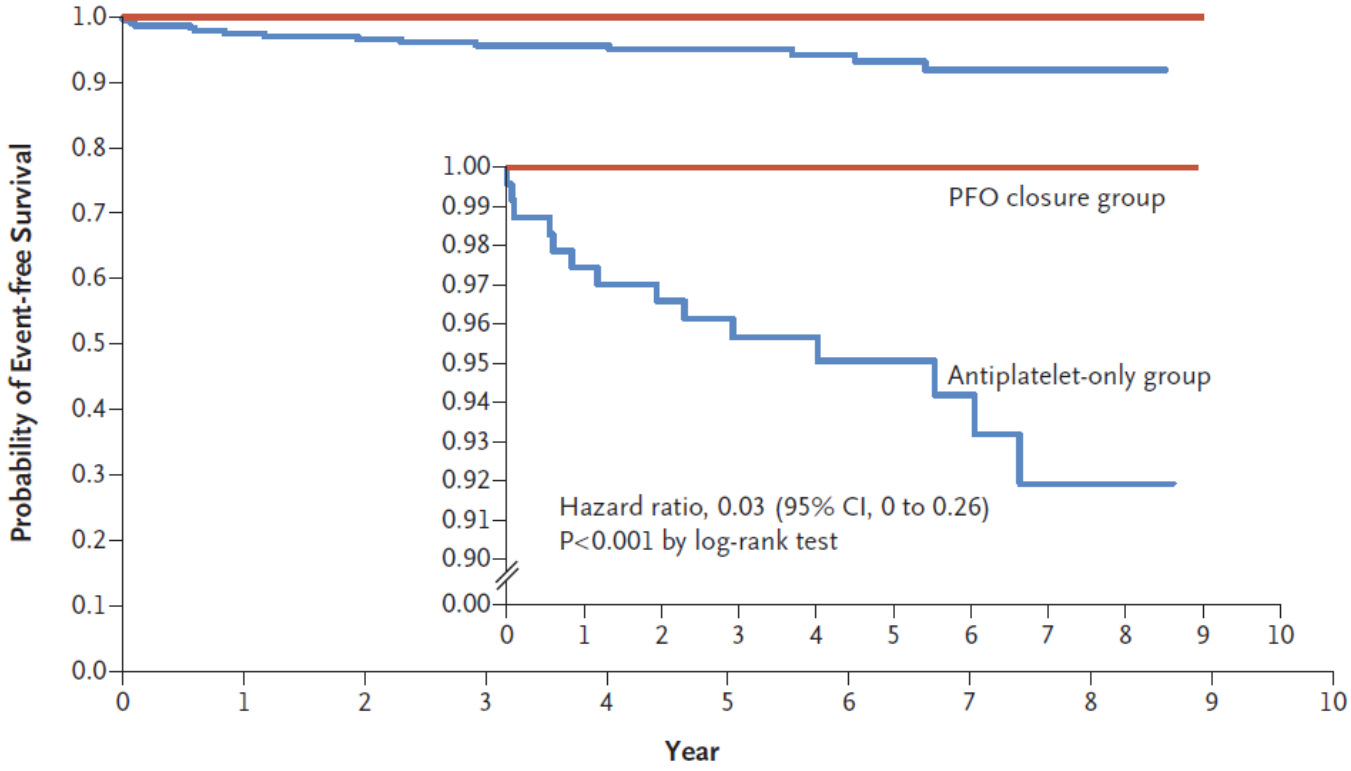


Probability of Freedom from Recurrent Stroke

No. at Risk
PFO closure group
Antiplatelet-o group

Figure 1. Pro
Stroke.

A



No. at Risk											
PFO closure group	238	238	232	200	179	141	99	64	20	0	0
Antiplatelet-only group	235	229	223	198	160	130	96	55	19	0	0

N
P
M

Figure 2. Kaplan–Meier Cumulative Estimates of Probability of Stroke in the PFO Closure Group versus the Antiplatelet-Only Group.

Product labeling: patient handout

50% less strokes with the device compared to medication

Rate
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of the RESPECT Trial were analyzed at two time
e follow-up was about 3 years, showed that the
vith the AMPLATZER™ PFO Occluder plus blood-
cation alone. However, it is important to
either treatment group. The analysis suggested
that if 1000 patients were treated with PFO closure, about 6 of these patients would have a stoke after
1 year compared with about 12 o

Of 1000 people, there were 6 less strokes with the device compared to medication

The second analysis, performed w
patients were treated with PFO cl
compared with about 10 out of 1

Conclusion

- FDA mandates age, neurology and cardiology assessment of stroke etiology, and device
- Recommendation for shared decision making in IFU
- Controversial: is PFO closure in cryptogenic stroke a preference-sensitive decision?