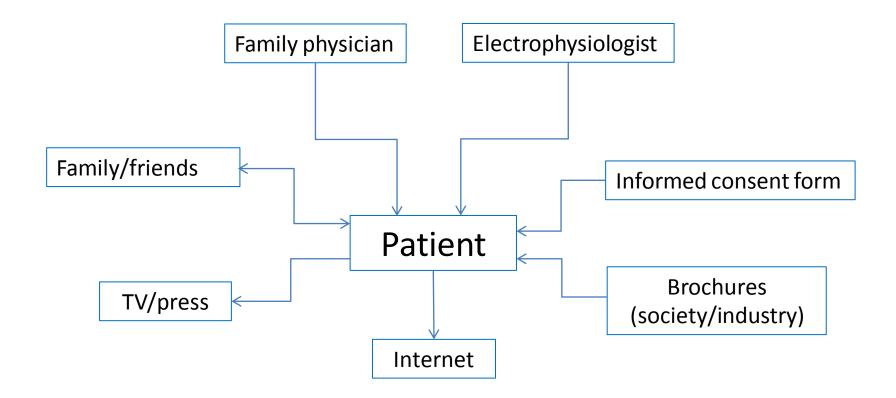
# Managing information flow regarding EP for patients

Haran Burri Associate Professor University Hospital of Geneva



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# **Information flow**



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Maps Vidéos	Electrophysiology study - Wikipedia, the free encyclopedia en.wikipedia.org/wiki/Electrophysiology_study - Traduire cette page An electrophysiology study (EP test or EP study) is a minimally invasive procedure	
Actualités	which tests the electrical conduction system of the heart to assess the → Preparation - Procedure - Recovery - See also	
Shopping Plus	The Electrophysiology Study heartdisease.about.com/od//a/EPStudy.htm - Traduire cette page 13 Nov 2011 – If you have an EP study, you will be brought to the electrophysiology	
Genève Changer le lieu	Iaboratory (a specialized catheterization laboratory) and you will lie down Intracardiac electrophysiology study (EPS): MedlinePlus Medical www.nlm.nih.gov/medlineplus/ency//003867.ht Traduire cette page	
Le Web Pages en français	Intracardiac <b>electrophysiology study</b> (EPS) is a test to look at the heart's electrical function. It allows doctors to check for abnormal heartbeats or heart rhythms.	
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The Free Encyclopedia

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### Electrophysiology study

From Wikipedia, the free encyclopedia

An electrophysiology study (EP test or EP study) is a minimally invasive procedure which tests the electrical conduction system of conduction pathways of the heart. During EPS, sinus rhythm as well as supraventricular and ventricular arrhythmias of baseline card investigate the cause, location of origin, and best treatment for various abnormal heart rhythms. This type of study is performed by a catheters situated within the heart through a vein or artery.

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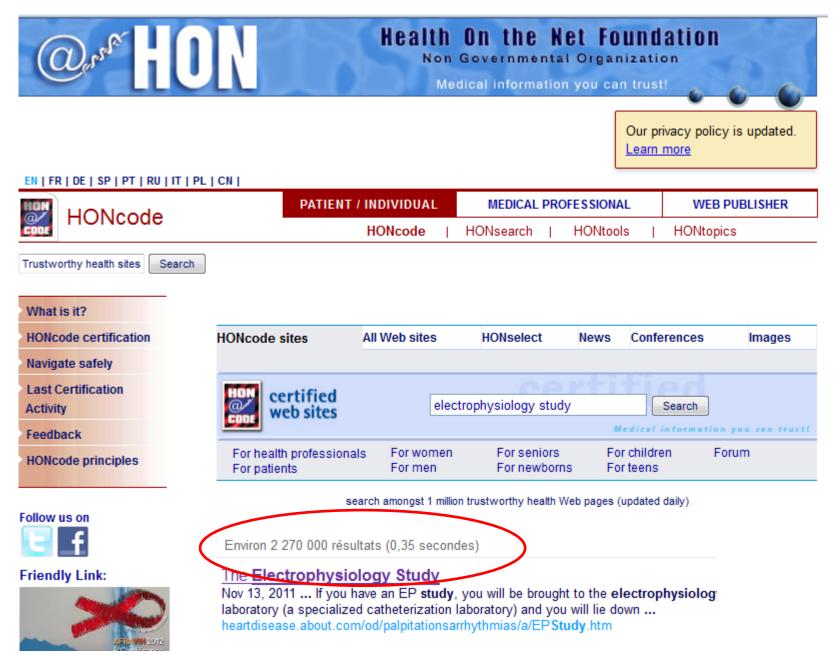
#### Preparation

It is important for patients not to eat or drink for up to 12 hours before the procedure. This is to prevent vomiting, which can result in insertion site of the catheter. Failure to follow this simple preparation may result in dangerous consequences. Generally small amou the exam. Patients should try to schedule the exam at a time when they will be having symptoms and will not need to drive for 2 to 2

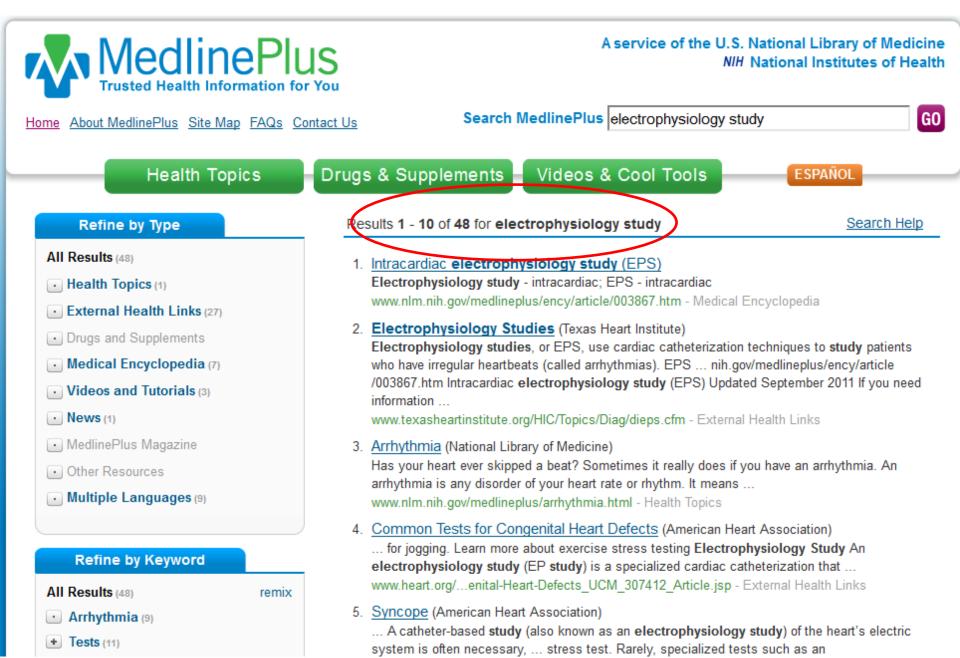
#### Procedure

This procedure is performed in a cath lab which is a specially equipped operating room. More modern cath labs contain a video X-ray diameter) for manipulating the electrodes, in addition to other necessary equipment.

# www.hon.ch



# http://www.nlm.nih.gov/medlineplus/medlineplus.html

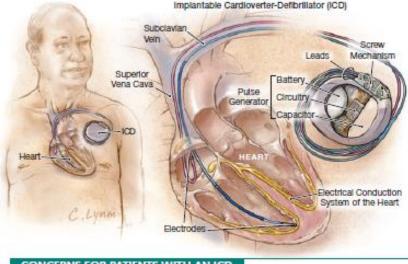


# Implantable Cardioverter-Defibrillators

Persons who have cardiac arrhythmias (abnormal heart rhythms) may need an electrical shock to restore a normal heart rhythm, particularly if the abnormal rhythm is ventricular fibrillation or ventricular tachycardia (rapid but ineffective contractions of the main heart muscle). This can be done from outside the chest (usually in an emergency situation) using defibrillator paddles that deliver an electrical shock or by an automated external defibrillator (AED), a device now available in many public buildings and airports that can detect and correct dangerous arrhythmias. Implantable cardioverter-defibrillators (ICDs) allow for automated detection of arrhythmias. Automated treatment occurs either by delivery of a high-energy electric shock to the heart muscle (called defibrillation or cardioversion) or by repeated low-energy signals (cardiac pacing) to correct the abnormal rhythm. The May 2, 2007, issue of JAMA includes an article about the decision to implant a cardioverter-defibrillator. This Patient Page is based on one previously published in the April 26, 2006, issue of JAMA.

#### HOW DO ICDs WORK?

Electrodes are placed into the heart via one of the large veins in the chest. This is done in an operating room or cardiac laboratory, using sterile techniques and local anesthetic. After successful electrode placement and testing, a small generator (circuitry, capacitor, and battery) is placed under the skin in the chest. The device monitors heart rhythm, and when an abnormality is sensed, the ICD automatically restores a healthy heart rhythm, either by delivering a shock to the heart muscle or by cardiac pacing if the heart rate is too slow or too fast. The device records when abnormal heart rhythms occur and when shocks are delivered.



#### CONCERNS FOR PATIENTS WITH AN ICD

- Careful monitoring of the functioning of the ICD is essential.
- · Persons with an ICD must take precautions to avoid electrical interference, such as

#### REASONS FOR ICD PLACEMENT

HEART DISEASE

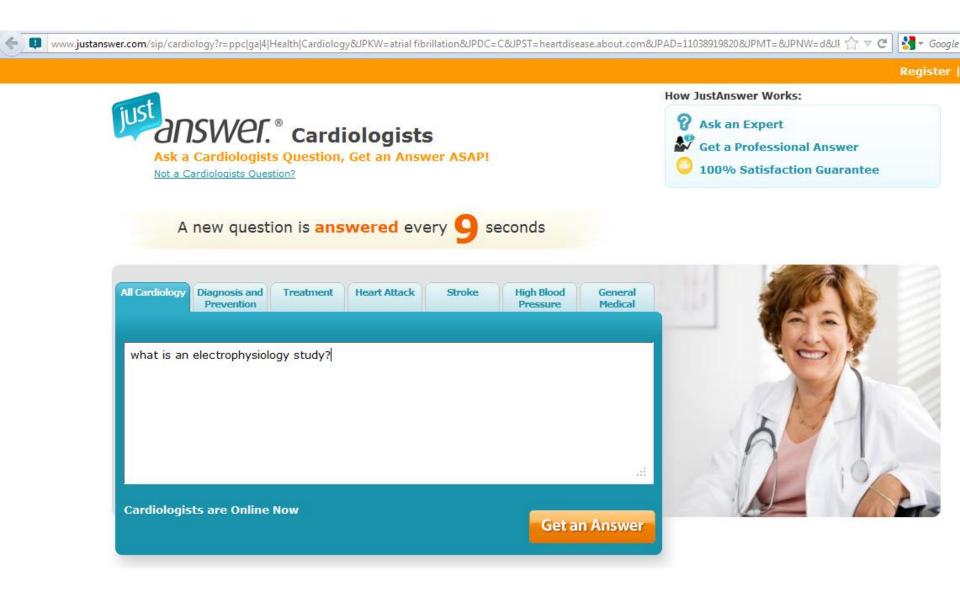
- Serious arrhythmias not controlled by medication
- Risk of arrhythmias due to underlying heart disease
- Hereditary predisposition to dangerous arrhythmias

#### FOR MORE INFORMATION

- American Heart Association www.americanheart.org
- National Heart, Lung, and Blood Institute www.nhlbi.nih.gov
- American College of Cardiology
   Www.acc.org

#### INFORM YOURSELF

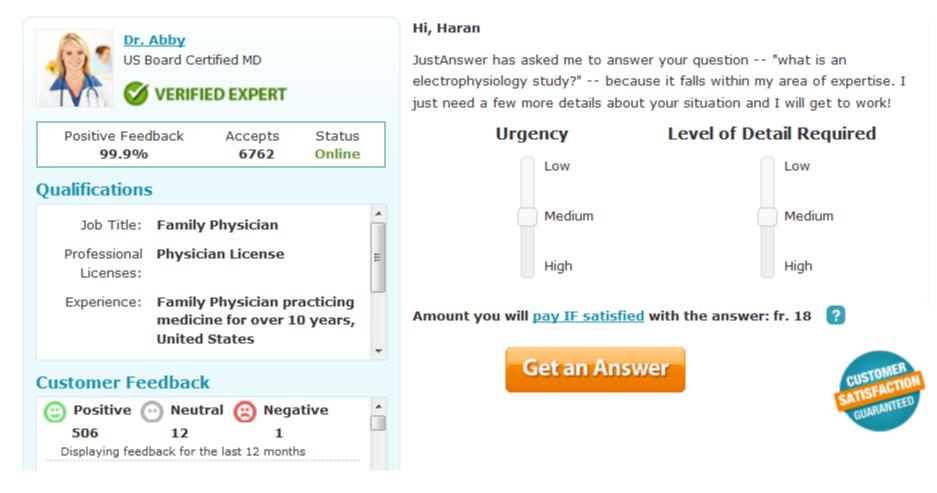
To find this and previous JAMA Patient Pages, go to the Patient Page link on JAMA's Web site at www.jama.com. Many are available in English and Spanish. A Patient Page on pacemakers was published in the August 15, 2001, issue; one on cardiomyopathy was published in the December 15, 2004, issue; and one on cardiac arrest was published in the January 4, 2006, issue.





Ask a Cardiology Question, Get an Answer ASAP!

## A Cardiologist wants to answer your question





Ask a Cardiology Question, Get an Answer ASAP!

# **Confirm your appointment with a Cardiologist**

Place your deposit of Fr. 27 and get your answer from a Live Expert. Your question: "what is an electrophysiology study?"



TVO	by e Feedback: 99.9 % ed Answers: 6766		You have an Appointment! Your Expert is waiting.
Deposit Method	Visa 💌 VISA	Maximum PayPal	
Card Number			
Expiration Date	Month 💌 Year 💌		
Your information	on is secure. Privacy & Securit	tv	

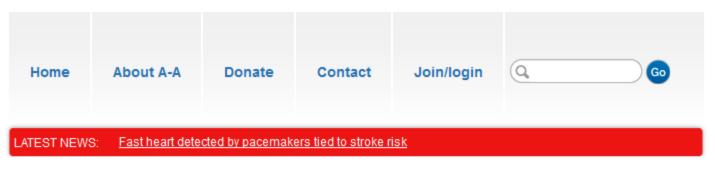
## **Click "Continue" to confirm your appointment**

By clicking "Continue" you indicate that you agree to the terms of service and are 18+ years old

### http://www.heartrhythmcharity.org.uk/



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- » What is an Arrhythmia
- » Patient Information
- » FAQs
- » Treatment Options
- » Diagnostic Tools
- » Living with an Arrhythmia
- » News Archive
- » Patient Groups
- » Patient Stories
- » NSF Chapter 8
- » International Patient Information
- 🔶 Medical Area
- News & Events
- Projects & Campaigns



You Are Here: Home » Patient Area » Patient Information

### **Patient Information**

These information booklets are available in adobe PDF format, the latest adobe reader is available here.

- \*NEW\* A-A Policy Article (Information Sheet)
- Atrial Fibrillation (Information Sheet)
- Bradycardia (Information Sheet)
- Brugada Syndrome (Information Sheet)
- <u>Catheter Ablation (Information Sheet)</u>
- CRT/ICD (Information Sheet)
- CRT/Pacemaker (Information Sheet)
- \*NEW\* Department of Health White Paper Equity and Excellence: Liberating the NHS (Information Sheet)
- Drug Treatments (Information Sheet)
- EPS Studies (Information Sheet)
- Fundraising Booklet



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LATEST NEWS: Heart screenings increasingly vital for student athletes								

You Are Here: Home » Patient Area » International Patient Information

#### **International Patient Information**

Here you can access information for patients prepared with the guidance of the International Medical Advisory Committee of Arrhythmia Alliance. A range of fact sheets are available to provide you with support and information on your diagnosis and treatment.



- Información para pacientes con DAI/ ICD Patient Information
- Información para pacientes con marcapasos/ Pacemaker Booklet

Deutsch/German

- ICD Patienteninformation/ ICD Patient Information
- Herzschrittmacher Patienteninformation/ Pacemaker Booklet
- Kennen Sie Ihren Puls Pulse Check-Führer/ Pulse Check Guide



### http://www.hrsonline.org/PatientInfo/

rhythm) disorders.

Resource Center

SCA 360



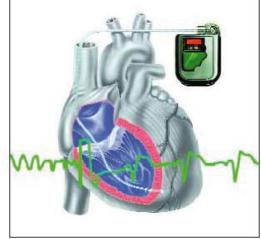
Although generalized and not intended to cover all aspects of any medical condition, a wide variety of information is available to you. Get started with the "quick links" above or the topic areas below to begin learning more.

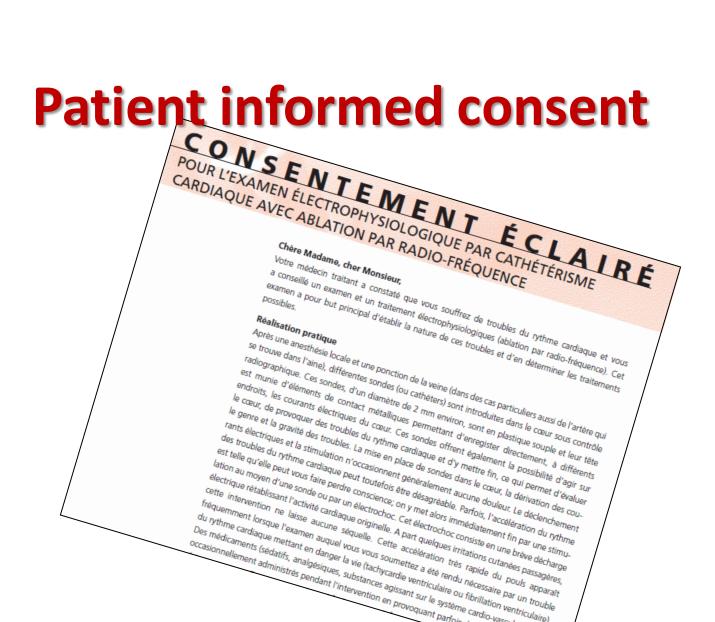




#### Der implantierbare Defibrillator

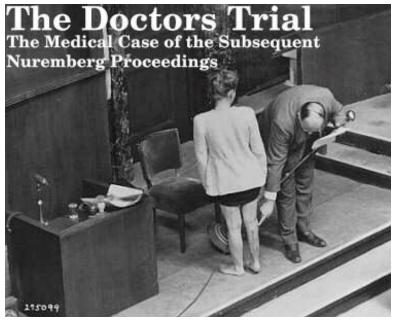
Patienteninformation





# **History of informed consent**

- Simple consent to medical treatment well established before World War II
- "every human being of adult years and sound mind has a right to determine what shall be done with his own body." Schloendorff v Society of New York Hospital, 105 NE 92 (NY 1914)
- Requirement of international law since the Nuremberg "Doctor trial" of Nazi physicians in 1946



# **Informed consent**

- <u>Aim</u>: Promote patient autonomy in medical decision-making
- <u>Physician's role</u>: to explain the various possibilities for the diagnosis or treatment of a particular condition
- <u>Patient's role</u>: to consider this information in the context of his or her own values and then choose a course of treatment suited to him or her
- <u>Shared process of decision making</u>: physician not restricted to providing facts and the patient to supplying all the values (role of medical adviser)

# What informed consent should not be

- " a laundry list of potential risks recited to a patient who has already committed to a procedure, followed by the requisite signatures on a form." Schenker JAMA. 2011;305(11):1130-1131
- A legal nuisance without true meaning

# Informed consent: Swiss federal law

- Without valid consent, any treatment, however reasonable or necessary, is deemed unlawful
- The patient should be informed in clear and intelligible terms of:
  - diagnosis and prognosis
  - potential for spontaneous evolution
  - treatment (type, duration, advantages, chances of success, risks)
    therapeutic alternatives
- The patient should have sufficient time (>72hrs) to reflect upon the procedure
- Consent may be given in a written or oral form
- The burden of proof of adequate patient information is borne by the physician
- The burden of proof that leges artis has been breached rests with the patient (claimants often seek to get around this hurdle by alleging inadequate information )

# Medicare

# **Consent to Treatment**

The informed-consent process should include:

- Description of the procedure or surgery, including anesthesia
- Why procedure is recommended
- Risks and benefits to the patient and degree of severity or likelihood of complications
- Treatment alternatives, including related risks and benefits

Source: Center for Medicare and Medicaid Services

- Probable consequences of declining recommended or alternative therapies
- Name of doctor or surgeon conducting procedure and administering anesthesia
- Other physicians, including residents, performing tasks related to procedure



# **Myths regarding informed consent**

- A signed consent form is informed consent
- Protects agains physician liability

- provides little protection, although may be useful in a lawsuit, unless the form is inadequate (e.g. too complex or detailed and thus unintelligible) in which case it defends the patient.

- Patients must be told everything about treatment
  - more is not always better.

- disclosure of risks depends on severity and frequency (threshold of >0.5-1%, or >0.1% if the procedure is not strictly necessary).

- physicians may also exercise discretion to withhold information on a particular risk, if it is believed that this would unduly alarm the patient, thereby putting the treatment at risk.

Patients must be given information whether they want it or not

- right to waive to be informed and/or to decide (e.g. attributed to family member). Physicians are advised to document this as fully as possible.

# Effect of informed consent on anxiety in patients undergoing diagnostic electrophysiology studies

Jeffrey J. Goldberger, MD, Jane Kruse, RN, Michele A. Parker, RN, MS, and Alan H. Kadish, MD Chicago, Ill.

The process of informed consent has been suspected to raise patient anxiety, but this supposition has not been well studied or validated. The aim of this study was to evaluate the effect of a detailed informed consent protocol on patient anxiety. Fifty patients (36 men, 14 women, mean age  $55 \pm 18$  years) undergoing diagnostic cardiac electrophysiologic studies were enrolled. Patients were randomly assigned to receive either a consent that did not detail specific risks regarding the procedure (consent A) or one that detailed the risks (consent B). The Spielberger State-Trait Anxiety Inventory was administered before obtaining consent (state 1), immediately after the consent protocol (state 2), and after the electrophysiologic testing procedure, when the results of the test were known to the patient (state 3). Midazolam was administered during the procedure by staff who were blinded to the state/trait anxiety scores and the type of consent the patient had received. Patients receiving consent A had a significant decrease in state 2 anxiety compared with those who received consent B (adjusted mean difference 3.3; 95% confidence intervals 0.2 to 6.4). In the consent A group, 74% of patients received midazolam as opposed to 96% in the consent B group (p <0.02). Patients without inducible ventricular arrhythmias had a significant decrease in state 3 anxiety compared with increased anxiety relative to a consent that does not detail specific risks. However, the difference in anxiety is mild and its clinical impact requires further exploration. (Am Heart J 1997;134:119-126.)

# Effect of informed consent format on patient anxiety, knowledge, and satisfaction

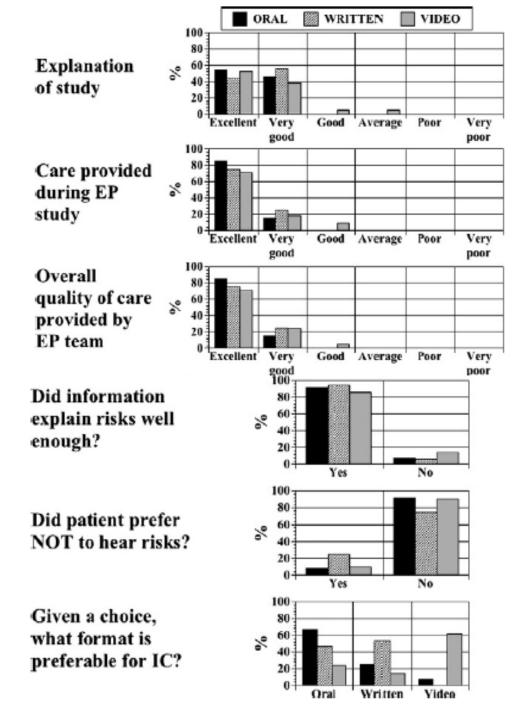
Jeffrey J. Goldberger, MD, Jane Kruse, RN, BSN, Alan H. Kadish, MD, Rod Passman, MD, MSCE, and Daniel W. Bergner, MD *Chicago, IL* 

**Background** Multiple formats have been used to deliver information needed for informed consent before a medical procedure, but data comparing formats are conflicting.

**Methods** Sixty-three patients (45 men, age 61 ± 16 years) undergoing an initial diagnostic cardiac electrophysiology study were randomly assigned to 1 of 3 groups: oral, written, or video informed consent using a standardized text for all 3 formats. Anxiety levels were assessed with the Spielberger State-Trait Anxiety Inventory (STAI), and questionnaires were used to assess patient comprehension and satisfaction with the informed consent process. Physician time needed to obtain informed consent was also measured. The effect of informed consent format on anxiety state was evaluated by comparing STAI before and after consent. Multivariable analysis was performed to assess the effects of baseline characteristics on the state anxiety scores.

**Results** For the oral, written, and video formats, the mean anxiety trait scores were  $39 \pm 9$ ,  $34 \pm 8$ , and  $31 \pm 7$ , respectively (P = .005), and baseline anxiety state scores were  $49 \pm 12$ ,  $37 \pm 12$ , and  $36 \pm 11$ , respectively (P = .0006). None of the formats had a significant effect on patient anxiety state after consent was obtained. After the procedure, anxiety state declined (P < .0001). There were no differences among the comprehension scores, and patient satisfaction was equivalent among formats. The oral format required the longest physician time (P = .06).

**Conclusion** For electrophysiologic testing, all 3 formats have similar effects on anxiety and produce equivalent patient comprehension. The oral format requires more physician time. Given the standardization achievable with a written or video format, physicians may consider these options to facilitate obtaining informed consent. (Am Heart J 2011;162:780-785.e1.)



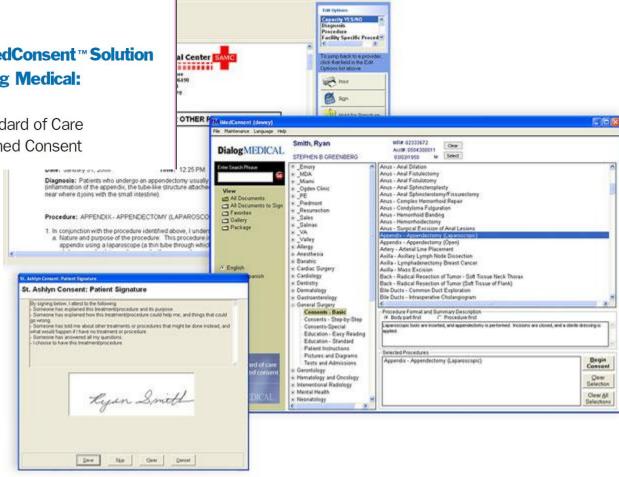




#### The iMedConsent<sup>™</sup> Solution by Dialog Medical:

The Standard of Care for Informed Consent

### Used by Veterans' Health Administration hospitals



6 10

Cost for a 250-bed hospital: \$200,000 -\$300,000 for initial license, and annual fees of \$50,000 - \$100,000 for information updates and maintenance

### Enhancement of Surgical Informed Consent by Addition of Repeat Back

A Multicenter, Randomized Controlled Clinical Trial

Aaron S. Fink, MD,\*† Allan V. Prochazka, MD, MSc,‡§ William G. Henderson, PhD,§ Debra Bartenfeld, RN, MSN,\* Carsie Nyirenda, MB, ChB, MPH,§ Alexandra Webb, MD,\*† David H. Berger, MD, MHCM,¶ Kamal Itani, MD,|| Thomas Whitehill, MD,\*\* James Edwards, MD,†† Mark Wilson, MD, PhD,‡‡ Cynthia Karsonovich, MD,§§ and Patricia Parmelee, PhD¶¶

**Objective:** In this randomized, controlled, unblinded trial, we sought to test Repeat Back's (RB) effect on comprehension following informed consent discussions.

Summary Background Data: RB has been suggested as a method to improve patient comprehension when obtaining informed consent. In this technique, patients are asked to recount what they have been told in the informed consent discussion. Despite preliminary data, this practice has not been evaluated in any large scale study.

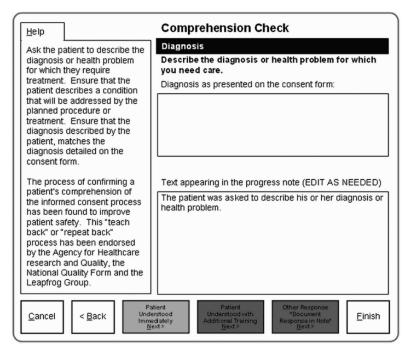
Methods: This study was conducted in 7 Veterans Health Administration Medical Centers where informed consent is obtained using iMedConsent, the VA's computer based platform. Patients scheduled for elective surgeries were randomized to RB (a module added to the iMedConsent package) or standard iMedConsent (no RB). Comprehension was tested after the informed consent using procedure-specific questionnaires. Time stamps in the iMedConsent program estimated the time spent completing the informed consent process. Provider and patient satisfaction were measured using 5-point Likert scales. Statistical comparisons of groups were performed using t-tests and  $\chi^2$  tests.

**Results:** A total of 575 patients were enrolled. In the RB group, providers spent 2.6 minutes longer (P < 0.0001) obtaining informed consent. The mean comprehension score was significantly higher in the RB group (71.4%) versus the no RB group (68.2%, P = 0.03); the effect was greatest in carotid endarterectomy patients (RB = 73.4% vs. no RB = 67.7%, P = 0.02). Quality of decision making was rated similarly. Providers were neutral to slightly favorable regarding RB.

**Conclusions:** RB implemented within an electronic informed consent system improved patient comprehension. The additional time required was acceptable to providers. RB should be considered as an enhancement to surgical informed consent.

This clinical trial was registered at http://www.clinicaltrials.gov (Identifier NCT00288899).

(Ann Surg 2010;252: 27–36)





Schweizerische Gesellschaft für Kardiologie Société Suisse de Cardiologie Società Svizzera di Cardiologia

Groupe de travail stimulation cardiaque et électrophysiologie



Active contre les maladies cardiaques et l'attaque cérébrale

### CONSENTEMENT ÉCLAIRÉ POUR L'EXAMEN ÉLECTROPHYSIOLOGIQUE PAR CATHÉTÉRISME CARDIAQUE AVEC ABLATION PAR RADIO-FRÉQUENCE

#### Chère Madame, cher Monsieur,

Votre médecin traitant a constaté que vous souffrez de troubles du rythme cardiaque et vous a conseillé un examen et un traitement électrophysiologiques (ablation par radio-fréquence). Cet examen a pour but principal d'établir la nature de ces troubles et d'en déterminer les traitements possibles.

#### Réalisation pratique

Après une anesthésie locale et une ponction de la veine (dans des cas particuliers aussi de l'artère qui se trouve dans l'aine), différentes sondes (ou cathéters) sont introduites dans le cœur sous contrôle radiographique. Ces sondes, d'un diamètre de 2 mm environ, sont en plastique souple et leur tête est munie d'éléments de contact métalliques permettant d'enregister directement, à différents endroits, les courants électriques du cœur. Ces sondes offrent également la possibilité d'agir sur le cœur, de provoquer des troubles du rythme cardiaque et d'y mettre fin, ce qui permet d'évaluer le genre et la gravité des troubles. La mise en place de sondes dans le cœur, la dérivation des courants électriques et la stimulation n'occasionnent généralement aucune douleur. Le déclenchement des troubles du rythme cardiaque peut toutefois être désagréable. Parfois, l'accélération du rythme est telle qu'elle peut vous faire perdre conscience; on y met alors immédiatement fin par une stimulation au moyen d'une sonde ou par un électrochoc. Cet électrochoc consiste en une brève décharge électrique rétablissant l'activité cardiaque originelle. A part quelques irritations cutanées passagères, cette intervention ne laisse aucune séquelle. Cette accélération très rapide du pouls apparaît fréquemment lorsque l'examen auquel vous vous soumettez a été rendu nécessaire par un trouble du rythme cardiaque mettant en danger la vie (tachycardie ventriculaire ou fibrillation ventriculaire). Des médicaments (sédatifs, analgésiques, substances agissant sur le système cardio-vasculaire) sont occasionnellement administrés pendant l'intervention en provoquant parfois de légers effets secon-



"I don't need informed consent to give you a sponge bath."