Dodson01 Patient Preferences

Version1 Patient Preferences

Participant ID code		
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COVER				
Interview Date	/			
Interviewer ID #				
Interview Outcome	 1 - COMPLETED 2 - Partial (refusal) 3 - Partial (other) 5 - Partial (Medical Condition/Illness) 6 - Partial (Other) 7 - Not Done: Other 			
Specify				

Introduction and Consent

Hi, my name is [name of interviewer] and I am calling from Yale School of Medicine as a follow-up to the letter we sent you in the mail last week. We are conducting a study of patients who have received an implantable cardioverter-defibrillator, also known as an ICD, at Yale in the past. We are trying to get a sense of patients understanding about their devices, and whether there were situations where they would want the shocking function of their device deactivated if they were very ill. The interview should last about 30 minutes, and you will be compensated 25 dollars for your time. Are you willing to speak with me, and if so is now a good time?

Consent

Before beginning the interview, I wanted to tell you about the study and what you can expect by being a participant. Feel free to ask me any questions you may have while I am explaining things.

The purpose of our study is to speak with patients who have received an implantable defibrillator at Yale and to assess their general understanding about their device. We also would like to obtain some measures of peoples' health status at the current time. Finally, we will be asking about scenarios in which people may become very sick, and whether they would want the shocking function of their defibrillator to be deactivated.

If you agree to participate, you will be asked to complete an interview that is approximately 30 minutes in duration. You can stop at any point if you need to.

There are no physical risks associated with this study. Some of our questions do concern future situations in which people could be very ill, and some people may find thinking about these situations uncomfortable. While we do not think this will be very common, please remember that you can withdraw from the study at any point. This interview will not impact your medical care in any way, and will not be discussed with your doctors or anyone else outside of the research personnel.

The benefit of this study will be to advance our general medical knowledge surrounding implantable defibrillators and hopefully help improve the quality of life of ICD patients if they become very sick with other diseases later in their lives. You will be compensated 25 dollars for your time.

We are using information including age, race, and time of ICD implantation, in order to identify patients for our study. All of your answers, as well as your other medical information, will be kept completely confidential.

Before we get started, do you have any questions about the study?

1. Do I have your consent to start the interview? 1 - Yes

2 - **No**

Patient Information

Just as a reminder, this discussion is just for research purposes, and will not impact your clinical care in any way. You should discuss your wishes with your doctor should the occasion arise.

I am going to obtain some basic demographic information first

1.	Gender	1 - Male 2 - Female
2.	Date of Birth	/
3.	Do you consider yourself to be	 White/Caucasian Black/African-American Asian American Indian/Alaska Native Native Hawaiian/Pacific Islander Other or more than one race Unknown
3a.	Race - if other, specify	
4.	Are you Hispanic or Latino?	1 - Yes 2 - No
5.	What was the highest grade of regular school you completed? [CODE ANY RESPONSE OVER 17 AS 17.] Elementary School 0-8 High School 9-12 College 13-17	
6.	Are you currently	 1 - Single/Never Married 2 - Separated 3 - Divorced 4 - Widowed 5 - Married
7.	What is your current employment status?	1 - Employed2 - Not employed3 - Retired

Chronic Conditions

Do you have, or have you had in the past, any of the following medical problems?

		Yes	No
1.	Heart Attack	1	2
2.	Congestive heart failure	1	2
3.	Peripheral vascular disease	1	2
4.	Stroke	1	2
5.	Dementia	1	2
6.	Chronic lung disease	1	2
7.	Connective tissue disease	1	2
8.	Ulcer disease	1	2
9.	Liver disease	1	2
10.	Diabetes	1	2
11.	Hemi-paralysis	1	2
12.	Kidney disease	1	2
13.	Cancer	1	2
14.	Liver disease	1	2
15.	Dizziness	1	2
16.	Chronic pain	1	2
17.	Frequent falls	1	2
18.	Hearing loss	1	2
19.	Vision loss	1	2
20.	Incontinence	1	2
21.	Arthritis	1	2

Depression

Over the last 2 weeks, how often have you been bothered by any of the following problems?

1. Little interest or pleasure in doing things 1 - Not at all

2 - Several days

3 - More than half the days

4 - Nearly every day

2. Feeling down, depressed, or hopeless \dots 1 - Not at all

2 - Several days

3 - More than half the days

4 - Nearly every day

Activities of Daily Living

Do you have any problems with doing any of the following by yourself?

		Yes	No
1.	Feeding	 1	2
2.	Bathing	 1	2
3.	Dressing	 1	2
4.	Using the toilet	 1	2
5.	Transferring from bed to chair	 1	2
6.	Shopping	 1	2
7.	Preparing meals	 1	2
8.	Housekeeping	 1	2
9.	Laundry	 1	2
10.	Transportation	 1	2
11.	Taking medications	 1	2
12.	Handling finances	 1	2

Health

Does your health limit you in the following activities? If so, how much?

Climbing a flight of stairs ... 1 - Yes, a lot 2 - Yes, a little 3 - Not at all
 Walking one block ... 1 - Yes, a lot 2 - Yes, a little 3 - Not at all

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	ICD	
1.	What do you feel are the potential benefits of your ICD? (Responses will be open-ended; general themes may include "to deliver a shock if heart stops", "to pace heart", "to prevent heart attack", etc.)	
2.	What do you feel are the potential harms of your ICD? (Responses will be open-ended; general themes may include "giving an inappropriate shock", "getting infected", "needing the battery replaced", etc.)	
3.	How many years ago did you receive your ICD? (if you don't know exactly, you can give approximate number of years)	
4.	Have you ever received a shock from your ICD?	1 - Yes 2 - No
5.	Are you aware that the shocking function of your ICD can be deactivated by your cardiologist?	1 - Yes 2 - No

ICD Follow-up

As you may know, the purpose of your ICD is to deliver an electrical shock to your heart if it goes into a life-threatening abnormal rhythm. Most of the time the device is just listening to the heartbeat, and as long as the heartbeat is normal, is doesnt do anything. If your heart does develop a rhythm which otherwise might be lethal, it will give the heart a shock. As your doctors have probably explained to you, if you havent received one previously, a shock is like a kick in the chest. The device is not the same as a pacemaker, which provides a continuous electrical input that paces the heart. All ICDs do have a pacemaker function, but the shocking and pacemaker functions work separately.

Approximately 25% of ICDs deliver a life-saving shock during the lifetime of patients who have received them.

A physician may deactivate an ICD if a patient does not wish to receive any more electrical shocks, without affecting the pacemaker. Sometimes patients are at a point in their lives when the ICD may seem like more of a burden than a benefit and they choose to ask their doctor to deactivate it, to avoid painful shocks from the device when the end of their life may be approaching. Everyone feels differently about this. For the purposes of this questionnaire we are only going to be talking about the shocking function of the device.

Before survey part 2, if subject's answer to questions ICD 1 2 imply they don't know function of their ICD

1. Did patient responses imply they don't know function of their ICD

1 - Yes

2 - **No**

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Survey Part 2

The next set of questions refers to the ICD function of your device, and not the pacemaker function. I am going to give you five hypothetical scenarios, and I would like you to answer on a scale of 1 to 5 for each question. 1 means 'definitely no', 2 means 'possibly no', 3 means 'uncertain', 4 means 'possibly yes', and 5 means 'definitely yes'. Since this is a research study, your answers are confidential and will have absolutely no effect on your usual care. They will not be shared with your cardiologist

1.	Do you think you would want the ICD turned off if you were permanently unable to get out of bed by yourself, and needed other people to help you get up? SCALE: 1 (Definitely No) to 5 (Definitely Yes)	
2.	Do you think you would want the ICD turned off if you had permanent memory problems, so that you could no longer recognize your friends or family members? SCALE: 1 (Definitely No) to 5 (Definitely Yes)	
3.	Do you think you would want the ICD turned off if you were ill for a long time and caring for you was a significant burden to your family members? SCALE: 1 (Definitely No) to 5 (Definitely Yes)	
4.	Do you think you would want the ICD turned off if you were ill in the hospital on an artificial breathing machine for longer than one month? SCALE: 1 (Definitely No) to 5 (Definitely Yes)	
5.	Do you think you would want the ICD turned off if you had an advanced disease that was incurable, such as metastatic cancer? SCALE: 1 (Definitely No) to 5 (Definitely Yes)	
6.	Are there any other situations that you have thought about or discussed with your cardiologist where you would want your ICD deactivated? (responses will be open-ended and recorded by the interviewer).	

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Patient Preferences when ill

The following set of questions refers to other preferences that people may have when they are very ill. Again, your answers will not affect your health care at all, and everything is completely confidential. I would like you to answer on the same scale as above: 1 means 'definitely no', 2 means 'possibly no', '3 means 'uncertain', 4 means 'possibly yes', and 5 means 'definitely yes'

1.	Do you think you would want to be kept alive by artificial feeding (such as a feeding tube) if you were unable to take food by mouth?	_
	SCALE: 1 (Definitely No) to 5 (Definitely Yes)	
2.	Do you think you would want to receive dialysis if your kidneys failed? SCALE: 1 (Definitely No) to 5 (Definitely Yes)	_
3.	Do you think you would want to be on a mechanical ventilator for a prolonged period of time (greater than one month), if you were	

SCALE: 1 (Definitely No) to 5 (Definitely Yes)

unable to breathe on your own?

Questions

AFTER PATIENT PREFERENCES QUESTIONS:

Just as a reminder here at the end of the interview, this discussion is just for research purposes, and will not impact your clinical care in any way. Your answers here will not be shared with your physician, and you should discuss your wishes with your doctor should the occasion arise.

Thank you very much for your time. Thank you again

4. Do you have any questions before we conclude?

1 - Yes

2 - **No**