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The ability to consent to Parkinson disease research

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WHAT IS THIS ARTICLE ABOUT? This issue of *Neurology*[®] includes an article by Karlawish et al.¹ on giving consent to be part of Parkinson disease (PD) research. People with PD often want to help doctors and scientists learn more about their disease. Being part of a research study is one way to do this. A person must consent to be part of a research study. This is a legal and ethical requirement.² PD can affect the ability to give consent. Sometimes it is not easy to tell whether someone with PD has the ability to consent.

The ability to think through and make a choice is called decision-making capacity. Decision-making capacity can be affected in diseases that can cause dementia, like Alzheimer disease and PD. Dementia is an ongoing problem of thinking caused by a disease or brain injury and usually involves problems with memory, personality, or other areas of thinking. This study examined the topic of decision-making capacity in PD research. The researchers used an interview tool to measure decision-making capacity in people with PD. They also used thinking tests that doctors often give to patients with PD. Both kinds of tools may help researchers decide who can consent to be part of research. They may also show who needs extra protection.

HOW DID THE AUTHORS STUDY DECISION-MAKING CAPACITY? People with PD were divided into 3 groups based on their level of dementia measured by a test called the Dementia Rating Scale–2; some were normal, some were borderline, and some were impaired. The authors then gave short thinking tests to all 3 groups and to a normal group without PD. People without PD scored high on these short tests. Some people with PD scored high on these short tests

but others scored low. The researchers then asked all groups to think about 2 stories. Each story was about a possible future experimental treatment for PD. One story was about a medication and the other was about a surgery. All groups were asked to think about volunteering to be part of these experimental treatments.

People in the study were asked questions about the stories. Did they understand the stories? Did they imagine themselves as part of the story? Did they weigh the pros and cons of being a volunteer? Could they tell researchers whether they would want to volunteer? Experts asked the participants questions about their understanding, appreciation, reasoning, and choice. These 4 areas make up decision-making capacity³ (table). The 4 areas in the table are parts of a tool called the MacArthur Competence Assessment Tool for Clinical Research. Researchers sometimes use this tool to see whether someone can consent to join a research study.

WHAT WAS FOUND? Experts judged the answers that people gave. The experts found that some people were able to give consent to be a part of research. Others were not. The thinking tests given to all groups were an important clue about how people would do on the stories. People who did well on these thinking tests also did well answering questions about the research stories. People who did not do well on the tests had a lot of trouble with the stories. People with borderline scores on the thinking tests answered some of the story questions well and others not so well. The authors of the study concluded that thinking tests, like those commonly given to patients with PD or other problems with thinking, are a helpful guide for judging capacity to consent for research.

Table Four areas of decision-making capacity		
Types of abilities	Meaning of abilities	Examples of abilities
Understanding	Know the basic facts about a study—what, when, why, how	"Tell me in your own words what you understand the research project to be about and how it will go."
Appreciation	Imagine how one's own health, such as having Parkinson disease, could be affected by participating in a research study	"What do you think will happen to you if you join this study?"
Reasoning	Weigh the possible good and bad of choosing to participate in a research study	"What points will you consider when you decide and how will you weigh these?"
Choice	Express whether or not to participate in a study	"Tell me what choice you will make."

WHAT STILL NEEDS TO BE KNOWN? Research is critical to improving diagnosis and treatment in PD. But so is protecting volunteers who have thinking problems. This is why understanding decision-making capacity is so important—to help people with PD volunteer safely for research. This study shows that more needs to be known about the ability to give consent in PD. Are hypothetical stories, like those in the study, a good substitute? Are there better or worse ways to present information about a study to people at different stages of PD? This study does not fully answer these questions. But it does provide important new information on the

topic of consent in PD. This study will be useful for researchers and patients in PD research.

REFERENCES

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About Parkinson disease

From Karczeski S. Parkinson disease and polyneuropathy. 2011;77:e132–e133.

WHAT IS PARKINSON DISEASE? Parkinson disease (PD) is named after James Parkinson. He first described the illness in 1817. PD mostly causes problems with moving around. It can cause a person to move very slowly. A person with PD appears stiff or rigid. At times, a person with PD may appear to suddenly “freeze up” or be unable to move for a short period of time.

A tremor of the hands is common. It is called a “pill-rolling” tremor because of how it looks. Many years ago, pharmacists used to make their own tablets. In order to make the medications into a tablet, they would “roll” the medicine into a small ball. The motion that it takes to roll a small ball looks very similar to the tremor in PD. When a person has PD, he or she often will have one or more of these symptoms.

WHAT CAUSES PD? In PD, the underlying problem has to do with a neurotransmitter called dopamine. A few very specific brain cells make dopamine. Though only a few cells make dopamine, these cells send the neurotransmitter to many different regions of the brain. Changes in dopamine levels can have widespread effects within the brain.

When we are young, our brains make plenty of dopamine. As we get older, this amount decreases. In PD, the amount of dopamine becomes critically low. In PD, the amount of dopamine changes very slowly over time. This causes the very gradual worsening of movement. In early PD, the symptoms may be mild.

TREATMENT OF PD Understanding the link between dopamine and PD has led to the development of many treatments. The answer seems simple enough: take

dopamine. Unfortunately, the body does not allow dopamine to cross over into the brain where it is needed. This is why people with PD take levodopa. Levodopa can cross over into the brain. The brain converts the medication into dopamine.

There are many other treatments for PD. For the most part, these treatments are aimed at increasing the amount of dopamine in the brain. Other treatments help to keep the dopamine where it is needed most. These treatments maintain the levels of dopamine. By keeping the levels constant, these treatments prevent the motor symptoms from returning.

A physician may not know which treatment is best for a specific person. Every person is different. Some people may require only one medication. Others may need 2 or more medicines. Physicians must therefore tailor the treatment to the individual.

Although studies can tell us which medicines work, they do not tell us which ones work best for a specific person. Sometimes, more than one medicine must be tried before the best treatment plan can be found. A person with PD can become frustrated if the first treatment does not work. By talking honestly with your doctor, the best treatment can be found.

FOR MORE INFORMATION

AAN Patients and Caregivers site
<http://patients.aan.com/gol/home>

American Parkinson Disease Association
<http://www.apdaparkinson.org>

National Parkinson Foundation
<http://www.parkinson.org>

Michael J. Fox Foundation for Parkinson’s Research
<http://www.michaeljfox.org>

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