

PROFESSION

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will my child face by taking part in the study? What will the researchers do to protect my child against these risks?

Risks of side effects are common with any medicine, and the risks for Painaway are similar to alternative forms of narcotic therapy for adults to severe pain. Based on past experiences, the common (most common) side effects of Painaway occur in about 31 out of 100 patients (31%). Nausea, vomiting, constipation. Rarely, in less than 3 out of 100 children that requires a dose of Painaway, the side effects will be treated with nausea medicines, or the dose of Painaway will be reduced. The controlled-release tablet is of taste. Taking tablets, chewed or crushed Painaway tablets will lead to the rapid release and absorption of a potentially harmful dose of Painaway requiring emergency treatment. Your child should not participate if he/she cannot swallow pills or tablets.

There is a possibility of drug interactions with Painaway and other drugs such as sedatives, sleeping pills, and antacids. You should not take Painaway and other drugs. In addition, there are certain medications that might increase or decrease these effects. Therefore, you must tell your doctor of any drug your child is currently taking, and he will advise you of what he/she can or cannot take during the study. As with any drug, your child may experience an allergic reaction that could be life threatening.

The potential side effects of blood collection are low and include pain and/or bruising at the procedure site. To measure these effects, samples will be taken from an IV catheter whenever possible, and standard blood-drawing techniques will be used.

Researcher Risks:

The researchers that are doing this study may be bothered by your children. These researchers will be done, as much as possible, when he/she is awake, or during other routine nursing activities.

Risk Associated With Pregnancy:

During participation in this study may involve risks to unborn children, if your child is a female of childbearing potential. You will be asked to sign only if there are no risks to your child and that you agree to undergo to become pregnant during the study. If your child is having surgery, a pre-operative pregnancy test will suffice. Acceptable forms of birth control include but are not limited to the following: abstinence, York method, patch, contraceptive device, Depo-Provera and implant preparations.

Unforeseen Risks:

Problems and side effects, which are unforeseen at this time, may occur. If more information becomes known during your participation, you will be told so that you are informed of the study. Such information will also be provided to the Institutional Review Board (IRB), and a new informed consent may be required.

5.2 What happens if my child gets hurt, becomes sick, or has other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, there may still be problems or side effects, some of which researchers are not used to seeing these. Please tell the researchers listed in Section 6 about any unforeseen side effects or other problems that your child experiences during this study. You should also tell your child's regular doctor.

5.3 If my child takes part in this study, can he/she also participate in other studies?

Being in one or two research study at the same time, or even in different times, may increase the risks to your child. It may also affect the results of the studies. You should not have your child take part in more than one study without approval from the researchers involved in each study.

5.4 How could my child benefit if he/she takes part in this study? How could others benefit?

You child will receive an injection that may relieve pain and will have access to additional pain medications, as appropriate. The treatment your child is given in every or may not directly benefit him or her, however, approximately 74 out of 100 patients (74%) who have received Painaway as the pain has had good pain relief. Your child's part will help to learn about how to best manage pain in children who may need Painaway for severe pain.

WHAT ARE THE RISKS OF THE STUDY?

The risks for Painaway are similar to other narcotic-like drugs.

About 31 out of 100 children (31%) may experience these common side effects:

- **Side effects:** Nausea and vomiting.
- **Constipation:**

Less than 3 out of 100 children (3%) may experience:

- **Excessive sleepiness (sedation):**
- **Slowed breathing:**

● **Children who cannot swallow pills should NOT be in the study, since Painaway CR tablets must be swallowed whole. If these pills are broken, chewed, or crushed they are dangerous.**

● **Allergic reaction is possible with any drug, and will be watched for.**

● **Risks of taking blood are low, and include for pain, from a needle stick, and/or bruising. Blood samples will be taken from an IV line if possible to avoid these effects.**

REDESIGNED CONSENT FORM

Table 1. Possible Side Effects of Painaway

Side effects	Description or Treatment
Common effects that may occur in 70 out of 100 children (70%)	
Light-headedness or dizziness	Adhesive bandages
Nausea and vomiting	Rest
Constipation	Medicines for nausea
	Stool softeners or laxatives
Rare, but potentially serious effects may occur in less than 1 out of 100 children (1%)	
Excessive sleepiness	Caution monitoring
Slowed breathing	Lowering the dose of Painaway
	Medicines to reverse Painaway
	Oxygen

Two examples of the documents used in the consent form study. At left is a traditional consent form written at the 12th-grade level. At right is a redesigned document that combines an eighth-grade reading level, bigger type and graphic display of risk information to enhance understanding.

Research uncovers formula for enhancing informed consent

■ Combining several comprehension-aiding techniques yields documents that are vastly superior to traditional forms, but legal fears still impede changes that could improve patient understanding.

By KEVIN B. O'REILLY (HTTP://WWW.AMEDNEWS.COM/APPS/PBCS.DLL/PERSONALIA?ID=KOREILLY) amednews staff — Posted June 5, 2013

Informed-consent documents that are shorter and use simpler language, bigger type and graphics lead to dramatically improved understanding of risks and benefits, said a study posted online May 13 in *JAMA Pediatrics*, formerly *Archives of Pediatrics & Adolescent Medicine*.

Researchers tested various types of forms — some long and complex, some shorter and simpler, some with graphics and some without — among 640 parents of children scheduled for elective surgery. The forms were designed to deliver the traditional elements of an informed consent-document for the clinical trial of a fictional pain-relieving drug called Painaway. The parents were quizzed after going through the informed-consent process to determine whether they understood what was presented about the risks and benefits of trial participation.

Parents had 50% better odds of understanding documents that included pictures displaying risk information in graphic form. They also were 35% likelier to understand forms with size 14 font and wider margins.

Meanwhile, the odds of comprehension dipped by 75% when forms were written at the 12th-grade reading level compared with documents written at the eighth-grade level. Documents that were just a few pages longer were 71% less likely to be understood than shorter forms, said the study ([link](#)).

The more readability elements a document had, the more likely it was to do its job of informing parents, researchers found. Parents who went through an informed-consent process with all five of what the study dubbed “positive message attributes” — text written at the eighth-grade reading level, bigger type, graphic display, oral explanations and shorter forms — scored 75% better on a test of understanding risks and benefits than parents whose experience included only one of those methods.

Small fixes, big impact

The research shows it is important to combine as many comprehension-aiding techniques as possible when crafting informed-consent documents, said Alan R. Tait, PhD, the study’s lead author and director of clinical research in the Division of Anesthesiology at the University of Michigan Medical School.

“It’s not universally successful to do just one intervention,” Tait said. “We thought if you multiplied the number of positive message attributes you put in there, you’d get a better result. These are simple things to do. These are not expensive. These are easy fixes, easy to incorporate, and yet they make a big difference.”

The complexity and length of informed-consent documents have long been lamented, and a wide body of research has shown that many patients and potential research subjects struggle to understand the forms. Tait said the consent forms at the University of Michigan are simpler and easier for research subjects to understand now than they were a decade ago. But in an editorial that accompanied the *JAMA Pediatrics* study, Mark S. Schreiner, MD, wrote that the problem is getting worse nationwide. Dr. Schreiner is an associate professor of anesthesiology and critical care at the Children’s Hospital of Philadelphia.

“Instead of simplicity and plain language, subjects face an overwhelming deluge of information written in technical and legalistic terms. Instead of brevity, consent forms remain verbose, increasing in length by approximately 1.5 pages per decade, with some well in excess of 20 pages,” said the editorial ([link](#)).

Medical liability fears often drive research sponsors and institutional review boards to resist simpler, easier-to-understand forms, experts said.

BACK TO TOP