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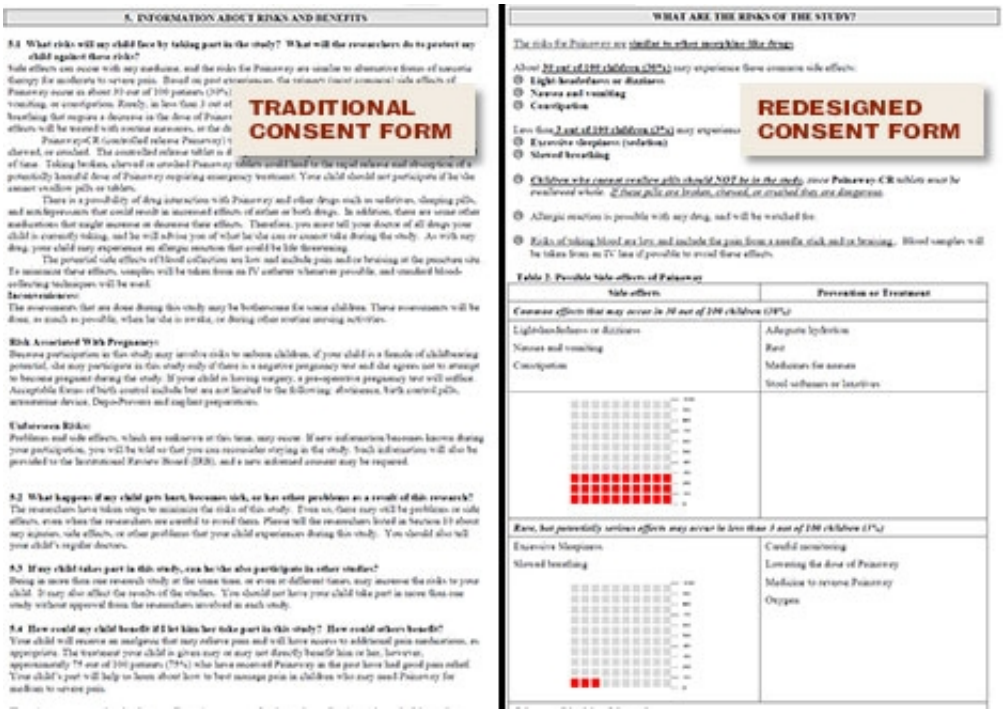

Two examples of the documents used in the consent form study. At left is a traditional consent form written at the 12th-grade level. At right is a redesigned document that combines an eighth-grade reading level, bigger type and graphic display of risk information to enhance understanding.

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.

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