FULL TITLE
Scenario-tailored opioid messaging program (STOMP): An interactive intervention to prevent opioid-related adverse drug events in children and adolescents

NCT03287622

REGULATORY APPROVAL DATES OF CONSENT
Approval: 10/22/2018 Expiration: 5/30/2019

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You and your child are eligible to take part in a research study. This form gives you important information about the purpose of the study, as well as the possible risks and benefits of taking part in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the possible risks and benefits to you and your child.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:

STOMP (Scenario **T**ailored **O**pioid **M**essaging **P**rogram**)**
Education to Improve Opioid Safety and Efficacy among Parents of Youth Prescribed Opioids for Home Use

1.2 Company or agency sponsoring the study: National Institute of Health (NIH) -NIDA

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Principal Investigator: Terri Voepel-Lewis, PhD, RN,
Study Coordinators: Elizabeth Stamps, BA, Monica S. Weber, RN
University of Michigan Department of Anesthesiology

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
Pain medicine is often prescribed to children to improve their comfort after surgery. Parents need to understand the risks and benefits of pain medicines in order to safely use them.

The overall aim of this study is to see if our new teaching method will improve parents' understanding about the risks and benefits of prescribed pain medicines.

We will also see if the program helps parents make better decisions about when to give prescribed and over-the-counter pain medicines.

3. INFORMATION ABOUT THOSE WHO TAKE PART

Taking part in this study is completely **voluntary**. You do not have to take part if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study? Parents and their children (age 5-17 yrs living in the home with the parent) who are undergoing surgery and who are expected to go home with a prescribed narcotic pain medicine like oxycodone or Vicodin.

3.2 How many people will take part in this study? 840 Parents and their children

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me or my child in this study?

Your child will receive routine care and pain management. No treatment will be changed for the purpose of this study. Also, all parents will receive routine information about pain management that is provided by your child's doctors and nurses. This will not be changed.

While your child is in surgery you will complete a baseline survey that will take about 20 minutes:

This survey will ask you:

- How familiar you are with common pain drugs
- About your family's past pain and pain medicine use
- What you think and know about prescribed pain relievers
- How well, in general, you understand medical information
- You will also make 4 mock or pretend decisions that will show us how you would use commonly prescribed drugs to treat a child's pain when different situations (scenarios) arise

Educational Feedback:

- After completing the mock decision questions you will receive, in a random manner (like flip of a coin) either: 1) general information about risks and benefits of pain medicines *OR* 2) the scenario-tailored information that is more detailed. You will also be randomized to get more specific versus routine strategies about what to do with left-over pain medicine.

After Surgery:

- You will use a diary to record all pain drugs you give to your children at home for 2 weeks. You will also record your child's reported pain level and other symptoms each day (for example, nausea, sleepiness, constipation, or other side effects that may occur after surgery).
- We will send you a text (via Twilio) or email (via gmail) reminder (whichever you prefer) on days 3, 7 and 14.

In 3 days and at 1 week:

- Parents will get an email link with shorter follow-up surveys that have some items that are similar to those completed on the day of surgery and a few that address your child's pain and medicine use and handling. If you don't have easy access to email, we can send paper surveys home with you so that you can still take part.

2 – 3 weeks after discharge:

- Parents will get an email link with a shorter and final survey about pain drug perceptions, preferences, storage and disposal.
- We will contact you by text, phone or email (whatever you prefer) to bring your child's drug diary to your child's post-op clinic visit if one is scheduled or will ask you to return it in the pre-stamped envelope.

Summary of your part:

Day of Surgery	Day 3 after discharge	Day 7 after discharge	Day 14-21
Complete survey (20 mins)	Complete shorter survey (10 mins)	Complete shorter survey (5 mins)	Complete final survey (15 mins)
	Record in diary (2-3 mins per day)		Return diary

Child's Medical Record Review:

- We will look at your child's medical file to record what surgery was performed, what pain drugs were given in the hospital and what you were told about treating pain when you left the hospital. We will also record any adverse effects that happened to your child for up to 1 month after surgery.

4.2 How much of my time will be needed to take part in this study?

Completing surveys and receiving medication information on the day of surgery will take around **20 minutes**. Parents will complete these while the child is in surgery.
Completing the medication diary will take only **a few minutes each day** for about a week or until the last dose of pain reliever is given.
The follow-up surveys via email link should take less than **10 minutes each**.

4.3 When will my part in the study be over?

Your part in the study will end after the **final survey**

4.4 What will happen with my information used in this study?

With appropriate permissions, your collected (de-identified) information may be shared with other researchers, here, around the world, and with companies. Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. RISKS AND BENEFITS OF THIS RESEARCH

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

The only risk to you and your child is the possible breach of privacy.
We will lessen this risk by giving you and your child a study ID number that will be used on all surveys and datasheets. This ID will connect your surveys to your child's data.
The database **will not** contain any information that could identify you or your child. All information that could identify you or your child (such as name, email, medical record ID) will be kept in a separate file from your research data. **We will destroy this list of identifiers** when the study is complete.
Some of the survey questions ask you to share sensitive information. You may skip any question that you would rather not answer.

As with any research, there may be risks that are not yet known or expected. Please tell us about any effect or concern that comes up while you and your child are in the study.

5.2 What happens if I have any problems as a result of this research?

If you have any problems as a result of this study you should tell a researcher listed in Contacts.

5.3 If I take part in this study, can I also take part in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. Please tell us if you are in another study so that we can decide if it is ok to take part in this one.

5.4 How could I benefit if I take part in this study? How could others benefit?

It is possible that you may learn something that will help you better care for your child at home after surgery. However, you may not receive any added benefit from being in this study.

We hope to learn about how to give parents information that will help them better and more safely manage pain when the child is prescribed opioid pain medicine.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study? Yes, the researchers will tell you if they learn of new information that may change your willingness to stay in this study.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

If you do not want to take part, you and your child will receive the routine information about how to manage pain and will not have to complete any surveys.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before your part is done, there will be no harm or loss of benefit for you or your child. If you choose to tell us why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information".

7.2 Could there be any harm to me if I decide to leave the study before it is finished? No.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. Though unlikely, we may need to end your part in the study early for things like:

- ✓ It is not in your child's best interest to stay in the study
- ✓ Your child's eligibility changes (example, your child stays in the hospital longer than expected)
- ✓ The study is suspended or canceled

8. FINANCIAL INFORMATION

8.1 Will I or my health plan be billed for any costs of the study?

There are no added costs for taking part in this study.

8.2 Will I be paid or given anything for taking part in this study?

Yes. At the end of your participation, you will receive a check in the mail. The amount of the check will correspond to the parts of the study you have successfully completed. If you complete all parts, you will receive a check for $50. If you complete some but not all parts, your check will reflect the parts of the study you have completed as follows:

- $20 total for completing both the day of surgery and 3-day follow-up surveys
- $15 for completing the 1-week email survey
- $15 for completing both the final (2 to 4 week) survey and returning the diary

In order to mail you the check, we will collect your name and mailing address. We will keep this information separate from any research data.

8.3 Who could profit or financially benefit from the study results?

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

9.1 How will the researchers protect my privacy?

We will not record yours or your child's name or identifying information on any survey, data sheet, or in our database. Your assigned ID number will be used to link your surveys without exposing your identity. We will keep your identifying information in a separate file only to send emails, to pay you, and to record your child's medical information. The link between your ID number and identifiers will be destroyed at the end of the study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. We can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you or your child. The Certificate cannot be used to resist a demand for information from the sponsoring agency (National Institute of Health) who may need the information to audit or evaluate their funded projects. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

The only information we will collect about you is what you provide in the surveys and from our review of your child's medical record. We will only record details about your child's surgery, medicine use during and after surgery and about any adverse effects after surgery. Though we may see other medical information, we will not record anything that is not directly needed for this research.

Signing this form gives the researchers permission to obtain, use, and share your **de-identified** information, within the limits of the Certificate of Confidentiality, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- University, and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
- Make sure the study is done safely and properly
- Analyze the results of the study
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would **not include any information that would let others know who you are**.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

To avoid losing study results that have already included your information

To provide limited information for research, education, or other activities (This information would not include your name or anything else that could let others know who you are.)

To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below for any and all questions that you have about this study, to report any events, or to leave the study early:

Principal Investigator: Terri Voepel-Lewis PhD, RN
Study Coordinator: Monica Weber RN, CCRP (monij@umich.edu)
Mailing Address: Room 4911, 1540 E. Hospital Drive, Mott Children's Hospital, Ann Arbor MI 48109-4245
Telephone: 734 936-6986 or 734 936 0734

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Parent or legal guardian Permission:

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Parent or Guardian Name: _____

Signature: _____Date of Signature:_____

Relationship to subject: ☐ Parent ☐ Legal guardian ☐ Other _____

Principal Investigator or Designee:

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Name/ Title: _____

Signature: _____Date:_____