Promoting Clinical Guidelines for Opioid Prescribing

NCT #04044521

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University of Wisconsin-Madison
Consent to Participate in Research

Title of Study: The Balanced Opioid Initiative

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Invitation
The Implementation Science and Engineering Lab is conducting a research study about promoting the implementation of clinical guidelines for opioid prescribing in primary care clinics. The site lead (UW Health) or team leader (Bellin Health) at your clinic has agreed to forward to clinic staff the opportunity to participate in this study. We invite you to participate in this study because you are a clinician or works with a clinician who prescribes opioids at one of clinics participating in this study.

Why are researchers doing this study?

The purpose of this research study is to determine the most effective way(s) to help prescribers address the needs of patients with chronic non-cancer pain, balancing opioid use with patient pain and function. This study will offer you different types of support to adopt clinical guidelines for opioid prescribing. This research is being done because opioids are commonly prescribed in primary care to relieve chronic pain. In fact, about half of opioid prescriptions are written in primary care. Although opioids are potentially effective for relieving chronic pain, accompanying burdens have become clear and widespread. In 2017, drug overdose was the leading cause of accidental death in the United States. Although the volume of opioids prescribed in the US declined each year from 2010 to 2015, about three times more opioids were prescribed per person in 2015 as in 1999, and prescribing rates still vary greatly, with the highest-prescribing counties prescribing six times more opioids per person than the lowest-prescribing counties. In 2015, 63.1% of drug-overdose deaths involved an opioid, and approximately half of opioid-related deaths involved prescription opioids.

This study is being done at the University of Wisconsin-Madison and other health systems in Wisconsin. A total of about 40 clinics and 300 people will participate in this study.

Funding for this study is provided by the National Institutes of Health.

What will happen in this study?

Your participation in this study starts with attending an educational meeting. During this meeting, the study team will discuss the conduct of this study and review clinical guidelines for opioid prescribing and clinic workflows that help meet these guidelines.

Your attendance at this meeting is completely voluntary. You may leave the meeting at any time.

Prior to this meeting we asked your clinic to create a change team composed of a change team leader and up to 6 other clinic staff.

During the meeting, the study team will explain the study activities that you may be asked to participate in following the educational meeting and you will be asked to complete an assessment. The assessment will be an in-person or online survey, and will ask you questions to elicit contextual characteristics of your clinic such as experience with quality improvement, clinic size, and opioid prescribing policies. This will take you no longer than 10 minutes to complete. You may skip any questions on the assessment that you do not wish to answer. Completing the assessment is voluntary. You can participate in the meeting without completing the assessment.

Following this meeting, you will receive feedback reports prepared and delivered to you by your health system. Then, your clinic will work on workflow changes to improve the clinic's concordance with opioid prescribing guidelines by going back to your clinic and making any changes you learned in the educational meeting that you think will improve guideline-concordant prescribing. Educational meetings touching on different opioid prescribing topics will be hosted every three months via webinar.

Three months after the first educational meeting, half of participating clinics will be randomly assigned to receive practice facilitation, which consists of an hour long in-person site visit plus nine hour long follow-up conference calls (5 monthly, then 4 quarterly).

For clinics that do not get practice facilitation, the change team leader may be asked to participate in a 15-30 minute call with the research team once every 3 months to learn about changes the clinic made. These calls will not be recorded.

For clinics that do get practice facilitation, a trained facilitator will visit your clinics for a site visit. The site visit will include a clinic walkthrough and an hour meeting of round-table discussions with the change team to understand and plan workflow changes to achieve guideline concordance for your clinic. After the site visit, you will be asked to put these plans in action and partake in up to five monthly and four quarterly hour-long follow-up conference calls to assess further workflow changes. Participation in the walkthrough, round-table discussions, or conference calls is optional.

Nine months after the regional meeting, clinics will be randomized so that some receive prescriber peer consulting. Hour-long one-on-one prescriber peer consulting sessions between individual prescribers at your clinic and prescriber peer consultants will take place up to four times (once per quarter) over video or phone call. Prescriber peer consultants are study team members experienced in opioid prescribing. Prescriber peer

consultants will discuss with prescribers topics such as how to handle tough cases and panels and how to safely taper patients to a safer morphine milligram equivalent dose.

An audio recording will be made of the practice facilitation and prescriber peer consulting calls. Only research team members will have access to these recordings. The recordings will not be transcribed.

Throughout the study, the Health Innovation Program will obtain clinic- and provider-level data on opioid prescribing guideline concordance, such as average morphine milligram equivalent, percent of patients who have treatment agreements, percent of patients who have urine drug screens, percent of patients with mental health screenings, rate of opioid/benzodiazepine co-prescribing, the percent of patients above 90 daily milligram morphine equivalent, rates of buprenorphine prescribing, patient depression screening scores, and PEG-3 tool use rates and patient screening scores. These data will be collected through month 27.

In addition, you may be asked to take up to three post-meeting assessments to help the research team better understand when clinicians benefit most from each type of support. These assessments will be paper or online surveys. These assessments are completely voluntary.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time. If you do take back your permission, you will not be able to take part in future research activities. Any data that was collected during your participation may still be used and shared with other members of the study, but no new data about you will be collected. You can choose to take back your permission at any time by letting the researchers know in writing. Please send your request to take back your permission to the lead researcher, Andrew Quanbeck, at 800 University Bay Drive, Suite 210 Madison, WI 53705.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any relationship you have at UW-Madison, UW Health, or any affiliated organizations, or any services you receive from them. Your employment status will not be affected by any choice you make. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose any legal rights.

Will being in this study help me in any way?

Being in this study will not help you directly, although it may benefit your patients on long-term opioid therapy. Your participation in the study may also benefit other people in the future by helping us learn more about improving patient outcomes, prescriber practices, and mitigating the ongoing opioid epidemic.

What are the risks?

There is a risk that your information could become known to someone not involved in this study. If this happens, it could result in damage to your reputation, which could also affect your relationships with family and friends, affect your employment, or make it harder to get insurance or a job.

Will I be paid or receive anything for being in this study?

Individuals who participate in this study are eligible to receive one category 1 continuing medical education (CME) credit through the American Academy of Family Physicians for attending each educational meeting. Individuals who participate in practice facilitation sessions may be eligible to receive additional MOC Part IV CME credits.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information. We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials responsible for monitoring the safety of this study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers 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--for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project that will be used for auditing or program evaluation of agency-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that 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. If an insurer, medical care provider, or

other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Who at UW-Madison can use my information?

- Members of the UW-Madison research team
- UW-Madison regulatory and research oversight boards and offices
- Personnel at the Health Innovation Program who create coded datasets for the study team

Who outside the UW-Madison may receive my information?

- Researchers at the University of Michigan
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if I have questions?

If you have questions about this research, please contact the lead researcher Andrew Quanbeck at 608-262-7385. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

AGREEMENT TO PARTICIPATE IN THIS STUDY

Your participation is completely voluntary. You can decide not to participate or to withdraw from the study at any time.

Your signature indicates that you have read this consent form, had an opportunity to ask any questions about your participation in this research, and voluntarily consent to participate. You will receive a copy of this form for your records.

Name of Participant (please print): _____

_____ _____
Signature Date

Your signature below indicates that you consent to be directly quoted in any publications that result from this research. Your name will not be used.

_____ _____
Signature Date

_____ _____
Signature of Person Obtaining Consent Date

Study Participant Demographics

The collection of study participant demographic information for this research is required by the National Institutes of Health (NIH). If you do not wish to report your demographic information, you may choose "Unknown/Not Reported" for any of the categories listed below.

Sex

- ☐ Female
- ☐ Male
- ☐ Unknown/Not Reported

Race

- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Black or African American
- ☐ White
- ☐ More than one race
- ☐ Unknown/Not Reported

Ethnicity

- ☐ Hispanic or Latino
- ☐ Not Hispanic or Latino
- ☐ Unknown/Not Reported