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Consent to Participate in Research

Study Title: Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee

Principal Investigator: Kevin Bozic, MD, MBA UT Health Austin Musculoskeletal Institute 1601 Trinity Street, Building A

Study Sponsor: Agency for Healthcare Research and Quality Identification of Investigator and Purpose of Study

You are invited to participate in a research study, called “Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee.” The study is being done by Dr. Kevin Bozic, Professor of Surgery and Perioperative Care of The University of Texas at Austin, Dell Medical School.

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study may help us understand the usefulness of this educational tool for knee replacement candidates. You are free to contact the researcher at the email address below (under “Contacts”) to discuss the study.

If you agree to participate:

You will be randomly selected to either: 1) a group receiving educational materials and personalized estimates of your likely benefit and harm from knee replacement surgery, to 2) a group receiving the educational materials only. There is an equal likelihood (chance) of being selected to each group. This study uses several questionnaires. The questionnaires will take approximately 10 minutes total of your time today. Three (3) months from now and six (6) months from now, we will ask you to fill out a few more questionnaires. If you don’t have a follow-up clinic appointment around that time, we will email or call you to complete the surveys on the web or by phone. All information will be securely stored to protect your confidentiality. If you complete both surveys, you will be compensated for your time and participation in this project with a $25 gift card.

Risks/Benefits/Confidentiality of Data

There are no known risks to participating in the study. However, answering the questions might make you feel uncomfortable. If you feel discomfort at any time during this interview, you may stop participating right away. The information gathered in this study will be coded. This means that instead of your name, we will use a participant ID number that is specifically created for this study to link your answers to personal information like phone number and email address. A limited number of research team members will have access to the data. The UT Institutional Review Board (responsible for overseeing ethical conduct of research) may inspect research records and thus access your data. Despite the steps taken to protect your confidentiality, there is a small risk that someone not involved in the study may see the data you provide as part of this study. There will be no costs for participating, nor will you benefit from participating. The information that you provide will not affect your relationship with the University of Texas.
What will happen to the information we collect about you after the study is over?

Information collected as part of the research will not be used or distributed for future research studies. Participation or Withdrawal

Your participation in this study is voluntary. You may decline to answer any question and you have the right to stop participating at any time. If you decide not to participate or withdraw, it will not affect your relationship with The University of Texas in any way. If you do not want to participate, please tell the research assistant.

Contacts

If you have any questions about the study, contact the lead researcher, Dr. Kevin Bozic, by sending an email to kevin.bozic@austin.utexas.edu. This study has been reviewed by The University of Texas at Austin Institutional Review Board and the study number is 2018-11-0042.

Questions about your rights as a research participant.

If you have questions about your rights or are dissatisfied at any time with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 232-1543 or email at irb@austin.utexas.edu.

HIPAA Authorization for Research

The purpose of this form is to seek your authorization (permission) for the Principal Investigator listed above and their research team to use and share your individual health information for the above study.

State and federal privacy laws protect your patient information. These laws say that, in most cases, your health care provider can release your identifiable patient information to the research team only if you give permission by signing this form. The research team will use and protect your information as described in the attached Consent Form.

However, once your health information is released it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team. You will get a copy of this form.

What organizations’ information will you use and share for the study?

Seton/Ascension UT Health

What information will you use and share for the study?

If you give your permission and sign this form, the Principal Investigator and their research team will use and share information from your medical records and other information that can identify you.

For this study the research team will use and share any information from the marked here:
☐ Research Record ☐ Genetic testing information

☐ Entire Medical Record ☐ Information about mental health diagnosis or treatment

☐ History & Physical Exams ☐ Information about drug or alcohol abuse, diagnosis or treatment

☐ Lab & Pathology Results ☐ HIV/AIDS testing information [Texas DSHS’ rules require health care providers and laboratories to report cases of HIV and AIDS to local DSHS offices (See https://www.dshs.texas.gov/hivstd/reporting/).]

☐ Financial records

☒ Other (describe): name, telephone number, email and mailing address, dates (date of birth, date of knee replacement surgery, patient reported outcomes from KOOS JR, DQI, PHQ-2, GAD-2, CollaboRATE, satisfaction and PROMIS-10 surveys, other diagnosed health conditions, smoking status, number of emergency room visits past 12 months, number of overnight hospitalizations past 12 months)

Why will this information be used and shared with others?

To do the research study described in this document

Who is this information shared with?

We may share information that might identify you with:

People who oversee research to make sure it is done safely and correctly (like staff or affiliates from the study sponsor, or the UT Institutional Review Board). For studies or procedures that are related to your medical care, study information may be placed in your medical record. Staff that sees your medical record as part of your care may be aware that you are/were in a research study.

What happens if I say no?

You do not have to sign this form. If you do not, you will not be able to be in the research study. Your decision to not sign this form will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

May I change my mind later?

Your permission to use and share information for this study does not have an expiration date unless a time frame is described here: ____________________

At any time, you can tell us to stop using and sharing health information that identifies you. If you want us to stop, you have to tell us in writing. You can get the researcher’s address by calling 512-495-5090.

When we stop, no new health information identifying you will be used or shared. Information that has already been collected may still be used and given to others for limited purposes. For
example, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

Giving permission

By signing this form, I agree to participate in this research study and I allow the use and disclosure of my health information for the purposes described above.

Typed Name (First, Last) _____________________________

Signature _____________________________

(Please sign with finger. Click green "Add Signature" to sign.)

Date _____________________________

Time _____________________________

Relationship of Subject or Authorized Representative _____________________________
Consent to Participate in Research

**Study Title:** Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee

**Principal Investigators:** Joel Tsevat, MD, MPH
7411 John Smith Drive
Suite 1050
San Antonio, TX 78229

**Study Sponsor:** Agency for Healthcare Research and Quality

**Key Information**
You are invited to participate in a research study. Your participation is voluntary (of your free will).

- **Purpose of the research:** The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions.
- **What is involved:** If you choose to participate, you will be interviewed to learn more about your treatment decision experience. This interview will take about 15 minutes and can be scheduled in person or as a virtual interview (through Zoom).
- **Risks:** There are no known risks to participating in the study. However, answering the questions might make you feel uncomfortable. If you feel discomfort at any time during the interview, you may stop participating right away.
- **Benefits:** There are no direct benefits for participating in the study. However, we hope the information we learn will be helpful for improving care for patients with knee pain in the future.
- **Alternatives to participation:** If you decide not to participate, it will not affect your relationship with the University of Texas Health Science Center at San Antonio or UT Physicians in any way.

**Identification of Investigator and Purpose of Study**
You are invited to participate in a research study called “Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee.” The study is being led by Dr. Joel Tsevat, Professor of Medicine, Director, ReACH Center at the University of Texas Health Science Center at San Antonio and Dr. Kevin Bozic, Professor of Surgery and Perioperative Care of The University of Texas at Austin, Dell Medical School.

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study may help us understand the usefulness of this educational tool for knee replacement candidates. You are free to contact the researchers at the email address below (under “Contacts”) to discuss the study.

If you agree to participate:
- You will be interviewed to learn more about your treatment decision experience. Please note that your participation in this study involves remote and/or virtual research interactions with our research staff. This interview will take approximately 15 minutes and can be scheduled in-person or through the Zoom web conferencing platform.
- Therefore, privacy and confidentiality is not guaranteed due to the nature of the research environment.
- All information will be securely stored to protect your confidentiality.
To compensate you for your participation, upon completing the questionnaires and interview, the research team will give you a $25 MasterCard® ClinCard (gift card). Your name, address and date of birth will be shared with a third-party solely for the purposes of processing the compensation. This information will otherwise be kept strictly confidential.

**Risks/Benefits/Confidentiality of Data**
There are no known risks to participating in the study. However, answering the questions might make you feel uncomfortable. If you feel discomfort at any time during this interview, you may stop participating right away. The information gathered in this study will be coded. This means that instead of your name, we will use a participant ID number that is specifically created for this study to link your answers to personal information like phone number and email address. A limited number of research team members will have access to the data. The UT Institutional Review Board (responsible for overseeing ethical conduct of research) may inspect research records and thus access your data. Despite the steps taken to protect your confidentiality, there is a small risk that someone not involved in the study may see the data you provide as part of this study. There will be no costs for participating, nor will you benefit from participating. The information that you provide will not affect your relationship with the University of Texas Health Science Center at San Antonio or UT Physicians.

**What will happen to the information we collect about you after the study is over?**
Information collected as part of the research will not be used or distributed for future research studies.

**Participation or Withdrawal**
Your participation in this study is voluntary. You may decline to answer any question and you have the right to stop participating at any time. If you decide not to participate or to withdraw, it will not affect your relationship with the University of Texas Health Science Center at San Antonio or UT Physicians in any way. If you do not want to participate, please tell the research assistant.

**Contacts**
If you have any questions about the study, contact the lead researcher, Dr. Joel Tsevat, by sending an email to tsevat@uthscsa.edu. This study has been reviewed by The University of Texas at Austin Institutional Review Board and the study number is 2018-11-0042.

**Questions about your rights as a research participant.**
If you have questions about your rights or are dissatisfied at any time with any part of this study, you can contact, anonymously if you wish, the University of Texas Health Science Center at San Antonio, which is the local Institutional Review Board (IRB) committee that reviews research on human subjects. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

**HIPAA Authorization for Research**
The purpose of this form is to seek your authorization (permission) for the Principal Investigator listed above and their research team to use and share your individual health information for the above study.

State and federal privacy laws protect your patient information. These laws say that, in most cases, your health care provider can release your identifiable patient information to the research team only if you give permission by signing this form. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released it may not be
protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team. You will get a copy of this form. Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What organizations’ information will you use and share for the study?

- The University of Texas Health Science Center at San Antonio/UT Physicians

What is Protected Health Information (PHI)?

Protected Health Information is information about a person’s health that includes information that would make it possible to figure out who the person is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this research study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for the study. In carrying out this research, the health information we will see and use about you will include:

- your medical history and blood work,
- information from interviews or from questionnaires
- demographic information like your age, marital status, the type of work you do and the years of education you have completed.

We will get this information by looking at your chart at UT Physicians and interviewing you about your experience meeting with your physician.

What information will you use and share for the study?

If you give your permission and sign this form, the Principal Investigator and their research team will use and share information from your medical records and other information that can identify you.

For this study the research team will use and share any information from the marked here:

- Research Record
- Entire Medical Record
- History & Physical Exams
- Lab & Pathology Results
- Imaging Reports
- Emergency Dept. Record
- Financial records
- Genetic testing information
- Information about mental health diagnosis or treatment
- Information about drug or alcohol abuse, diagnosis or treatment
- HIV/AIDS testing information [Texas DSHS’ rules require health care providers and laboratories to report cases of HIV and AIDS to local DSHS offices (See https://www.dshs.texas.gov/hivstd/reporting/).]
- Other (describe): name, telephone number, email and mailing address, dates (date of birth, date of knee replacement surgery)

Why will this information be used and shared with others?

- To do the research study described in this document
**Who is this information shared with?**

We may share information that might identify you with:

- Members of the local research team
- The sponsor funding the study, Agency for Healthcare Research and Quality, and the entities that they use to monitor, administer, or conduct the research.
- The following collaborators at other institutions that are involved with the study: the University of Texas at Austin, Dell Medical School.
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out; and
- the Research offices at the University of Texas Health Science Center at San Antonio
- For studies or procedures that are related to your medical care, study information may be placed in your medical record. Staff that sees your medical record as part of your care may be aware that you are/were in a research study.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in this research study.

**How will my information be protected?**

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside the University of Texas Health Science Center at San Antonio or the University of Texas at Austin for review or testing. If the results of this study are reported in medical journals or at meetings, you will not be identified.

**Do you have to allow the use of your health information?**

You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you must provide this in writing and send your letter to Sarah Lill at 7411 John Smith Drive, Suite 1050, San Antonio, TX 78229-3900. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

**Can you ask to see the PHI that is collected about you for this study?**

The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study. You will only have access to your PHI until the end of this study.

**What happens if I say no?**
You do not have to sign this form. If you do not, you will not be able to be in the research study. Your decision to not sign this form will not affect any other treatment, health care, enrollment in health plans or eligibility for benefits.

**May I change my mind later?**
Your permission to use and share information for this study does not have an expiration date unless a time frame is described here: ____________________________

At any time, you can tell us to stop using and sharing health information that identifies you. If you want us to stop, you have to tell us in writing. You can get the researcher’s address by calling 210-562-5551.

When we stop, no new health information identifying you will be used or shared. Information that has already been collected may still be used and given to others for limited purposes. For example, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

**Giving permission**
By signing this form, I agree to allow the use and disclosure of my health information for the purposes described above.

Printed Name of Subject

<table>
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<th>Signature of Subject or Authorized Representative</th>
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Printed Name of Witness

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Consent to Participate in Research

Study Title: Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee

Principal Investigators: Joel Tsevat, MD, MPH
7411 John Smith Drive
Suite 1050
San Antonio, TX 78229

Study Sponsor: Agency for Healthcare Research and Quality

Identification of Investigator and Purpose of Study

You are invited to participate in a research study called “Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee.” The study is being led by Dr. Joel Tsevat, Professor of Medicine, Director, ReACH Center at the University of Texas Health Science Center at San Antonio and Dr. Kevin Bozic, Professor of Surgery and Perioperative Care of The University of Texas at Austin, Dell Medical School.

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study will help us understand more about how we can successfully implement the Joint Insights decision making tool into your clinical practice and may help us understand the usefulness of this educational tool for knee replacement candidates. You are free to contact the researchers at the email address below (under “Contacts”) to discuss the study.

If you agree to participate:

- You will be interviewed to learn more about your clinical practice and current shared decision making interactions with patients with Osteoarthritis of the knee. Please note that your participation in this study involves remote and/or virtual research interactions with our research staff. This interview will take approximately an hour and can be scheduled in-person or through the Zoom web conferencing platform.
- Therefore, privacy and confidentiality is not guaranteed due to the nature of the research environment.
- All information will be securely stored to protect your confidentiality.

Risks/Benefits/Confidentiality of Data

There are no known risks to participating in the study. However, answering the questions might make you feel uncomfortable. If you feel discomfort at any time during this interview, you may stop participating right away. The information gathered in this study will be coded. This means that instead of your name, we will use a participant ID number that is specifically created for this study to link your answers to personal information like phone number and email address. A limited number of research team members will have access to the data. The UT Institutional Review Board (responsible for overseeing ethical conduct of research) may inspect research records and thus access your data. Despite the steps taken to protect your confidentiality, there is a small risk that someone not involved in the study may see the data you provide as part of this study. There will be no costs for participating, nor will you benefit from participating. The information that you provide will not affect your relationship with the University of Texas Health Science Center at San Antonio or UT Physicians.
What will happen to the information we collect about you after the study is over?

Information collected as part of the research will not be used or distributed for future research studies.

Participation or Withdrawal

Your participation in this study is voluntary. You may decline to answer any question and you have the right to stop participating at any time. If you decide not to participate or to withdraw, it will not affect your relationship with the University of Texas Health Science Center at San Antonio or UT Physicians in any way. If you do not want to participate, please tell the research assistant.

Contacts

If you have any questions about the study, contact the lead researcher, Dr. Joel Tsevat, by sending an email to tsevat@uthscsa.edu. This study has been reviewed by The University of Texas at Austin Institutional Review Board and the study number is 2018-11-0042.

Questions about your rights as a research participant.

If you have questions about your rights or are dissatisfied at any time with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 471-8871 or email at orsc@uts.cc.utexas.edu.

The University of Texas Health Science Center at San Antonio is the local Institutional Review Board committee that reviews research on human subjects (Institutional Review Board) and can also answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.
Patient Interview (Baseline and Post-Implementation)

Good Day Mr./Ms.______

You have been selected to participate in a research study called "Incorporating Patient-Reported Outcomes into Shared Decision Making with Patients with Osteoarthritis of the Knee." You were identified as a potential participant in this study because you are a patient of __________ and you have arthritis of the knee.

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study may help us improve care in this clinic.

If you agree to participate:

- You will be interviewed to learn more about your treatment decision experience.
- This interview will take approximately 15 minutes and can be scheduled in-person (right now if you are available) or through the Zoom web conferencing platform.
- Therefore, privacy and confidentiality are not guaranteed due to the nature of the research environment.
- All information will be securely stored to protect your confidentiality.
- Your information will not be shared with your providers or anyone in this clinic.
- To compensate you for your participation, upon completing the interview, the research team will give you a $25 MasterCard® ClinCard (gift card). Your name, address and date of birth will be shared with a third-party solely for the purposes of processing the compensation. This information will otherwise be kept strictly confidential.

Patient History, Functional Impact, and Concerns

1. Please tell me a little bit about your knee. How long has it been bothering you, and how does it impact you?

2. Have you ever had treatment for your arthritis before? [If yes:] can you tell me more about that? What prompted you to get treatment? How did that turn out?

3. What are your priorities in coming to this clinic? Why are you here seeing ________ for your knee? What are you hoping for from treatment? [What are you hoping this going to do for you?]

Patient Experiences of Care, Communication, and Decision-Making

4. How did you feel about your appointment (with the orthopedist)?

5. How did the appointment go? Can you walk me through what happened during your appointment?
   - What are some of the things you talked about?
   - What sort of questions did your provider ask?
6. Do you have a plan now for treatment? Can you tell me a little bit about that?

7. Can you walk me through how you and your provider(s) came to that treatment plan?
   o Did you discuss different treatment options?
   o What treatment did you decide on? Why was this plan selected?
   o Was there information you found helpful in making the treatment plan?
   o Was there anything you found difficult or confusing about making the treatment plan?

8. Did you feel like all of your questions were answered?
   o Were there questions you would have liked to ask but didn’t? If so, what were they?

Patient Understanding and Expectations for Next Steps in their Treatment Process

9. Can you tell me a little bit about what happens next with your treatment?

10. How do you feel about your treatment plan overall?

11. How did you feel in general about the care you received? Were there things that could have been better?

12. Is there anything additional you think we should know or you’d like to tell me?

Thank you so much for your time and input!
Baseline Provider Interview

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study is voluntary and will help us to understand more about how we can successfully implement the Joint Insights decision making tool into your clinical practice and may help us understand the usefulness of this educational tool for knee replacement candidates. You are free to contact the researchers at the e-mail address provided on the consent document.

You are being interviewed to learn more about your clinical practice and current shared decision making interactions with patients with osteoarthritis (OA) of the knee. Since this interview is taking place over an online platform, your privacy and confidentiality cannot be fully guaranteed due to the nature of the research environment. All information collected in this interview will be securely stored to protect your confidentiality.

We are recording interviews to allow for learning and analysis – do you mind if we record? [If yes, start the recording and ask again for verbal consent once recording has begun: “We have started the recording – do you mind confirming that you are ok with us recording?” If no, say, “Ok. We will be taking notes throughout the interview.”]

Professional Background/Baseline Behaviors

1. Can you first tell me a little bit about your professional experience and training?

2. How long have you been at this facility and what is your role here? [Professional role]

3. Please briefly describe the population of patients you see in this clinic.

4. Now I’d like to ask specifically about how you would normally go about identifying the appropriate treatment for a patient with knee OA in this clinic. What would that process ordinarily look like? [Baseline behaviors]
   - Probe if needed: Do patient history, pain status, or other evaluations play a role in your decision making?
   - What strategies or criteria do you use for identifying an appropriate treatment? How do you evaluate whether patients may be more likely to benefit from or be at risk of negative outcomes from a particular treatment?
   - What information is typically included in the chart, and how do you reference that information as part of your treatment planning and discussions with patients?

5. How do you generally approach treatment planning with your patients?

6. How do you talk with your patients about the available treatments for knee OA?

General PRO Awareness/Perceptions

7. How familiar are you with the idea of patient-reported outcomes or PROs? What do you think about them? Have you ever worked with them?

Probes:
Some examples might include the PHQ-9, KOOS Jr, or PROMIS Global. Are there any measures like this that you routinely use for patients with knee OA?

[If yes:] What role do these measures play in your evaluation and treatment planning process for patients with knee OA?

8. Has your clinic tried to implement PROs in the past? If so, how did that go?

9. Do you feel like your clinic is able to integrate PROs as they become available?

Joint Insights: Perceived Feasibility and Acceptability, Contextual Readiness, Barriers/Facilitators

As you know, we are working toward implementing a tool called Joint Insights into your clinic. Joint Insights is a predictive analytic tool co-developed by OM1 and UT Health Austin that uses PRO scores (KOOS Jr and PROMIS Global) and clinical data to estimate the likelihood of a successful clinical outcome with total knee replacement. It provides individualized estimates at the point of care of the potential risk and benefits of treatment modalities.

10. How do you feel about the idea of adding the Joint Insights tool into your clinic? Are there things that make you feel motivated to do this? Are there concerns that make you feel less motivated? [motivation and barriers]

   o What do you think the benefits of this tool in your clinic would be?

   o What concerns do you have about use of this tool in your setting?

   o Do you think this tool will help meet the needs of your patients? Why or why not?

11. To what degree do you feel able to integrate the Joint Insights tool into your routine practice? Do you feel like this is something you can get yourself to do? Why or why not? [ability and barriers]

12. Thinking a little more broadly, to what degree do you feel like your clinic will be able to integrate the Joint Insights tool into routine practice? Do you feel like this will work in your clinic? Why or why not? [ability and barriers]

   o Do you think other providers in this setting will use this tool in their routine practice?

   o What do you think might be potential problems trying to implement this tool in your clinic?

13. Now I’d like to think together in a little bit more detail about workflow. Let’s walk together through the diagram below. As we walk through, I’d love to hear your thoughts on how well you think this will work in your clinic, and what might make this tool easier to use or incorporate into workflow.
Recommendations for Tailoring and Implementation  
[Note: revisit diagram as needed.]

13. Are there prompts that could be inserted into the workflow (or that already exist) to aid in remembering to use the tool?

14. Do you feel clear about how you’ll talk to patients using the PRO information gathered by the tool? What are your thoughts on including this as part of your conversation with them?

15. Two of the options for integrating patient reports into the workflow include printing out a paper report for each patient on their PRO measures and individualized estimates of risks and benefits, or have that information integrated into EPIC. Which of those options do you think would be more helpful or a better fit for your clinic?

16. Are there other data you’d like to see captured for accurate results or clinic needs?

14. Our goal from here is to take this information and develop a plan for implementing the tool. We’ll continue to be in touch with you about building out that plan and other progress. Do you have any final thoughts on the tool or what would be most helpful to you and your team going forward?

Thank you for your time!
Post-implementation Provider Interview

The purpose of this research study is to understand whether giving patients with knee pain information about their likely benefits and risks from surgery improves the quality of their treatment decisions. Your participation in the study is voluntary and will help us to understand more about how we can successfully implement the Joint Insights decision-making tool into your clinical practice and may help us understand the usefulness of this educational tool for knee replacement candidates. You are free to contact the researchers at the e-mail address provided on the consent document.

You are being interviewed to learn more about your clinical practice and current shared decision-making interactions with patients with osteoarthritis (OA) of the knee. Since this interview is taking place over an online platform, your privacy and confidentiality cannot be fully guaranteed due to the nature of the research environment. All information collected in this interview will be securely stored to protect your confidentiality.

We are recording interviews to allow for learning and analysis – do you mind if we record? [If the patient agrees, start the recording and ask again for verbal consent once recording has begun: “We have started the recording – do you mind confirming that you are ok with us recording?” If the patient does not want the interview to be recorded, say, “Ok. We will be taking notes throughout the interview.”]

Professional Background/Post-Implementation Behaviors

1. [If new staff since baseline:] Can you first tell me a little bit about your professional experience and training?

2. [If new staff since baseline:] How long have you been at this facility and what is your role here? [Professional role]

3. Do you mind if we start by walking through the normal check-in, assessment and treatment planning process for a patient with knee OA being evaluated for surgery in this clinic? What does that process look like? [Post-implementation behaviors]
   
   o Probe if needed: What kind of evaluations (e.g., patient history, pain status) play a role in your decision making?
   
   o How do you generally approach treatment planning with your patients?
   
   o How do you talk with your patients about the available treatments for knee OA?

Experience with PROM/Joint Insight Implementation

4. Can you tell me a little bit about the effort to implement patient-reported outcome measures (PROMs) in the clinic? How has that process been going?

   o Are patients completing PROMs? How frequently? What have been some of the challenges in getting patient-reported outcomes (PROs) integrated into the clinic?
   
   o How are patients completing the PROMs (e.g., in MyChart, on paper, on tablet)? How well is that working?
1. What have been some of the key ingredients in getting PROMs integrated as part of the clinic’s workflow?
2. What additional supports would be valuable in supporting implementation of PROMs for patients?
3. Do you have recommendations for other clinics trying to make PROMs part of their routine workflow?

5. Once a patient completes the PROMs, how are those data made available to the clinical team (e.g., entered into record by staff member, forms left in exam room, etc.)?
   - How well is that process working? What have been some of the challenges?
   - Are there improvements that you would like to see in how the process works?

6. Do you feel like having PROMs available has resulted in any change to the evaluation and treatment planning process for patients with knee OA in your clinic at all? [If yes:] How so? [If no:] Can you say a little bit more about that?
   - If applicable: Are there particular measures (e.g., KOOS Jr, PROMIS Global) that are more or less likely to impact treatment planning or the conversation with patients? How so?

7. Can you tell me a little bit about the effort to implement Joint Insights in the clinic?
   - If a reminder is needed: Joint Insights is a predictive analytic tool co-developed by OM1 and UT Health Austin that uses PRO scores (KOOS Jr and PROMIS Global) and clinical data to estimate the likelihood of a successful clinical outcome with total knee replacement. It provides individualized estimates at the point of care of the potential risk and benefits of treatment modalities. How has that process been going?
   - Is the Joint Insights tool being used with patients being assessed for total knee replacement at this clinic? How frequently? What have been some of the challenges in getting Joint Insights up and running in the clinic?
   - How are patient data being entered into Joint Insights? How well is that working?
   - If Joint Insights is being implemented: What have been some of the key ingredients in getting Joint Insights integrated as part of the clinic’s workflow?
   - What additional supports would be valuable in supporting implementation of Joint Insights?
   - Do you have recommendations for other clinics trying to make Joint Insights part of their routine workflow?

8. Do you feel like having Joint Insights available has resulted in any change to the evaluation and treatment planning process for patients with knee OA in your clinic at all? [If yes:] How so? [If no:] Can you say a little bit more about that?
   - If applicable: Are there particular elements of the Joint Insights tool that are more or less likely to impact treatment planning or the conversation with patients? How so?
9. [If Joint Insights implemented:] How satisfied do you feel with the Joint Insights tool at this point? Can you say a little more about what you are appreciating or not appreciating about the tool?

10. [If Joint Insights implemented:] Have you gotten any sense of what patients think about the Joint Insights tool?
   1. Have you heard any negative feedback about the tool from patients? What have you heard?
   2. Have you heard any positive feedback about the tool from patients?

11. What has been the response, if any, to the Joint Insights tool from other providers and staff in the clinic? Has there been negative or positive feedback about the tool or its implementation?

12. Looking ahead, to what degree do you feel that your clinic is likely to continue using PROMs and/or Joint Insights [note to interviewer: only ask about sustaining program elements that were implemented] as part of your practice? Do you feel like this will be sustainable in your clinic? Why or why not? [ability and barriers]
   - Do you think other providers in this setting will adopt/continue use of this tool in their routine practice?
   - What do you think might be potential problems trying to keep PROMs and/or Joint Insights going as part of routine practice in your clinic?
   - Are there additional resources or supports that would be helpful in trying to continue use of the PROMs or Joint Insights in your clinic?

13. Thinking about working together with the study/implementation team to get PROMs and Joint Insights up and running in the clinic, how well did that process work?
   0. Were there things that would have made that progress work better or be more efficient?
   1. What recommendations would you have for the team about improving how they support clinics in implementing PROMs/Joint Insights in working with future sites? Are there things the team could do better next time?

14. Are there any other thoughts or reflections you would like to share regarding these tools or the implementation process?

Thank you for your time!