WARRIOR-SCD: Whole-person Assessment of Response and Risk after transformative therapies:

Investigating Outcomes and Resilience in Sickle Cell Disease

A Cure Sickle Cell Initiative Long Term Follow-Up Study

What are patient reported outcomes (PRO)?

PRO surveys ask patients questions about their physical, mental, social, and financial health as well as other domains that give researchers an idea of how their quality of life is affected after treatment.

Who is eligible for the PRO protocol?

Any patient with sickle cell disease aged 8+ who are comfortable reading or speaking English or Spanish. To be enrolled, they must be approved for gene therapy by a product manufacturer and consent to be contacted by CIBMTR at the end of the research consent form.

When are the PRO timepoints?

- Baseline/before gene therapy or transplant
- Day 100
- Day 180
- Year 1
- Annually, thereafter

What types of questions are asked on the surveys?

- Pain (acute and chronic)
- Global Health
- Physical Health (fatigue, sleep, etc.)
- Mental Health (depression, anxiety, etc.)
- Social Health (ability to participate in social roles, peer and family relationships)
- Sexual Function (adult only)
- Reproductive Health
- Financial Toxicity
- Occupational Function (work or school)
- Social Determinants of Health

How long are the surveys?

The baseline survey is the longest and will take anywhere from 20-25 minutes to complete.

How many times will patients be contacted to participate?

The survey research group (SRG) will try to contact patients up to 6 times at each timepoint. For patients who do not respond or do not actively decline, SRG will attempt to enroll them up until day 100 (D100). After D100, SRG will assume the patient is lost to follow-up and will discontinue outreach.

Will patients be compensated for completing surveys?

Patients will receive a $50 gift card for completing their first survey, and a $25 gift card for every survey completed after that for UP TO 15 years, pending available funding for the study.

Can someone else fill out the survey for the patient?

For minors (<18), the survey will be sent in 2 parts, in 2 different emails, with 2 different links. The minor will receive a survey on their physical health and symptoms, and the caregiver/guardian will receive a survey on social determinants of health and financial impact. For minors, only ONE gift card will be given per timepoint.

Who is receiving the informational flyer and why?

Any patient 8 and up who has sickle cell disease and has been approved for cell or gene therapy should receive an informational study flyer to take home with them. There is an adult flyer for patients over 18 years old and a minor flyer for patients aged 8-17.

How do patients consent to the PRO surveys?

Within the clinical data informed consent form, patients are asked if they agree to be contacted for additional research. If they answer "Yes" to this question, patients will be approached via email, telephone, or text to participate in the PRO survey portion of this study. Patients will be offered 3 types of approaches to learn more about the PRO portion of the study:

1. A warm handoff virtual call, telephone conversation, or other modality where a care team member will introduce the patient to the survey research group (SRG) team member in real time
2. An opportunity to connect with a patient representative to provide personal experience and answer questions the patient might have.
3. A flyer and other mixed medias will be shared to introduce the study

Regardless of the choice the patient makes, a member of the SRG will reach out to obtain consent to the PRO Protocol, ask for preferred method of communication (telephone, email, text), and share the initial baseline survey. Consent is collected centrally at CIBMTR on paper or electronically and maintained in CIBMTR's ePRO system.

More questions?

Visit the WARRIOR-SCD Webpage at https://cibmtr.org/CIBMTR/Utility-Nav/Patients/Warrior-SCD-Study or by scanning the QR code: