

Interview Guide

Action Actor Context Target Time (AACTT):

Action: Deciding to enrol in an early phase CAR-T clinical trial

Actor: People diagnosed with haematological malignancies

Target: People diagnosed with haematological malignancies eligible for trial participation

Context: Hospitals, clinics

Time: During recruitment phase of trial

Interview Guide for Patients with Hematologic Malignancies

Explanation (*read to patient*)

Thanks for agreeing to speak with me today. As we discussed, we are planning a clinical trial and before we design and run that trial, we want to make sure we capture the views of patients so that our trial takes their – and your – views into account. Our trial will be testing whether a type of white blood cell that attacks cancer cells can be extracted from patients, changed to recognize and kill a particular cancer cell, and then reintroduced into patients as a potentially new treatment therapy for blood cancers. We call these cells “CAR-T cells”. Ok so far?

Did you get a chance to read over the information sheet? If ‘yes’ move forward; if ‘no’, describe the background of this study and what their participation will involve.

Our discussion shouldn't take more than an hour (probably less) but please take as much time as you need. As discussed and if still ok with you, I will audio-record our discussion just to make sure that I capture all your thoughts so that I can listen back to them later.

All identifying information (your name or the names of others) that you mention will be removed from the interview transcripts; making this anonymous. If you want to take a break or stop our discussion before I have asked all of the questions or if you wish to withdraw from this interview study you are completely free to do so. There are no right or wrong answers to the questions; we are simply interested in your views about potentially receiving CAR-T cells. Your responses will be anonymized so that no one will know what your specific answers were.

Just to clarify: you may never be asked to participate in the CAR-T cell trial yourself; instead, our discussion today is all about getting views from patients who have had experience with blood cancer treatments about the potential of receiving CAR-T cells. This is to help design a more effective clinical trial program and to maximize the benefits that future patients and care givers will receive. Also, so you know, my background is in research and I am not a clinician (e.g. doctor or a nurse). If anything isn't clear, don't be shy to ask me to clarify.

All ok so far? Any questions?

To begin with, for the rest of our discussion, I'd like you think about the hypothetical situation as it might apply to you if you were in that situation: **enrolling and participating in a clinical trial of CAR-T cells to treat your blood cancer.**

Background Questions

- Male or Female (to keep track of, will not be asked)
 - What year were you born?
 - Could you briefly describe your diagnosis?
 - o What is the name of your cancer?
 - o Have you had the cancer come back?
 - o What kind of treatment have you received? (E.g. which kind of chemotherapy? Radiation?)
 - o Have you had a transplant? If so, which kind have you had? (E.g. Self or donor transplant? Auto transplant or allogenic transplant?)
1. Have you or anyone that you know been involved in clinical research? Have you ever been involved in agreeing to take part in a clinical trial? (DOMAIN: NATURE OF THE BEHAVIOUR)
 2. What do you know about clinical trials? (If they don't know, explain the phases and which phase this trial would be) (DOMAIN: KNOWLEDGE)
PROMPT: Describe that this trial is a phase I/II trial and what that entails

Phase I: Researchers test a new drug or treatment in a small group of people (less than 10) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects. Patients are monitored very closely. The study is not designed to conclusively say if the treatment is effective, but it may still be effective for a given patient.

Phase II: The drug or treatment is given to a larger group of people (around 100 or so) to see if it is effective at the dose tested in Phase I and to further evaluate its safety. Patients are monitored closely. Phase II studies are designed to test if the treatment is effective, but may or may not be effective for every patient.

Phase III: The drug or treatment is given to large groups of people (hundreds, sometimes thousands) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.

Phase IV: Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

3. Can you tell me about what you know about CAR-T cells? Have you heard about them? Do you know how they are collected? What do you think about that? (DOMAIN: KNOWLEDGE)

Brief background: Currently, small clinical trials have been conducted involving extracting a patient's own T cells (a type of white blood cell that attacks virus-infected or cancer cells), changed to recognize and kill a particular cancer cell, and then reintroduced into the patient as a new treatment therapy for blood cancers. These are known as CAR-T cells.

These CAR-T cell studies have all been very small, but the evidence so far shows that the patients who respond CAN BE cured of their cancer. This is really promising, but we need to run a bigger clinical trial to make sure these effects are as promising as they appear. This will be a Canadian-based trial involving researchers, academics, and health care professionals across Canada.

4. What are some of the benefits that you see in participating in this clinical trial? (DOMAIN: BELIEFS ABOUT CONSEQUENCES)
 - PROMPT: For you, for future patients, research
5. And what are some of potential negative aspects that you see of participating in this clinical trial? (DOMAIN: BELIEFS ABOUT CONSEQUENCES)
 - PROMPT: For you, for future patients, for anyone else
 - Do you know of any potential negative side effects? What are your thoughts on these side effects?

DESCRIBE POSSIBLE SIDE EFFECTS HERE AND POSSIBLE DURATION OF TRIAL PARTICIPATION AFTER ASKING WHAT CONCERNS THEM

- Side effects:
 - Negative:
 - Cytokine-release syndrome (CRS), Tumour lysis syndrome (TLS), Neurologic toxicity, “on target/off tumour” recognition (B-cell aplasia), Anaphylaxis, graft v. host disease for allogenic cells
 - Positive:
 - Remission; increase in progression free survival; cure of cancer
6. Thinking about your own experiences, what might affect whether you would decide to enrol in this clinical trial? (DOMAIN: DEPENDS ON ANSWER)

- PROMPT: Have you ever been in a clinical trial yourself?
 - PROMOT: (If yes) How did that go?
7. What information would you need to feel comfortable participating in a trial of CAR-T cells for blood cancer? (DOMAIN: DEPENDS ON ANSWER) From who would you like to receive that information? (DOMAIN: SOCIAL INFLUENCES)
- PROMPT: Who would you feel more comfortable hearing about the study? From your doctor? From the doctors working within the research team? From the trained research nurse or assistant? Anyone else?
8. If you heard about an available clinical trial of CAR-T cells, how would you go about enrolling or participating? (DOMAIN: KNOWLEDGE)
9. How would receiving CAR-T cells as part of this trial fit with how you see yourself as a person and what is important to you? (DOMAIN: SOCIAL ROLE AND IDENTITY)
- PROMPT: any moral/ethical issues?
10. How confident are you that you could participate in a trial of CAR-T cells for blood cancer? What might make you feel less confident that you could? What might help to feel more confident? (DOMAIN: BELIEFS ABOUT CAPABILITIES)
- PROMPT: Any moral/ethical issues?
11. Do you expect that participating in a trial of CAR-T cells for blood cancers will result in more good things than bad things for yourself? In what way? (DOMAIN: OPTIMISM)
12. What would you like to achieve by participating in a trial of CAR-T cells? (DOMAIN: GOALS)
- PROMPT: Personal achievement
13. What would motivate you to participate in a trial of CAR-T cells for blood cancer? (DOMAIN: GOALS)
- PROMPT: Health benefits, altruism/making a difference
14. How motivated would you be to participate in a trial of CAR-T cells if its goal was to test the safety of CAR-T cells, but not to test if it improved your health as a primary goal? (DOMAIN: INTENTION)
- PROMPT: How would the possibility of a placebo control affect your motivation?
15. If you were considered eligible, would you participate in a trial of CAR-T cells for blood cancers if one is available in the next year? (DOMAIN: INTENTION)

- PROMPT: If yes, why? If no, why not?
16. What resources do you need to be made available to you in order to participate in a trial of CAR-T cells? (DOMAIN: ENVIRONMENTAL CONTEXT AND RESOURCES)
- PROMPT: Transportation/parking, financial, caregiver, childcare
 - PROMPT: What tools?
17. Can you rely on the health system to support you when things get tough if you participated in a trial of CAR-T cell therapy for blood cancer? (DOMAIN: ENVIRONMENTAL CONTEXT AND RESOURCES)
- PROMPT: “Things get tough”, health (mental/physical)
 - Use scenario as PROMPT: Based on your experiences with the health care system since your diagnosis of a blood cancer....
18. Whose opinion is important to you when considering whether to participate in a CAR-T cell trial for blood cancers? (DOMAIN: SOCIAL INFLUENCES)
- PROMPT: Other patients, family members, caregiver, physician, nurse
 - PROMPT: Who would influence your decision most?
19. When you imagine participating in CAR-T cell trial, what types of feelings come to mind? (DOMAIN: EMOTION)
- PROMPT: Guilt, worry, satisfaction, inspired, nervous, stressed, happy, sad
 - How would these emotions influence whether you wish to participate in the CAR-T cell trial?
20. What strategies would you have in place for keeping track of appointments during the trial, such as follow-ups? And for attending the appointments? (DOMAIN: BEHAVIOURAL REGULATION)
- PROMPT: What can you do specifically? (Not the clinic or anyone else)
 - PROMPT: Is there anything specific that you already do that helps you keep track of appointments and follow-ups?
21. Thinking about everything that you mentioned that might impact on your decision to participate in a CAR-T cell trial, what would you say is the most important factor that would influence your decision?
22. Is there anything else that is a barrier to you participating in a trial on CAR-T cells as a therapy?

Any final thoughts?

Thanks so much for your time.

