Communicating about a clinical trial of gene therapy in a hospital setting – Scenario E

Case Study to Guidance for Communicating on Gene Technology 2025[1]

In two weeks, the Welcome Life Hospital[2] in Melbourne will start a first-in-human clinical trial of gene therapy for a serious, heritable skin condition. The gene therapy was developed by Welcome Life[2] researchers.
John Agnassi[2] is a nurse who will be caring for the patients in the trial. John has heard the researchers talk about the research being "ground-breaking" and "revolutionary". He knows that the Welcome Life leadership expect the clinical trial to enhance the hospital's global reputation as a research powerhouse. CEO Jane Mwamba[2] has made it clear she wants the trial to be a "success" and for nothing to go wrong.
John worries about the risk that he or other staff could be unintentionally exposed to gene therapy or to the viral vector that is being used to introduce it into the body. He has shared his concerns with other staff, and they have requested a meeting with Hospital leadership.
Use the Guiding Questions to help Ms Mwamba and the executive team prepare for the meeting. How should they communicate with staff?

Hypothetical Responses to the Guiding Questions

1. **What is your purpose or goal (i.e., why do you want to communicate) and on what time scale do you hope to achieve that goal?**

The Welcome Life executive team wishes to communicate to:

- Understand the pressure felt by staff to deliver a 'successful' trial and how that may influence perceptions of safety or the quality of decision-making.
- Learn about potential safety issues from the staff.
- Share information about how the hospital assesses and manages risks of exposure to gene therapy and the viral vector.
- Reinforce the need for open, safety-centred practice for all advanced-therapy trials.
- Address any misperceptions — the executive team hopes this will help preserve the hospital's reputation for ethical, world-class research.

As the trial will start in two weeks, the executive team hopes to begin to realise these goals within days. But they understand that one meeting will not be enough and are considering other ways of communicating with staff both now, and for the six-month duration of the trial... *(the reader on further reflection may have additional responses)*

[1] Gene Technology Ethics & Community Consultative Committee Guidance for Communicating on Gene Technology 2025
[2] The scenario is realistic but the names are fictional.

2. **With whom do you wish to engage—that is, who is your audience or target?**

The executive team has several target audiences:

- Front-line nursing and allied-health staff who will be caring for trial participants — they understand that these staff have already expressed concerns and consider them a priority.
- Ancillary teams (pathology, cleaning, waste management) who may handle vector-contaminated material — the executive team believes they should communicate proactively, including with staff who have not expressed concerns.
- Contractors and casual staff.
- Hospital volunteers — the executive team wants to think broadly so as not to miss anyone…

3. **How can you ensure that your communication is transparent and that you are open about assumptions and uncertainties, benefits and risks?**

The executive team will:

- Share the risk matrix including probability and consequence ratings for accidental exposure. The executive team understands that staff will have different levels of knowledge of risk management so plan to explain the risk matrix in plain language.
- Provide information about the post-exposure protocol and staff vaccination policy.
- Provide plenty of time and prompts to encourage staff to ask questions.
- Acknowledge unknowns (e.g. long-term vector shedding) and outlining the plan for monitoring and management.
- Share planned external communication strategies with staff, and align both internal and external communication as much as possible
- Commit to releasing safety data to staff…

4. **Are you communicating based on your specific expertise, and what evidence will you use to ensure that your claims are accurate and can be externally fact checked?**

   The executive team understand that they are not experts on the technical aspects of the gene therapy clinical trial. They consider:

- Asking experts on different aspects of gene therapy trials to attend the meeting. For example, the Principal Investigator could present peer-reviewed evidence about the vector platform and pre-clinical safety data.
- Referring to OGTR safety guidelines and AS/NZS 2243.3 biosafety standards and how the hospital complies.
- Providing written material with citations or hyperlinks to trustworthy sources for independent verification…

5. **How can you move away from simply giving people information — which assumes that the problem is their lack of knowledge and has been shown to rarely work — and instead, have two-way conversations and shared reflection between you and the target audience?**

The executive team understand that hospital workers are diverse and have unique insights into safety. They also think that some workers may be reticent to express their concerns to the hospital's senior management. They consider:

- Collecting questions anonymously before the meeting via physical drop-box and online forms.
- Using real-time polling or breakout groups during the meetings to identify issues or co-design practical safety improvements (e.g. signage, waste streams, communication procedures).
- How to develop processes to encourage two-way conversations beyond the meeting — for example, by establishing fortnightly 30-minute 'safety huddles' with involved staff...

6. What forms of media and forums are the best for communicating your message and why?

- The executive team believes that a face-to-face meeting between hospital leadership and gene therapy and safety experts and staff (recorded for shift workers) is essential for starting the conversation.
- They consider visual aids e.g. infographics showing workflow for vector handling and personal protective equipment requirements.
- They plan ongoing updates possibly via a dedicated intranet page with Frequently Asked Questions (FAQs) and contact details or a fortnightly email bulletin for after the meeting...

7. What values, meanings, attitudes, beliefs, or other underlying considerations should be articulated when crafting your communication plan and the language used within it?

The executive team plans to:

- Emphasize patient welfare, staff safety and professional integrity — values that are shared by the hospital and its staff.
- Avoid acronyms and jargon — there use could imply that gene therapy safety should only be discussed by 'experts'.
- Avoid superlatives such as 'revolutionary' or 'breakthrough' when describing gene therapy and the Welcome Life Hospital trial — the words are inaccurate and imprecise and may communicate a belief that the gene therapy trial is certain to benefit patients.
- Recognise and respect that some staff may feel uncertain about novel therapies...

8. Given the rapid pace of developments in gene technology research, how can your communication strategy be designed to remain relevant and valid for as long as possible?

The executive team will keep the communication approach under review for the duration of the trial, including processes to encourage two-way conversations beyond the meeting...

9. What are likely to be the most effective and ethical strategies for communicating about gene technology in the face of mis/disinformation and fake news?

The executive team:

- Plans to ensure that all information provided at the meeting is evidence based.
- Will monitor social media and internal messaging prior to the meeting to understand what misinformation may be circulating. They are aware that sometimes providing accurate information will be enough to counter misinformation, but not always.
- Use language that distinguishes foreseeable, manageable hazards from speculative risks.
- Will provide handouts describing in plain-language the gene-therapy protocol including biosafety measures and exposure controls, and a contact person — possibly an Occupational Health Nurse — for staff who have further questions after the meeting…

Version Control Table:

Version	Author	Date	Changes
1.0	GTECCC	15/12/2025	Version 1.0 Final