Early Phase Clinical Trials information:
Recommendations for equitable resources

VCCC Alliance
Overcoming cancer together

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Aim

Early-phase clinical trials (EPCTs) possess unique recruitment challenges, especially in minority populations. EPCTs, defined by restrictive eligibility criteria, focus on safety and testing novel treatments (often for the first time) in patients who may have limited treatment options, reflecting common anxieties associated with clinical trials in general. Often, information to support the decision to participate in EPCTs relies on the patient information and consent form (generally only available in English). However, misconceptions around clinical trials and the nature of EPCTs suggest that additional information is warranted and addressing this knowledge gap would facilitate better engagement in the decision-making process and more equitable access.

Method

Approached as a quality improvement exercise, the VCCC Alliance performed a literature review and scoping exercise, contacting Clinical Trials Units (CTUs) in Australia and internationally regarding the information and process used in EPCTs. Four broad focus groups including consumers and consumer advocates (n= 29) were undertaken to review the material and methods for their appropriateness.

Results

The literature review and scoping exercises demonstrated the diverse range of materials available. However, the focus groups indicated that needs of the potential participants were not met.

Several key themes were identified that would assist in enabling potential participants to decide about taking part in EPCTs. These have been divided into two areas: People providing the information and the information itself and presented as recommendations.

Recommendation

How to provide information

- Include the whole team – the specialist (eg oncologist), the clinical trials team and GPs were all considered trustworthy and reliable sources of information
- Ensuring there was time to discuss the information after it was provided and before a decision needed to be made. Time should allow for discussions with GP, specialists, trials staff, their family and friends.
- Discussions around EPCT participation to also include wider concerns such as palliative care, logistics (time commitment), financial costs and discussions around hope.

What information to provide

- The amount of information was considered overwhelming. Being directed toward trusted sources was important.
- Information on EPCTs should include general clinical trials information.
- Health literacy levels should be considered and the information not being 'text heavy'.
- All clinical trial information should be staged, allowing for the information needs to the patient and /or their family.
- EPCT patients were likely to have 'chemo fog' so information needed to be clear.
- Hard copies were preferred in addition to digital formats.
- A range of resources allowed for differing needs – e.g. general clinical trial information, specific trial information and question prompt tools.
- Information needed to be culturally relevant. This included translations.

Conclusion

Approaching the needs of potential participants from the perspective of consumers and consumer advocates ensures that resources will be relevant and appropriate. Providing a range of easily readable materials to suit the needs of the consumer, tailored to the audience (including translations), allowing time to digest them and someone to discuss them with were all considered vital.

Considering these recommendations will assist those creating or assessing EPCT information for potential participants and ensure that the resources provide equitable solutions.

The full recommendations will shortly be launched on the VCCC Alliance website with translated examples of resources freely available, where applicable.

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