Stakeholder Engagement Cabbage Toss

Objective: Participants will be able to be explain the fundamental concepts and key terminology of stakeholder engagement.

Methods: Group game/discussion

Materials:
- Loose leaf or notebook paper 15-20 sheets
- Flip chart
- Markers
- Small ball (rubber band ball, small ball of paper)

To conduct this activity:

First
- o Explain to learners this activity will help reinforce the importance and of stakeholder engagement.
- o If necessary, review the key GPP concepts and terms prior to beginning the game.

Second
- o Have participants stand in a circle
- o Present the "cabbage" and begin by tossing it to one of the participants standing in the circle
- o Have the recipient unwrap the outermost layer of the "cabbage" and answer the question written on it.
- o Ask the other participants whether they understand and agree with the answer. Have them offer additions or corrections until the question is answered comprehensively and accurately.
- o Continue the game by having the individual holding the cabbage toss it to another participant, who then unwraps the next layer and answers the question on it.
- o Play until all Cabbage Questions have been answered
- o Crinkle up several sheets of paper into a small ball and set aside.
- o One a clean sheet of paper write one question.
- o Wrap each individual layer of paper around the original small ball. Continue adding the layers of paper until you have at least one question per session attendee
- o Wrap the rubber band around the entire ball for security.

Third
- o Wrap up the session by asking participants their interpretations of the session.
- o Write any major takeaways on the flipchart.

Questions

1. Define "community"
2. Name the six principles of engagement
3. Give an example of a national broader stakeholder
4. Name three stakeholder advisory mechanisms other than CABs
5. Describe the difference between social vs. physical harms. Can you provide an example of each?
6. Give one example of a communication strategy
7. Are research teams considered stakeholders?
8. What is the meaning behind the principle of community stakeholder autonomy?
9. Why is an education plan important to stakeholder engagement?
10. How does are the Good Participatory Practices different than Good Clinical Practice?
11. What is the importance of engaging in early phase research?
12. What are the Denver Principles?
13. Name three specific ways formative research can impact a trial?
14. How can good stakeholder engagement advance clinical research?
15. How can stakeholders uphold the GPP principle of "transparency"?
16. How is the GPP guideline different from other ethical documents?
17. How does GPP address power inequalities that might exist among stakeholders?

Discussion Guide

1. Define "community"
Community is a fluid concept that can be loosely defined by geographic borders, personal/physical traits. It is a membership that can include or exclude individuals. The definition

2. Name the six principles of engagement.
Autonomy, Community Stakeholder Autonomy, Integrity, Mutual Understanding, Respect & Transparency

3. Give an example of a broader stakeholder.
Local media, NGOs, Local policymakers, Medical professionals. Learners may name specific organizations within these categories. Ask them to define the organizations role if you are unfamiliar with the organization.

4. Name three stakeholder advisory mechanisms other than CABs.
Focus group discussions, Local events, talk show radios, social media, NGO advisory groups, participant groups.

5. Describe the difference between social vs. physical harms. Can you provide an example of each?
Physical harms are any undesired physical change that occurs directly from taking the study project. These arms can range from minor irritations to death. Social harms are the nonphysical negative impacts of a trial. Social harms can range from minor life disturbances to a larger life changes.

6. Give one example of a communication strategy.
Communication strategies are how news transfers between stakeholders. Answers can focus on any stakeholder group as the main function of delivery. Modes of communicating should be part of the list of stakeholder advisory mechanisms.

7. Are research teams considered stakeholders?
Yes. Research teams are often referred to as the origin of engagement, meaning they are the central relationship that provides the start of engagement. This central relationship does not exempt researchers as stakeholders and they are a crucial part of the engagement process.

8. What is the meaning behind the principle of community stakeholder autonomy?
Community activities are often funded through research organizations. As bodies that rely on research intuitions and funder support to exist there is a potential pressure that can force a bias within the organizations.

9. Why is an education plan important to stakeholder engagement?
An education plan assess and builds community literacy. Having thoughtful and insightful discussions about the research process is critical to conducting ethical research. Participants must have a certain

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basic level of scientific knowledge in order to give careful and informed consent during the scientific process.

10. How does are the Good Participatory Practices different than Good Clinical Practice?
GCP provides guidance specifically for the relationship between researchers and participants and preserving the integrity of data. GPP is the only global guidance document to provide guidance about the relationship between trial related stakeholders at all levels.

11. What is the importance of engaging in early phase research?
Building trust in the research site
Establishing a cooperative relationship between the research site and the local participants
Establishing cultural competency and literacy among both the research site staff and local community

12. What are the Denver Principles?
A set of guidelines that were created by HIV positive individuals. These guidelines asserted how the HIV-positive community should be treated.

13. Name three specific ways formative research can impact a trial?
Build or reinforce cooperative relationships with the local community
Learn about specific language or best practices that can influence trial design
Increase acceptability and understanding of the trial and research process

14. How can good stakeholder engagement advance clinical research?
Good stakeholder engagement may increase enrollment and retention in a trial.

15. How can stakeholders uphold the GPP principle of "transparency"?
Open, honest, timely and clear communication enables transparency and fosters collaborative, trusting and constructive relationships. Stakeholders can uphold the principle of transparency by communicating about circumstances that may affect previously agreed upon levels of consultation, involvement, collaboration, and decision making.

16. How is the GPP guideline different from other ethical documents?
The GPP guidance documents are not intended to provide ethical guidance on any other aspect of a clinical trial outside of the stakeholder engagement process. Other ethical documents provide guidance on research with human participants but offer very little perspective on stakeholder engagement.

17. How does GPP address power inequalities that might exist among stakeholders?
Section 1.4, p. 19: There are many correct answers to this question. Power inequities might exist between funders and funding recipients, between sponsors or headquarters-based teams and local research teams, and between local research teams and community stakeholders. Examples of inequalities might be related to decision-making processes, control of resources, variation in cultures,

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infrastructure, research experience, imbalances in literacy, education, and economic resources, as well as those inherent in patient-provider relationships.

GPP provides a framework for research teams to try to understand these power inequities and engage with a broad range of stakeholders who can provide essential advice to research teams about how best to mitigate the ramifications of these differences through participatory processes with relevant stakeholders.