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Colorectal Cancer Vaccine Clinical Trial: Internship Experience in Population Science

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CRC Vaccine Clinical Trial
Internship Objectives

- Review the literature to identify factors that are likely to influence clinical trial participation
- Pretest vaccine trial scenario
- Conduct mock decision counseling session
Literature Review

- Classes with Dan Kipnis, MIS, educational services librarian
- Review articles in Division’s RefWorks
- Identify articles using PubMed and enter into RefWorks database
Literature Review

- Identify factors that are likely to influence people to and not to participate in cancer clinical trials
Keywords

- Cancer trials, recruitment, participation
- Barriers to clinical trials, cancer
- Psychosocial factors
Preventive Health Model

A self-regulation model that incorporates decision-making theory in a framework that identifies factors that explain patient decision making about taking preventive action.\textsuperscript{13}
Representations

- External to the individual
- Internal to the individual
## External Factors and Effects on Participation

(Pro – Increase; Con – Decrease)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Pro</th>
<th>Con</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complexity of protocol</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Eligibility criteria, restrictive</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Financial cost of participation</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Accessibility</td>
<td>High</td>
<td>Low</td>
</tr>
</tbody>
</table>

1, 6, 11

4, 8

4, 7, 8, 11
## Internal Factors and Effects on Participation

(Pro – Increase; Con – Decrease)

<table>
<thead>
<tr>
<th>Factor</th>
<th>Pro</th>
<th>Con</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fear of side effects 2, 4, 5, 7</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Fatalism 2</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Trust in study personnel &amp; institution 3, 6, 7, 8, 11</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Know others who participated in research 2, 8</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Social Support 3, 6, 11</td>
<td>High</td>
<td>Low</td>
</tr>
</tbody>
</table>
CRC Vaccination Scenario

- Develop written scenario describing the vaccine trial
- Pretest scenario with convenience sample
- Analyze feedback to learn how to improve scenario
Colon Cancer Vaccine Study

Colon Cancer Vaccine Trial Vignette/Scenario

A study to develop a vaccine to prevent recurrence of colorectal cancer
Colorectal cancer (CRC) recurs in 3 out of 10 patients in the general population, who had surgery for early stage (stage I or II) disease. Recurrence is somewhat higher for African Americans. At present, there is no treatment that prevents recurrence. A research study is being conducted to find out if a new vaccine can prevent CRC recurrence. The vaccine is designed to stimulate the immune cells to attack any hidden colon cancer cells. You are being asked to consider participating in this study.

How to participate in the colon cancer vaccine study
Individuals who decide to be in the study will be asked to meet with a study coordinator, sign a consent form, and have baseline/eligibility testing such as blood studies, medical history, physical exam and a CT scan.

Receiving the vaccine
If you are eligible and wish to receive the vaccine, an injection will be given in the upper arm. You will be observed for at least 30 minutes for any reaction to the vaccine and receive a few follow up telephone calls at home. It is fairly common to have a little redness, swelling, warmth, and discomfort at the injection site for a day or so. Occasionally, someone may have mild flu-like symptoms that may last 1–4 days. Severe reactions to vaccines like this are very rare.

Follow-up after vaccination
You will meet with the study coordinators at one, three, and six months to evaluate your response to the vaccine, including blood studies, and have another CT scan at six months when your study participation is completed.

Determining study results
The research team will review information for all study participants to assess response to the vaccine.

Participation is voluntary
Individuals who decide not to be in the study will continue to have regular follow up care with their doctors after being treated for early stage CRC.
I would like to introduce you to a new colon cancer vaccine study that I am working on and ask you for your thoughts about it. Would that be ok?

It would be helpful if you could look at the information on this page from the point of view of someone who has had early detected and surgically removed colon cancer.

Your comments will help us approach patients who will be asked to consider joining the study.

*Review the scenario with your "client". Follow up with the following questions:*

1) What is your general understanding about what this research project intends to achieve?

2) What is your general understanding about what participants will be asked to do?

3) How likely is it that you would participate in the study?

4) Why would you or why would you not participate?

5) What could be done to explain the study more clearly or completely?

*Please collect the following demographics from the person reviewing the scenario:*

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*Thomas Jefferson University*

*Colon Cancer Vaccine Scenario Review*

Date: __________________________________________

Scenario presenter: __________________________________________

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Pretest Demographics (N=6)

- **Race** - 3 African-Americans, 3 Asian-Americans
- **Gender** – 1 man, 5 women
- **Age** - 24 to 68 years
- **Education** - All more than 12 years
- **Marital status** - 4 out of 6 married
What does this research project intend to achieve?

- “...to help patients [receive a] cure [for] colorectal cancer recurrence.”
What is your general understanding of a participant’s responsibilities?

- “…to receive a vaccine shot and be evaluated in a study participating for 6 months.”
Why would you participate in the trial? (Pros)

- “Seems simple and non-invasive”
- “...help treat cancer with vaccine”
- “...help contribute to health study in curing cancer”
- “...help others in the future”
Why would you **not** participate in the trial?  (Cons)

- “Bad facility reputation”
- “Fear of flu-like symptoms”
- “Side effects unknown”
- “Not enough research done”
- “Unknown outcomes”
- “More literature needed, before put in my body”
- “Assure that there would be **no** side effects”
What can be done to explain the clinical trial more clearly?

- Describe “how the vaccine is developed”
- “Include pictures (with the written scenario) to help follow along”
Decision Counseling Session

- Step 1 - Provide information about decision situation
- Step 2 - Clarify personal preference for decision alternatives
- Step 3 - Encourage selection of an alternative
Procedures for Clarifying Preference

I. Elicit decision factors (pros and cons) related to participation

II. Rank top 3 factors and compare each reason

III. Compute participant’s preference score
Participant Demographics (N=6)

- **Race** - 4 African-Americans, 1 Hispanic, 1 Caucasian
- **Gender** - men (n=3), women (n=3)
- **Age** - 23 to 53 years
- **Education** - >12 years (n=5), 12 years (n=1)
- **Marital status** - <?
## Computing a Preference Score

<table>
<thead>
<tr>
<th>Decision Factor</th>
<th>Score</th>
<th>Range</th>
<th>Influence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pro</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overwhelming</td>
<td>1.9</td>
<td>&lt; 0.333</td>
<td></td>
</tr>
<tr>
<td>Very Much</td>
<td>1.7</td>
<td>0.334 - 0.356</td>
<td></td>
</tr>
<tr>
<td>Much</td>
<td>1.5</td>
<td>0.357 - 0.383</td>
<td></td>
</tr>
<tr>
<td>Somewhat</td>
<td>1.3</td>
<td>0.384 - 0.416</td>
<td></td>
</tr>
<tr>
<td>A little</td>
<td>1.1</td>
<td>0.417 - 0.454</td>
<td></td>
</tr>
<tr>
<td><strong>Con</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutral</td>
<td>1.0</td>
<td>0.455 - 0.545</td>
<td></td>
</tr>
<tr>
<td>A little</td>
<td>1.1</td>
<td>0.546 - 0.583</td>
<td></td>
</tr>
<tr>
<td>Somewhat</td>
<td>1.3</td>
<td>0.584 - 0.616</td>
<td></td>
</tr>
<tr>
<td>Much</td>
<td>1.5</td>
<td>0.617 - 0.643</td>
<td></td>
</tr>
<tr>
<td>Very Much</td>
<td>1.7</td>
<td>0.644 - 0.666</td>
<td></td>
</tr>
<tr>
<td>Overwhelming</td>
<td>1.9</td>
<td>&gt; 0.667</td>
<td></td>
</tr>
</tbody>
</table>
Include slide with pdf of Decision Counseling Summary Form
Pro Decision Factors

- To prevent CRC recurrence
- To improve medical research
Con Decision Factors

- Privacy concerns
- Unexpected medical issues
- Financial liability
Preference Scores for Participants in Decision Counseling Sessions

Preference Scores

For

Against

Participants

Level of Participation

Preference Scores

Level of Participation

Participants

1

2

3

4

5

6

For

Against

For

Against

For

Against

For

Against

For

Against
Summary

Preventive Health Model integrates preference clarification and facilitates selection

- Identifying barriers and influences
- Decision-counseling

~ Encourage selection alternatives
Participant preferences are impacted by internal and external factors that determine preference regarding clinical trial participation.

The scenario pretest provided feedback to improve comprehension of the clinical trial description.
Summary

Decision counseling helps clarify personal preferences for or against clinical trial participation
Students’ Experience

- Goals
- Literature search
- Scenario pretest interviews
- Decision counseling experience
- Program evaluation
Thank you for your time and attention.

Questions/Concerns?
References


