Colorectal Cancer (CRC) Vaccine Study: Aim 2 Internship Experience

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Colorectal Cancer (CRC) Vaccine Study:
Aim 2 Internship Experience

Selasie Goka
August 9, 2011
Department of Medical Oncology
Division of Population Science

In 2008, the Department of Medical Oncology and the Kimmel Cancer Center at Thomas Jefferson University established the Division of Population Science to provide a central focus for institutional research activities related to cancer prevention and control.

The division was formed to advance applied research in behavioral, social, and epidemiological science; and to develop new methods that can be used to improve the quality of cancer care in diverse populations and reduce the burden of cancer.
Phases of Aim 2

- **Phase 1**
  - Literature review
  - CRC vaccine study informational booklet & survey
  - Prepare web-based decision counseling program
  - Prepare phase 2 recruitment survey

- **Phase 2**
  - Collection of survey questionnaire data from 50 patients who would be eligible for the CRC vaccine study

- **Phase 3**
  - Approach 250-300 patients eligible for the vaccine study, complete decision counseling and refer interested patients to study coordinator for enrollment (44 patients)
Activities

- Conducted literature review
- CRC vaccine study booklet & survey
- Recruitment survey questionnaire
- Prepare web-based decision counseling program
Literature Review

Factors identified by previous interns:
- Complexity of protocol
- Eligibility criteria, restrictive
- Financial cost of participation
- Accessibility
- Fear of side effects
- Fatalism
- Trust in study personnel & institution
- Know others who participated in research
- Social Support

Additional factors
- Lack of knowledge about the existence of clinical trials and their benefits\(^1,2\)
- Not wanting to change existing medical care/receive substandard care\(^1\)
- Use of placebo controls\(^3\)
- Randomization\(^4\)
- Previous trial experience\(^4\)
- Being male\(^4\)
- Altruism\(^5,6,7,8\)
Literature Review

Older population considers:
- Concern about age and health status
- Physician recommendation
- Potential health benefits
- Altruism, esp. for other people their age
Literature Review

Ways to maximize enrollment of African Americans (AA)

- Recruit at churches, community centers
- Advertise on radio stations and in places that AA frequent, magazines
- Design study specific informational booklets with easy-to-understand language and pictures they can relate to
Literature Review

Ways to maximize enrollment of African Americans (continued)

- Maintain interaction with participants and their families to encourage retention\(^\text{10}\)
- Form partnerships with organizations that serve AA with cancer\(^\text{10}\)
- Give back to the community/participants eg by providing a forum for education and discussion about CRC\(^\text{10}\)
- Encourage physicians to offer trial participation to this group of patients\(^\text{12}\)
Activities

- Conducted literature review
- CRC vaccine study booklet & survey
- Recruitment survey questionnaire
- Prepare web-based decision counseling program
Patient Recruitment for Informational Booklet Review

Method 1: Referral by Clinicians
   a. Informatics for integrating biology and the bedside (i2b2) list
   b. Clinic log

Method 2: Registry

Method 3: Media Advertisement
I2b2 Method

An informatics framework that integrates information from multiple sources into a common data warehouse.

- Data sources:
  - Hospital EMR
  - JeffChart and other ancillary data sources
  - Tumor Registry data
  - Biospecimen data from caTissue Suite

- Query of warehouse to generate list
Send “opt-out” letter to potential eligible individuals
Assess eligibility and obtain consent
Arrange for review of booklet and completion of survey
Clinic Log Method

- Review appointment list on a daily basis
- Meet eligible patients at clinic
Method 2 - Registry

- Inspect central registry of patients who have consented to contact for research studies
- Honest broker oversees process up to arranging booklet review
# Booklet Review Recruitment Summary

## Study Sites:
- Thomas Jefferson University,
- University of Pittsburgh,
- Fox Chase Cancer Center

## Participant Identification and Recruitment Strategies

<table>
<thead>
<tr>
<th>Clinic Log/i2b2</th>
<th>Registry</th>
<th>Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
</tbody>
</table>

- Approached (N = XX)
- Eligible (N = XX)
- Enrolled (N = XX)
  (XX whites, XX African Americans)
## Booklet Review Patient Recruitment Update

### Where are we now?

<table>
<thead>
<tr>
<th></th>
<th>Whites</th>
<th>African Americans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Current</td>
<td>9</td>
<td>4</td>
</tr>
</tbody>
</table>

### Number of Patients Recruited via Different Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician referral</td>
<td>10</td>
</tr>
<tr>
<td>Registry Identification</td>
<td>3</td>
</tr>
<tr>
<td>Media Advertisement</td>
<td>0</td>
</tr>
</tbody>
</table>
Patient Recruitment Update

Next steps

- i2b2: Send “opt out” letters to eligible African Americans
- Continue to use the other methods
Informational Booklet

- Introduction and background
- Eligibility criteria
- Vaccination and follow-up
- Benefits & Risks
- Safety & Confidentiality
- Resources & Contact Information
Booklet Survey

Basic sociodemographic background

- 4 male, 9 female
- Mean age: 59
- Education: 1 <HS, 4 HS grad, 8 >HS
- 9 white, 4 AA
- 9 married, 2 widowed, 2 not married
Please look over the booklet that was given to you by the patient educator. After you have reviewed the booklet, please respond to each statement below by placing a checkmark in the box provided. Feel free to add comments. Your answers will be kept confidential.

1. The booklet is easy to read.
   - [ ] Strongly Disagree
   - [ ] Mildly Disagree
   - [ ] Uncertain
   - [ ] Mildly Agree
   - [ ] Strongly Agree

   Comment: [ ]

2. The purpose of the vaccine trial is described well in the booklet.
   - [ ] Strongly Disagree
   - [ ] Mildly Disagree
   - [ ] Uncertain
   - [ ] Mildly Agree
   - [ ] Strongly Agree

   Comment: [ ]

3. The booklet clearly explains who is eligible for the vaccine trial.
   - [ ] Strongly Disagree
   - [ ] Mildly Disagree
   - [ ] Uncertain
   - [ ] Mildly Agree
   - [ ] Strongly Agree

   Comment: [ ]
<table>
<thead>
<tr>
<th>No.</th>
<th>Question</th>
<th>Strongly Disagree</th>
<th>Mildly Disagree</th>
<th>Uncertain</th>
<th>Mildly Agree</th>
<th>Strongly Agree</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.</td>
<td>The booklet provides enough information about what people will be asked to do in the vaccine trial.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>2</td>
</tr>
<tr>
<td></td>
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<td></td>
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<td>3</td>
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<td></td>
<td></td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>5.</td>
<td>Vaccine trial safety and confidentiality are addressed adequately in the booklet.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>1</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>6.</td>
<td>I would recommend the booklet to people who are thinking about participating in the vaccine trial.</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>5</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>8</td>
</tr>
</tbody>
</table>
Comments from the Survey

- Provide more details about the vaccine
  - How vaccine works in body
  - Length of time on market
  - Pre-trial safety data
  - Information on risks and long-term effects of the vaccine, especially for older patients
“My question throughout reading it was this…If we do not know what causes cancer, then how did we come up with [a] vaccine to prevent recurrence?”

“Maybe go into potential risks a little further - such as the inflammatory bowel disease - reasons? Chance?”
Comments from Survey

- Provide more details about study requirements
  - Time/travel commitment

- Recommendation of the booklet to others
  - Would recommend as base for more information
To summarize...

- Participants agree that the booklet is easy to understand
- Participants do not seem convinced that vaccine trial safety has been adequately described
Activities

- Conducted literature review
- CRC vaccine study booklet & survey
- Recruitment survey questionnaire
- Prepare web-based decision counseling program
Survey on Factors Likely to Affect Participation in the Study

- Participation Decision Stage
- Knowledge about the Colorectal Cancer (CRC) Vaccine Study
- Perceptions about Participating in the CRC Vaccine Study
- Perceptions about Religion and Health
- Perceptions about Health Care Research
- Basic Demographics
Survey Items Included as a Result of the Literature Review

- Perceptions about the study
  - Taking part in the study will be too expensive for me.
  - Taking part in the study will require too much of my time and effort.
  - Participating in the study will help other people like me.
Survey Items Included as a Result of the Literature Review (Adapted Scale)

Perceptions about Health Care Research

- I think that health care researchers
  - do their best to find out how to improve patients’ health
  - often cover up their mistakes
  - make too many mistakes
  - deal with patients the same way, no matter what the patients’ race or ethnicity
  - experiment on patients without them knowing

- I think that patients who participate in health care research receive high quality medical care
Activities

- Conducted literature review
- CRC vaccine study informational booklet
- Patient survey questionnaire
- Prepare web-based decision counseling program
Web-based decision counseling program

- Participated in Usability Testing of the program
  - Troubleshooting
  - Making suggestions
Division of Population Science
Preference Report: GERA

Decision to be Made - Option 1: Be tested or Option 2: Not be tested
Session results indicate your preference is Be tested.

<table>
<thead>
<tr>
<th>Option 1</th>
<th>0.596</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 2</td>
<td>0.404</td>
</tr>
</tbody>
</table>

Option Not Preferred 0.000 - 0.454
Neutral Preference 0.455 - 0.545
Option Preferred 0.546 - 1.000

Top Decision Factors, Direction of Influence, and Intensity of Feeling:

<table>
<thead>
<tr>
<th>Factor</th>
<th>Direction</th>
<th>Intensity</th>
</tr>
</thead>
<tbody>
<tr>
<td>for my family</td>
<td>Pro</td>
<td>Medium</td>
</tr>
<tr>
<td>to know if I am at risk</td>
<td>Pro</td>
<td>Low</td>
</tr>
<tr>
<td>needles</td>
<td>Con</td>
<td>Low</td>
</tr>
</tbody>
</table>

Comments:

I understand and agree with the Preference Report results shown above.

Participant ID: 321
Participant First Name: Ann
Participant Last Name: Doe
Participant Signature: __________________________________________
Date: 06/27/2011
Decision Counseling Experience

- Trained in Decision Counseling in GERA Study
  - Genetic Environmental Risk Assessment test
Summary

- Literature review
- Patient review of booklet
- Recruitment survey development
- Preparation of web-based decision counseling program
- Experience with decision counseling
Acknowledgements

- Ronald E. Myers, DSW, Ph.D
- Anett Petrich, MSN, RN
- Christine Bonaccorso, RN, CCRP
- Heidi Swan, MPH
- Elizabeth Rappaport, M.D
- Everyone else in the Myers lab 😊
  – I felt right at home!
Questions?
References


References


8. McCann SK, Campbell MK, Entwistle VA. Reasons for participating in randomised controlled trials: Conditional altruism and considerations for self. Trials [Internet]. 2010;11


